

The Cochrane Database of Systematic Reviews

The Cochrane Library, Copyright 2006, The Cochrane Collaboration Volume (3), 2006, [no page #]

Patient education for preventing diabetic foot ulceration [Reviews]

Valk, GD; Kriegsman, DMW; Assendelft, WJJ

Date of Most Recent Update: 18-November-2004

Date of Most Recent Substantive Update: 20-August-2001

Cochrane Wounds Group
Gerlof Valk, Senior Researcher; University Medical Center Utrecht,
Department of Internal Medicine, P.O. Box 85500, 3508 GA Utrecht,
NETHERLANDS. Phone: +31 20 444 8199, Fax: +31 20 444 8361, E-mail:
G.Valk@xs4all.nl.

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.

Because of conflicting results and the methodological shortcomings more RCTs are needed.

Issue protocol first published

1999 Issue 1

Date of last minor update

01 October, 2004

Date new studies found and included or excluded

10 September, 2004

Issue first published

2001, Issue 4

Plain language summary

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 will 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.

Background

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 [pounds]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 on reports of the currently available randomised controlled trials (RCTs).

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 methods for identification of studies

See: methods used in reviews.

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
- 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. There was no restriction on language of the publications.

Details of search strategies used for the original review are detailed in Additional Table 04.

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), e, 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 (Hamlainen 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 (Hamlainen 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; Hamlainen 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 3: Results from trials.

1. Intensive versus brief educational interventions

We identified four RCTs comparing intensive with brief educational interventions (Barth 1991; Hamalainen 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 (Hamalainen 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 (Hamalainen 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; Hamalainen 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 (Hamalainen 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 ($p < 0.02$). However, 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; Hamalainen 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 (Hamalainen 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 digits) was statistically significantly improved at one year ($p = 0.009$), whereas calcaneal callus was not ($p = 0.14$) (Hamalainen 1997).

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

One RCT with 749 people evaluated the effect of foot care education as part of general diabetes education in primary care (Bloomgarden 1987).

Primary outcomes (See Graph Comparison 3, Outcome1)

No significant effect was found on ulcer or amputation occurrence 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 assessment 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 intervention and control groups after 1.5 years (Peto OR: 0.75 (95% CI 0.38 - 1.45)).

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

One RCT evaluated the effect of a complex intervention that included 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-ulcerated 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. Therefore, the results of this review are presented in a study-by-study narrative form.

This is the first review in which a validated extensive methodological 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 possible 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 podiatry 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 (Hamlainen 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 Sonnaville 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; Rettig 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.

Potential conflict of interest

None known.

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

Characteristics of included studies

Study Barth 1991

Methods RCT

Participants Study setting: Secondary care, outpatient care in Australia

Inclusion criteria: patients with type 2 diabetes mellitus > 3 months and current treatment > 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

Interventions Intervention group:

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

Content -

1. recommendations and footcare education
2. demonstration and practising foot care procedures

Control group:

Method - fourteen hours group patient education including one hour lecture and discussion by podiatrist

Content - standard diabetes education, on hour on footcare and footwear

Outcomes Primary outcomes: not reported

Secondary outcomes: foot care knowledge, behaviour assessment score, foot problems requiring treatment

Notes

Allocation concealment B - Unclear

Study Bloomgarden 1987

Methods RCT

Participants Study setting: Primary care, diabetes clinic in the US

Inclusion criteria: Insulin treated diabetes mellitus (unclear which type of diabetes)

Interventions Intervention group:

Method - nine group patient education sessions by nurse educator and nutritionist using film

and card games and individual instruction

Content -

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

2. individual diet instruction

Control group: Usual care

Outcomes Primary outcomes: ulcer or amputations

Secondary outcomes: callus, nail dystrophy or fungal infection, behaviour assessment score

Notes

Allocation concealment B - Unclear

Study Corbett 2003

Methods RCT

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 - Adequate

Study Hamalainen 1997

Methods RCT

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 - Unclear

Study Kruger 1992

Methods RCT

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 - Unclear

Study Litzelman 1993

Methods RCT

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 [μ]mol/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:

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

Outcomes Primary outcomes: serious foot lesions, all foot lesions, amputation rate

Secondary outcomes: behaviour assessment scores

Notes

Allocation concealment B - Unclear

Study Malone 1989

Methods RCT

Participants Study setting: Secondary care, outpatient podiatric or vascular surgery care in the US

Inclusion criteria: Diabetic patients (unclear which type) with foot infection, ulceration or prior amputation referred for podiatry or vascular surgery

Interventions Intervention group:

Method -

1. one hour group patient education with slides given by podiatrist and set of patient instructions

2. routine patient education

Content -

1. slides of infected diabetic feet and amputated diabetic limbs, simple set of patient instructions for diabetic foot care

2. routine diabetic teaching on diet, weight, exercise and medication

Control group:

Method - routine patient education

Content - routine diabetic teaching on diet, weight, exercise and medication

Outcomes Primary outcomes: ulcer incidence, incidence of infections, amputation rate

Secondary outcomes: none

Notes

Allocation concealment B - Unclear

Study Mazzuca 1986

Methods RCT

Participants Study setting: Primary care, academic general medicine clinic in the US

Inclusion criteria: Either two fasting blood glucose > 130mg/dl or one > 150 mg/dl or two hour value > 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

Interventions Intervention group:

Method -

1. diagnosis of educational needs according to protocol

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

3. Reinforcement by phone contact two and six weeks after instruction.

Content - depending on individual educational needs: understanding diabetes, acute complications, antidiabetic medication, antihypertensive medication, diet and activity, foot care and urine testing

Control group: usual care

Outcomes Primary outcomes: none reported

Secondary outcomes: level of foot care knowledge

Notes

Allocation concealment B - Unclear

Study Rettig 1986

Methods RCT

Participants Study setting: home environment

Inclusion criteria: identified as diabetic inpatient of participating hospitals (unclear which type of diabetes), age < 65 years (at begin of study), no terminal illness, physician approval

Interventions Intervention group:

Method - up to 12 home patient education sessions provided by nurses who attended special four day intensive course in diabetes self care

Content - according to judgement of nurse tailored to patient self management needs according to 100 short answer and yes/no questions

Control group: usual care

Outcomes Primary outcomes: none

Secondary outcomes: foot appearance score, foot care knowledge, behaviour assessment score

Notes

Allocation concealment B - Unclear

Characteristics of excluded studies

Study Reason for exclusion

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 Weerd 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

