

# Effectiveness of a Patient Education Module on Diabetic Foot Care in Outpatient Setting: An Open-label Randomized Controlled Study

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## Abstract

**Background:** A large number of patients with diabetes mellitus are unaware of foot care and are at risk of developing foot ulcer and amputation. This increases healthcare burden due to preventable complication of diabetes. **Aims:** We conducted this study to assess the effectiveness of a foot care education module for diabetes developed by us. **Materials and Methods:** One hundred and twenty-seven patients with diabetes mellitus attending our outpatient were randomized into intervention ( $n = 63$ ) and control groups ( $n = 64$ ). At first visit, 1 and 3 months later, both groups filled a questionnaire regarding foot care knowledge and practice. The intervention group was administered foot care education module and the control group received routine care at baseline and 1 month. Patient education module consisted of an audio-visual display and a pamphlet on diabetes foot care. Change in score at 3 months was assessed by Student's *t*-test. **Results:** Knowledge scores in the intervention group at first, second, and third visits were  $9.8 \pm 1.8$ ,  $10.2 \pm 1.6$ , and  $11.0 \pm 1.7$ , respectively. The knowledge scores in the control group at first, second, and third visits were  $9.9 \pm 1.7$ ,  $9.8 \pm 1.6$ , and  $10.0 \pm 1.8$ , respectively. The change in knowledge score was statistically significant ( $P < 0.001$ ) at third visit compared to first in the intervention group but not in the control group ( $P = 0.62$ ). Practice score also improved significantly ( $P < 0.001$ ) in the intervention group in the second visit but not in the control group. **Conclusion:** Audio-visual foot care patient education module in outpatient setting is an effective means to improve foot care knowledge and practice in patients with diabetes.

**Keywords:** Audio-visual aid, diabetic foot, foot care education, patient education module

## INTRODUCTION

Diabetic foot adds to economic burden due to huge expenditure on treatment, loss of productivity, frequent recurrence of the problem, and high rate of amputation. An estimated 40,000 legs are amputated each year in India, of which 75% are because of neuropathy and secondary infection and these are potentially preventable.<sup>[1]</sup> In terms of expenditure, patients without diabetic foot problem spent 9.3%, whereas patients with foot problem spent 32.3% of their total income on their treatment.<sup>[2]</sup> This underscores the importance of prevention of diabetic foot.

In a previous study,<sup>[3]</sup> from our institute, a tertiary care hospital in India, it was found that 33% of diabetes patients attending our outpatient department (OPD) had loss of protective sensations, 19% had peripheral vascular disease, and 10% had both. More alarmingly, 95% had never received foot

care advice. In another study,<sup>[4]</sup> the average knowledge about diabetic foot care of our patients was poor.

It is reported that consultation time given by the treating doctors to their patients with diabetes was <5 min in nearly 50% of cases, and foot care education to prevent complications was least emphasized by doctors.<sup>[5]</sup> This could be attributed to high patient load and lack of time and resources. On the other hand, simple foot care education measures have been shown to reduce foot problems such as corns and callosities and promote healing of foot ulcer.<sup>[6]</sup>

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Above studies<sup>[3,4]</sup> highlight the importance of delivering foot education in patients with diabetes in our setup which can fit into present health-care delivery system. This prompted us to develop a patient education module on diabetes foot care and to assess the effectiveness of this module on foot care knowledge and practice in patients with diabetes.

## MATERIALS AND METHODS

Adult patients (>18 years age) with the diagnosis of diabetes mellitus type 1 or 2 attending endocrinology OPD, All India Institute of Medical Sciences (AIIMS), New Delhi, from July 2015 to December 2016, ready for follow-up at 1 and 3 months, were included in this study. Diabetes was diagnosed according to the American Diabetes Association (ADA) 2014 criteria.<sup>[7]</sup> Patients with history of previous or present foot ulcer, cognitive, and visual or hearing impairment were excluded from the study. Participants were recruited after obtaining approval from the Institutional Ethics Committee and informed consent from participants.

