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

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ABSTRACT

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

Methods and analysis This single-arm pilot study adopts a mixed-methods approach to assess the feasibility and acceptability of the HEALing intervention. HEALing is a practical, low-intensity, clinic-integrated personalised self-care support intervention, comprising three 30 min face-to-face sessions delivered over 6 weeks by trained wound care nurses, aiming to enhance self-care behaviours and support emotional adjustment in patients with DFU. Data will be collected from a battery of questionnaire-based surveys with patients (n=30), and in-depth individual interviews with both 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, foot care confidence, diabetes distress, foot self-care behaviour, DFU knowledge, autonomy support and health-related quality of life, taken at baseline and post-intervention. Post-intervention interviews with patients and wound care nurse facilitators will be conducted to collect feedback on the programme and its implementation feasibility.

Ethics and dissemination The study protocol has been approved by the local ethics committee, and written informed consent will be obtained from all participants. Findings will be disseminated through the first author's PhD thesis, peer-reviewed journals, national and international conferences and public events.

Trial registration number NCT06540170; Pre-results.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Key strengths include the substantial patient and public involvement in the development and implementation of the Healing DFU through Empowerment and Active Listening (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.

INTRODUCTION

Diabetes mellitus (DM) is a significant global health threat.[1] Diabetic foot ulcers (DFUs), one of its most complex complications, affect approximately 18.6 million people worldwide each year,[2] with recurrence rates reaching 42% within 1 year of wound closure[3] and a 5 year mortality of around 30%.[4] Up to 20% of patients require lower extremity amputation,[5] often due to infection or progressive gangrene.[6]

In Singapore, approximately 1400 incident DFUs occur annually within a single healthcare cluster.[7] A retrospective primary care study of 520 patients with DFU found that

over half presented with infected ulcers requiring oral antibiotics, nearly half experienced recurrence, and one-quarter had a history of amputation.[8] Five-year mortality for patients with DFU reached 37.9% (2013–2017),[9] whilst ten-year amputation rates among individuals with diabetes remained persistently high and stable (2008–2017), exceeding those reported in other countries.[10]

Most DFUs are preventable with adequate self-care behaviours, including adhering to recommended footwear, performing regular foot inspections, seeking immediate advice from healthcare professionals for any ulcerative lesion, maintaining optimal foot and skin care,[11–13] in addition to the demands of optimal diabetes self-management. However, these behaviours are often ignored or suboptimal. Non-adherence to diabetic foot screening—an objective measure of self-care—is common, affecting nearly 50% of patients with DFU[8] and those with type 2 diabetes without a DFU.[14] Similarly, non-attendance at multidisciplinary DFU care appointments is high, with patient-related factors accounting for 50.4% of missed visits.[15]

DFU care outcomes are contingent on both system and individual level factors. Systemic factors, such as limited access or delayed referral to DFU care,[5] are critical barriers, but these alone cannot account for the poor outcomes for those already known to specialist DFU care. Individual factors, including beliefs about DFU or treatment and mood, have been shown to hinder timely help-seeking and self-care.[16–19] Patients with DFU often report low treatment effectiveness beliefs, as well as feelings of hopelessness and high DFU and diabetes distress that can undermine motivation towards treatment and self-care.[18–20] These challenges highlight an urgent need for interventions to empower them (skills, knowledge) and to support emotional adjustment.

To date, most self-care interventions for DFU have focused mainly on psychoeducation targeting knowledge and skills, but evidence on the effectiveness remains mixed. While some psychoeducational interventions yielded significant improvements in self-care behaviours they had limited efficacy in terms of patients agency/autonomy and psychological adjustment.[21–23] More intensive psychoeducational interventions (weekly 3 hours sessions over 3 months) that combined patient, family education and nurse-led psychosocial care were associated with reduced anxiety and depression symptoms related to DFU, but self-care outcomes were not evaluated.[24] Similarly, a programme offering twice-weekly 50 min self-management and family-management support sessions over 3 months improved self-care and clinical outcomes;[25] however, psychological effects were not assessed, and potential challenges to real-world implementation remain. The high resource demands of these interventions limit their integration into routine DFU care. In contrast, Motivational Interviewing (MI) interventions have been shown to be effective in brief (even a single) healthcare consultations in primary care and diabetes, both for behavioural change and emotional adjustment,[26–28] but evidence in DFU is limited.

