Feasibility and acceptability of a personalised self-care support program for primary care patients with diabetic foot ulcer delivered by wound care nurses: the HEALing study protocol

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Introduction

Diabetic foot ulcers (DFU) are highly prevalent and recurrent complications of diabetes mellitus (DM) that have significant health and cost implications. Self-care is critical for preventing or delaying DFU yet adherence to self-care recommendation is low. Interventions using motivational interviewing (MI) have been effective in supporting behaviour change but evidence for DFU is scarce. This study will assess the acceptability, feasibility and preliminary efficacy of an MI-guided program, Healing DFU through Empowerment and Active Listening (HEALing), and its integration in usual wound care practice.ProtocolP

Methods and analysis

This single-arm pilot study uses a mixed-method approach to assess the feasibility and acceptability of the HEALing intervention. HEALing, a practical, low-intensity, clinic-integrated intervention consists of three 30-minute face-to-face sessions of a personalised care support over a period of 6 weeks conducted by trained wound care nurses seeking to support self-care behaviours and emotional adjustments among patients who have DFU. Data will be collected from a battery of questionnaire-based surveys with patients (N=30), and with in-depth individual interviews with patients (N=30) and wound care nurse facilitators (N=10) from nurse-led wound clinics in a large primary care sector in Singapore.

The primary feasibility outcomes will include enrolment, retention (≥ 80%), data completion (≥ 80% of surveys), and participant satisfaction. Secondary outcomes will include self-report measures of illness perceptions, self-efficacy, diabetes distress, foot self-care, DFU knowledge, autonomy support, and quality of life, taken at baseline and 2-4 weeks post completion of HEALing. Exit interviews with patients and wound care nurse facilitators will collect feedback on program and its implementation feasibility.

Ethics and dissemination

The study protocol was approved by the local ethics committees and written informed consent is required from every participant. The findings will be disseminated through various means including peer-reviewed journals, as well as well as national and international conferences and public events.

Trial registration number Prospectively registered; NCT06540170

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇨ Key strengths include the substantial patient and public involvement in the development and implementation of HEALing intervention.
- ⇨ Another strength is the mixed-method design, with interview data used to complement quantitative survey findings.

- ⇨ The design of a single arm has some limitations, such as being unable to compare outcomes between groups.
- ⇨ Only short- term outcomes will be evaluated; hence sustainability of effects will not be known.

METHODS

Study design

To determine feasibility and acceptability, a single-arm hybrid effectiveness-implementation pilot study using a mixed-methods design will be used to collect data on recruitment, retention, completion and feedback on program and its implementation using in-depth interviews with patients and HCPs involved in the delivery of HEALing (see Figure 1 for patient recruitment and study procedures). To determine the preliminary effectiveness of HEALing, a single group pre- and post-assessment design will be used. Assessments using validated questionnaires listed in Table 1 will be taken at baseline and 4 weeks from last session of HEALing intervention. Qualitative interviews will be used at the end of the main trial to examine HCPs' and patients' experiences of delivering and receiving the program at end of the study to identify implementation issues in need of refinement. A triangulated mixed method approach combining and contrasting perspectives of patients and HCPs will allow for a comprehensive scope of the feasibility and acceptability of the programme.

Participants

Patient participants

All patients who have T2DM and DFU aged 21 years or above receiving treatment in the eight polyclinics will be eligible and invited to participate in the study over a period of six months. Patients are excluded if they: (i) do not have a minimum toe pressure of 30mmHg; (ii) have active osteomyelitis; (iii) are diagnosed with Charcot foot; or (IV) have cognitive, hearing or vision impairment. A sample size of 25-30 patient participants is chosen in accordance with published guidance for pilot studies and allowance for dropouts[1].

A study team member will meet with eligible and interested participants to review the consent form, answer any questions, and assure the patient that participation is not a requisite for concomitant care. Patients with DFU receiving the HEALing program will be invited to take part in the quantitative surveys and qualitative interviews.

Data collection

Quantitative data including sociodemographic characteristics, clinical indicators, healthcare utilisation data, and patient reported outcome measures (PROM) will be collected at baseline upon enrolment and at post HEALing completion (i.e., at week 4

from the last/third session of HEALing intervention, or three months from enrolment, whichever comes first).