Vinikor 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

Additional tables

Table 01

Table 02

Table 03

Table 04

Analyses

Comparison 01

Comparison 02

Comparison 03

Comparison 04

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

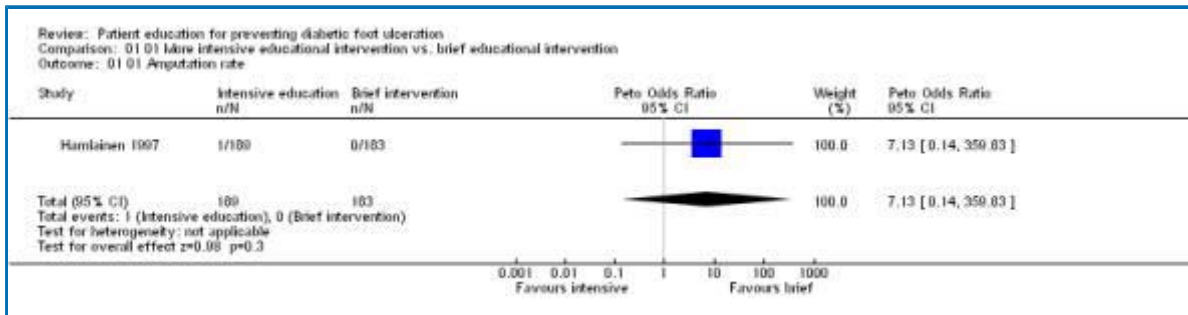
* Dutch Cochrane Centre NETHERLANDS

Notes

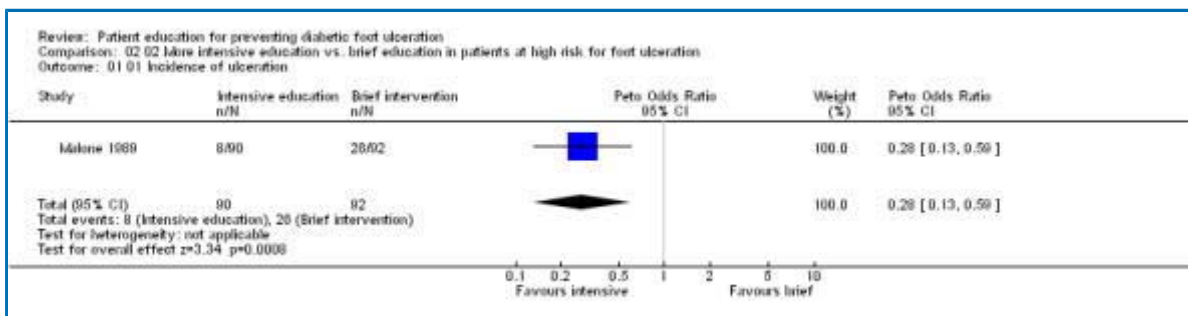
History of this review:

This review was first published in the Cochrane Library, Issue 4, 2001, with 8 included studies.

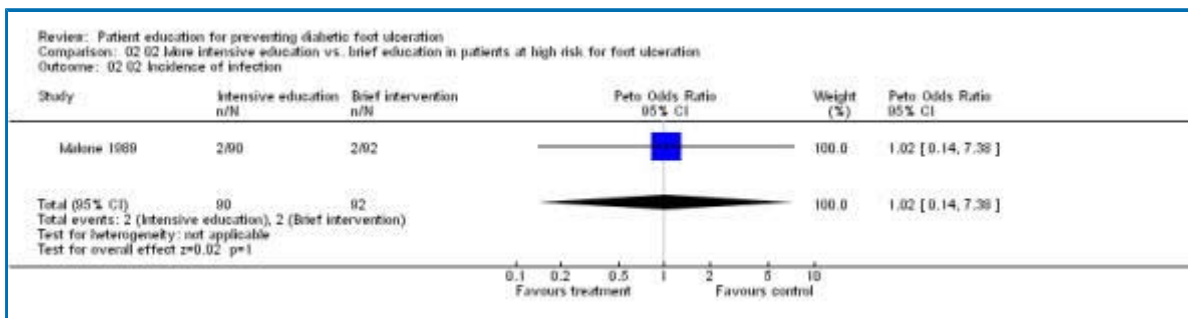
The synopsis was prepared by the Cochrane Consumer Network



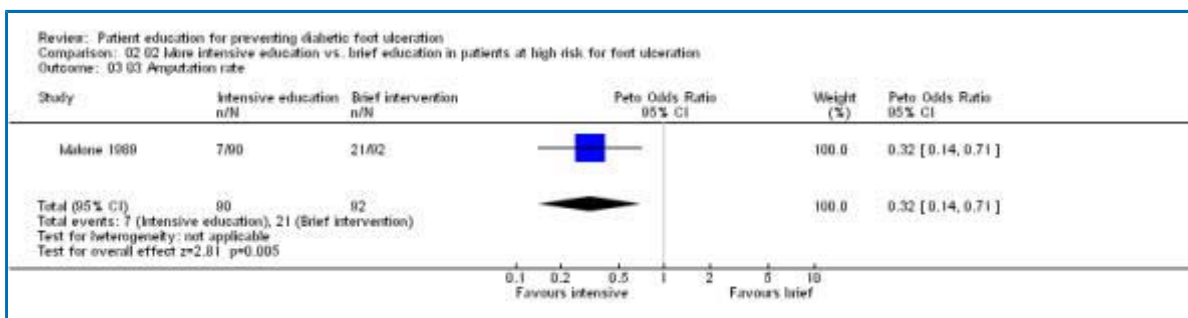
Comparison 01 01 More intensive educational intervention vs. brief educational intervention, Outcome 01 01 Amputation rate



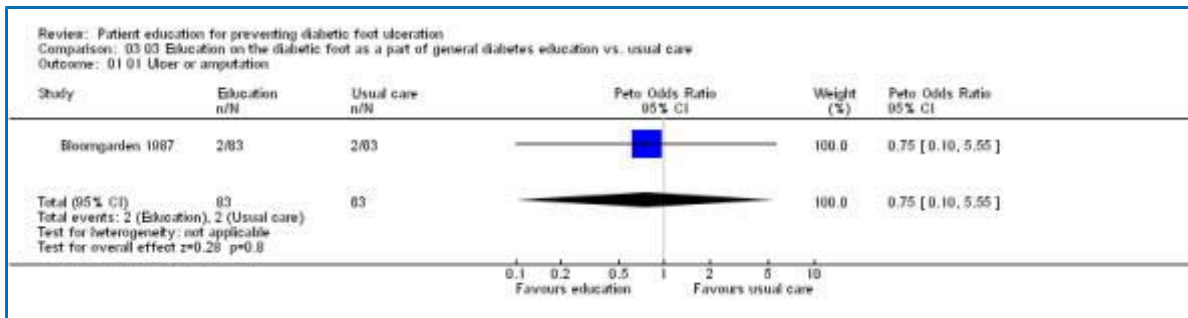
Comparison 02 02 More intensive education vs. brief education in patients at high risk for foot ulceration, Outcome 01 01 Incidence of ulceration