MI is a collaborative and goal-oriented counselling style for strengthening a person's own commitment to behaviour change.[29] Self–determination theory (SDT) is a framework for understanding personality development and self–motivated behaviour change.[30] MI's supportive yet directive strategies can be leveraged to maximise the theoretical principles of SDT in designing interventions that enhance engagement and motivations. Interventions guided by MI and informed by SDT in the health domains have been widely used to foster behaviour change and support health treatments through patient empowerment.[26 31] This approach increases autonomous motivation, supporting change arising from within the individual rather than being imposed by others.[30 32]

There is ample evidence that MI counselling and provision of an autonomy-supporting environment improve self-management, self-efficacy and treatment adherence amongst patients with diabetes, whilst decreasing depressive symptoms and emotional distress to achieve better clinical outcomes.[28 33–42] Emerging MI-guided proof-to-concept interventions designed to support podiatrists in empowering patients with DFU to engage with self-care treatment (specifically for limiting weight-bearing activities) suggested that integrating MI principles into routine consultations holds potential for enhancing adherence to treatment recommendations.[43 44] However, these interventions are constrained by limited resources and mainly targeted self-care adherence without addressing diabetes-related distress.[19]

Emerging evidence supports personalised self-care programmes that, through comprehensive assessment and effective patient–provider communication, improve engagement, emotional adjustment, adherence and outcomes.[45] By integrating clinical treatment with tailored education, behaviour change strategies and stress management, these programmes address patients' unique clinical and psychological needs, including distress and motivation. Such approaches have shown promise in enhancing diabetes self-management across diverse settings, including Singapore primary care.[46]

Given the limited existing support, there is growing interest in healthcare to develop brief yet effective interventions that are sufficiently intensive to improve DFU outcomes and feasible for integration into routine care. This study addresses a critical gap by conducting a pilot trial of Healing through Empowerment and Active Listening (HEALing), an innovative clinic-integrated MI brief intervention designed to target multiple interrelated risks in DFU—including wound care, foot care, diabetes self-management and diabetes distress. Details of the HEALing intervention have been published elsewhere.[47] Adopting a personalised approach, HEALing consists of three sessions delivered at the point of care by trained wound care nurses in primary care wound clinics.

This protocol details the trial methods, analytical plan and key intervention components. The pilot aims to: (a)

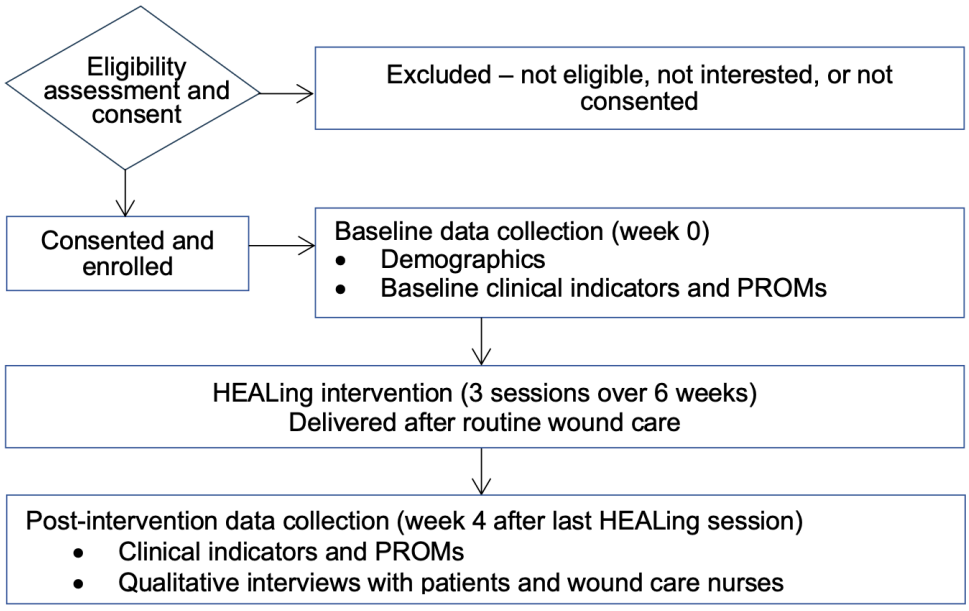

Figure 1 Flow diagram of the study design to assess the feasibility and acceptability of the HEALing intervention. HEALing, Healing through Empowerment and Active Listening; PROM, patient-reported outcome measures.

assess the acceptability and feasibility of HEALing from the perspectives of patients with DFU and wound care nurses involved in its delivery and (b) provide preliminary data on its effectiveness for key patient and DFU outcomes.

