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Nurse-led education programme enhancing foot care self-efficacy in high-risk diabetes population: pilot randomised controlled study

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Aims: The purpose of this study was to evaluate of a 5-week nurse-led educational programme on foot care self-efficacy in high-risk diabetic patients with current foot ulcers.
Methods: A pilot randomised controlled study was conducted in five acute care hospitals in Switzerland. Nineteen subjects (16 males and 3 females, aged 44–84 years) were randomly assigned to receive foot care education or standard care. Included were patients with diabetes, aged 18 years or older and in treatment for ulceration and/or amputation of the lower limp. The primary outcome measure was the development of foot care self-efficacy determined by the Foot Care Confidence Scale questionnaire (FCCS). The outcome was assessed 5 weeks after randomisation and education.
Results: The results demonstrated that an evidence-based education programme for high-risk patients can promote short-time foot care-related self-efficacy. While the group comparison showed no significant difference between the groups before and after the intervention, there was a significant difference in self-efficacy comparing the change of the FCCS from baseline to Week 5. Self-efficacy in the intervention group (IG) ($M = 9.5$, SD ± 7.6) was significantly enhanced compared to the control group (CG) ($M = 0.64$, SD ± 8.4, $t(17) = 2.4$, $p = 0.031$, $r = 0.5$). The FCCS score in the IG was significantly higher after the intervention ($T = 0$, $p = 0.02$, $r = 0.5$) compared to the CG after 5 weeks ($T = 26.5$, $p = 0.92$, $r = 0.02$).
Conclusions: This pilot study demonstrated that nurses successfully accomplish interventions to enhance foot care-related self-efficacy. It is therefore necessary that nurses continue taking such important supporting roles. A larger study, however, is needed to confirm this preliminary data.

Key words: Diabetic foot, self-efficacy, education, nursing

Introduction

One of the most severe complications for patients with diabetes mellitus (DM) is the diabetic foot. The prevalence of developing a foot ulcer in patients with DM can be as high as 25%.[1] The first-year incidence rates vary between 7 and 34%.[2,3] After 3 years, the reported incidence rate is as high as 62% and after 5 years, this rate increases to 70%.[3] The risk of an amputation of the lower limp is 3% in the first year, 10% after 3 years and 12% after 5 years. In 80–85% of all cases, amputation is due to foot ulcerations.[4] Patients with a history of foot ulcerations or previous amputations, who have been diagnosed as having DM for over 10 years, badly controlled glucose levels and who already experience decreased vision are at highest risk for further amputations.[1] Therefore, guidelines state that instruction on foot care and self-monitoring has to be included in nurse-led education in order to decrease amputations or at least delay the occurrence of it.[5] In spite of the needs of this high-risk population, little evidence exists about effective diabetes nursing intervention programmes to decrease amputation or re-amputation rates by educating patients in proper foot care.

According to a Cochrane review, there is only one randomised controlled trial (RCT) that investigated the effects of an intervention with high-risk patients who had current ulcerations or recent amputations.[6] This study from the United States enrolled 203 patients and evaluated the long-term effects (2 years) of a 1 hour foot care education programme on its impact on ulceration and amputation rate.[7] Overall, there was a highly significant difference in favour of the intervention group (IG). The success rate, measured by 'no further amputation' in the IG, was 90% (160 of 177 limbs) versus 72% (128 of 177 limbs) in the control group (CG) ($p \leq 0.0005$). Ulceration in this study was three times as likely in the CG (15%) compared to the IG ($p \leq 0.005$). However, these results are questioned by Valk *et al.*[6] They criticised the use of 'legs' instead of 'patients' as the unit of analysis, with a probable overestimation of the precision of the study.[6] A more recent

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study conducted in the United Kingdom with the purpose of confirming the study findings of Malone *et al*. was unable to demonstrate significant reductions.[8] However, patients' knowledge about foot care and foot care behaviour increased in the IG in this study. Nevertheless, no definite conclusion can be drawn and the evidence for educational interventions for high-risk patients with diabetes foot ulcers is still limited. Consequently, it is a vital activity of diabetes nurses to carefully examine ways to enhance a diabetes patient's ability to perform self-care behaviours.[9] Hence, this pilot study evaluated a nurse-led education programme for high-risk patients with current diabetic foot ulcers. The aim of the pilot study was to test the short-term effect of the educational programme and to describe the benefit of educational contents relating to foot care self-efficacy. It was hypothesised that a 5-week nurse-led education programme leads to a significant enhanced foot care self-efficacy in comparison with a CG without such an intervention.

