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Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings (Review)

Renders CM, Valk GD, Griffin SJ, Wagner E, van Eijk JT, Assendelft WJJ

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[Intervention Review]

Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings

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ABSTRACT

Background

Diabetes is a common chronic disease that is increasingly managed in primary care. Different systems have been proposed to manage diabetes care.

Objectives

To assess the effects of different interventions, targeted at health professionals or the structure in which they deliver care, on the management of patients with diabetes in primary care, outpatient and community settings.

Search methods

We searched the Cochrane Effective Practice and Organisation of Care Group specialised register, the Cochrane Controlled Trials Register (Issue 4 1999), MEDLINE (1966-1999), EMBASE (1980-1999), Cinahl (1982-1999), and reference lists of articles.

Selection criteria

Randomised trials (RCTs), controlled clinical trials (CCTs), controlled before and after studies (CBAs) and interrupted time series (ITS) analyses of professional, financial and organisational strategies aimed at improving care for people with Type 1 or Type 2 diabetes. The participants were health care professionals, including physicians, nurses and pharmacists. The outcomes included objectively measured health professional performance or patient outcomes, and self-report measures with known validity and reliability.

Data collection and analysis

Two reviewers independently extracted data and assessed study quality.

Main results

Forty-one studies were included involving more than 200 practices and 48,000 patients. Twenty-seven studies were RCTs, 12 were CBAs, and two were ITS. The studies were heterogeneous in terms of interventions, participants, settings and outcomes. The methodological quality of the studies was often poor. In all studies the intervention strategy was multifaceted. In 12 studies the interventions were targeted at health professionals, in nine they were targeted at the organisation of care, and 20 studies targeted both. In 15 studies patient education

was added to the professional and organisational interventions. A combination of professional interventions improved process outcomes. The effect on patient outcomes remained less clear as these were rarely assessed. Arrangements for follow-up (organisational intervention) also showed a favourable effect on process outcomes. Multiple interventions in which patient education was added or in which the role of the nurse was enhanced also reported favourable effects on patients' health outcomes.

Authors' conclusions

Multifaceted professional interventions can enhance the performance of health professionals in managing patients with diabetes. Organisational interventions that improve regular prompted recall and review of patients (central computerised tracking systems or nurses who regularly contact the patient) can also improve diabetes management. The addition of patient-oriented interventions can lead to improved patient health outcomes. Nurses can play an important role in patient-oriented interventions, through patient education or facilitating adherence to treatment.

PLAIN LANGUAGE SUMMARY

Diabetes management in primary care, outpatient and community settings can be improved by interventions targeting health professionals, and organisational interventions that increase continuity of care

Diabetes is a major and growing health problem. This review examined the effects of interventions targeting health professionals or the way care is organised, with the aim of improving the management of people with diabetes in primary care, outpatient and community settings. The review found that multifaceted professional interventions (for example combinations of postgraduate education, reminders, audit and feedback, local consensus processes, and peer review) could enhance the performance of care providers. Organisational interventions that increased structured recall, such as central computerised tracking systems or nurses who regularly contacted patients, could also lead to improved care for patients with diabetes. The effectiveness of these interventions on patient outcomes (glycaemic control, cardiovascular risk factors, wellbeing) is less clear.

BACKGROUND

Description of the condition

Diabetes mellitus is a major and still growing health problem. It is expected that the number of people with diabetes will double by 2010 (Amos 1997). In particular, the number of patients with Type 2 diabetes is continuing to rise due to the increasing number of elderly people, the better recognition of prevalent undiagnosed diabetes and the better care for and survival of people with clinically diagnosed diabetes (Burke 1999; Meneilly 1995). Furthermore, the adoption of a more affluent and westernised lifestyle (characterised by decreased physical activity, greater fat consumption and subsequent obesity) by some non-Western populations is also contributing to an increase in the diabetic population (Roman 1997). Though the rise in prevalence of patients with diabetes mellitus is mainly due to Type 2 diabetes, alarming increases in Type 1 diabetes have also been observed (Gardner 1997; Libman 1998; Onkamo 1999).

Description of the intervention

Since 1970 the responsibility for the routine review of patients with diabetes has shifted away from hospitals to primary care (Wood 1990; Griffin 1997). Nowadays health professionals working in primary care, outpatient and community settings often play a key role in the care of patients with diabetes (Laine 1996). In particular, centralised, computer-based systems for prompted recall and regular review of patients play a very important part in delivering a good standard of diabetes care (Wood 1990; Griffin 1998a).

Nevertheless, empirical data suggest that care for diabetic patients in primary care, outpatient and community settings could be improved. Studies in the USA have shown that a large proportion of elderly patients with diabetes mellitus are not receiving care in accordance with the published guidelines of the American Diabetes Association (ADA) (Weiner 1995; Beckles 1998). In addition, a Dutch study observed that general practitioners' management of patients with Type 2 diabetes only partly adhered to the published guidelines of the Dutch College of General Practitioners (Grol 1990; Konings 1995). Physicians' management of patients with Type 1 diabetes has also been found to be sub-optimal (Tuttleman 1993).

How the intervention might work

Achieving good glycaemic control is important. The Diabetes Control and Complications trial proved that good glycaemic control in patients with Type 1 diabetes reduced the occurrence of retinopathy, nephropathy and neuropathy (DCCT 1993). The United Kingdom Prospective Diabetes Study (UKPDS 1998) found the same to be true for patients with Type 2 diabetes. Furthermore, patients with Type 1 and Type 2 diabetes with good glycaemic control reported a better functional status and greater well-being (Ahoroni 1994; van der Does 1996; Reichard 1996). Many diabetic patients, however, have poor glycaemic control (Mazze 1995; Nathan 1995).

Attention to other cardiovascular risk factors is also an important aspect of diabetes management. Type 2 diabetes in particular is associated with a greater risk of heart disease and stroke, because of the interaction between raised concentrations of glucose and other cardiovascular risk factors (Turner 1998; Kuusisto 1994). Patients with Type 2 diabetes have a two- to three-fold increased risk of macrovascular disease (Garcia 1974; Stamler 1993). These cardiovascular risk factors often go unrecognised and undertreated in patients with Type 2 diabetes (Stolar 1995).

Why it is important to do this review

In the last few years a wide range of interventions targeting professional behaviour or the structure of care has been implemented to achieve better metabolic control or to improve care delivered to patients with diabetes. This review aims to identify and describe interventions to improve the management of patients with diabetes mellitus in primary care, outpatient and community settings.

OBJECTIVES

The objectives of this review are to determine the effectiveness of different interventions, targeted at health care professionals or the structure in which health care professionals deliver their care, to improve the care for patients with diabetes in primary care, outpatient and community settings.

Secondary questions are:
Which intervention strategy or parts of intervention strategies are the most effective? What do the most effective strategies have in common?

METHODS

Criteria for considering studies for this review

Types of studies

1) Randomised or quasi-randomised controlled trials (RCTs)
2) Controlled clinical trials (CCTs)
3) Controlled before and after studies (CBAs)
4) Interrupted time series (ITSs)

Types of participants

Health care professionals (including physicians, nurses, pharmacists), taking care of non-hospitalised patients with Type 1 or Type 2 diabetes mellitus in a primary care, outpatient (eg ambulatory care provided by specialists/hospitals) or community setting (managed care organisations, general medical clinics)

Types of interventions

Intervention strategies to improve the care for patients with diabetes, including organisational, professional and financial interventions. These were classified according to the Cochrane Effective Practice and Organisation of Care Group (EPOC) taxonomy of interventions (see EPOC 2008).

Studies that only evaluated patient oriented interventions (eg patient education, mail order pharmacies, consumer participation in health care organisation) were excluded. However, we abstracted information about patient oriented interventions included alongside professional and organisational interventions.

Types of outcome measures

Objectively measured health professional performance or patient outcomes in a clinical setting and self report measures with known validity and reliability.

1) Health professional performance, including (process outcomes):

- Measurement of blood pressure, blood glucose, HbA1c, weight, cholesterol, HDL-cholesterol, triglycerides, serum creatinine; urinalysis; making a follow-up; referral; examination of the feet; visual acuity and retinal fundi.

2) Patient outcomes, including:

- Glycaemic control: HbA1c, blood glucose
- Micro- or macro-vascular complications: nephropathy, retinopathy, neuropathy, cardiovascular diseases, amputations
- Cardiovascular risk factors: weight, cholesterol, triglycerides, albumin, serum creatinine, blood pressure, BMI
- Hospital admissions
- Mortality

3) Self report measures with known validity and reliability, including:

- Well-being/perceived health/quality of life/functional status/ patient satisfaction: scores on validated generic and disease-specific measures
- Patient satisfaction
- Provider satisfaction

Search methods for identification of studies

Electronic searches

Relevant studies meeting the inclusion criteria for the review were identified by:

a) Searching MEDLINE (from 1966 to 1999), EMBASE (from 1980 to 1999), Cinahl (from 1982 to 1999), the Cochrane Diabetes Group specialised register, the Cochrane Effective Practice and Organisation of Care Group specialised register (Issue 4 1999) and The Cochrane Library (Issue 4 1999).

b) Screening references given in relevant reviews and studies.

The methodological terms from the existing EPOC search strategy were combined with:
1. family practice/
2. family pract$.tw.
3. general practice.sh.
4. general pract$.tw.
5. primary health care/
6. primary care/
7. community health services/
8. community care
9. shared care
10. patient care team
11. integrated care
12. ambulatory care
13. family medicine/
14. family physician/
15. family phys$.tw.
16. exp diabetes mellitus/
17. diabet$.tw.
18. diabetes insipidus/
19. 17 not 18
20. 16 or 19
21. or/1-15
22. 20 and 21

The search terms were refined following initial experience.

Studies published in languages other than English were included.

Data collection and analysis

Full text copies of all potentially relevant studies, determined by reviewing the abstracts, were obtained. For each part of the review, studies were assessed for inclusion independently by two reviewers (CMR/GDV). All studies that appeared initially to meet our inclusion criteria, but on closer examination failed to, are detailed in the Characteristics of excluded studies. When there was a difference of opinion between reviewers concerning the inclusion of a trial the opinion of the EPOC contact editor was sought.

The data extraction was performed independently by two reviewers (CMR, GDV) using an adapted version of the EPOC Data Collection Checklist (see METHODS USED IN REVIEWS under GROUP DETAILS). Any discrepancies between reviewers were resolved by discussion or referred to the EPOC contact editor. The quality of all eligible trials was assessed using the criteria described by the EPOC group (see ADDITIONAL INFORMATION, ASSESSMENT OF METHODOLOGICAL QUALITY under GROUP DETAILS). (The EPOC data collection checklist, which contains information on the quality criteria used to assess studies, is available from the EPOC web site: EPOC a) Missing information about study design and intervention characteristics was sought from the main authors.

Initial disagreement about the assessment of the most important items (study design, classification of the intervention strategy and the quality criteria: blinding assessment, baseline measurement, follow-up of patients and 'unit of analysis' error), was calculated per criteria item and expressed as percentage agreement .

Data analysis:

Given the likely heterogeneity of interventions, settings and patient populations, we decided a priori not to use meta-analysis to pool the results of studies. Instead we present the results of studies in tabular form and make a qualitative assessment of the effects of studies, based upon the study quality, the size and direction of effect observed and the statistical significance of the studies.

We present the following data (where available): pre-intervention study and control data in natural units and statistical significance across groups; post-intervention study and control data in natural units and statistical significance across groups; absolute and relative percentage improvement. If a unit of analysis error was present, we presented the point estimates of effects without p-values or 95% confidence intervals.

We assessed whether the type of intervention (eg professional or organisational), source of intervention (eg whether the intervention was carried out or supported by a professional organisation) and type of diabetes influence the effectiveness of the interventions (Type 1 diabetes requires more intensive follow-up and more intensive management).

The included studies are presented in three groups as we classified the intervention strategies in professional, organisational or a combination of both interventions. In the results paragraph a

detailed description is given of the individual studies followed by a more general conclusion of the effectiveness of that group of interventions.

In Table 1, Table 2, Table 3, detailed information is given about the process and patient outcomes assessed in the studies. In addition, a summarised table of results is presented.

RESULTS

Description of studies

The search of the computerised databases identified a total of 1294 citations. After excluding duplicates and studies clearly not related to the objective of our review, 147 abstracts were considered in the selection procedure. Based on full text review, 37 studies were included in the review. Screening of references resulted in another 4 studies that met the inclusion criteria. Consequently, 41 studies were included in the review. Both reviewers agreed in 92% about the inclusion of the studies. The agreement between both reviewers on the five most important items (study design, classification of the intervention strategy and the quality criteria: blinding assessment, baseline measurement, follow-up of patients and 'unit of analysis' error), scored with the DATA COLLECTION CHECKLIST, varied from 82% to 95%.

The studies in this review evaluate a wide range of interventions targeted at health professionals to improve the management of patients with diabetes including professional and organisational interventions. Studies evaluating the effectiveness of a financial intervention were not found.

Forty-one studies met all the inclusion criteria for the scope of the review. Of the included studies 27 were RCTs, 12 had a CBA design and two studies were classified as an ITS study. Fourteen RCTs and one CBA study used patient randomisation. The other studies randomised care providers or practices. Only four studies were multi-arm trials comparing three (Ward 1996; Hoskins 1993) or four groups (Mazzuca 1990; Vinicor 1987). The others were two arm trials.

Targeted behaviours

The targeted behaviour in all studies was the general management of care for patients with diabetes. The interventions implemented in the different studies, focused on different aspects of this general management including more regular review, clinical prevention services, referrals, record keeping, professional-patient communication, patient education/advice, patient outcomes or combinations of these.

Type of diabetes

The studied patient population was restricted to patients with Type 2 diabetes in 14 studies. Another 15 studies also included patients with Type 1 diabetes. In 11 studies the type of diabetes was not reported. Only one study focused on improving the care for people with Type 1 diabetes (Marrero 1995).

Characteristics of providers

In the included studies care was delivered mainly by physicians. However, in the majority of studies nurses were also involved and participated in the intervention program as part of the practice team or to give patient education. In only eight studies did the nurses (partly) replace physicians in providing diabetes care. The general management of patients with diabetes was provided solely by a pharmacist in two studies (Hurwitz 1993; Jaber 1996).

Most studies were located in community settings (27), 11 in outpatient settings and three studies in a combination of both settings. In these latter studies conventional care in an outpatient setting (control group) was compared with a new approach to the delivery of care in a community setting (Hoskins 1993; Hurwitz 1993; Naji 1994). The alternative approaches in two studies were still supported by conventional clinical practice because routine reviews shifted to the community setting but annual reviews were still performed in the clinic (Hoskins 1993; Naji 1994).

The majority of studies were undertaken in the United States (24). Nine studies were carried out in the United Kingdom, two in Australia, three in the Netherlands, one in Germany, one in Austria and one in Sweden.

Characteristics of interventions (see EDITORIAL INFORMATION under GROUP DETAILS for METHODS USED IN REVIEWS)

A wide range of organisational and professional interventions was implemented in the studies. In all studies the intervention strategy was multifaceted. Twelve studies used professional interventions alone. Most included educational materials (nine studies) or educational meetings (seven studies) in combination with other interventions: local consensus processes (six studies), audit and feedback (five studies), reminders (five studies), educational outreach (four studies) and patient education (four studies). One study evaluated two interventions in combination, five studies evaluated a combination of three interventions, three studies combined four interventions and one study evaluated five interventions.

Nine studies implemented interventions only directed at the organisation of care. Most of these studies also included patient education (five studies). The organisational interventions consisted of arrangements for follow-up (four studies), revision of professional roles (three studies), multidisciplinary team (three studies), changes in medical record systems (two studies), changes to the setting/site of service delivery (two studies), case management (one study), integration of services (one study) or communication and case discussion between distant health professionals (one study). Three studies implemented a single intervention, three a combination of two interventions, two studies combined three interventions and one study implemented seven interventions.

Twenty studies evaluated a combination of professional and organisational interventions. Fifteen of these studies included distribution of educational materials, six included educational meetings, six reminders, five audit and feedback, three local consensus processes, three patient mediated interventions, two educational outreach visits, one marketing, 11 changes in medical record systems, eight arrangements for follow-up, four multidisciplinary teams, three revision of professional roles, three skill mix changes, two communication and case discussion between distant health professionals, two case management, two changes in facilities and equipment, and six patient education. In this group that combined professional and organisational interventions two (two studies), three (seven studies), four (four

studies), five (three studies), six (two studies) or seven different interventions (two studies) could be distinguished.

The follow-up period was less than two years in 30 studies. The shortest follow-up period was four months (Jaber 1996) and the longest lasted for three years (Day 1992; Sullivan 1991; Peters 1998; Rith-Najarian 1998) (mean ± sd = 16 months ± 9.28).

Barriers to change

Most included studies identified one or more barriers to change in diabetes care and interventions were designed to address these barriers. Reported barriers to change were lack of acceptance of guidelines, lack of knowledge of diabetology, poor co-operation of staff members, poor quality of documentation of provided care that leads to discontinuous care, the complexity of the guidelines and the lack of information needed to incorporate them into practice, non-attendance and poor compliance of patients.

Strength of evidence for the desired change in practice

For 29 studies, the published report did not refer to a RCT or systematic review documenting the desired change in professional practice. Lobach (Lobach 1997) and See Tai (Tai 1999) were the only studies that referred to a systematic review. The other ten studies referred to one or more RCTs (Kinmonth 1998; Mazzuca 1990; Ward 1996; Sadur 1999; Smith 1987;Hurwitz 1993; Marrero 1995; Naji 1994; Nilasena 1995; Weinberger 1995).

The intervention was based upon clinical practice guidelines or clear recommendations for practice in 27 studies, in the others it was not described. In 14 of the 27 studies the recommendations were locally developed, in 11 studies they were clearly based on national guidelines and in two studies the source of the recommendations was not specified (Boucher 1987; Naji 1994). Two studies (Lobach 1997; Mazze 1994) stated explicitly that the intervention was based on national guidelines but that they were adapted through a consensus building process to ensure that non-compliance with care guidelines was not the result of clinician disagreement with the guidelines. In one of the studies (Benjamin 1999) the formal consensus process was described.

Risk of bias in included studies

The methodological quality of each study is described in the table of included studies. The quality criteria applied to RCTs, CBAs and interrupted time series are described in detail in the EPOC module of the Cochrane Library (see METHODS USED IN REVIEWS under EDITORIAL INFORMATION in GROUP DETAILS).

RCTs

In only six of the 27 RCTS was allocation to groups clearly concealed. Of 19 studies that reported patient outcomes, in seven the patient follow-up was satisfactory (outcome measures were obtained of at least 80% of the patients allocated to groups or for patients who entered into the study). One study (Aubert 1998) undertook an additional analysis in which they made the conservative assumption of no change in glycaemic control if a patient was lost to follow-up, to ensure that loss to follow-up did not bias the results. This was only done for the major outcome of interest: change in HbA1c. The percentage of care providers of which follow-up data were available, was not explicitly stated in most studies in which these were the units of allocation. This item was scored positive in only three studies.

Outcomes were assessed blindly or were objective in 13 studies. In ten studies blinding of the outcome assessment was partly adequate because the laboratory outcomes scored positive on this criterion (were objective) and clinical outcomes (eg measurements of blood pressure, weight, foot examination) or process outcomes (mostly obtained by chart extraction) scored 'not clear' or 'not done'.

No substantial baseline differences were detected in all reported outcomes in ten RCTs. In six studies there were no baseline differences for some of the reported outcome measures (including the most important outcome glycaemic control). In the other 11 studies it was unclear whether baseline measures were substantially different across study groups or whether initial differences were noticed that are likely to have undermined the post intervention differences.

All outcomes were reliably assessed in 11studies and in a further 11 studies if only glycaemic control was considered. The remaining studies were rated as 'not clear' on this item.

Protection against contamination scored 'done' in 13 studies and 'not clear' in 13 studies. In these 13 studies units of allocation were care providers but they were working in the same setting or patients in the intervention as well as in the control group received (part of) possibly their care (eg the annual review) from the same provider or from different providers in the same setting. In one study the protection against contamination was clearly 'not done', because it had a crossover design (Shultz 1992).

In seven of the 27 included RCTs the unit of allocation was different from the unit of analysis (eg unit of allocation was the provider/ practice and the unit of analysis was the patient). Only if the different unit of analysis makes practical sense and is independent of the unit of allocation estimated by the intra-cluster variability will precision not be influenced. One study calculated the intra-class correlation coefficient and corrected the patient outcomes for clustering at practice level (Kinmonth 1998).

CBA

Eleven of the 12 CBA studies allocated providers or practices. Only one of these studies reported characteristics of the study and control providers (Hartmann 1995) to compare both groups. The percentage of care providers of which follow-up data were available, was not explicitly stated in most studies. Only two studies reported follow-up rates of greater than 80%.

Of eight studies that reported patient outcomes, four reported follow up rates of greater than 80%. Outcomes were assessed blindly or were objective (assessed by a standardised test) in seven studies. In four studies blinding of the outcome assessment was partly adequate.
No baseline differences were detected between the intervention and control group in three studies. All the outcomes were reliably assessed in seven studies and if only glycaemic control was taken into account four studies could be added (assessed by laboratory test).

In two studies patients or care providers were allocated within a clinic or practice, so communication between the intervention and control group could have occurred. The effect of the intervention might have carried over in this way. In one study it was likely that the control group received the intervention because it was stated

that both the intervention and control clinic were staffed by the same personnel (Day 1992).

ITS

For both ITS studies, the intervention occurred independent of other changes. No statistical analysis was performed in one study and in the other it was limited, because only a chi-square test was performed. The intervention was unlikely to affect data collection because sources and methods of data collection were the same before and after the intervention. One study assessed the outcomes blindly (Rith-Najarian 1998) but in both studies it was unclear whether the data were obtained in a reliable way. One study reported that the data set covered more than 80% of total number of participants in the study (Rith-Najarian 1998).

Power calculations were included in six studies (Benjamin 1999; Feder 1995; Kinmonth 1998; Pill 1998; Hartmann 1995; Weinberger 1995). The smallest effect size for the most reported patient outcome, glycated haemoglobin, likely to be found on the basis of these calculations, was 1% difference in mean glycated haemoglobin if a predictive power of 80% at the 0.05 level was used (Benjamin 1999; Kinmonth 1998, Pill 1998). Only one study appeared to have sufficient statistical power to detect this effect (Kinmonth 1998).

The sample size in the study of Weinberger (Weinberger 1995) was primarily based on the statistical consideration to detect a moderate effect size of 0.45 difference in mean glycohaemoglobin between study groups. They had 90% power for this outcome and in addition they had 80% power to detect a 12 mg/dl change in total cholesterol in a subgroup of hyperlipidemic patients.

In Feder et al (Feder 1995) power calculations were undertaken to detect a 50% relative increase in the recording of blood glucose concentrations with a power of 95% at a significance level of 5%.

A power calculation included in Hartmann et al (Hartmann 1995) showed that a significant change in the main process outcomes from 5% to 7.5% would be detected in a sample of 200 patients out of ten practices with a power of 90%. These main process outcomes were: documentation of funduscopy, screening for hypopallaesthesia and albuminuria.

None of the studies appeared to have taken clustering into account during the sample size calculation.

The studies are grouped by type of intervention. The key results are presented on a study-by-study basis in order of number of interventions that are implemented. An overall conclusion is given for the three types of interventions that were distinguished in this review.

Effects of interventions

Comparisons: professional intervention versus usual care

We located 12 studies (see Table 4) in which the effectiveness of professional interventions versus usual care was studied (Benjamin 1999; Feder 1995; Kinmonth 1998; Litzelman 1993; Lobach 1997; Mazze 1994; Mazzuca 1990; Palmer 1985; Pieber 1995; Pill 1998; Ward 1996; Carlson 1991). None of the studies tested a single intervention. Combinations of two, three, four or five interventions were used. In four of the studies the professional intervention was combined with patient education (Kinmonth 1998; Litzelman 1993; Mazzuca 1990; Pieber 1995).

One study determined the effect of a combination of two interventions: educational meetings and educational outreach visits (Pill 1998). In this study GPs and practice nurses were trained in providing patient centred care. This approach to diabetes care encourages practitioners to integrate patients' perspectives within the consultation. Only 19% of the professionals in the study applied this method systematically, and no significant biochemical or functional improvements could be demonstrated.

A combination of three interventions was studied in six studies (Kinmonth 1998; Litzelman 1993; Lobach 1997; Palmer 1985; Pieber 1995; Ward 1996):
Two studies combined educational meetings, educational materials and patient education. In these studies only patient outcomes were measured (Kinmonth 1998; Pieber 1995). Pieber et al (Pieber 1995) found a significant difference in change in HbA1c, BMI, diastolic blood pressure and triglycerides between the intervention and control group. This study however, had a potential unit of analysis error. In the study of Kinmonth et al (Kinmonth 1998) no positive change in glycaemic control or blood pressure was detected. Triglycerides and BMI were significantly worse in the intervention group, possibly due to more intensive managment. Favourable effects were reported on patients' wellbeing. The education implemented in this study consisted of a training program for care providers to provide patient-centred care.
Litzelman et al (Litzelman 1993) studied the effectiveness of educational materials, reminders and patient education on patient and process outcomes related to the diabetic foot. The documentation of provided care in patient records was very low at baseline, so there was a lot of room for improvement. Significant differences were found between the intervention and control group after a follow-up period of one year, although the documentation of care was significantly better in the intervention group it was still relatively low. Patients in the intervention group had a relative risk of 0.41 ($p<0.05$) for serious foot lesions and of 0.62 ($p<0.05$) to have dry cracked skin when compared to the control (unit;error)).

Palmer et al (Palmer 1985) did not find an effect on practice performance of the combination of educational meetings, audit and feedback and local consensus procedures. However, the baseline care was already good and therefore there was limited room for improvement.
A combination of educational meetings, educational outreach visits and personalised audit and feedback positively affected items recorded in the medical records in accordance with a 'recommended standard' (Ward 1996). In this study statistically significant differences were found between the data that were collected by two nurses. The study demonstrated no difference in the effect whether personalised audit and feedback was performed by nurse or doctor, but there was a significant difference between different doctors.

A study in which local consensus processes, reminders, and audit and feedback using a computerised decision support system were combined, demonstrated a favourable effect on compliance rates of care providers (Lobach 1997) (unit;error). The effect of the combination of interventions in the three last mentioned studies on patient outcomes remained unclear because these were not assessed (Lobach 1997; Palmer 1985; Ward 1996).

Three studies tested a combination of four different interventions (Benjamin 1999; Feder 1995; Mazze 1994):
Benjamin et al (Benjamin 1999) implemented audit and feedback, educational materials, educational meetings and local consensus processes. They reported a favourable effect on both patient and process outcomes. The effect of the combination of guidelines developed by local consensus, practice based education materials, educational outreach visits and reminders, was studied in Feder et al (Feder 1995). This study showed better recording of patient outcomes, significant improvements were found in all recorded variables. The control group was offered a set of guidelines concerning care for asthma.