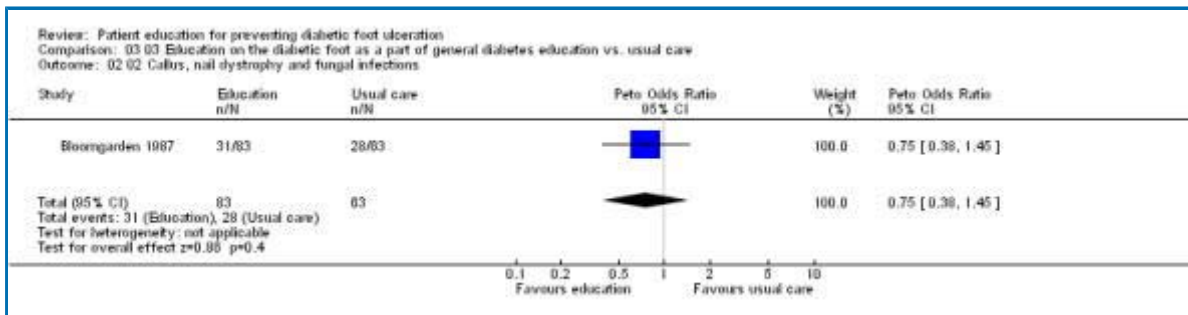
Comparison 02 02 More intensive education vs. brief education in patients at high risk for foot ulceration, Outcome 02 02 Incidence of infection



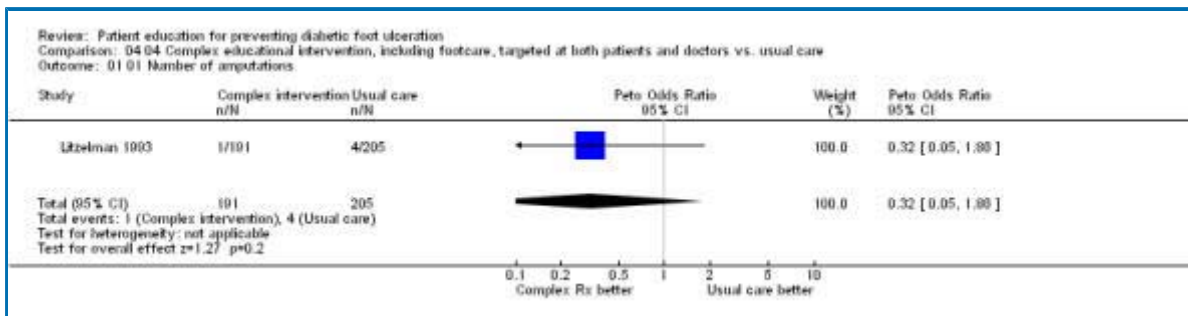
Comparison 02 02 More intensive education vs. brief education in patients at high risk for foot ulceration, Outcome 03 03 Amputation rate



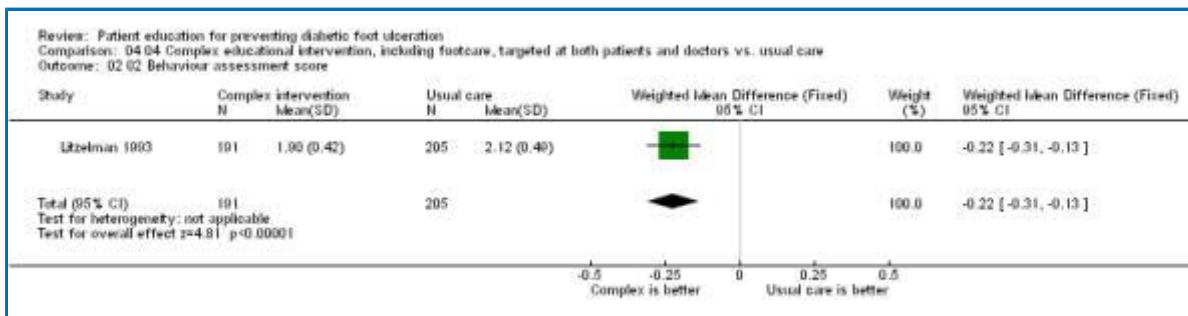
Comparison 03 03 Education on the diabetic foot as a part of general diabetes education vs. usual care, Outcome 01 01 Ulcer or amputation



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



Comparison 04 04 Complex educational intervention, including footcare, targeted at both patients and doctors vs. usual care, Outcome 01 01 Number of amputations



Comparison 04 04 Complex educational intervention, including footcare, targeted at both patients and doctors vs. usual care, Outcome 02 02 Behaviour assessment score

Criteria for the methodological assessment of randomized controlled trials

criterion: PATIENT SELECTION

description:

score:

criterion: a.

description: Were the eligibility criteria specified?

score: Yes / No / Inadequate

criterion: TREATMENT ALLOCATION

description:

score:

criterion: b1.

description: Was a method of randomization performed?

score: Yes / No / Don't know

criterion: b2.

description: Was the treatment allocation concealed?

score: Yes / No / Don't know

criterion: c.

description: Were the groups similar at baseline regarding the most important prognostic indicators?

score: Yes / No / Don't know

criterion: INTERVENTION

description:

score:

criterion: d.

description: Were the index and control interventions explicitly described?

score: Yes / No / Don't know

criterion: e.

description: Was the care provider blinded to the intervention?

score: Yes / No / Don't know

criterion: f.

description: Were co-interventions avoided or comparable?

score: Yes / No / Don't know

criterion: g.

description: Was the compliance acceptable in all groups?

score: Yes / No / Don't know

criterion: h.

description: Was the patient blinded to the intervention?

score: Yes / No / Don't know

criterion: OUTCOME MEASUREMENT

description:

score:

criterion: i.

description: Was the outcome assessor blinded to the intervention?

score: Yes / No / Don't know

criterion: j.

description: Were outcome measures relevant?

score: Yes / No / Don't know

criterion: k.

description: Was there a description of adverse effects?

score: Yes / No

criterion: l.

description: Was the withdrawal/drop-out rate described and acceptable?

score: Yes / No / Don't know

criterion: m.

description: Timing follow-up measurements

score:

criterion: m1.

description: Was a short-term follow-up measurement performed?

score: Yes / No / Don't know

criterion: m2.

description: Was a long-term follow-up measurement performed?

score: Yes / No / Don't know

criterion: n.

description: Was the timing of the outcome assessment in both groups comparable?

score: Yes / No / Don't know

criterion: STATISTICS

description:

score:

criterion: o.

description: Was the sample size for each group described?

score: Yes / No / Don't know

criterion: p.

description: Did the analysis include an intention-to-treat analysis?

score: Yes / No / Don't know

criterion: q.

description: Were point estimates and measures of variability presented for the primary outcome measures?

score: Yes / No / Don't know

criterion:

description: Operationalization of the criteria list, each criterion must be applied independently of the other criteria.

score:

criterion: a.

description: In order to score a 'yes' the risk for foot ulceration, previous or current foot

ulceration needs to be described appropriately.

score:

criterion: b.

description: In order to receive a yes for item b, both b1 and b2 must score 'yes'.

score:

criterion: b1.

description: 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.

score:

criterion: b2.

description: 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.

score:

criterion: c.

description: In order to receive a 'yes' groups have to be similar regarding: age, risk for foot ulceration, baseline main outcome measures.

score:

criterion: d.

description: 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.

score:

criterion: e.

