Journal of Endocrinology, Metabolism and Diabetes of South Africa 2022; 27(1):20–31
https://doi.org/10.1080/16089677.2021.1980972

JEMDSA
ISSN 1608-9677 EISSN 2220-1009

ARTICLE

The effectiveness of diabetic foot-care education in a South African regional hospital: a randomised controlled trial*

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Background and aims: Improving foot-care knowledge and practice is the foundation of curbing diabetic foot disease and subsequent amputation. This study aimed to determine the effectiveness of a foot-care education module on change in knowledge and behaviour among patients living with diabetes mellitus (DM).
Methods: A total of 120 participants with Type 2 diabetes mellitus (T2DM were recruited) from Addington Hospital Medical Outpatient Department and randomised them into three groups. A pre- and post-test questionnaire was administered to participants on recruitment and six weeks later. All groups received baseline treatment and Group 1 did not receive any further treatment. Participants in Group 2 received a foot-care handout with instructions. Group 3 received a teaching session, foot-care handout with instructions and pictures on practices as well as five lower-limb exercises. Group 2 and 3 participants were requested to follow the instructions on the handouts.
Results: Transfer of knowledge of foot care was successful and practice of foot care improved among all groups following the intervention. Groups 2 and 3 showed significant improvement in behaviour and this was highest in Group 3. Knowledge transfer of exercises was successful in Group 3.
Conclusion: A face-to-face education module improves foot-care knowledge and practice among patients with DM.

Keywords: knowledge of foot care, practice of foot care, self-care activities, lower limb exercises, foot-care intervention

Introduction

Complications of diabetes mellitus (DM) are financially demanding on the health system.[1] The total worldwide health expenditure due to DM was approximately US$ 673 billion in 2015 and this amount is expected to increase to US$ 802 billion by 2040.[2] Approximately 85% of diabetes-related amputations are as a result of diabetic foot ulcers (DFU) and account for more than half of non-traumatic lower extremity amputations (LEAs).[3] A previous local study by this author showed that more than 50% of amputations were attributed to DM, indicating an urgent need for foot-care intervention.[4] The financial implications of diabetic LEA include direct costs of treatment and indirect costs relating to the loss of productivity and a reduction in the quality of life.[5]

The literature is exhaustive with information on knowledge and practice of good foot care.[6,7] However, there is variability in foot-care knowledge and its practice among participants in these studies, with some studies showing little or no knowledge and not practising good foot care while others demonstrate reasonable to good knowledge and practice.[6,7] Poor or suboptimal foot care is known to increase the risk of developing DFUs and subsequent amputation, and this has been explained by inadequate and/or inappropriate patient education provided by primary care clinicians.[8] This emphasises the need for diabetes self-management education programmes that aim to prevent complications of DM.

Studies on self-managed foot care in patients diagnosed with DM have not been investigated in the province of KwaZulu-Natal or indeed the rest of South Africa. Whilst foot-care management programmes may be an established clinical practice in other countries, there is a scarcity of literature on educational management programmes in South Africa. Furthermore, despite ample reports on foot-care knowledge and practice, there is very little information globally on the role of intervention strategies to reduce the complications of DM.[9–11] Admittedly, a few isolated studies have reported on specific forms of intervention such as flip-chart display[12] and audiovisual display with a pamphlet followed by reinforcement.[13]

To address this dearth of data, the authors developed and tested a diabetic self-management educational programme for patients living with DM and attending Addington Hospital. The investigator developed a new questionnaire based on well-established foot-care principles. The questionnaire was used for the initial and follow-up interviews. The investigator developed two separate interventions, namely Group 2 (instructional handout) and Group 3 (educational intervention) using the well-established foot-care principles. The questionnaire and interventions were thereafter translated by a professional language practitioner for patients whose first language is isiZulu. As per the language practitioner, the process of translation included read, translate, edit, proofread and back-translate.

*Trial Registered with Pan African Clinical Trials Registry: PACTR202104860816372.

Author Contributions: Concept and study design: PM, TEM, SR; Data collection: PM; Draft and subsequent versions: PM, TEM; A critical review of the draft manuscript and final version: PM, SR, TEM; All authors approved the final version of this manuscript.

We hypothesised that an educational programme would be beneficial to patients with DM in improving their understanding of foot-care practices and also adopting these principles into their daily routine. The educational programme described here included components of knowledge and practice of foot care and a short exercise programme for the lower limbs. This study evaluated the level of foot-care knowledge and practices among patients with DM and sought to establish if a structured education programme would provide any change in knowledge and behaviour regarding foot care. The objectives of the study were to, (i) assess current knowledge of foot care and lower limb exercise, (ii) assess the current practice of foot care and lower limb exercise, (iii) educate patients on a simple self-management foot care and exercise module, and (iv) evaluate the effect of the education and exercise programme on the patient's knowledge and changes in behaviour.

Methods

Study design

A randomised control trial (RCT) consisting of three groups was conducted on participants with T2DM. A pre- and post-test survey design was used. This educational study was conducted and reported on in keeping with the requirements of the Consolidated Standards of Reporting Trials (CONSORT) statement.[14]

Study setting

The study was conducted at Addington Hospital (ADH), Durban, South Africa. Addington Hospital, classified as a district and regional hospital, is located in the eThekwini District and provides healthcare services to many patients in the eThekwini area. It is also a referral hospital for many hospitals and clinics in the area, providing services to patients that the surrounding smaller hospitals or clinics cannot provide.

Participants

All participants diagnosed with T2DM attending ADH Medical Outpatients Department (MOPD) were recruited into the study on the day of presentation to the MOPD from January 2020 to March 2020 until the sample size of 120 was reached. Inclusion criteria were all patients who presented with a diagnosis of T2DM, patients without foot complications and patients who were able to converse in English and/or isiZulu. Exclusion criteria included patients with foot complications, those who did not give consent, patients with mental illness and children.

To assess the change in foot-care knowledge and practice scores, before and after interventions, among patients with DM, the minimum required sample size for each group was 26. With a probability of 95% and a change of +2 detected in scores, the statistical power of the study was 80%. This assumes a baseline score of 3 and a standard deviation of 2.5. If the loss to follow up at 6 weeks was 20%, a sample size of 33 per group was required. The sample size was calculated using Stata V13.1 statistical software (StataCorp, College Station, TX, USA). We chose to round this number off at 40 per group for consideration of a greater loss to follow-up; this is because most of the patients serviced by ADH fall into the low-to-middle socioeconomic category and may sometimes forgo their appointments due to financial constraints and other socioeconomic challenges.