Mazze et al (Mazze 1994) studied the effect of the combination of local consensus processes, educational materials , educational meetings and a scheme to make decisions for treatment of patients (Staged Diabetes Management). The intervention increased the percentage of patients with recorded examinations after 6 months and also a lower HbA1c was found in the intervention group in comparison to the control group. In this study statistical analyses were not performed and insufficient data were available for a post hoc analysis.

The most complex professional intervention strategy combined five interventions (Mazzuca 1990):
Mazzuca et al (Mazzuca 1990) tested in a multi arm trial of four groups of residents in four clinics clinics the benefit of a combination of educational materials, educational meetings, audit and feedback, reminders and patient education. The group of residents that received a combination of audit and feedback, reminders and postgraduate education did not differ in their performance with regard to the frequency of measurement of glycated haemoglobin from the group that only received educational materials and educational meetings. However, both groups differed with regard to their performance in ordering home blood glucose monitoring. The third intervention group was also equipped with a set of consumable clinical materials (such as equipment for measurement of blood sugar, a detailed dietary consult form, self care contracting forms for patients) besides education, reminders and audit and feedback. This group produced the highest level of laboratory orders for glycated haemoglobin. At the time of the study this was a newly available measure of blood sugar control. The authors speculated that the reason for the high level of laboratory orders for glycated haemoglobin in the third group was that this group was equipped with an apparatus to measure blood sugar quickly and at no expense to the patient. If this measurement was done, the physicians were free to try out the new test of glycated haemoglobin without an unusual financial burden to the patient and/or insurance carrier. The level of laboratory orders for glycated haemoglobin was higher in the third group than in the fourth group in which patient education was added to all other interventions. Presumably, as stated by the authors, this is due to the confounding of the four clinic nurses working in the four clinics who were all patient educators in their clinics.

To improve the quality of diabetes care Carlson et al (Carlson 1991) chose an alternative to a centrally designed diabetes-control program. In this approach patients and health-care providers were educated and trained to develop their own local organisation of diabetes care by local consensus processes. They were trained to identify problems in local diabetes care and to develop the means to solve these problems. After 18 months significant differences in favour of the intervention group were found in the frequency of HbA1c measurements ($p<0.001$), and eye examinations ($p<0.01$) (unit;error). The two groups had a similar degree of glycaemic control, although p-values were not reported. Since the unit of allocation and unit of analysis differed in these studies multivariate analyses were performed to adjust for some organisational, professional characteristics. After these adjustments involvement in the diabetes-control program was still associated with a positive effect on the routine care as described earlier.

Conclusion:

Postgraduate education in combination with reminders, audit and feedback, educational outreach visits or combinations of these interventions improved the provided diabetes care in all studies that did not demonstrate a good standard of care at baseline (Benjamin 1999; Feder 1995; Litzelman 1993; Lobach 1997; Mazze 1994; Mazzuca 1990; Ward 1996; Carlson 1991). The effect on patient outcomes is less clear as in most studies these outcomes were not assessed. The studies that did report patient outcomes found mainly improvements on these outcomes (Benjamin 1999; Litzelman 1993; Mazze 1994). However, the effect in one study was just to significance (Litzelman 1993) and in another study it was not statistically tested (Mazze 1994).

Education for both care providers and patients showed conflicting results (Kinmonth 1998; Pieber 1995).

The main care provider in the studies that were classified as studying the effectiveness of professional interventions was the physician.

Comparisons: organisational intervention versus usual care

Nine studies (see Table 5) compared organisational interventions with usual care (Branger 1999; Day 1992; De Sonnaville 1997; Halbert 1999; Hawkins 1979; Jaber 1996; Sadur 1999; Smith 1987; Sullivan 1991). In five studies two forms of patient orientated interventions were also implemented: patient education (De Sonnaville 1997; Jaber 1996; Sadur 1999; Smith 1987) and a learner-centred counselling approach, allowing patients to identify problems and agree potential solutions (Day 1992). Combinations of one, two, three and seven interventions were implemented.

Three studies determined the effect of a single intervention strategy: changes in medical record system, arrangements for follow-up or revision of professional roles (Branger 1999; Halbert 1999; Hawkins 1979):
Branger et al (Branger 1999) studied the effects of changes in a medical record system, aimed at facilitating the exchange of information between physicians caring for diabetic patients. Significantly more measurements of glycaemic control, blood pressure-, weight- and lipids were performed in the intervention group. The HbA1c level decreased slightly but the change was not statistically significant (unit;error).
Arrangements for follow up by mailing multiple patient reminders resulted in improved rates of diabetes eye examination (Halbert 1999). However, the reported improvement was modest and seemed to be short-lived, because in the second six months following the intervention, the effect diminished. The third study, in which a pharmacist replaced the physician, showed several methodological limitations: 45% of the patients were lost to follow-up and information about the methodological quality of this study

was scarcely reported (Hawkins 1979). No significant differences in levels of fasting blood glucose were reported between the patients managed by the pharmacist and those managed by the physician.

In three studies a combination of two interventions was studied (Jaber 1996; Smith 1987; Sullivan 1991):
The addition of patient education to the substitution of the physician by a pharmacist in providing diabetes care, showed a favourable effect on glycaemic control (Jaber 1996). However this study included only 39 patients. Smith et al (Smith 1987) evaluated a strategy in which arrangements for follow-up were combined with patient education. Patients were sent educational materials and appointment reminders and received telephone calls for rescheduling of failed encounters. This resulted in more kept scheduled visits in the intervention group compared to the control group ($p<0.01$). The third study that was carried out to examine the effect of a combination of two interventions studied a joint GP-nurse review system in combination with arrangements for follow-up. An interrupted time series design was used to assess the effect of the intervention on process outcomes (Sullivan 1991). The intervention increased the percentage of patients with recorded examinations during the period 1983-1988. In this study a statistical analysis was not performed and insufficient data were available for a post hoc analysis.

A combination of three intervention strategies was tested in two studies (Day 1992; Sadur 1999):
Sadur et al (Sadur 1999) conducted a trial to evaluate the effectiveness of a multidisciplinary team, case management and patient education. The multidisciplinary team was led by a diabetes nurse educator who was supported by two diabetologists. After 6 months patients in the intervention group had significant lower HbA1c levels and had significant lower rates of hospital admissions than patients in the control group. Another study combined revision of professional roles (enhancing the role of the nurse), changes to the setting (a new purpose-designed building to provide integrated educational clinical care) and a patient orientated intervention (learner-centred counselling approach) (Day 1992). A positive effect on glycaemic control was found in this study.

One study combined seven interventions: a clinical multidisciplinary team, formal integration of services, arrangements for follow-up, communication and case discussion between distant health professionals, changes to the setting, changes in medical record systems and patient education (De Sonnaville 1997). The combination of these interventions significantly improved glycaemic control. Furthermore, the decrease in cholesterol level was significantly larger in the intervention group than in the control group (unit;error). In this study, the number of patients in the intervention group was five times higher than in the control group.

Conclusion:

Changes in medical record systems improved process outcomes (Branger 1999).

The effectiveness of the implementation of revision of professional roles as a single intervention remains unclear (Hawkins 1979).
Revision of professional roles in combination with a patient-orientated part was associated with a small beneficial effect on glycaemic control (Day 1992; Jaber 1996). The results of these studies have to be interpreted with some caution because of a limited methodological quality.

Intensive follow-up improves the process of care in terms of scheduled visits and rates of diabetic eye examinations, although there is variation with the type and intensity of methods used (Halbert 1999; Smith 1987). Telephone calls for rescheduling visit failures combined with patient education (Smith 1987) are more effective than sending multiple reminders to patients, which only affected process outcomes in the short term in comparison to a single reminder (Halbert 1999).

The effectiveness of intensive follow-up on patient outcomes remains unclear as these were not assessed in these studies.
The effect of arrangements for follow-up in combination with the formation of a multidisciplinary team is not clear because of the limitations of the statistical analysis in the only study that examined this (Sullivan 1991).

The combination of a multidisciplinary team with case management and patient education showed favourable effects on process and patient outcomes (Sadur 1999). A combination of six organisational interventions and patient education also found favourable effects on patient outcomes (De Sonnaville 1997).

Comparisons: professional in combination with organisational interventions versus usual care

Most studies (20; see Table 6) in this review implemented a complex intervention consisting of a combination of professional and organisational interventions (Aubert 1998; Boucher 1987; Deeb 1988; Hartmann 1995; Hoskins 1993; Hurwitz 1993; Legorreta 1996; Marrero 1995; Naji 1994; Nilasena 1995; O'Connor 1996; Peters 1998; Rith-Najarian 1998; Rutten 1990; Tai 1999; Sullivan 1991; Stein 1974; Taplin 1998; Vinicor 1987; Weinberger 1995). In fifteen studies the care providers received education by distribution of educational materials and/or through educational meetings in combination with organisational interventions.

The most common intervention targeted at the organisation of care was a change in the medical record system (Boucher 1987; Hartmann 1995; Hurwitz 1993; Legorreta 1996; Marrero 1995; Marrero 1995; Naji 1994; Nilasena 1995; Peters 1998; Tai 1999; Taplin 1998). This medical record system was used for arrangements for follow-up (Boucher 1987; Hurwitz 1993; Legorreta 1996; Marrero 1995), audit and feedback (Hartmann 1995, to generate reminders to the care provider (Naji 1994; Nilasena 1995; Tai 1999), or a combination of these (Peters 1998; Taplin 1998). In six studies patient education was added to professional and organisational interventions (Aubert 1998; Deeb 1988; O'Connor 1996; Stein 1974; Vinicor 1987; Weinberger 1995). The effectiveness of a combination of two, three, four, five, six or seven interventions was studied.

Two studies determined the effect of a single professional in combination with a single organisational intervention (Rutten 1990; Tai 1999):
Rutten et al (Rutten 1990) stimulated outpatient management of patients by self-monitoring and also implemented a diabetes protocol with a therapeutic scheme to manage diabetic patients (case management and distribution of educational materials). The aim was to make the frequency of consultations dependent on the metabolic control. HbA1 decreased significantly more in the intervention group than in the control group (unit;error) and for

body weight no effect was found. See Tai et al (Tai 1999) evaluated the effect of reminders and changes in medical record systems. The results showed a positive change in process outcomes, however, because of the small numbers of practices involved no statistical testing was undertaken.

Seven studies evaluated a combination of three interventions (Nilasena 1995; Hurwitz 1993; Rith-Najarian 1998; Hoskins 1993; Stein 1974; Weinberger 1995; Shultz 1992):
Nilasena et al (Nilasena 1995) studied the effectiveness of educational materials, reminders and changes in medical record systems. This strategy showed a positive effect on process outcomes, although this effect was found in both the intervention and control group. Therefore, no significant difference between both groups in the change in compliance score was demonstrated. This could be due to contamination because both intervention and control residents worked in the same clinics and the supervisors that served as opinion leaders for the residents interacted with both groups. If the reminders in the strategy described before were substituted by arrangements for follow-up, improvements in process outcomes were reported but not in patient outcomes (Hurwitz 1993).

An ITS study was carried out to determine whether educational materials in combination with a multidisciplinary foot-care team and reminders affected the rate of lower-extremity amputations (LEA) among American Indians (Rith-Najarian 1998). No significant reductions in average annual incidence of LEA were seen. Although the study population has an extremely high prevalence of Type 2 diabetes and also suffered disproportionately higher rates of LEA, the number of LEA/1000 diabetic years in this study was quite low.

Hoskins et al (Hoskins 1993) conducted a trial to evaluate the effect of educational materials, educational outreach visits and arrangements for follow-up. A research nurse was assigned to liaise with patient and doctor to stimulate continuity of care and to remind them of the need to assess metabolic control, blood pressure and weight on a 4-monthly basis. This system of shared care was compared to general practitioner care and conventional clinic care. In all three groups a comparable improvement in glycaemic control ($p<0.05$) and a decrease in attendance rates after the initial assessment was demonstrated. However, the decrease in attendance rates was lowest for the shared care group.

A combination of educational materials, revision of professional roles (nurse case management) and patient education did not improve glycaemic control or weight in a trial that included 28 female patients (Stein 1974).

The effectiveness of the implementation of arrangements for follow-up, patient mediated interventions and patient education was studied by Weinberger et al (Weinberger 1995). Nurses attempted to call patients at least monthly in order to educate patients, monitor their health status and facilitate compliance by reviewing prescribed regimens and reinforcing the importance of compliance. Additionally, they alerted the patients' physician to identified problems and reminded them of upcoming clinic appointments. In this study glycohaemoglobin appeared to be better controlled in the intervention group in this study compared to the control group ($p=0.046$).

A cross-over trial was carried out to assess the effectiveness of an intervention strategy consisting of a patient mediated intervention,
changes in physical facilities and equipment and changes in medical records systems (Shultz 1992). A telecommunication system was implemented to assist in the outpatient management of patients with Type 1 diabetes. Only a small selected group of 30 patients was included from the veterans hospital: patients with the highest blood glycohaemoglobins. For the intervention group the blood glycohaemoglobin dropped significantly.

In four studies a combination of four interventions was used (Hartmann 1995; Naji 1994; O'Connor 1996; Aubert 1998):
A combination of educational materials, educational meetings, audit and feedback and changes in medical record systems demonstrated to be beneficial on the documentation of process of care (Hartmann 1995). These effects were only seen in items documented annually: lipid spectrum, serum creatinine, funduscopy and foot examination (unit;error). In contrast, changes in quarterly documented items such as blood glucose, HbA1c, blood pressure and BMI did not differ between the intervention and control groups. Educational materials, reminders, arrangements for follow-up and changes in medical record systems were combined in the study of Naji et al (Naji 1994). This intervention improved process outcomes but did not change patients' metabolic control.

O'Connor et al (O'Connor 1996) implemented local consensus processes, audit and feedback, skill mix changes and patient education. Nurses were authorised to initiate patient visits for nurse education or for dilated eye examinations when indicated and to order laboratory tests. Physicians' practice improved as much in the control as in the intervention group. However, glycaemic control was significantly better in the patients in the intervention group. The combination of educational materials, revision of professional roles, arrangements for follow-up and patient education resulted in a significantly improved glycaemic control (Aubert 1998). This favourable effect was not found for lipid spectrum, blood pressure and weight.

In three studies the effectiveness of a combination of five interventions was studied (Deeb 1988; Boucher 1987; Peters 1998):
The combination of educational materials, educational meetings, educational outreach visits, a clinical multidisciplinary team and patient education was studied by Deeb et al (Deeb 1988). Within the intervention group process outcomes improved more than within in the control group. Unfortunately, at baseline there were substantial differences across study groups, 38% of the patients were lost to follow-up and in the statistical analyses outcomes were not adjusted for baseline values (unit;error). For some outcomes a possible ceiling effect was noticed. Consequently, the effectiveness of this intervention remains inconclusive.

In the study by Boucher (Boucher 1987) educational materials were combined with educational meetings, arrangements for follow-up, communication and case discussion between distant health professionals, and changes in medical record systems. Mean glycated haemoglobin values fell significantly in the intervention group but did not change in the control group (unit;error). Process outcomes seemed to improve by the intervention also, however this was not statistically tested. It is noticeable that in this study only 44% of the patients that entered the study had initial and follow-up data. The combination of educational materials, audit

and feedback, revision of professional roles (nurses made clinical diabetes management decisions based on detailed protocols), arrangements for follow-up and changes in medical record systems showed an improvement of glycaemic control (Peters 1998). In this study a favourable effect was demonstrated on process outcomes also, although this was not statistically tested.

Two studies combined six interventions (Legorreta 1996; Marrero 1995):
Legorreta et al (Legorreta 1996) determined the effectiveness of educational materials, educational meetings, a multidisciplinary team, skill mix changes (nurses were more involved in diabetes management), changes in medical record systems and arrangements for follow-up. Glycaemic control significantly improved more in the intervention group.

In the study by Marrero (Marrero 1995) the following interventions were implemented: educational materials, patient mediated intervention, skill mix changes (enhanced role for the nurse), case management, changes in facilities and equipment and changes in medical record systems. A telecommunication system was implemented to assist in the outpatient management of patients. This study was the only one in the review that included paediatric patients with Type 1 diabetes. No changes were reported between the intervention and control group in glycaemic control.

A combination of seven interventions was looked at in two studies (Taplin 1998; Vinicor 1987):
The effectiveness of educational materials, local consensus processes, audit and feedback, reminders, marketing (establishing a team and after that regular team meetings to discuss and achieve clinical goals), a multidisciplinary team and changes in medical record systems did not significantly improve the compliance with guidelines on diabetic eye care (Taplin 1998). This finding could be explained by a possible ceiling effect. In the control practices a significant improvement was found, probably due to their low initial levels of compliance.

A combination of educational materials, educational meetings, local consensus processes, audit and feedback, reminders, communication and case discussion between distant health professionals and patient education was studied by Vinicor et al (Vinicor 1987). The intervention strategy was studied in a multi-arm trial with four study groups. The first group was the control group, the second group received only patient education, the third group received a combination of all professional interventions combined with communication and case discussion between distant health professionals, the fourth group received a combination of the intervention implemented in the second and third group. The fourth group showed the greatest improvements in glycaemic control and body weight, although improvements were also seen in the second and third group. These results have to be interpreted with some caution because only 50% of the patients were reassessed after 26 months (unit;error). For the assessment of process outcomes the first and second group as well as the third and fourth group were combined. The intensive instruction of internal medicine residents resulted in more fasting blood glucose determinations among their patients than in the control group after 11 months (39% of the patients dropped out because they did not remain active in the clinic). Additionally lipid monitoring was increased by instruction. No effects were seen on the monitoring for chronic complications.

Conclusion:

Postgraduate education of care providers was included in most studies. In only five studies (Marrero 1995; O'Connor 1996; Tai 1999; Shultz 1992; Weinberger 1995) was this element not mentioned.

The effectiveness of using a telecommunication system to assist in the outpatient management of patients with Type 1 diabetes remains unclear (Marrero 1995; Shultz 1992).

Computerised reminders for care providers, audit and feedback or a combination of both seem to improve process outcomes (Hartmann 1995; Naji 1994; Nilasena 1995; Tai 1999; Taplin 1998; Vinicor 1987). The effect on patient outcomes remains unclear because these were assessed in only two studies (Naji 1994; Vinicor 1987). One of these studies did not demonstrate an effect on patient outcomes (Naji 1994) and the study that reported a positive effect had a limited methodological quality (Vinicor 1987). Moreover in this study both process and patient outcomes were assessed after different follow-up periods (11 and 26 months respectively).

A centrally organised computerised database to make arrangements for follow-up, to track patient appointments and to generate reminder cards for patients is associated with improvements in process outcomes (Hurwitz 1993; Naji 1994) but does not improve patient outcomes.
In studies in which patient outcomes were assessed, those that featured greater involvement of nurses in diabetes management reported positive effects on patient outcomes (Aubert 1998; Legorreta 1996; O'Connor 1996; Peters 1998; Weinberger 1995). Nurses facilitated compliance (Weinberger 1995), (partly) replaced physicians (Aubert 1998; Legorreta 1996; O'Connor 1996; Peters 1998) and/or gave patient education (Aubert 1998; O'Connor 1996; Weinberger 1995). Another recurring theme is that the studies that reported a positive effect on patient outcomes tended to include patient education (Aubert 1998; O'Connor 1996; Vinicor 1987; Weinberger 1995).

DISCUSSION

This review was performed to identify effective intervention strategies to improve the management of patients with diabetes mellitus in primary care, outpatient and community settings.

It is important to note that the studies identified for the review are heterogeneous in terms of interventions, participants, settings and outcomes. In addition, the methodological quality was often limited: there were high dropout rates among patients and the possibility of unit of analysis errors increasing the apparent precision of estimates was often noticed. Moreover, essential information about concealment of allocation and the number of professionals included in the study was often missing. Therefore, it is not possible to draw clear conclusions. However, some common elements in the heterogeneous interventions that showed a favourable effect can be distinguished.

Types of interventions

Professional and organisational interventions

Postgraduate education was part of the complex intervention in almost all studies. Understandably, care providers first need the skills and knowledge to improve their performance. Moreover, they must be convinced of the importance of changing their practice and

motivated to do so. This type of intervention seemed to be effective on process outcomes in combination with other interventions like reminders, audit and feedback, local consensus processes, peer review or combinations of these strategies (Benjamin 1999; Feder 1995; Litzelman 1993; Lobach 1997; Mazze 1994; Mazzuca 1990; Ward 1996; Carlson 1991;Hartmann 1995; Nilasena 1995; Vinicor 1987).

Patient tracking systems or other systems for regular follow-up also improved quality of care at the process level (Halbert 1999; Smith 1987; Sullivan 1991; Aubert 1998; Boucher 1987; Hoskins 1993; Hurwitz 1993; Naji 1994; Peters 1998; Weinberger 1995). These interventions may decrease the number of patients getting lost to follow-up. This is particularly important because loss to follow-up carries an increased risk of diabetes complications. Central computerised systems can be of additional value as they may provide feedback to providers and can also generate reminders to providers for management of their patients. Furthermore, in an easy reliable way data can be obtained to measure improvements in the performance of care providers and patient outcomes.

Only thirteen (Benjamin 1999; Litzelman 1993; Mazze 1994; Pill 1998; Carlson 1991; Smith 1987; Boucher 1987; Hoskins 1993; Hurwitz 1993; Naji 1994; O'Connor 1996; Peters 1998; Vinicor 1987) of the forty-one studies studied both effects on process outcomes and on related patient outcomes. Only seven of these studies demonstrated a favourable effect on patient outcomes besides a positive effect on process outcomes (Benjamin 1999; Litzelman 1993; Boucher 1987; Hoskins 1993; O'Connor 1996; Peters 1998; Vinicor 1987)). One component that was included in the intervention strategies in four of the positive studies was a patient-oriented part: patient education (Litzelman 1993; Vinicor 1987), a research nurse was assigned to liaise with patient and doctor (Hoskins 1993), or a combination of both (O'Connor 1996). However, three studies probably overestimated the effect because of a unit of analysis error (Litzelman 1993; O'Connor 1996; Vinicor 1987). In five studies improvements in quality of provided care were not accompanied by improvement in patient outcomes (Pill 1998; Carlson 1991; Smith 1987; Hurwitz 1993; Naji 1994) and in one study it was not clear as the statistical analyses were limited (Benjamin 1999).

Patient-oriented intervention

The addition of a patient-oriented intervention to professional and/or organisational interventions generally led to improvements of patient outcomes next to improvements in process outcomes.

Revision of professional roles

The seven studies in which nurses replaced (partly) physicians in providing diabetes care generally demonstrated a positive impact on glycaemic control (Day 1992; Aubert 1998; Legorreta 1996; Marrero 1995; O'Connor 1996; Peters 1998; Stein 1974). The effectiveness of a pharmaceutical care model in which a pharmacist solely provided all diabetes-related management aspects needs further exploration as the two studies that evaluated this were of poor methodological quality (Hawkins 1979; Jaber 1996)

Telecommunication systems

The interventions aimed at improving diabetes care for patients with Type 1 diabetes focused on using a telecommunication system to assist in outpatient management of these patients. One of the two studies (Shultz 1992) in which this intervention was studied was of poor quality. The other study was the only study in the review that only included paediatric patients (Marrero 1995). Thus it is still difficult to draw conclusions about the effectiveness of this intervention strategy.

Financial interventions

No studies were identified that dealt with financial interventions. The explanation may be that studies of these strategies are often not restricted to primary care.

Types of populations

One identified study restricted the study population to patients with Type 1 diabetes. A lot of studies dealt with a study population of both patients with Type 1 and Type 2 diabetes or did not mention which type of diabetes was involved. None of these studies reported the effectiveness of an intervention separately for different types of diabetes. Therefore no conclusions can be made about whether the type of diabetes influences the effectiveness of the interventions.

Methodological considerations

Unit of analysis error

If a unit of analysis error was present a reanalysis would be indicated. However, the great number of studies lacking the essential information in the paper (18 out of 39 studies) made this practically impossible.

Effect sizes

Differences in guidelines and also in methods and reference values to assess glycated haemoglobin meant that a uniform effect size could not be valued and presented, thereby hindering between-study comparisons. In addition, in some studies a possible ceiling effect was identified because of very low initial values and in others there was much more room for improvement because of very high initial values.

Generalisability

In this review we determined the effectiveness of different interventions, targeted at health care professionals or the structure in which health care professionals deliver their care. The studies that are described include selected practitioners that were willing to implement sometimes very complex interventions. The representativeness of the care providers and practices was variable, from only one practice with one provider (Rith-Najarian 1998) to almost all local practices in a big area (Ward 1996). In addition, it is not clear if the patients in the studies are representative for the population of diabetes patients because participating patients often are a selected group of patients that are younger, less ill, and more accomodating than the general population (Greenhalgh 1997). Studies were all carried out in primary care, outpatient and community settings but still had a specific practice structure often dependent of the organisation of the national or local organisation of health care. Most studies were located in the US. Thus conclusions from this review should be generalised with caution.

Study size and loss-to-follow-up

Most studies of strategies to improve diabetes care limit the evaluation to patients who are motivated enough to consent to participate in clinical trials. This usually drops the number of eligible patients entering the study. Only six studies included a power calculation, many of the studies would have been underpowered to detect small changes in patient outcomes.

Among patients who entered the study high dropout rates were experienced, which may have affected the reported effects. There are many factors that predispose to non-attendance eg patient health beliefs, attitudes of health professionals and financial costs of attendance (Griffin 1998b). On the other hand, because diabetes affects a population of mainly elderly people with a chronic complex disease, some loss to follow-up is inevitable in primary care to follow-up because of severe illness, death and hospitalisation.

Hawthorne-effect

Another issue that could influence the effect of the intervention is the Hawthorne effect. In an RCT the effect size could be underestimated as both the intervention and control group could improve their performance by virtue of participation in a study in which both groups were motivated to implement an intervention to improve their performance. On the other hand the effect could be overestimated in a controlled before after study in which the control group provide usual care and is not necessarily motivated to implement an intervention and is possibly not (completely) informed about the intervention and the purpose of this. The intervention group could improve their delivered care just because they participate in a study aimed at improving diabetes management.

Inclusion of Interrupted Time Series (ITS) and Controlled Before After studies (CBA)

The decision to include interrupted time series in this review did not have much influence on the conclusions because of limited methodological quality and the statistical methods used were not sufficient. Insufficient data were given to calculate reliable effect sizes. Moreover, as RCTs are not always feasible for interventions aimed at improving professional practice we included CBA studies. Studies with a CBA design often provide useful and reliable information that can help to further explain the results of randomised controlled trials. To expand the inclusion criteria for study design with CBA studies added 12 studies to the review. RCTs clearly offer the highest level of evidence to determine whether interventions are efficacious, followed by CBA and ITS studies.