Method

Design

To test the above stated hypotheses, a quantitative analysis after 5 weeks of a longitudinal pilot RCT with four measurement-point's over 6 months and a follow-up after 12 months was carried out.

Participants

Participants were recruited in five acute care hospitals in the German-speaking part of Switzerland. Inclusion criteria were adults with diabetes being treated for ulceration and/or amputation of the lower limp. Excluded were patients with cognitive impairment and psychiatric diseases. After confirming eligibility and given written informed consent all participants took part in the baseline data collection.

Data collection instruments

Baseline data were collected before randomisation in order to ensure unbiased data collection with respect to group assignment (demographic data, medical data and data about foot care self-efficacy, self-management). Demographic data were obtained, including age, gender, living status and occupation. Medical data consisted of diabetes type and duration, diabetes control (HbA_{1c}), body mass index (BMI), the ankle brachial index and details of previously healed ulcerations and amputations. To assess peripheral neuropathy, the Michigan neuropathy screening instrument (MNSI) was used.[10] Therefore, the history of a possible neuropathy is assessed and a foot inspection is conducted. A total of 23 points can be obtained. Results higher than 7 points indicate a diabetic peripheral neuropathy. The Nottingham Assessment of Functional Footcare (NAFF) was used to measure foot care knowledge and behaviour and the effectiveness of foot care education.[11] The 29-item questionnaire was developed, based on questions in standard educational leaflets. The participant responds to the questions on a 5-point likert scale. A total of 87 points can be obtained. Higher scores indicate better foot care behaviour and knowledge. And finally, to measure the primary outcome self-efficacy in foot care, we used the Foot Care Confidence Scale (FCCS).[12] The development of the FCCS was guided by the self-efficacy theory and was designed to combine the three dimensions: magnitude, strength and generality. The FCCS consists of 12 statements about the 'confidence' people have in undertaking various foot-care activities using a 5-point likert scale response. In response to a statement about undertaking foot care behaviour (e.g. 'I can protect my feet'), the participant can respond with the following likert responses: 'strongly not confident', 'moderately not confident', 'confident', 'moderately confident' and 'strongly confident'.[12] The FCCS score ranges from 12 to 60. A higher score indicates a high self-efficacy. The primary outcome measure was the development of foot care self-efficacy determined by the FCCS questionnaire. This outcome was assessed 5 weeks after randomisation.

Procedure

After completing the baseline data collection, a computer generated simple 1 : 1 randomisation list for concealed allocation of participants was used. Participants were stratified by study centre and drawn consecutively using separate randomisation lists.

All participants received three specially developed brochures with information regarding the diabetic foot. The brochures contained explanations to (a) the cause and warning sign of diabetic foot ulcers, (b) precautions patients can take in daily life and (c) helpful foot gymnastics for at home.[13,14] Participants randomised in the CG received standard care. Standard care consists of either inpatient or outpatient, physician prescribed, wound care. Participants randomised in the IG additionally received standardised foot care education. The nurse-led intervention started a few days after randomisation and lasted for 5 weeks. The content of the educational sessions were based on the Nurses Best Practice Guideline.[15] To enhance foot care self-efficacy participants received a 1 hour education, skill training and counselling in weekly intervals.

Each participant received a foot care kit with essential foot care material and a foot care diary. Participants were advised to set weekly goals for their foot are. The dairy assisted participants to record observed skin alterations or new symptoms and document which foot care activities they performed and whether they experienced difficulties or uncertainties. During the weekly sessions, the SN discussed the foot care dairy with the patient and evaluated their goals.

Data analysis

All statistical analyses were carried out using SPSS version 19.0. To outline the characteristics of the participants, descriptive statistics was used. Owing to partly non-normal distributed data parametric and non-parametric tests were performed. Groups were checked for baseline comparability to identify potential confounders using independent *T*-tests, Fisher's exact and Mann–Whitney *U* tests. After 5 weeks, the group comparison was performed with the Mann–Whitney *U* tests. For the within group comparison of variables over time, the Wilcoxon signed-rank test was used. The primary variable was tested using the independent *T*-test due to normal sampling distribution of the differences between scores. The data are presented reporting mean or median and effect sizes. Results were statistically significant if the two-tailed *p*-values were less than 0.05.

Results

Fifty-nine patients were screened between October 2010 and February 2012. A total of 25 of these were excluded due to the exclusion criteria and 17 patients declined to participate in the study. The remaining 19 patients were eligible and agreed to participate in this study; 8 patients were allocated to the IG and 11 to the CG. The recruitment and follow-up of participants is shown in Fig. 1.