description: The reviewer determines when enough information about the blinding is given in order to score a 'yes'.

score:

criterion: f.

description: Co-interventions other than education are either standardised or avoided in trial design. A report on co-interventions for each group separately.

score:**criterion:** g.

description: 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.

score:**criterion:** h.

description: The reviewer determines when enough information about the blinding is given in order to score a 'yes'.

score:**criterion:** i.

description: The reviewer determines (per outcome parameter) when enough information about blinding is given to score a 'yes'.

score:**criterion:** j.

description: The reviewer determines whether the outcome measures were relevant. The relevant outcome parameters are the primary outcome measures.

score:**criterion:** k.

description: Not applicable.

score:**criterion:** l.

description: 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'.

score:**criterion:** m1.

description: Outcome assessment at the end of the intervention period.

score:**criterion:** m2.

description: Outcome assessment longer than 6 months after randomisation.

score:

criterion: n.

description: Timing of outcome assessment should be identical for all intervention groups and for all important outcome assessments.

score:

criterion: o.

description: To be presented for each group at randomisation and for most important outcome assessments.

score:

criterion: p.

description: All randomised patients are reported/analysed for the most important moments of effect measurements (minus missing values) irrespective of non-compliance and co-interventions.

score:

criterion: q.

description: 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.

score:

Methodological quality of included trials

Criteria: A

Barth: ?

Bloomgarden: ?

Kruger: ?

Ronemaa / Hamalainen: ?

Litzelman: ?

Malone: +

Mazzucca: ?

Rettig: ?

Corbett: +

Criteria: B1

Barth: ?

Bloomgarden: ?

Kruger: ?

Ronemaa / Hamalainen: ?

Litzelman: ?

Malone:-

Mazzucca: ?

Rettig: ?

Corbett: +

Criteria: B2

Barth: ?

Bloomgarden: ?

Kruger: +

Ronemaa / Hamalainen: ?

Litzelman:-

Malone: ?

Mazzucca: ?

Rettig: ?

Corbett: +

Criteria: C

Barth:-

Bloomgarden: ?

Kruger: ?

Ronemaa / Hamalainen: ?

Litzelman: ?

Malone: ?

Mazzucca: ?

Rettig: ?

Corbett: ?

Criteria: D

Barth: +

Bloomgarden: +

Kruger: +

Ronemaa / Hamalainen: +

Litzelman: +

Malone: +

Mazzucca: +

Rettig:-

Corbett:-

Criteria: E

Barth: ?

Bloomgarden: ?

Kruger: ?

Ronemaa / Hamalainen: ?

Litzelman:-

Malone: ?

Mazzucca: ?

Rettig: ?

Corbett: +

Criteria: F

Barth: ?

Bloomgarden: ?

Kruger: ?

Ronemaa / Hamlainen: ?

Litzelman: ?

Malone: ?

Mazzucca: ?

Rettig: ?

Corbett: ?

Criteria: G

Barth: ?

Bloomgarden: ?

Kruger: ?

Ronemaa / Hamlainen: ?

Litzelman: ?

Malone: ?

Mazzucca:-

Rettig: ?

Corbett: +

Criteria: H

Barth:-

Bloomgarden:-

Kruger:-

Ronemaa / Hamlainen:-

Litzelman:-

Malone:-

Mazzucca:-

Rettig:-

Corbett:-

Criteria: I

Barth: +

Bloomgarden: ?

Kruger: ?

Ronemaa / Hamlainen: ?

Litzelman: +

Malone: ?

Mazzucca: ?

Rettig: +

Corbett: ?

Criteria: J

Barth: +

Bloomgarden: +

Kruger: +

Ronemaa / Hamlainen: +

Litzelman: +

Malone: +

Mazzucca: +

Rettig: +

Corbett: +

Criteria: K - see note 3

Barth: NA

Bloomgarden: NA

Kruger: NA

Ronemaa / Hamlainen: NA

Litzelman: NA

Malone: NA

Mazzucca: NA

Rettig: NA

Corbett: NA

Criteria: L

Barth: +

Bloomgarden: +

Kruger:-

Ronemaa / Hamalainen: +

Litzelman: ?

Malone: +

Mazzucca:-

Rettig: ?

Corbett:-

Criteria: M1

Barth: +

Bloomgarden:-

Kruger: +

Ronemaa / Hamalainen:-

Litzelman:-

Malone:-

Mazzucca:-

Rettig: +

Corbett: +

Criteria: M2

Barth:-

Bloomgarden: +

Kruger:-

Ronemaa / Hamlainen: +

Litzelman: +

Malone: +

Mazzucca: +

Rettig:-

Corbett:-

Criteria: N

Barth: +

Bloomgarden: +

Kruger: +

Ronemaa / Hamlainen: +

Litzelman: +

Malone: +

Mazzucca: +

Rettig: +

Corbett: +

Criteria: O

Barth: +

Bloomgarden: +

Kruger: +

Ronemaa / Hamlainen: +

Litzelman: +

Malone: +

Mazzucca: +

Rettig: +

Corbett: +

Criteria: P

Barth:-

Bloomgarden:-

Kruger:-

Ronemaa / Hamlainen:-

Litzelman:-

Malone:-

Mazzucca:-

Rettig:-

Corbett:-

Criteria: Q

Barth:-

Bloomgarden:-

Kruger:-

Ronemaa / Hamlainen:-

Litzelman:-

Malone:-

Mazzucca:-

Rettig: +

Corbett:-

Criteria: TOTAL QUALITY SCORE - see note 1

Barth: 4

Bloomgarden: 3

Kruger: 2

Ronemaa / Hamlainen: 3

Litzelman: 3

Malone: 3

Mazzucca: 2

Rettig: 3

Corbett: 5

Criteria: Note 1

Barth: sum of score of internal validity criteria (range 0-10)

Bloomgarden:

Kruger:

Ronemaa / Hamalainen:

Litzelman:

Malone:

Mazzucca:

Rettig:

Corbett:

Criteria: Note 2

Barth: CRITERIA AS DEFINED BY VERHAGEN (1998)

Bloomgarden:

Kruger:

Ronemaa / Hamalainen:

Litzelman:

Malone:

Mazzucca:

Rettig:

Corbett:

Criteria: Note 3

Barth: + = yes

Bloomgarden: - = no

Kruger: ? = don't know

Ronemaa / Hamlainen: NA = not applicable to this intervention type

Litzelman:

Malone:

Mazzucca:

Rettig:

Corbett:

Results from trials

Study ID: Barth 1991

Sample: 70 patients with type 2 diabetes mellitus randomised

I: 38 vs C: 32

62 patients completed follow-up

I: 33 vs C: 29

Baseline risk for foot ulceration: PVD, I: 19 vs C: 6

Number of foot problems: 'No significant difference between groups'

Baseline outcome measures: 'No significant difference between groups'

Treatment adherence: Not described for I and C

Follow-up: I and C: 6 months

Primary outcomes: No ulcer outcomes reported

Secondary outcomes: Foot problems requiring treatment:

- after 1 month: Significant increase ($p < 0.006$)

- after 6 months: No change ($p = 0.216$)

Foot care knowledge: Increased in intervention group ($p < 0.001$)

Foot care routine compliance: Increased in intervention group ($p = 0.012$)

Notes: Outcome measures

multiple choice questions on knowledge and compliance: number of questions and range of outcomes:?

