Effectiveness of a theory-based foot care education program (3STEPFUN) in improving foot self-care behaviours and foot risk factors for ulceration in people with type 2 diabetes

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ABSTRACT

Aims: To evaluate the effectiveness of a theory-based foot care education intervention program (3STEPFUN) for people with type 2 diabetes at low risk of developing a foot ulcer.
Methods: A controlled, pre-test/ post-test quasi-experimental design was used. From 119 participants, 60 participants in the control group received usual care and a foot care brochure. Those in the intervention group received (1) a small group intensive education and hands-on skills session; (2) a foot care kit and documents; and (3) three regular booster follow-up phone calls over 6 months. Generalised Estimating Equations models were undertaken to examine the impact of the intervention on outcomes over time.
Results: The intervention group had significantly improved outcomes compared to the control group over 6 months in the following aspects: improved preventive foot care behaviour (p = 0.001); and decreased prevalence of foot risk factors for ulceration (i.e. dry skin, corns/ callus) (OR: 0.04, 95% CI 0.01 – 0.13, p < 0.001).
Conclusions: The study's findings provide evidence of 3STEPFUN on improving foot self-care behaviour and preventing minor foot problems. Further study with formal RCT design and longer follow-up time to examine the effects on decreasing foot ulcer incidence is recommended.

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1. Introduction

Diabetic foot ulcers (DFUs) and their subsequent complications are a global threat and challenge. Global prevalence of DFUs is 6.3% [1]. Treatment for diabetic foot ulcers is complicated and costly. Also, the recurrence rate is estimated from 40% to 65% in the first five years [2,3].

In Vietnam, the prevalence of type 2 diabetes in adults has doubled from 2.7% to 5.5% from 2002 to 2017 [4–7]. Of these, 85% of patients already had at least one complication when they were first diagnosed [8]. No national statistics of DFU prevalence in Vietnam are available. However, some cross-sectional, case-control and retrospective studies have high-

lighted DFUs as a significant issue in the country. In Vietnamese patients with diabetes, the DFU issues occurred in the early stage of the disease (first diagnosis of diabetes or less than five years) [9–11], with severe foot complications such as infection or gangrene in more than 90% of the cases [10,11]. More importantly, death and amputation were observed in nearly one-third of the cases [10]. These studies highlighted that DFUs and their subsequent problems are a challenge for healthcare systems in Vietnam. However, the issue has been inadequately addressed, especially in the preliminary stage [12]. A foot ulcer primary prevention is required more than ever.

Diabetic foot ulcers are largely preventable [13,14]. Among prevention strategies, patient health education is considered important and can improve patients' knowledge of diabetes-related foot problems, foot care behaviour and reducing foot problems (i.e. neuropathy, foot disability, lesion, ulcer, tinea pedis and callus grade [2,15]. Nevertheless, evidence of the effectiveness of education alone, without any additional preventive measures, in reducing the occurrence of ulcers and amputations is insufficient and requires further research [16]. Additionally, programs targeted to those still at low risk of developing foot ulceration, to prevent the initial development of complications and abnormalities, are sparse [17]. Diabetes is a silent disease until apparent signs of complications are exposed. Thus, despite being at 'low-risk' of developing foot ulceration, people with diabetes can quickly develop foot complications at any stage of the disease if they have poor blood glucose control and foot self-care practices [17–19]. It is believed that if the first ulcer is prevented or delayed, the burden of ulceration will considerably decrease [14]. Thus, there should be more attention to this patient group.

Recently, an increasing number of theory-based interventions in patient education to prevent foot ulcers have been published. Social Cognitive Theory or Self-efficacy Theory of Bandura was most commonly applied in the identified foot care education studies, and effectiveness of theory-based foot care education programs was also confirmed [20–24]. Researchers recommended that diabetes self-management intervention programs underpinned by this theory should be adapted for Vietnamese adults with diabetes [25,26]. This study aimed to develop a self-efficacy theory based foot care education intervention program (3STEPFUN) and evaluate the effectiveness of the program on foot self-care behaviours and minor foot problems which precede foot ulceration for adults with T2DM at low risk of developing a foot ulcer.

2. Materials and methods

Ethical approval for the study was obtained from the Human Research Ethics Committee of the Queensland University of Technology (Ethical Approval No.: 1600000483) and Ethics Research Committee of University of Medicine and Pharmacy at Ho Chi Minh City (Ethical approval No: 16,141 – ĐHYD).