Duration of follow-up

One concern is whether the positive effects of the complex and often intensive interventions can be maintained on the long-term. The follow-up period was less than two years in 30 studies of the 41 studies and 1 year or less in 25 studies. On the other hand for some of the studies there is the possibility that the evaluation was premature and that patients had not been exposed to the intervention for long enough to detect any changes or the maximum change. The inexorable progress of diabetes might also be a reason for not finding favourable effects on patient outcomes.

Micro- and macrovascular complications

The primary process and patient outcomes studied in most studies in this review concerned glycaemic control. However, recent studies emphasise the importance of combining monitoring and treatment of glycaemic control with that of other cardiovascular risk factors in diabetes patients: blood pressure and lipid spectrum (Turner 1998; Kuusisto 1994; UKPDS 1998). A high blood glucose interacts with cardiovascular risk factors. Unfortunately, only one study (Peters 1998) evaluated outcomes on process and patient level concerning the lipid spectrum and additionally two other studies assessed patient and process outcomes on blood pressure (Naji 1994; Vinicor 1987). Peters (Peters 1998) showed a clearly better compliance with ADA guidelines related to a greater number of lipid tests in the intervention group than in the control group, although this was not statistically tested. Moreover, in the subgroup of patients with a cholesterol level >6.2 mmol/l, total cholesterol levels fell significantly in the intervention group, but did not change in the control group. The study population in the subgroups, however, was very low. Naji (Naji 1994) reported an increase in frequency of measurement of blood pressure, but did not find a different change in systolic and diastolic blood pressure between the intervention and control group. In the second study both process outcomes and patient outcomes were assessed after different follow-up periods. Improvements were found on patient outcomes only.

In six studies the effect of the intervention strategy on lipid spectrum of patients was evaluated without determining changes in process of care (Kinmonth 1998; Pieber 1995; De Sonnaville 1997; Jaber 1996; Aubert 1998; Weinberger 1995). Two studies showed a significant decrease in cholesterol and/ or triglycerides concentrations compared to the control groups (Pieber 1995; De Sonnaville 1997). Eight studies measured the effect of the intervention on blood pressure and in all of these studies no difference in change between the intervention and control group was found (Kinmonth 1998; Pieber 1995; Pill 1998; De Sonnaville 1997; Aubert 1998; Hoskins 1993; Naji 1994; Vinicor 1987). However, in 3 studies (Pieber 1995; De Sonnaville 1997; Hoskins 1993) significant decreases were found within both groups.

It was noticeable that in the process of diabetes care more attention was paid to monitoring microvascular complications: especially in relation to eye and feet examination, potentially because of low initial levels. The effect of the interventions on micro- and macrovascular endpoints, however, needs further examination in the long term.

AUTHORS' CONCLUSIONS

Implications for practice

From the review it is difficult to know whether the postgraduate education components did contribute to improvements in care. There were no trials solely evaluating postgraduate education - all had other components. Postgraduate education in combination with other professional interventions improves the process of diabetes care.

Also strategies that increase structured recall contribute to a better quality of diabetes care. This can be achieved by central computerised tracking systems or by nurses who regularly contact

patients. These arrangements for follow-up improve process outcomes.
The effectiveness of these professional and organisational interventions on patient outcomes (clinical outcomes and wellbeing) is less clear.

The addition of patient education or a more enhanced role of a nurse to a complex intervention strategy seems to be important to improve patient outcomes besides process outcomes. Nurses can play an important role in facilitating compliance or giving patient education. They can even replace physicians in delivering many aspects of diabetes care, if detailed management protocols are available, or if they receive training.

Implications for research

This review demonstrates that at present there are a large number of multifaceted models being tested. The choice of components within the models has often not been based on a theoretical or empirical rationale. Future research should either aim to use designs that would allow disentangling of the effects of the different components or evaluate reproducible complex interventions and encourage replications of using the same intervention model.

A great number of studies evaluating the effectiveness of complex interventions to improve diabetes management were identified. Unfortunately, only thirteen of these studies reported outcomes on process and outcomes at the patient level. Both measures contribute to a better understanding of how to improve the quality of care. Process indicators contribute to understanding heterogeneity in outcomes. Poor implementation of complex interventions (masked in the absence of process indicators) may undermine excellent design, power and recruitment. Thus recommendations for current research most usefully draw on a combination of process indicators and outcome measures.

Studies need to focus more on process and patient outcomes in relation to cardiovascular risk factors, because of the interaction between glycaemic control and these risk factors.

Furthermore the effectiveness of the complex and often very intensive interventions has to be evaluated in the long term.

In relation to methodological quality, the following aspects should be given particular attention if new studies are undertaken: they should have sufficient power, adequate follow-up of patients and providers and they should calculate the intra-class correlation coefficient and correct patient outcomes for clustering at practice level. The issue of clustering is particularly relevant here as many of the interventions are aimed at the practitioner. Furthermore, it needs to be taken into consideration in both sample size calculations and analysis.

There is also a need for investigators to adopt standard measurement techniques and reference values for glycated haemoglobin, the primary outcome to assess glycaemic control. Also more comparable guidelines would be advisable. Both would facilitate comparison of effectiveness across different interventions and provide a benchmark against which clinicians could measure success. However, consensus between providers about guidelines is important, otherwise lack of compliance may be due to disagreement with them.

The absence of data on the cost-effectiveness of interventions is a serious omission that should be assessed.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Aubert 1998

Methods	RCT (randomisation was based on a 1:1 allocation ratio and block size of three, randomised by patient) Randomisation concealment: DONE Follow up: - providers: N/A - patients: NOT DONE Blinded assessment: DONE for laboratory outcomes and self-reported health status score NOT CLEAR for blood pressure and weight Baseline: DONE Reliable outcomes: DONE for laboratory outcomes and self-reported health status score NOT CLEAR for blood pressure and weight Protection against contamination: D
Participants	Two of the largest clinics within the Jacksonville Health Care Group, which provides primary care services for the Prudential HealthCare HMO plan of Jacksonville, Florida (US). A nurse case manager was the primary care provider under the direction of a board-certified family medicine physician and an endocrinologist who were still responsible for all diabetes management decisions for patients in the intervention group. Patients visiting the clinic (Type 1 and Type 2 diabetes) providers - ? (nurse) patients - 138 practices - 2
Interventions	Intervention group: Professional intervention (distribution of educational materials (detailed management algorithms) + organisational intervention (revision of professional roles (nurse case management) + arrangements for follow-up) + patient education Control group: usual care (patients in the control group were encouraged to discuss enrolment in the diabetes education class with their physicians) Length of intervention: 1 year in which patients received follow-up telephone calls every two weeks. Patients who were taking insulin received weekly calls
Outcomes	PROCESS: Renal assessment: -Dipstick test

Aubert 1998 *(Continued)*

	-Quantitative protein/microalbumin PATIENT: HbA1c Mean fasting blood glucose Insulin dose Systolic blood pressure Diastolic blood pressure Weight Serum cholesterol Serum triglycerides Serum HDL-cholesterol Serum LDL-cholesterol Self-reported health status score
Notes	Algorithms locally developed by a multidisciplinary team -directed at adjustments in medication, meal planning and reinforcement of exercise -target: improvement of glycaemic control and monitoring of renal complications

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Benjamin 1999

Methods	CBA Characteristics of studies using second site as control: NOT DONE Follow up: - providers: NOT CLEAR - patients: NOT DONE Blinded assessment: DONE for HbA1c, NOT CLEAR for process measures Baseline: DONE for HbA1c, NOT DONE for eye exam, urine test for albumin/protein Reliable outcomes: DONE for HbA1c, NOT CLEAR for process outcomes Protection against contamination: DONE unit of analysis error
Participants	Outpatient clinics of Baystate Medical Center, Springfield (US). This Medical Center has a "firm" system that is an academic group practice that includes attending physicians, residents, nurses, a nutritionist and patients. The firm system creates two group practices that are essentially parallel groups of providers and patients. Patients are predominantly minority patients of Hispanic and African-American descent. (Type 2 diabetes) providers - ? (physicians, residents, nurses, nutritionist) patients - 144 practices - 2 firms
Interventions	Intervention group: Professional intervention (distribution of educational materials (guidelines) + educational meetings + local consensus processes + audit and feedback) Control group: usual care Length of intervention: 15 months

Benjamin 1999 *(Continued)*

Outcomes	PROCESS: Compliance with standards of care: -Annual urine test for albumin/protein -Annual cholesterol determination -Annual diabetes education -Annual dilated retinal exam -Annual influenza vaccinations -Annual nutrition education PATIENT: HbA1c
Notes	Guidelines were locally developed by residents and faculty -directed at adjustments in treatment and monitoring -target: improvement of glycaemic control and compliance with recommended standards

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Boucher 1987

Methods	CBA Characteristics of studies using second site as control: NOT DONE Follow up: - providers: NOT CLEAR - patients: NOT DONE Blinded assessment: DONE for GHQ NOT CLEAR for completion of planned clinical review Baseline: DONE NOT CLEAR for completion of planned clinical review Reliable outcomes: DONE for GHQ NOT CLEAR for completion of planned clinical review Protection against contamination: NOT CLEAR unit of analysis error
Participants	Three group general practices in an inner city district of London (UK), serving about 15% of the district's diabetic population Patients receiving diabetes care in the three practices (not clear which type of diabetes). providers - ? (physicians, supported by nurses) patients - 217 practices - 3
Interventions	Intervention group: Professional intervention (distribution of educational materials + educational meetings) + organisational intervention (arrangements for follow-up + communication and case discussion between distant health professionals + changes in medical record systems) Control group: usual care in diabetic clinic Length of intervention: 2 years
Outcomes	PROCESS:

Boucher 1987 *(Continued)*

	Completion of planned clinical review PATIENT: Glycosylated haemoglobin
Notes	A protocol for clinical review was agreed -directed at monitoring -target: improvement of glycaemic control and adequacy of clinic reviews

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Branger 1999

Methods	CBA Characteristics of studies using second site as control: NOT DONE Follow up: - providers: DONE - patients: NOT CLEAR Blinded assessment: DONE Baseline: DONE for patient contacts NOT CLEAR for recorded parameters per patient, letters send from GP to consultant and vice versa Reliable outcomes: DONE Protection against contamination: NOT CLEAR unit of analysis error
Participants	32 general practitioners in the Apeldoorn region (The Netherlands) that were working with the computer based patient record and with electronic data interchange (EDI). In addition one internal medicine consultant participated. Patients treated by the GP (Type 1 and Type 2 diabetes). providers - 32 general practitioners + 1 internal medicine consultant patients - 275 practices - 1 hospital and ? practices
Interventions	Intervention group: Organisational intervention (changes in medical record systems) Control group: usual care without electronic data interchange between different care providers Length of intervention: 1 year
Outcomes	PROCESS: Patient contacts with GP Patient contacts with internal medicine consultant Letters from GP to consultant and vice versa Recorded items per patient: Kidney function: -Creatinine level -Proteinuria Eye condition:

Branger 1999 *(Continued)*

	Assessment ophthalmologist Insulin control Glucose level HbA1c level Fructosamine level Other Blood pressure Cholesterol level Triglyceride level Weight PATIENT: NONE
Notes	Guidelines not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Carlson 1991

Methods	RCT (incomplete block design randomised by practices; 2 groups of practices (where nurses were involved or nurses were not involved) were randomised in two groups) Randomisation concealment: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: NOT DONE Blinded assessment: DONE for HbA1c NOT CLEAR for measurements of professional practice Baseline: NOT CLEAR Reliable outcomes: DONE for HbA1c NOT CLEAR for measurements of professional practice Protection against contamination: DONE unit of analysis error
Participants	34 primary health care centres (PHCC) in the Stockholm area in Sweden Patients who had visited the PHCC during the 12 months prior to the evaluation (not clear which type of diabetes) providers- ? (mixed: physicians, nurses, nurse assistants, managers, administrators, laboratory technicians) patients - 4492 (measurements on professional practice) patients - 566 (measurements on HbA1c) practices - 3
Interventions	Intervention group: Professional intervention (educational meetings + local consensus processes to identify problems and to create plans to improve diabetes care + educational outreach visits) Control group: usual care Length of intervention: 18 months

Carlson 1991 *(Continued)*

	Follow up period: lasted 12 months
Outcomes	PROCESS: -Patients height noted in case notes during previous year -HbA1c value measured during previous year: -Eye examination performed during previous year PATIENT: HbA1c
Notes	A national Diabetes Control Program was initiated in 1979 -directed at organization of care - target glycaemic control and care routines as measured by audit of case records

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Day 1992

Methods	CBA Characteristics of studies using second site as control: NOT DONE Follow up: - providers: NOT CLEAR - patients: DONE Blinded assessment: DONE Baseline: NOT CLEAR Reliable outcomes: DONE Protection against contamination: NOT DONE unit of analysis error
Participants	A new purposed-designed diabetes centre in which a new integrated system of diabetes care was implemented with an enhanced role of the diabetes specialist nurse (UK) Every second insulin-treated and every fourth non-insulin-treated subject under the age of 65 years (Type 1 and Type 2 diabetes) providers - ? (physicians + diabetes specialist nurse) patients - 367 practices - 3 clinics
Interventions	Intervention group: Organisational intervention (revision of professional roles + changes to the setting: a new purpose-designed building to provide integrated educational clinical care in a relaxed environment) + a learner-centred counselling approach was adopted allowing patients to identify problems and agree potential solutions Control group: usual care in diabetic clinic Length of intervention: 3 years
Outcomes	PROCESS: NONE PATIENT: HbA1c

Day 1992 *(Continued)*

Notes	Guidelines not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

De Sonnaville 1997

Methods	CBA Characteristics of studies using second site as control: NOT DONE Follow up: - providers: NOT CLEAR - patients: NOT DONE Blinded assessment: DONE for laboratory outcomes, NOT CLEAR for BMI, wellbeing, treatment satisfaction Baseline: NOT DONE for fasting glucose, systolic blood pressure DONE for HbA1c, triglycerides, HDL cholesterol, serum cholesterol, BMI, diastolic blood pressure NOT CLEAR-> wellbeing, treatment satisfaction Reliable outcomes: DONE for HbA1c, fasting glucose, HDL cholesterol, serum cholesterol, triglycerides NOT CLEAR-> BMI, wellbeing, treatment satisfaction Protection against contamination: DONE unit of analysis error
Participants	22 of 29 eligible GPs in the western part of Amsterdam (The Netherlands). GPs were requested to enrol all their known and newly diagnosed NIDDM patients. Of the 570 eligible patient in the intervention group 167 did not participate. Two-year follow-up data were available of 350 of 459 patients. In the control group follow-up data were available of 68 of 102 participants (Type 2 diabetes) providers - 22 physicians patients - 561 practices - ?
Interventions	Intervention group: Organisational intervention (clinical multidisciplinary team + formal integration of services + arrangements for follow up + communication and case discussion between distant health professionals + changes to the setting /site of service delivery + changes in medical records systems) + patient education (GP was supported by a laboratory with facilities to visit patients at home, a computerised patient register and recall system, a diabetes nurse educator and a podiatrist) Control group: usual care Length of intervention: 2 years
Outcomes	PROCESS: NONE PATIENT: Fasting glucose HbA1c BMI

De Sonnaville 1997 *(Continued)*

	Blood glucose lowering therapy Total cholesterol HDL-cholesterol Triglycerides Systolic blood pressure Diastolic blood pressure
Notes	National guidelines (Dutch GP Guidelines) based upon the guidelines of the European NIDDM Policy Group -directed at monitoring and treatment -targets: glycaemic control and cardiovascular risk factors

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Deeb 1988

Methods	CBA Characteristics of studies using second site as control: NOT DONE Follow up: - providers: NOT CLEAR - patients: NOT DONE Blinded assessment: DONE Baseline: NOT DONE Reliable outcomes: DONE Protection against contamination: DONE unit of analysis error
Participants	6 of the 27 federally funded primary-care centres in Florida (US). The intervention group consisted of the three centres with the most diabetic patients. The control sites were the centres with the next largest number of diabetes encounters (not clear which type of diabetes) providers - ? (physician+nurses) patients - 1029 were identified and their records were reviewed at baseline. Only 636 of the patients were seen during the year after the intervention practices - 6
Interventions	Intervention group: Professional intervention (distribution of educational materials + educational meetings + educational outreach visits) + organisational intervention (clinical multidisciplinary team (specific nurse as liaison and co-ordinator for the diabetes program)) + a packet of education (modules targeted at the preventable complications of diabetes -> These modules served as a nidus for patient-education programs) Control group: usual care Length of intervention: 1 year
Outcomes	PROCESS: Documentation of search for complication in clinical record: -Retinopathy

Deeb 1988 *(Continued)*

	(History, Exam,
	Referral)
	-Nephropathy
	(Urinalysis,
	If urinalysis then
	proteinuria,
	If proteinuria then
	BUN/creatinine)
	-Lower-extremity care
	(History, Exam)
	-Hypertension
	(Blood pressure taken,
	Hypertension
	diagnosed,
	Last blood pressure
	reading
	>140 or >90 mmHg,
	Last blood pressure
	reading
	>160 or >95 mmHg)
	
	PATIENT:
	NONE

Notes	National guidelines: "The prevention and treatment of five complications of Diabetes: a guide for primary care practitioners" -directed at treatment and monitoring -targets: visual impairment, adverse outcomes on pregnancy, lower-extremity and kidney poblems and ketoacidosis

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Feder 1995

Methods	RCT (2x2 balanced incomplete block design, randomised by practice) Randomisation concealment: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: N/A Blinded assessment: NOT CLEAR Baseline: DONE Reliable outcomes: DONE except for examination of feet Protection against contamination: DONE no unit of analysis error
Participants	24 of 49 non-training practices in Hackney , East London (UK). 39 providers and per provider a sample size of 10 patients was selected by a method using random numbers (not clear which type of diabetes). providers - 39 physicians supported by nurses patients - 390 practices - 24

Feder 1995 *(Continued)*

Interventions	Intervention group: Professional intervention (distribution of educational materials + local consensus processes + educational outreach visits + reminders) Control group: practices who received guidelines on asthma and provided usual diabetes care Length of intervention: 1 year
Outcomes	PROCESS: Recording of: Funduscopy Blood glucose Weight Blood pressure Smoking habit Feet HbA1 PATIENT: NONE
Notes	Guidelines were developed by local general practitioners working through informal consensus with local hospital specialists and relevant professionals. They were based on the St Vincents' declaration -directed at monitoring -targets: glycaemic control, visual impairments, blood pressure, weight, feet examination, smoking habit

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Halbert 1999

Methods	RCT (design not clear randomised by patient) Randomisation concealment: NOT CLEAR Follow up: - providers: N/A - patients: NOT CLEAR Blinded assessment: DONE Baseline: NOT CLEAR Reliable outcomes: DONE Protection against contamination: DONE
Participants	Diabetic patients who were enrolled in a large network-based Health Maintenance Organisation (HMO) in California (US) and the medical groups that treated the identified diabetic patients (Type 1 and Type 2 diabetes) providers - ? patients - 19,523 practices - 1 Health Maintenance Organisation, the number of medical group is not clear
Interventions	Intervention group:

Halbert 1999 *(Continued)*

	Organisational intervention (arrangements for follow-up) Control group: as in the intervention group, they received guidelines, a list of their diabetes patients with their diabetic retinopathy screening exam status and patients without a record of diabetic retinopathy exam received educational materials. In contrast with the patients in the intervention group who received multiple reminders, the patients received a single reminder
Outcomes	PROCESS: Rates of retinal examination PATIENT: NONE
Notes	National guidelines (ADA guidelines) -directed at monitoring -target: retinopathy screening

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Hartmann 1995

Methods	CBA Characteristics of studies using second site as control: DONE Follow up: - providers: NOT CLEAR - patients: DONE Blinded assessment: NOT CLEAR Baseline: NOT CLEAR Reliable outcomes: NOT CLEAR Protection against contamination: DONE unit of analysis error
Participants	10 physicians in Germany took part in the intervention group as a response to a bulletin in the office of the local physicians' association. 7 physicians from a different area took part in the control group. They were recommended by a local diabetologist as being interested in diabetes care. In all practices a random sample of 25 charts (every second to fourth patient of a list of all diabetic patients) was evaluated (Type 1 and Type 2 diabetes). providers - 17 physicians patients - 403 practices - 17
Interventions	Intervention group: Professional intervention (distribution of educational materials + educational meetings + audit and feedback) + organisational intervention (changes in medical record systems (special forms for diabetic patients)) Control group: usual care Length of intervention: 1 year

Hartmann 1995 *(Continued)*

Outcomes	PROCESS: Documentation of Funduscopy Pallaesthesia Albuminuria Serum Creatinine Total cholesterol Triglyceride HDL cholesterol Blood glucose Blood pressure HbA1c Body weight Glucose self-measurement (blood or urine) PATIENT: NONE
Notes	It was reported that guidelines were provided. These were not specified in the paper.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Hawkins 1979

Methods	RCT (randomised by patient) Randomisation concealment: NOT CLEAR Follow up: - providers: N/A - patients: NOT CLEAR Blinded assessment: NOT CLEAR Baseline: NOT CLEAR Reliable outcomes: DONE Protection against contamination: NOT CLEAR
Participants	A medical follow-up clinic at the Robert B. Green Hospital in San Antonio, TX (US). It serves as a primary care training facility. 1148 of 1722 patients enrolled in the clinic were included in the study. 90% of the patients were Mexican American and more than 95% were indigent. Patients were being followed for hypertension, diabetes or both. The number of included patients with only diabetes is not clear, but 315 patient with diabetes were included in the analyses and completed the 29 month trial (not clear which type of diabetes) providers - ? (pharmacist (interv group) + physicians (control group)) patients - 315 practices - 1 clinic
Interventions	Intervention group: Organisational intervention (revision of professional rules (A clinical pharmacist was responsible for follow-up care of patient with diabetes)) Control group: usual care Length of intervention: 29 months

Hawkins 1979 *(Continued)*

Outcomes	PROCESS: NONE PATIENT: Fasting blood glucose
Notes	Not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Hoskins 1993

Methods	RCT (randomised by patient) Randomisation concealment: NOT CLEAR Follow up: - providers: N/A - patients: NOT CLEAR Blinded assessment: DONE for HbA1c, attendance rates, completeness of documentation. NOT CLEAR for blood pressure, weight Baseline: DONE for HbA1c, blood pressure, weight NOT CLEAR for attendance rates, completeness of documentation. Reliable outcomes: DONE for HbA1c NOT CLEAR for blood pressure, weight, attendance rates, and completeness of documentation. Protection against contamination: NOT CLEAR
Participants	A teaching hospital situated in an inner-city area with a predominantly low socio-economic population (Australia). Patients referred by their GP for assessment and management to the diabetic clinic (Type 1 and Type 2 diabetes). providers - ? (physician+nurse) patients - 206 practices - ?
Interventions	Intervention group: Professional intervention (distribution of educational materials + educational outreach visits (a research nurse liaises with patient and physician to assist with follow up)) + organisational intervention (arrangements for follow-up (prompting physician and patient by nurse)) Control group: traditional form of diabetes follow-up care provided by hospital-based clinics Length of intervention: 1 year
Outcomes	PROCESS: Attendance rates (%) Completeness of documentation: -HbA1c -Weight -Blood pressure PATIENT: HbA1c Systolic blood pressure Diastolic blood pressure

Hoskins 1993 *(Continued)*

	Weight
Notes	Guidelines not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Hurwitz 1993

Methods	RCT (randomised by patient) Randomisation concealment: DONE Follow up: - providers: N/A - patients: DONE Blinded assessment: DONE Baseline: DONE for laboratory outcomes NOT CLEAR for process outcomes Reliable outcomes: DONE Protection against contamination: NOT CLEAR
Participants	Two hospital outpatient clinics, 38 general practices and 11 optometrists in the catchment area of a district general hospital in Islington (UK) Of 415 eligible patients registered at the hospital 181 agreed to take part and were included in the study (Type 2 diabetes) providers - ? physicians patients - 181 practices - 38 general practices and 2 hospital outpatient clinics no unit of analysis error
Interventions	Intervention group: Professional intervention (educational meetings) + organisational intervention (arrangements for follow-up + changes in medical record systems -> patient tracking system) Control group: usual care in hospital clinic Length of intervention: 2½ years
Outcomes	Professional intervention: B: educational meetings Organisational interventions Provider orientated interventions E: continuity of care-> arrangements for follow-up C: changes in medical record systems -> patient tracking system Control group: usual care in hospital clinic Length of intervention: 2½ years
Notes	Local guidelines

Hurwitz 1993 *(Continued)*

	-directed at monitoring -targets: measurements of glycaemic control, weight, blood pressure, urinary albumin value, foot examination, examination of visual acuity and retinoscopy through dilated pupils

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Jaber 1996

Methods	RCT (randomised by patient) Randomisation concealment: NOT CLEAR Follow up: - providers: N/A - patients: DONE Blinded assessment: DONE for laboratory outcomes, health related quality of life NOT CLEAR for blood pressure, weight, patient compliance Baseline: DONE for fasting plasma glucose, glycated haemoglobin, serum Creatinine, BMI microalbumin/Creatinine ratio, total body weight NOT CLEAR for the other outcomes Reliable outcomes: DONE for laboratory outcomes, health related quality of life NOT CLEAR for blood pressure, weight, patient compliance Protection against contamination: NOT CLEAR
Participants	A university-affiliated general internal medicine outpatient clinic (US). Intervention group received care by a pharmacist, the control group by physicians. Urban African-American patients attending the clinic. Of 156 eligible patients 45 were randomised and 39 completed the study (Type 2 diabetes). providers - ? (pharmacist + physicians) patients - 45 practices - 1 outpatient clinic
Interventions	Intervention group: Organisational intervention (revision of professional roles (all diabetes-related management aspects were solely provided by a pharmacist) + patient education on glycaemic control and self-monitoring of blood glucose Control group: usual care by physician Length of intervention: 4 months
Outcomes	PROCESS: NONE PATIENT: Primary outcomes: Fasting plasma glucose Glycated haemoglobin Secondary outcomes: Blood pressure Body weight Serum lipid measurements Renal function parameters

Jaber 1996 *(Continued)*

	Quality of life
Notes	Care was provided consistent with, but broader than that described by Helper and Strand (reference 16 in study). The guidelines are not specified. -directed at treatment -targets: glycaemic control secondary targets: blood pressure, body weight serum lipid measurements, renal function parameters, quality of life