Based on previous study,<sup>[4]</sup> the average knowledge score of diabetic foot care is likely to be  $5 \pm 3$  out of a total score 14 among patients with diabetes. After intervention of 3 months, expecting this knowledge score improves to  $8 \pm 3.5$  among cases, while in controls, it improves to  $6 \pm 3.5$ , we required 50 subjects in each group to detect a significant difference in the knowledge scores at 3 months postrandomization in two-sided Student's *t*-test with 5% alpha error and 80% power. After giving an allowance of 20% loss to follow-up, we needed to randomize 125 patients into two groups.

Patients were divided into intervention and control groups using block randomization. The size of the blocks was variable from 2 to 8. The sequence of random number generated was transferred to a sealed opaque envelopes for the implementation of randomization. At baseline, both intervention and control groups were given a questionnaire to fill up. Then, both groups received routine care which consisted of education regarding glycemic control, dietary advice, exercise, medications, and foot care provided by the health-care personnel in the OPD. In addition, the intervention group was shown a short audio-visual display and given a pamphlet on diabetic foot care. After 1 month, both groups once again filled up the questionnaire following which they received routine care. In addition, the intervention group was again shown the audio-visual display. At 3 months, both groups filled up the questionnaire for the third time [Figure 1].

The questionnaire had two parts: the first part had 14 questions on knowledge, yes/no type – each right answer scored one and wrong response scored zero; the second part had five questions on practice – the best answer scored two, the wrong one zero, and for other response score was one. Total score was calculated separately for knowledge and practice at baseline, 1 month, and 3 months. The questionnaire [Table 1]

**Table 1: Questionnaire used to assess knowledge and practice**

|   | Yes/no  |
|---|---|
| Questions on knowledge  |   |
| 1. A person with diabetes is more prone to foot ulcer/ amputation compared to person without diabetes   |   |
| 2. A person with diabetes may develop numbness and loss of sensation in his/her feet  |   |
| 3. A person with diabetes should inspect his/her feet for any cracks, cuts, red spots, or blisters once a week                                      |   |
| 4. A person with diabetes should not walk bare footed   |   |
| 5. A person with diabetes should always wear socks with shoes   |   |
| 6. A person with diabetes should wear dark-colored, nylon socks with tight elastic  |   |
| 7. A person with diabetes should check inside of shoes before wearing   |   |
| 8. A person with diabetes should keep their feet warm using heaters in winters  |   |
| 9. Person with diabetes should regularly apply lotion/ moisturizer on both sides of feet to prevent cracks and should keep skin in between toes dry |   |
| 10. Person with diabetes should avoid trimming their toe nails  |   |
| 11. Blood sugar control has no role in preventing foot problems   |   |
| 12. Smoking does not increase the chance of amputation in person with diabetes  |   |
| 13. A person with diabetes should wear footwear with large front space, covering all toes or with adjustable Velcro                                 |   |
| 14. Corns and calluses may be removed by blade/ corn caps/chemical  |   |
| Questions on practice   |   |
| 1. How often do you inspect your feet for any cracks, cuts, red spots, or blisters?   | Daily/once a week or once a month/never                                       |
| 2. How often do you use footwear within home?   | Always/sometimes/never  |
| 3. During winters do you warm your feet using heaters?  | Yes regularly/yes whenever needed/never                                       |
| 4. How frequently do you apply lotion/moisturizer on top and bottom of feet?  | Daily/as and when needed/never  |
| 5. What is your current smoking status (or tobacco use)?  | Never smoked/used to smoke, now don't or have reduced/currently smoking daily |

was made on the basis of foot care practices advised by the ADA 2014<sup>[7]</sup> and the National Diabetes Education Program (NDEP).<sup>[8]</sup> It comprised questions assessing patient's knowledge on foot care practices and why patient should adopt these practices.