METHODS

Study design

A mixed-methods design was chosen to capture the intervention's complex impact. Quantitative methods assess feasibility and preliminary effectiveness on key psychological and behavioural outcomes, whilst qualitative methods explore acceptability and experiences of patients and wound care nurse facilitators. This single-arm hybrid effectiveness-implementation pilot study will collect data on recruitment, retention, completion and programme feedback through in-depth interviews with patients and wound care nurse facilitators (see figure 1). Validated questionnaires (table 1) will be administered at baseline and 4 weeks post-intervention. Qualitative interviews at study completion will identify implementation challenges. Triangulating patient and wound care nurse perspectives will provide a comprehensive evaluation of feasibility and acceptability.

The intervention protocol accords with the standards outlined in the Standard Protocol Items: Recommendations for Interventional Trials checklist.[48] The protocol was approved by the National Healthcare Group Domain Specific Review Board ethics committee (Ref No. 2022/00895) and the Nanyang Technological University Institutional Review Board (Ref No. NTU IRB-2022-338) and is registered on ClinicalTrial.gov (registration number: NCT06540170). Informed written consent (see online supplemental file 1) will be obtained for wound care nurses and patients' participation in the study.

Study setting

The study will be conducted at National Healthcare Group Polyclinics (NHGP), one of the large primary care institutions in Singapore, serving the central and northern regions. NHGP is part of diabetic foot in primary and tertiary (DEFINITE) care programme, an inter-institutional, multi-disciplinary initiative delivering optimal DFU care across the healthcare cluster.[49] At NHGP, nurses routinely provide DFU assessments, wound dressings and education on wound and foot self-care every three to five days, often continuing for months until wound closure.[19] Nurse-led wound services are delivered by nurses with advanced wound management training. The HEALing programme is integrated into the regular wound care sessions and conducted by MI-trained wound care nurses.

Participants

Patient participants

All patients with DFU aged 21 years or above receiving wound care at NHGP will be eligible and invited to participate in the study over a period of 6 months. Patients will be excluded if they: (a) do not have a minimum toe pressure of 30 mm Hg, (b) have active osteomyelitis, (c) are diagnosed with Charcot foot or (d) 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.[50]

A study team member will meet eligible and interested participants to review the consent form, answer questions and reassure them that participation is voluntary and will not affect ongoing care. Patients with DFU receiving the HEALing programme will be invited to complete quantitative surveys and participate in qualitative interviews.

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

Variable/construct	Item/Scale	Baseline	Post-intervention
Sociodemographic and clinical characteristics			
Sociodemographic characteristics	Age, ethnicity, gender, education qualification, living arrangement, relationship status, employment status, type of footwear, smoking history and ambulatory status	x	
Clinical characteristics (diabetes and diabetic foot ulcer)	Type of diabetes, duration of diabetes, number of DFU, history of DFU, location of DFU, history of amputation, history of hypertension, history of coronary artery disease, history of congestive heart failure, and history of renal impairment	x	
Clinical characteristics (diabetes and diabetic foot ulcer)	HbA1C, wound size, wound exudate level, wound bed appearance, peri-wound conditions, and DFU—related unplanned hospitalisation	x	x
Patient-reported outcome measures (PROM)			
Autonomy support	Health care climate questionnaire[53]—6 items	x	x
Foot self-care behaviour	Diabetes foot self-care behaviour scale[57]—7 items	x	x
Illness belief	Brief illness perception questionnaire[54]—8 items	x	x
Foot care confidence	Foot care confidence scale[56]—12 items	x	x
Diabetes distress	Diabetes distress scale[55]—17 items	x	x
Knowledge of warning signs of foot ulcer deterioration	Warning signs of diabetic foot ulcer deterioration questionnaire[58]—12 items	x	x
Health-related quality of life	Health-related quality of life—EQ-5D-5L[59]	x	x

DFU, diabetic foot ulcer; HbA1C, glycated haemoglobin.

Wound care nurse participants

Wound care nurses who completed the training to deliver HEALing and facilitated the programme will be invited to participate in a qualitaitve interview after they have finished delivering the programme.

Data collection

Quantitative data, including sociodemographic characteristics, clinical indicators, healthcare utilisation data (ie, unplanned hospitalisation related to DFU), and patient-reported outcome measures (PROMs) will be collected at baseline upon enrolment and post-intervention at week 4 after the last HEALing session.

Clinical data will be collected from consented participants or extracted from their medical records. A questionnaire survey will be self-administered or assisted by a designated researcher on request by participants. Table 1 lists the variables of interest, scales and measurement time points.

Qualitative data will be audio-recorded semi-structured individual interviews lasting up to 45 min with patient and wound care nurse participants using a flexible topic guide with prompts. Interviews will be conducted face-to-face in a private consultation room within the participant's primary clinic. Virtual interviews via secured videoconferencing will be an alternative for wound care nurse participants to accommodate their work commitments. The interviews will be conducted by researchers who have prior experience in qualitative methodology but are uninvolved in the HEALing intervention delivery, to ensure freedom of expression. Data collection will cease

at the point of saturation, where the research team agrees by consensus that no new themes are emerging from the data.