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Kinmonth 1998

Methods	RCT (pragmatic parallel group design, randomisation by practices) Randomisation concealment: DONE Follow up: - providers: DONE - patients: NOT DONE Blinded assessment: DONE Baseline: DONE for BMI, blood pressure, NOT CLEAR HbA1c, total cholesterol, triglyceride, urinary albumin/Creatinine Reliable outcomes: DONE for laboratory outcomes NOT CLEAR for blood pressure, BMI Protection against contamination: DONE no unit of analysis error, because patients' results were corrected for clustering at practice level
Participants	41 practices of 245 eligible practices in a health region in southern England. 245/467 of all practice teams were eligible. 360 of 522 patients were eligible for inclusion. 250 patients completed the study (Type 2 diabetes). providers - 43 doctors supported by 64 nurses patients - 360 practices - 41
Interventions	Intervention group: Professional intervention (distribution of educational materials + educational meetings (training in patient centred care)) + patient education (booklet for patients) Control group: received no training in patient centred care but were also offered special support sessions focusing on use of guidelines and materials Length of intervention: 1 year
Outcomes	PROCESS: NONE PATIENT: HbA1c

Kinmonth 1998 *(Continued)*

	Total cholesterol Triglyceride BMI Systolic blood pressure Diastolic blood pressure Urinary albumin/Creatinine Quality of life Depressed Wellbeing Wellbeing overall Subscales Depression Anxiety Energy Positive wellbeing
Notes	National guidelines -directed at monitoring and treatment -targets: clinical, social and psychological outcomes

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Legorreta 1996

Methods	CBA Characteristics of studies using second site as control: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: NOT CLEAR Blinded assessment: DONE Baseline: DONE for site A, NOT DONE for site B Reliable outcomes: DONE Protection against contamination: DONE unit of analysis error
Participants	Two large medical groups that contract to provide health care to HMO members in California (US) Site A was a typical participating medical group (PMG); site B was an independent physician association (IPA). For the PMG provider a single, separate site was chosen as control. For the IPA provider, data were collected from 13 nonexperimental physician office sites. At the experimental sites, approximately 15 patients were randomly selected each month for 6 months. In addition all patients with new-onset diabetes were included. In the control group from the randomly generated list, the patients whose charts provided glycated haemoglobin levels were selected. After the first 6 months primary care providers in the intervention group were allowed to assign patients for inclusion (Type 1 and Type 2 diabetes) providers - ? physicians+nurses/ physician assistant patients - Site A: 205 - Site B: 195 practices ?
Interventions	Intervention group

Legorreta 1996 *(Continued)*

	Professional intervention (distribution of educational materials + educational meetings) + organisational intervention (clinical multidisciplinary teams (nurse or physician assistant, endocrinologist and a staff assistant) + skill mix changes (nurse treating patients) + arrangements for follow-up + changes in medical records systems) Control group: usual care Length of intervention: 18 months
Outcomes	PROCESS: NONE PATIENT: Glycated haemoglobin
Notes	Nurses followed detailed clinical protocols. -directed at monitoring and treatment -target: glycaemic control

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Litzelman 1993

Methods	RCT (randomised by practice team) Randomisation concealment: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: NOT DONE Blinded assessment: DONE Baseline: NOT CLEAR Reliable outcomes: NOT CLEAR Protection against contamination: NOT CLEAR unit of analysis error
Participants	Academic general medicine practice of the Regenstrief Health Center in Indianapolis, Indiana (US). The practice is subdivided in 4 practice teams. Only patients that were seen at least two times in the preceding year by the same provider were included. Patients of investigators involved in the protocol were also excluded. Of 728 eligible patients, 395 patients entered the study and 352 completed the study (Type 2 diabetes). providers - ? (physicians supported by nurses (education)) patients - 395 practices - 1
Interventions	Intervention group: Professional intervention (distribution of educational materials + reminders) + patient education sessions + behavioural contracts + reminders for patients Control group: usual care Length of intervention: 1 year

Litzelman 1993 *(Continued)*

Outcomes	PROCESS: Percentage of patients with documentation: Ulcers Pulse examination done Dry or cracked skin Calluses or corns Fungal infection (foot or nail) Ingrown nails Improperly trimmed nails Foot or leg cellulitis Foot deformities Sensory examination done PATIENT: Serious foot lesions All foot lesions Dry or cracked skin Ingrown nails Fungal nail infection Fungal skin infection Interdigit maceration
Notes	Local guidelines -directed at foot-care practice for assessment, diagnostic work-up, treatment and referral recommendations -targets: physicians' documentation of the presence of lower extremity clinical abnormalities and the prevalence of lower extremity clinical abnormalities

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Lobach 1997

Methods	RCT (randomised by provider) Randomisation concealment: NOT CLEAR Follow up: - providers: NOT DONE - patients: NOT CLEAR Blinded assessment: DONE Baseline: DONE Reliable outcomes: NOT DONE Protection against contamination: DONE unit of analysis error
Participants	Primary care clinic at Duke University Medical Center (North Carolina, US) 20 family physicians, 1 general internist, 2 nurse practitioners, 2 physician's assistants, 33 family medicine residents were randomised. 30 were included because they met predefined criteria for minimum exposure to diabetic patient care. 359 charts were included with 884 encounters in which diabetes was addressed (not clear which type of diabetes) providers - 30 primary care clinicians patients - 359 encounters - 884

Lobach 1997 *(Continued)*

	practices - 1 primary care clinic
Interventions	Intervention group: Professional intervention (local consensus processes + audit and feedback + reminders) Control group: usual care Length of intervention: 6 months
Outcomes	PROCESS: Compliance rate overall Compliance rate with regard to specific guidelines on: Foot examination Complete physical examination Chronic glycemia monitoring Urine protein determination Cholesterol level Ophthalmologic examination Influenza vaccination Pneumococcal vaccination PATIENT: NONE
Notes	National guidelines (ADA-guidelines), adapted through a consensus building process -directed at monitoring and treatment -targets: compliance with guidelines

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Marrero 1995

Methods	RCT (randomised by patient) Randomisation concealment: NOT CLEAR Follow up: - providers: N/A - patients: NOT CLEAR Blinded assessment: DONE for HbA1, diabetes-specific quality of life, psychological status NOT CLEAR for hospitalisation/emergency room visits Baseline: DONE for HbA1 NOT CLEAR for diabetes-specific quality of life, psychological status hospitalisation/emergency room visits Reliable outcomes: DONE for HbA1, diabetes-specific quality of life, psychological status NOT CLEAR for hospitalisation/emergency room visits Protection against contamination: NOT CLEAR
Participants	Paediatric diabetes clinic, Indianapolis (US) Recruitment was conducted during routine visits in which patients and their families were approached (Type 1 diabetes) providers - ? (nurse practitioners)

Marrero 1995 *(Continued)*

	patients - 106 practices - 1 clinic
Interventions	Intervention group: Professional intervention (distribution of educational materials + patient mediated interventions (a telecommunication system was used to assist in outpatient management)) + organisational intervention (skill mix changes (nurse practitioners reviewed data on self-monitoring of blood glucose and made insulin adjustments) + case management + changes in facilities and equipment (modem+glucose reflectance meters with memory) + changes in medical record systems) Control group: usual care Length of intervention: 1 year
Outcomes	PROCESS: NONE PATIENT: HbA1 Hospitalisation/Emergency Room visits Psychological status Diabetes-specific quality of life
Notes	Local developed algorithms -directed at monitoring and treatment -targets: glycaemic control

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Mazze 1994

Methods	RCT (randomised by patient) Randomisation concealment: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: NOT CLEAR Blinded assessment: DONE for HbA1c NOT CLEAR for process measures Baseline: NOT CLEAR Reliable outcomes: DONE for HbA1c NOT CLEAR for process measures Protection against contamination: NOT CLEAR
Participants	A university family practice clinic in Minneapolis (USA). 8 family practitioners were included. 50% of 33 patients scheduled for visits were randomly selected for the study with between one and five patients being seen by a single physician. A second group was randomly selected for the intervention group (Type 1 and Type 2 diabetes) providers - 8 family practitioners patients - 26 practices - 1 family practice clinic

Mazze 1994 *(Continued)*

Interventions	Intervention group: Professional intervention (distribution of educational materials + educational meetings + local consensus processes + reminders) Control group: usual care Length of intervention: 6 months
Outcomes	PROCESS: Visits Renal evaluation Retinal ecaluation Education Health survey PATIENT: HbA1c
Notes	A data-based approach to diabetes management (Staged Diabetes Management) was developed consistent with national practice standards. Local consensus was reached on the Staged Diabetes Management guidelines -directed at monitoring and treatment -targets: compliance with guidelines

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Mazzuca 1990

Methods	RCT (nonequivalent control group design, randomised by clinic area) Randomisation concealment: DONE Follow up: - providers: DONE - patients: N/A Blinded assessment: DONE Baseline: NOT CLEAR Reliable outcomes: DONE Protection against contamination: DONE no unit of analysis error
Participants	A general medicine clinic, Indianapolis (US). 99 internal medicine residents and 15 faculty internists, 98 were included (Type 2 diabetes). providers - 98 patients - 2791 encounters - 8132 practices - 1 clinic
Interventions	Intervention group: Professional intervention (distribution of educational materials + educational meetings, reminders + audit and feedback) + patient education Control group: only received a postgraduate seminar Length of intervention: 11 months

Mazzuca 1990 *(Continued)*

Outcomes	PROCESS: GHb Fasting blood sugar Home-monitored blood glucose Diet Oral hypoglycaemic agents PATIENT: NONE
Notes	National guidelines (ADA-guidelines) -directed at monitoring and treatment -targets: adherence to five key program recommendations (see process outcomes)

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Naji 1994

Methods	RCT (pragmatic randomised trial, randomised by patient) Randomisation concealment: NOT CLEAR Follow up: - providers: N/A - patients: DONE Blinded assessment: DONE for glycated haemoglobin, Creatinine, Diabetes Health, process measures NOT CLEAR for blood pressure , BMI Baseline: DONE for glycated haemoglobin, Creatinine, BMI, blood pressure NOT CLEAR for Diabetes Health, process measures Reliable outcomes: DONE for glycated haemoglobin, Creatinine, Diabetes Health NOT CLEAR for blood pressure , BMI, process measures Protection against contamination: DONE
Participants	A hospital clinic and general practice groups in Grampian (UK). Adult patients attending the clinic for at least one year and registered with any of the three general practices (Type 2 diabetes) providers - ? (GPs + clinic staff involved in diabetes care) patients - 274 practices - 1 clinic + 3 general practices
Interventions	Intervention group: Professional intervention (distribution of educational materials + reminders) + organisational intervention (arrangements for follow-up + changes in medical record systems) Control group: Received reminders for routine appointments at the clinic (arrangements for follow-up) Length of intervention: 2 years
Outcomes	PROCESS: Routine diabetic care visits Glycated haemoglobin

Naji 1994 *(Continued)*

	Blood pressure Creatinine Visual acuity Funduscopy Peripheral pulses Neurological examination Feet % patients that had seen a dietician % patients that had seen a chiropodist PATIENT: Glycated haemoglobin BMI Creatinine Systolic blood pressure Diastolic blood pressure Diabetes health questionnaire COSTS: Annual costs per patient
Notes	Not clear if the guidelines that the practices received were national or local developed -directed at montoring and treatment -targets: metabolic control and frequency of measurement and examination during routine visits

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Nilasena 1995

Methods	RCT (incomplete block design, randomised by provider) Randomisation concealment: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: N/A Blinded assessment: NOT CLEAR Baseline: DONE Reliable outcomes: NOT CLEAR Protection against contamination: NOT CLEAR no unit of analysis error
Participants	Outpatient clinics at the University of Utah and Salt Lake Veterans Affairs Hospital (US). Internal medicine residents. Patients who had been treated at one of the two sites within one year prior to the study (Type 1 and Type 2 diabetes). providers - 35 of 36 patients - 164 practices - 2 clinics
Interventions	Intervention group: Professional intervention (distribution of educational materials + reminders) + organisational intervention (changes in medical records systems) Control group: usual care Length of intervention:

Nilasena 1995 *(Continued)*

	6 months
Outcomes	PROCESS: Compliance score PATIENT: NONE
Notes	National guidelines (selection of ADA-guidelines was used) -directed at monitoring -targets:glycaemic control and renal-, foot-, eye-, macrovascular-, and neurologic care

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

O'Connor 1996

Methods	CBA Characteristics of studies using second site as control: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: DONE Blinded assessment: DONE Baseline: DONE Reliable outcomes: DONE Protection against contamination: DONE unit of analysis error
Participants	Two primary care clinics at a staff model HMO in Minneapolis (US). Family physicians + trained resource nurses. Patients enrolled at both clinics. Attention was focused on patients who were most in need of change and who were ready to change (Type 1 and Type 2 diabetes). providers - ? (physicians + nurses) patients - 267 practices - 2 clinics
Interventions	Intervention group: Professional intervention (local consensus procedures + audit and feedback) + organisational intervention (skill mix changes (nurses more actively assist in providing diabetes care)) + patient education (a more aggressive educational outreach to targeted patients) Control group: usual care Length of intervention: 18 months
Outcomes	PROCESS: Number of outpatient visits At least 1 HbA1c-test PATIENT: HbA1c

O'Connor 1996 *(Continued)*

Notes	Guidelines not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Palmer 1985

Methods	RCT (incomplete block design, randomised by practice) Randomisation concealment: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: N/A Blinded assessment: DONE Baseline: DONE Reliable outcomes: DONE Protection against contamination: DONE no unit of analysis error
Participants	Primary care practices in Boston, Massachusetts (US) Internists, residents and non-physicians (mostly nurse practitioners). Proportions of different care providers are not clear because more care tasks regarding other diseases are reported in this study. The settings and participating providers are not described separately for each task. Visits potentially eligible for evaluation were identified from laboratory files and billing tapes. Within each 3-month period, if the number of patients exceeded the sample of 38, a random sample was taken. No more than one visit per patient was sampled within the baseline and within the experimental period (not clear which type of diabetes) providers - ? patients - 1943 practices - 8
Interventions	Intervention group: Professional intervention (distribution of educational materials + local consensus procedures + audit and feedback) Control group: usual care Length of intervention: 9 months Follow up period: 18 months
Outcomes	PROCESS: Case-variant score (case-variant score=(criteria not met/ criteria applicable)*100) PATIENT: NONE
Notes	Evaluation criteria were formulated by local consensus -directed at monitoring, diagnosing and treatment -targets: improve performance in accordance with the formulated criteria

Risk of bias

Palmer 1985 *(Continued)*

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Peters 1998

Methods	CBA Characteristics of studies using second site as control: NOT DONE Follow up: - providers: N/A - patients: DONE after one year NOT DONE after three years Blinded assessment: DONE for HbA1c, Creatinine, cholesterol level NOT CLEAR for blood pressure, compliance with ADA guidelines Baseline: NOT DONE Reliable outcomes: DONE for HbA1c, Creatinine, cholesterol level NOT CLEAR for blood pressure, compliance with ADA guidelines Protection against contamination: DONE
Participants	Cedars Sinai Medical Center (US) + a local group model Health Maintenance Organisation (HMO) as control group. Main providers were nurses using specific detailed protocols. Patients referred by their GP at the new implemented Comprehensive Diabetes Care Service at the clinic. A subset of patients who had attended a diabetes education course was included in this study (Type 1 and Type 2 diabetes). providers - ? (nurse practitioners) patients - 164 practices - one medical centre and one HMO
Interventions	Intervention group Professional interventions (distribution of educational materials + audit and feedback) + organisational intervention (revision of professional roles (nurses provided diabetes care based on protocols) + arrangements for follow-up + changes in medical record systems) Control group: usual care Length of intervention: 3 years
Outcomes	PROCESS: Compliance with ADA guidelines: HbA1c levels Lipid panels Foot exams Ophthalmology referrals PATIENT: HbA1c Total median cholesterol concentrations in the subgroup of patients with an initial total cholesterol level>6.2 mmol/l
Notes	Protocols were used based on national (ADA-guidelines) -directed at monitoring and treatment -targets: glycaemic control, lipid management, foot exams and ophthalmology referrals

Peters 1998 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Pieber 1995

Methods	CBA Characteristics of studies using second site as control: NOT DONE Follow up: - providers: DONE - patients: DONE Blinded assessment: DONE Baseline: DONE Reliable outcomes: DONE Protection against contamination: DONE unit of analysis error
Participants	General practices in a rural area in Austria. Patients with type 2 diabetes attending the general practices were included (Type 2 diabetes) providers - 14 GPs patients - 94 practices - 14
Interventions	Intervention group: Professional intervention (distribution of educational materials + educational meetings plus) + patient education by GPs and office staff Length of intervention: 6 months
Outcomes	PROCESS: NONE PATIENT: HbA1c Cholesterol Triglycerides BMI Body weight Systolic blood pressure Diastolic blood pressure Treatment without OHG Daily dosage of OHG (tablets per patient per day) Treatment with sulphonylurea (tablets per patient per day) Foot care: Callus formation: Interdigital cracks, interdigital Margins of the toenails were cut back, or ingrown toe nails were cut out.
Notes	A Diabetes Treatment and Teaching Programme was used developed and evaluated in Germany -directed at treatment and education -targets: metabolic control and risk factors including foot status

Risk of bias

Pieber 1995 *(Continued)*

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Pill 1998

Methods	RCT (block design, randomised by practice) Randomisation concealment: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: NOT CLEAR Blinded assessment: DONE Baseline: NOT CLEAR except NOT DONE for Glyc-Hb Reliable outcomes: NOT CLEAR Protection against contamination: DONE unit of analysis error
Participants	General practices in South Glamorgan (UK), that had been committed for at least two years to an annual peer review clinical audit of diabetic care. 29 of 33 eligible practices participated. All practices were asked to recruit 12 patients who met the inclusion criteria (type 2 diabetes) providers - ? patients - 190 (165 completed follow-up) practices - 29
Interventions	Intervention group: Professional intervention (educational meetings + educational outreach visits (continuing support by research nurse for providing patient centred care)) Control group: usual care Length of intervention: 18 months
Outcomes	PROCESS: Attendance at practice over last 12 months PATIENT: Glyc-Hb BMI Weight Systolic blood pressure Diastolic blood pressure Measure of complications Mean satisfaction score Health status (SF-36)
Notes	Guidelines not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Rith-Najarian 1998

Methods	ITS Intervention independent of other changes: DONE Sufficient data points to enable reliable statistical inference: NOT DONE Formal test of trend: N/A Intervention unlikely to affect data collection: DONE Blinded assessment: DONE Completeness of data set: DONE Reliable outcomes: NOT CLEAR
Participants	Rural primary care clinic in northern Minnesota (US). A foot-care team was formed consisting of a family physician, two clinic nurses, a home care nurse, a nutritionist and a registrar. Patients were American Indians identified through surveillance having diabetes. They were entered into a diabetes registry and followed thereafter (not clear which type of diabetes). Provider - 1 physician + 3 nurses (+nutritionist+registrar) patients - 449 practices - 1
Interventions	Intervention group: Professional intervention (distribution of educational materials + reminders) + organisational intervention (clinical multidisciplinary team) Control group: N/A Length of intervention: 3 years
Outcomes	PROCESS: NONE PATIENT: Lower-extremity amputation (LEA) First LEA Major LEA (defined as either a "below the knee amputation" or an "above the knee amputation")
Notes	Local guidelines -directed at diagnosis, treatment, monitoring and risk factor assessment -targets: to reduce lower-extremity amputations

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Rutten 1990

Methods	RCT (incomplete block design, randomised by practice) Randomisation concealment: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: DONE Blinded assessment: DONE for HbA1 NOT CLEAR for weight Baseline: DONE for weight NOT CLEAR for HbA1 baseline measures were different between both groups at baseline, but in the analyses the results were adjusted for this difference

Rutten 1990 *(Continued)*

	Reliable outcomes: DONE for HbA1 NOT CLEAR for weight Protection against contamination: DONE unit of analysis error
Participants	Eight practices were selected from a total of 57 practices of which detailed information was available from earlier studies. Selection was based on traceability of the diabetes in the record index; percentages of referrals to internists; numbers of prescriptions of oral hypoglycaemic agents; practice list; distance to nearest hospital; sex and age distribution of practice population. The variables were divided into quartiles and practices from the two middle quartiles were chosen. Patients attending the practices and treated for type 2 diabetes for at least 6 months (Type 2 diabetes) providers - ? (GPs supported by nurses) patients - 149 (127 completed follow-up) practices - 8
Interventions	Intervention group Professional intervention (distribution of educational materials) + organisational intervention (case management) Control group: usual care Length of intervention: 1 year
Outcomes	PROCESS: NONE PATIENT: HbA1 Body weight
Notes	A detailed protocol was introduced (local developed) -directed at treatment and monitoring -targets: glycaemic control and body weight reduction

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Sadur 1999

Methods	RCT (randomised by patient) Randomisation concealment: DONE Follow up: - providers: N/A - patients: DONE Blinded assessment: DONE Baseline: DONE Reliable outcomes: DONE Protection against contamination: NOT CLEAR
Participants	Pleasanton facility of the Kaiser Permanente medical care Program, Northern California (US). Providers were primary physicians who were temporarily replaced by a multidisciplinary team in the intervention group.

Sadur 1999 *(Continued)*

	Patients that had had a recent Hb A1c>8.5% or not had an HbA1c concentration measured during the previous year. 70% of the eligible patients agreed to participate (Type 1 and Type 2 diabetes) providers - ? (? physicians + 1 dietitian + 1 behaviorist + pharmacist + 1 diabetes nurse educator + 2 diabetologists) patients - 185 practices - 1 HMO-setting
Interventions	Intervention group: Organisational intervention (clinical multidisciplinary teams + case management) + patient education Control group: usual care Length of intervention: 6 months
Outcomes	PROCESS: NONE PATIENT: HbA1c Inpatient and outpatient services (self-reported measures are not included in the review)
Notes	Guidelines not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Shultz 1992

Methods	RCT (incomplete block cross-over design, randomised by patient) Randomisation concealment: NOT CLEAR Follow up: - providers: N/A - patients: NOT DONE Blinded assessment: DONE Baseline: DONE Reliable outcomes: DONE Protection against contamination: NOT DONE
Participants	Veterans Administration Hospital (US) Patients using insulin were selected by virtue of having the highest blood glycohaemoglobins on record during the preceding 18 months (not clear which type of diabetes). providers - ? (physicians) patients - 30 (20 completed follow-up) practices - 1 hospital
Interventions	Intervention group: Professional interventions (patient mediated intervention

Shultz 1992 *(Continued)*

	(a telecommunication system was used to assist in outpatient management) + organisational intervention (changes in physical structure, facilities and equipment (modem + glucometer-M) + changes in medical record systems) Control group: usual care Length of intervention: 9 months Follow up: 15 months
Outcomes	PROCESS: NONE PATIENT: Glycohemoglobin
Notes	Guidelines not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Smith 1987

Methods	RCT (block design with a block size of two, randomised by patient) Randomisation concealment: DONE Follow up: - providers: N/A - patients: DONE Blinded assessment: DONE Baseline: NOT CLEAR Reliable outcomes: DONE Protection against contamination: NOT CLEAR
Participants	The outpatient facility of Wishard Memorial Hospital in Indianapolis (US) General medicine patients who had insulin or oral hypoglycemic agents prescribed or continued during the index visit and who had visited the clinic in the previous year and had a scheduled appointment to return to the clinic (Type 1 and Type 2 diabetes). providers - ? patients - 859 practices - 1 general medicine clinic
Interventions	Intervention group: Organisational intervention (arrangements for follow up) + patient education Length of intervention: Average 12 months. Data were standardised for duration of follow up
Outcomes	PROCESS: Kept scheduled visits Prescription refills Walk-in visits Total contacts Visit failures Total scheduled visits (kept and failed)

Smith 1987 *(Continued)*

	Hospitalisations PATIENT: Hospitalisations
Notes	Guidelines not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Low risk	A - Adequate

Stein 1974

Methods	RCT (randomised by patient) Randomisation concealment: NOT DONE Follow up: - providers: N/A - patients: DONE Blinded assessment: DONE for blood glucose, NOT CLEAR for weight Baseline: NOT CLEAR Reliable outcomes: DONE for blood glucose, NOT CLEAR for weight Protection against contamination: NOT CLEAR
Participants	Alachua General Hospital Medical Clinic (Outpatient Care) (Florida, US). 28 female patients having a blood glucose > 140 mg/100 ml after they were given a 75 gm glucose load and that did not have a prior history of ketoacidosis (Type 2 diabetes). providers - nurse practitioner + clinic physician(s) patients - 28 practices - 1 general hospital medical clinic
Interventions	Intervention group: Professional interventions (distribution of educational materials) + organisational intervention (revision of professional roles) + patient education Control group: usual care Length of intervention: 6 months
Outcomes	PROCESS: NONE PATIENT: Blood sugar Body weight
Notes	Guidelines not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement

Stein 1974 *(Continued)*

Allocation concealment?	High risk	C - Inadequate

Sullivan 1991

Methods	ITS Intervention independent of other changes: DONE Sufficient data points to enable reliable statistical inference: NOT DONE Formal test of trend: N/A Intervention unlikely to affect data collection: DONE Blinded assessment: NOT CLEAR Completeness of data set: NOT CLEAR Reliable outcomes: NOT CLEAR
Participants	One general practice in Lanarkshire (UK). A relatively young practice. 4 GP principals and a practice nurse deliver diabetes care. All patients under the care of the practice during the period 1983-1988 (Type 1 and Type 2 diabetes). providers - 5 patients - 1983: 53 1984: 51 1985: 56 1986: 61 1987: 67 1988: 70 practices - 1
Interventions	Intervention group: Organisational intervention (clinical multi-disciplinary teams (A joint GP/nurse review system) + arrangements for follow-up) Control group: N/A Length of intervention: 3 years
Outcomes	PROCESS: Percentage of patients with recording examinations of: Weight Blood pressure Injection sites Visual acuity Funduscopy Foot examination HbA1c Urinary protein estimation PATIENT: NONE
Notes	Guidelines not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Tai 1999

Methods	RCT (2x2 balanced design randomised by practice) Randomisation concealment: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: NOT DONE Blinded assessment: DONE Baseline: NOT CLEAR Reliable outcomes: DONE Protection against contamination: DONE no unit of analysis error
Participants	General practitioner tutors from two medical schools who practised locally in North London (UK) and used an EMIS (Egton medical Information Services) computer system. Patients who gave consent for access to records (not clear which type of diabetes). providers - 17 general practitioners and 11 practice nurses patients - 167 practices - 6
Interventions	Intervention group: Professional intervention (reminders) + organisational intervention (changes in medical record systems (use of computer templates)) Control group: using new computer templates for asthma Length of intervention: 1 year
Outcomes	PROCESS: Use of diabetes templates PATIENT: NONE
Notes	National guidelines (developed by the British Diabetes Association) -directed at monitoring -targets: glycaemic control, lipid profile, serum creatinine, current medication

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Taplin 1998

Methods	CBA Characteristics of studies using second site as control: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: NOT CLEAR Blinded assessment: DONE Baseline: DONE