A randomised sampling technique was used, with participants allocated into three groups of 40 participants per group. The randomisation was performed by an independent healthcare practitioner through random stratification using numbers 1, 2, 3, etc., and the sealed envelope system. The independent healthcare practitioners at the outpatient clinic were blinded to the intervention for each group.

Interventions

Baseline care

All groups in this study received baseline care. Participants in Group 1 (Control Group) received baseline treatment from the clinic and no additional information. Baseline treatment included regular vitals check by the nurses before consultation with a doctor in the clinic as per their appointment.

At the initial interview, participants were administered the pre-test questionnaire and thereafter the intervention as per their randomisation.

Instructional handout intervention group

Group 2 (Instructional handout intervention group) received an instructional handout, with instructions only, on foot-care practices for each foot-care principle that they were instructed to follow (see supplementary file 1). The handout was provided to the participant within one minute following the pre-test questionnaire. Participants were told that it was a handout for foot care and no further reinforcement was provided.

Educational intervention group

Participants in Group 3 (Educational Intervention Group) were given the following: (i) a handout with instructions and pictures on foot-care practices for each foot-care principle (see supplementary file 2) and instructions with pictures on five simple lower limb exercises, (ii) individual instructions on how to apply the foot-care practices described on the handout, (iii) teaching and demonstration of the exercises on the handout by the Principal Investigator (PI) or a trained research assistant for those patients whose first language was isiZulu. Only participants in this group were provided with a handout that consisted of pictures of foot-care practices and exercises. Participants in all groups were given a series of appropriate exercises and random inappropriate exercises for people living with diabetes (in the form of pictures) and they were asked to choose the appropriate ones. This was performed before and after the intervention. Thereafter, the correct exercises were taught and demonstrated only to participants in Group 3 by the researcher or trained research assistant. This was to establish whether a successful knowledge transfer and a change in behaviour could be achieved with an active education module. The investigator also supervised the participants during the conduct of the exercises. The exercises were simple, low-intensity and could be done by all ages without exertion. Participants in Group 3 were given a 30-minute teaching session on foot-care instructions and exercises in addition to the pre-test questionnaire as described above.

Measurements

The primary outcome in the current study was to establish if there was a change in knowledge and behaviour following a face-to-face teaching module. The secondary outcome was to determine if the instructional handout alone (as provided to Group 2) led to any change in knowledge and behaviour.

Data were collected over four days from 20 to 23 January 2020 for the first interview and from 2 to 5 March 2020 for the second interview, six weeks later. A close-ended questionnaire (see

supplementary file 3) was developed for data gathering and was administered at the first (pre-test) and second (post-test) interviews. One questionnaire was administered to the participants for both visits and the responses for each visit were captured in a separate column (one column for visit 1 and one column for visit 2). The questionnaire included various components such as demographic information, risk factors of DM, knowledge on foot care (scored out of 11, pre- and post-test), foot-care practices (scored out of 11, pre- and post-test), and knowledge on exercises. The section on knowledge of exercises was presented as pictures that required participants to identify exercises they found suitable for patients with DM (scored out of 5, pre- and post-test). Finally, a participant feedback component on knowledge and practices of foot care was administered to the intervention group (Group 3).

After obtaining consent from the participant, the questionnaire was investigator administered by the PI or by a trained research assistant if the participant's first language was isiZulu. The research assistant was first briefed on the aims and objectives of the study. The questionnaire and the interventions were then explained in detail by the PI. The PI also performed a mock trial interview of the questionnaire and interventions with a volunteer participant in the physiotherapy department as part of a practice session for the research assistant. The investigator was present for all interviews irrespective of language. If a participant did not grant consent, the next eligible participant was recruited until the sample size of 120 was reached. The five lower limb exercises given to Group 3 were extracted from established exercises directed at improving blood circulation, muscle strength and mobility in the limbs.[15–19] The post-test questionnaire was administered by a trained research assistant to eliminate post-test bias.

Table 1 provides an understanding of the five different exercises chosen for this study, the type of exercise and the benefits it provides to patients with DM. Participants in Groups 2 and 3 were advised to follow the instructions on the pamphlets. All groups were re-tested at six weeks at their follow-up clinic appointment.

Table 1: Exercises, types of exercise and benefits to patients with diabetes

Exercise	Type of exercise	Benefit to patient
1. Ankle plantarflexion and dorsiflexion	Active, resistance, stretching	Active exercise—maintains good joint mobility[19] Resistance exercise—enhances insulin activity, increases muscle strength, enhances functional status and glycaemic control[14] Stretching exercise—in the ankle reduces arch deformation, excessive pronation, rear foot valgus and improves ankle joint mobility, in other joints improves mobility[19] A general exercise training programme improves and maintains the foot biomechanics[19] A simple, routine exercise programme could result in fewer ulcerations of the plantar foot[19]
2. Ankle circumduction	Active, stretching	
3. Knee flexion and extension	Active, resistance, stretching	
4. Knee lifts	Active, resistance, stretching	
5. Walking on the spot	Active, resistance	

While we did not adapt an available foot-care questionnaire or intervention, the development of the questionnaire for the current study was devised using the various principles of foot care reported in current global literature.[20,21] The questionnaire and interventions were guided by the International Working Group on the Diabetic Foot (IWGDF) who reported evidenced-based guidelines for the prevention of foot ulcers[21] and principles of foot care reported in other global literature.[20] The use of these exercises has been supported by Thent *et al*., who have emphasised that the various types of exercise such as aerobic, resistance, short-term, endurance etc. are beneficial for people living with DM.[15] The terminology used in the questionnaire and interventions was simple language to ensure understanding by all participants at various levels of education.