The sample consisted of Caucasian population. The two groups were comparable at baseline. All MNSI scores but one were over the cut-off point of 7 and presented equal diabetic peripheral neuropathy in both groups. According to the NAFF score both groups showed no significant differences in foot care knowledge. Risk behaviours like examining the feet less than once a day, wearing socks with seams or changing socks less than once a day appeared in both groups equally. All baseline characteristics are summarised in Table 1.

The 5-week educational programme had a mean of 184 (SD ±57.0) minutes intervention per participant, consisting of 52% education (M = 96, SD ±27.0 minutes), 32% counselling (M = 59, SD ±30.2 minutes) and 16% skills training (M = 29, SD ±20.5 minutes).

The primary outcome foot care self-efficacy was measured with the FCCS. The FCCS score did not differ significantly at baseline between groups (IG Md = 40.5, CG M = 56.0, U = 25.0, $p = 0.12$), however, indicating that the median self-efficacy score in the IG was lower than the median score in the CG at baseline. After the 5-week education programme, there was no significant difference in the median score of the IG (Md = 55.0) compared to the CG (Md = 54.0, U = 37.5, $p = 0.55$), whereas self-efficacy in the IG was significantly higher after the intervention (T = 0, $p = 0.02$, $r = 0.5$) compared to the CG after 5 weeks (T = 26.5, $p = 0.92$, $r = 0.02$). Comparing the difference of the FCCS from baseline to Week 5 showed a significant large effect. There was a significant increase of self-efficacy in the IG (M = 9.5, SD ±7.6) and a decrease in the CG (M = 0.64, SD ±8.4, $t(17) = 2.4$, $p = 0.031$, $r = 0.5$) (see Table 2).

Discussion

This is the first nurse-led pilot RCT to gather data on the feasibility of an intensive education programme for high-risk patients with current diabetic foot ulcers. The

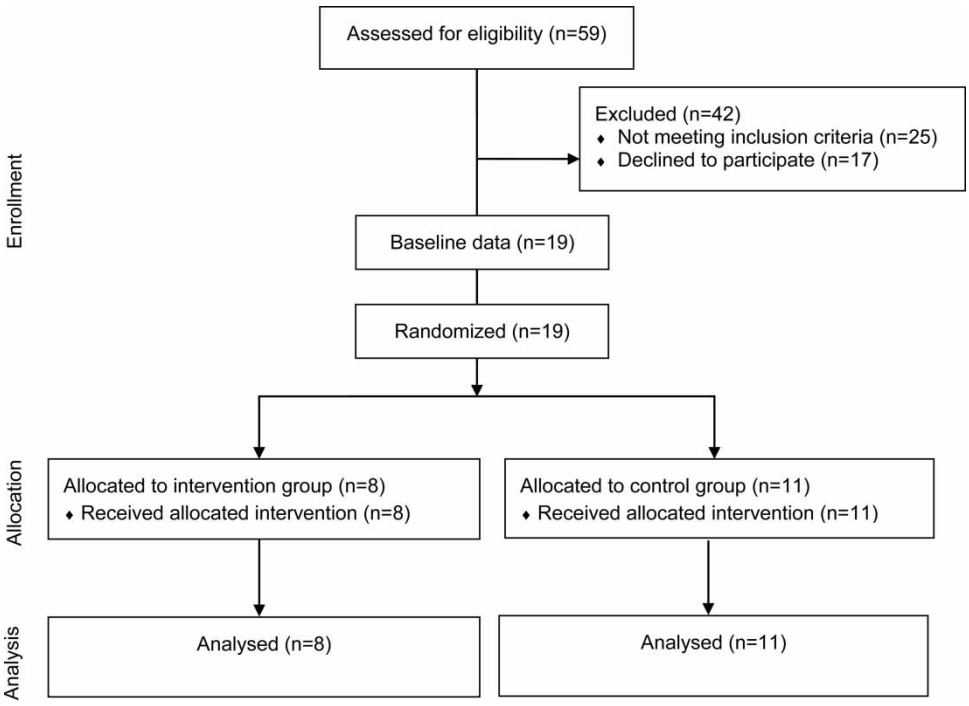

Figure 1 Flow of participants through trial.

Table 1 Baseline characteristics of participants.