2.1. Design, population and setting

A controlled, observer-blinded, pre-test/ post-test quasi-experimental design was conducted. Participants were recruited from a community health care centre in Ho Chi Minh City, Vietnam. Potential participants were adults diagnosed with type 2 diabetes (T2DM) who met the criteria: (1) having at least two months treatment and follow-up at the adult clinic of the centre, (2) able to speak, read and understand Vietnamese, (3) contactable via telephone and (4) were at low risk of developing foot ulcer (i.e. no history of previous foot ulceration and absence of current ulceration, no foot deformity, normal lower extremities circulation: dorsal pedis and the posterior tibial pulses, normal protective sensation: test with monofilament). Those who had cognitive impairment, or serious co-morbidity (i.e. stroke, dementia) were excluded from the study.

Patients with type 2 diabetes who came for follow-up treatment at the centre during the recruitment time were identified and referred to the researcher by staff nurses. The potential participants were verbally informed about the study and screened for diabetic foot risk by the researcher. Patients who met the study criteria and were willing to participate had the study explained in detail about their involvement and written informed consent was obtained. Depending on their admission dates (the first two weeks or the last two weeks of the recruiting month), participants were assigned to either the control group or the intervention group.

2.2. Sample size calculation

Sample size calculations initially suggested a total sample of 56 participants was required (i.e. 28 per group), based on the following parameters: 90% power; 95% significance level, able to detect 30% difference in the proportions of cracked skin (one of foot risk factors for ulceration among patients with diabetes) between pre-test and post-test [22]. The sample of 120 was further inflated by a cluster effect of 1.49 and 40% to compensate for the loss of follow-up.

2.3. Usual care

The usual care for patients with T2DM in the centre consisted of (1) anthropometric measurements (height, weight, BMI, waist circumference, body fat percentage, body fat distribution), (2) regular biochemistry test, (3) consultations and treatment by medical doctors specialised in diabetes and chronic disease and (4) professional diet and exercise consultation (if required) by dietitian or medical staff.

2.4. Control group

In addition to usual care, participants in the control group received a foot care brochure. At the end of the study, each of the participants in this arm was offered foot care written materials (a booklet and A3-steps guide waterproof tip sheet), a foot care kit and a foot care education session (in group or individually, optional).

2.5. Intervention group

People in the intervention group received usual care and were involved in the 3STEPFUN and followed-up for six months. The 3STEPFUN was developed based on self-efficacy theory

of Bandura. All four principal sources of information of self-efficacy: performance accomplishments, vicarious experiences, verbal persuasion, and physiological states was utilised in intervention strategies [27]. This included 60–75 min of small group multifaceted education and hands-on skills session; foot care written materials, a foot care kit; and three regular booster follow-up phone calls over six months (at week 2, 10 and 20). The study process and component of the 3STEPFUN are summarised in Supplemental 1.

2.6. Variables and measurements

2.6.1. Screening
Patients with diabetes were screened for their risk of developing foot ulcers – those who had the following criteria: (1) normal protective sensation, (2) normal lower extremities circulation, (3) absence of foot deformity or ulceration, and (4) no previous foot ulcer or amputation were classified as low risk and were recruited for the study [28,29]. Patients who had any abnormal findings were excluded. Then they were provided with a foot care brochure as a reference and referred to medical doctors for further consultation and treatment.

2.6.2. Participants' characteristics
Demographic data including age, gender, ethnic group, religions, marital status, socioeconomic status (educational level, employment status, occupation, monthly income, financial assistance and income hardship) were recorded. Health-related data were collected and recorded including BMI, duration of diabetes, type of treatment, latest Fasting Blood Sugar (FBG), glycated haemoglobin (HbA1C) and comorbidities (retinopathy, renal impairment, hypertension) were also collected from patients' medical record with patients' permission.

2.6.3. Outcome measures
Foot self-care behaviour was examined by using Foot Self-Care Behaviour (FSCB) questionnaire [30]. The instrument included 17 items and two subscales: Preventive Foot Self-Care (p-FSC) (9 items) and Potentially Foot – Damaging Behaviour (p-FDB) (8 items). The frequency of performing foot care activities was judged by using two different rating scales: a 6 point-scale (i.e. twice a day, daily, every other day, twice a week, once a week or never) and a 4 point-scale (i.e. always, most of the time, occasionally, or never). Each item was converted to a 0 to 1 scale before scoring as per the author's instruction [30,31]. A linear transformation was done to convert the old scale to the new one [32]. Mean scores were computed for each subscale. A higher score indicates more preventive and potentially damaging behaviours respectively. Testing of the Vietnamese translated FSCB found an excellent content validity index (CVI) and acceptable internal consistency reliability, 0.96 and 0.68, respectively.