Study ID: Bloomgarden

1987

Sample: 749 insulin treated patient with diabetes mellitus randomised;

I: 165 vs C: 180 included;

266 patients completed follow-up: I: 127 vs C: 139

146 patients had no foot lesion at initial evaluation, I: 83 vs C: 63

100 patients had callus, nail dystrophy or fungal infection at initial evaluation, I: 37 vs C: 63

20 patients had an ulcer or amputation at initial evaluation, I: 7 vs C: 13

Baseline risk for foot ulceration:

% of patients with callus, nail dystrophy or fungal infection: I: 29% vs C: 45%

% of patients with ulcer or amputation: I: 6% vs C: 9%

Treatment adherence: I: 57% of patients = 7 of 9 educational group sessions (graduates)

C: not applicable

Follow-up: I: 1.6+/-0.3 years vs C: 1.5+/-0.3 years

Primary outcomes: 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)

Secondary outcomes: 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

Patients with an ulcer or amputation at initial evaluation - I: 1/7 (14%) vs C: 1/13 (8%) - no significant difference

Behaviour score: No significant difference - data not provided

Notes: Outcome measures

behaviour score: 7 questions of which one on foot care

Study ID: Corbett 2003

Sample: 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'

Treatment adherence: 1 education session in intervention group for 19 of 20 patients

Follow-up: I and C: 6 weeks

Primary outcomes: No ulcer outcomes reported

Secondary outcomes: Foot care knowledge: I: 4.9 -> 6.1 vs C: 4.6 -> 5.2 ($p=0.03$), foot care practices: I: 4.3 -> 5.6 vs C: 4.1 -> 4.3 ($p=0.007$), self confidence: I: 33.2 -> 36.1 vs C: 33 -> 33.6 (ns)

Notes: 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

Study ID: Hamalainen 1997

Sample: 530 patients with diabetes mellitus, unclear which type, randomised

I: 267 vs C: 263

459 completed 1 year of follow-up: I: 233 vs C: 226

332 completed 7 years of follow-up: I: 169 vs C: 163

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.

Treatment adherence: I: mean number of podiatry visits 4.7 in first year. After first and before seventh follow-up year at least one podiatry visit in 82.3% of patients in I and in 49.7% in C

Follow-up: I and C: Both at 1 and 7 years

Primary outcomes: follow-up 7 years:

amputation rate: 0 (I: 1.0 vs C: 0, $p=0.499$)

ulcer prevalence: 0 (I: 0.6% vs C: 0.6%, $p=1.0$)

Secondary outcomes: Follow-up 1 year:

% patients with callosities calcaneal region: I: 18.5-> 12.0 vs C: 16.8-> 15.5, no significant difference (p=0.14)

% patients with callosities other regions: I: 54.5-> 39.5 vs C: 51.3-> 48.2 - significant decrease in callosities in intervention group (p<0.009)

Diameter of callosities at calcaneal region: I: 40.5-> 25.5 vs C: 30.6-> 28.3, Statistically significant decrease in area of callosities at calcaneal region in intervention group (p=0.065)

Diameter of callosities other sites than calcaneum I: 16.6-> 11.4 vs C: 15.2-> 14.4, Statistically significant decrease in area of callosities in intervention group (p<0.001)

Level of foot care knowledge: I: 26.7-> 32.1 vs C: 26.1-> 29.2, Statistically significant increase in intervention group (p=0.004)

Behaviour assessment scores: I: 5.4-> 7.0 vs C: 5.3-> 6.0, (p<0.001) Statistically significant increase in intervention group

Follow-up 7 years:

Knowledge and behaviour scores: No significant difference

Callosities calcaneal region: No significant difference

Callosities other regions: No significant difference

Notes: Outcome measures:

diameter callus in millimeters

knowledge score: 19 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

Study ID: Kruger 1992

Sample: 50 patients with diabetes mellitus, unclear which type, randomised

I: 23 vs C: 27

30 patients completed follow-up: I: 15 vs C: 15

Baseline risk for foot ulceration:

Comparability of I and C not described

Treatment adherence: Not described for I and C

Follow-up: I and C: 6 months

Primary outcomes: No ulcer outcomes reported

Secondary outcomes: Foot status: No significant difference

Foot care knowledge: I: 9.1->10.0 vs C: 8.66->9.86, Statistically significant increase in control group (p=0.02)

Daily foot inspection: I: 52.5-> 66.7 vs C: 34.8-> 66.7, No significant difference

Daily foot washing: I: 82.6-> 86.7 vs C: 74.1-> 73.3, Statistically significant increase in intervention group

Use of pumice stones for corns: I: 4.3-> 26.7 vs C: 3.7-> 26.7, No significant difference

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

Notes: Outcome measures:

foot status: 67 assessment items

foot care knowledge: 12-item test

Study ID: Litzelman 1993

Sample: 484 patients with type 2 diabetes mellitus randomised

393 patients baseline assessment: I: 191 vs C: 205

352 completed follow-up

baseline risk for foot ulceration: comparability of I and C not described

Treatment adherence: Not described for I and C

Follow-up: I and C: 11.8 +/- 1.5 months

Primary outcomes: Serious foot lesions: OR:0.41 (95%CI:0.16-1.00), No significant difference

All foot lesions: OR:0.65 (95%CI:0.36-1.17), No significant difference

Amputation rate: I:1 vs C:4, No significant difference

Secondary outcomes: Dry cracked skin: OR:0.62 (95%CI:0.39-0.98), Statistically significant decreased risk in intervention group

Ingrown nails: OR:0.59 (95%CI:0.39-0.92) Statistically significant decreased risk in intervention group

Fungal nail infection: OR:0.70 (95%CI:0.46-1.07), No significant difference

Fungal skin infection: OR:0.58 (95%CI:0.30-1.12), No significant difference

Interdigit macerations: OR:0.63 (95%CI:0.34-1.15), 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

Notes: Outcome measures:

only odds ratios and baseline prevalences in total group (I and C) described

behaviour assessment score measured on 5-point scale (1= almost always, 5= almost never)

Study ID: Malone 1989

Sample: 227 patients with diabetes mellitus, unclear which type, and foot infection ulceration or prior amputation randomised

203 patients included: I: 103 vs C: 100

182 patients completed follow-up: I: 90 vs C: 92

Baseline risk for foot ulceration:

Although described as 'not significant', prior vascular reconstruction higher in C; incidence of foot callous higher in I (p<0.05) No significant differences in foot deformities, neuropathy, gangrene, prior amputation or ulcer, level of distal pulses

Treatment adherence: Not described for I and C

Follow-up: I: mean 12, median 13.2 months (range 1-26) C: mean 8, median 9.2 months (range 1-26)

