Title： The effectiveness of a short message-based customized standardized education program in promoting wound healing and quality of life of patients with diabetic foot ulcers

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INTRODUCTION

Diabetic foot ulcers need complex treatment and have poor prognoses. Thus, they consume medical resources and impede patients' quality of life. Most of the time, patients are required to perform diabetic foot ulcer self-management at home. However, their self-management behaviors are inadequate.

Individualized patient education messages can promote and maintain appropriate diabetes self-management behaviors. The short message-based customized standardized patient education program combines several smartphone message-based standardized educational contents to construct a customized patient education program that is according to patients' needs, thus promptly providing individualized patient education. The short message-based customized standardized patient education program may improve diabetic foot ulcer self-management behavior and self-efficacy on diabetic foot ulcer self-management, thereby promoting wound healing and improving quality of life.

This study aims to develop a short, message-based, customized standardized education program and to test the effect of the program on diabetic foot ulcer self-management behavior, self-efficacy, wound prognosis, and quality of life.

2. METHODS

2.1 Study design

A customized standardized patient education module will be developed and evaluated. A randomized controlled study design will be adopted.

Participants will be assigned to two parallel groups for the duration of the study.

2.2 Study setting and participants

The participants will be recruited from August 2023 to July 2026 and followed up for eight weeks at a medical center in northern Taiwan. Recruited criteria were: (1) outpatients with DFUs over 20 years old; (2) can be interviewed in Mandarin or Taiwanese.

The exclusion criteria were: patients (1) planning to return visits within eight weeks less than two times; (2) without using a smartphone; (3) being unable to read text messages on a mobile phone or with impaired hearing; (4) with impaired fine hand movements; (5) unwilling to use the communication software LINE to receive text messages.

2.3 Sample size and statistical power

In this study, we will use the generalized estimating equation (GEE) to detect the effectiveness of intervention in improving the quality of life. Since no previous research results are available for reference, we assume that the intervention in this study has a moderate effect. We set the effect amount as 0.25, the statistical power as 0.95, the alpha value as 0.05, and the number of repeated measurements as 3. The G*power 3.1 statistical software shows that the required sample size was 178.

2.4 Intervention group

At each visit of the research subjects to the plastic clinic, the research team records the attending prescriptions and patient education given by the medical team members and evaluates whether the research subjects and caregivers need additional mental support. Then, according to the

above evaluation and records, items of a designed patient education menu will be selected, and the selected patient education messages will be sent according to the transmission frequency and period proposed by the research subject

2.5 Control group

Subjects will receive routine care.

2.6 Measurements

2.6.1 Sociodemographic and clinical information

This study collected data by foot assessment, medical record review, and questionnaire interviews.

2.6.2 Whether the Wound Shrinks

This study will measure the wound size at baseline, four and eight weeks. Then, whether the wound has shrunk will be determined by subtracting the pre-measurement area from the post-measurement area.

2.6.3 Diabetes-related Foot Ulcer Quality of Life

A questionnaire on quality of life with chronic wounds (Wound QoL-14) will be used to evaluate the change in QOL. The questionnaire on quality of life with chronic wounds (Wound-QoL) has 14 items to measure patients' quality of life with chronic wounds. Using the 5-point Likert scale, the influence of chronic wounds in the past seven days ranges from 0 (not at all) to 4 (significantly affected), with higher scores indicating poorer quality of life. The range of scores is 0 to 56.

2.6.4 Diabetes-related foot ulcer self-management behavior

In this study, Chin et al. (2019) used the Diabetes-related Foot Ulcer Self-Management Behavior Scale (DFUSMB) to measure DFU

self-management behavior. The DFUSMB measures behaviors that promote wound healing and prevent wound deterioration with 18 items in total, using the five-point Likert scale. "Never," "Seldom," "Sometimes," "Often," and "Always" are scored from 1 to 5, respectively. Reverse questions are scored in reverse. The higher the total score, the better the self-management behavior. The DFUSMB has sufficient reliability and validity (Chin et al., 2019).

2.6.5 Diabetes-related Foot Ulcer Self-management Self-efficacy

We used 11 questions to measure the diabetes-related foot ulcer self-management self-efficacy, using an 11-point scale, with 0 indicating no confidence and 10 indicating complete confidence. The high scores reflect high self-efficacy. The sum score of the above 11 items indicates the DFU self-management self-efficacy with a range from 0 to 110.

2.6.6 Diabetes-related foot self-care behavior

This study used Chin & Huang's (2013) Diabetes-related Foot Self-Care Behavior Scale (DFSBS) to measure participants' diabetes-related foot-care behavior. The DFSBS has seven questions measuring the frequency of foot care behaviors delivery. The higher the score, the better the foot care behavior. The DFSBS has sufficient reliability and validity (Chin & Huang, 2013).

2.6.7 Diabetes self-care behaviors

In this study, the summary of the diabetes self-care activity questionnaire (SDSCA) will be used. Deborah Toobert developed the SDSCA questionnaire. It focuses on general diet, diabetes-specific diet, physical activity, blood-glucose testing, foot care, and smoking. The instrument

assesses the absolute frequency or consistency of ten diabetes health-related regimen behaviors (e.g., number of days per week on which respondents engage in physical activity sessions; number of days in the past 7 days respondents ate five or more servings of fruits and vegetables). Reverse questions are scored in reverse, and the higher the total score, the better the diabetes self-care activity. The total SDSCA score ranges from 1-63.

2.7 Data collection

Before the study delivery, we will perform block randomization of four categories according to the statistical software (Sealed Envelope Ltd., 2022), with four as the block, and create label categories and case acceptance order according to the software allocation group, then putting the group name into the envelope. This study adopted categorical random allocation, with four categories: patients with neuropathic foot ulcers who received hemodialysis, patients with neuropathic foot ulcers who did not receive hemodialysis, patients without neuropathic foot ulcers who received hemodialysis, patients without neuropathic foot ulcers who did not receive hemodialysis.

After the research subjects agree to participate, the project leader will open envelopes to arrange their group location. Then, the data collection begins, including basic information on the research subjects, self-care behavior for diabetes, foot, and diabetic foot ulcers, self-efficacy in preventing and treating foot ulcers, quality of life, and wound measurement. Two post-tests (questionnaire interview and wound

assessment) will be conducted four and eight weeks after baseline data collection.

2.8 Data analysis

The data will be analyzed with SPSS statistical software for Windows 20.0 (SPSS, Inc., Chicago, IL, USA). The chi-square and Mann-Whitney U tests will be used to determine the homogeneity between the intervention and control groups. An intention-to-treat analysis approach (ITT) will be used. Generalized estimating equations (GEEs) will be used to examine the effects of intervention measures on improving the study subjects' self-care behavior, self-efficacy, and quality of life. The chi-square test will be used to detect whether there was any difference in the proportion of wounds reduced by 50% or more between the two groups of study subjects four weeks after admission.