The patient education module consisted of an audio-visual display and a pamphlet. First, a script covering all important preventive aspects of foot care practices as advised by ADA and NDEP was prepared.<sup>[7,8]</sup> Then, with the help of Centre for

Medical Education and Technology, AIIMS, New Delhi, a short audio-visual display (~9 min) on foot care education was prepared. An educational pamphlet covering important aspects of foot care was made with the help of Centre for Community Medicine, AIIMS, New Delhi.

The YouTube links of the audio-visual aid prepared are <https://youtube/N6W1ooSLdf8> and <https://youtube/fgCifUg2pIA>

The knowledge and practice scores regarding diabetic foot care between the intervention and control were compared using two-sided Student's *t*-test. The change in scores in both groups was also compared by Student's *t*-test. *P* < 0.05 was considered statistically significant.

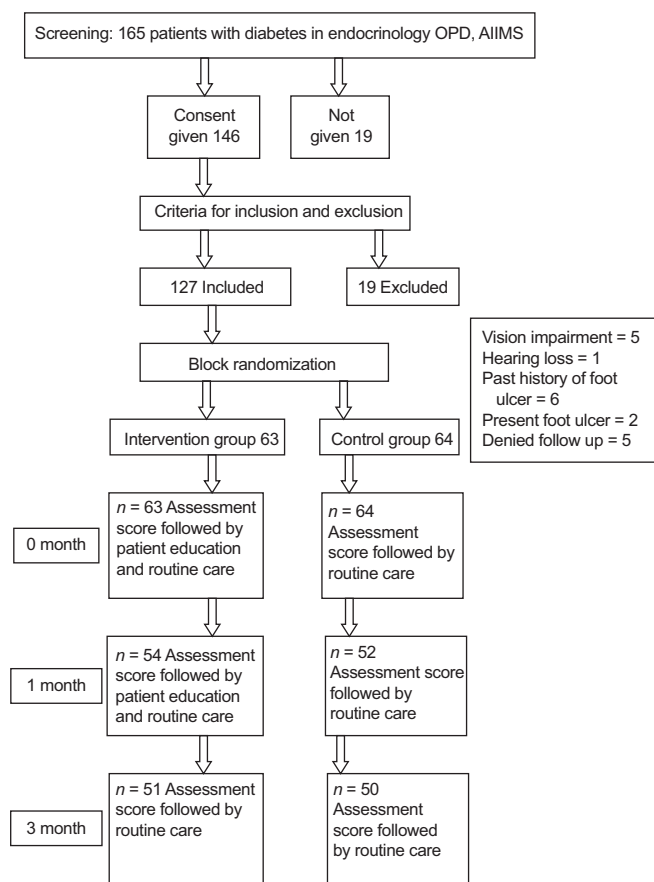


Figure 1: Consort diagram of the study

## RESULTS

Of 64 patients, 51 enrolled in the intervention group and 50 of 63 patients in control group completed all three visits. At baseline, both groups were similar with respect to duration and control of diabetes [Table 2]. Baseline knowledge scores in the intervention and control groups were  $9.8 \pm 1.8$  and  $9.9 \pm 1.7$ , respectively, which changed in second visit to  $10.2 \pm 1.6$  and  $9.8 \pm 1.6$ , respectively. Finally, in third visit, this knowledge score reached to  $11.0 \pm 1.7$  and  $10.0 \pm 1.8$  in both groups, respectively.

The practice scores at baseline in the two groups were  $6.0 \pm 1.9$  versus  $6.6 \pm 2.0$ , respectively. In the second visit, it was  $7.0 \pm 1.8$  versus  $6.9 \pm 1.8$  and in final visit the values were  $7.6 \pm 1.6$  versus  $7.1 \pm 1.7$  in intervention and control groups, respectively.

