Patient education for preventing diabetic foot ulceration
(Review)

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This record should be cited as:

This version first published online: 23 October 2001 in Issue 4, 2001.
Date of most recent substantive amendment: 20 August 2001

ABSTRACT

Background
Ulceration of the feet, which can result in loss of limbs and even death, is one of the major health problems for people with diabetes mellitus.

Objectives
To assess the effectiveness of patient education on the prevention of foot ulcers in patients with diabetes mellitus.

Search strategy
Eligible studies were identified by searching the Cochrane Wounds Group Specialised Register, (September 2004) and the Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library Issue 3, 2004).

Selection criteria
Prospective randomised controlled trials (RCTs) which evaluated educational programmes for the prevention of foot ulcers in people with diabetes mellitus. There was no restriction on language of the publications.

Data collection and analysis
Two reviewers undertook data extraction and assessment of study quality independently.

Main results
Nine RCTs were included. Four trials compared the effect of intensive with brief educational interventions; two of these reported clinical endpoints. One study involving high-risk patients reported a reduction in ulcer incidence (Peto OR: 0.28 (95% CI 0.13 - 0.59)) and amputation rate (Peto OR: 0.32 (95% CI 0.14 - 0.71)) after one year. The other RCT did not find an effect at seven years follow-up. Participants’ foot care knowledge significantly improved with education in two trials. In one trial foot care knowledge improved significantly in the control group, in contrast to the intervention group. Non-calcaneal callus was significantly reduced by education in one trial.

One RCT did not find that patient foot care education, as part of a general diabetes education program, reduced foot ulceration compared with usual care. Patient education as part of a complex intervention, targeted at both people with diabetes and doctors, reduced the number of serious foot lesions at one year in one RCT (OR: 0.41 (95% CI 0.16 - 1.00)) and improved foot care behaviour.

Evidence from three RCTs comparing the effect of patient-tailored education in addition to usual care was conflicting.

The methodological quality of the nine included RCTs was poor. The internal validity score (range 0 - 10) of individual RCTs ranged from 2 to 5.

Authors’ conclusions
RCTs evaluating education for people with diabetes, aimed at preventing diabetic foot ulceration, are mostly of poor methodological quality. Weak evidence suggests that patient education may reduce foot ulceration and amputations, especially in high-risk patients. Foot care knowledge and behaviour of patients seem positively influenced by patient education in the short term.
S Y N O P S I S

Educating people with diabetes about foot care may help reduce foot ulcers and amputations, particularly in those at high risk

Foot ulcers (open sores) are common in people with diabetes, especially those with problems in the nerves (peripheral neuropathy) and/or the blood supply to their legs (peripheral vascular disease). People with ulcers due to diabetes sometimes need an amputation (surgical removal of part of the limb). The review of trials found that educating people with diabetes about the need to look after their feet might help prevent ulcers and amputations, especially for people at high risk of developing these problems. Education seems to improve people’s foot care knowledge and behaviour, but the research is not strong.

B A C K G R O U N D

Ulceration of the foot is one of the major health problems for people with diabetes mellitus, and it can result in limb loss and death. Foot ulceration is estimated to affect 15% of people with diabetes at some time in their life (Palumbo 1985) and 70% of healed foot ulcers recur within five years (Apelqvist 1993). Diabetic foot ulcers precede approximately 85% of amputations (Pecoraro 1990). The risk of a lower extremity amputation in people with diabetes is 15 times higher than in people without diabetes (Most 1983).

Several factors are involved in the development of foot ulcers including peripheral neuropathy, peripheral vascular disease (PVD), limited joint mobility and repeated trauma from abnormal load distribution on the foot (Edmonds 1982; Mueller 1989; Shaw 1997; Wieman 1992).

Diabetic foot ulcers and diabetes-related lower extremity amputations represent a substantial part of diabetes-related health care costs. In 1992, in the Netherlands, the mean cost per hospitalisation for diabetes-related amputations was £10,531, accounting for approximately 10% of the total of diabetes-related health-care costs per year in the Netherlands (van Houtum 1995). In the US the direct hospital cost of an amputation was estimated at $8,000–$12,000, or $500 million per year for all amputations in the diabetic population (Bild 1989). In a retrospective economic analysis, the costs of health care were $43,100 over the three years following a minor amputation (below the ankle) and $63,100 following a major amputation (above the ankle). These costs include the costs due to complications and disability related to the initial ulcer, costs related to recurrence of ulcers, and costs for prevention of new ulcers (Apelqvist 1995).

In 1989, one of the five-year targets of the European Declaration of St. Vincent was a 50% reduction in amputations caused by diabetes mellitus. However, lack of awareness of patients and health care professionals of the risk factors for diabetic foot problems, as well as inappropriate management still lead to unnecessary morbidity and substantial health care costs. At present, standard practice usually involves the provision of unstructured and ad hoc information about foot care to people with diabetes mellitus. Life-long surveillance of the feet of people with diabetes, as well as educational programmes have long been thought to reduce the incidence of foot ulcers (Boulton 1998; Holewski 1989; Pecoraro 1990). However, before education programmes for the prevention of diabetic foot ulceration can be widely advocated and implemented in standard practice, there must be evidence of the effectiveness of such programmes.

Education programmes for the prevention of diabetic foot ulceration can be targeted at people with diabetes and/or the health care professionals managing their care. This review focuses on the education of people with diabetes. It is generally thought that all people with diabetes, especially those at high risk of foot ulceration, should learn the principles of self-examination of the feet and foot care (Boulton 1995; Edmonds 1996b). However, previous systematic reviews of patient education for adults with asthma and neck pain have suggested that health outcomes were unlikely to be improved by limited patient education (Gibson 1998; Gross 2004).

Several review articles on the diabetic foot, which include education among the prevention strategies discussed, have already been published (Armstrong 1998; Assal 1985; Bild 1989; Boulton 1995; Edmonds 1996a; Larsson 1995; Levin 1995; Majid 2000; Mason 1999; Mayfield 1998). The overall conclusion of these review articles was that education is effective for the prevention of diabetic foot ulceration, but since only two of these reviews were systematic (Majid 2000; Mason 1999) and most of the previous reviews dealt primarily with uncontrolled studies, their conclusions must be treated with care. Furthermore, only one of the previous reviews assessed the methodological quality of the included studies and none of the reviews attempted to perform a meta-analysis. Thus, after reviewing the available evidence, we decided to perform a systematic review of the effectiveness of education targeted at people with diabetes for the prevention of foot ulceration, based
OBJECTIVES

To determine the effectiveness of educational programmes for people with diabetes mellitus, aimed at preventing foot ulceration.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Prospective randomised controlled trials (RCTs) evaluating educational programmes for the prevention of foot ulcers in people with diabetes mellitus. We excluded studies that were solely aimed at optimising blood glucose concentration. An explicit focus on foot care was required.

Types of participants

People aged 18 years or older with Type 1 or Type 2 diabetes mellitus in any health care setting.

Types of intervention

Educational programmes (or programmes which include education) aiming to reduce the incidence of foot ulceration in people with diabetes mellitus.

The foot care education could be part of a larger educational programme, but had to contrast with the control intervention. All types of control intervention were included in the review. Additional interventions, i.e. education as part of more comprehensive diabetic foot programmes or as part of complex interventions, were eligible.

Types of outcome measures

The primary outcomes of interest were:

- incidence of foot ulceration, infection, amputation and ulcer recurrence.

Secondary outcomes of interest were:

- callus development;
- resolution of callus;
- number and duration of hospital admissions for diabetic foot problems;
- foot care knowledge scores;
- patients’ behaviour assessment scores.

Trials were included even if only secondary outcomes were reported.

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

See: Wounds Group search strategy

For the update of this review we searched the Cochrane Wounds Group Specialised Register (September 2004) and The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library Issue 3, 2004), using the following strategy:

1. EDUCATION explode tree 1 (MeSH)
2. INSERVICE TRAINING explode tree 1 (MeSH)
3. TEACHING explode all trees (MeSH)
4. education*
5. pamphlet*
6. (leaflet* or booklet* or poster or posters)
7. (written near information)
8. (printed near information)
9. (oral near information)
10. (multidisciplinary near approach*)
11. (academic near detailing)
12. (training next program)
13. (algorithm* or (decision next tree*))
14. teaching
15. (#1 or #2 or #3 or #4 or #5 or #6 or #7)
16. (#8 or #9 or #10 or #11 or #12 or #13 or #14)
17. (#15 or #16)
18. FOOT ULCER explode all trees (MeSH)
19. DIABETIC FOOT explode all trees (MeSH)
20. (foot and ulcer*)
21. (diabetic near foot)
22. (diabet* near ulcer*)
23. (diabet* near infection*)
24. (diabet* near wound*)
25. amputation*
26. (#18 or #19 or #20 or #21 or #22 or #23 or #24 or #25)
27. (#17 and #26)

We searched CINAHL (1982 to 2003), using the following search strategy:

1.(foot-ulcer* or leg-ulcer* or skin-ulcer*) in de
2.(diabetic-foot* or diabetic-neuropathies*) in de
3.(diabetic-angiopathies*) in de
4.(plantar or diabetic or heel (arterial near ulcer*)) in ti,ab
5.(foot or diabetic or ischaemic near ulcer*) in ti,ab
6. diabetic near foot in ti,ab
7.#1 or #2 or #3 or #4 or #5 or #6
8. patient-education* in de
9.(education or clinic* or therap*)in de
10.#8 and #9
11. prevent* in de
12.#10 and #11 and #7
13.(clinical-trials or single-blind-studies or double-blind-studies) in de
METHODS OF THE REVIEW

Full copies of potentially eligible studies were obtained and two reviewers (GDV, DMWK), acting independently, decided on inclusion or exclusion.