Taplin 1998 *(Continued)*

	Reliable outcomes: DONE Protection against contamination: DONE for comparison with surrounding practices unit of analysis error
Participants	6 primary care facilities within the Group Health Cooperative of Puget Sound, a consumer-governed health maintenance organisation (HMO), Seattle (US). In one practice the intervention was implemented, 5 practices served as control group. In the intervention group were 2 physicians who shared, 2 registered nurses, a licensed practical nurse and a family nurse practitioner. In the control group it is not clear. Patients attending the practices for breast cancer screening, colon cancer screening, warfarin control or diabetic care (not clear which type of diabetes) providers - ? (physicians supported by nurses) patients - ? (the number of patients that visited the practice for diabetes care is not reported separately. In total 9754 patients were included for studying compliance with guidelines for the different areas practices - 6
Interventions	Intervention group: Professional intervention (distribution of educational materials + local consensus processes + audit and feedback + reminders + marketing (establishing a team and after that regular team meetings to discuss and achieve clinical goals)) + organisational interventions (clinical multidisciplinary teams (physicians, nurses, clinic manager, a clinic pharmacist and a trained facilitator (a registered nurse with a master's degree in public health and training in the application of total quality management tools) attended the group meetings) + changes in medical record systems) Control group: usual care Length of intervention: 2 years
Outcomes	PROCESS: Compliance with guideline for diabetic eye care PATIENT: NONE
Notes	It is mentioned that guidelines were partly based on existing recommendations, but these are not specified

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	D - Not used

Vinicor 1987

Methods	RCT (incomplete block design, randomised by resident clinic team) Randomisation concealment: NOT CLEAR Follow up: - providers: NOT CLEAR - patients: NOT DONE

Vinicor 1987 *(Continued)*

	Blinded assessment: DONE for fasting plasma glucose, A1Hgb, post-prandial plasma glucose, process measures NOT DONE for weight, blood pressure Baseline: DONE for fasting plasma glucose, A1Hgb, weight , blood pressure, process measures NOT DONE for post-prandial plasma glucose Reliable outcomes: DONE for fasting plasma glucose, A1Hgb, post-prandial plasma glucose and the process measures fasting blood glucose and random blood glucose NOT CLEAR for weight, blood pressure and other process measures Protection against contamination: NOT CLEAR unit of analysis error
Participants	General medicine clinic at Wishard Memorial hospital, Indiana University Medical Center (US). Physicians (residents) responsible for care of patients with diabetes. 994 patients were contacted, 728 agreed to participate, 532 completed baseline and 275 were re-assessed post intervention for patient outcomes and 323 were reassessed for process measures (Mazzuca) (Type 1 and Type 2 diabetes). Provider- 86 residents patients - 532 practices - 1 general medicine clinic
Interventions	Intervention group: Professional intervention (distribution of educational materials + educational meetings + local consensus processes + audit and feedback + reminders) + organisational intervention (communication and case discussion between distant health professionals) + patient education Control group: usual care Length of intervention: 11 months Follow up period for reassessment patients: Average of 26 months (patient education began 13 months after baseline assessment)
Outcomes	PROCESS: % of total clinic visits for monitoring metabolic control: Fasting blood glucose Random blood glucose Urine test record History of hypoglycaemia % of patients for whom dietary management recommendations were followed: Diet prescription Calories per formula Teach patient caloric limit: Advise patient to minimise concentrated CHO Negotiate a target weight with obese patients Refer to diet clinic % of patients for whom recommendations for monitoring chronic complications were followed on at least an annual basis Visual symptoms Visual acuity Fundus examination BUN or Creatinine Foot examination Discuss foot care Neurologic examination History of peripheral pain History of urinary symptoms Postural hypotension

Vinicor 1987 *(Continued)*

	Impotence (males only) Blood pressure Baseline electrocardiography Smoking history Cholesterol or triglycerides Carotid and femoral bruits PATIENT: fasting plasma glucose A1Hgb 2 hour postprandial weight systolic blood pressure diastolic blood pressure
Notes	Protocols evolved from discussions with general internists as well as review of patient baseline data -directed at treatment and diagnostics -targets: obesity, hyperglycemia, retinopathy, foot disease, neuropathy, and risk factors for cardiac, renal and vascular disease

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Ward 1996

Methods	RCT (incomplete block design, randomised by provider) Randomisation concealment: NOT CLEAR Follow up: - providers: DONE - patients: N/A Blinded assessment: NOT DONE Baseline: NOT CLEAR Reliable outcomes: NOT CLEAR Protection against contamination: DONE no unit of analysis error
Participants	General practitioners in the Perth metropolitan region (Australia) who participated in a previous study (Kamien 1994). In that study 42% of the GPs approached (393 of 600 GPs in the district) finally recruited patients into the study; the next five consenting patients with type 2 diabetes that consulted the GP after he had completed a questionnaire. Patients that were recruited in the previous study were also used in this study. (Type 2 diabetes). 139 of 160 providers asked to participate in this study, were included providers- 139 patients - 386 practices- ?
Interventions	Intervention group: Professional intervention (distribution of educational materials + educational outreach visits (interview by academic GP or nurse) + audit and feedback) Control group: received recommended standard of Adequate Competent Care score and postal feedback Length of intervention:

Ward 1996 *(Continued)*

	8 months
Outcomes	PROCESS: History recorded Duration of known diabetes Dietary inquiry and advice Alcohol intake inquiry and advice Exercise inquiry and advice Smoking inquiry and advice Impotence/vaginitis inquiry and advice Annual physical examination Blood pressure Eye examination (or referral to ophthalmologist) Body weight Feet examined -Pulses -Sensation -Nails -Reflexes HbA1 Blood glucose Cholesterol Triglyceride Creatinine Urinalysis Glucose Protein Nitrite Modified ACC score PATIENT: NONE
Notes	A local recommended standard was formulated based on information obtained in a previous study

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Weinberger 1995

Methods	RCT (blocked randomisation scheme in a 3:1 ratio, to increase the power to detect also differences across 3 study nurses (intervention strategy). Randomisation by patient) Randomisation concealment: NOT CLEAR Follow up: - providers: N/A - patients: DONE Blinded assessment: DONE Baseline: DONE Reliable outcomes: DONE Protection against contamination: NOT CLEAR
Participants	Veterans Affairs general medical clinic (US).

Weinberger 1995 *(Continued)*

	Patients that were currently using an oral hypoglycemic agent or insulin and received primary care from the General Medical Clinic (GMC) and had at least one GMC visit during the previous year and had a pending GMC appointment and kept a scheduled GMC appointment during a six-month enrolment period in 1991 (Type 2 diabetes). providers - ? patients - 275 practices - 1 general medical clinic
Interventions	Intervention group Professional intervention (patient mediated interventions (nurses attempted to telephone patients to facilitate compliance, monitor patients' health status, facilitate resolution of identified problems, facilitate access to primary care)) + organisational intervention (arrangements for follow-up) + patient education by telephone Control group: usual care Length of intervention: 1 year
Outcomes	PROCESS: NONE PATIENT: Glycohemoglobin Fasting blood glucose Health-related quality of life: Physical functioning Social functioning Physical role functioning Emotional role functioning Mental health Vitality Bodily pain General health perceptions In the subgroup of hyperlipidemic patients (total cholesterol >=200mg/dl): Seen by dietician % taking lipid-lowering medications Total cholesterol Triglycerides LDL cholesterol HDL cholesterol In the subgroup of obese patients (weight at study enrolment>=120% of ideal body weight): Change in weight Seen by dietician
Notes	Guidelines not specified in the paper

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Albisser 1996	Patient orientated intervention
Domurat 1999	Quasi-experimental design - poor chioce of control site (the intervention focused only on a high-risk subpopulation, this was compared with all diabetes patients receiving usual care)
Harrower 1995	Quasi-experimental design (No contemporous data collection-> no parallel groups)
Ronnemaa 1997	Patient orientated intervention
Rosenqvist 1988	Quasi-experimental design - poor choice of control site (intervention group - general practices who received an educational intervention to change practice and implemented the recommended changes, control site practices - received the educational intervention but did not implement the recommended changes)
Williams 1990	Quasi-experimental design - controlled before -after study but no baseline measurement in the control group

ADDITIONAL TABLES

Table 1. Table of summarised results for professional interventions vs usual care

Study	Comparison	Effect on practice	Effect on patient	Notes
Benjamin 1999	Educational materials + educational meetings + local consensus processes + audit and feedback vs no intervention on diabetes	chol (+)# microv (+)#	glyc (+)#	No post intervention screening rates were reported for the control group. The authors stated that there was little change in screening rates for the control group over the entire study period compared with improvements seen in the intervention group +=positive effect 0=no effect -=negative effect, +/-=unclear #= a possible unit of analysis error glyc=glycaemic control bp=blood pressure, BMI=BMI chol=cholesterol alb=albumin creat=creatinin microv/macrov=micro- macrovascular complications well=wellbeing hlth surv=health survey compl=compliance care provider att pat=attendance patients hosp=hospitalisations s-rep health=self reported health qual life=quality of life

Table 1. Table of summarised results for professional interventions vs usual care *(Continued)*

Feder 1995	Educational materials + local consensus processes + educational outreach visits + reminders vs no intervention on diabetes	glyc (+) bp (+) weight (+) microv (+)	N/A	
Kinmonth 1998	Educational materials + educational meetings + educational materials for patients vs no intervention to support patient centred care, but support sessions focusing on use of guidelines and materials	N/A	glyc (0) bp (0) chol (0) BMI (-) alb (0) well (+)	
Litzelman 1993	Educational materials + reminders + patient education + behavioural contacts with patients + reminders for patients vs no intervention	microv (+)#	microv (+)#	
Lobach 1997	Local consensus processes + audit and feedback + reminders vs no intervention	glyc (0)# chol (+)# ur prot (+)# microv (-)# compl (+)#	N/A	
Mazze 1994	Distribution of educational materials + educational meetings + local consensus processes + reminders vs no intervention	visits (+/-) microv (+/-) educ (+/-) hlth surv (+/-)	glyc (+/-)	No statistical analyses were undertaken, but there was a positive trend
Mazzuca 1990	Group A (control group) postgraduate seminar vs Group B: A+reminders vs Group C: B+clinical materials vs Group D: C+diabetes patient education service	glyc (+)	N/A	
Palmer 1990	Educational materials + local consensus procedures + audit and feedback vs no intervention	compl (0)	N/A	Possible ceiling effect: baseline variant scores are low
Pieber 1995	Educational materials + educational meetings + patient education vs no intervention	N/A	glyc (+)# bp (0) # chol (0)# BMI (+)# microv (+)#	The difference in microvascular complications was only tested within groups, not between groups
Pill 1998	Educational meetings + educational outreach visits vs no intervention	att pat (0)#	glyc (0)# bp (0)# BMI (0)# mic/ macrov (0)#	
Ward 1996	Educational materials + educational outreach visits + audit and feedback by interview vs educational materials + postal feedback	glyc (+) bp (0) chol (+) weight (+)	N/A	Only the difference in compliance rate was tested between groups, the differences in the other outcomes were tested within groups.

Table 1. Table of summarised results for professional interventions vs usual care *(Continued)*

		alb (+) microv (+) compl (+)	
Carlson 1991	Educational meetings + local consensus processes to identify problems and to create plans to improve diabetes care	glyc (+)# microv (+)#	glyc (0)#

Table 2. Table of summarised results for organisational interventions vs usual care

Study	Comparison	Effect on practice	Effect on patient	Notes
Branger 1999	Changes in medical record systems (electronic communication between different physicians who both provide diabetic care to the same diabetic patients) vs no intervention	glyc (+)# bp (+)# chol (+)# weight (+)# microv (0) att pat (0)	N/A	+=positive effect 0=no effect -=negative effect, +/-=unclear #= a possible unit of analysis error glyc=glycaemic control bp=blood pressure, BMI=BMI chol=cholesterol alb=albumin creat=creatinin microv/macrov=micro- macrovascular complications well=wellbeing hlth surv=health survey compl=compliance care provider att pat=attendance patients hosp=hospitalisations s-rep health=self reported health qual life=quality of life
Day 1992	Revision of professional roles + changes to the setting + a learner-centred counselling approach was adopted allowing patients to identify problems and agree potential solutions vs no intervention	N/A	glyc (+)#	
De Sonnaville 1997	A clinical multidisciplinary team (general practitioner, diabetes nurse educator, dietician, podiatrist, diabetologist) + formal integration of services (general practitioner was supported by laboratory) + arrangements for follow up + communication and case discussion between distant health professionals + changes to the setting /site of service delivery + changes in medical records systems + patient education vs no intervention	N/A	glyc (+)# bp (0)# chol (+)# BMI (-)#	
Halbert 1999	Arrangements for follow up (multiple reminders to patients) vs single reminder	microv (+)	N/A	
Hawkins 1981	Revision of professional rules (A clinical pharmacist was responsible for follow-up care of patient with diabetes) vs no intervention	N/A	glyc (0)	The baseline fasting blood glucose was significant different between both groups (p<=0.05)

Table 2. Table of summarised results for organisational interventions vs usual care *(Continued)*

Jaber 1996	Revision of professional roles (all diabetes-related management aspects were solely provided by a pharmacist) + patient education vs no intervention	N/A	glyc (+) bp (0) chol (0) microv (0)	The difference in blood pressure was only tested within groups not between groups. For chol, BMI and microv no values were reported, it was only stated in the text that there were no differences in these outcomes between both groups
Sadur 1999	Clinical multidisciplinary teams + skill mix changes + case management + patient education vs no intervention	hosp (+)	glyc (+)	
Smith 1987	Arrangements for follow up + patient education + appointment reminders for patients vs no intervention	att pat (+)	N/A	
Sullivan 1991	Interrupted Time Series (ITS): Clinical multi-disciplinary teams (A joint GP/nurse review system) + arrangements of follow-up	glyc (+/-) bp (+/-) weight (+/-) microv (+/-)	N/A	No results of statistical analyses were reported by the authors, but there was a positive trend

Table 3. Table of summarised results for professional+organisational interv vs usual care

Study	Comparison	Effect on practice	Effect on patient	Notes
Aubert 1998	Educational materials (detailed management algorithms) + revision of professional roles (nurse case management) + arrangements for follow-up + patient education vs no intervention	microv (+)	glyc (+) bp (0) chol (0) BMI (0) s-rep health (+)	+=positive effect 0=no effect -=negative effect, +/-=unclear #= a possible unit of analysis error glyc=glycaemic control bp=blood pressure, BMI=BMI chol=cholesterol alb=albumin creat=creatinin microv/macrov=micro- macrovascular complications well=wellbeing hlth surv=health survey compl=compliance care provider att pat=attendance patients hosp=hospitalisations s-rep health=self reported health qual life=quality of life
Boucher 1987	Educational materials + educational meetings + arrangements for follow up + communication and case discussion between distant health professionals + changes in medical record systems vs no intervention	att pat (+/-)	glyc (+)#	For the attendance rates no statistical analyses were undertaken. The difference in glycaemic control was tested within groups, not between groups

Table 3. Table of summarised results for professional+organisational interv vs usual care *(Continued)*

Deeb 1988	Educational materials + educational meetings + educational outreach visits + clinical multidisciplinary team + patient education vs no intervention	bp (0) microv (+)	N/A	The difference in process outcomes was tested within groups, not between groups
Hartmann 1995	Educational materials + educational meetings + audit and feedback + changes in medical record systems vs no intervention	glyc (0) bp (0) chol (+) weight (0) creat (+) microv (+)	N/A	A possible ceiling effect was identified by the reviewers for blood pressure and glyceamic control
Hoskins 1992	Educational materials + educational outreach visits + arrangements for follow up (prompting of patient and physician by nurse) vs routine care by GP care vs routine care by specialist diabetic clinic	att pat (-)	glyc (+) bp (+) weight (+) (only in the shared care group)	Differences in attendance rates and patient outcomes were tested within groups, not between groups. It was stated by the authors that there was no difference in the magnitude of the improvement in HbA1c between groups.
Hurwitz 1993	Educational meetings + arrangements for follow-up + changes in medical record systems vs no intervention	glyc (+) microv (+) alb (+) att pat (+)	glyc (0) microv (0) hosp (0)	
Legorreta 1996	Educational materials + educational meetings + clinical multidisciplinary teams + skill mix changes (nurse treating patients) arrangements for follow up + changes in medical records systems vs no intervention The comparisons were made at two sites: Site A: a typical participating medical group (PMG) Site B: independent physician association	N/A	glyc (+)#	
Marrero 1995	Educational materials + a telecommunication system + skill mix changes (nurse practitioners reviewed data on self-monitoring of blood glucose and made insulin adjustments) + case management + changes in facilities and equipment + changes in medical record systems vs no intervention	N/A	glyc (0) qual life (0) hosp (0)	
Naji 1994	Educational materials + reminders + arrangements for follow up + changes in medical record systems vs no intervention, however, the patients in the control group also received reminders for routine appointments	glyc (+) bp (+) creat (0) microv (+) att pat (+)	glyc (0) bp (0) BMI (0) creat (0)	
Nilasena 1995	Educational materials + reminders + changes in medical records systems vs no intervention	compl (0)	N/A	The change in compliance rates was significant within both groups, but there was no significant difference in the change in compliance rates between both groups

Table 3. Table of summarised results for professional+organisational interv vs usual care *(Continued)*

O'Connor 1995	Local consensus procedures + audit and feedback + skill mix changes (nurses more actively assist in providing diabetes care) + more aggressive educational outreach to patients vs no intervention	glyc (+/-)# att pat (+/-)#	glyc (+)#	No statistical analyses were undertaken to test the change in process outcomes within or between groups. The process outcomes however seemed to improve during the follow-up in both groups.
Peters 1998	Educational materials + audit and feedback + revision of professional roles (nurses provided diabetes care based on protocols) + changes in medical records systems + arrangements for follow up vs no intervention	glyc (+) chol (+) microv (+)	glyc (+) chol (+/-)	*For the process outcomes no statistical tests were undertaken **Only in patients with a total cholesterol >6.2 mmol/l cholesterol levels fell significantly in the intervention group. In the control group no significant change was found.
Rith-Najarian 1998	Interrupted Time Series (ITS): Educational materials + reminders + clinical multidisciplinary team vs pre intervention period	microv (-)	microv (-)	
Rutten 1990	Educational materials + case management vs no intervention	N/A	glyc (+)# weight (0)#	
See Tai 1999	Reminders + changes of medical record system (implementation of new diabetes templates) vs usual diabetes care (usual basic template), but implementation of new asthma templates	compl (+/-)	N/A	No statistical tests were undertaken for the compliance rate, but the compliance rates improved more in the intervention group
Shultz 1992	A telecommunication system + changes in facilities and equipment + changes in medical record systems vs no intervention	N/A	glyc (+)	
Stein 1974	Distribution of educational materials + revision of professional roles (a nurse practitioner trained in the management of diabetes mellitus) + patient education vs usual care	N/A	glyc (0) weight (0)	The authors did not report p-values. They reported in the text that there were no significant differences between groups
Taplin 1998	Educational material + local consensus processes + audit and feedback + reminders + marketing (establishing a team and after that, regular team meetings to discuss and achieve clinical goals) + clinical multidisciplinary team + changes in medical record systems vs no intervention	compl microv (0)#	N/A	The eye care compliance was high in the intervention group at baseline, but still improved with time, but not significantly, probably of insufficient power.
Vinicor 1987	For patient outcomes four different groups were compared: Group 1: no intervention Group 2: patient education Group 3: physician education consisting of: educational materials + educational meetings + local consensus processes + audit and feedback + reminders + communication and case discussion between distant health professionals + Group 4: patient education + physician education (publication of Vinicor 1987)	glyc (+)# bp (0)# chol (+)# creat (0)# microv (0)#	glyc (+)# (group 2,3,4) bp (+)# (group 2) weight (+)# (group 2,4)	A possible ceiling effect was noticed: the lower baseline glycosylated haemoglobin levels of patients who were reassessed, especially in group 1 and group 3 could have made it more difficult to detect significant effects of the interventions

Table 3. Table of summarised results for professional+organisational interv vs usual care *(Continued)*

	For process outcomes: Group 3 and group 4 were combined as also group 1 and group 2 were combined ->\n\nEducational materials + educational meeting + local consensus processes + audit and feedback + reminders + Communication and case discussion between distant health professionals + vs no intervention (publication of Mazzuca 1988)		
Weinberger 1995	Patient mediated interventions (nurses attempted to telephone patients to facilitate compliance, monitor patients' health status, facilitate resolution of identified problems, facilitate access to primary care) + arrangements for follow up + patient education vs no intervention	N/A	glyc (+) chol (0) weight (0) qual life (0)

Table 4. Professional interventions vs usual care

Study	Comparison	Effect on practice	Effect on patient	Notes
Benjamin 1999	Educational materials + educational meetings + local consensus processes + audit and feedback vs no intervention on diabetes	Rates of compliance with standards of care:\n\nAnnual urine test for albumin/protein (%): Baseline: 45 vs 67** Post intervention: 91 vs NA Absolute difference: NA Relative improvement: NA\n\nAnnual cholesterol determination (%): Baseline: 58 vs 52 Post intervention: 77 vs NA Absolute difference: NA Relative improvement: NA\n\nAnnual diabetes education (%): Baseline: 23 vs 21 Post intervention: 84 vs NA Absolute difference: NA Relative improvement: NA\n\nAnnual dilated retinal exam (%): Baseline: 32 vs 59** Post intervention: 63 vs NA Absolute difference: NA Relative improvement: NA\n\nAnnual influenza vaccinations (%): Baseline: 30 vs 24 Post intervention: 73 vs NA Absolute difference: NA Relative improvement: NA\n\nAnnual nutritional education (%):	HbA1c (ref. 3.5-6.0%): Baseline: 9.30 ±0.32 vs 9.21±0.32 Post intervention (9 months): 8.42 ± 0.30 vs 9.41± 0.29 (p=0.001) Post intervention (15 months): 8.68 ±0.28 vs 9.15± 0.32 (p=0.009) Absolute difference (9 months): 1.01 Absolute difference (15 months): 0.47 Relative improvement: 11% Relative improvement: 5% DE-DC= 1.08 (9 months) DE-DC= 0.56 (15 months) HbA1c (ref. 3.5-6.0%): Baseline: 9.30 ±0.32 vs 9.21±0.32 Post intervention (9 months): 8.42 ± 0.30 vs 9.41± 0.29 (p=0.001) Post intervention (15 months): 8.68 ±0.28 vs 9.15± 0.32 (p=0.009) Absolute difference (9 months): 1.01 Absolute difference (15 months): 0.47 Relative improvement: 11% Relative improvement: 5% DE-DC= 1.08 (9 months)	*No post intervention screening rates were reported for the control group. The authors stated that there was little change in screening rates for the control group over the entire study period compared with improvements seen in the intervention group\n\n**Significant difference between both groups at baseline: for annual urine test for albumin/protein (p<0.05) and for eye exams (p<0.01)\n\n***Rates of compliance with standard outcomes significantly improved for all process outcomes in the intervention group (p<0.001). For an-

Table 4. Professional interventions vs usual care *(Continued)*

		Baseline: 37 vs 43 Post intervention: 67 vs NA Absolute difference: NA Relative improvement: NA Rates of compliance with standards of care: Annual urine test for albumin/protein (%): Baseline: 45 vs 67** Post intervention: 91 vs NA Absolute difference: NA Relative improvement: NA Annual cholesterol determination (%): Baseline: 58 vs 52 Post intervention: 77 vs NA Absolute difference: NA Relative improvement: NA Annual diabetes education (%): Baseline: 23 vs 21 Post intervention: 84 vs NA Absolute difference: NA Relative improvement: NA Annual dilated retinal exam (%): Baseline: 32 vs 59** Post intervention: 63 vs NA Absolute difference: NA Relative improvement: NA Annual influenza vaccinations (%): Baseline: 30 vs 24 Post intervention: 73 vs NA Absolute difference: NA Relative improvement: NA Annual nutritional education (%): Baseline: 37 vs 43 Post intervention: 67 vs NA Absolute difference: NA Relative improvement: NA	DE-DC= 0.56 (15 months)	nual cholesterol determination p<0.02
Feder 1995	Educational materials + local consensus processes + educational outreach visits + reminders vs no intervention on diabetes	Average % of patients with variable recorded at baseline and after one year (average is weighted by number of patients sampled in practice) Funduscopy (%): Baseline: 20.5 vs 19.4 Post intervention: 38.1 vs 20 Absolute difference: 18.1% Difference in proportions (95% CI) 17.6 (6.9 to 33.9) Relative improvement: 88% Blood glucose (%): Baseline: 56.8 vs 57.8 Post intervention: 75.2 vs 57.8 Absolute difference: 17.4% Difference in proportions (95% CI) 20.2 (6.4 to 33.9)	Not done	*Intervention and control practices had similar distributions of variables at baseline, except for the recording of smoking habit, which was significantly greater in the diabetes practices. Differences at baseline were taken into account in the regression models testing the effect of the guidelines (reported difference in proportions).

