Malabu *et al. Diabetology & Metabolic Syndrome* (2025) 17:246
https://doi.org/10.1186/s13098-025-01817-2

Diabetology & Metabolic Syndrome

RESEARCH Open Access

Telemedical treatment of diabetic foot ulcer in rural and remote areas: a prospective single centre randomised controlled clinical trial

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Abstract

Objectives The role of telemedical treatment for patients with diabetic foot ulcers residing in rural areas remains uncertain. Therefore, our objective was to conduct a randomized controlled trial comparing the effectiveness of telemedical treatment in rural settings with the standard tertiary healthcare approach for managing diabetic foot ulcers.

Methods The study was conducted between 2016 and 2022. Participants were randomly assigned 2:1 to either face-to-face usual care (UC) group or telemedical treatment group. The protocol for the telemedical treatment group involved fortnightly consultations conducted by a locally trained nurse in the patients' rural hospital over 12 weeks compared to similar protocol for face-to-face podiatrist-treated UC group. The primary endpoints were complete healing of the ulcer or limb amputation while secondary outcomes included circulating markers of inflammation as a marker of wound healing.

Results One hundred and fifty-one participants out of 232 met the inclusion criteria and 50 were randomised to telemedical treatment group and 101 to the UC group. The clinical and demographic characteristics of the participants were similar in both groups. Following 12 weeks of treatment, we observed that complete ulcer healing was achieved in 16 out of 50 individuals (32%) in the telemedical treatment group, while 28 out of 101 individuals (28%) in the UC group achieved the same outcome ($p=0.58$). Amputation rates were 23% (11/50) in the telemedicine and 25% (23/101) in the UC group ($p=0.080$).

Conclusions Our study found no statistically significant differences in wound healing (32% vs. 28%, $p=0.58$) or amputation rates (23% vs. 25%, $p=0.80$) between nurse-led telemedicine in rural settings and usual care for diabetic foot ulcers over 12 weeks. This promising result suggests that telemedicine could be a viable option for rural patients; however, further research exploring other clinically relevant endpoints and vulnerable subgroups is needed to solidify its role.

The known Diabetic foot ulcers pose a significant burden on rural and remote communities with limited access to specialists' care and high limb amputation rates.

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The new Our randomised controlled trial demonstrated that nurse-led telemedicine in rural hospitals is equally effective as podiatrist care in tertiary hospitals for healing diabetic foot ulcers within 12 weeks. Key ulcer measurements and wound healing biomarkers further support this finding.

The implications Telemedicine offers a viable solution for management of diabetic foot ulcer in rural and remote areas. It has the potential to enhance patient outcomes and significantly reduce healthcare disparities.

Introduction

Diabetic foot ulcer (DFU) is one of the most common, severe, feared, and costly complications of diabetes. It accounts for >90% of lower limb amputations and is a leading cause of prolonged hospitalization, costing over $40,000 per event [1, 2]. The Australian government spends $1.6 billion annually on direct cost of diabetes-related limb amputations [3, 4]. Although many health disparities exist between urban and rural areas, managing DFU in remote areas ranks as one of the most significant health concerns [5, 6]. Data from the Australian Commission on Safety and Quality in Health Care supported by others' findings have shown that regional and rural/remote areas have among the highest diabetes-related amputations in the country [7, 8]. Compared to major cities, people in rural/remote Australia are 11 times more likely to have diabetes-related amputations than those in metropolitan areas, mainly due to inadequate access to health services and lack of coordinated healthcare [9]. Aboriginal and Torres Strait Islander (ATSI) people who preferentially live in rural/remote areas are 10 times more likely to be admitted for diabetic foot complications and 30 times more likely to have diabetes-related lower limb amputations than non-ATSI people [4, 5, 9].