Foot risk factors for ulceration were examined by using a Foot Assessment Form which was designed based on previous literature [22,33,34]. Instruction and training for examining the participants' feet were undertaken to minimise the bias in evaluation among the assessors. Common skin conditions were inspected such as (1) dry skin, (2) cracked skin or fissure,

(3) fungal skin infection (presenting as itchy, scaly, scratchy foot skin and moist, white, cracked, macerated in areas between toes), (4) corns/calluses (thickened and hardened area of the skin caused by friction and pressure), (5) redness (from sunburn, abnormal rubbing of shoes or socks or irritations on feet, often comes with itching, rash, hives, warmth, swelling), (6) blisters (fluid-filled sacs developed from skin traumatised, often caused by ill-fitted footwear), and (7) minor skin lesions (on the epidermis and part of the dermis, e.g. cuts, scratches, broken blister and ulcers) [33,35,36].

Toenail problems were recorded including: (1) hygiene status: toenails clean, no dirt or visible debris under the nails, (2) length:the edge reaches the tip of the toe, (3) thickness: thickened nail plate caused by age, fungal infection, repeated trauma or injury, (4) toenail atrophy: reduction in size and thickness of the nail plate, (5) toenail trauma: signs of subungual hematoma appearing as red, purple or dark red under the nail, (6) ingrown toenails: nails grown into surrounding skin, causing pain, swelling, and infection; (7) toenail fungal infection: signs of whitish or yellowish, discoloured, thickened and crumbling of the nail [33,35,36].

2.6.4. Other variables of interest
Diabetes self-care behaviours were assessed using the Summary of Diabetes Self-Care Activities (SDSCA) scale [37]. Each item was scored from 0 to 7 based on the number of days of the week that specific self-care activity was performed. Subscale scores (i.e. General Diet, Special Diet, Exercise, and Blood Glucose Testing, Medication) were determined by the average scores of items in a subscale. Higher scores suggested better diabetic self-care in specific activities.

Foot self-care knowledge was assessed by a 27 items-Foot Self-Care Knowledge Questionnaire. Seven items were derived from two subscales: the Physical Causes of Ulcers subscale and Acute Foot Ulcer Onset subscale of the Patient Interpretation of Neuropathy (PIN) [30]. Each subscale was calculated by the average item scores; scores ranged from 1 to 5 [30]. Twenty items were from a Vietnamese Foot Care Knowledge survey (KFC)[38]. Each correct answer scored 1 point, an incorrect or "don't know" answer scored 0 points. Then the total score was transformed to 0 – 10 [38]. The higher scores indicated better knowledge towards physical causes of ulcers, acute foot ulcer onset and proper foot care.

Foot care self-efficacy was examined by using the Foot Care Confidence Scale (FCCS) [39]. Each item score ranged from 1 (strongly not confident) to 5 (strongly confident). A cumulative score was calculated ranging from 12 to 60. The higher score indicated a higher level of confidence and vice versa. The Cronbach's α and CVI of the scale in the Vietnamese population were 0.97 and 0.93, respectively.

2.7. Statistical analysis

Data analysis was performed using SPSS v22 and the p-value equal or <0.05 level (2 tailed) was the criterion for statistical significance. Descriptive statistics were undertaken to summarise the demographic and health-related characteristics and outcome measures. Bivariate statistical testing (i.e. T-test or Mann Whitney U tests, Chi-square statistics or Fisher's exact test) was used to compare data between the interven-

tion group and control group. For hypothesis testing, Generalised Estimating Equations (GEE) was employed to examine the differential changes of outcome measures throughout six months between the intervention group and the control group after adjusting for covariates' effects. To adjust for the effect of covariates, all variables which were found significantly related to the outcomes at the bivariate level were simultaneously included in the multivariable model. The modified-intention to treat (mITT) approach, a deviation of the ITT principle analysis, was conducted. In this study, mITT allowed exclusions of randomised subjects who changed their mind re participation after consenting and who had not received baseline assessment nor received any allocated intervention.