The content validity of the questionnaire for the current study was guided by the Delphi method[22] and was ensured by forwarding the questionnaire for review to several healthcare professionals. These professionals were chosen based on their expertise in their field of education and employment. The healthcare professionals included in the review were nurses,[4] physiotherapists[9] and occupational therapists[4] employed at ADH at the time. The healthcare providers chosen for the feedback of the questionnaire were selected because they are or were actively involved in the management of amputees at ADH and in the institutions (private and public) at which they were previously employed. Before providing the questionnaire to the selected individuals for review, the investigator requested permission from the healthcare professionals to participate in this process of validation. Following verbal consent from the healthcare professionals, the investigator hand-delivered the questionnaires to each healthcare professional together with a briefing on the aims and objectives of the current study. They were requested to assess the accuracy and appropriateness of the questionnaire, taking into cognizance the objectives of the study, and provide feedback that would improve the questionnaire. The feedback was documented in a space available adjacent to each question. They were allocated a timeframe of two weeks to undertake this process and thereafter the investigator met with the participants on a one-on-one basis for a discussion on their findings. Only three physiotherapists provided comments for consideration while all the other healthcare professionals conceded that the questionnaire was ideal for the population that was to be evaluated. The questionnaire was amended to incorporate the feedback received to ensure accuracy and appropriateness. Modifications of the questionnaire included redrafting two questions to ensure appropriateness, the addition of certain questions, and redrafting into simpler terminology. Once these modifications were complete, the investigator met with the physiotherapists[9] only, for the second time, to discuss the revisions. The other participants excused themselves from this discussion as they were satisfied with the original version. A week later, the PI revisited the physiotherapists on a one-to-one basis and discussed the modified questionnaire. A consensus was reached by all nine physiotherapists that the questionnaire was adequate, appropriate and relative to the study objectives. The final version of the questionnaire was assessed by a senior surgeon (TEM) and a statistician who reached the same consensus as did the physiotherapists.

A pilot study was conducted amongst 15 randomly selected participants diagnosed with T2DM, distributed amongst the three groups. After the pilot study, revisions to the questionnaire included revision of (a) three ambiguous questions,

(b) the order of questions, and (c) to improve conciseness. Also, some instructions on the handouts were revised for clarity. In addition, the initially allocated time limit of 15–20 minutes to complete the questionnaire was increased to 30. This excluded the 30 minutes allocated for the teaching session for Group 3.

An independent observer was present during all interviews to ensure that the questions were asked in the same manner of each participant, and that participant responses were entered accurately ensuring that there was no bias in the procedure. To eliminate post-test bias, the research assistant performed

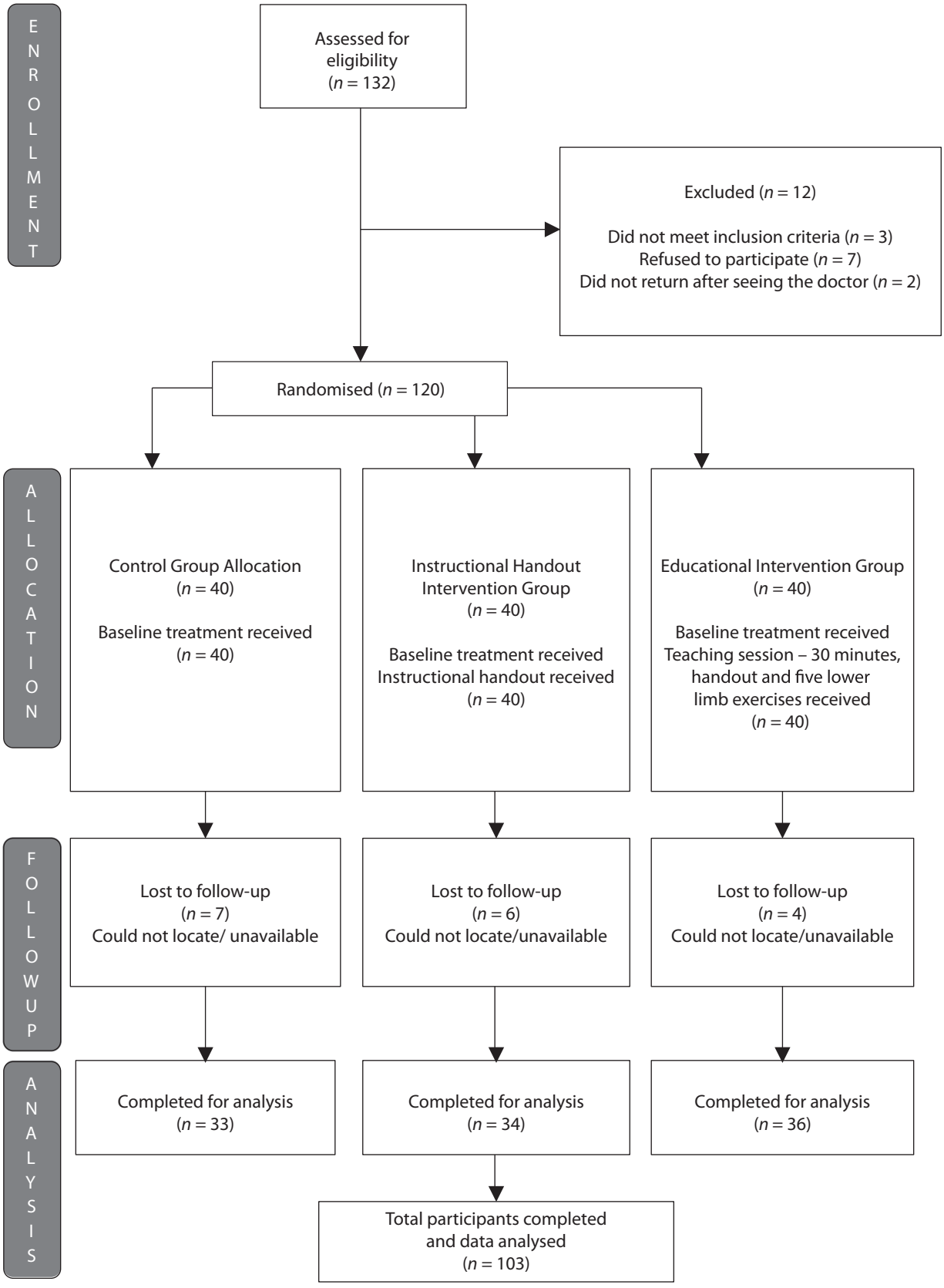

Figure 1: Participant flow diagram.

the post-test interviews in the presence of the PI. The Cronbach's alpha coefficient[23] was used to ensure the reliability of the questionnaire. Internal consistency was ensured by determining the Cronbach's alpha coefficient, which was 0.812 for knowledge and 0.837 for practice, making these areas reliable for this study.