Primary outcomes: Ulcer incidence: I: 8 vs C: 26, rate lower in intervention group (p<=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<0.025)

Secondary outcomes:

Notes: Outcome measures:

Outcomes are presented per limb randomised

Study ID: Mazzuca 1986

Sample: 532 patients with diabetes mellitus, unclear which type, randomised

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

Treatment adherence: 139 of 208 (67%) patients needing instruction on foot care completed this

Follow-up: Median interval between instruction and follow-up measurement 11.8-14.3 months

Primary outcomes: No ulcer outcomes reported

Secondary outcomes: Level of foot care knowledge: No significant difference

Notes: Outcome measure:

knowledge objectives unclear

Study ID: Rettig 1986

Sample: 471 patients with diabetes mellitus, unclear which type, randomised

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

Treatment adherence: Not described for I and C

Follow-up: I and C: 6 months

Primary outcomes: No ulcer outcomes reported

Secondary outcomes: Foot appearance at follow-up: I: 70.2+/-0.7 vs C: 68.8+/-0.7, No significant difference

Foot care knowledge at follow-up: I: 62.2+/-1.7 vs C: 53.1+/-1.8, (p=0.001) Significant increase in intervention group

Skills score at follow-up: I: 71.8+/-2.0 vs C: 68.9+/-1.8, No significant difference

Notes: 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 1

skills assessed by nurse examination of patients' feet

Search strategies used for the original review

Search strategies: Eligible studies were identified by searching the Cochrane Wounds Group Specialised Trials Register (March2001) 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,

arterial 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.(PILONIDAL 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.(((PILONIDAL and CYST) or (PILONIDAL 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
- 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.

01 More intensive educational intervention vs. brief educational intervention

Outcome title: 01 01 Amputation rate

No. of studies: 1

No. of participants: 332

Statistical method: Peto Odds Ratio 95% CI

Effect size: 7.13 [0.14, 359.63]

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

Outcome title: 01 01 Incidence of ulceration

No. of studies: 1

No. of participants: 182

Statistical method: Peto Odds Ratio 95% CI

Effect size: 0.28 [0.13, 0.59]

Outcome title: 02 02 Incidence of infection

No. of studies: 1

No. of participants: 182

Statistical method: Peto Odds Ratio 95% CI

Effect size: 1.02 [0.14, 7.38]

Outcome title: 03 03 Amputation rate

No. of studies: 1

No. of participants: 182

Statistical method: Peto Odds Ratio 95% CI

Effect size: 0.32 [0.14, 0.71]

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

Outcome title: 01 01 Ulcer or amputation

No. of studies: 1

No. of participants: 146

Statistical method: Peto Odds Ratio 95% CI

Effect size: 0.75 [0.10, 5.55]

Outcome title: 02 02 Callus, nail dystrophy and fungal infections

No. of studies: 1

No. of participants: 146

Statistical method: Peto Odds Ratio 95% CI

Effect size: 0.75 [0.38, 1.45]

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

Outcome title: 01 01 Number of amputations

No. of studies: 1

No. of participants: 396

Statistical method: Peto Odds Ratio 95% CI

Effect size: 0.32 [0.05, 1.86]

Outcome title: 02 02 Behaviour assessment score

No. of studies: 1

No. of participants: 396

Statistical method: Weighted Mean Difference (Fixed) 95% CI

Effect size: -0.22 [-0.31, -0.13]

Contribution of Reviewer(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.

Most recent changes

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.

References

References to studies included in this review

Barth 1991

Barth R, Campbell LV, Allen S, Jupp JJ, Chisholm DJ. Intensive education improves knowledge, compliance and foot problems in type 2 diabetes. *Diabetic Medicine* 1991;8:111-17. [Bibliographic Links](#) | [\[Context Link\]](#)

Bloomgarden 1987

Bloomgarden ZT, Karmally W, Metzger MJ, Brothers M, Nechemias C, Bookman J, Fairman D, Ginsberg-Felner F, Rayfield E, Brown WV. Randomized controlled trial of diabetic patient education: improved knowledge without improved metabolic status. *Diabetes Care* 1987;10(3):263-72. [\[Context Link\]](#)

Corbett 2003

Corbett CF. A randomized pilot study of improving foot care in home health patients with diabetes. *The Diabetes Educator* 2003;29:273-82. [Bibliographic Links](#) | [\[Context Link\]](#)

Hamlainen 1997

Hamalainen H, Ronnema T, Toikka T, Liukkonen I. Long-term effects of one year of intensified podiatric activities on foot-care knowledge and self-care habits in patients with diabetes. *The Diabetes Educator* 1998;24(6):734-40. [Bibliographic Links](#) | [\[Context Link\]](#)

Ronnema T, Hamalainen H, Toikka T, Liukkonen I. Evaluation of the impact of podiatrist care in the primary

prevention of foot problems in diabetic subjects. *Diabetes Care* 1997;20(12):1833-37. [Ovid Full Text](#) | [Bibliographic Links](#) |

Kruger 1992

Kruger S, Guthrie D. Foot care: knowledge retention and self-care practices. *The Diabetes Educator* 1992;18(6):487-90. [Bibliographic Links](#) | [Context Link](#)

Litzelman 1993

Litzelman DK, Slemenda CW, Langeveld CD, Hays LM, Welch MA, Bild DE, Ford ES, Vinicor F. Reduction of lower extremity clinical abnormalities in patients with non-insulin-dependent diabetes mellitus. *Annals of Internal Medicine* 1993;119(1):36-41. [Context Link](#)

Malone 1989

Malone JM, Snyder M, Anderson G, Bernhard VM, Holloway GA, Bunt TJ. Prevention of amputation by diabetic education. *The American Journal of Surgery* 1989;158:520-524. [Bibliographic Links](#) | [Context Link](#)

Mazzuca 1986

Mazzuca SA, Moorman NH, Wheeler ML, Norton JA, Fineberg NS, Vinicor F, Cohen SJ, Clark CM. The diabetes education study: a controlled trial of the effects of diabetes patient education. *Diabetes Care* 1986;9(1):1-10. [Context Link](#)

Rettig 1986

Rettig BA, Shrauger DG, Recker RR, Gallagher TF, Wiltse H. A randomized study of the effects of a home diabetes education program. *Diabetes Care* 1986;9(2):173-78. [Ovid Full Text](#) | [Bibliographic Links](#) | [Context Link](#)

References to studies excluded from this review

Dargis 1999

Dargis V, Pantelejeva O, Jonushaite A, Vileikyte L, Boulton AJM. Benefits of a multidisciplinary approach in the management of recurrent diabetic foot ulceration in Lithuania - a prospective study. *Diabetes Care* 1999;22:1428-31. [Ovid Full Text](#) | [Bibliographic Links](#) |

Davidson 2000

Davidson MB, Karlan VJ, Hair TL. Effect of a pharmacist-managed diabetes care program in a free medical clinic. *American Journal of Medical Quality* 2000;15:137-41. [Bibliographic Links](#) |

De Weerd 1991

Weerd I de, Visser AP, Kok GJ, Weerd O de, Veen EA van der. Randomized controlled multicentre evaluation of an education programme for insulin-treated diabetic patients: effects on metabolic control, quality of life, and costs of therapy. *Diabetic Medicine* 1990;8:338-45. [Bibliographic Links](#) |

Donohoe 2000

Donohoe ME, Fletton JA, Hook A, Powell R, Robinson I, Stead JW, Sweeney K, Taylor R, Tooke JE. Improving foot care for people with diabetes mellitus - a randomized controlled trial of an integrated care approach. *Diabetic Medicine* 2000;17:581-7. [Bibliographic Links](#) |

Glasgow 1992

Glasgow RE, Toobert DJ, Hampson SE, Brown JE, Lewinsohn PM, Donnelly J. Improving self-care among

older patients with type II diabetes: the 'sixty something[horizontal ellipsis]' study. *Patient Education and Counseling* 1992;19:61-74.