2.8. Quality assurance

The intervention was provided by the principal researcher (nurse educator). The minor foot conditions were assessed by medical doctors at the clinic, while other study measures were collected by research assistants. Before commencing the study, they were trained to be competent in collecting data and ensure consistency in the examination. They were blinded to patients' allocation.

3. Results

3.1. Recruitment and attrition

A total number of 175 adults with T2DM were assessed for eligibility. Ten patients did not meet the inclusion criteria. Twenty-five individuals declined to participate. Twenty-one participants were excluded after consenting. The most common reasons for declination were family-related issues (i.e. household duties for their children or grandchildren, lack of family support). Finally, 119 people participated in the study, 60 patients for the control group and 59 patients for the intervention group. Over the six months follow up time, eight patients in the control group and seven patients in the intervention group dropped out (total of 15 patients, 12.6%). No adverse events related to the intervention were reported. There were no significant differences in baseline demographic and health-related characteristics between the completed and discontinued groups, except the former had a longer median duration of diabetes, more people treated with insulin and more who had received foot care information before. The research flow is demonstrated in Fig. 1.

3.2. Participants' characteristics

The mean age of the participants in the study was 62.22 years (SD 9.33). There were more females (72.3%) than males (27.7%). The majority were married (71.4%), and had not received foot care information before (62.7%). At baseline, there were some differences in gender, education level, income adequacy, smoking, diabetes controlled by diet, and retinopathy. However, no difference in other demographic and health-related characteristics between groups comparison was observed (see Table 1).

3.3. Effects of the intervention on foot self-care behaviour

Effects of the intervention of foot self-care behaviour are reported in Table 2. For preventive foot care behaviour (p-FCB), the final adjusted GEE model (adjusted for SDSCA - exercise subscale, blood glucose testing, baseline KFC, baseline FCCS) highlighted a statistically significant higher increase in the p-FCB changes of the intervention group compared to those in the control group at 1-month ($\beta = 0.10$, $p = 0.001$), at 3-months ($\beta = 0.15$, $p < 0.001$), and 6-months ($\beta = 0.13$, $p < 0.001$) relative to baseline. For potentially foot damaging behaviour, the significant effects were only observed at 1-month ($\beta = -0.05$, $p = 0.03$). Similar results were obtained in the unadjusted GEE model.

3.4. Effects of the intervention on foot risk factors for ulceration

At baseline, there was no significant difference in the proportion of foot risk factors for ulceration between the intervention group and the control group. Among 14 items, three main modifiable foot risk factors which were found in the sample were dry skin, cracked skin and corns/callus. A combined variable of the three items named DCC (an abbreviation of dry skin, cracked skin, corn/callus) was examined in multivariate analysis. Within-group comparison, using McNemar's test, showed that within the intervention group, the proportion of DCC significantly decreased from a baseline value of 78% to 34.6% at 6 months, ($p < 0.001$). On the contrary, within the control group, there was an increase in the proportion of DCC from a baseline value of 66.7% to 84.6% at 6 months, $p < 0.01$. For the between groups comparison, there was no significant difference in the proportion of DCC between the intervention group and the control group at baseline, χ^2 (1, n = 119) = 1.37, p = 0.24. However, at the sixth month, the intervention group had a significantly lower proportion of DCC than those in the control group, χ^2 (1, n = 104) = 24.96, p < 0.001.

In the adjusted GEE binary logistic regression model (see Table 3), the ratio of the odds of having DCC at 6-month relative to the baseline in the intervention group compared to those in the control group was 0.045 (95% CI: 0.014 – 0.141, p < 0.001). In other words, the odds of having DCC in the intervention group were 22.22 times (i.e. 1/0.045) lower than the odds of having DCC in the control group over six months (95% CI 7.09 – 71.43).