Despite the high prevalence of diabetic foot complications in rural/remote areas, there are surprisingly no special programs aimed at reducing the burden of DFUs at the rural primary care level. Significant challenges such as access to health care centres and staffing limitations have made the quality-of-care comparisons between rural/remote areas and metropolitan areas of the country difficult. Currently, patients with DFU living in rural/remote areas of Northern Australia have to travel long distances, in some instances >1000 km, to and from a specialist tertiary hospital weekly or fortnightly for wound care. To correctly diagnose and treat a foot ulcer in rural/remote settlements, it is essential to train local healthcare professionals on treating and monitoring DFU using novel technologies to assess the ulcer objectively. A three-dimensional (3D) camera provides exact measurements of superior quality and is a quick and innovative method for determining width, length, depth, and surface area of a foot ulcer [10, 11]. Thus, a 3D camera has the potential to significantly improve the field of DFU treatment in rural/remote areas of regional Australia. The foremost advantage of the 3D camera is that it provides precise ulcer measurements and thus ensures better monitoring of ulcer healing, which can be assessed remotely by specialists in regional and metropolitan hospitals. Wound healing is likely achieved with a better-trained local nurses and close supervision by podiatrists and diabetes specialists in tertiary referral hospitals. With an innovative automated method of measuring ulcers, unnecessary and often inaccurate manual measurements, which may lead to wound contamination and infection of the DFU, can be avoided. As the camera is portable and handheld, patients can be examined and treated in their local rural/remote health centres which has a positive physical and psychological effect on their health. We have implemented a novel technique that allows for the electronic storage and transmission of 3D images and clinical details to tertiary hospitals, facilitating multidisciplinary specialists' review and decision-making when necessary. This innovative approach to DFU treatment is ideal for becoming a part of telemedicine. It presents an opportunity to manage foot ulcers effectively in resource-deprived communities, potentially leading to its widespread adoption as a standard practice in rural and remote areas.

While previous studies have explored telemedicine for DFU management, few have focused on nurse-led interventions in rural and remote settings, particularly in Australia, where healthcare disparities are pronounced. Moreover, the integration of advanced 3D wound imaging technology in telemedical care remains underexplored. This study addresses these gaps by evaluating the effectiveness of a novel telemedicine approach using trained nurses and 3D imaging to manage DFUs in underserved Australian populations, potentially offering a scalable model for resource-limited regions.

To evaluate the clinical utility of telemedicine in addressing the scarcity of specialists' diabetes wound care in underserved rural and remote health centres, we conducted a comparative analysis. Specifically, we compared the DFU parameters of telehealth patients with those who had face-to-face appointments at tertiary hospitals. We also examined changes in circulating inflammatory and wound healing markers among the two groups.

Methods

The study was conducted from January 2016 to January 2022. Ethics approvals were obtained from the Townsville Hospital and Health Service's (THHS) Human Research Ethics Committee (HREC) (HREC/14/QTHS/211 and

SSA/15/QTHS/157) and was registered on the Australian and New Zealand Clinical Trial Registry (ANZCTR) with registration number ACTRN12615001215516. Informed consent was obtained from all participants. Ethical considerations for Aboriginal and Torres Strait Islander (ATSI) participants included community consultation with local health leaders to ensure cultural appropriateness, provision of translated materials, and involvement of Indigenous health workers during recruitment and consent processes.

Twelve clinical nurses, three from each of the four enrolled rural health centres, with Townsville University Hospital being the usual care centre (Fig. 1), completed a one-day wound care and telemedicine training conducted by a certified podiatrist and endocrinologist experienced in managing DFU and telehealth. Weekly assessments followed this until competency was achieved.

The Modified Monash Model (MMM) was used in this study in defining whether a location is metropolitan, rural, remote, or very remote [12]. The model measures remoteness and population size on a scale of MMM categories MMM 1 to MMM 7, with MMM 2 a regional centre, MMM 4 a medium rural town, and MMM 7 a very remote community as shown in Fig. 1.

All subjects aged > 18 years with DFU of full-thickness skin defect requiring 14 days of healing who live > 30 km from TUH were included in the study and were followed up for 12 weeks. Subjects were excluded from the study if they had the following: clinically significant lower-extremity ischemia (as defined by an ankle/brachial index of < 0.65) and planned surgical intervention for the DFU. Other exclusion criteria included subjects with significant medical conditions that would impair wound healing including hepatic, respiratory, or cardiac failures, treatment with immunosuppressive agents or steroids, and major surgery within 6 months of the study. Active Charcot's foot as determined by clinical and radiographic examination and ulcer of a non-diabetic pathophysiology, active malignancy other than basal cell carcinoma, and inability to comply with study protocol were also excluded from the study.

Sample size, treatment assignment and randomization

Sample size was calculated for an equivalence trial to compare amputation rates between TM and UC, with an equivalence margin (Δ) of 25%. With 80% power, a two-sided α of 0.05, and a 2:1 allocation ratio, a minimum of 45 TM and 90 UC participants (total 135) was required. Adjusting for 10% attrition, the target was 50 TM and 100 UC participants was determined to be required sample size for the study. sample size also provided sufficient power to detect clinically meaningful differences in wound healing rates, assuming a 20% difference between groups (based on prior studies suggesting 30–50% healing rates in 12 weeks). The randomization list was prepared by an independent statistician using computer-generated random numbers for each treatment. Allocation concealment was achieved using sealed opaque