Ethical considerations

Data collection commenced following regulatory approvals for the study from the Biomedical Research Ethics Committee of the University of KwaZulu-Natal (BREC 236/19) and on-site approval was given by the Hospital Manager of Addington Hospital. The trial was registered with the Pan African Clinical Trials Registry: PACTR202104860816372.

Data management and analysis

The data from the questionnaire were analysed after being coded and transferred to Microsoft Excel (Microsoft Corp, Redmond, WA, USA). Stata V15.1 was used in the statistical analysis. The knowledge and practice of foot care were expressed as scores. The scale chosen by the researcher for answers by participants and allocation of marks for a score for each question on knowledge and practice of foot care was as follows: 'Always/Yes = 1 mark'; 'Sometimes = 0 mark'; 'Never/No = 0 mark'; 'Don't know' = 0 marks'. This scoring was adapted from Desalu *et al*.[24] Demographics and risk factors were compared among the groups. Median and interquartile range (IQR) were used to summarise age. Means and standard deviations were used to summarise BMI. The Shapiro–Wilks test was used to test for normality. One-way ANOVA was used in the comparison of age where the assumption of normality was met. BMI did not meet the assumption of normality, so the Kruskal–Wallis test was used in the comparison. The chi-square test was used in the comparison of categorical characteristics. However, where expected cell sizes were less than 5, Fisher's exact test was used. Knowledge and practice were scored as 1 for 'one mark' and 0 for 'no mark' as stated above. A total score for each section was calculated as the sum of the correct answers in each section. The mean differences in knowledge and practice were normally distributed and a paired Student *t*-test was used to compare the change in each group. Analysis of variance was used to compare the change in knowledge and practice scores among the three groups. Comparisons of responses between pre- and post for each knowledge and practice question were compared for each question in each group using McNemar's chi-square test. For assessment of exercise responses, the number of correctly identified pictures was counted. The number of responses was ordinal, ranging from 0 to 5. The number of correct exercises identified by participants was reported using percentages. Because of the ordinal nature of the data, the Wilcoxon signed-

Table 2: Demographic information according to groups

	Control Group (1)		Intervention Group (2) (Handout)		Intervention Group (3) (Education)		Total	Overall *p*-value
	(*n* = 33)		(*n* = 34)		(*n* = 36)		(*n* = 103)	
Age (median, IQR)	61 (55–66)		62.5 (54–70)		62.5 (58–73)		62 (55–70)	0.55***
Age group	*n*	%	*n*	%	*n*	%	*n*	0.85*
< 55	8	24.2%	9	26.5%	6	16.7%	23	
55–64	13	39.4%	11	32.4%	14	38.9%	38	
65–88	12	36.4%	14	41.2%	16	44.4%	42	
Sex:								0.69*
Female	25	75.8%	28	82.4%	30	83.3%	83	
Male	8	24.2%	6	17.6%	6	16.7%	20	
Co-morbid conditions:								
Heart disease	16	48.5%	24	70.6%	18	50.0%	58	0.12*
High blood pressure	25	75.8%	30	88.2%	33	91.7%	88	0.17**
High cholesterol	26	78.8%	32	94.1%	28	77.8%	86	0.11**
Lung disease	1	3.0%	5	14.7%	2	5.6%	8	0.21**
Breast cancer	0	0.0%	0	0.0%	1	2.8%	1	0.90**
Eczema	0	0.0%	0	0.0%	1	2.8%	1	0.90**
Renal disease	4	12.1%	8	23.5%	5	13.9%	17	0.45**
HIV	1	3.0%	1	2.9%	0	0.0%	2	0.54**
Anaemia	0	0.0%	1	2.9%	0	0.0%	1	0.65**
Osteoarthritis	1	3.0%	4	11.8%	2	5.6%	7	0.39**
Educational level:								0.36**
Read and write	0	0.0%	2	5.9%	2	5.6%	4	
Primary	8	24.2%	12	35.3%	16	44.4%	36 (35%)	
Secondary	24	72.7%	18	52.9%	17	47.2%	59 (57%)	
Tertiary	1	3.0%	2	5.9%	1	2.8%	4 (3.9%)	
Employment:								0.94*
Yes	3	9.1%	3	8.8%	4	11.1%	10	
No	30	90.9%	31	91.2%	32	88.9%	93	

*Chi-square test; **Fisher's exact test; ***Kruskal–Wallis test.

Table 3: Risk factors of patients

Risk factors		Control Group (1) (*n* = 33)		Intervention Group (2) (Handout) (*n* = 34)		Intervention Group (3) (Education) (*n* = 36)		Total	*p*-value
		n	%	*n*	%	*n*	%	*n*	
Smoking	Yes	7	21.2%	9	26.5%	9	25.0%	25	0.88*
	No	26	78.8%	25	73.5%	27	75.0%	78	
Alcohol	Yes	7	21.2%	8	23.5%	7	19.4%	22	0.92*
	No	26	78.8%	26	76.5%	29	80.6%	81	
Parents/siblings with DM	Yes	26	78.8%	26	76.5%	25	69.4%	77	0.65*
	No	7	21.2%	8	23.5%	11	30.6%	26	
Parents/siblings with LLA	Yes	6	18.2%	10	29.4%	7	19.4%	23	0.48*
	No	27	81.8%	24	70.6%	29	80.6%	80	
Referral to dietitian	Yes	12	36.4%	14	41.2%	19	52.8%	45	0.37*
	No	21	63.6%	20	58.8%	17	47.2%	58	
Physical exercise	Yes	13	39.4%	13	38.2%	11	30.6%	37	0.70*
	No	20	60.6%	21	61.8%	25	69.4%	66	
Information on foot care	Yes	5	15.2%	2	5.9%	6	16.7%	13	0.35*
	No	28	84.8%	32	94.1%	30	83.3%	90	
Body mass index (BMI) category									0.018**
Normal (18.5–24.9)		3	9.1%	14	41.2%	10	27.8%	27	
Overweight (25–29.9)		26	78.8%	16	47.1%	18	50.0%	60	
Obese (>30)		4	12.1%	4	11.8%	8	22.2%	16	
BMI, mean (SD)		27.7 (2.5)	26.3 (4.4)	27.1 (3.6)	27 (3.6)	0.019***			

*Chi-square test; **Fisher's exact test; ***Kruskal–Wallis test.

rank test was used to compare pre- and post-responses in each group. The Kruskal–Wallis test was used to compare the change in the number of correct answers between pre- and post- among the three groups that were significant. This was followed by Dunn's test with no adjustment for pairwise comparisons. A *p*-value of <0.05 was considered statistically significant.