Table 4. Professional interventions vs usual care *(Continued)*

			Relative improvement: 34.9% Weight (%): Baseline: 40.4 vs 37.5 Post intervention: 68.1vs 40 Absolute difference: 28.1% Difference in proportions (95% CI) 26.5 (7.7 to 45.4) Relative improvement: 66.3% Blood pressure (%): Baseline: 69.0 vs 66.1 Post intervention: 79.5 vs 58.3 Absolute difference: 21.2% Difference in proportions (95% CI) 18.1 (2.8 to 33.4) Relative improvement: 31% Smoking habit (%): Baseline: 34.8 vs 23.2 Post intervention: 62.4 vs 31.7 Absolute difference: 30.7% Difference in proportions (95% CI) 25.5 (8.7 to 42.3) Relative improvement: 80.4% Feet examination (%): Baseline: 31.4 vs 28.3 Post intervention: 51.8 vs 27.2 Absolute difference: 24.6% Difference in proportions (95% CI) 24.7 (7.1 to 42.3) Relative improvement: 90.8% HbA1 recorded (%): Baseline: 24.8 vs 20.6 Post intervention: 48.1 vs 30 Absolute difference: 18.1% Difference in proportions (95% CI) 13.8 (1.2 to 26.3) Relative improvement: 46%	
Kinmonth 1998	Educational materials + educational meetings + educational materials for patients vs no intervention to support patient centred care, but support sessions	Not done	Means with 95% confidence intervals HbA1c (ref. 4.68-6.8%): Post intervention: 7.07 (4.17-12.83) vs 7.17 (4.16-14.05) (N=131 vs 100) Absolute difference: 0.10 Relative improvement: 1.4% Adjusted p-value=0.31* Total cholesterol (mmol/l): Post intervention: 6.04 (3.70-9.80) vs 5.99 (3.30-9.10) (N=138 vs 102) Absolute difference: -0.05 Relative improvement: -0.8%	*Analysis was by intention to treat. Multiple or logistic regression was used as appropriate. Adjustments were made for district general hospital, practice list size, organisation of diabetes care, clustering for patients by practice **The two groups did not differ in micro-albuminuria, smoking status,

Table 4. Professional interventions vs usual care *(Continued)*

	focusing on use of guidelines and materials		Adjusted p-value=0.92 Triglycerides (mmol/l): Post intervention: 2.62 (0.60-13.5) vs 2.23 (0.60-11.6) (N=130 vs N=101) Absolute difference: -0.39 Relative improvement: -17.5% Adjusted p-value=0.02 BMI (kg/m^2): Baseline: 30.6 (18.7-49.6) vs 29.7 (18.9-52.2) (N=142 vs 108) Post intervention: 31.3 (19.8-51.9) vs 29.5(19.1-48.5) (N=138 vs 102) Absolute difference: -1.8 Relative improvement: -6% DE-DC= -0.9 Adjusted p-value=0.03 Systolic blood pressure (mmHg): Baseline: 144.1 (80.0-190.0) vs 141.5 (100.0-200.0) (N=142 vs 108) Post intervention: 144.3 (99.0-193.5) 142.8 (87.0-204.0) (N=138 vs 107) Absolute difference: -1.5 Relative improvement: -1% DE-DC= 1.1 Adjusted p-value p=0.18 Diastolic blood pressure (mmHg): Baseline: 85.5 (60.0-118.0) vs 83.7 (50.0-110.0) (N=142 vs 108) Post intervention: 89.0 (59.5-133.5) vs 87.2 (60.5-131.0) (N=138 vs 107) Absolute difference: -1.8 Relative improvement: -2% DE-DC= 0.0 Adjusted p-value=0.10 Generic Wellbeing questionnaire overall: Post intervention: 48.0 (15.0-66.0) vs 45.9 (3.0-66.0) Absolute difference: 2.1 Relative improvement:	diabetes specific quality of life

Table 4. Professional interventions vs usual care *(Continued)*

			5% Adjusted p-value=0.03	
Litzelman 1993	Educational materials + reminders + patient education + behavioural contacts with patients + reminders for patients vs no intervention	Percentage of patients with documentation: Ulcers (%): Post intervention: 23.8 vs 11.1 Absolute difference: 12.7% Relative improvement: 114% Pulse examination done: Post intervention: 9.2 vs 3.0 Absolute difference: 6.2% Relative improvement: 207% Dry or cracked skin Post intervention: 8.7 vs 2.0 Absolute difference: 6.7% Relative improvement: 335% Calluses or corns: Post intervention: 6.5 vs 1.0 Absolute difference: 5.5% Relative improvement: 550% Fungal infection (foot or nail): Post intervention: 3.2 vs 0.5 Absolute difference: 2.7% Relative improvement: 540% Ingrown nails: Post intervention: 2.7 vs 0.5 Absolute difference: 2.2% Relative improvement: 440% Improperly trimmed nails: Post intervention: 2.4 vs 0.5 Absolute difference: 1.9% Relative improvement: 380% Foot or leg cellulitis Post intervention: 2.7 vs 1.5 Absolute difference: 1.2% Relative improvement: 80% Foot deformities: Post intervention: 1.6 vs 1.0 Absolute difference: 0.6% Relative improvement: 60% Sensory examination done: Post intervention: 4.9 vs 2.5 Absolute difference: 2.4% Relative improvement: 96%	Serious foot lesions: Baseline prevalence intervention group: 2.9% OR: 0.41 [0.16-1.00]** All foot lesions: Baseline prevalence intervention group: 10.5% OR: 0.65 [0.36-1.17] Dry or cracked skin: Baseline prevalence intervention group: 83.5% OR: 0.62 [0.39-0.98] Ingrown nails: Baseline prevalence intervention group: 18.5% OR: 0.59 [0.39-0.92] Fungal nail infection: Baseline prevalence intervention group: 67.0% OR: 0.70 [0.46-1.07] Fungal skin infection: Baseline prevalence intervention group: 12.3% OR: 0.58 [0.30-1.12] Interdigit maceration: Baseline prevalence intervention group: 18.8% OR: 0.63 [0.34-1.15]	*No p-value given because of potential unit of analysis error **adjusted for baseline measurements ***Authors reported significant differences between both groups on 1) the process outcomes: ulcers, pulse examination done, dry or cracked skin, calluses or corns 2) patient outcomes: dry or cracked skin
Lobach 1997	Local consensus processes + audit and feed-	Compliance rate: Median baseline compliance levels during 6 months prior to the intervention: 21.2% vs 18.0% Post intervention: 32.0% vs 15.6% Absolute difference: 16.4%	Not done	*No p-value given because of potential unit of analysis error

Table 4. Professional interventions vs usual care *(Continued)*

	back + reminders vs no intervention	Relative improvement: 105% DE-DC= 13.2 Foot examination: Post intervention: 55.6% vs 30.0% Absolute difference: 25.6% Relative improvement: 85% Complete physical examination: Post intervention: 33.3% vs 6.7% Absolute difference: 26.6% Relative improvement: 397% Chronic glycemia monitoring: Post intervention: 57.4% vs 52.8% Absolute difference: 4.6% Relative improvement: 9% Urine protein determination: Post intervention: 73.3% vs 3.9% Absolute difference: 69.4% Relative improvement: 1779% Cholesterol level: Post intervention: 43.7% vs 13.4% Absolute difference: 30.3% Relative improvement: 226% Ophthalmologic examination: Post intervention: 18.8% vs 3.2% Absolute difference: 15.6% Relative improvement: 488% Influenza vaccination: Post intervention: 29.2% vs 22.7% Absolute difference: 6.5% Relative improvement: 29%		**Authors reported p=0.02 for compliance rate. Furthermore, only significant differences between intervention and control group were found for urine protein determination (p=0.01)
Mazze 1994	Distribution of educational materials + educational meetings + local consensus processes + reminders vs no intervention	Visits (mean±SD):* Baseline: 3.0±1.2** Post intervention: 4.3±1 vs 3.2±1.4 Absolute difference: 1.1 Relative improvement: 34% Renal evaluation: Baseline: 50% Post intervention: 98% vs 50% Absolute difference: 48% Relative improvement: 96% Retinal evaluation: Baseline: 43% Post intervention: 98% vs 43% Absolute difference: 55% Relative improvement: 127% Education: Baseline: 62% Post intervention: 98% vs 63% Absolute difference: 35%	HbA1c (ref. ??)* (mean ±SD)**: Baseline: 10.2±2.8 Post intervention: 8.8±0.7 vs 10.3±0.7 Absolute difference: 1.5 Relative improvement: 15%	*No p-values were reported **The process outcomes and patient outcomes were not reported separately at baseline

Table 4. Professional interventions vs usual care *(Continued)*

		Relative improvement: 56% Health survey: Baseline: 45% Post intervention: 98% vs 45% Absolute difference: 53% Relative improvement: 118%		
Mazzuca 1990	Group A (control group) postgraduate seminar vs Group B: A+reminders vs Group C: B+clinical materials vs Group D: C+diabetes patient education service	GHb: Post intervention B vs A: t=0.44 (n.s.) Post intervention C vs B: 35% vs 21% Absolute difference: 14% Relative improvement: 67% p<0.05 Post intervention D vs C: 21% vs 35% Absolute difference: -14% Relative improvement: -67% p<0.05 Difference between groups (ANOVA): F=3.42 (p<0.05) Fasting blood sugar (only physicians staffing morning clinics N=47): B vs A: t=0.70 (n.s.) C vs B: t=-0.77 (n.s) D vs C: t=0.14 (n.s) Difference between groups: (ANOVA): F=0.25 (n.s.) Home-monitored blood glucose: B vs A: t=1.65 (n.s.) C vs B: t=1.38 (n.s.) D vs C: t=-0.84 (n.s.) Difference between groups: (ANOVA): F=3.27 (p<0.05) Diet: B vs A: t=1.10 (n.s.) C vs B: t=-0.90 (n.s.) D vs C: t=1.29 (n.s.) Difference between groups: (ANOVA): F=1.02 (n.s.) Oral hypoglycaemic agents: B vs A: t=0.62 (n.s.) C vs B: t=0.24 (n.s.) D vs C: t=0.62 (n.s.) Difference between groups: (ANOVA): F=0.75 (n.s.)	Not done	
Palmer 1985	Educational materials + local consensus procedures + audit and feedback vs no intervention	Case-variant score*: Baseline mean variant score: 7 vs 6 Change in mean case variant score between baseline and experimental periods in control practices: +3.3 Difference in trend between experimental and control practices: -2.0 p=0.26 (SE=1.8)	Not done	*(case-variant score=(criteria not met/ criteria applicable)*100) **Possible ceiling effect: baseline variant scores are low

Table 4. Professional interventions vs usual care *(Continued)*

Pieber 1995	Educational materials + educational meetings + patient education vs no intervention	Not done	HbA1c (ref. 4.3-6.1%): Baseline (mean ± sd): 8.57±1.79 vs 8.77±2.08 Post intervention: 8.11±1.55 vs 9.03±1.79 Absolute difference: 0.92 [0.23-1.61] Relative improvement: 11% DE-DC= 0.72 Cholesterol (mmol/l): Baseline: 6.47±1.31 vs 6.57±1.65 Post intervention: 6.07±1.01 vs 6.52±1.77 Absolute difference: 0.45 (n.s.) Relative improvement: 7% DE-DC= 0.35 Triglycerides (mmol/l): Baseline: 2.99±2.32 vs 2.62±1.79 Post intervention: 2.36±1.75 vs 2.79±2.53 Absolute difference: 0.43 [0.12-0.84] Relative improvement: 15% DE-DC= 0.80 BMI (kg/m^2): Baseline: 30.2±4.8 vs 30.2±4.7 Post intervention: 29.2±4.5 vs 30.3±4.9 Absolute difference: 1.1 [0.3-1.9] Relative improvement: 4% DE-DC= 1.1 Body weight (kg): Baseline: 82.1±14.5 vs 81.8±13.1 Post intervention: 79.4±13.9 vs 82.1±13.6 Absolute difference: 2.7 [1.0-4.3] Relative improvement: 3% DE-DC= 3 Systolic blood pressure (mmHg): Baseline: 161±20 vs 157±21 Post intervention: 144±21 vs 150±24 Absolute difference: 6 (n.s.) Relative improvement: 4% DE-DC= 10	*No p-value given because of potential unit of analysis error **Authors report significant differences (p=0.01), except for systolic blood pressure (p=0.11), diastolic blood pressure (p=0.05) and cholesterol (p=0.06). For foot care significant changes were found in the intervention group, but changes remained unchanged in the intervention group

Table 4. Professional interventions vs usual care *(Continued)*

			Diastolic blood pressure (mmHg): Baseline: 92±11 vs 91±13 Post intervention: 81±10 vs 86±14 Absolute difference: 5 [0.3-10.9] Relative improvement: 6% DE-DC= 6 Foot care: Callus formation: Baseline: 78% vs 82% Post intervention: 49% vs 82% Absolute difference: 33% Relative improvement: 40% DE-DC= 29 Interdigital cracks, interdigital fissures or mycosis Baseline: 58% vs 53% Post intervention: 49% vs 65% Absolute difference: 16% Relative improvement: 25% DE-DC= 21 Margins of the toe nails were cut back, or ingrown toe nails were cut out Baseline: 87% vs 92% Post intervention: 27% vs 92% Absolute difference: 65% Relative improvement: 71% DE-DC= 60	
Pill 1998	Educational meetings + educational outreach visits vs no intervention	Attendance at practice over last 12 months: Mean difference in intervention group (N=73): +0.192 (6.35) Mean difference in control group (N=84): +1.96 (NA)	**Glyc-Hb: Hospital A : Mean baseline values (SD): 11.70 (2.16) vs 12.06 (2.65) Mean difference (time1-time2) (N=56 vs 49): 0.998 (2.70) vs 1.62 (2.95) Hospital B: Mean baseline values (SD): 10.20 (1.35) vs 11.53 (1.74) Mean difference (time1-time2) (N=15 vs 27): -0.447 (2.17) vs 0.311 (2.07) Hospital A +B: Mean difference (time1-time2): 0.693 (2.65) vs 1.153 (2.73) BMI (kg/m2):	*No p-value given because of potential unit of analysis error **In hospital B Glyc-Hb was significant different in both groups at baseline for the other outcomes it is not clear ***The reference ranges for glyco-Hb over time were revised by the laboratories during the study period, thus giving a potentially false impression of overall improve-

Table 4. Professional interventions vs usual care *(Continued)*

			Mean difference: 0.382 (2.44) vs 0.858 (3.73) Weight (kg) (men): Mean difference: -0.254 (5.56) vs -0.379 (7.41) Weight (kg) (women): Mean difference: 1.92 (4.55) vs 1.29 (4.93) Systolic blood pressure (mmHg): Mean difference: -1.47 (21.45) vs 3.12 (19.45) Diastolic blood pressure (mmHg): Mean difference: -0.343 (11.56) vs 0.650 (10.81) Measure of complications: Mean difference: 0.291 (0.497) vs 0.273 (0.597)	ment if the raw data alone were inspected. Authors reported no significant differences in changes over time between both groups. Only for one item with regard to health status (SF-36) a sign difference over time was found: physical functioning, as measured by self-reports of limitations to everyday activities: P=0.02 (women p=0.03) (men p=0.31)
Ward 1996	Educational materials + educational outreach visits + audit and feedback by interview vs educational materials + postal feedback	Group 1=doctor interview Group 2=nurse interview Group 3=control group History: Duration of known diabetes recorded: Baseline: 56.9% vs 33.9% vs 31.1% Post intervention: 60.8% vs 38.0% vs 31.1% Absolute difference group 1: 22.8% Absolute difference group 2: 6.9% Relative improvement group 1: 95% Relative improvement group 2: 22% DE-DC group 1= 3.9 DE-DC group 2= 4.1 * No significant changes within groups Dietary inquiry and advice: Baseline: 60.0% vs 43.0% vs 43.7% Post intervention: 64.6% vs 55.4% vs 44.4% Absolute difference group 1: 20.2% Absolute difference group 2: 11.0% Relative improvement group 1: 45% Relative improvement group 2: 25% DE-DC group 1= 3.9 DE-DC group 2= 11.7 * Only significant change within group 2: p<0.05 Annual physical examination Blood pressure Baseline: 86.2% vs 81.0% vs 85.9% Post intervention: 90.0% vs 85.1% vs 88.1% Absolute difference group 1: 1.9% Absolute difference group 2: -3.0% Relative improvement group 1: 2% Relative improvement group 2:-3% DE-DC group 1= 1.6	Not done	Other reported items: With regard to history: alcohol intake inquiry and advice, exercise inquiry and advice, smoking inquiry and advice and impotence/vaginitis inquiry and advice showed significant differences within the doctor interview group and also within the nurse interview group With regard to blood tests: creatinine showed significant differences within the doctor interview group (p<0.0001) and within the nurse interview group (p<0.01) With regard to urinalysis: glucose and nitrite showed no significant differences

Table 4. Professional interventions vs usual care *(Continued)*

DE-DC group 2= 1.9 * No significant changes within groups Eye examination (or referral to ophthalmologist) Baseline: 23.1% vs 19.8% vs 29.6% Post intervention: 42.3% vs 40.5% vs 31.1% Absolute difference group 1: 11.2% Absolute difference group 2: 9.4% Relative improvement group 1: 36% Relative improvement group 2: 30% DE-DC group 1= 7.7 DE-DC group 2= 19.2 * Significant changes within group 1 (p<0.01) and within group 2 (p<0.001) Body weight Baseline: 47.7% vs 38.0% vs 35.6% Post intervention: 67.7% vs 46.3% vs 43.3% Absolute difference group 1: 24.4% Absolute difference group 2: 3.0% Relative improvement group 1: 56% Relative improvement group 2: 7% DE-DC group 1= 12.3 DE-DC group 2= 0.6 * Significant changes within group 1 (p<0.001) Feet examined: Pulses: Baseline: 18.5% vs 7.4% vs 15.6% Post intervention: 38.5% vs 26.4% vs 15.6% Absolute difference group 1: 22.9% Absolute difference group 2: 10.8% Relative improvement group 1: 147% Relative improvement group 2: 69% DE-DC group 1= 20.0 DE-DC group 2= 19.0 * Significant changes within group 1 (p<0.001) and within group 2 (p<0.0001) Sensation: Baseline: 9.2% vs 9.1% vs 10.4% Post intervention: 26.2% vs 20.7% vs 11.9% Absolute difference group 1: 14.3% Absolute difference group 2: 8.8% Relative improvement group 1: 120% Relative improvement group 2: 74% DE-DC group 1= 15.5 DE-DC group 2= 10.1 * Significant changes within group 1 (p<0.001) and within group 2 (p<0.05) Nails: Baseline: 14.6% vs 8.3% vs 10.4% Post intervention: 20.0% vs 12.4% vs 8.1% Absolute difference group 1: 11.9% Absolute difference group 2: 4.3% Relative improvement group 1: 147% Relative improvement group 2: 53% DE-DC group 1= 7.8 DE-DC group 2= 6.4 * No significant changes within groups	within groups. Only protein showed a slight significant difference within the nurse interview group (p<0.05)

Table 4. Professional interventions vs usual care *(Continued)*

Reflexes:
Baseline: 4.6% vs 5.0% vs 5.2% Post intervention:
21.5% vs 17.4% vs 8.1%
Absolute difference group 1: 13.4%
Absolute difference group 2: 9.3%
Relative improvement group 1: 165%
Relative improvement group 2: 115%
DE-DC group 1= 14.0
DE-DC group 2= 9.5
* Significant changes within group 1 (p<0.001)
and within group 2 (p<0.01)

HbA1 (1 per 8 months):
Baseline: 36.9% vs 28.9% vs 46.7%
Post intervention: 54.6% vs 44.6% vs 40.7%
Absolute difference group 1: 13.9%
Absolute difference group 2: 3.9%
Relative improvement group 1: 34%
Relative improvement group 2: 10%
DE-DC group 1= 23.7
DE-DC group 2= 21.7
* Significant changes within group 1 (p<0.001)
and within group 2 (p<0.05)

Blood glucose (2 per 8 months):
Baseline: 46.2% vs 48.8% vs 36.3%
Post intervention: 58.5% vs 52.1% vs 37.8%
Absolute difference group 1: 20.7%
Absolute difference group 2: 14.3%
Relative improvement group 1: 55%
Relative improvement group 2: 38%
DE-DC group 1= 10.8
DE-DC group 2= 1.8
* Significant changes within group 1 (p<0.05)

Cholesterol (1 per 8 months):
Baseline: 26.2% vs 19.8% vs 23.7%
Post intervention: 39.2% vs 25.6% vs 25.9%
Absolute difference group 1: 13.3%
Absolute difference group 2: -0.3%
Relative improvement group 1: 51%
Relative improvement group 2:
-1%
DE-DC group 1= 10.8
DE-DC group 2= 3.6
* Significant changes within group 1 (p<0.05)

Triglycerides (1 per 8 months):
Baseline: 21.5% vs 19.0% vs 20.7%
Post intervention: 34.6% vs 24.8% vs 23.0%
Absolute difference group 1: 11.6%
Absolute difference group 2: 1.8%
Relative improvement group 1: 50%
Relative improvement group 2: 8%
DE-DC group 1= 10.8
DE-DC group 2= 3.5
* Significant changes within group 1 (p<0.01)

Overall modified Adequate Competent Care (ACC)
score (SD):

Table 4. Professional interventions vs usual care *(Continued)*

		Baseline: 4.3 (2.3) vs 3.5 (2.0) vs 3.7(2.0) Post intervention: 6.1 (3.1) vs 4.8 (2.9) vs 4.0 (2.2) Absolute difference group 1: 2.1 Absolute difference group 2: 0.7% Relative improvement group 1: 53% Relative improvement group 2: 20% DE-DC group 1= 1.5 DE-DC group 2= 1.0 * Significant difference between groups p<0.0001 Contrast ACC-score: No interview vs interview: p<0.001 No interview vs doctor interview: p<0.001 No interview vs nurse interview: p<0.01 Doctor interview vs nurse interview: N.S.		
Carlson 1991	Educational meetings + local consensus processes to identify problems and to create plans to improve diabetes care + educational outreach visits vs no intervention	Patients height noted in case notes during previous year: Post intervention: 73% vs 50% Absolute difference: 23% Relative improvement: 46% HbA1c value measured during previous year: Post intervention: 27% vs 8% Absolute difference: 19% Relative improvement: 238% Eye examination performed during previous year: Post intervention: 40% vs 28% Absolute difference: 12% Relative improvement: 43%	Of a 20% secondary sample (806 patients) 566 patients had their HbA1c value measured HbA1c (mean±SD): Post intervention: 8.1±1.8 vs 7.8±1.6 Absolute difference: -0.3 Relative improvement: -4%	*No p-value given because of potential unit of analysis error **Authors report significant differences for patients height noted in case notes (p<0.01), HbA1c value measured (p<0.001) and eye examination performed p<0.01. For HbA1c they report that both groups have a similar degree of metabolic control, p-value is not reported.

Table 5. Organisational interventions vs usual care

Study	Comparison	Effect on practice	Effect on patient	Notes
Branger 1999	Changes in medical record systems (electronic communication between different physicians who both provide diabetic care to the same diabetic patients) vs no intervention	Patient contacts with GP (average number per patient per year): Baseline: 12 vs 12 Post intervention: 14 vs 14 Absolute change: 0 Relative improvement: 0% DE-DC= 0 Patient contacts with consultant (average number per patient per year): Baseline: 4 vs 4 Post intervention: 4 vs 4 Absolute change: 0 Relative improvement: 0% DE-DC= 0	Not done	*No p-value given because of potential unit of analysis error The authors reported a significant increase in the number of letters sent by the consultant to the intervention GPs when compared to the control group (p<0.01). Furthermore the patient records in the intervention group contained significantly more data on Hba1c, fructosamine,

Table 5. Organisational interventions vs usual care *(Continued)*

	Letters from GP to consultant: (average number per patient per year): Baseline: 0.2 vs 0.2 Post intervention: 0.7 vs 0.2 Absolute change: 0.5 Relative improvement: 250% DE-DC= 0.5 Letters from consultant to GP: (average number per patient per year): Baseline: 0.5 vs 0.5 Post intervention: 0.4 vs 1.6 Absolute change: 1.2 Relative improvement: 300% DE-DC= 1.2 Recorded items per patient: Creatinine level: Baseline: 0.2 vs 0.2 Post intervention: 0.5 vs 0.4 Absolute change: 0.1 Relative improvement: 25% DE-DC= 0.1 Proteinuria: Baseline: 0.1 vs 0.2 Post intervention: 0.1 vs 0.5 Absolute change: 0.4 Relative improvement: -80% DE-DC= -0.3 Assessment ophthalmologist: Baseline: 0.2 vs 0.3 Post intervention: 0.3 vs 0.3 Absolute change: 0.0 Relative improvement: 0% DE-DC= 0.1 Glucose level: Baseline: 1.0 vs 1.6 Post intervention: 1.9 vs 1.8 Absolute change: 0.1 Relative improvement: 6% DE-DC= 0.7 HbA1c: Baseline: 0.0 vs 0.0 Post intervention: 0.8 vs 0.2 Absolute change: 0.1 Relative improvement: 300% DE-DC= 0.6 Fructosamine: Baseline: 0.1 vs 0.0 Post intervention: 0.2 vs 0.0 Absolute change: 0.2 Relative improvement: N/A DE-DC= 0.1	blood pressure, cholesterol, triglyceride and weight. *The change in HbA1c is not reported in this review because both measurements were assessed after implementation of the intervention (first half and second half of 1994, as the intervention was implemented in 1994)

Table 5. Organisational interventions vs usual care *(Continued)*

		Blood pressure: Baseline: 0.6 vs 1.3 Post intervention: 1.9 vs 1.4 Absolute change: 0.5 Relative improvement: 36% DE-DC= 1.2 Cholesterol level: Baseline: 0.1 vs 0.1 Post intervention: 0.7 vs 0.4 Absolute change: 0.3 Relative improvement: 75% DE-DC= 0.3 Triglyceride level: Baseline: 0.0 vs 0.0 Post intervention: 0.2 vs 0.1 Absolute change: 0.1 Relative improvement: 100% DE-DC= 0.1 Weight: Baseline: 0.3 vs 0.2 Post intervention: 2.1 vs 0.5 Absolute change: 1.6 Relative improvement: 320% DE-DC= 1.5		
Day 1992	Revision of professional roles + changes to the setting + a learner-centred counselling approach was adopted allowing patients to identify problems and agree potential solutions vs no intervention	Not done	HbA1c (mean±SEM) (N=174 vs 154): Baseline: 11.9±2.3 vs 12.2±2.3 Post intervention: 9.9±1.9 vs 11.3±2.6 Absolute difference: 1.4 Relative improvement: 12% DE-DC= 1.1	*No p-value given because of potential unit of analysis error **The authors reported a significant fall in HbA1 in the intervention group ($p<0.0001$) and in the control group ($p<0.01$) during the period of 1985 to 1988 ***In the study the effect of the intervention was also measured in a group of patients aged >65 studied from 1986-1988 (N=144) (baseline measurement is missing) and in the clinic population as a whole using cross sectional analysis in 1985 and in 1988 (N=700) ****The initial mean values of patients in group 4 were identical to those in group 3. The mean HbA1 value showed in 1988 a significant larger decrease in group 3 than in group 4

Table 5. Organisational interventions vs usual care *(Continued)*

de Sonnaville 1997	A clinical multidisciplinary team (general practitioner, diabetes nurse educator, dietician, podiatrist, diabetologist) + formal integration of services (general practitioner was supported by laboratory) + arrangements for follow up + communication and case discussion between distant health professionals + changes to the setting /site of service delivery + changes in medical records systems + patient education vs no intervention	Not done	Fasting glucose (mmol/l) (mean±SD): Baseline: 8.9±2.5 vs 9.6±3.4 Post intervention: 8.1±2.5 vs 9.8±2.9 Absolute difference: 1.7 Relative improvement: 17% DE-DC= 1.0 HbA1c (%) (ref 4.3-6.1%): Baseline: 7.4±1.6 vs 7.4±1.9 Post intervention: 7.0±1.3 vs 7.6±1.5 Absolute difference: 0.6 Relative improvement: 8% DE-DC= 0.8 BMI (kg/m2): Baseline: 28.7±4.6 vs 26.8±4.0 Post intervention: 29.0±4.6 vs 26.5±3.8 Absolute difference: 2.5 Relative improvement: -9% DE-DC= -0.6 HbA1c >8.5%: Baseline: 21.4% vs 23.5% Post intervention: 11.7% vs 27.9% Absolute difference: 16.2% Relative improvement: 58% DE-DC= 14.1% HbA1c <7.0%: Baseline: 43.4% vs 54.4% Post intervention: 54.3% vs 44.1 Total cholesterol (mmol/l): Baseline: 6.1±1.3 vs 5.9±1.0 Post intervention: 5.8±1.1 vs 5.9±1.0 Absolute difference: 0.1 Relative improvement: 2% DE-DC= 0.3 HDL (mmol/l): Baseline: 1.21±0.36 vs 1.14±0.35 Post intervention: 1.16±0.32 vs 1.13±0.37 Absolute difference: 0.03 Relative improvement: 3% DE-DC= -0.04 Triglycerides (mmol/l):	*No p-value given because of potential unit of analysis error **baseline characteristics are comparable except for gender, fasting glucose, BMI, HDL-cholesterol and blood pressure ***For the comparison between study and control population corrected deltas (=[baseline value-final value]/baseline value) were calculated. The main endpoint (corrected delta HbA1c) was adjusted for differences in baseline characteristics applying linear regression analysis. ****The authors reported significant differences in changes between both groups for fasting glucose (p=0.004), HbA1c (p=0.002), BMI (p=0.000), total cholesterol (p=0.002). Differences in change in blood glucose lowering therapy were also reported mainly due to an increase in insulin in the intervention group