We extracted details of eligible studies and summarised them using a data extraction sheet. We recorded the content of the educational package, plus the content of the total programme if education was merely one component. If data were missing from reports, we then attempted to contact the authors. We regarded studies that had been published in multiple locations as one source and if different but relevant outcomes were available from different publications of the same RCT, we recorded all outcomes. Data regarding the interventions studied, type of outcome measures, duration of follow up, loss to follow up, and outcomes were extracted by two reviewers (GDV, DMWK) independently. Disagreements were resolved by discussion.

After we had included all available eligible studies in the review, we assigned two reviewers (GDV, DMWK) to independently critique each study using the Amsterdam/Maastricht consensus list to assess methodological quality (Table 01) (van Tulder 1997). We calculated initial disagreement per item and expressed it as percentage agreement (Brennan 1992). We discussed any disagreement in a consensus meeting. The Amsterdam/Maastricht consensus list includes criteria listed by Jadad et al (Jadad 1996; Schulz 1994; Verhagen 1998), and is subdivided into 10 internal validity criteria (b (b1 and b2), c, f, g, h, i, j, l, n, p), five descriptive criteria (a, c, d, k, m) and two statistical criteria (o, q).

To determine internal validity, we evaluated the presence of sufficient information and the likelihood of potential bias for each validity criterion. If sufficient information was available and bias was considered to be unlikely, we rated the criterion positive. If bias was considered likely, we rated the criterion negative. In cases where information was lacking, we rated the criterion inconclusive (don’t know). We calculated a total score for internal validity of the study (‘study validity score’) by adding the number of positive criteria. Equal weights were applied, resulting in a validity score with a range of 0 to 10, with higher scores indicating lower likelihood of bias. The explicit assessment of internal validity indicates the weight the reader may give to the results of the particular studies.

The various outcome measures are presented separately. Depending on the available data and event rate, we have expressed the various outcome measures as effect sizes, odds ratios or risk ratios (Lau 1997; Mulrow 1997; Rosenthal 1994).

Possible sources of variation among studies that would require pre-planned stratified analysis were: 1. character of patient groups (e.g. patients with an ulcer versus patients without an ulcer; newly diagnosed versus known patients with diabetes mellitus etc.); 2. health care setting; 3. quality of studies; 4. outcome measures used; 5. type of intervention (e.g. content of educational package; brief versus intensive programmes; education only versus complex intervention; education targeted at patients only versus education targeted at both patients and health care providers); 6. nature of contrast (e.g. intervention versus control intervention; patient-education plus co-intervention A versus intervention A alone; intervention versus no intervention).

DESCRIPTION OF STUDIES

Nine RCTs were eligible for inclusion. The characteristics of the included RCTs are described in the table ‘Characteristics of Included Studies’. The short- and long-term results of one RCT were described in two different publications (Hamalainen 1997) and these were regarded as one report for the purposes of the data analysis.

Study settings

Two RCTs were performed in the home environment (Corbett 2003; Rettig 1986), three studies in a primary care setting (Bloomgarden 1987; Litzelman 1993; Mazzuca 1986), one in a podiatry outpatient care setting (Hamalainen 1997), and three in an outpatient care setting (Barth 1991; Kruger 1992; Malone 1989). In one of the nine included RCTs, patients at high risk of ulceration or amputation only were included (they had been referred for podiatry or vascular surgery due to a current foot infection, ulceration, or prior amputation) (Malone 1989). In five RCTs patients were at low or medium risk (Barth 1991; Bloomgarden 1987; Corbett 2003; Hamalainen 1997; Litzelman 1993) and in three RCTs, the level of risk of ulceration or amputation could not be determined (Kruger 1992; Mazzuca 1986; Rettig 1986).

Interventions (see Table: Characteristics of Included Studies)

Four RCTs compared the effectiveness of intensive foot care education for people with diabetes with less proactive educational
interventions. One study compared nine hours of group foot care education, conducted in four weekly sessions, with a one hour lecture and discussion on foot care as part of a 14 hour group diabetes education (Barth 1991). A second study compared a 'hands-on' foot care approach, a patient education kit, instructional videotapes and daily foot care sheets with instructional videotapes and daily foot care sheets alone (Kruger 1992). A third study compared 45 minutes of individual patient education and podiatric care visits with written instructions for patients (Hamlainen 1997). The fourth study compared one hour of group patient education including slides and a set of instructions on the care of the diabetic foot with regular diabetes education (Malone 1989).

One RCT compared one group session of patient education on foot care and skin hygiene that was part of a general diabetes group patient education program with no intervention (Bloomgarden 1987). Two RCTs compared patient education on diabetes in general, including the diabetic foot, that was tailored to individual patient educational needs, with usual care (Mazzuca 1986; Rettig 1986). One RCT compared patient education on the diabetic foot tailored to individual needs with no intervention (Corbett 2003). In one study, patients were enrolled in appropriate modules of instruction depending on their educational needs. Those educational needs were identified using a set of safety-level objectives selected by a multidisciplinary group of health care professionals. These objectives covered seven areas of patient education, of which foot care was one (Mazzuca 1986). In another study, specific areas of diabetes self-management most in need of improvement were determined using a needs assessment instrument (100 short answer and yes-no questions, brief patient demonstrations of urine testing and insulin injection techniques) (Rettig 1986). In the last study, education was individualised according to the patients' risk factors and foot care knowledge, self efficacy, and reported self care behaviours (Corbett 2003).

Finally, one RCT compared a complex intervention aimed at preventing the diabetic foot with usual care (no intervention). The intervention included educational components targeted at both people with diabetes and doctors (Litzelman 1993).

METHODOLOGICAL QUALITY

The methodological quality of every included RCT was poor. Details of the quality of the nine RCTs are presented in Additional Table 02: Methodological Quality of Included Trials.

The internal validity score (range of possible scores 0-10) of the individual RCTs ranged from 2 to 5. True randomisation with allocation concealment was evident in only one of the included RCTs (Corbett 2003). A description of co-interventions or confirmation that co-interventions were avoided was not evident in any RCT, neither was it evident that adherence to the interventions reached an acceptable level. Only three RCTs (Barth 1991; Litzelman 1993; Rettig 1986) described blinded outcome assessment. The withdrawal/drop-out rate was not reported in 2 studies (Litzelman 1993, Rettig 1986) and was unacceptable in another two RCTs (Kruger 1992; Mazzuca 1986). In none of the RCTs was an intention-to-treat analysis performed.

The eligibility criteria with regard to risk for foot ulceration were sufficiently described in only one of the RCTs (Malone 1989). The most important baseline prognostic indicators for foot ulceration were clearly incomparable in one RCT (Barth 1991) and inadequately described in the other RCTs.

RESULTS

Twenty-five RCTs were considered for selection and nine RCTs were eligible based on full text review. There was disagreement between the reviewers about inclusion of two RCTs (Mazzuca 1986; McMurray 2002) this was resolved by discussion.

Data on 136 items were extracted for each RCT, relating to methodological quality, study characteristics, interventions, and outcomes. There was initial agreement on 123 items (agreement 90% (84%, 95%)). All disagreements were resolved by discussion.

Details of the included RCTs are presented in the Characteristics of Included Studies Table and in Additional Table 03: Results from trials.

1. Intensive versus brief educational interventions

We identified four RCTs comparing intensive with brief educational interventions (Barth 1991; Hamlainen 1997; Kruger 1992; Malone 1989). All four were performed in an outpatient care setting.

Primary outcomes

Two studies reported the incidence of amputation, ulcers and/or infection (Hamlainen 1997; Malone 1989). In one, (Malone 1989) the reduction in ulcer incidence (Peto OR: 0.28 (95% CI 0.13 - 0.59)) and amputation rate (Peto OR: 0.32 (95% CI 0.14 -0.71)) were both statistically significant at one year follow-up with no effect on the incidence of infection. The patients in this RCT were at high risk of foot ulceration as they had been referred to podiatry or vascular surgery due to foot infection, ulceration or prior amputation. (See Graph Comparison 2, Outcome 1 & Outcome 3).

The other RCT that reported amputation rate and ulcer prevalence at seven year follow-up did not find a difference between intervention and control groups with regard to either outcome (Hamlainen 1997). Because of the large difference in baseline risk of foot ulceration of the patient populations in these RCTs, the results of these two RCTs were not pooled.

Secondary outcomes (See Additional Table 03: Results from Trials)
Patients’ knowledge of foot care was reported in three of the four
RCTs (Barth 1991; Hamlainen 1997; Kruger 1992) this outcome
was significantly improved in two RCTs; at 6 months in one (Barth
1991) (p=0.001), and one year in the other (Hamlainen 1997)
(p=0.004). In one study (Kruger 1992) foot care knowledge
improved statistically significantly in the control group, in contrast
to the intervention group, at 6 month follow up (p=0.02). How-
ever, this study dealt with extremely small groups (23 patients in
the intervention group and 27 in the control group), and also had
a relatively high dropout rate.

Behaviour assessment scores, measured in all studies using newly
developed and non-validated scoring lists, were also reported in
these three RCTs (Barth 1991; Hamlainen 1997; Kruger 1992).
The foot care behaviour of patients (e.g. washing, creaming, foot
inspection, cutting toe nails, use of pumice stones, foot gymnastics)
improved significantly at six months (Barth 1991) (p=0.012),
(Kruger 1992) and one year (Hamlainen 1997) (p=0.001).

In the one RCT in which callus development was assessed, non-
calcaneal callus (e.g. under metatarsal heads or under the digi-
ts) was statistically significantly improved at one year (p=0.009),
whereas calcaneal callus was not (p=0.14) (Hamlainen 1997).

2. Footcare education as part of general diabetes education
versus usual care.

One RCT with 749 people evaluated the effect of foot care educa-
tion as part of general diabetes education in primary care (Bloom-
garden 1987).