Litzelman 1997

Litzelman DK, Marriot DJ, Vinicor F. The role of footwear in the prevention of foot lesions in patients with NIDDM. *Diabetes Care* 1997;20(2):156-62. [Ovid Full Text](#) | [Bibliographic Links](#) |

McCabe 1998

McCabe CJ, Stevenson RC, Dolan AM. Evaluation of a diabetic foot screening and protection programme. *Diabetic Medicine* 1998;15:80-4. [Ovid Full Text](#) | [Bibliographic Links](#) |

McMurray 2002

McMurray SD, Johnson G, Davis S, McDougall K. Diabetes education and care management significantly improve patient outcomes in the dialysis unit. *American Journal of Kidney Diseases* 2002;40:566-75. [Bibliographic Links](#) | [Context Link](#)

McMurray SD, McDougall K. Improving Diabetes Foot Care in the Dialysis Facility. *Nephrology News & Issues* 2003;17(10):57, 60-1, 65-6.

Pieber 1995

Pieber TR, Holler A, Siebenhofer A, Brunner GA, Semlitsch B, Schattenberg S, Zapotoczky H, Rainer W, Krejs GJ. Evaluation of a structured teaching and treatment programme for type 2 diabetes in general practice in a rural area of Austria. *Diabetic Medicine* 1995;12:349-54. [Bibliographic Links](#) |

Plank 2003

Plank J, Haas W, Rakovac I, Gorzer E, Sommer R, Siebenhofer A, Pieber TR. Evaluation of the impact of chiropodist care in the secondary prevention of foot ulcerations in diabetic subjects. *Diabetes Care* 2003;26:1691-5. [Ovid Full Text](#) | [Bibliographic Links](#) |

Reichard 1993

Reichard P, Nilsson BY, Rosenqvist U. The effect of long-term intensified insulin treatment on the development of microvascular complications of diabetes mellitus. *The New England Journal of Medicine* 1993;329(5):304-9. [Bibliographic Links](#) |

Vinicor 1985

Vinicor F, Cohen SJ, Mazuca SA, Moorman N, Wheeler M, Kuebler T, Swanson S, Ours P, Fineberg SE, Gordon EE, Duckworth W, Norton JA, Fineberg NS, Clark CM. Diabeds: a randomized trial of the effects of physician and/or patient education on diabetes patient outcomes. *Journal of Chronic Disease* 1987;40(4):345-56. [Bibliographic Links](#) |

Ward 1999

Ward A, Metz L, Oddone EZ, Edelman D. Foot education improves knowledge and satisfaction among patients at high risk for diabetic foot ulcer. *The Diabetes Educator* 1999;25(4):560-7. [Bibliographic Links](#) |

Wooldridge 1996

Wooldridge J, Bergeron J, Thornton C. Preventing diabetic foot disease: lessons from the medicare therapeutic shoe demonstration. *American Journal of Public Health* 1996;86(7):935-8. [Ovid Full Text](#) | [Bibliographic Links](#) |

Additional references

Apelqvist 1993

Apelqvist J, Larsson J, Agardh CD. Long-term prognosis for diabetic patients with foot ulcers. *Journal of Internal Medicine* 1993;233:485-491. [Bibliographic Links](#) | [\[Context Link\]](#)

Apelqvist 1995

Apelqvist J, Ragnarson-Tennvall G, Larsson J, Persson U. Long-term costs for foot ulcers in diabetic patients in a multidisciplinary setting. *Foot and Ankle International* 1995;16:388-394. [\[Context Link\]](#)

Armstrong 1998

Armstrong DG, Lavery LA. Diabetic foot ulcers: prevention, diagnosis and classification. *American Family Physician* 1998;57:1325-1332. [Bibliographic Links](#) | [\[Context Link\]](#)

Assal 1985

Assal JP, Muhlhauser I, Pernet A, Gfeller R, Jorgens V, Berger M. Patient education as the basis for diabetes care in clinical practice and research. *Diabetologia* 1985;28:602-613. [Ovid Full Text](#) | [Bibliographic Links](#) | [\[Context Link\]](#)

Begg 1996

Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, Pitkin R, Rennie D, Schulz KF, Simel D, Stroup DF. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *Journal of the American Medical Association* 1996;276(8):637-9. [Ovid Full Text](#) | [Bibliographic Links](#) | [\[Context Link\]](#)

Bild 1989

Bild DE, Selby JV, Sinnock P, Browner WS, Braveman P, Showstack JA. Lower-extremity amputation in people with diabetes. *Epidemiology and prevention. Diabetes Care* 1989;12:24-31. [Bibliographic Links](#) | [\[Context Link\]](#)

Boulton 1995

Boulton AJM. Why bother educating the multi-disciplinary team and the patient - the example of prevention of lower extremity amputation in diabetes. *Patient Education and Counseling* 1995;26:183-188. [\[Context Link\]](#)

Boulton 1998

Boulton AJ, Gries FA, Jervell JA. Guidelines for the diagnosis and outpatient management of diabetic peripheral neuropathy. *Diabetic Medicine* 1998;15:508-514. [Bibliographic Links](#) | [\[Context Link\]](#)

Brennan 1992

Brennan P, Silman A. Statistical methods for assessing observer variability in clinical measures. *British Medical Journal* 1992;304:1491-1494. [Bibliographic Links](#) | [\[Context Link\]](#)

De Sonnaville 1997

De Sonnaville JJJ, Colly LP, Wijkkel D, Heine RJ. The prevalence and determinants of foot ulceration in type 2 diabetic patients in a primary health care setting. *Diabetes Research and Clinical Practice* 1997;35:149-56. [\[Context Link\]](#)

Edmonds 1982

Edmonds ME, Roberts VC, Watkins PJ. Blood flow in the diabetic neuropathic foot. *Diabetologia* 1982;22:9-15. [Bibliographic Links](#) | [\[Context Link\]](#)

Edmonds 1996a

Edmonds ME, Van Acker K, Foster AVM. Education and the diabetic foot. *Diabetic Medicine* 1996;13:S61-S64. [Bibliographic Links](#) | [\[Context Link\]](#)