4. Discussion

4.1. Foot self-care behaviour

Compared to people in the control group, those involved in the 3STEPFUN demonstrated significant improvement in preventive foot care behaviour over six months. It is suggested that receiving the written materials only (e.g. foot care brochure) was not enough to improve foot care behaviour in patients with diabetes. This finding has important implications for developing comprehensive foot care education programs such as in this study. The reduction in potentially
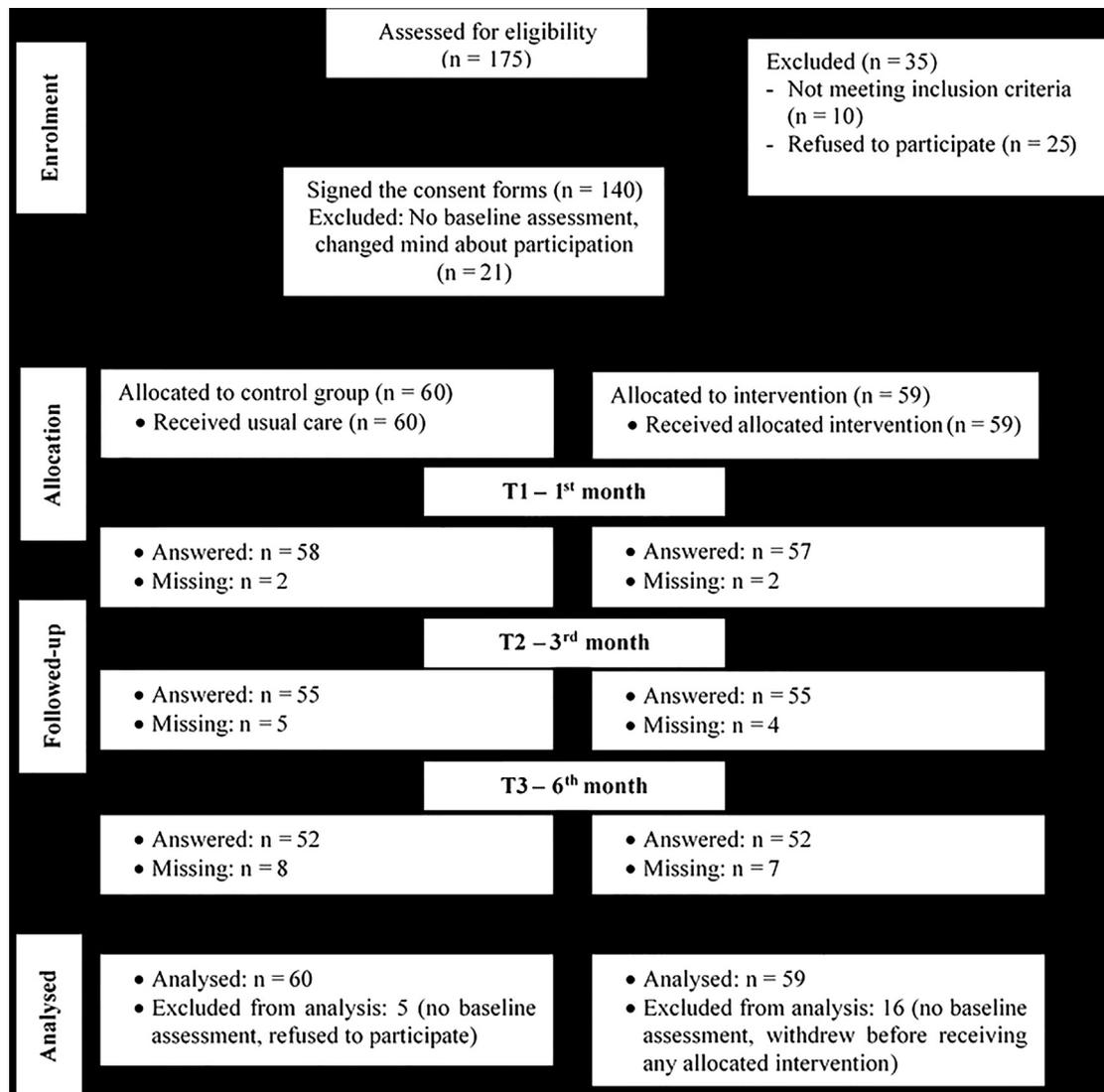
Fig. 1 – The research flow of participants.

foot damaging behaviour only occurred during the first month and was then maintained over the remaining study period. However, significant main effects for time and for group were noted. This indicated that regardless of group, all participants reduced p-FDB scores across 6 months; and regardless of time, the intervention group had better p-FDB scores (lower) than those in the control group.