Primary outcomes (See Graph Comparison 3, Outcome1)
No significant effect was found on ulcer or amputation occur-
rence after a follow up of approximately 1.5 years (Peto OR: 0.75
(95%CI 0.10 - 5.55).

Secondary outcomes (See Graph Comparison 3, Outcome2)
In addition, no significant effect was found on the behaviour as-
essment scores (seven questions on diabetes self-care, of which
one asked how often the feet were checked for sores). Callus, nail
dystrophy and fungal infections were not different between inter-
vention and control groups after 1.5 years (Peto OR: 0.75 (95%
CI 0.38 - 1.45)).

3. Complex educational intervention, including foot care, tar-
geted at both patients and doctors versus usual care.

One RCT evaluated the effect of a complex intervention that in-
cluded patient education on foot care, in a primary care setting
(Litzelman 1993). This intervention was targeted at both patients
and doctors.

Primary outcomes (See Graph Comparison 4, Outcome1)
The number of serious foot lesions (defined as minor non-ulcer-
ated lesions with clinical evidence of healing as a minimum) was
reduced (OR: 0.41(95% CI 0.16 -1.00)). However, no statistically
significant effect was found on the composite outcome of ‘all foot
lesions’ (OR: 0.65 (95% CI 0.36 -1.17)) or ‘amputations’ (Peto
OR: 0.32 (95% CI 0.05 -1.86)).

Secondary outcomes (See Additional Table 03: Results from Trials)
In this RCT a statistically significant positive effect was also found
on patients’ foot care behaviour (p=0.0001). However odds ratios
only were presented in the absence of event rates and baseline
prognostic data and the proportion of patients in each group that
completed follow up was not provided and could therefore not be
compared.

4. Patient education tailored to educational needs versus usual
care. (See Additional Table 03: Results from ‘Trials)
Three RCTs evaluated the effect of patient education, tailored
to the educational needs of the patients (Corbett 2003; Mazzuca
1986; Rettig 1986). One was performed in primary care (Mazzuca
1986), the other 2 studies in the home environment (Corbett
2003; Rettig 1986).

These studies did not report on the primary outcomes identified
by this review.

Secondary outcomes
In one study, foot care knowledge only was assessed at one year,
and no effect was found (Mazzuca 1986). In another there was a
statistically significant improvement in foot care knowledge at six
months follow up (p=0.001)(Rettig 1986). However, no positive
effects were found on foot appearance and foot care skills score
(Rettig 1986). In the last study, significant improvement in foot
care knowledge (p=0.03) and self-care practices (p=0.007) was
found at six weeks follow up (Corbett 2003).

DISCUSSION

A range of patient educational interventions have been evaluated
for the prevention of diabetic foot ulceration. These interventions
varied from brief patient education to intensive patient education
including demonstration and ‘hands-on’ teaching, and include a
complex intervention in which both patients and doctors were
educated.

The ultimate aim of foot care education for people with diabetes is
to prevent foot ulceration and amputations. However, these end-
points were assessed in only four of the nine RCTs; heterogeneity
precluded pooling of the results of these separate studies. There-
fore, the results of this review are presented in a study-by-study
narrative form.

This is the first review in which a validated extensive methodolog-
ical quality assessment of the included studies has been made, and
one of the most important findings of the present review is the
very poor quality of the included RCTs. All of the RCTs scored
between 2 and 5 on the internal validity score (maximum possi-
bile score of 10), which means that all had serious methodological
flaws. The low scores were mainly caused by a lack of important
information in trial reports. Because of the low internal validity
scores of the included RCTs, the few positive effects that were
found should be interpreted with great caution. Another consequence of the general poor quality of the included studies was that the planned stratified analysis, and the assignment of appropriate weights to studies in the analysis with respect to methodological quality was not possible.

We requested additional data for only two studies, because effect size had not been reported (Corbett 2003; Mazzuca 1986). We were unable to contact other authors for further additional information on study design, execution or outcomes. Overall, it appears that little evidence is available to support patient education for the prevention of diabetic foot ulceration or amputations, but this amounts to an absence of evidence rather than evidence of ineffectiveness.

Only one RCT showed that, after one year follow-up, the incidence of foot ulcers and amputations was lower in the patient group that received one hour of group education on the diabetic foot by a podiatrist compared to the patient group that did not (Malone 1989). In this RCT, the number of legs instead of the number of patients was taken as the unit of analysis (so-called ‘unit of analysis error’) leading to an overestimation of the precision of the study and thus the ability to reach statistical significance. Moreover, diabetes education, vascular surgery and podiatric care were available for both the intervention and control patients and it was not clear if the regular care providers were blinded to the treatment group. In this RCT, the patients were at high risk of foot ulceration, and there is the possibility that education might be particularly effective in high-risk patients. Furthermore the positive results of this single RCT cannot be extrapolated to people with diabetes at a lower baseline risk. In another RCT, a complex intervention targeted at both patients and doctors, resulted in a significant reduction of minor non-ulcerated foot lesions at 1 year (Litzelman 1993). No significant effects were demonstrated in the two other RCTs that evaluated the effect of patient education on foot ulceration and amputation (Hamlein 1997; Bloomgarden 1987).

It is not likely that publication bias has greatly affected the results of this review. The heterogeneity of the outcomes and RCTs meant it was not possible to make a funnel-plot to assess the presence of publication bias. However, publication bias is unlikely to account for these results because in general, it would be likely to lead to an overestimation of the effects. In this case most of the RCTs identified reported non-significant findings and it is therefore unlikely that we overestimated the effect.

Most of the studies in this review recruited too few participants to be able to detect clinically important differences in outcome. For example, in order to detect a 50% reduction in the incidence of diabetic foot ulceration, 430 - 870 patients would be required per treatment group (based on an annual incidence of foot ulceration in the general diabetes population of 2-4% per year or 4-8% over 2 years) (De Sonnville 1997; Reenders 1993) Whilst trials of this magnitude are costly, the benefits in terms of potential reduction in costs associated with treatment are potentially significant. Unfortunately, the smaller trials do not share a common set of patient characteristics and outcome measures. Therefore, it is unlikely that the role of foot care education will be clarified in the near future by pooling existing or similar trials. The present review demonstrates a short-term effect of education on patients’ foot care knowledge, which improved in four of the five RCTs in which this outcome was assessed (Barth 1991; Corbett 2003; Hamlainen 1997; Retig 1986). However, in the one RCT with longer follow up, this positive effect had disappeared at seven years (Hamlainen 1997). Similarly patient behaviour at 6 - 18 months improved in four of the six RCTs in which this outcome was assessed. This difference disappeared at seven years (Hamlainen 1997). It must be stressed that foot care knowledge and patient behaviour were measured using very subjective outcome measures and are therefore prone to bias.

The effects on callus, nail problems and fungal infections were inconclusive. These effects varied from no effect to a positive effect after a follow-up period of from 6 to 18 months.

Authors’ Conclusions

Implications for practice

The RCTs that have been conducted on the topic of patient education for the prevention of diabetic foot ulceration are generally of poor methodological quality. Consequently, whilst some of the results are suggestive of a positive effect on ulcer incidence, this result must be viewed with caution. The conflicting results and methodological shortcomings of the existing RCTs mean that further high quality research is needed to clarify the impact of patient education on ulcer incidence, and to explore if educational interventions have different effects for a range of levels of baseline risk. Foot care knowledge and patient behaviour seem to be positively influenced by education in the short-term, but the goal of education interventions (improving knowledge and behaviour) is the prevention of foot ulceration and amputations, and sufficient evidence of this has not yet been delivered.

Implications for research

Well-designed RCTs of sufficient size to detect clinically important differences are now needed to evaluate the effect of patient education on the hard end points of foot ulceration and amputation in the diabetic population. For diabetes patients not selected on the basis of risk for foot ulceration, this means at least 430 to 870 patients per treatment arm. Obviously, for reliable estimates in the subgroup of low-risk patients, more participants than in the above-mentioned projection would be needed. Patients in future trials should be properly randomised with concealed allocation, regular care providers and outcome assessors should be blind to the intervention, and co-interventions need to be avoided or comparable between groups. In addition, economic evaluations are required.
These RCTs must be reported in accordance with CONSORT guidelines (Begg 1996). Future research should study the effect of patient education separately and as part of (protocol driven) complex interventions. These programs should include patient education on complications such as foot ulceration and amputations and in patients at varying levels of baseline risk. Particular consideration should be given to the adequate reporting of exclusion and inclusion criteria (i.e. methods of assessment of the ‘at risk’ foot) to enable proper analysis and enhance generalisability.

ACKNOWLEDGEMENTS

The reviewers would like to thank:
- Nicky Cullum for putting her existing work on education for the diabetic foot at our disposal.
- The Cochrane Wounds Group referees (Neil Baker, Althea Foster, Sue O’Meara, Jude Smith) and Editors (Nicky Cullum, Andrew Jull) who commented on the original review.