Table 5. Organisational interventions vs usual care *(Continued)*

			Baseline: 2.12±1.64 vs 2.01±1.46 Post intervention: 1.96±1.72 vs 2.03±1.55 Absolute difference: 0.07 Relative improvement: 3% DE-DC= 0.18 Systolic blood pressure (mmHg): Baseline: 146.9±20.9 vs 155.4±24.0 Post intervention: 147.7±23.5 vs 155.3±22.9 Absolute difference: 7.6 Relative improvement: 5% DE-DC= -0.9 Diastolic blood pressure (mmHg): Baseline: 87.4±10.8 vs 88.8±11.4 Post intervention: 83.0±12.6 vs 85.3±11.4 Absolute difference: 2.3 Relative improvement: 3% DE-DC= 0.9	
Halbert 1999	Arrangements for follow up (multiple reminders to patients) vs single reminder	Diabetes eye exam rates: Baseline: Not available Post intervention first 6 months: 25.4 vs 24.3 p=0.074 Post intervention second 6 months: 11.6 vs 11.2 p=0.306 Post intervention full year: 37.0 vs 35.4 p=0.0203	Not done	
Hawkins 1979	Revision of professional rules (A clinical pharmacist was responsible for follow-up care of patient with diabetes) vs no intervention	Not done	Fasting blood glucose (mg/dl) Baseline: 192 (±46) vs 182 (±39) In mmol/l: 10.7 (±2.6) vs 10.1 (±2.2) Post intervention: 184 (±42) vs 189 (±49) In mmol/l: 10.2 (±2.3) vs 10.5 (±2.7) Absolute difference: 0.3 Relative improvement: 3% DE-DC= 0.9	*The baseline fasting blood glucose was significant different between both groups (p<=0.05). Analysis of covariance showed the post intervention assessments fell short of achieving significance (p<0.058)
Jaber 1996	Revision of professional roles	Not done	Fasting plasma glucose (mmol/l) Baseline: 11.1±4.0 vs 12.7±4.7	*No significant differences at baseline

Table 5. Organisational interventions vs usual care *(Continued)*

	(all diabetes-related management aspects were solely provided by a pharmacist) + patient education vs no intervention		Post intervention: 8.5±2.3 vs 11.0±3.9 Absolute difference: 2.5 Relative improvement: 23% DE-DC= 0.9 Within the intervention group the change was sign p<0.05 The post intervention value was sign different between groups p<0.05 Glycated haemoglobin (%) (ref 4.0-8.0%): Baseline: 11.5±2.9 vs 12.2±3.5 Post intervention: 9.2±2.1 vs 12.1±3.7 Absolute difference: 2.9 Relative improvement: 24% DE-DC= 2.2 Within the intervention group the change was sign p<0.05 The post intervention value was sign different between groups p<0.05 The change in glycated haemoglobin was sign different between groups p<0.05	*No significant changes in blood pressure, body weight, serum lipid measurements and renal function parameters + quality of life were noted between or within groups. Values are not reported.
Sadur 1999	Clinical multidisciplinary teams + skill mix changes + case management + patient education vs no intervention	Not done	HbA1c (ref. ??) (N=82 vs 74): Baseline: 9.48 vs 9.55 Post intervention (6 months): 8.18 vs 9.33 (adjusted p-value<0.0001) Absolute difference (9 months): 1.15 Relative improvement: 12% DE-DC= 1.08 Adjusted p-value for difference in change: p<0.001 Hospital discharge rates (per 1000 months): Baseline (year before intervention): 17 vs 19 Post intervention (12 months after intervention period) 16 vs 28 Absolute difference: 12 Relative improvement: 43% DE-DC= 10 Adjusted p-value=0.04 Outpatient physician visit rates (per 1000 months): Baseline (6 months before intervention):	*No significant differences at baseline **p-values are adjusted for baseline values

Table 5. Organisational interventions vs usual care *(Continued)*

			310 vs 360 During 6 months of intervention: 250 vs 340 Post intervention (12 months after intervention period) 270 vs 370 Absolute difference: 100 Relative improvement: 27% DE-DC= 50 Adjusted p-value=0.06 Outpatient non-physician visit rates (per 1000 months): Baseline (6 months before intervention): 100 vs 100 During 6 months of intervention: 810 vs 170 Post intervention (12 months after intervention period) 180 vs 270 Absolute difference: 90 Relative improvement: 33% DE-DC= 90 Adjusted p-value=0.001	
Smith 1987	Arrangements for follow up + patient education + appointment reminders for patients vs no intervention	Kept scheduled visits: Post intervention: 4.13±2.88 vs 3.61±2.46 Absolute difference: 0.52 Relative improvement: 14% P=0.00062 Prescription refills: Post intervention: 1.00 vs 0.94 Absolute difference: 0.06 Relative improvement: 6% P=N.S. Walk-in visits: Post intervention: 0.72 vs 0.63 Absolute difference: 0.09 Relative improvement: 14% P=N.S. Total contacts: Post intervention: 5.84±4.06 vs 5.18±3.60 Absolute difference: 0.66 Relative improvement: 13% P=0.0105 Visit failures: Post intervention: 1.13 vs 1.16 Absolute difference: -0.03 Relative improvement: 3% P=NS	Mean hospitalisations per patient per month: Patients with low risk**: 0.030 vs 0.029 Absolute difference: -0.001 Relative improvement: -3% Patients with medium risk: 0.039 vs 0.040 Absolute difference: 0.001 Relative improvement: 3% Patients with high risk: 0.068 vs 0.073 Absolute difference: 0.005 Relative improvement: 7% Overall intervention effect on hospitalisations: P=0.8	*No sign difference between both groups at baseline **Previous studies at the center identified characteristics associated with non-elective hospitalisation of ambulatory patients taking antidiabetic agents

Table 5. Organisational interventions vs usual care *(Continued)*

		Total scheduled visits (kept and failed) Post intervention: 5.26±3.39 vs 4.77±2.84 Absolute difference: 0.49 Relative improvement: 10% P=0.040		
Sullivan 1991	Interrupted Time Series (ITS): Clinical multi-disciplinary teams (A joint GP/nurse review system) + arrangements of follow-up	Percentage of patients with recording examinations during 1983-1988. In 1986 the GPs were joined by a practice nurse (intervention) Weight: 1983: 76 1984: 61 1985: 58 1986: 68 1987: 77 1988: 86 Blood pressure: 1983: 80 1984: 66 1985: 64 1986: 72 1987: 84 1988: 90 Visual acuity: 1983: 75 1984: 52 1985: 56 1986: 70 1987: 77 1988: 86 Funduscopy: 1983: 62 1984: 41 1985: 64 1986: 76 1987: 72 1988: 77 Foot examination: 1983: 66 1984: 48 1985: 56 1986: 77 1987: 81 1988: 87 HbA1c: 1983: 71 1984: 59 1985: 52 1986: 66 1987: 81 1988: 86	Not done	No results of statistical analyses were reported by the authors

Table 6. Professional - in combination with organisational interventions vs usual care

Study	Comparison	Effect on practice	Effect on patient	Notes
Aubert 1998	Educational materials (detailed management algorithms) + revision of professional roles (nurse case management) + arrangements for follow-up + patient education vs no intervention	Renal assessment: Dipstick test: Baseline: 68.6% vs 70.0% Post intervention: 51.0% vs 58.0% Absolute difference: 7% Relative improvement: -12% DE-DC=-5.6% Quantitative protein/microalbumin test: Baseline: 33.3% vs 28.1% Post intervention: 80.7% vs 51.9% Absolute difference: 28.8% Relative improvement: 55% DE-DC=23.6% p<0.05	HbA1c (%) (ref??-6.1%): Mean change: -1.7 vs -0.6 DE-DC= -1.1 [-1.62 to 0.58] p** <0.001 Mean fasting blood glucose (mmol/l): Mean change: -2.68 vs -0.80 DE-DC= -1.88 [-3.12 to 0.64] p=0.003 Systolic blood pressure (mmHg): Mean change: 1.9 vs 6.1 DE-DC= -4.2 [-9.81 to 1.41] p >0.2 Diastolic blood pressure (mmHg): Mean change: -0.8 vs 1.5 DE-DC= -2.3 [-5.79 to 1.19] p >0.2 Weight (kg): Mean change: -0.21 vs -0.4 DE-DC= -0.19 [-1.6 to 2.0] p >0.2 Serum cholesterol (mmol/l): Mean change: -0.31 vs -0.19 DE-DC= -0.12 [-0.56 to 0.31] p >0.2 Serum triglycerides (mmol/l): Mean change: -0.24 vs 0.11 DE-DC= -0.35 [-1.47 to 0.76] p >0.2 Serum HDL-cholesterol (mmol/l): Mean change: 0.05 vs 0.02 DE-DC= 0.03 [-0.06 to 0.12] p >0.2 Serum LDL-cholesterol (mmol/l): Mean change: -0.16 vs -0.26 DE-DC 0.11 [-0.21 to 0.42] p >0.2 Self-reported health status score***: Mean change: 0.47 vs 0.20 DE-DC= 0.27 [-0.03 to 0.57] p =0.02	*At baseline the intervention group had fewer members of ethnic minority groups, more smokers, and more insulin-treated patients. **p-value for comparison of change scores adjusted for the baseline values of the covariates ***Self reported health status was assessed by Behavioural Risk Factor Surveillance System ****Patients lost to follow-up did not sign differ by sex, type of diabetes, therapeutic regimen, baseline mean HbA1c or treatment group. However, patients 18 to 44 years of age were more likely than patients 45 years of age and older to be lost to follow up (52 % compared with 23%; p=0.002) Also non-white patients were more likely than white patients lost to follow up (41 % compared with 26%; p=0.10) ***** If intention to treat analysis were used to account for patients who were lost to follow up, the intervention group continued to show a statistically significantly greater improvement in HbA1c compared with usual care group

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

			(p-value adjusted such that it is possible for it to be inconsistent with the CI, which is not adjusted)	
Boucher 1987	Educational materials + educational meetings + arrangements for follow up + communication and case discussion between distant health professionals + changes in medical record systems vs no intervention	Completion of clinical review: Post intervention: 40.1% vs 15.0% Absolute difference: 25.1% Relative improvement: 167% DE-DC=NA	Glycosylated haemoglobin (upper limit of normal is 10.5%) (mean±SD): Baseline: 13.4 ± 2.9 vs 12.6 ± 3.2 Post intervention I: 11.4 ± 2.3 vs 12.5 ± 2.6 Mean difference: 1.1 Relative improvement: 9% DE-DC=1.9 In the intervention group 94 of the 142 patients who entered the study had follow-up data. In the control group 44% of 200 patients had follow-up data	*No p-value given because of potential unit of analysis error *No sign difference in GHQ values between both groups at baseline. For completion of clinical review no baseline values reported Authors reported a significant fall in GHb values in the intervention group (p<0.001) in contrast with the control group in which the change was not significant. For the comparison of both groups with regard to the completion of clinical review no statistical test was done *Patients in control group were sign younger and were sign more treated by diet+OHAs or diet+insulin
Deeb 1988	Educational materials + educational meetings + educational outreach visits + clinical multidisciplinary team + patient education vs no intervention	Documentation of search for complication in clinical record: Intervention group (N=399) Control group (N=237) Retinopathy History Baseline: 28% vs 5% (p<0.001) Post intervention: 38% vs 7% Absolute difference: 31% Relative improvement: 443% DE-DC=8 Exam Baseline: 11% vs 24%** Post intervention: 46% vs 23% Absolute difference: 23% Relative improvement: 100% DE-DC=36 Referral Baseline: 9% vs 21%** Post intervention: 43% vs 33%	Not done	*No p-value given because of potential unit of analysis error **Differences at baseline were not tested ***The mean age, duration of diabetes and sex distribution were different between the intervention and control group at 0.05 level ****249 of 648 patients from the first census were no longer active in the post intervention period (defined as seen during the year). At the control sites, the same sort of patient turnover seemed apparent Two of the centres with 449 of the original patients were able to follow up on clinical dropouts. For those lost to follow-up, there was no difference in age, race, sex, duration of diabetes or treatment compared with those followed the 2nd year

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

	Absolute difference: 10% Relative improvement: 30% DE-DC=22	
	Lower-extremity care History Baseline: 45% vs 11%** Post intervention: 73% vs 17% Absolute difference: 56% Relative improvement: 329% DE-DC=22	
	Exam Baseline: 66% vs 27%** Post intervention: 94% vs 41% Absolute difference: 53% Relative improvement: 129% DE-DC=14	
	Hypertension Blood pressure taken Baseline: 100% vs 99% Post intervention: 100% vs 99% Absolute difference: 1% Relative improvement: 1% DE-DC=0	
	Hypertension diagnosed Baseline: 66% vs 60%** Post intervention: 68% vs 64% Absolute difference: 4% Relative improvement: 6% DE-DC=-2	
	Last blood pressure reading >140 or >90 mmHg Baseline: 64% vs 38%** Post intervention: 56% vs 50% Absolute difference: 6% Relative improvement: 12% DE-DC=-20	
	Last blood pressure reading >160 or >95 mmHg Baseline: 21% vs 20%** Post intervention: 17% vs 20% Absolute difference: -3% Relative improvement: -15% DE-DC=-4	
		The authors reported significant changes within the intervention group for: 1) history (p<0.01), exam (p<0.001) and referral (p<0.001) for retinopathy 2) history, exam for lower-extremity care(p<0.001) 3) last blood pressure reading >140 or >90 mmHg (p<0.05) In the control group significant changes were found for: 1) referral for retinopathy (p<0.01) 2) history, exam for lower-extremity care (p<0.05) 3) Last blood pressure reading >140 or >90 mmHg (p<0.05).

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

Hartmann 1995	Educational materials + educational meetings + audit and feedback + changes in medical record systems vs no intervention	Documentation of diabetes-relevant data (% patients with >=1 measurement documented per year) Funduscopy Baseline: 8.4% vs 5.5% Post intervention: 32.2% vs 13.4% Absolute difference: 18.8% Relative improvement: 71% DE-DC=15.9% Pallaesthesia Baseline: 0.4% vs 4.9% Post intervention: 35.1% vs 4.9% Absolute difference: 30.2% Relative improvement: 622% DE-DC=34.7% Albuminuria Baseline: 1.2% vs 8.5% Post intervention: 19.7% vs 12.2% Absolute difference: 7.5% Relative improvement: 61% DE-DC=14.8% Serum creatinine Baseline: 62.8% vs 72.6% Post intervention: 71.1% vs 62.0% Absolute difference: 9.1% Relative improvement: 15% DE-DC=18.9% Total cholesterol Baseline: 57.3% vs 76.8% Post intervention: 61.5% vs 64.0% Absolute difference: 2.5% Relative improvement: -4% DE-DC=17% Triglyceride Baseline: 30.1% vs 68.9% Post intervention: 47.2% vs 60.4% Absolute difference: 13.2% Relative improvement: -22% DE-DC=25.6% HDL cholesterol Baseline: 4.6% vs 21.9% Post intervention: 14.3% vs 8.5%	Not done	*No p-value given because of potential unit of analysis error **A possible ceiling effect was identified by the reviewers: In the initial evaluation blood pressure and blood glucose measurements were documented quite frequently in both groups; these values had not changed sign at re-evaluation. Compared to other studies the number of measurements was high ***The authors reported significant differences in changes between both groups for all items documented yearly. For items documented quarterly no significant differences were found except for glucose self-measurement

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

		Absolute difference: 5.8% Relative improvement: 68% DE-DC=23.1% Documentation of diabetes-relevant data (% patients with >=1 measurement documented per quarter) Blood glucose Baseline: 87.9% vs 70.1% Post intervention: 78.7% vs 67.1% Absolute difference: 11.6% Relative improvement: 17% DE-DC=-6.2% Blood pressure Baseline: 72.0% vs 62.8% Post intervention: 69.9% vs 65.2% Absolute difference: 4.7% Relative improvement: 7% DE-DC=-4.5% HbA1c Baseline: 27.6% vs 24.4% Post intervention: 26.8% vs 32.3% Absolute difference: -5.5% Relative improvement: -17% DE-DC=-8.7% Body weight Baseline: 36.0% vs 18.3% Post intervention: 35.1% vs 12.2% Absolute difference: 22.9% Relative improvement: 22% DE-DC=5.2% Glucose self-measurement (blood or urine) Baseline: 7.9% vs 21.3% Post intervention: 11.3% vs 17.1% Absolute difference: -5.8% Relative improvement: -34% DE-DC=7.6%	
Hoskins 1992	Educational materials + educational outreach visits +	Attendance rates (%): Initial assessment: 100% vs 100% vs 100% Post intervention (after 12 months) 72% vs 35% vs 53% Absolute difference 1: 37%	HbA1c (%) (ref 3.5-6.0%) (mean ± SD): Baseline: 8.5 ± 2.2 vs 8.4 ± 2.6 vs 8.9 ± 2.5 Post intervention: 6.6 ± 1.6 vs 6.9 ± 1.3 vs 7.3 ± 1.6 Absolute difference 1: 0.3

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

arrangements for follow up (prompting of patient and physician by nurse) vs routine care by GP care vs routine care by specialist diabetic clinic Comparison 1: Shared care vs routine care by GP Comparison 2: Shared care vs routine care by specialist diabetic clinic	Absolute difference 2: 19% Relative improvement 1: 106% Relative improvement 2: 36% DE-DC (1)=37 DE-DC (2)=19 Complication assessment after 12 months: 61% vs 57% vs N/A Absolute difference 1: 4% Relative improvement 2: 7% DE-DC=4 * Analysis confirmed that the only significant predictor for continuing attendance at 12 months was the assigned treatment group (p<0.036) Completeness of documentation (proportion of clinical information sent back by the GP to the clinic according to the protocol) HbA1c: Post intervention: 66.0% vs 45.6% vs 98.4 Absolute difference 1: 20.4% Absolute difference 2: -32.4% Relative improvement 1: 45% Relative improvement 2: -33% Weight: Post intervention: 93.5% vs 70.6% vs 98.3 Absolute difference 1: 22.9% Absolute difference 2: -4.8% Relative improvement 1: 32% Relative improvement 2: -5% Blood pressure: Post intervention: 94.8% vs 89.7% vs 92.7 Absolute difference 1: 5.1% Absolute difference 2: 2.1% Relative improvement 1: 6%	Absolute difference 2: 0.6 Relative improvement 1: 4% Relative improvement 2: 10% DE-DC (1)=0.4 DE-DC (2)=0.3 Systolic blood pressure (mmHG) (mean ± SD): Baseline: 145 ± 24 vs 148 ± 23 vs 150 ± 23 Post intervention: 130 ± 25 vs 136 ± 14 vs 133 ± 19 Absolute difference 1: 6 Absolute difference 2: 3 Relative improvement 1: 4% Relative improvement 2: 2% DE-DC (1)=3 DE-DC (2)=-2 Diastolic blood pressure (mmHg) (mean ± SD): Baseline: 88 ± 13 vs 90 ± 15 vs 90 ± 13 Post intervention: 81 ± 11 vs 81 ± 11 vs 81 ± 13 Absolute difference 1: 0 Absolute difference 2: 0 Relative improvement 1: 0% Relative improvement 2: 0% DE-DC (1)=-2 DE-DC (2)=-2 Weight (kg) (mean ± SD): Baseline: 77 ± 16 vs 77 ± 18 vs 80 ± 20 Post intervention: 75 ± 14 vs 76 ± 19 vs 79 ± 19 Absolute difference 1: 1 Absolute difference 2: 4 Relative improvement 1: 1% Relative improvement 2: 5% DE-DC (1)=1 DE-DC (2)=1 *All three groups showed a comparable improvement for Hba1c, systolic and diastolic blood pressure (p<0.05). *Weight decreased marginally in all three groups but this reached statistical significance only in the shared care group (p<0.04)

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

		Relative improvement 2: 2%		
Hurwitz 1993	Educational meetings + arrangements for follow-up + changes in medical record systems vs no intervention	% of patients without doctor diabetes review during study period: Post intervention: 3.4% vs 15.2% Absolute difference: 11.8% Relative improvement: 78% p=0.013 Mean No of doctor diabetes reviews per patient per year (SD): Post intervention: 3.0 (3.8) vs 2.4 (1.3) Absolute difference: 0.6 Relative improvement: 25% p=NS Mean No of diabetes reviews per patient per doctor (SD): Post intervention: 3.2 (1.9) vs 2.2 (2.0) Absolute difference: 1.0 Relative improvement: 45% p<0.001 Mean No of urine tests for albumin per patient per year (SD): Post intervention: 3.0 (4.5) vs 2.3 (1.4) Absolute difference: 0.7 Relative improvement: 30% p=0.03 Mean No of plasma glucose estimations per patient per year (SD): Post intervention: 3.1 (4.5) vs 2.3 (1.4) Absolute difference: 0.8 Relative improvement: 35% p=0.003 Mean No of glycated haemoglobin estimations per patient per year (SD): Post intervention: 2.4 (3.8) vs 0.9 (0.9) Absolute difference: 1.5 Relative improvement: 167% p<0.001 % of patients referred to dietician:	Mean random plasma glucose (mmol/l) (SD): Baseline: 9.6 (3.8) vs 9.9 (4.1) Post intervention: 11.2 (4.2) vs 11.2 (4.2) Absolute difference: 0 Relative improvement: 0% DE-DC=-0.3 p=NS Mean glycated haemoglobin (%) (SD): Baseline: 10.4 (2.5) vs 10.3 (2.3) Post intervention: 10.3 (2.3) vs 10.6 (2.5) Absolute difference: 0.3 Relative improvement: 3% p=NS *Baseline measures were assessed in 28 patients in the intervention group and 41 patients in the control group. Post intervention outcomes were assessed in respectively 85 and 81 patients.	*No sign difference for patient outcomes between both groups at baseline and at follow up **Changes in diabetes treatment, the number of patients admitted to hospital for diabetes related reasons, mortality, diabetic retinopathy, referrals to hospital eye clinics were similar or identical in the two groups. The number of patients with new cataract or cataract extraction during the study was significant larger in the intervention group (p<0.001)

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

			Post intervention: 34% vs 41% Absolute difference: 7% Relative improvement: -17% p=NS % of patients referred to chiropodist: Post intervention: 8 % vs 13% Absolute difference: 5% Relative improvement: -38% p=NS	
Legorreta 1996	Educational materials + educational meetings + clinical multidisciplinary teams + skill mix changes (nurse treating patients) arrangements for follow up + changes in medical records systems vs no intervention The comparisons were made at two sites: Site A: a typical participating medical group (PMG) Site B: independent physician	Not done	Glycated haemoglobin (%) (ref??) Site A (N=116 vs 46): Baseline: 8.8 vs 8.2 Post intervention: 7.2 vs 8.5 Absolute difference: 1.3 Relative improvement: 15% DE-DC=1.9 Site B (N=122 vs 19): Baseline: 10.3 vs 9.0 Post intervention: 9.4 vs 8.8 Absolute difference: 0.6 Relative improvement: 7% DE-DC=0.7 In the control group there were much less patient that received a follow-up measurement within 1 year. So also endpoints were compared defined as: the last reported value after a patient had participated in the program, or had been identified in the control site, for at least 12 months but for no longer than 28 months. Site A (N=117 vs 88): Baseline: 8.9 vs 8.3 Post intervention: 6.9 vs 9.1 Absolute difference: 2.2 Relative improvement: 24% DE-DC=-2.7 Site B (N=123 vs 62): Baseline: 10.3 vs 8.6 Post intervention: 9.0 vs 8.4 Absolute difference: 0.6 Relative improvement: -7% DE-DC=1.1	*No p-value given because of a potential unit of analysis error **No differences between intervention and control group in baseline glycated haemoglobin levels were found at site A. In site B, however, a difference was found (p<0.05) ***Authors reported a significant difference in change between both groups after 1 year at site A, not at site B. The difference in change from baseline to endpoints between both groups was significant at both site A (p=0.0001) and site B (p=0.0028).