Figure 1 presents the flow diagram of the study design, using a mixed-methods approach to assess the feasibility and acceptability of HEALing intervention. Participants will receive a grocery voucher as reimbursement upon completing of the survey and interview.

The HEALing intervention

The HEALing intervention, guided by MI principles and underpinned by SDT, was co-designed with patients living with DFU and healthcare professionals through detailed identification of intervention targets and subsequent co-design workshops. Its co-design process was inspired by and adapted from the UK guidance on how to develop complex interventions to improve health and healthcare[51] and the Experience-Based Co-Design approach,[52] including (a) identifying determinants and prioritising intervention targets, (b) engaging key stakeholders to identify intervention contents and delivery options and (c) refining intervention pathways for the pilot study. Details of the HEALing co-design have been previously described.[47]

In brief, the programme involved three face-to-face sessions (30 min each) delivered over six weeks by trained wound care nurses, who also provide routine wound dressings and regular foot and wound education. The HEALing session outline is presented in table 2.

Wound care nurses, employed in the organisation and serving as the primary wound care providers (wound examination/dressing and wound care patient education), will be trained as HEALing facilitators. HEALing training includes a half-day refresher course on diabetes education (e-learning) and a two-day MI training face-to-face workshop (total of 20 hours). The MI workshop comprises a series of activities aimed at increasing MI knowledge and skills (day 1) and experiential exercises using agenda mapping, affirmation for DFU (ie, card sorting exercise) and ask-offer-ask framework for DFU education (day 2). One coaching session (role play with the first author) will be scheduled for each facilitator to support learning and competency in the consistent delivery of the HEALing programme.

Following enrolment, patients with DFU will receive three 30-minute face-to-face HEALing sessions, typically every 2 weeks, scheduled to coincide with routine wound care appointments (augmented usual care). Each visit will include 30 min for wound dressing (usual care), followed by a 30-minute HEALing session post dressing.

Outcome measures

Primary outcomes

The primary outcomes include the feasibility indicators: recruitment (ie, number of eligible participants invited over number consented), retention (ie, 80% complete all sessions), data completion (80%) and the acceptability of the intervention. Recruitment will be tracked using participant screening logs, recording the number of individuals who accept the invitation, receive the intervention and complete the programme.

Feasibility of retention will be recorded, including the number of people who complete the intervention—retention rates on HEALing completion, that is, the number of sessions delivered, attended and completed by wound care nurses and patients. Measurement feasibility will be assessed through the time required to conduct HEALing sessions and complete questionnaires, as well as the completeness of data capture.

Acceptability of the intervention will be explored through individual semi-structured interviews with patients and wound care nurse facilitators at the end of the programme, focusing on satisfaction, perceptions of the programme, barriers and challenges encountered, and reasons for discontinuation or drop out.

Secondary outcomes

The secondary outcomes include PROMs that will be assessed using standardised and psychometrically sound instruments in English, that is, patients' percpetions of autonomy support measured by Health Care Climate Questionnaire[53], illness/DFU perceptions measured by Brief Illness Perception Questionnaire,[54] diabetes distress measured by Diabetes Distress Scale,[55] foot care confidence measured by Foot Care Confidence Scale,[56] foot self-care behaviour measured by Diabetes Foot Self-Care Behaviour Scale,[57] knowledge on warning signs of DFU deterioration measured by Warning Signs of DFU Deterioration Questionnaire[58] and health-related quality of life measured by EQ-5D-5L.[59] Various clinical endpoint characteristics (ie, related to DM and DFU) will be assessed at baseline and at HEALing completion. Table 1 lists the variables of interest, scales and measurement time points for secondary outcomes.

Data analysis

Quantitative data analysis

Data will be entered into a secure database and analysed using SPSS Statistics V.28. Descriptive statistics (median (IQR), mean (SD), number (%)) will summarise recruitment, retention, adherence to self-care activities and session attendance to assess feasibility. PROMs at baseline and post-intervention will be compared to evaluate HEALing's impact on illness beliefs, foot care confidence, diabetes distress, knowledge of DFU warning signs, quality of life, autonomy support and foot self-care behaviours. Normality of distributions will be assessed. Paired t-tests or non-parametric equivalents (Wilcoxon signed-rank test) will examine pre-post differences for continuous variables, while χ^2 tests will be used for categorical variables. Significance will be set at $p<0.05$ (two-tailed).