NOTES

History of this review:
This review was first published in the Cochrane Library, Issue 4, 2001, with 8 included studies.
The synopsis was prepared by the Cochrane Consumer Network

POTENTIAL CONFLICT OF INTEREST

None known

SOURCES OF SUPPORT

External sources of support
- No sources of support supplied

Internal sources of support
- EMGO Institute, VU Medical Center Amsterdam NETHERLANDS
- Department of General Practice, Academic Medical Center, Amsterdam NETHERLANDS
- Dutch Cochrane Centre NETHERLANDS

REFERENCES

References to studies included in this review
Barth 1991 [published data only]

Bloomgarden 1987 [published data only]

Corbett 2003 [published data only]

Hamlainen 1997 [published data only]


Kruger 1992 [published data only]

Litzelman 1993 [published data only]

Malone 1989 [published data only]

Mazzuca 1986 [published data only]

Rettig 1986 [published data only]
References to studies excluded from this review

Dargis 1999

Davidson 2000

De Weerdt 1991

Donohoe 2000

Glasgow 1992

Litteman 1997

McMurray 1998


Pieper 1995

Plank 2003

Reichard 1993

Vinicor 1985

Ward 1999

Wooldridge 1996

Additional references

Apelqvist 1993

Apelqvist 1995

Armstrong 1998

Assal 1985

Begg 1996

Bild 1989

Boulton 1995

Boulton 1998
Brennan 1992

De Sonnaville 1997

Edmonds 1982

Edmonds 1996a

Edmonds 1996b

Gibson 1998

Gross 2004

Holewski 1989

Jadad 1996

Larsson 1995

Lau 1997

Levin 1995

Majid 2000

Mason 1999

Mayfield 1998

Most 1983

Mueller 1989

Mulrow 1997

Palumbo 1985

Pecoraro 1990

Reenders 1993

Rosenthal 1994

Schulz 1994

Shaw 1997

van Houtum 1995

van Tulder 1997

Verhagen 1998
Verhagen AP, Yet HCW de, Bie RA de, Kessel AGH, Boers M, Bouter LM, et al. The Delphi list: a criteria list for quality assessment of

**Wieman 1992**

*Indicates the major publication for the study

### TABLES

#### Characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Method</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Barth 1991</strong></td>
<td>RCT</td>
<td>Study setting: Secondary care, outpatient care in Australia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inclusion criteria: patients with type 2 diabetes mellitus &gt; 3 months and current treatment &gt; 1 month, suboptimal glucose control, BMI not less than 25, energy fat intake at least 35%, no education in previous 6 months, competence in English language</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention group:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method - Four weekly group patient education sessions of 1.5-2.5 hours (total 9 hours), three by podiatrist, one by psychologist on the base of cognitive motivation theory</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Content -</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. recommendations and footcare education</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. demonstration and practising foot care procedures</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Control group:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method - fourteen hours group patient education including one hour lecture and discussion by podiatrist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Content - standard diabetes education, on hour on footcare and footwear</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Outcomes Primary outcomes: not reported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Secondary outcomes: foot care knowledge, behaviour assessment score, foot problems requiring treatment</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Notes</td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>B</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Method</th>
<th>Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bloomgarden 1987</strong></td>
<td>RCT</td>
<td>Study setting: Primary care, diabetes clinic in the US</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inclusion criteria: Insulin treated diabetes mellitus (unclear which type of diabetes)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Interventions Intervention group:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method - nine group patient education sessions by nurse educator and nutritionist using film and card games and individual instruction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Content -</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. one group session of education on footcare and skin hygiene, the other sessions on understanding diabetes, basic nutrition, weight loss, food purchasing, meal planning, insulin administration, emergencies, risk factors for macrovascular disease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. individual diet instruction</td>
</tr>
</tbody>
</table>
### Characteristics of included studies (Continued)

**Control group:** Usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Control group: Usual care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary outcomes: ulcer or amputations</td>
<td></td>
</tr>
<tr>
<td>Secondary outcomes: callus, nail dystrophy or fungal infection, behaviour assessment score</td>
<td></td>
</tr>
</tbody>
</table>

**Notes**

<table>
<thead>
<tr>
<th>Allocation concealment</th>
<th>B</th>
</tr>
</thead>
</table>

**Study** | **Corbett 2003**

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT</th>
</tr>
</thead>
</table>
| Participants | Study setting: home environment, patients with type 2 diabetes mellitus admitted to home care in the U.S.  
Inclusion criteria: physically and mentally able to participate, able to read and understand English, age 18 years or older, no lower-extremity ulcer, no history of lower-extremity amputation  |
| Interventions | Intervention group: Method - 10-20 minutes individualised patient education including verbal and written instructions according to participants’ risk factors and foot care knowledge, self-efficacy and reported self care behaviour by research nurse  
Content - Foot care education topics: individual risk factors, washing and drying feet, toenail care, footwear, moisturising feet, reportable foot problems. If desired: demonstration of nail trimming and problem-solving discussion to discover alternative care solutions  
Control group: no intervention  |
| Outcomes | Primary outcomes: not reported  
Secondary outcomes: foot care knowledge score, foot care practice score, self efficacy score  |

**Notes**

| Allocation concealment | A |

**Study** | **Hamlainen 1997**

<table>
<thead>
<tr>
<th>Methods</th>
<th>RCT</th>
</tr>
</thead>
</table>
| Participants | Study setting: Podiatrist in outpatient care in Finland  
Inclusion criteria: Using antidiabetic drugs (unclear which type of diabetes), no obvious need for podiatry, no visit with podiatrist in previous 6 months, age between 10-79 years  |
| Interventions | Intervention group:  
Method - 1. 45 minutes individual patient education  
2. podiatric care visits of 30-60 minutes duration as necessary; all performed by three independent podiatrists  
Content - 1. education on use of proper footwear, daily hygiene, cutting of toenails, use of emollient cream, avoidance of high risk situations and foot gymnastics,  
2. preventative podiatric care as debridement of callus, preparation of insoles, treatment of ingrowing toenails, guidance for foot gymnastics  
Control group:  
Method - written instructions for patients  
Content: footcare  |
| Outcomes | Primary outcomes: amputation rate, ulcer prevalence  
Secondary outcomes: callus development, foot care knowledge, behaviour assessment scores  |

**Notes**

| Allocation concealment | B |
### Characteristics of included studies (Continued)

<table>
<thead>
<tr>
<th>Study</th>
<th>Kruger 1992</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methods</strong></td>
<td>RCT</td>
</tr>
</tbody>
</table>
| **Participants** | Study setting: Secondary care, outpatient care in the US  
Inclusion criteria: Diabetes duration at least 5 years (unclear which type of diabetes), no frank pathology, entering weekly hospital diabetes program |
| **Interventions** | Intervention group:  
Method - one week patient education on diabetes care including 'hands-on' foot care approach:  
1. hands-on teaching and learning sessions  
2. patient education kit (buff pads and mirror)  
3. instructional videotape with explanation of instructor  
4. daily foot check sheets  
(Unclear who performed intervention)  
Content -  
1. actual foot washing, inspection, assessment, demonstration of care of corns and callus, toenail cutting, identification of potential foot problems, evaluation foot care  
2. foot care education  
3. encouragement to perform daily foot inspection  
Control group:  
Method - one week patient education on diabetes care including usual teaching on foot care:  
1. instructional videotape with explanation of instructor  
2. daily foot check sheets  
Content -  
1. foot care education  
2. encouragement to daily foot inspection |
| **Outcomes** | Primary outcomes: none reported  
Secondary outcomes: foot status, foot care knowledge, behaviour assessment scores |
| **Notes** | Allocation concealment: B |

<table>
<thead>
<tr>
<th>Study</th>
<th>Litzelman 1993</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methods</strong></td>
<td>RCT</td>
</tr>
</tbody>
</table>
| **Participants** | Study setting: Primary care, academic general medicine clinic in the US  
Inclusion criteria: Type 2 diabetes mellitus, seen least two times by same provider in previous year, intention to obtain care in the academic general medicine clinic in preceding two years, > 40 years, diagnosis of diabetes > 30 years, serum creatinin less than or equal to 440 µmol/l, body weight at least 'ideal', no previous bilateral amputation, able to provide any self care |
| **Interventions** | Intervention group:  
Method - patient part:  
1. One group (1-4 patients) education session by nurses, slides, audiotape, pamphlets and postcards  
2. behavioural contracts  
3. telephone reminder after 2 weeks  
4. postcard reminder after 1 and 3 months  
Method - Doctor part:  
1. colourful folder on patient chart  
2. Information flow sheet in patient chart  
Content - patient part:  
education on foot care behaviour and foot ware  
Content - Doctor part: |
Characteristics of included studies  *(Continued)*

1. folder prompting doctors to ask patient to remove foot wear, to perform foot examinations and to provide foot care education
2. flow sheet providing patient specific risk factors and foot-care practice guidelines for assessment, diagnostic work-up, treatment and referral recommendations

Control group: usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Primary outcomes: serious foot lesions, all foot lesions, amputation rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Secondary outcomes: behaviour assessment scores</td>
</tr>
</tbody>
</table>

Notes

Allocation concealment  B

<table>
<thead>
<tr>
<th>Study</th>
<th>Malone 1989</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>RCT</td>
</tr>
<tr>
<td>Participants</td>
<td>Study setting: Secondary care, outpatient podiatric or vascular surgery care in the US</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria: Diabetic patients (unclear which type) with foot infection, ulceration or prior amputation referred for podiatry or vascular surgery</td>
</tr>
<tr>
<td>Interventions</td>
<td>Intervention group:</td>
</tr>
<tr>
<td></td>
<td>Method -</td>
</tr>
<tr>
<td></td>
<td>1. one hour group patient education with slides given by podiatrist and set of patient instructions</td>
</tr>
<tr>
<td></td>
<td>Content -</td>
</tr>
<tr>
<td></td>
<td>1. slides of infected diabetic feet and amputated diabetic limbs, simple set of patient instructions for diabetic foot care</td>
</tr>
<tr>
<td></td>
<td>2. routine diabetic teaching on diet, weight, exercise and medication</td>
</tr>
<tr>
<td></td>
<td>Control group:</td>
</tr>
<tr>
<td></td>
<td>Method - routine patient education</td>
</tr>
<tr>
<td></td>
<td>Content - routine diabetic teaching on diet, weight, exercise and medication</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Primary outcomes: ulcer incidence, incidence of infections, amputation rate</td>
</tr>
<tr>
<td></td>
<td>Secondary outcomes: none</td>
</tr>
</tbody>
</table>