Table 1 Sociodemographic/clinical characteristics and constructs, variables of interest, scales and measurement time points for secondary outcomes

Variable/Construct	Scale	Baseline	*HEALing completion
Sociodemographic and clinical characteristics			
Sociodemographic characteristics	Age, ethnicity, gender, highest education qualification, living arrangement, relationship status, employment status, type of dwelling	x	
Clinical characteristics (diabetes and diabetic foot ulcer)	Type of diabetes, duration of diabetes, diabetes treatment, number of DFU, history of DFU, location of DF	x	
Clinical characteristics (diabetes and diabetic foot ulcer)	HbA1C, wound size reduction, wound exudate level, wound bed appearance, peri-wound conditions, DFU related hospitalization	x	x
Patient Reported Outcome Measures (PROM)			
Autonomy support	Patients' perceptions of autonomy support[2]-6 items	x	x
Foot self-care behaviour	Diabetes Foot Self-Care Behaviour Scale[3] – 7 items	x	x
Illness belief	Brief Illness Perception Questionnaire[4] – 8 items	x	x
Foot care confidence	Foot Care Confidence Scale[5] – 12 items	x	x
Diabetes distress	Diabetes Distress Scale[6]– 17 items	x	x
Warning signs of wound deterioration	Warning Signs of Diabetic Foot Ulcer Deterioration Questionnaire[7] – 12 items	x	x
Health-related quality of life	Health-Related Quality of Life - EQ-5D-5L[8]	x	x

*HEALing completion: 2-4 weeks from the last HEALing session, or 3 months from the enrolment, whichever first; DFU: diabetic foot ulcer

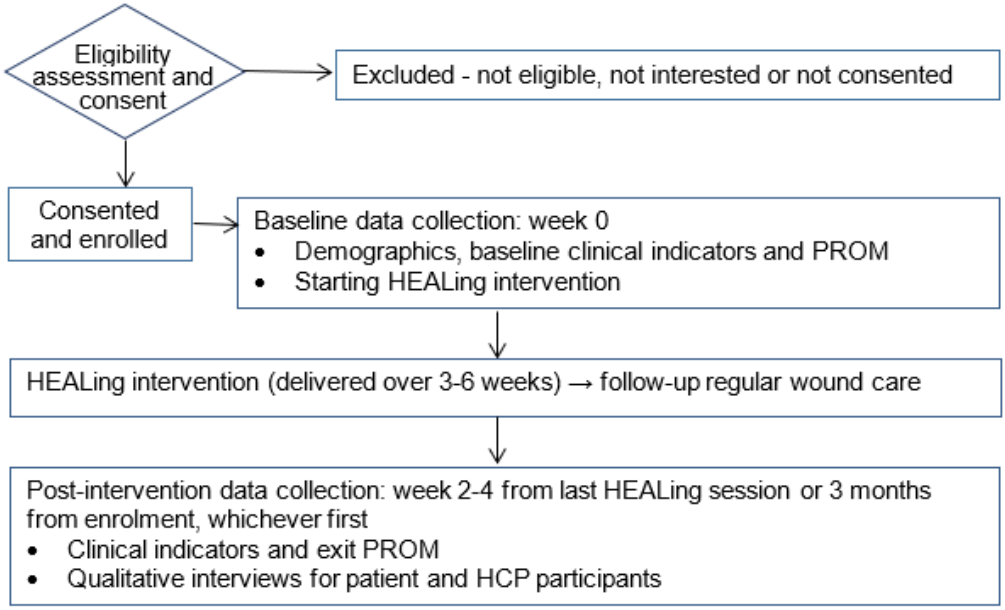

Figure 1 Flow diagram of the study designed to assess the feasibility and acceptability of a novel self-care support intervention (HEALing). PROM: patient reported outcome measures

The HEALing Intervention

The HEALing programme was co-designed with patients living with DFU and their healthcare providers (i.e., wound care nurses). In brief, the programme involved three face-to-face sessions (30 minutes per session) and will be delivered over a 3-6-week period (i.e., 1-2 times weekly) by trained wound care nurses who also perform patients' routine wound dressings and conduct regular foot wound education. The HEALing session outlines are presented in Table 2.

