FOOTSTEP: a randomized controlled trial investigating the clinical and cost effectiveness of a patient self-management program for basic foot care in the elderly


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
A self-management programme (SMP) of basic foot care in the elderly was studied. This was compared with usual podiatric consultation among self-initiated or primary referred non-urgent demands for podiatry services.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged 60 or older, who were seeking self-initiated or primary referred consultations at an NHS podiatry clinic. Usual screening by podiatry services was used to identify those patients requiring only basic foot health treatment and to exclude those with serious foot morbidity or medical conditions associated with poor foot health. Patients with diabetes, vascular disease, thickened nails, foot pathology requiring further care, or with long-term anticoagulant or steroid use were excluded from the study, as were those whose medical history was unavailable. Also excluded, were patients with multiple problems, neurological disease or Parkinson's disease, or psychiatric problems, and those under hospital care.

Setting
The setting was secondary care. The study was set in the Calderdale local authority of West Yorkshire, UK. Four of the Calderdale HealthCare NHS Trust Podiatry Clinics were involved. This represented 50% of the Trust’s contacts.

Dates to which data relate
The effectiveness and resource use data was gathered for 13 months starting from 2 November 1999. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
Neither the source of the cost data nor their relation to the effectiveness data were reported.

Study sample
A power calculation determined that 125 patients per group were required to achieve 80% power at the 5% significance
level. The ability and suitability of eligible consented patients and volunteer self-care assistants was assessed at baseline. All of the participants were given the opportunity to have an assistant attend. The patients were then randomly allocated to the experimental or control group. The sample was appropriate since the focus of the study was non-urgent podiatry demands by the elderly. Of the 1,013 patients, 261 (25.77%) declined to participate or failed to attend, and 599 (59.13%) were excluded for reasons stated already. Seventy-eight patients (7.70%) were randomised to the intervention group and 75 (7.40%) to the control group.

**Study design**
The study was a randomised controlled trial that was conducted at four sites in the same district. Allocation was stratified by gender, whether the individual was a new or existing patient, and if they required the aid of an assistant. All the patients were followed up for 6 months. A second podiatrist, who was blinded to the experimental group, undertook the assessment at this time. After randomisation, 12.42% of the participants dropped out of the study, 5.23% in the intervention group and 7.19% in the control group.

**Analysis of effectiveness**
The basis of the analysis was treatment completers only. The primary health outcome was foot disability, as measured by the Manchester Foot Disability Questionnaire (MFDQ). The participants also completed the Modified Foot Morbidity Index (MFMI), a Foot Health Knowledge Questionnaire (FHKQ), and a Patient Enablement Instrument (PEI). The number of, and reasons for additional podiatry treatments were also recorded. Although the baseline demographic and medical characteristics were reported and described as being "very similar", no statistical test was reported.

**Effectiveness results**
After 6 months, the difference between the median SMP and usual care MFDQ scores was -1.0 (95% confidence interval, CI: -2, 0; p=0.019).

The difference between the median PEI scores was -2.0 (95% CI: -3, 0; p=0.008).

There was no significant difference between morbidity (MFMI) and knowledge (FHKQ) scores.

The 51 additional podiatry treatments required by the usual care group was significantly greater than the 25 required by the SMP group, (p<0.001).

More treatment sessions were reported by the usual care group (92) than the SMP group (39).

The usual care group also presented with more lesions (96) than the SMP group (28).

**Clinical conclusions**
At 6 months, the intervention group had lower foot disability scores and presented for fewer treatments than the control group.

**Measure of benefits used in the economic analysis**
The authors did not develop a summary benefit measure for use in the economic analysis. As such, a cost-consequences approach was adopted.

**Direct costs**
The costs and the quantities were not reported separately but as the cost per patient. Only the direct costs to the Trust's podiatry services were reported. These were the average cost of additional treatments for both groups and, for the SMP group, the cost of implementing the programme. The implementation costs covered patient training, volunteers, answer
phone, video production, brochures, video copies, nail care packs and telephone bills. The source of the cost data was not reported. Discounting was not relevant and was therefore not applied. The price year was not stated. The costs of overheads, staff travel and patient travel (when paid by the Trust) were assumed to be equal between the groups and were consequently excluded from the analysis.