Notes

Allocation concealment  B

<table>
<thead>
<tr>
<th>Study</th>
<th>Mazzuca 1986</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods</td>
<td>RCT</td>
</tr>
<tr>
<td>Participants</td>
<td>Study setting: Primary care, academic general medicine clinic in the US</td>
</tr>
<tr>
<td></td>
<td>Inclusion criteria: Either two fasting blood glucose &gt; 130mg/dl or one &gt; 150 mg/dl or two hour value &gt; 250 mg/dl, able to perform two basic self care tasks, no psychiatric or terminal illness, under care of an internal medicine resident, informed consent</td>
</tr>
<tr>
<td>Interventions</td>
<td>Intervention group:</td>
</tr>
<tr>
<td></td>
<td>Method -</td>
</tr>
<tr>
<td></td>
<td>1. diagnosis of educational needs according to protocol</td>
</tr>
<tr>
<td></td>
<td>2. patient education in appropriate modules of instruction by nurses and dieticians by group education using lecture, discussion and/or audio-visual materials, demonstration, return demonstration and feedback, goal setting, and written contract on goals</td>
</tr>
<tr>
<td></td>
<td>3. Reinforcement by phone contact two and six weeks after instruction.</td>
</tr>
<tr>
<td></td>
<td>Content - depending on individual educational needs: understanding diabetes, acute complications, antidiabetic medication, antihypertensive medication, diet and activity, foot care and urine testing</td>
</tr>
</tbody>
</table>
### Characteristics of included studies (Continued)

<table>
<thead>
<tr>
<th>Control group: usual care</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcomes</strong></td>
</tr>
<tr>
<td>Primary outcomes: none reported</td>
</tr>
<tr>
<td>Secondary outcomes: level of foot care knowledge</td>
</tr>
<tr>
<td><strong>Notes</strong></td>
</tr>
<tr>
<td>Allocation concealment: B</td>
</tr>
</tbody>
</table>

### Study: Rettig 1986

<table>
<thead>
<tr>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
</tr>
<tr>
<td>Participants</td>
</tr>
<tr>
<td>Study setting: home environment</td>
</tr>
<tr>
<td>Inclusion criteria: identified as diabetic inpatient of participating hospitals (unclear which type of diabetes), age &lt; 65 years (at begin of study), no terminal illness, physician approval</td>
</tr>
<tr>
<td>Interventions</td>
</tr>
<tr>
<td>Intervention group:</td>
</tr>
<tr>
<td>Method - up to 12 home patient education sessions provided by nurses who attended special four day intensive course in diabetes self care</td>
</tr>
<tr>
<td>Content - according to judgement of nurse tailored to patient self management needs according to 100 short answer and yes/no questions</td>
</tr>
<tr>
<td>Control group: usual care</td>
</tr>
<tr>
<td><strong>Outcomes</strong></td>
</tr>
<tr>
<td>Primary outcomes: none</td>
</tr>
<tr>
<td>Secondary outcomes: foot appearance score, foot care knowledge, behaviour assessment score</td>
</tr>
<tr>
<td><strong>Notes</strong></td>
</tr>
<tr>
<td>Allocation concealment: B</td>
</tr>
</tbody>
</table>

### Characteristics of excluded studies

- **Dargis 1999**: No randomised controlled study design
- **Davidson 2000**: No randomised controlled study design and no educational program that includes patient-education aiming at the reduction of the diabetic foot
- **De Weerdt 1991**: No educational program that included patient education aiming on the reduction of the diabetic foot and no relevant outcomes reported
- **Donohoe 2000**: No educational program targetted at patients that includes patient-education aiming on the reduction of the diabetic foot
- **Glasgow 1992**: No relevant outcomes reported
- **Litzelman 1997**: No randomised controlled study design
- **McCabe 1998**: Education is not the main contrast with the control
- **McMurray 2002**: Education is not the main contrast with the control
- **Pieber 1995**: No randomised controlled study design
- **Plank 2003**: No educational program targetted at patients that includes patient-education aiming on the reduction of the diabetic foot and education not the main contrast with the control
- **Reichard 1993**: No educational program that includes patient education aiming on the reduction of the diabetic foot
- **Vinicor 1985**: No educational program that includes patient education aiming on the reduction of the diabetic foot and no relevant outcomes reported
- **Ward 1999**: No randomised controlled study design
- **Wooldridge 1996**: No randomised controlled study design
Characteristics of excluded studies *(Continued)*

### ADDITIONAL TABLES

#### Table 01. Criteria for the methodological assessment of randomized controlled trials

<table>
<thead>
<tr>
<th>criterion</th>
<th>description</th>
<th>score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PATIENT SELECTION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a.</td>
<td>Were the eligibility criteria specified?</td>
<td>Yes / No / Inadequate</td>
</tr>
<tr>
<td><strong>TREATMENT ALLOCATION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b1.</td>
<td>Was a method of randomization performed?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>b2.</td>
<td>Was the treatment allocation concealed?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>c.</td>
<td>Were the groups similar at baseline regarding the most important prognostic indicators?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td><strong>INTERVENTION</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td>Were the index and control interventions explicitly described?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>e.</td>
<td>Was the care provider blinded to the intervention?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>f.</td>
<td>Were co-interventions avoided or comparable?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>g.</td>
<td>Was the compliance acceptable in all groups?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>h.</td>
<td>Was the patient blinded to the intervention?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td><strong>OUTCOME MEASUREMENT</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i.</td>
<td>Was the outcome assessor blinded to the intervention?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>j.</td>
<td>Were outcome measures relevant?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>k.</td>
<td>Was there a description of adverse effects?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>l.</td>
<td>Was the withdrawal/drop-out rate described and acceptable?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>m.</td>
<td>Timing follow-up measurements</td>
<td></td>
</tr>
<tr>
<td>m1.</td>
<td>Was a short-term follow-up measurement performed?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>m2.</td>
<td>Was a long-term follow-up measurement performed?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>n.</td>
<td>Was the timing of the outcome assessment in both groups comparable?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td><strong>STATISTICS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>o.</td>
<td>Was the sample size for each group described?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>p.</td>
<td>Did the analysis include an intention-to-treat analysis?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>q.</td>
<td>Were point estimates and measures of variability presented for the primary outcome measures?</td>
<td>Yes / No / Don't know</td>
</tr>
<tr>
<td>Operationalization of the criteria list, each criterion must be applied independently of the other criteria.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a.</td>
<td>In order to score a ‘yes’ the risk for foot ulceration, previous or current foot ulceration needs to be described appropriately.</td>
<td></td>
</tr>
<tr>
<td>b.</td>
<td>In order to receive a yes for item b, both b1 and b2 must score ‘yes’.</td>
<td></td>
</tr>
<tr>
<td>b1.</td>
<td>A random (unpredictable) assignment sequence. Methods of allocation using date of birth, date of admission, hospital numbers, or alternation should not be regarded as appropriate.</td>
<td></td>
</tr>
</tbody>
</table>
Table 01. Criteria for the methodological assessment of randomized controlled trials  

<table>
<thead>
<tr>
<th>criterion</th>
<th>description</th>
<th>score</th>
</tr>
</thead>
<tbody>
<tr>
<td>b2.</td>
<td>Assignment generated by an independent person not responsible for determining eligibility of the patients. This person has no information about the persons included in the trial and has no influence on the assignment sequence or the decision about eligibility of the patient.</td>
<td></td>
</tr>
<tr>
<td>c.</td>
<td>In order to receive a ‘yes’ groups have to be similar regarding: age, risk for foot ulceration, baseline main outcome measures.</td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td>Adequate description of the content, method, number of sessions and duration of the education programme for both the index intervention and control intervention in order to replicate the study.</td>
<td></td>
</tr>
<tr>
<td>e.</td>
<td>The reviewer determines when enough information about the blinding is given in order to score a ‘yes’.</td>
<td></td>
</tr>
<tr>
<td>f.</td>
<td>Co-interventions other than education are either standardised or avoided in trial design. A report on co-interventions for each group separately.</td>
<td></td>
</tr>
<tr>
<td>g.</td>
<td>The reviewer determines when the adherence to the interventions is acceptable when based on the number of reported education sessions followed for both the index intervention and control intervention.</td>
<td></td>
</tr>
<tr>
<td>h.</td>
<td>The reviewer determines when enough information about the blinding is given in order to score a ‘yes’.</td>
<td></td>
</tr>
<tr>
<td>i.</td>
<td>The reviewer determines (per outcome parameter) when enough information about blinding is given to score a ‘yes’.</td>
<td></td>
</tr>
<tr>
<td>j.</td>
<td>The reviewer determines whether the outcome measures were relevant. The relevant outcome parameters are the primary outcome measures.</td>
<td></td>
</tr>
<tr>
<td>k.</td>
<td>Not applicable.</td>
<td></td>
</tr>
<tr>
<td>l.</td>
<td>Participants who were included in the study but did not complete the observation period or were not included in the analysis must be described. No drop-outs reported scores ‘don’t know’, a withdrawal/drop-out rate of 20% or less per year is considered ‘acceptable’.</td>
<td></td>
</tr>
<tr>
<td>m1.</td>
<td>Outcome assessment at the end of the intervention period.</td>
<td></td>
</tr>
<tr>
<td>m2.</td>
<td>Outcome assessment longer than 6 months after randomisation.</td>
<td></td>
</tr>
<tr>
<td>n.</td>
<td>Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.</td>
<td></td>
</tr>
<tr>
<td>o.</td>
<td>To be presented for each group at randomisation and for most important outcome assessments.</td>
<td></td>
</tr>
<tr>
<td>p.</td>
<td>All randomised patients are reported/analysed for the most important moments of effect measurements (minus missing values) irrespective of non-compliance and co-interventions.</td>
<td></td>
</tr>
<tr>
<td>q.</td>
<td>For each important outcome measure both point estimates and measures of variability should be presented separately. Point estimates are: means, medians, modes, etc.; measures of variability are: standard deviations, 95% confidence intervals, etc. For dichotomous or categorical data proportions have to be presented.</td>
<td></td>
</tr>
</tbody>
</table>
### Table 02. Methodological quality of included trials