The present findings are in accordance with other research which found positive outcomes from foot care education interventions in enhancing preventive foot care practice despite variability in target groups (i.e. participants' risk of foot ulceration), educators, mode of intervention (i.e. groups, individuals), intervention structures (intensive, home visit, phone call follow-up), multifaceted teaching strategies, whether theory-driven, and content covered [20,23,24,40–46]. Most of the previous studies identified short-term effects of interventions in changing foot care behaviour, and there are limited studies which examined long-term effects. Only one study focused on patients at low risk of developing a foot ulcer, similar to our target group, however, explored the outcomes only for a short time of three months with a one group

pre-and post-test design in a small sample [22]. Though findings from that study were similar to the current study, weakness in the design means the outcomes need to be interpreted with caution. The current study supported that a theory-based, comprehensive program could sustain foot care behaviour for a longer time. Longer-term observations are recommended to confirm the long-term effects of the intervention. Unfortunately, as different instruments were used in the literature, it was difficult to compare the effect size among studies. We suggest that well-validated instruments of foot care behaviour should be developed to facilitate further *meta*-analysis of the effect of foot care education intervention on foot self-care behaviour for patients with diabetes.

Findings from this study also identified the critical factors of baseline knowledge of foot care, foot care self-efficacy, and other diabetic self-care activities (i.e. exercise, self-monitoring blood sugar) in improving preventive foot care behaviour. The role of self-monitoring of blood glucose was also found to be a predictor of reduction of potentially damaging foot care behaviour. From these findings, it is recommended that such modifiable factors

Table 1 – Participants' characteristics by study groups (n = 119).			
Characteristics	Intervention group (n = 59) n (%)	Control group (n = 60) n (%)	p
Age (mean, SD)	62.51 (8.68)	61.93 (9.99)	0.74
Gender			0.02[*]
Male	10 (16.9%)	23 (38.3%)	
Female	49 (83.1%)	37 (61.7%)	
Marital status			0.28
Single/ Divorced/Widowed	20 (33.9%)	14 (23.3%)	
Married	39 (66.1%)	46 (76.7%)	
Ethnicity			0.36
Kinh	58 (98.3%)	56 (93.3%)	
Other	1 (1.7%)	4 (6.7%)	
Religion			0.14
No religion	10 (16.9%)	18 (30.0%)	
Have a religion	49 (83.1%)	42 (70.0%)	
Education level			0.002[**]
Lower high school	19 (32.2%)	37 (61.7%)	
High school or upper	40 (67.8%)	23 (38.3%)	
Primary income source			0.43
Salary/wage/age pension/self-funded	37 (64.9%)	33 (55.9%)	
Family support	20 (35.1%)	26 (44.1%)	
Income adequacy			<0.001[***]
≤ Just right	51 (86.4%)	23 (39.0%)	
≥ Enough	8 (13.6%)	36 (61.0%)	
Ever received foot care information before			0.07
No	35 (59.3%)	46 (76.7%)	
Yes	24 (40.7%)	14 (23.3%)	
BMI			0.10
Normal	29 (50.0%)	20 (33.3%)	
Underweight/overweight	29 (50.0%)	40 (66.7%)	
Duration of diabetes in years (median, IQR)	10 (5–13.0)	10 (7–14.75)	0.31
FBG (mmol/l) (median, IQR)	7.72 (6.8–9.1)	8.05 (7.0–9.2)	0.53
HbA1C (%) (median, IQR)	7 (6.5–7.5)	7 (6.36–7.59)	0.82
Diabetes control by diet			0.002[**]
No	21 (35.6%)	6 (10.0%)	
Yes	38 (64.4%)	54 (90.0%)	
Diabetes control by medication			0.98
No	6 (10.2%)	5 (8.3%)	
Yes	53 (89.8%)	55 (91.7%)	
Diabetes control by insulin			0.69
No	48 (81.4%)	46 (76.7%)	
Yes	11 (18.6%)	14 (23.3%)	
Hypertension			0.41
No	34 (57.6%)	29 (48.3%)	
Yes	25 (42.4%)	31 (51.7%)	
Retinopathy			0.01[*]
No	41 (69.5%)	54 (90.0%)	
Yes	18 (30.5%)	6 (10.0%)	
Renal impairment			0.62
No	58 (98.3%)	57 (95.0%)	
Yes	1 (1.7%)	3 (5.0%)	
Smoking			0.04[*]
Never smoked	53 (89.8%)	44 (73.3%)	
Ever smoked	6 (10.2%)	16 (26.7%)	

[*] p < 0.05.
[**] p < 0.01.
[***] p < 0.001.

should be considered in developing a foot care education program. For example, a foot care self-efficacy enhancing program should be supported for further application to not only improve patient's knowledge of foot care but also their confidence in performing foot care practice. Integrat-ing other educational sessions to improve other diabetic self-care activities (i.e. exercises, self-monitoring blood sugar) should be considered to achieve optimal effects in changing foot care behaviour in patients with diabetes.