Following enrolment, patients with DFU will be scheduled to receive three 30-minute face-to-face HEALing sessions typically every 1-2 weeks to coincide with routine care appointments (augmented usual care (AUC)). Each session will comprise 30 minutes wound dressing (usual care) followed by 30 minutes HEALing session post dressing.

Table 2 HEALing session outlines

Session and theme	Outline of session
Session 1 Self-management/ self-care skills, and setting goals related to treatment (week 1-2)	Introduce HEALing program; agenda mapping of self-care tasks to identify areas of competency and areas in need of improvement; provide information/advice with permission using the Ask-Offer-Ask framework to support the chosen self-care task; review and issue patient education leaflets as appropriate/available for chosen topic of session; set a short-term goal using confidence rulers considering its benefits, barriers, and importance to practice before the next session.
Session 2 Managing mood-- acceptance and hope [*This topic to be brought in with permission by nurse*] (week 3-4)	Invite patient to choose topic (see card sorting task photo); use affirmation (see card sorting task) and review of the 1st goal from session 1 to evoke and strengthen confidence that progress is underway. If topic on low mood/worry OR suggest topic with permission (e.g. low mood/ worry about would deterioration or topic that is deemed of high clinical importance e.g. self-wound care)

	– listen to concerns, use validation and normalization to stabilize emotion (e.g. anxiety/worry as expected, adaptive response to a real threat; this threat can be mitigated with self-care); with permission use Ask-Offer-Ask framework to provide advice related to self-care and timely recognition or actions as means to reduce threat and adverse DFU outcomes; summary to start with worry is expected and normal, and finish with the steps taken or progress made with self-care to show that progress is being made). Offer/Ask feedback and then set a short-term goal using confidence rulers considering its benefits, barriers, and importance to practice before the next session.
Session 3 HEALing in Action-living life beyond foot disease (repeat card sorting task) (week 5-6)	Repeat card sorting task; affirm steps in right direction (even if goal is not met or perhaps with partial successes – good intentions) review goal *step up or down etc; review goal setting progress and problems solve barriers (if any) for goal(s) set in session 1 & 2, and revise goals as needed; use Ask-Offer-Ask framework to problem solve lapses and barriers; use agenda mapping (as above) to address any pending important concerns; provide information/advice on chosen topic using the Ask-Offer-Ask framework; goal setting (using importance and confidence rulers to tailor goals and behaviour); conclude with Ask-Offer-Ask framework to provide additional advice and links to available resources as patients continue to move forward with their goals.

Outcome Measures

Primary outcomes

The primary outcomes include the feasibility indicators: recruitment (i.e., number eligible participants invited over number consented), retention (i.e., 80% complete all sessions), data completion (80%), and the acceptability of the intervention. The following recruitment metrics will be monitored: recruitment will be monitored using participant screening logs including number of people accept the invitation to participate in the study, number of people receive the intervention, and number of people complete the intervention.

Feasibility of retention will be recorded including number of people complete the intervention - retention rates upon HEALing completion, i.e., number of sessions delivered/attended/completed by HCPs and patients. Feasibility of measurement tools include time taken to conduct the HEALing sessions and fill in questionnaires, as well as missing or completion of data capture from questionnaires.

Acceptability of the intervention to patient and HCP participants will be determined by semi-structured individual interviews at the end of study focusing on satisfaction and perceptions, i.e., barriers, challenges and reasons for not taking part/discontinuation or dropping out.

Secondary outcomes

The secondary outcomes include PROMs that will be assessed using standardized English version and psychometrically sound instruments, i.e., illness/DFU perceptions

measured by Brief Illness Perception Questionnaire[4], diabetes distress measured by Diabetes Distress Scale[6], foot care confidence measured by Foot Care Confidence Scale[5], foot self-care behaviour measured by Diabetes Foot Self-Care Behaviour Scale[3], knowledge on warning signs of diabetic foot ulcer deterioration measured by Warning Signs of Diabetic Foot Ulcer Deterioration Questionnaire[7], and quality of life measured by EQ-5D-5L[8]. Various clinical endpoints characteristics (i.e., related to DM and DFU) will be assessed at baseline and HEALing completion. Table 1 lists variables of interest, scales and measurement time points for secondary outcomes.