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Barth</th>
<th>Bloomgren</th>
<th>Kruger</th>
<th>Ronemaa / Hamlainen</th>
<th>Litzelman</th>
<th>Malone</th>
<th>Mazzucca</th>
<th>Rettig</th>
<th>Corbett</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<td>+</td>
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<td>+</td>
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<td>+</td>
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<tr>
<td>K - see note 3</td>
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<td>NA</td>
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<tr>
<td>TOTAL QUALITY SCORE - see note 1</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
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<td>3</td>
<td>5</td>
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Note 1: sum of score of internal validity criteria (range 0-10)

Note 2: CRITERIA AS DEFINED BY VERHAGEN (1998)

Note 3: + = yes, - = no, ? = don’t, NA = not

---

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<table>
<thead>
<tr>
<th>Criteria</th>
<th>Barth</th>
<th>Bloomgarden</th>
<th>Kruger</th>
<th>Ronemaa / Hamlainen</th>
<th>Litzelman</th>
<th>Malone</th>
<th>Mazzucca</th>
<th>Rettig</th>
<th>Corbett</th>
</tr>
</thead>
<tbody>
<tr>
<td>know applicable to this intervention type</td>
<td></td>
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<td></td>
<td></td>
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<td></td>
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<tr>
<td>Study ID</td>
<td>Sample</td>
<td>Treatment adherence</td>
<td>Follow-up</td>
<td>Primary outcomes</td>
<td>Secondary outcomes</td>
<td>Notes</td>
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<tr>
<td>Barth 1991</td>
<td>70 patients with type 2 diabetes mellitus randomised</td>
<td>Not described for I and C</td>
<td>I and C: 6 months</td>
<td>No ulcer outcomes reported</td>
<td>Foot problems requiring treatment: - after 1 month: Significant increase (p&lt;0.006) - after 6 months: No change (p=0.216) Foot care knowledge: Increased in intervention group (p&lt;0.001) Foot care routine compliance: Increased in intervention group (p=0.012)</td>
<td>Outcome measures multiple choice questions on knowledge and compliance; number of questions and range of outcomes?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bloomgarden 1987</td>
<td>749 insulin treated patient with diabetes mellitus randomised; I: 165 vs C: 180 included; 266 patients completed follow-up; I: 127 vs C: 139</td>
<td>I: 57% of patients = 7 of 9 educational group sessions (graduates) C: not applicable</td>
<td>I: 1.6±0.3 years vs C: 1.5±0.3 years</td>
<td>Ulcer or amputation at final evaluation: patients with no foot lesions at initial evaluation ulcer or amputation at final evaluation:0 (I: 2/83 vs C: 2/63) patients with callus, nail dystrophy or fungal infection at initial evaluation:0 (I: 2/37 vs C: 3/63) patients with an ulcer or amputation at initial evaluation:0 (I: 6/7 vs C: 11/13)</td>
<td>Callus, nail dystrophy and fungal infection at final evaluation: Patients with no foot lesions at initial evaluation Ulcer or amputation at final evaluation - I: 31/83 (37%) vs C: 28/63 (44%) - no significant difference Patients with callus, nail dystrophy or fungal infection at initial evaluation - I: 24/37 (65%) vs C: 46/63 (25%) - no significant difference</td>
<td>Outcome measures behaviour score; 7 questions of which one on foot care</td>
<td></td>
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</table>
### Table 03. Results from trials  (Continued)

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Sample</th>
<th>Treatment adherence</th>
<th>Follow-up</th>
<th>Primary outcomes</th>
<th>Secondary outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corbett 2003</td>
<td>40 patients with type 2 diabetes mellitus randomised: I: 20 vs C: 20; 35 patients completed follow-up I: 19 vs C: 16; Baseline risk for foot ulceration: 70% had loss of protective sensation and 67% impaired lower extremity circulation, 50% had a foot deformity; no significant difference in foot risk assessment between groups; baseline outcome measures: ‘no group differences’</td>
<td>1 education session in intervention group for 19 of 20 patients</td>
<td>I and C: 6 weeks</td>
<td>No ulcer outcomes reported</td>
<td>Foot care knowledge: I: 4.9 -&gt; 6.1 vs C: 4.6 -&gt; 5.2 (p=0.03), foot care practices: I: 4.3 -&gt; 5.6 vs C: 4.1 - &gt; 4.3 (p=0.007), self confidence: I: 33.2 -&gt; 36.1 vs C: 33 -&gt; 33.6 (ns)</td>
<td>Outcome measures: foot care knowledge: 7 questions with 4 choices; foot care practices: 7 questions with 4 choices; patients' self confidence: 7 aspects of foot care rated from 1 to 6</td>
</tr>
<tr>
<td>Hämäläinen 1997</td>
<td>530 patients with diabetes mellitus, unclear which type, randomised</td>
<td>I: mean number of podiatry visits 4.7 in first year. After first and before seventh follow-</td>
<td>I and C: Both at 1 and 7 years</td>
<td>follow-up 7 years; amputation rate: 0 (I: 1.0 vs C: 0, p=0.499) ulcer prevalence: 0</td>
<td>Follow-up 1 year: % patients with calllosities calcaneal region: I: 18.5 -&gt; 12.0</td>
<td>Outcome measures: diameter callus in millimeters knowledge score: 19</td>
</tr>
</tbody>
</table>
### Table 03. Results from trials  (Continued)

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Sample</th>
<th>Treatment adherence</th>
<th>Follow-up</th>
<th>Primary outcomes</th>
<th>Secondary outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I: 267 vs C: 263</td>
<td>up year at least one podiatry visit in 82.3% of patients in I and in 49.7% in C</td>
<td>459 completed 1 year of follow-up: I: 233 vs C: 226</td>
<td>(I: 0.6% vs C: 0.6%, p=1.0)</td>
<td>vs C: 16.8-&gt; 15.5, no significant difference (p=0.14)</td>
<td>three-choice questions of which 1-2 correct answers: correct = 1, unknown = 0, incorrect = 1 (total score range from 0-57), behaviour score: range from 0-12</td>
</tr>
<tr>
<td></td>
<td>332 completed 7 years of follow-up: I: 169 vs C: 163</td>
<td></td>
<td>49.7% in C</td>
<td></td>
<td>% patients with callosities other regions: I: 54.5 -&gt; 39.5 vs C: 51.3 -&gt; 48.2 - significant decrease in callosities in intervention group (p&lt;0.009)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Baseline risk for foot ulceration: Comparability of I and C not described, callus development, foot care knowledge and behaviour assessment scores 'were comparable' between I and C.</td>
<td></td>
<td></td>
<td></td>
<td>Diameter of callosities at calcaneal region: I: 40.5 -&gt; 25.5 vs C: 30.6 -&gt; 28.3, Statistically significant decrease in area of callosities at calcaneal region in intervention group (p=0.065)</td>
<td></td>
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<td>Diameter of callosities other sites than calcaneum: I: 16.6 -&gt; 11.4 vs C: 15.2 -&gt; 14.4, Statistically significant decrease in area of callosities in intervention group (p&lt;0.001)</td>
<td></td>
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<td>Level of foot care knowledge: I: 26.7 -&gt; 32.1 vs C: 26.1 -&gt; 29.2, Statistically significant increase in intervention group (p=0.004)</td>
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<td></td>
<td>Behaviour assessment</td>
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<tr>
<td>Study ID</td>
<td>Sample</td>
<td>Treatment adherence</td>
<td>Follow-up</td>
<td>Primary outcomes</td>
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<td>Notes</td>
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<tr>
<td>Kruger 1992</td>
<td>50 patients with diabetes mellitus, unclear which type, randomised</td>
<td>Not described for I and C</td>
<td>I and C: 6 months</td>
<td>No ulcer outcomes reported</td>
<td>Foot status: No significant difference</td>
<td>Outcome measures: foot status: 67 assessment items, foot care knowledge: 12-item test</td>
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<tr>
<td></td>
<td>I: 23 vs C: 27</td>
<td></td>
<td></td>
<td></td>
<td>Foot care knowledge: I: 9.1-&gt;10.0 vs C: 8.66-&gt;9.86, Statistically significant increase in control group (p=0.02) Daily foot inspection: I: 52.5-&gt; 66.7 vs C: 34.8-&gt; 66.7, No significant difference Daily foot washing: I: 82.6-&gt; 86.7 vs C: 74.1-&gt; 73.3, Statistically significant increase in intervention group Use of pumice stones for corns: I: 4.3-&gt; 26.7 vs C: 3.7-&gt; 26.7, No significant difference</td>
<td></td>
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<tr>
<td></td>
<td>30 patients completed follow-up: I: 15 vs C: 15</td>
<td>Baseline risk for foot ulceration: Comparability of I and C not described</td>
<td></td>
<td></td>
<td>No significant difference Callosities calcaneal region: No significant difference Callosities other regions: No significant difference</td>
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</table>