On comparing the changes in knowledge scores in both groups at different visits [Table 3], there was increase in knowledge score at 1 month, which became statistically significant at 3 months in the intervention group. However, in control group, knowledge score decreased at 1 month and showed no significant difference at 3 months [Figure 2]. The change in practice score was statistically significant in the intervention group in first to second visit [Figure 3].

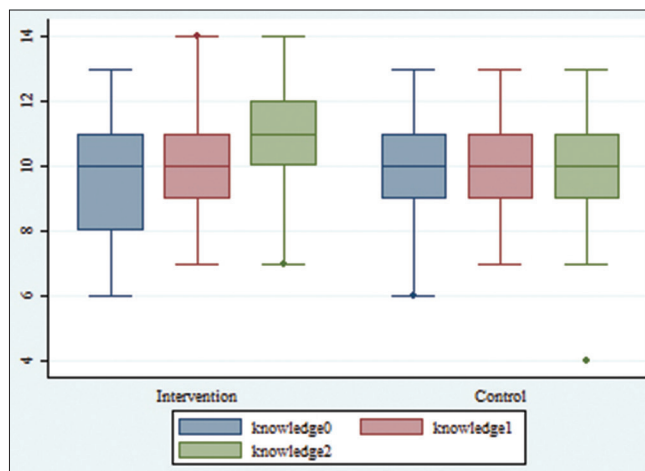


Figure 2: Box whisker plot showing change in knowledge score over three visits in both intervention and control groups

Table 2: Baseline parameters of both groups

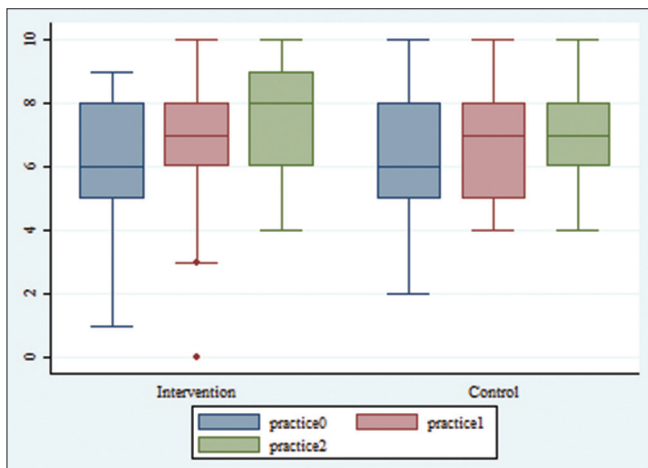
| Parameters                         | All participants    |                | Those who completed all three visits |                |
|------------------------------------|---------------------|----------------|--------------------------------------|----------------|
|                                    | Intervention (n=64) | Control (n=63) | Intervention (n=51)                  | Control (n=50) |
| Age                                | 48.7±11.7           | 44.1±12.8      | 47.9±12.1                            | 46.0±11.9      |
| Sex (%)                            |                     |                |                                      |                |
| Female                             | 26 (41.3)           | 31 (48.4)      | 20 (39)                              | 26 (52)        |
| Duration of DM (year)              | 9.3±8.4             | 6.9±6.3        | 9.5±8.9                              | 7.6±6.7        |
| Fasting blood glucose (mg/dL)      | 155.5±57.8          | 146.5±44.0     | 162.1±58.0                           | 150.4±45.5     |
| Postprandial blood glucose (mg/dL) | 219.8±66.1          | 208±65.8       | 223.7±65.3                           | 212.5±71       |
| Glycated haemoglobin (%)           | 8.1±1.8             | 8.5±2.4        | 8.2±1.7                              | 8.6±2.5        |