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

	association			
Marrero 1995	Educational materials + a telecommunication system + skill mix changes (nurse practitioners reviewed data on self-monitoring of blood glucose and made insulin adjustments) + case management + changes in facilities and equipment + changes in medical record systems vs no intervention	Not done	HbA1 (%) (ref: 6.5-8.0%) (mean (SD)): Baseline: 9.4 (1.9) vs 9.9 (1.5) Post intervention: 10.0 (1.6) vs 10.3 (1.8) Absolute difference: 0.3 Relative improvement: 3% DE-DC=-0.2 p=0.544	*No sign difference between both groups at baseline **Between groups no significant differences were found in hospitalisations or emergency room visits ***There were no sign between- or within-group differences for the self-esteem, dependency, body image, depression or need for acceptation subscales of the OFFER-questionnaire. ****Over time, the control group showed a trend towards increased coping (p=0.06) and a decrease in mastery (p=0.06). Both groups exhibited an increase over time in importance of control (p=0.01) *****No sign between- or within-group differences were found on the communication, roles, affective responsiveness, behaviour control, or general family functioning subscales of the Family Assessment Device. Over time, the experimental group had a decrease in problem solving scores, while the control group had an increase (P=0.01). Also, both groups had a small but significant decrease in affective involvement scores (P=0.03) ******Diabetes-specific quality of life showed no between- or within- group- group differences over the course of the study
Naji 1994	Educational materials + reminders + arrangements for follow up + changes in medical record	Routine diabetic care visits (mean (SD)): Post intervention: 5.3 (1.4) vs 4.8 (1.7) Absolute difference: 0.5 Relative improvement: 10% 95% C.I. for difference:[0.1;0.9]	Glycated haemoglobin (%) (mean (SD)): Baseline: 5.3 (1.4) vs 5.3 (1.4) Post intervention: 5.3 (1.7) vs 5.3 (1.7) Absolute difference: 0.0 Relative improvement: 0% DE-DC=0.0 95% C.I. for difference:[-0.31; 0.037]1) 1)The comparison between both groups, for which baseline information	*No sign difference between both groups at baseline **Separate analyses for Type 1 and Type 2 diabetes patients also found no differences between the intervention and control group

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

systems vs no intervention, however, the patients in the control group also received reminders for routine appointments	% with no record of assessment: Post intervention: 0% vs 0% Absolute difference: 0.0 Relative improvement: 0% Glycated haemoglobin (mean (SD)): Post intervention: 4.5 (1.4) vs 1.3 (1.0) Absolute difference: 3.2 Relative improvement: 246% 95% C.I. for difference:[2.9;3.5] % with no record of assessment: Post intervention: 0% vs 22% Absolute difference: 22% Relative improvement: x% 95% C.I. for difference:[14;29] Blood pressure (mean (SD)): Post intervention 4.2 (1.4) vs 1.2 (1.0) Absolute difference: 3.0 Relative improvement: 250% 95% C.I. for difference:[2.7;3.3] % with no record of assessment: Post intervention: 0% vs 21% Absolute difference: 21% Relative improvement: x% 95% C.I. for difference:[13;28] Visual acuity (mean (SD)): Post intervention: 2.6 (1.1) vs 0.7 (0.7) Absolute difference: 1.9% Relative improvement: 271% 95% C.I. for difference:[1.7;2.1] % with no record of assessment: post intervention: 2% vs 50% Absolute difference: 48% Relative improvement: 96% 95% C.I. for difference:[39;58]	was collected on a different scale from that collected at final review, was performed by analysis of covariance. The reported means have been adjusted at the mean level of the baseline scale BMI (kg/m2) (mean (SD)): Baseline: 27.6 (8.5) vs 28.3 (5.6) Post intervention 28.7 (7.6) vs 27.9 (4.5) Absolute difference: 0.8 Relative improvement: -3% DE-DC=1.5 95% C.I. for difference:[-2.4; 0.8] Systolic blood pressure (mmHg) (mean (SD)): Baseline: 155.9 (27.1) vs 153.9 (24.8) Post intervention: 161.5 (25.1) vs 156.4 (25.7) Absolute difference: 5.1 Relative improvement: -3% DE-DC=-3.1 95% C.I. for difference:[-11.7; 1.5] Diastolic blood pressure (mmHg) (mean (SD)): Baseline: 85.6 (15.6) vs 84.8 (11.5) Post intervention: 84.3 (11.1) vs 83.5 (9.9) Absolute difference: 0.8 Relative improvement: -1% DE-DC=0.0 95% C.I. for difference:[-3.5; 1.9] COSTS: Urban practice (integrated care) vs coastal practice (integrated care) vs conventional care Annual costs per patient: £78.29 vs £101.22 vs £55.15 **** Patient borne costs (integrated care vs conventional care) Mean costs per visit: £8 (95% CI £5.23 to £12.12) vs £1.70 (95% CI £1.16 to £2.47)	***The diabetes health questionnaire only showed a significant difference between both groups for the item "support" for patients with non-insulin dependent diabetes ****The discrepancy between the two practices with integrated care is partly explained by differences in their organisation of care

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

	Funduscopy (mean (SD)): Post intervention: 1.1 (0.6) vs 0.9 (0.7) Absolute difference: 0.2% Relative improvement: 22% 95% C.I. for difference:[0.04;0.4] % with no record of assessment: Post intervention: 10% vs 30% Absolute difference: 20% Relative improvement: 67% 95% C.I. for difference:[10;30] Peripheral pulses (mean (SD)): Post intervention: 1.9 (1.1) vs 0.5 (0.6) Absolute difference: 1.4% Relative improvement: 280% 95% C.I. for difference:[1.2;1.6] % with no record of assessment: Post intervention: 7% vs 56% Absolute difference: 49% Relative improvement: 87% 95% C.I. for difference:[39;60] Neurological examination (mean (SD)): Post intervention: 1.9 (1.1) vs 0.5 (0.6) Absolute difference: 1.4% Relative improvement: 280% 95% C.I. for difference:[1.2;1.6] % with no record of assessment: Post intervention: 7% vs 59% Absolute difference: 52% Relative improvement: 88% 95% C.I. for difference:[41;62] Feet (mean (SD)): Post intervention: 1.4 (1.0) vs 0.5 (0.6) Absolute difference: 0.9 Relative improvement: 180%

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

		95% C.I. for difference:[0.7;1.1] % with no record of assessment: Post intervention: 22% vs 58% Absolute difference: 36% Relative improvement: 62% 95% C.I. for difference:[24;48] % patients that had seen a dietician: Post intervention: 26% vs 40% Absolute difference: 14% Relative improvement: -35% 95% C.I. for difference:[2;26] % patients that had seen a chiropodist: Post intervention: 58% vs 26% Absolute difference: 32% Relative improvement: 123% 95% C.I. for difference:[20;44]		
Nilasena 1995	Educational materials + reminders + changes in medical records systems vs no intervention	Compliance score: Baseline: 38.0% vs 34.6% Post intervention: 54.9% vs 51.0% Absolute difference: 3.9% Relative improvement: 8% DE-DC=0.5 *A significant change in compliance scores was found within both groups (p=0.0001). However, the difference in the change between both groups was not significant.	Not done	
O'Connor 1995	Local consensus procedures + audit and feedback + skill mix changes (nurses more actively assist in pro-	Mean number of outpatient visits: Baseline: 7.86 vs 7.40 Post intervention: 9.08 vs 8.96 Absolute difference: 0.12 Relative improvement: 1% DE-DC=-0.34 At least 1 HbA1c-test (N=134 vs 133): Baseline: 78% vs 71%	HbA1c (ref. 4.3-6.1%) (SE) (N=99 vs 87): Baseline: 8.4% (0.19) vs 8.9% (0.22) (p=0.06) Post intervention: 7.9% (0.17) vs 8.8% (0.17) Absolute difference: 0.9 Relative improvement: 10% DE-DC=-0.4**	*No p-value given because of potential unit of analysis error **Authors reported a significant difference between both groups (p=0.01) after analysis of covariance with adjustments for baseline measurements

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

	viding diabetes care) + more aggressive educational outreach to patients vs no intervention	Post intervention: 91% vs 91% Absolute difference: 0% Relative improvement: 0% DE-DC=-7%		
Peters 1998	Educational materials + audit and feedback + revision of professional roles (nurses provided diabetes care based on protocols) + changes in medical records systems + arrangements for follow up vs no intervention	Intervention group vs control group: Year 1: N=98 vs N=64 Year 2: N=74 vs N=55 Year 3: N=42 vs N=42 Compliance with ADA guidelines*: HbA1c levels (%): Year 1: 87% vs 24% Year 2: 69% vs 14% Year 3: 71% vs 11% Absolute difference 1: 63% Absolute difference 2: 55% Absolute difference 3: 60% Relative improvement 1: 263% Relative improvement 2: 393% Relative improvement 3: 545% Lipid panels (%): Year 1: 100% vs 36% Year 2: 92% vs 39% Year 3: 93% vs 49% Absolute difference 1: 64% Absolute difference 2: 53% Absolute difference 3: 44% Relative improvement 1: 178% Relative improvement 2: 136% Relative improvement 3: 90% Foot exams (%): Year 1: 100% vs 11% Year 2: 96% vs 9% Year 3: 93% vs 9% Absolute difference 1: 89% Absolute difference 2: 87% Absolute difference 3: 84% Relative improvement 1: 809% Relative improvement 2: 967%	HbA1c (%) (ref??-6.8) (Baseline: N=96 vs N=66 Year 1: N=95 vs N=56 Year 2: N=73 vs N=46 Year 3: N=47 vs N=28) Baseline: 11.9 vs 10.0** Year 1: 8.8 vs 9.8 Year 2: 8.7 vs 10.1 Year 3: 8.6 vs 10.4 Absolute difference 1: 1.0 Absolute difference 2: 1.4 Absolute difference 3: 1.8 Relative improvement 1: 10% Relative improvement 2: 14% Relative improvement 3: 17% (1) DE-DC =2.9 (2) DE-DC =3.3 (3) DE-DC =3.7 Total median cholesterol concentrations in patients with an initial total cholesterol level>6.2 mmol/l (baseline values are compared with the mean value for all 3 years in each patient) (N=29 vs N=13) Baseline: 7.24 vs 7.54 Post intervention: 6.21 vs 7.45*** Absolute difference: 1.24 Relative improvement: 17% DE-DC =0.94	*No statistical tests were undertaken for the process outcomes. The frequency of HbA1c testing met these standards if it was performed >=2 times/year in patients not taking insulin and >=4 times/year in patients taking insulin. Lipid panel frequency should be carried out at least yearly and foot exams should be carried out >=2 times/year **Differences at baseline between both groups in HbA1c p<0.005 ***A significant difference within the intervention group was reported over 3 years (p<0.001). In the control group no significant change was found ****The profiles of repeated observations on individuals were compared using generalised estimating equations. The effects of subject-specific variables (experimental group, recent onset or compliance) were tested for interaction with the time contrast. Intervention versus control group: Baseline(rank sum test): p<0.001 Year 1: p<0.09 Year 2 : p<0.05 Year 3 : p<0.01 *****Authors reported that serum creatinine levels and the presence or absence of proteinuria or microalbumiuria were not different at baseline or throughout the course of the study. Similar-

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

			Relative improvement 3: 933% Ophthalmology referrals (%): Year 1: 99% vs 19% Year 2: 92% vs 24% Year 3: 95% vs 19% Absolute difference 1: 80% Absolute difference 2: 68% Absolute difference 3: 76% Relative improvement 1: 421% Relative improvement 2: 283% Relative improvement 3: 400%	ly, there were no differences in the baseline blood pressure levels or mean levels throughout the study. Furthermore total cholesterol levels in the total population did not differ between both groups. No values were given.
Rith-Najarian 1998	Interrupted Time Series (ITS): Educational materials + reminders + clinical multidisciplinary team vs pre intervention period	Not done	Average annual incidence of lower-extremity amputation (LEA): Any LEA (rate/1000 diabetic person years): 1990: 18 1991: 21 1992: 18 1993: 28 1994: 10 1995: 22 1996: 13 First LEA (rate/1000 diabetic person years): 1990: 3 1991: 14 1992: 16 1993: 16 1994: 3 1995: 7 1996: 7 Major LEA (defined as either a "below the knee amputation" or an "above the knee amputation"): (rate/1000 diabetic person years): 1990: 3 1991: 8 1992: 13 1993: 8 1994: 10 1995: 11 1996: 4	Authors reported no significant differences calculated by chi-square method. p-values comparing pre intervention period (90-93) vs post intervention period: Any LEA: 0.22 First LEA: 0.071 Major LEA: 0.85
Rutten 1990	Educational materials + case management vs no intervention	Not done	Intervention vs control group (N=55 vs N= 72) Mean HbA1 (ref 5.3-7.7%): Baseline: 9.7% vs 8.9%** Post intervention: 9.2% [8.8;9.6]) vs 9.4% [9.2-9.7] Absolute difference: 0.2	*No p-values are given because of potential unit of analysis error **Significant differences in HbA1 were found at baseline p<0.05

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

			Relative improvement: 2% DE-DC =1.0 Mean individual change adjusted for diabetes regulation at the start of the study: Adjusted change: -0.38 vs 0.46 (In the intervention a favourable effect in contrast to the control group) Change in HbA1 in subgroups: Subgroup 1: patients that proved to be able to carry out accurate self-monitoring (N=33 at baseline) Subgroup 2: patients that were unwilling or incapable of self-monitoring (N=20 at baseline) Subgroup 3: patients who had up to then been under specialist care (N=13 at baseline) Subgroup 4: patients in control group who remained under conventional GP care Subgroup 5: patients in control group who remained under specialist care Subgroup 1: -0.47 (SD±1.57 ; CI [-1.0;0.07]) Subgroup 2: -0.28 (SD±1.29 ; CI [-0.35;0.91]) Subgroup 3: -0.60 (SD±1.76; CI [-1.9;0.7]) Subgroup 4: +0.41 (SD±1.03 ; CI [0.14;0.68]) Subgroup 5: +0.98 (SD±1.39 ; CI [0.32;1.64]) Body weight (kg): Baseline: 73.3 (SD±15.3) vs 76.7 (SD ±13.0) Post intervention: 72.9 (SD±14.9) vs 76.8 (SD±12.7) Absolute difference: 3.9 Relative improvement: 5% DE-DC =0.5 Mean individual change adjusted for diabetes regulation at the start of the study: Adjusted change: -0.3 vs -0.1	***Authors reported a significant difference in mean individual change in HbA1 between both groups (p<0.01) after adjusting for the diabetes regulation at the start of the study. This significant difference was not found for body weight.
See Tai 1999	Reminders + changes of medical record	Use of diabetes templates: Number of patients on whom the template was	Not done	No results of statistical analyses were reported by the authors

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

	system (implementation of new diabetes templates) vs usual diabetes care (usual basic template), but implementation of new asthma templates	used at least once (mean percentage per practice): Baseline: 21% vs 1% Post intervention: 43% vs 4% Absolute difference: 39% Relative improvement: 975% DE-DC= 19%		
Shultz 1992	A telecommunication system + changes in facilities and equipment + changes in medical record systems vs no intervention	Not done	Glycohaemoglobin (mg/dl): Baseline: Group 1: 7.2± 1.8 mmol/l Group 2: 7.5± 1.8 mmol/l The data were combined for all patients using the device and graphs and compared with all patients using the diaries. For the group using the intervention the blood glycohaemoglobin dropped significantly (p<0.003) whereas no change overall was found in the group using diaries. Post intervention values are not reported	*No sign difference between both groups at baseline **The study design is a cross-over trial. Group 1 began with the communication device to report glucose data for the first 6 months and then used a paper diary for the next 9 months. Group 2 used a paper diary for the first 6 months and followed with the communication device for the following 9 months
Stein 1974	Distribution of educational materials + revision of professional roles (a nurse practitioner trained in the management of diabetes mellitus) + patient education vs usual care	Not done	Blood sugar (mg/ml) Baseline: 121 (range 62-198) vs 172 (range 90-300) Post intervention: 140 (range 90-275) vs 130 (range 90-226) Absolute difference: -10 Relative improvement: -8% DE-DC= -61 Weight (LB): Baseline: 188 (range 136-271) vs 208 (range 150-306) Post intervention: 192 (range 138-268) vs 212 (range 149-304) Absolute difference: 20 Relative improvement: 9% DE-DC= 0	*The comparison patients were slightly more obese with higher blood sugar levels **Changes within each group and between the study and the comparison group were not statistically significant (no p-values are stated)
Taplin 1998	Educational material + lo-	Group 1: study population (part of Group Health Cooperative) (N=59)	Not done	*Not clear whether there is a significant difference between both groups at baseline

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

	cal consensus processes + audit and feedback + reminders + marketing (establishing a team and after that, regular team meetings to discuss and achieve clinical goals) + clinical multidisciplinary team + changes in medical record systems vs no intervention	Group 2: total population of Group Health Cooperative (393,628) Group 3: surrounding practices (8294) % compliance with guideline for diabetic eye care: Baseline: 64% vs 53% vs 45% Post intervention: 72% vs 60% vs 56% Absolute difference 1: 12% Absolute difference 2: 16% Relative improvement 1: 20% Relative improvement 2: 29% (1)DE-DC =1% (2)DE-DC =-3%		**No p-values are given because of potential unit of analysis error ***Eye care compliance was high in the study population at baseline and improved with time, but not significantly, probably because of insufficient power to detect the difference. Eye care did improve in the surrounding practices (p=0.034) and in GHC as a whole (p<0.0001), but this improvement was in part due to their low initial levels of compliance
Vinicor 1987	For patient outcomes four different groups were compared: Group 1: no intervention Group 2: patient education Group 3: physician education consisting of: educational materials + educational meetings + local consensus processes + audit	% of total clinic visits for monitoring metabolic control: Fasting blood glucose: Post intervention: 40% vs 31% Absolute difference: 9% Relative improvement: 29% Random blood glucose: Post intervention: 65% vs 74% Absolute difference: 9% Relative improvement: -12% Urine test record: Post intervention: 58% vs 52% Absolute difference: 6% Relative improvement: 12%1) History of hypoglycaemia: Post intervention: 78% vs 77% Absolute difference: 1% Relative improvement: 1%1)	Group 2 vs Group 3 vs Group 4 vs Group 1 (control group) Fasting plasma glucose (mg/dl) (Mean ± SD) (N=61 vs 58 vs 54 vs 65): Baseline: 11.9±4.8 vs 11.6±4.6 vs 12.7±6.0 vs 11.2±5.1 Post intervention: 11.0±4.4 vs 10.9±5.0 vs 10.6±4.5 vs 11.6±6.4 Absolute difference (2-1): 0.6 Absolute difference (3-1): 0.7 Absolute difference (4-1): 1.0 Relative improvement (2-1): 5% Relative improvement (3-1): 6% Relative improvement (4-1): 9% (2-1)DE-DC =1.3 (3-1)DE-DC =1.1 (4-1)DE-DC =1.6 A1Hgb (%)(Mean ± SD): (N=64 vs 60 vs 56 vs 67): Baseline: 10.17±2.53 vs 10.51±2.84 vs 11.34±3.16 vs 10.19±3.32 Post intervention: 10.23±2.53 vs 10.64±2.52 vs 10.42±2.94 vs 10.74±3.14 Absolute difference (2-1): 0.51	*No significant differences between both groups at baseline in process measures. These values are not reported. Furthermore also for patient outcomes no significant differences were found at baseline with the exception of postprandial plasma glucose. **No p-values are given because of potential unit of analysis error ***Authors reported significant differences between the intervention and control group for the process outcomes: fasting blood glucose (p=0.004), random blood glucose (p=0.002), diet prescription (p<0.001), cholesterol or triglycerides (p=0.016) For patient outcomes significant differences were found between group 2 and group 1 for fasting plasma glucose (p<0.05), glycated haemoglobin (p<0.05), body weight (p<0.05), systolic- (p<0.05)

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

and feedback + reminders + communication and case discussion between distant health professionals + Group 4: patient education + physician education (publication of Vinicor 1987) For process outcomes: Group 3 and group 4 were combined as also group 1 and group 2 were combined -> Educational materials + educational meeting + local consensus processes + audit and feedback + reminders + Communication and case discussion between distant health professionals +	1) denominator reflect only those visits in which a prescription for insulin or oral hypoglycaemic agents was in force % of patients for whom dietary management recommendations were followed: Diet prescription Post intervention: 80% vs 62% Absolute difference: 18% Relative improvement: 29% % of patients for whom recommendations for monitoring chronic complications were followed on at least an annual basis Visual symptoms: Post intervention: 82% vs 78% Absolute difference: 4% Relative improvement: 5% Visual acuity: Post intervention: 38% vs 30% Absolute difference: 8% Relative improvement: 27% Fundus examination: Post intervention: 38% vs 34% Absolute difference: 4% Relative improvement: 12% BUN or creatinine Post intervention: 79% vs 72% Absolute difference: 7% Relative improvement: 10% Foot examination: Post intervention: 92% vs 87% Absolute difference: 5% Relative improvement: 6% Discuss foot care: Post intervention: 68% vs 64% Absolute difference: 4% Relative improvement: 6% Neurologic examination: Post intervention: 6% vs 6%	Absolute difference (3-1): 0.10 Absolute difference (4-1): 0.32 Relative improvement (2-1): 5% Relative improvement (3-1): 1% Relative improvement (4-1): 3% (2-1)DE-DC =0.61 (3-1)DE-DC =0.68 (4-1)DE-DC =1.47 2 Hour postprandial (mg/dl)*: (N=58 vs 55 vs 52 vs 63): Baseline: 18.0±6.0 vs 18.1±5.9 vs 20.6±6.3 vs 17.2±6.6 Post intervention: 17.2±5.8 vs 17.2±6.0 vs 17.0±5.7 vs 17.8±7.6 Absolute difference (2-1): 0.6 Absolute difference (3-1): 0.6 Absolute difference (4-1): 0.8 Relative improvement (2-1): 3% Relative improvement (3-1): 3% Relative improvement (4-1): 4% (2-1)DE-DC =1.4 (3-1)DE-DC =1.5 (4-1)DE-DC =4.2 Weight (LBS)**: (N=66 vs 61 vs 53 vs 65): Baseline: 186.6±39.8 vs 188.8±42.2 vs 193.8±43.1 vs 185.3±44.8 Post intervention (adjusted for baseline): 184.7 vs 184.9 vs 183.9 vs 189.3 Absolute difference (2-1): 4.6 Absolute difference (3-1): 4.4 Absolute difference (4-1): 5.4 Relative improvement (2-1): 2.4% Relative improvement (3-1): 2.3% Relative improvement (4-1): 2.9% (2-1)DE-DC =4.7 (3-1)DE-DC =4.5 (4-1)DE-DC =5.8 Systolic blood pressure** (N=69 vs 62 vs 58 vs 67): Baseline: 139.9±16.0 vs 142.5±21.1 vs 140.4±16.5 vs 137.2±17.5 Post intervention: 138.9 vs 145.0 vs 144.7 vs 146.3 Absolute difference (2-1): 7.4 Absolute difference (3-1): 1.3 Absolute difference (4-1): 1.6 Relative improvement (2-1): 5%	and diastolic blood pressure (p<0.01). Between group 3 and group 1 significant differences were found for fasting plasma glucose (p=0.05), glycosylated haemoglobin (p<0.05), weight (p=0.05). Between group 4 and group 1 significant differences were found for fasting plasma glucose (p<0.01), glycosylated haemoglobin (p<0.01), weight (p<0.01) and diastolic blood pressure (p<0.005). ****Possible ceiling effect: The lower baseline glycosylated haemoglobin levels of patients who were reassessed, especially in group 1 and group 3 could have made it more difficult to detect significant effects of the interventions

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

	vs no intervention (publication of Mazzuca 1988)	Absolute difference: 0% Relative improvement: 0% History of peripheral pain: Post intervention: 33% vs 43% Absolute difference: -10% Relative improvement: 23% History of urinary symptoms: Post intervention: 68% vs 64% Absolute difference: 4% Relative improvement: 6% Postural hypotension: Post intervention: 7% vs 7% Absolute difference: 0% Relative improvement: 0% Impotence (males only) Post intervention: 10% vs 10% Absolute difference: 0% Relative improvement: 0% Blood pressure (q visit): Post intervention: 89% vs 88% Absolute difference: 1% Relative improvement: 1% Baseline electrocardiography: Post intervention: 85 vs 78% Absolute difference: 7% Relative improvement: 9% Smoking history Post intervention: 56% vs 49% Absolute difference: 7% Relative improvement: 14% Cholesterol or triglycerides (q 2 years: Post intervention: 70% vs 58% Absolute difference: 12% Relative improvement: 21% Carotid and femoral bruits: Post intervention: 8% vs 9% Absolute difference: 1% Relative improvement: 11%	Relative improvement (3-1): 1% Relative improvement (4-1): 1% (2-1)DE-DC =8.7 (3-1)DE-DC =3.8 (4-1)DE-DC =3.1 Diastolic blood pressure**: (N=69 vs 62 vs 58 vs 67): Baseline: 84.7±9.5 vs 83.1±9.9 vs 81.8±9.6 vs 81.4±9.2 Post intervention: 81.9 vs 83.4 vs 81.5 vs 85.5 Absolute difference (2-1): 3.6 Absolute difference (3-1): 2.1 Absolute difference (4-1): 4.0 Relative improvement (2-1): 4% Relative improvement (3-1): 3% Relative improvement (4-1): 5% (2-1)DE-DC =6.1 (3-1)DE-DC =4.1 (4-1)DE-DC =4.3	
Weinberger 1995	Patient mediated	Not done	Glycohaemoglobin (%) (ref 4.7-7.2%) (mean±SE):	*No significant differences between both groups at baseline

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

interventions (nurses attempted to telephone patients to facilitate compliance, monitor patients' health status, facilitate resolution of identified problems, facilitate access to primary care) + arrangements for follow up + patient education vs no intervention	Baseline: 10.7±3.3 vs 10.7±3.4 Post intervention: 10.5±0.2 vs 11.1±0.3 Absolute difference: 0.6 Relative improvement: 5% DE-DC =0.6 P=0.046* Fasting blood glucose (mmol/l) (mean ±SE): Baseline: 10.3±3.7 vs 10.2±4.2 Post intervention: 9.7±0.2 vs 10.7±0.4 Absolute difference: 1.0 Relative improvement: 9% DE-DC =1.1 P=0.011* Analyses of subgroups 1) Hyperlipidemic patients (total cholesterol ^{3}200mg/dl) (N=97(interv)+34(contr)): Seen by dietician (%): Post intervention: 31% vs 6% Absolute difference: 25% Relative improvement: 417% P=0.003 % taking lipid-lowering medications: Post intervention: 22% vs 9% Absolute difference: 13% Relative improvement: 144% P=0.096 Total cholesterol (mmol/l) (mean±SD): Absolute change: -0.30±0.86 vs -0.11±0.85 Relative improvement: 173% P=0.270 Triglycerides (mmol/l) (mean±SD): Absolute change: -0.50±5.40 vs -1.15±6.47 Relative improvement: -57% P=0.572 LDL cholesterol (mmol/l): (mean±SD): Absolute change: -0.21±0.63 vs 0.008±0.73 Relative improvement: NA P=0.161 HDL (mg/dl) (mean±SD): Absolute change: -0.07±0.28 vs 0.005±0.19 P=0.378	**Authors reported no significant difference in health-related quality of life (SF-36) change scores between the intervention and control groups

Table 6. Professional - in combination with organisational interventions vs usual care *(Continued)*

	Obese patients (weight at study enrolment>=120% of ideal body weight) (N=115(interv)+41(contr)) Change in weight (kg) (mean±SD): Absolute change: -0.9±5.3 vs -0.1±3.6 Relative improvement: P=0.202 Seen by dietician (%): Post intervention: 30% vs 7% Absolute difference: 23% Relative improvement: 329% P=0.003

WHAT'S NEW

Date	Event	Description
12 November 2008	Amended	Minor changes

HISTORY

Protocol first published: Issue 2, 1999
Review first published: Issue 1, 2001

Date	Event	Description
6 November 2008	Amended	Converted to new review format.
29 June 2000	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

CM Renders and JThM van Eijk conceived the review, CM Renders, GD Valk and WJJ Assendelft designed the review, CM Renders co-ordinated the review, CM Renders and GD Valk collected, analysed and interpreted data. CM Renders, GD Valk, SJ Griffin, EH Wagner, JThM van Eijk and WJJ Assendelft wrote the review. CM Renders is guarantor for the review.

DECLARATIONS OF INTEREST

None known.

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INDEX TERMS

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