Table 03. Results from trials (Continued)
<table>
<thead>
<tr>
<th>Study ID</th>
<th>Sample Description</th>
<th>Treatment adherence</th>
<th>Follow-up</th>
<th>Primary outcomes</th>
<th>Secondary outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Litzelman 1993</td>
<td>484 patients with type 2 diabetes mellitus randomised</td>
<td>Not described for I and C</td>
<td>I and C: 11.8 ± 1.5 months</td>
<td>Serious foot lesions: OR:0.41 (95%CI:0.16-1.00), Statistical difference</td>
<td>Dry cracked skin: OR:0.62 (95%CI:0.39-0.98), Decreased risk in intervention group</td>
<td>Outcome measures: only odds ratios and baseline prevalences in total group (I and C) described.</td>
</tr>
<tr>
<td></td>
<td>393 patients baseline assessment: I: 191 vs C: 205</td>
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<td></td>
<td>All foot lesions: OR:0.65 (95%CI:0.36-1.17), No significant difference</td>
<td>All foot lesions: OR:0.65 (95%CI:0.36-1.17), No significant difference</td>
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<tr>
<td></td>
<td>352 completed follow-up</td>
<td></td>
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<td>Amputation rate: I:1 vs C:4, No significant difference</td>
<td>Amputation rate: I:1 vs C:4, No significant difference</td>
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<td></td>
<td>baseline risk for foot ulceration: comparability of I and C not described</td>
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<td></td>
<td>Fungal nail infection: OR:0.70 (95%CI:0.46-1.07), No significant difference</td>
<td>Fungal nail infection: OR:0.70 (95%CI:0.46-1.07), No significant difference</td>
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<td></td>
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<td></td>
<td>Fungal skin infection: OR:0.58 (95%CI:0.30-1.12), No significant difference</td>
<td>Fungal skin infection: OR:0.58 (95%CI:0.30-1.12), No significant difference</td>
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<td></td>
<td>Interdigit macerations: OR:0.63 (95%CI:0.34-1.15),</td>
<td>Interdigit macerations: OR:0.63 (95%CI:0.34-1.15),</td>
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</table>

Trimming toenails regularly: + (I: 34.8-> 80.0 vs C: 66.7-> 66.7, Statistically significant increase in intervention group
Improvement in keeping toenails shorter: I: 30.4-> 80.0 vs C: 66.7-> 86.7, No significant difference
<table>
<thead>
<tr>
<th>Study ID</th>
<th>Sample</th>
<th>Treatment adherence</th>
<th>Follow-up</th>
<th>Primary outcomes</th>
<th>Secondary outcomes</th>
<th>Notes</th>
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</thead>
<tbody>
<tr>
<td>Malone 1989</td>
<td>227 patients with diabetes mellitus, unclear which type, and foot infection ulceration or prior amputation randomised</td>
<td>Not described for I and C</td>
<td>I: mean 12, median 13.2 months (range 1-26) C: mean 8, median 9.2 months (range 1-26)</td>
<td>Ulcer incidence: I: 8 vs C: 26, rate lower in intervention group (p&lt;0.005) Incidence of infections: I: 2 vs C: 2, No significant difference Amputation rate: I: 7 vs C: 21, Significant increase in intervention group (p&lt;0.025)</td>
<td>No significant difference Behaviour assessment score: I:1.90±0.42 vs C:2.12±0.49, (p=0.0001) Statistically significant increase in intervention group</td>
<td>Outcome measures: Outcomes are presented per limb randomised</td>
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<td>Mazzuca 1986</td>
<td>532 patients with 139 of 208 (67%)</td>
<td>Median interval</td>
<td>No ulcer outcomes</td>
<td>Level of foot care</td>
<td>Outcome measure:</td>
<td></td>
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<tr>
<td>Study ID</td>
<td>Sample</td>
<td>Treatment adherence</td>
<td>Follow-up</td>
<td>Primary outcomes</td>
<td>Secondary outcomes</td>
<td>Notes</td>
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<tr>
<td></td>
<td>diabetes mellitus, unclear which type, randomised</td>
<td>patients needing instruction on foot care completed this</td>
<td>between instruction and follow-up measurement 11.8-14.3 months</td>
<td>reported</td>
<td>knowledge: No significant difference</td>
<td>knowledge objectives unclear</td>
</tr>
<tr>
<td>Rettig 1986</td>
<td>471 patients with diabetes mellitus, unclear which type, randomised</td>
<td>Not described for I and C</td>
<td>I and C: 6 months</td>
<td>No ulcer outcomes reported</td>
<td>Foot appearance at follow-up: I: 70.2±0.7 vs C: 68.8±0.7, No significant difference</td>
<td>Outcome measures: foot appearance assessed by a nurse who used 16-item checklist knowledge measured using 70 multiple-choice questions covering 4 areas of which foot care was skills assessed by nurse examination of patients' feet</td>
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<tr>
<td></td>
<td>I: 263 vs C: 269 275 patients completed follow-up: I: 135 vs C: 140 Baseline risk for foot ulceration: comparability of I and C not described</td>
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<tr>
<td></td>
<td>I: 228 vs C: 243 373 completed follow-up: I: 180 vs C: 193 Baseline risk for foot ulceration: comparability of I and C not described</td>
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</table>
Table 04. Search strategies used for the original review

Search strategies

Eligible studies were identified by searching the Cochrane Wounds Group Specialised Trials Register (March 2001) using the following strategy:
Condition = diabetic ulcers
Site = foot
Outcome = prevention
Intervention = education or clinics.
Free text searching was used for the following text words:
ulcer,
foot ulcer,
leg ulcer,
skin ulcer,
plantar ulcer,
artrial ulcer,
pressure ulcer,
amputation,
diabetic foot,
diabetes mellitus,
diabetes,
NIDDM,
IDDM.
The Cochrane Central Register of Controlled Trials (CENTRAL) was also searched on Cochrane Library CD ROM 2001 Issue 2, using the following strategy:
1. (DECUBITUS and ULCER)
2. (FOOT and ULCER)
3. (#1 or #2)
4. (LEG and ULCER)
5. (VARICOSE and ULCER)
6. (#4 or #5)
7. (PIOLONIDAL and CYST)
8. (SKIN and ULCER)
9. (DIABETIC and FOOT)
10. (PRESSURE or (BED and SORE*))
11. (((((PLANTAR or DIABETIC) or HEEL) or VENOUS) or STASIS) OR (ARTERIAL and ULCER*))
12. ((((DECUBITUS or FOOT) or DIABETIC) or ISCHAEMIC) OR (PRESSURE and ULCER*))
13. (((PIOLONIDAL and CYST) or (PIOLONIDAL and SINUS)) OR BEDSORE*)
14. (DIABETIC and FOOT) or (CAVITY and WOUND))
15. (VARICOSE or LEG) OR (SKIN and ULCER*)
16. (DECUBITUS or (CHRONIC and WOUND*))
17. (SINUS and WOUND) OR (CAVITY and WOUND))
18. ((((((((#3 or #6) or #7) or #8) or #9) or #10) or #11) or #12) or #13) or #14) or #15) or #16) or #17)
19. EDUCATION
20. PREVENTION
21. TREATMENT
22. THERAPY
23. ((#19 or #20) or #21) or #22)
24. (#18 and #23)
CINAHL was searched to December 2000 using the following search strategy:
1. (foot-ulcer* or leg-ulcer* or skin-ulcer*) in de
Table 04. Search strategies used for the original review  

(Continued)

Search strategies

2. (diabetic-foot* or diabetic-neuropathies*) in de
3. (diabetic-angiopathies*) in de
4. (plantar or diabetic or heel (arterial near ulcer*)) in ti,ab
5. (foot or diabetic or ischaemic near ulcer*) in ti,ab
6. diabetic near foot in ti,ab
7. #1 or #2 or #3 or #4 or #5 or #6
8. patient-education* in de
9. (education or clinic* or therap*) in de
10. #8 and #9
11. prevent* in de
12. #10 and #11 and #7
13. (clinical-trials or single-blind-studies or double-blind-studies) in de
14. (control-group or placebos or meta-analysis) in de
15. (random* near clinical near trial*) or ((prospective near random*) in ti,ab)
16. (random near allocation) or random* or controlled-clinical-trial*) in ti,ab
17. #13 or #14 or #15 or #16
18. #17 and #12

The bibliographies of all retrieved and relevant publications identified by these strategies were searched for further studies.

GRAPHS

Comparison 01. 01 More intensive educational intervention vs. brief educational intervention

<table>
<thead>
<tr>
<th>Outcome title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 01 Amputation rate</td>
<td>1</td>
<td>332</td>
<td>Peto Odds Ratio 95% CI</td>
<td>7.13 [0.14, 359.65]</td>
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</table>

Comparison 02. 02 More intensive education vs. brief education in patients at high risk for foot ulceration

<table>
<thead>
<tr>
<th>Outcome title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 01 Incidence of ulceration</td>
<td>1</td>
<td>182</td>
<td>Peto Odds Ratio 95% CI</td>
<td>0.28 [0.13, 0.59]</td>
</tr>
<tr>
<td>02 02 Incidence of infection</td>
<td>1</td>
<td>182</td>
<td>Peto Odds Ratio 95% CI</td>
<td>1.02 [0.14, 7.38]</td>
</tr>
<tr>
<td>03 03 Amputation rate</td>
<td>1</td>
<td>182</td>
<td>Peto Odds Ratio 95% CI</td>
<td>0.32 [0.14, 0.71]</td>
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</tbody>
</table>

Comparison 03. 03 Education on the diabetic foot as a part of general diabetes education vs. usual care

<table>
<thead>
<tr>
<th>Outcome title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 01 Ulcer or amputation</td>
<td>1</td>
<td>146</td>
<td>Peto Odds Ratio 95% CI</td>
<td>0.75 [0.10, 5.55]</td>
</tr>
<tr>
<td>02 02 Callus, nail dystrophy and fungal infections</td>
<td>1</td>
<td>146</td>
<td>Peto Odds Ratio 95% CI</td>
<td>0.75 [0.38, 1.45]</td>
</tr>
</tbody>
</table>
Comparison 04. Complex educational intervention, including footcare, targeted at both patients and doctors vs. usual care

<table>
<thead>
<tr>
<th>Outcome title</th>
<th>No. of studies</th>
<th>No. of participants</th>
<th>Statistical method</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 01 Number of amputations</td>
<td>1</td>
<td>396</td>
<td>Peto Odds Ratio 95% CI</td>
<td>0.32 [0.05, 1.86]</td>
</tr>
<tr>
<td>02 02 Behaviour assessment score</td>
<td>1</td>
<td>396</td>
<td>Weighted Mean Difference (Fixed) 95% CI</td>
<td>-0.22 [-0.31, -0.13]</td>
</tr>
</tbody>
</table>

**INDEX TERMS**

Medical Subject Headings (MeSH)
- Diabetic Foot [prevention & control]; Patient Education; Randomized Controlled Trials

Medical MeSH check words
- Humans

**COVER SHEET**

Title: Patient education for preventing diabetic foot ulceration

Authors: Valk GD, Kriegsman DMW, Assendelft WJJ

Contribution of author(s): GD Valk conceived the review; GD Valk and WJJ Assendelft designed the review and wrote the protocol; GD Valk co-ordinated the review and GD Valk and DMW Kriegsman extracted, analysed and interpreted data. GD Valk, DMW Kriegsman and WJJ Assendelft wrote the review. GD Valk is guarantor for the review.