Table 2 – Effects of the intervention on preventive foot self-care behaviour and potentially foot damaging behaviour across time.

Outcome measures	Unadjusted model β (95% CI)	p	Adjusted model β (95% CI)	p
Foot self-care behaviour				
Preventive foot self-care behaviour				
Group	0.03 (−0.03 to 0.09)	0.31	−0.02 (−0.07 to 0.02)	0.33
Time 1	0.01 (−0.03 to 0.05)	0.58	0.01 (−0.03 to 0.05)	0.57
Time 2	0.01 (−0.04 to 0.06)	0.67	0.01 (−0.04 to 0.06)	0.68
Time 3	0.02 (−0.02 to 0.06)	0.26	0.02 (−0.02 to 0.06)	0.27
Group × Time 1	0.10 (0.04–0.15)	0.001	0.10 (0.04–0.15)	0.001[***]
Group × Time 2	0.15 (0.09–0.22)	<0.001	0.15 (0.08–0.22)	<0.001[***]
Group × Time 3	0.13 (0.07–0.19)	<0.001	0.13 (0.07–0.19)	<0.001[***]
Potentially foot damaging behaviour				
Group	−0.04 (−0.08 to 0.005)	0.08	−0.02 (−0.06 to 0.025)	0.38
Time 1	−0.02 (−0.05 to 0.008)	0.16	−0.02 (−0.05 to 0.008)	0.17
Time 2	−0.05 (−0.08 to −0.02)	0.002	−0.05 (−0.08 to −0.02)	0.002[**]
Time 3	−0.06 (−0.09 to −0.03)	<0.001	−0.06 (−−0.09 to −0.03)	<0.001[***]
Group × Time 1	−0.05 (−0.10 to −0.004)	0.03	−0.05 (−0.10 to −0.004)	0.03[*]
Group × Time 2	−0.02 (−0.07 to 0.03)	0.45	−0.02 (−−0.07 to 0.03)	0.45
Group × Time 3	−0.006 (−0.05 to 0.04)	0.80	−0.005 (−0.05 to 0.04)	0.82

β: beta coefficient, CI: confidence interval.
"Group" indicates between-group differences at baseline of the control group and the intervention group.
"Time 1", "Time 2", "Time 3" indicate the within-group differences of the control group at 1-month, 3-month and 6-month, respectively, compared with the baseline.
"Group × Time 1", "Group × Time 2", "Group × Time 3" indicates differences between the intervention group and the control group in the change of outcome at 1-month, 3-month and 6-month, respectively, relative to the baseline (change in the intervention group – change in the control group).
[*] p < 0.05.
[**] p < 0.01.
[***] p < 0.001.

Table 3 – GEE logistic regression analysing the effect of the treatment group and time on DCC (baseline and 6-month).

Outcome measures	Unadjusted model OR (95% CI)	p	Adjusted model aOR (95% CI)	p
Dry skin, cracked skin, corn/callus				
Group	1.769 (0.782–4.004)	0.17	2.260 (0.93–5.48)	0.07
Time	2.814 (1.391–5.691)	0.004[**]	3.052 (1.472–6.33)	0.003[**]
Group × Time	0.054 (0.019–0.157)	<0.001[***]	0.045 (0.014–0.141)	<0.001[***]
Primary income sources: family support[1]			0.483 (0.240–0.972)	0.04[*]
Baseline FCCS (12–60)			0.948 (0.906–0.992)	0.02[*]

The final model adjusted for primary income sources, and baseline foot care self-efficacy.
OR: odd ratio, aOR: adjusted odd ratio, CI: confidence interval.
Referent: [1]self-funded/ salary/wage/age pension.
FCCS – range 12–60, where higher scores indicate higher self-efficacy toward foot care.
"Group" indicates between-group differences at baseline of the control group and the intervention group.
"Time" indicates the within-group differences of the control group at 6-month compared with the baseline.
"Group × Time" indicates differences between the intervention group and the control group in the change of outcome at 6-month relative to the baseline (change in the intervention group – change in the control group).
[*] p < 0.05.
[**] p < 0.01.
[***] p < 0.001.

4.2. Foot risk factors for ulceration

The 3STEPFUN demonstrated effectiveness in reducing the proportion of foot risk factors for ulceration in the sample, which is similar to findings in previous studies, including dry skin, cracked skin [22,23], and corns/callus [47]. In relation to the combined three modifiable foot risk factors (i.e. dry skin, cracked skin and corns/callus, abbreviated as DCC), the percentage of the foot risk factors for ulceration was significantly lower in the intervention group compared to those in the control group.