Results

Figure 1 shows the participant flow diagram from enrolment to analysis. Seventeen participants (14.2%) did not return for the follow-up interview. Thus 103 (85.8%) participants were available for the second interview, namely 33 (32%) in Group 1, 34 (33%) in Group 2, and 36 (35%) in Group 3. Table 2 shows the demographic profile of the participants in the three groups. The median age was 62 (IQR 55–70) years. There were more females (83; 80.6%) giving a male-to-female ratio of 1:4. High blood pressure was the highest recorded co-morbid condition, followed by high cholesterol and heart disease. Fifty-nine participants (57%) had secondary school education and 36 (35%) had primary school education. Ninety-three participants (90%) were unemployed. As shown in Table 3 the risk factors for DM were similar in the three groups. There were no reports of any adverse effects from the interventions reported by the patients.

Figure 2 shows the mean knowledge scores in the three groups before and after the intervention as well as the change in scores following the intervention. There was no significant difference in the knowledge scores in Group 1. Significant improvement in knowledge scores in both Groups 2 and 3 was seen after the intervention and this improvement in knowledge was significantly higher in Group 2 compared with Group 1 ($p = 0.017$) and Group 3 compared with Group 1 ($p < 0.001$). The difference in improvement in knowledge in Group 3 vs. Group 2 was not statistically significant ($p = 0.058$). Detailed scores of the different responses to questions between pre-test and post-test are given in Table 4, which shows significant improvement in answers to each question after the intervention.

Figure 3 shows the mean practice scores in each group before and after the intervention. There was a significant improvement in practice in all groups when participants were tested at the second interview. There was no difference in the degree of improvement between Group 1 and Group 2 ($p = 0.13$) but there was a significant improvement in foot-care practice in Group 3 compared with Groups 1 and 2 ($p < 0.001$). Table 5

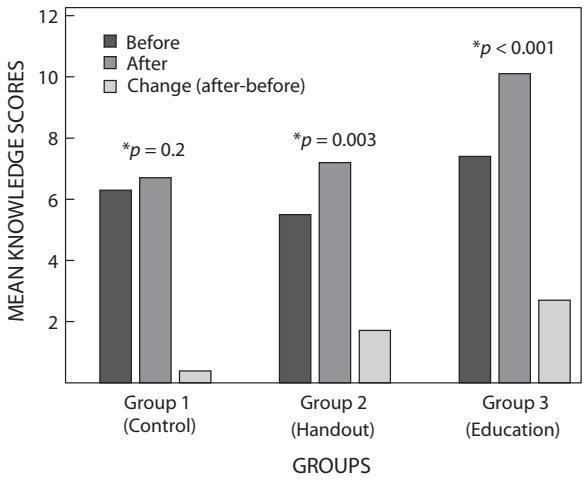

Figure 2: Results of mean knowledge scores before and after the intervention as well change in knowledge scores following the intervention.

**Legend: Change in score Group 1 vs. Group 2 $p = 0.017$; change in score Group 2 vs. Group 3 $p < 0.058$; change in score Group 1 vs. Group 3 $p < 0.001$. *Paired Student's *t*-test. **One-way ANOVA.

Table 4: Improvement in knowledge classified according to groups (*n* (%) = number of patients who responded 'Yes')

	Group 1 (Control)							Group 2 (Handout)							Group 3 (Intervention)						
	Pre-test		Post-test		Improvement			Pre-test		Post-test		Improvement			Pre-test		Post-test		Improvement		
	(*n* = 33)		(*n* = 33)					(*n* = 34)		(*n* = 34)					(*n* = 36)		(*n* = 36)				
Knowledge	***n***	**%**	***n***	**%**	***n***	**%**	***p*-value***	***n***	**%**	***n***	**%**	***n***	**%**	***p*-value***	***n***	**%**	***n***	**%**	***n***	**%**	***p*-value***
Are people with diabetes more prone to foot sores and amputations?	22	66.7%	20	60.6%	−2	−6.1%	0.69	19	55.9%	19	55.9%	0	0.00%	0.900	29	80.6%	32	88.9%	3	8.3%	0.375
Do people with diabetes have changes in the feeling in their feet?	21	63.6%	21	63.6%	0	0.0%	0.90	19	55.9%	20	58.8%	1	2.9%	0.900	27	75.0%	29	80.6%	2	5.6%	0.625
Should people with diabetes check their feet daily for redness, sores, blisters, cracks?	23	69.7%	25	75.8%	2	6.1%	0.63	22	64.7%	27	79.4%	5	14.7%	0.125	26	72.2%	36	100.0%	10	27.8%	0.002
Should people with diabetes dry their feet between the toes?	22	66.7%	25	75.8%	3	9.1%	0.38	23	67.6%	26	76.5%	3	8.8%	0.180	25	69.4%	36	100.0%	11	30.6%	0.001
Should people with diabetes wear closed shoes indoors and outdoors at all times?	13	39.4%	14	42.4%	1	3.0%	0.90	8	23.5%	18	52.9%	10	29.4%	0.013	14	38.9%	29	80.6%	15	41.7%	0.001
Should people with diabetes protect their feet from very hot and very cold temperatures?	24	72.7%	24	72.7%	0	0.0%	0.90	22	64.7%	26	76.5%	4	11.8%	0.219	28	77.8%	35	97.2%	7	19.4%	0.0156
Should people with diabetes moisturise the top and bottom of their feet daily?	19	57.6%	22	66.7%	3	9.1%	0.38	19	55.9%	28	82.4%	9	26.5%	0.012	24	66.7%	34	94.4%	10	27.8%	0.002
Should people with diabetes cut their toenails straight across?	16	48.5%	20	60.6%	4	12.1%	0.13	8	23.5%	19	55.9%	11	32.4%	0.003	20	55.6%	33	91.7%	13	36.1%	0.001
Do you think controlling blood sugar levels will help in preventing foot problems?	15	45.5%	16	48.5%	1	3.0%	0.90	22	64.7%	24	70.6%	2	5.9%	0.625	29	80.6%	31	86.1%	2	5.6%	0.5
Should people with diabetes have special footwear?	16	48.5%	19	57.6%	3	9.1%	0.45	12	35.3%	21	61.8%	9	26.5%	0.012	22	61.1%	33	91.7%	11	30.6%	0.001
Should people with diabetes be given specific exercises for their legs and feet?	17	51.5%	15	45.5%	−2	−6.1%	0.69	13	38.2%	17	50.0%	4	11.8%	0.125	22	61.1%	36	100.0%	14	38.9%	0.001
Total	208	55.6%	221	59.1%	13	3.5%		187	50.0%	245	65.5%	58	15.5%		266	71.1%	364	97.3%	98	26.2%	