Issue protocol first published: 1999/1

Review first published: 2001/4

Date of most recent amendment: 18 November 2004

Date of most recent SUBSTANTIVE amendment: 20 August 2001

What's New: This review was originally published in the Cochrane Library, Issue 4, 2001. For this first update, new searches were carried out in September 2004. Six new studies were identified. Of these, one study (Corbett 2003) was included in the review and five studies (Dargis 1999, Davidson, 2000, Donohoe, 2000, McMurray, 2002, Plank 2003) were excluded. The reviewers' conclusions remain unchanged.

Date new studies sought but none found: Information not supplied by author

Date new studies found but not yet included/excluded: Information not supplied by author

Date new studies found and included/excluded: 10 September 2004

Date authors' conclusions section amended: Information not supplied by author

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- Senior Researcher
- Department of Internal Medicine

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Fig. 1. **Comparison 01.01 More intensive educational intervention vs. brief educational intervention**

01.01.01 Amputation rate

**Review:** Patient education for preventing diabetic foot ulceration

**Comparison:** 01.01 More intensive educational intervention vs. brief educational intervention

**Outcome:** 01.01 Amputation rate

<table>
<thead>
<tr>
<th>Study</th>
<th>Intensive education</th>
<th>Brief intervention</th>
<th>Peto Odds Ratio</th>
<th>Weight (%)</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamlainen 1997</td>
<td>1/169</td>
<td>0/163</td>
<td>1</td>
<td>100.0</td>
<td>7.13 [0.14, 359.63]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>169</td>
<td>163</td>
<td>1</td>
<td>100.0</td>
<td>7.13 [0.14, 359.63]</td>
</tr>
</tbody>
</table>

Total events: 1 (Intensive education), 0 (Brief intervention)

Test for heterogeneity: not applicable

Test for overall effect z=0.98  p=0.3

- Favours intensive
- Favours brief
Fig. 2. Comparison of More intensive education vs. brief education in patients at high risk for foot ulceration

02.01 Incidence of ulceration

Comparison: 02.02 More intensive education vs. brief education in patients at high risk for foot ulceration
Outcome: 01.01 Incidence of ulceration

<table>
<thead>
<tr>
<th>Study</th>
<th>Intensive education</th>
<th>Brief intervention</th>
<th>Peto Odds Ratio</th>
<th>Weight (%)</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>95% CI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malone 1989</td>
<td>8/90</td>
<td>26/92</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>90</td>
<td>92</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 8 (Intensive education), 26 (Brief intervention)
Test for heterogeneity: not applicable
Test for overall effect z=3.34  p=0.0008

Fig. 3. Comparison of More intensive education vs. brief education in patients at high risk for foot ulceration

02.02 Incidence of infection

Comparison: 02.02 More intensive education vs. brief education in patients at high risk for foot ulceration
Outcome: 02.02 Incidence of infection

<table>
<thead>
<tr>
<th>Study</th>
<th>Intensive education</th>
<th>Brief intervention</th>
<th>Peto Odds Ratio</th>
<th>Weight (%)</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n/N</td>
<td>n/N</td>
<td>95% CI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malone 1989</td>
<td>2/90</td>
<td>2/92</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>90</td>
<td>92</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total events: 2 (Intensive education), 2 (Brief intervention)
Test for heterogeneity: not applicable
Test for overall effect z=0.02  p=1

Patient education for preventing diabetic foot ulceration (Review)

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**Fig. 4.** Comparison 02. More intensive education vs. brief education in patients at high risk for foot ulceration

**02.03 Amputation rate**

Review: Patient education for preventing diabetic foot ulceration

Comparison: 02. More intensive education vs. brief education in patients at high risk for foot ulceration

Outcome: 03. Amputation rate

<table>
<thead>
<tr>
<th>Study</th>
<th>Intensive education n/N</th>
<th>Brief intervention n/N</th>
<th>Peto Odds Ratio 95% CI</th>
<th>Weight (%)</th>
<th>Peto Odds Ratio 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malone, 1989</td>
<td>7/90</td>
<td>21/92</td>
<td></td>
<td>100.0</td>
<td>0.32 [0.14, 0.71]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>90</td>
<td>92</td>
<td></td>
<td>100.0</td>
<td>0.32 [0.14, 0.71]</td>
</tr>
</tbody>
</table>

Total events: 7 (Intensive education), 21 (Brief intervention)

Test for heterogeneity: not applicable

Test for overall effect z = 2.81, p = 0.005

Favours intensive

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**Fig. 5.** Comparison 03. Education on the diabetic foot as a part of general diabetes education vs. usual care

**03.01 Ulcer or amputation**

Review: Patient education for preventing diabetic foot ulceration

Comparison: 03. Education on the diabetic foot as a part of general diabetes education vs. usual care

Outcome: 01. Ulcer or amputation

<table>
<thead>
<tr>
<th>Study</th>
<th>Education n/N</th>
<th>Usual care n/N</th>
<th>Peto Odds Ratio 95% CI</th>
<th>Weight (%)</th>
<th>Peto Odds Ratio 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloomgarden, 1987</td>
<td>2/83</td>
<td>2/63</td>
<td></td>
<td>100.0</td>
<td>0.75 [0.10, 5.55]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>83</td>
<td>63</td>
<td></td>
<td>100.0</td>
<td>0.75 [0.10, 5.55]</td>
</tr>
</tbody>
</table>

Total events: 2 (Education), 2 (Usual care)

Test for heterogeneity: not applicable

Test for overall effect z = 0.28, p = 0.8

Favours education
Fig. 6. Comparison 03.03 Education on the diabetic foot as a part of general diabetes education vs. usual care

03.02 Callus, nail dystrophy and fungal infections

Review: Patient education for preventing diabetic foot ulceration
Comparison: 03.03 Education on the diabetic foot as a part of general diabetes education vs. usual care
Outcome: 02.02 Callus, nail dystrophy and fungal infections

<table>
<thead>
<tr>
<th>Study</th>
<th>Education</th>
<th>Usual care</th>
<th>Peto Odds Ratio</th>
<th>Weight</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bloomgarden 1987</td>
<td>31/83</td>
<td>28/63</td>
<td>100.0</td>
<td>0.75</td>
<td>[0.38, 1.45]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td></td>
<td></td>
<td>100.0</td>
<td>0.75</td>
<td>[0.38, 1.45]</td>
</tr>
<tr>
<td>Total events: 31 (Education), 28 (Usual care)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for heterogeneity: not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect z=0.86 p=0.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Fig. 7. Comparison 04.04 Complex educational intervention, including footcare, targeted at both patients and doctors vs. usual care

04.01 Number of amputations

Review: Patient education for preventing diabetic foot ulceration
Comparison: 04.04 Complex educational intervention, including footcare, targeted at both patients and doctors vs. usual care
Outcome: 01 Number of amputations

<table>
<thead>
<tr>
<th>Study</th>
<th>Complex intervention</th>
<th>Usual care</th>
<th>Peto Odds Ratio</th>
<th>Weight</th>
<th>Peto Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Litzelman 1993</td>
<td>1/191</td>
<td>4/205</td>
<td>100.0</td>
<td>0.32</td>
<td>[0.05, 1.86]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td></td>
<td>191</td>
<td>205</td>
<td>100.0</td>
<td>0.32 [0.05, 1.86]</td>
</tr>
<tr>
<td>Total events: 1 (Complex intervention), 4 (Usual care)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for heterogeneity: not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect z=1.27 p=0.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Fig. 8. **Comparison 04. 04 Complex educational intervention, including footcare, targeted at both patients and doctors vs. usual care**

**04.02 02 Behaviour assessment score**

Review: Patient education for preventing diabetic foot ulceration

Comparison: 04 04 Complex educational intervention, including footcare, targeted at both patients and doctors vs. usual care

Outcome: 02 02 Behaviour assessment score

<table>
<thead>
<tr>
<th>Study</th>
<th>Complex intervention</th>
<th>Usual care</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>Weight (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Litzelman 1993</td>
<td>191</td>
<td>205</td>
<td>2.12 (0.49)</td>
<td>100.0</td>
<td>-0.22 [-0.31, -0.13]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>191</td>
<td>205</td>
<td></td>
<td>100.0</td>
<td>-0.22 [-0.31, -0.13]</td>
</tr>
</tbody>
</table>

Test for heterogeneity: not applicable

Test for overall effect z=4.81 p<0.00001

-0.5 -0.25 0 0.25 0.5
Complex is better  Usual care is better