**Statistical analysis of costs**
The cost data were treated deterministically.

**Indirect Costs**
The indirect costs were not included.

**Currency**
UK pounds sterling (£).

**Sensitivity analysis**
No sensitivity analysis was undertaken.

**Estimated benefits used in the economic analysis**
See the 'Effectiveness Results' section.

**Cost results**
The total costs were 22.20 per patient for the SMP group compared with 10.71 per patient for the usual care group.

The authors reported that the total costs for the SMP group decreased to 10.92 per patient when the costs of developing the programme (4.29 per patient) and the lower number of additional treatments (6.99 per patient) were subtracted.

The entire cost of the nail care packs (8.58) was also included, although a co-payment for this item could, conceivably, have been introduced.

**Synthesis of costs and benefits**
Not applicable due to the cost-consequences approach adopted.

**Authors' conclusions**
The self-management programme (SMP) for basic foot care in the elderly did not compromise therapeutic outcomes during the study period. In addition, it actually resulted in less reported disability and fewer podiatric treatment sessions. Although the SMP was more expensive than usual care, adjusting for set-up costs and programme benefits may show the SMP to be more cost-effective than usual care in the long term.

**CRD COMMENTARY - Selection of comparators**
The justification given for the comparator used was that it represented standard practice. You should decide if this is a widely used health technology in your own setting.

**Validity of estimate of measure of effectiveness**
The basis of the analysis was a randomised controlled trial, which was appropriate for the study question. The study sample, however, was not representative of the study population since nearly 60% were excluded and a further 25%...
declined to participate or failed to attend. The patient groups were not shown to be comparable at analysis. Comparative data were supplied but they were not supported by a statistical analysis. Although a randomised controlled trial was conducted, only the outcomes for treatment completers were analysed. These aspects of the analysis tend to limit the validity of the results.

**Validity of estimate of measure of benefit**
The authors did not develop or use a summary health outcome in their economic analysis and the clinical outcomes were left disaggregated. The analysis was therefore based on a cost-consequences approach.

**Validity of estimate of costs**
All the categories of cost relevant to the perspective of an NHS Podiatry Trust were included in the analysis. Some relevant costs were omitted from the analysis since they were assumed to be the same for both groups. The intervention programme did not include the cost of care provided by relatives and volunteers, which in some cases obviated the need for a podiatrist to attend. Therefore, the cost of the intervention may have been underestimated. The costs and the quantities were not reported separately. No statistical analysis of the quantities was performed. The authors did not identify the source from which the prices were obtained or the price year to which they applied. Despite treating costs as point estimates, no sensitivity analysis was undertaken. Discounting was unnecessary since the costs were incurred during 13 months.

When examining the cost of the intervention, the authors suggested that the sum of 6.99 could be subtracted due to the reduction in additional treatments. Since the comparison of costs between the two groups already allowed for additional treatments, the rationale for this was not readily apparent. Presumably, the confusion was due to a lack of distinction between returning for "treatment" and "treatment sessions".

**Other issues**
The authors made appropriate comparisons of their findings with a limited number of other studies. They acknowledged that the generalisability of their results was limited by the low recruitment rate. The authors do not appear to have presented their results selectively. The study enrolled elderly patients who did not have complicated foot morbidity and this was reflected in the conclusions. The authors also reported a short follow-up period in their study and acknowledged the need to demonstrate the programme's effectiveness over a longer period.

**Implications of the study**
The results of the cost-effectiveness analysis of the SMP for basic foot care in the elderly were, at best, inconclusive. Increased morbidity may lead to longer appointment times with an associated increase in cost to the podiatry services. The authors also suggested extending the study to include other target groups, such as those diabetic patients who are at low risk of morbidity and school children, to foster a self-help attitude.

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