Data Analysis

Quantitative data analysis

Data collected will be entered into a secured database for analysis. Statistical analysis will be performed using the statistical software SPSS Statistics Version 28. Descriptive statistics—median (IQR); mean (SD); number (%)—will be used to analyse the numbers of patients recruited and retained, as well as patients' adherence to the self-care activities and session attendance. Analysis of the above outcome measures will be used to develop an assessment of the feasibility of delivering this intervention.

PROM recorded at baseline will be compared with PROM at HEALing completion to determine if the HEALing intervention had an impact on illness beliefs, foot care confidence, diabetes distress, knowledge of the warning signs of DFU deterioration, quality of life and diabetes foot self-care behaviours. The distribution of each outcome measure will be assessed for normality. Differences in PROMs between baseline and HEALing completion will be assessed using univariable analyses such as chi-square test for categorical variables and independent samples t-test or analysis of variance for continuous variables where appropriate. Paired t-test will be used to explore if there is a significant difference between the means of pre- and post-PROMs. Non-parametric (Mann-Whitney U test) statistics will be used for continuous variables if the data is skewed. Statistical significance (two-tailed) will be set at $p<.05$.

Qualitative data analysis

The audio-recorded interviews will be transcribed verbatim and analysed using reflexive thematic analysis as per 6 steps: familiarizing with the data; generating initial codes; searching for themes; reviewing potential themes; defining and naming themes; and producing the report)[9]. Analysis will be iterative and will be conducted by two independent qualitative researchers/coders. Triangulation will be used to cross-check the observational field notes and transcripts of the audio interviews to evaluate the extent to which all evidence converges and corroborates.

Patient and Public Involvement

Patients and public were involved in this study throughout the co-design process and feasibility evaluation of the intervention. Patients and public involvement (PPI) in the co-design process includes individual interviews, surveys, focus group discussions and participation in workshops and feedback meetings. PPI started from identifying the problem, understanding determinants, and the real-world workshop discussions for topic refinement and prototype optimization. In the present feasibility study, patient

and HCPs participants' feedback on the HEALing programme will be collected through individual interviews and surveys as part of the feasibility and acceptability analysis. Prior to disseminating findings in academic journals, we will conduct member checks with community partners, incorporating their comments into manuscripts, primarily in the discussion section (if any). When feasible, we invite community partners to co-present at conferences and coauthor manuscripts.

DISCUSSION

Strengths

This proof-of-concept study will provide evidence on the feasibility and acceptance of a personalised self-care support programme for primary care patients with DFU. The key strength of the study will be its substantial PPI throughout the intervention development and feasibility trial in the real world. Using PPI in direct collaboration with people affected by DFU will provide those who will receive the HEALing intervention an equal opportunity to make decisions about their own lives. People who use and receive the HEALing intervention with direct experience leading initiatives (co-designing intervention) and getting involved throughout the feasibility trial will be at the heart of person-centred care and patient empowerment. Another strength of the study is its mixed-method approach with interview data used to complement the quantitative survey findings. Qualitative in-depth interviews with people living with DFU will ensure their voices and in-depth views can be captured and are not misrepresented.

Limitations

The design of a single arm has some limitations, such as having no outcome comparisons between groups that may yield biases in interpreting the results. As parallel control is lacking, comparisons could only be made with external historical data to evaluate the validity the study population, hence potential for selection bias in external comparison groups could be another limitation. Lastly, only short-term outcomes will be evaluated, thus sustainability of effects (if any) will not be known. Future randomised controlled trials including long-term outcomes with long study duration are recommended.

Significance

This pilot feasibility study will establish whether the MI-guided HEALing programme is feasible and acceptable to be implemented for supportive self-care for primary care patients with DFU. The study findings will directly inform the next steps in HEALing programme development, adaptation and testing future versions for self-management in future studies with potentially diverse samples in a range of settings. The information (i.e., preliminary efficacy) from this trial can be used to guide the refinement of a future trial in a larger scale to evaluate the effectiveness of the program for self-management intending to enhance self-efficacy and self-care behaviours for patients with DFU, as well as improve sustainability and substantiality of patient education.

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