*McNemar's chi-square test.

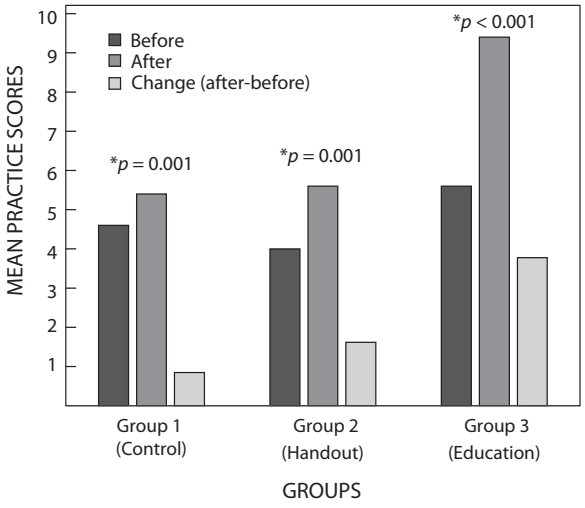

Figure 3: Showing the mean practice (behaviour) scores before and after the intervention as well as change in practice (behaviour) scores after the intervention

**Legend: Change in score Group 1 vs. Group 2 $p = 0.13$; change in score Group 2 vs. Group 3 $p < 0.001$; change in score Group 1 vs. Group 3 $p < 0.001$. *Paired Student's *t*-test. ** One-way ANOVA.

compares participants' foot-care behaviour before and after the intervention in all three groups. It shows the proportion of participants who admitted to having adopted foot-care behaviour. It also established the proportion of participants engaging in particular leg exercises that are specific for patients with DM. The highest number of correct answers to questions was seen in Group 3.

Figure 4 shows the mean scores of the exercises that were correctly identified. All three groups demonstrated an increase in scores after the intervention. This increase was more marked in Group 3. There was no significant difference in improvement in scores between Groups 1 and 2 ($p = 0.40$). There was a statistically greater improvement in scores seen in Group 3 vs. Group 2 ($p < 0.001$) and in Group 3 vs. Group 1 ($p < 0.001$). In addition (see Table 4), participants were asked, whether 'people with DM should be given specific exercises for the legs and feet'. Group 1 showed no improvement in knowledge on whether people with DM should be given specific exercises for their legs and feet ($p = 0.69$) whereas Group 2 showed slight improvement ($p = 0.125$). Group 3 showed significant improvement in the understanding of the role of leg exercise for people with DM ($p = 0.001$). Group 2 also showed a significant improvement in the practice of exercise ($p = 0.02$). The practice of exercise improved markedly after the intervention in Group 3 ($p = 0.01$). Participants were then asked if they did specific leg exercises. Nine of 33 participants in Group 1 (27.3%) answered in the affirmative to the question before and after the intervention. Eleven of 34 participants in Group 2 answered in the affirmative before the intervention (32.4%) and 12 of 34 (35.3%) ($p = 0.02$) after the intervention. Twelve of 36 participants in Group 3 (33.3%) answered in the affirmative and 35/36 (97.2%) did so after the intervention ($p = 0.01$). In addition, Table 6 indicates the number of correct exercises that were identified by participants before and after the intervention. Seventeen of 36 participants (47.2%) in Group 3 identified three correct exercises before the intervention, and 27 of 36 (75%) identified all five correct exercises ($p < 0.001$).

In Table 7, participants in Group 3 were asked to provide feedback regarding the intervention. The feedback comprised five questions. There was a 100% positive response rate for every question, indicating that participants in this group understood the foot-care practices and exercises taught to them. Participants also responded that they were more aware and confident to take care of their feet after the intervention. All the participants reported that the intervention would be of benefit to all patients with DM.

Discussion

This was an RCT in which participants were randomised into three groups, namely the Control Group, the Instructional Handout Intervention Group, and the Educational Intervention Group. The median age of the sample was 62 years. This falls within the 35–65-year range reported in the literature.[25,26] Female participants predominated. This is not in agreement with the world literature, which reports a male preponderance;[9,27–29] we concede that the selective nature of our sample may have introduced bias in these terms. Since this is a special select group of people living with DM, this female preponderance cannot be generalised to all patients with DM.