Edmonds 1996b

Edmonds M, Boulton A, Buckenham T, Every N, Foster A, Freeman D, Gadsby R, Gibby O, Knowles A, Pooke M, Tovey F, Unwin N, Wolfe J. Report of the diabetic foot and amputation group. *Diabetic Medicine* 1996;13:S27-S42. [Bibliographic Links](#) | [\[Context Link\]](#)

Gibson 1998

Gibson PG, Coughlan J, Wilson AJ, Hensley MJ, Abramson M, Bauman A, Walters EH. The effects of limited (information only) patient education programs on the health outcomes of adults with asthma. In: *The Cochrane Library*, 3, 1998. Oxford: Update Software. [\[Context Link\]](#)

Gross 2004

Gross AR, Acker PD, Goldsmith CH, Peloso P. Patient education for mechanical neck disorders (withdrawn). In: *The Cochrane Library*, 3, 2004. Chichester, UK: John Wiley & Sons, Ltd. [\[Context Link\]](#)

Holewski 1989

Holewski JJ, Moss KM, Stess RM, Graf PM, Grunfeld C. Prevalence of foot pathology and lower extremity complications in a diabetic outpatient clinic. *Journal of Rehabilitation Research and Development* 1989;26:35-44. [\[Context Link\]](#)

Jadad 1996

Jadad AR, Moore A, Carrol D, Jenkinson C, Reynolds DJM, Gavaghan DJ, McQuay HJ. Assessing the quality of reports of randomized clinical trials: is blinding necessary?. *Controlled Clinical Trials* 1996;17:1-12. [Bibliographic Links](#) | [\[Context Link\]](#)

Larsson 1995

Larsson J, Apelqvist J. Towards less amputations in diabetic patients. Incidence, causes, cost, treatment, and prevention - a review. *Acta Orthopaedica Scandinavica* 1995;66:181-192. [Bibliographic Links](#) | [\[Context Link\]](#)

Lau 1997

Lau J, Ioannidis JPA, Schmid CH. Quantitative synthesis in systematic reviews. *Ann Intern Med* 1997;127:820-826. [Ovid Full Text](#) | [Bibliographic Links](#) | [\[Context Link\]](#)

Levin 1995

Levin ME. Preventing amputation in the patient with diabetes. *Diabetes Care* 1995;18:1383-1394. [Ovid Full Text](#) | [Bibliographic Links](#) | [\[Context Link\]](#)

Majid 2000

Majid M, Cullum N, O'Meara S Sheldon T. Systematic reviews of wound care management: (4) diabetic foot ulceration. *Health Technology Assessment* 2000;21:113-238. [\[Context Link\]](#)

Mason 1999

Mason J, O'Keeffe C, McIntosh A, Hutchinson A, Booth A, Young RJ. A systematic review of foot ulcer in patients with type 2 diabetes mellitus. I: prevention. *Diabetic Medicine* 1999;16:801-12. [Bibliographic](#)

[Links](#) | [\[Context Link\]](#)

Mayfield 1998

Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM. Preventive foot care in people with diabetes. *Diabetes Care* 1998;21:2161-2177. [Ovid Full Text](#) | [Bibliographic Links](#) | [\[Context Link\]](#)

Most 1983

Most RS, Sinnock P. The epidemiology of lower extremity amputations in diabetic individuals. *Diabetes Care* 1983;6:87-91. [Bibliographic Links](#) | [\[Context Link\]](#)

Mueller 1989

Mueller MJ, Diamond JE, Delitto A, Sinacore DR. Insensitivity, limited joint mobility, and plantar ulcers in patients with diabetes mellitus. *Physical Therapy* 1989;69:453-462. [Bibliographic Links](#) | [\[Context Link\]](#)

Mulrow 1997

Mulrow CD, Oxman AD. *Cochrane Collaboration Handbook*. updated September 1997. Vol. 4, Oxford: Update Software, 1997. [\[Context Link\]](#)

Palumbo 1985

Palumbo PJ, Melton LJ. Peripheral vascular disease and diabetes. In: Harris MI, Hamman RF editor(s). *Diabetes in America*. Vol. XV, Washington DC: US Government Printing Office, 1985:1-21. [\[Context Link\]](#)

Pecoraro 1990

Pecoraro RE, Reiber GE, Burgess EM. Pathways to diabetic limb amputation. Basis for prevention. *Diabetes Care* 1990;13:513-521. [Bibliographic Links](#) | [\[Context Link\]](#)

Reenders 1993

Reenders K, de Nobel E, van den Hoogen HJM, Rutten GEHM, van Weel C. Diabetes and its long-term complications in general practice: a survey in a well-defined population. *Family Practice* 1993;10:169-72. [Ovid Full Text](#) | [Bibliographic Links](#) | [\[Context Link\]](#)

Rosenthal 1994

Rosenthal R. Parametric measures of effect size. In: Cooper H, Hedges HV editor(s). *The handbook of research synthesis*. New York: Sage Foundation, 1994:231-244. [\[Context Link\]](#)

Schulz 1994

Schulz KF, Chalmers I, Grimes DA, Altman DG. Assessing the quality of randomization from reports of controlled trials published in obstetrics and gynaecology journals. *Journal of the American Medical Association* 1994;272:125-128. [\[Context Link\]](#)

Shaw 1997

Shaw JE, Boulton AJM. The pathogenesis of diabetic foot problems. *Diabetes* 1997;46(suppl.2):S58-S61. [Bibliographic Links](#) | [\[Context Link\]](#)

van Houtum 1995

Houtum van WH, Lavery LA, Harkless LB. The cost of diabetes-related lower extremity amputations in the Netherlands. *Diabetic Medicine* 1995;12:777-781. [Bibliographic Links](#) | [\[Context Link\]](#)

van Tulder 1997

Tulder van MW, Assendelft WJJ, Koes BW, Bouter LM. Method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group for Spinal Disorders. Spine 1997;22:2323-2330. [Ovid Full Text](#) | [Bibliographic Links](#) | [Context Link](#)

Verhagen 1998

Verhagen AP, Vet HCW de, Bie RA de, Kessel AGH, Boers M, Bouter LM, et al. The Delphi list: a criteria list for quality assessment of randomised clinical trials developed by Delphi consensus. Journal of Clinical Epidemiology 1998;51(12):1235-41. [Context Link](#)

Wieman 1992

Wieman TJ, Griffiths GD, Polk HC. Management of diabetic midfoot ulcers. Annals of Surgery 1992;215:627-632. [Bibliographic Links](#) | [Context Link](#)

DIABETIC FOOT ULCERS; Prevention; Education; Patient education; Humans; *Diabetic Foot/pc (prevention & control); *Patient Education; Randomized Controlled Trials

Accession Number: 00075320-100000000-00837

Copyright (c) 2000-2006 [Ovid Technologies, Inc.](#)
Version: rel10.4.0, SourceID 1.12596.1.117