Qualitative data analysis

The audio-recorded interviews will be transcribed verbatim and analysed using reflexive thematic analysis as per the following six steps: familiarising with the

Table 2 Healing through Empowerment and Active Listening 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 programme; 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 a topic (see card sorting task photo); use affirmation (see card sorting task) and review the first goal from session one to evoke and strengthen confidence that progress is underway. If the topic is on low mood/worry, OR suggest a topic with permission (eg, low mood/ worry about deterioration or a topic that is deemed of high clinical importance, for example, self-wound care) – listen to concerns, use validation and normalisation to stabilise emotion (eg, anxiety/worry as expected, adaptive response to a real threat; this threat can be mitigated with self-care); with permission, use the 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 problem solve barriers (if any) for goal(s) set in sessions 1 and 2, and revise goals as needed; Use the 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.

DFU, diabetic foot ulcer; HEALing, Healing through Empowerment and Active Listening.

data, generating initial codes, searching for themes, reviewing potential themes, defining and naming themes and producing the report.[60] 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.

Integration of quantitative and qualitative data

Quantitative and qualitative findings will be integrated through triangulation, comparing results to identify agreement or divergence. Consistent findings will reinforce conclusions on feasibility and effectiveness. If discrepancies arise, qualitative insights will help explain differences, informing intervention refinement and future research.

Patient and public involvement

Patients and the public have been and will continue to be involved in this study throughout the co-design and feasibility evaluation of the intervention. Patient and public involvement (PPI) in the co-design process includes individual interviews, surveys, focus group discussions and

participation in workshops.[47]. This engagement began with understanding and identification determinants and the real-world workshop discussions for content refinement and implementation optimisation. In the present feasibility study, feedback from patient and wound care nurse participants on the HEALing programme will be collected through individual interviews and surveys to inform the feasibility and acceptability analysis. Prior to disseminating findings in peer-reviewed publications, we will conduct member checking with clinical partners, incorporating their comments into manuscripts, primarily in the discussion section (if any). When feasible, we invite clinical partners to co-present at conferences and co-author in publications.

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 living with DFU. The key strength of the study is its substantial PPI throughout the intervention development and feasibility trial in real world settings. Involving individuals directly affected by DFU ensures that those who will receive the HEALing intervention have equal opportunities to contribute to decisions about their own care. People with lived experience of DFU were engaged in leading initiatives such as co-designing the intervention and remained involved throughout the feasibility trial. This approach lies at the heart of person-centred care and patient empowerment. Another strength of the study is its mixed-method approach with qualitative interview data to complement the quantitative survey findings. Qualitative in-depth interviews with people living with DFU ensure their voices are captured and not misrepresented.

Limitations

The design of a single-arm study has some limitations, such as having no outcome comparisons between groups, which may yield biases in interpreting the results. Without a parallel control, comparisons are restricted to external historical data, to evaluate the validity of the study population, which carries the risk of selection bias. Lastly, only short-term outcomes will be evaluated, and the sustainability of effects over time (if any) will remain unknown. Future randomised controlled trials including long-term outcomes with long study duration are recommended.

Significance

This pilot feasibility study will assess the acceptability and feasibility of the MI-guided HEALing programme to support self-care among primary care patients with DFU. The findings will inform refinement, implementation and future evaluation of the programme across diverse populations and settings. Preliminary efficacy data from this trial will guide the design of a larger-scale study to evaluate the programme's effectiveness in enhancing self-care behaviours, patient education and empowerment.

ETHICS, DATA MANAGEMENT AND DISSEMINATION

Ethical approval

Ethical approval for this study was provided by the National Healthcare Group Domain Specific Review Board ethics committee (Ref No. 2022/00895) and the Nanyang Technological University Institutional Review Board (Ref No. NTU IRB-2022-338). Individual written consent will be obtained from each participant by the researchers.

Data management and monitoring

The principal investigator will preserve the confidentiality of participants taking part in the study and fulfil transparency requirements under the General Data Protection Regulation for health and care research. Data and all appropriate documentation will be confidentially and securely stored for a minimum of 10 years after the completion of the study, including the follow-up period.

Dissemination plan

Dissemination will include study progress report to Centre for Primary Healthcare Research and Innovation Funding agency (a partnership between Lee Kong Chian School of Medicine, Nanyang Technological University Singapore, and National Healthcare Group Singapore), publications in peer-reviewed journals, scientific conference presentations and feedback about study results which will be shared with patients through outreach efforts by collaborating with relevant organisations such as NHGP in Singapore. A toolkit will be developed to support future implementation plans.

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Correction notice This article has been corrected since it was published. The co-corresponding author has been added.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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