In addition to the observations already stated, several far-reaching observations have been made from this study. The presence of co-morbidity among patients with DM varies in the literature and hypertension was the most common co-morbidity in this series. Many of the participants (90.3%) were unemployed. The literature is not consistent with the level of employment among participants, where various studies reported unemployment to range between 18% and 68%.[3,10] The level of education varied greatly in this sample: 35% had a primary school level, 57% had a high school level and only 4% were at the tertiary education level. These findings mimic those in the literature, where variable levels of education are reported and participants with no formal education are reported to range between 11% and 58%.[3,9,10,24,30]

In the current study, the majority (58.6%) of participants were overweight, and 15.6% were classified as obese. In contrast, a Saudi Arabian study reported overweight in 39.8% and obesity in 38.3% of participants.[31] Only 35.9% of participants reported undertaking some form of physical activity, which is particularly concerning bearing in mind that overweight is a recognised risk factor for T2DM and physical inactivity has been demonstrated to be a significant contributor to the development of T2DM.[32]

The positive aspect of this study is that, while knowledge about foot care was variable at baseline, there was demonstrable improvement among all three groups following the intervention. The improvement in knowledge was statistically significant in Groups 2 and 3. Although Group 2 showed improvement in knowledge in the second interview, the level of improvement did not reach that of Group 3. This suggests that, although both the interventions conferred a benefit, it was more evident in the Educational Intervention Group. Similarly, the number of participants practising foot care was much higher in the second interview compared with the initial interview in all three groups, suggesting that the intervention led to an improvement in practice among participants in Groups 2 and 3. This emphasises the benefit of providing a handout together with a face-to-face teaching session; indeed, in this series, it provided better results compared with the provision of a handout alone. The unexpected improvement in the Control Group may be explained by the participants in the Control Group being exposed to the pre-test questionnaire, which may have

Table 5: Improvement in behaviour and practice stratified according to groups (*n* (%) = number of patients who responded 'Yes')

	Group 1 (Control)							Group 2 (Handout)							Group 3 (Education)						
	Pre-test		Post-test		Improvement			Pre-test		Post-test		Improvement			Pre-test		Post-test		Improvement		
	(*n* = 33)		(*n* = 33)					(*n* = 34)		(*n* = 34)					(*n* = 36)		(*n* = 36)				
Practice	***n***	**%**	***n***	**%**	***n***	**%**	***p*-value***	***n***	**%**	***n***	**%**	***n***	**%**	***p*-value***	***n***	**%**	***n***	**%**	***n***	**%**	***p*-value***
Is your blood sugar level within normal ranges?	17	51.5%	16	48.5%	−1	−3.0%	0.9	12	35.3%	11	32.4%	−1	−2.9%	0.9	13	36.1%	18	50.0%	5	13.9%	0.12
Do you check your feet daily for redness, sores, blisters, cracks??	12	36.4%	15	45.5%	3	9.1%	0.37	11	32.4%	22	64.7%	11	32.4%	0.001	18	50.0%	31	86.1%	13	36.1%	0.0002
Do you wash your feet daily?	33	100%	33	100%	0	0.0%	0.9	33	97.1%	33	97.1%	0	0.0%	0.9	36	100.0%	36	100.0%	0	0.0%	0.9
Do you dry your feet between the toes?	15	45.5%	27	81.8%	12	36.4%	0.0005	16	47.1%	21	61.8%	5	14.7%	0.23	24	66.7%	36	100.0%	12	33.3%	0.0005
Do you use talcum powder to keep your feet dry?	3	9.1%	2	6.1%	−1	−3.0%	0.9	0	0.0%	9	26.5%	9	26.5%	0.004	9	25.0%	25	69.4%	16	44.4%	<0.001
Do you moisturise the top and bottom of your feet daily?	12	36.4%	16	48.5%	4	12.1%	0.12	10	29.4%	20	58.8%	10	29.4%	0.01	17	47.2%	34	94.4%	17	47.2%	<0.001
Do you check the inside of your shoes before wearing them?	8	24.2%	11	33.3%	3	9.1%	0.51	8	23.5%	22	64.7%	14	41.2%	0.001	17	47.2%	35	97.2%	18	50.0%	<0.001
Do you always wear closed shoes indoors and outdoors?	3	9.1%	3	9.1%	0	0.0%	0.9	4	11.8%	6	17.6%	2	5.9%	0.63	7	19.4%	25	69.4%	18	50.0%	<0.001
Do you protect your feet from hot and cold temperatures?	21	63.6%	24	72.7%	3	9.1%	0.37	20	58.8%	24	70.6%	4	11.8%	0.29	26	72.2%	35	97.2%	9	25.0%	0.01
Do you do specific exercises for your legs and feet?	9	27.3%	9	27.3%	0	0.0%	ns	11	32.4%	12	35.3%	1	2.9%	0.02	12	33.3%	35	97.2%	23	63.9%	0.01
Do you cut your nails straight across?	18	54.5%	23	69.7%	5	15.2%	0.06	11	32.4%	11	32.4%	0	0.0%	0.9	23	63.9%	28	77.8%	5	13.9%	0.18
Total	151	41.6%	179	49.3%	28	7.7%		136	36.4%	191	51.1%	55	14.7%		202	51.0%	338	85.4%	136	34.3%	

*McNemar's chi-square test.

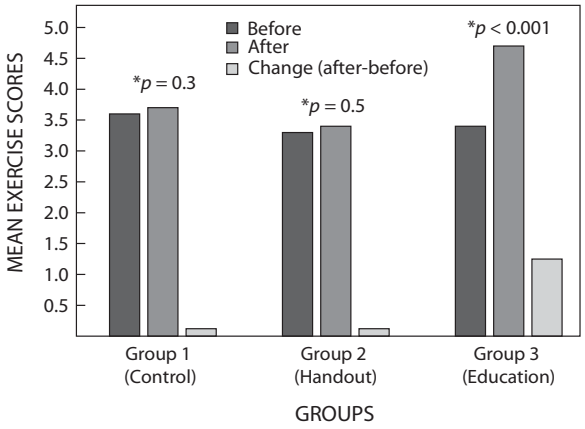

Figure 4: Showing the mean for knowledge of exercise scores before and after the intervention as well as change in knowledge of exercise scores after the intervention

**Legend: Change in score Group 1 vs. Group 2 $p = 0.40$; change in score Group 2 vs. Group 3 $p < 0.001$; change in score Group 1 vs. Group 3 $p < 0.001$. *Paired Student's *t*-test. **One-way ANOVA.