Effects on foot risk factors may be explained by the fact that participants in the intervention group had significant improvement in the frequency of applying moisturisers and

reducing the regularity of wearing sandals or thongs compared to those in the control group ($p < 0.001$). Dry skin and cracked skin were found to be strong predictors of diabetic foot ulcers (DFU) in Vietnam [48]. Although callus was not identified as a foot ulceration predictor in that study, callus formation has been confirmed as a factor increasing the risk of developing foot ulceration [49]. It is expected that the effectiveness of the 3STEPFUN on reducing common foot risk factors for ulceration among adults with diabetes at low risk of developing foot ulceration also can help to reduce the incidence of DFUs. However, a more extended period of follow up is necessary to confirm findings.

Previous pilot studies [22,23] also examined the effectiveness of a foot care education intervention program underpinned by Bandura's construct of self-efficacy in patients with diabetes. The former had a similar target population to our study, people with diabetes at low risk of developing a foot ulcer; however, the latter did not clearly identify risks of developing foot ulceration within participants. However, both studies conducted one group, pre and post-test design with a shorter follow-up period of three months. Limitations in the design and analysis of those studies could not control intrinsic and extrinsic bias; thus, interpretation of the effects of the intervention could not be certain. The strengths of the current study, despite not having individual randomisation, were a stronger design with a control group, using repeated measures at different time points and using mITT principles with GEE model for controlling confounding factors. This is believed to produce more precise estimation and stronger interpretation about the effect of the 3STEPFUN.

Interestingly, results from the GEE model also highlighted that the primary income source from family and higher foot care self-efficacy at baseline were statistically significantly related to the prediction of DCC. The results on primary income source might be related to the social support structure concept; family support is vital for elders in Vietnamese culture. Indeed, evidence from a systematic review confirmed the effectiveness of diabetic self-management with family support in enhancing self-management behaviours and health outcomes among uncontrolled glycaemia patients with type 2 diabetes [50]. Thus, it is recommended to involve family members in further foot care education intervention programs for people with diabetes, especially for older patients. Regarding our findings on increased baseline foot care self-efficacy in reducing the likelihood of DCC, this also supports the self-efficacy theoretical frameworks and theory underpinning the education program.

4.3. Limitations

Without individual randomisation, confounding caused by dissimilarities in baseline characteristics (e.g. gender, education level, smoking history) could not be minimised. Although potential confounding was adjusted in the study by multivariate analysis, hidden factors which were not measured during data collection cannot be adjusted. This may result in overestimates the effect of the intervention. Thus, the positive effects of outcome measures in the present study should be interpreted and generalised with caution. A formal RCT is suggested for future study to deliver stronger interpretation and estimation of the intervention effectiveness since it could minimise both measured and unmeasured confounding factors. The study was conducted in a healthcare setting in an urban area. Thus, the generalisation of the study outcomes population in the rural area is limited and should be further explored. Participants recruited in one setting may not represent all characteristics of patients with diabetes compared to those in multicentre studies. Biological and social attributes vary between male and female (e.g. risks of illness, duties, demands, compliance, access of care). Thus unequal male and female distribution may introduce sources of bias. Gender imbalance in the sample (i.e. much high prevalence of female than male), therefore, limits the external validity of the findings. Participants in the study were followed up over a six months period; which may be enough to evaluate the sustained effects of the intervention on the outcome measures. However, its effectiveness in reducing DFU incidence could not confidently be addressed. The current study only focused on clinical and behavioural outcomes evaluation; however, evaluation of the cost-effectiveness and potential health benefits of the primary prevention education intervention should be further explored. This would be helpful for policymakers in making decisions about which intervention solutions for health issues should be prioritised and allocated resources. Additionally, process evaluation, which provides a better understanding of the mechanism of behaviour change and identifies potential or emerging influencing factors in the delivery of the interventions on the outcomes, was not conducted in this study, which is considered a limitation.

Author's contributions

TPLN, TNDD, HE, KF: Study design; TPLN, TNDD: Data collection; TPLN, KF: Data analysis; TPLN, TNDD, HE, KF: Manuscript writing. All authors read and approved the manuscript.

Conflicts of interest

The authors declare no conflict of interest.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.diabres.2019.05.003.

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