Characteristics	Intervention $n = 8$	Control $n = 11$	p-Value
Age, M(±SD)	65 (±10.9)	60 (±9.3)	0.40
Male sex, *n*	7	9	1.0
Living with others, *n*	6	8	1.0
Currently working, *n*	1	4	0.34
Years since diagnosis M(±SD)	9 (±3.8)	15 (±8.7)	0.05
Type 2 diabetes, *n*	8	9	0.49
HbA_{1c}, M(±SD)	7.9 (±1.7)	7.6 (±1.5)	0.70
BMI, M(±SD)	30.2 (±6.6)	29.5 (±6.4)	0.23
Previous ulcers, *n*	4	6	1.0
Previous amputations, *n*	4	2	0.32
Ankle brachial index, M(±SD)	0.88 (±24)	1.10 (±0.31)	0.13
Peripheral neuropathy,[a] *n*	54 (±8.4)	54 (±5.6)	0.99
NAFF[b] M(±SD)	96 (79–126)	117 (66–138)	0.09

[a]MNSI ≥7.
[b]Higher scores indicate better foot care behaviour.
*Significant $p < 0.05$.

baseline data showed a male-dominated group, corresponding to literature demonstrating that male sex have a higher risk associated with foot ulceration and lower limp amputations.[16]

During the last few decades, patient education programmes for individuals with diabetes have been developed, with conflicting results. Our intervention targeted a high-risk population and consisted of education, skill training and counselling. The results show improvements in foot care self-efficacy in the IG compared to participants receiving no such programme. As hypothesised, the education programme significantly enhanced foot care self-efficacy in the IG over time despite the small sample size. This finding contradicts a previous study of diabetic foot care, which aimed to change foot care behaviours through patient education.[8] Other studies, however, do support the benefit of education programmes. To reduce the incidence of ulcers and foot and limb amputation in patients with diabetes, for example, a prospectively randomised trail demonstrated that a simple education programme can show significance[7]. Lincoln *et al.*, on the other hand, illustrated that education can be associated with improved foot care behaviour. However, the results showed that there was no clinical benefit for diabetic patients enrolled in an education programme.[8]

A recently conducted quasi-experimental trial divided 88 patients into four-risk groups and applied a two-year diabetic foot care programme according to each risk group. This nurse-led programme included callus removal, foot skin care and education. The results showed an improved foot status, especially in the high-risk group comparable to our participants.[17] Additionally, Dorresteijn *et al.*[18,19] demonstrated in a systematic review that five out of eight RCTs showed that patients' foot care knowledge improved in the short term. Hence, diabetic foot care programmes seem to be useful in enhancing foot care knowledge and self-efficacy in high-risk diabetes.

Table 2 FCCS score over time.

	Intervention ($n = 8$) Md (IQR[a])	Control ($n = 11$) Md (IQR[a])	p-Value
FCCS score baseline	40.5 (35.0; 53.5)	56.0 (46.0; 58.0)	0.129[b]
FCCS score after education	55.0 (49.5; 59.5)	54.0 (52.0; 58.0)	0.551[b]
p-Value[c]	0.018	0.919	

[a]Inter-quartile range.
[b]Results of Mann–Whitney *U*-test for comparison between groups.
[c]Results of Wilcoxon signed-rank test for comparison within groups.

Study limitations

This pilot study demonstrated the feasibility of the study protocol and the educational programme. The material and the frequency of the educational intervention seem to be successful. However, there are limitations to the study. Firstly, the pilot study was not well powered with only 19 subjects included. Owing to the small sample size subgroup analysis was not possible to be performed. Secondly, for practical reasons, neither participants nor the SNs were blinded to participants' allocation. But there was a strict separation in the SN giving the interventions and the SN collecting the outcome variables. A further limitation may be that the interventions have taken place in an institutional environment. We assume that through home care visits, nurses are closer to patient's everyday life and can direct their interventions to patient's individual needs.

Conclusion

To strengthen the findings and to show an enhanced self-efficacy in the long term, a larger well-powered study should be conducted. As this study collected only self-reported outcomes a longitudinal study could additionally report outcomes such as ulceration or amputation rates. If the results are proofed relevant the programme should be made available as parts of routine diabetes care for high-risk patients, as preventive foot care is an important issue in this population.

This study showed that nurses successfully administer interventions aimed at enhancing self-efficacy in high-risk patients with diabetes. Therefore, it is vital that diabetes nurses take a supporting and facilitating role.[20] In addition to learning new practical skills, patients have to cope with life-long diseases and may need help in accepting the changes which are occurring in their lives.[21] By incorporating such interventions into existing disease – management programmes, in which diabetes nurses already play a large role, quality of care may be enhanced.

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Disclaimer statements

Contributors AKS and LI initiated the study. AKS, RMI, and LI wrote the study protocol and developed the program. AKS coordinated the study, data collection, analysis, and interpretation, with the assistance of LI and SP. AKS wrote the article. All authors commented on the draft and have read and approved the final version of the article.

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