Table 7: Feedback from patients in Group 3

Questions	Yes (*n* = 36) *n*	%
Did you understand the foot-care practices taught to you?	36	100%
Did you understand the exercises taught to you?	36	100%
Do you think the foot-care practices and leg exercises taught to you have helped you become more aware of foot care?	36	100%
Are you more confident to take care of your feet?	36	100%
Do you think this programme will help all patients with DM?	36	100%

stimulated interest in diabetic foot care and encouraged the patients to adopt the practice. We therefore concur with the recommendation by Borges and Ostwald that a simple, relevant, consistent and repeated intervention can help in adding to patient education.[33] It was of concern that 87% of participants had not received any information regarding foot care from healthcare professionals in this series. The fact that the level of improvement was highest in Group 3 supports the view of others[7] that self-care management programmes bestow a positive impact on self-care behaviours, as well as health outcomes. An intervention study by Borges and Ostwald, albeit different in intervention from the present study, also showed improvement in foot-care practice in the Control Group.[33]

Diabetes mellitus is associated with a marked reduction in lower limb mobility and muscle strength,[19] and, because the prevalence of physical inactivity globally is of increasing concern,[34] many studies have promoted exercise in patients with T2DM.[15–19] Few studies in the international literature have reported on the assessment of knowledge and practice of foot care and thereafter proceeded to implement an intervention strategy.[12,20,33] In the present study, the authors chose to determine participants' knowledge of free active lower limb exercises that they (the participants) thought were suitable for patients with DM, went on to administer the educational programme and continued to test it at the second interview. The exercises given to participants were simple, low-intensity and could be done by all ages without exertion. Exercises specifically directed to patients with diabetes are essential if clinicians are to reduce lower limb mobility and thus prevent muscle strength reduction. The choice of exercises prescribed for the current study has previously been shown to provide effective lower limb mobility.[15,16,18] As the effectiveness of these exercises is already known from the global literature,[15–19] the current study did not measure the effect of the exercises on strength or mobility, as it was not an objective of the study.

The feedback from participants in the Educational Intervention Group indicated that all participants understood the programme provided to them and were more confident in taking care of their feet. We agree with Zanetti *et al*., who reported that patient satisfaction is valuable input from participants that assists in assessing the various approaches which are used in diabetes education programmes.[35]

In summary, the current study has demonstrated that an educational intervention has the potential to lead to an improvement in foot-care knowledge and practice. The improvement in knowledge and practice of foot care in Group 2 participants demonstrates the potential of a handout alone (without specific teaching sessions) to promote foot-care knowledge and practice. The display of improvement in knowledge and practice scores with just an instructional handout in Group 2 also displayed that this may be useful in resource-limited settings. It was of interest that improvement in foot-care practice was also seen among the controls. We postulate that the questions asked of the participants in the Control Group in the first interview may have aroused their interest, encouraging them to take it upon themselves to research the topic. It could also be postulated that these participants came in contact

Table 6: Knowledge of lower limb exercises—number of correct answers for exercises identified by participants

	Group 1 (Control) (*n* = 33)				Group 2 (Handout) (*n* = 34)				Group 3 (Education) (*n* = 36)			
	Pre		Post		Pre		Post		Pre		Post	
Number of correct answers	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
2 exercises	7	21.20%	6	18.20%	6	17.60%	7	20.60%	5	13.90%	0	0.00%
3 exercises	9	27.30%	8	24.20%	16	47.10%	11	32.40%	17	47.20%	2	5.60%
4 exercises	8	24.20%	9	27.30%	7	20.60%	10	29.40%	7	19.40%	7	19.40%
5 exercises	9	27.30%	10	30.30%	5	14.70%	6	17.60%	7	19.40%	27	75.00%
P-value*	0.3				0.48				< 0.001			

*Wilcoxon signed-rank test.

with participants from other groups and obtained information from them.

The Control Group (Group 1) showed improved scores at follow-up even though this did not reach statistical significance. This suggests that the baseline questionnaire may have initiated some foot-care interest among participants in this group. We found this improvement in Group 1 interesting, and we postulate that participants in Group 1 may have become interested after seeing the baseline questionnaire and strove to improve their knowledge and practice of foot care on their own.

There is a further suggestion in the literature that not all patients with DM follow the strict guidelines recommended by diabetic foot-care counsellors, and this has been noted more especially among patients with low educational levels and socioeconomic status.[36] This objective was not particularly tested in this study, and we believe that it needs to be explored in the South African context.

Strengths and limitations

This study has some limitations. It was a single-centre study carried out in one regional hospital with one follow-up session. More sessions could have provided better results, and this can be a suggestion for future research. Participants in this intervention study were a select group of participants with specific inclusion criteria and do not represent the general population of patients living with DM.

The strengths of the study are as follows. The study added more than one intervention arm to explore the efficacy of the pamphlet only and that of an educational module on knowledge and practice. The study has taken into account participants' barriers to knowledge and practice such as literacy, financial standing and socioeconomic status[27,37,38] by ensuring that all activities were completed in one teaching session. This was addressed by developing an educational plan that was presented in simple terminology using colour pictures with instructions and by avoidance of medical jargon. In addition, the five exercises were simple and low-intensity and could be performed by all ages without exertion. Furthermore, the face-to-face teaching strengthened the foot-care plan by demonstrating exactly what was presented in the handout. The addition of more effort in the form of an educational teaching programme in Group 3 (over and above Group 2) led to marked improvement, suggesting that this intervention may provide an effective training strategy for patients with DM attending outpatient clinics. The provision of one teaching session and handout showed that this programme can be suitable for those participants who have financial problems.

Conclusion

Hypertension was the highest recorded co-morbid condition. The majority of the participants were in the overweight category and did not perform any physical exercise. Poor foot-care knowledge and practice were observed at baseline and improvement was noted after the intervention in all groups, including the Control Group. Knowledge transfer was successful in all groups but significant in Groups 2 and 3 following the intervention and was more pronounced in the Educational Intervention group. The study highlights the importance of face-to-face teaching and learning in improving patients' knowledge and practice of foot care. A simple handout can also help in improving knowledge and practice of foot care for those institutions that lack resources and finances. We believe that this approach with an active education module will be effective in promoting successful knowledge transfer and a change in behaviour in patients with DM.

Disclosure statement – No potential conflict of interest was reported by the author(s).

Acknowledgements – Mrs Catherine Connolly is thanked for statistical analysis, and the staff at MOPD—Addington Hospital are also thanked.

Supplemental data – Supplemental data for this article can be accessed at https://doi.org/10.1080/16089677.2021.1980972.

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Received: 11-08-2021 Accepted: 13-09-2021