DM: Diabetes mellitus

**Table 3: Change in knowledge and practice score**

|                       | Change in knowledge score |        |                    |      | Change in practice score |        |                    |       |
|-----------------------|---------------------------|--------|--------------------|------|--------------------------|--------|--------------------|-------|
|                       | Intervention (n=51)       |        | Control (n=50)     |      | Intervention (n=51)      |        | Control (n=50)     |       |
|                       | Delta (95% CI)            | P      | Delta (95% CI)     | P    | Delta (95% CI)           | P      | Delta (95% CI)     | P     |
| First to second visit | 0.37 (-0.10-0.84)         | 0.12   | -0.08 (-0.48-0.32) | 0.69 | 0.92 (0.41-1.42)         | <0.001 | 0.32 (-0.003-0.64) | 0.52  |
| First to third visit  | 1.17 (0.70-1.64)          | <0.001 | 0.1 (-0.30-0.50)   | 0.62 | 1.6 (1.09-2.11)          | <0.001 | 0.48 (0.16-0.80)   | 0.004 |

CI: Confidence interval



**Figure 3:** Box whisker plot showing change in practice score over three visits in both intervention and control groups

## DISCUSSION

In our study, 80% of participants completed all three visits. Baseline knowledge and practice scores were comparable in the two groups. Knowledge score was significantly higher in the intervention group at third visit. When changes in knowledge scores at different visits were compared, a significant increase in knowledge score was observed in second to third visit in the intervention group.

The practice score was not different till second visit between the two groups. But, at third visit, intervention group had significantly higher practice score. However, a significant change in foot care behavior among participants as reflected in practice score was observed as early as second visit and this improvement persisted in third visit.

There are few randomized controlled trials (RCTs) to note the effect of health-care education on foot care knowledge and behavior in patients with diabetes, and their results are inconsistent.

Self-reported foot self-care behavior was significantly better in the intervention group at 1-month follow-up after a 15 min intervention in the Mexican-American population.<sup>[9]</sup> Another study on educational program on foot care behavior had to be terminated prematurely as there was significantly higher incidence of foot ulcer in the control group.<sup>[10]</sup> One recent RCT reported significantly lower incidence of new ulcer (18% vs. 31%) in the intervention group as compared to controls.<sup>[11]</sup> Various other studies also showed improvement

in patient knowledge and foot care behavior with educational intervention.<sup>[12-15]</sup>

However, Lincoln *et al.* found no significant difference between the control and intervention groups, in secondary prevention of foot ulcer at 6 or 12 months.<sup>[16]</sup>

In a systematic review of 12 rcts to look at the effect of patient education on prevention of foot ulcer in patients with diabetes,<sup>[17]</sup> only five rcts reported incidence of foot ulcer. One<sup>[18]</sup> of them showed reduction in incidence of foot ulcer (risk ratio 0.31, 95% Confidence interval 0.14–0.66). Over 1-year follow-up and rest of the studies did not demonstrate any benefit.<sup>[16,19-21]</sup> They concluded that the knowledge and foot care score were positively influenced in short term by patient education, but evidence for clinically significant reductions in diabetic foot ulcer and amputation incidence by patient education was insufficient. Another recent systematic review on 30 controlled (of which 19 rct) and 44 uncontrolled studies on prevention of first and recurrent plantar foot ulcers found no benefit of a single session of patient education but some evidence of benefit of integrated foot care (i.e., A combination of professional foot treatment, therapeutic footwear, and patient education).<sup>[22]</sup>

The strength of our study is that our patient education module is easily replicable and does not need much investment. It can be implemented in routine care outpatient setting in Indian context. However, we could not follow these patients on long-term basis to note the impact of improvement in knowledge and practice on development of foot ulcer.

## CONCLUSION

To have persistent change in foot care behavior, the patients need reinforcement on regular basis. Audio-visual aids on diabetic foot education shown on a routine basis in OPD waiting hours is an effective way to achieve this. Our study clearly demonstrates significant improvement in diabetic foot knowledge and foot care behavior in the patients who received foot care education through audio-visual aid. Regular reinforcement of foot care education through audio-visual aid in OPD waiting hours is a good option.

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### Conflicts of interest

There are no conflicts of interest.

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