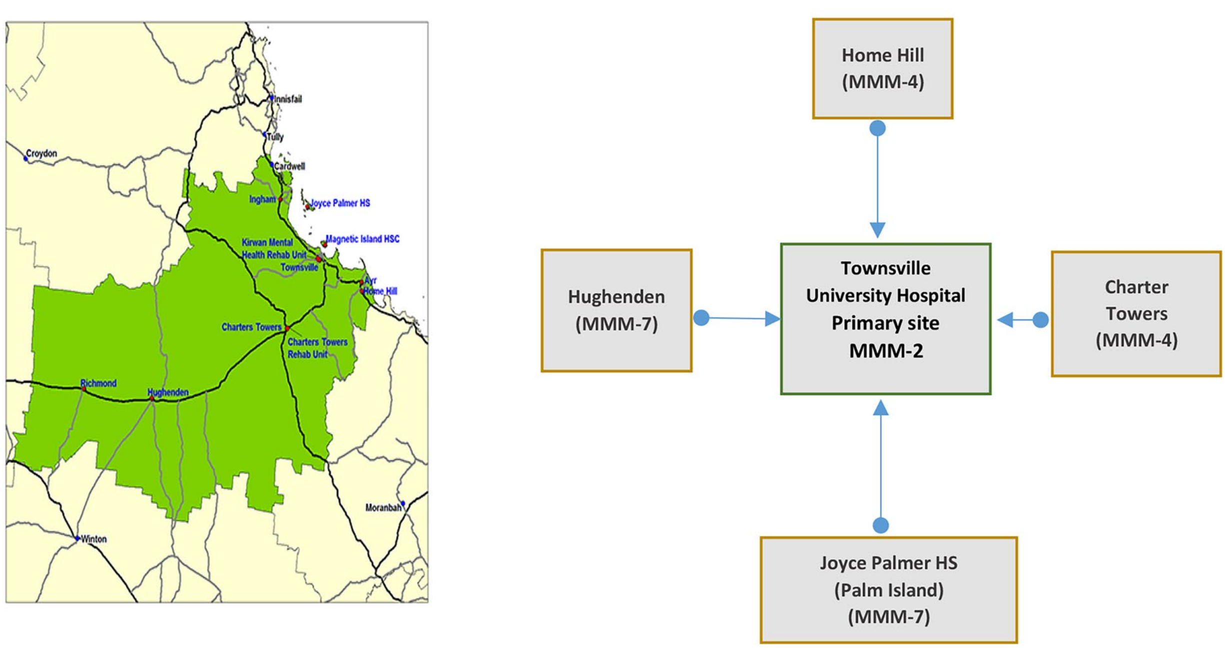

Fig. 1 THHS district (left), Study sites (right)

envelopes prepared by the independent statistician, opened only at the time of randomization to prevent selection bias. Patients in each stratum were assigned numbers using a central stratified randomization scheme to provide 2:1 of patients in the 2 groups. Patients were randomized to usual care (UC) or telemedicine (TM) group (Fig. 2). A 2:1 randomization ratio (UC: TM) was chosen to maximize recruitment feasibility in rural settings. Blinding of outcome assessors was not feasible due to the visible differences between telemedicine and face-to-face care delivery. Standardized protocols and objective 3D imaging measurements were used to minimize bias. Treatment adherence was monitored in both groups through regular consultation records for both the groups.

With the support of the TUH podiatry/diabetes team, the trained rural nurse delivered the DFU telemedical care at the rural health centre while face-to-face consultation and treatment were conducted at TUH by a podiatrist. Usual Care (UC) involved fortnightly face-to-face consultations at TUH, including wound cleansing, conservative debridement, dressing, and offloading with cushioning insoles, delivered by a podiatrist following the same standardized protocol as TM. The wound bed and margin were thoroughly cleansed with normal saline using gauze. The wound was debrided conservatively to remove necrotic tissues and expose a healthy bleeding margin. It was dressed using Melipex® XT foam as a dressing material. For offloading the DFUs at weight-bearing sites, cushioning insoles, and foam dressings with a hole on the ulcer site were applied where required. All participants at the rural health centres and TUH received the same treatment, i.e., debridement, wound dressing, and offloading. TM and UC consultations were scheduled regularly each fortnight and integrated into the clinical workflow of the TUH. The local nurse completed the online evaluation form, which was accessible remotely to the podiatrist at TUH before each telemedicine consultation. The evaluation form included skin condition, wound condition, ulcer/wound measurements, risk category, and treatment plan. As part of mentoring process, the podiatrist-medical specialist team at the tertiary hospital used the real-time, interactive telemedicine consultation to assess the rural nurses' evaluation for accuracy in line with standard practice. Telemedicine consultations involved fortnightly video conferencing between rural nurses and TUH specialists, supplemented by real-time

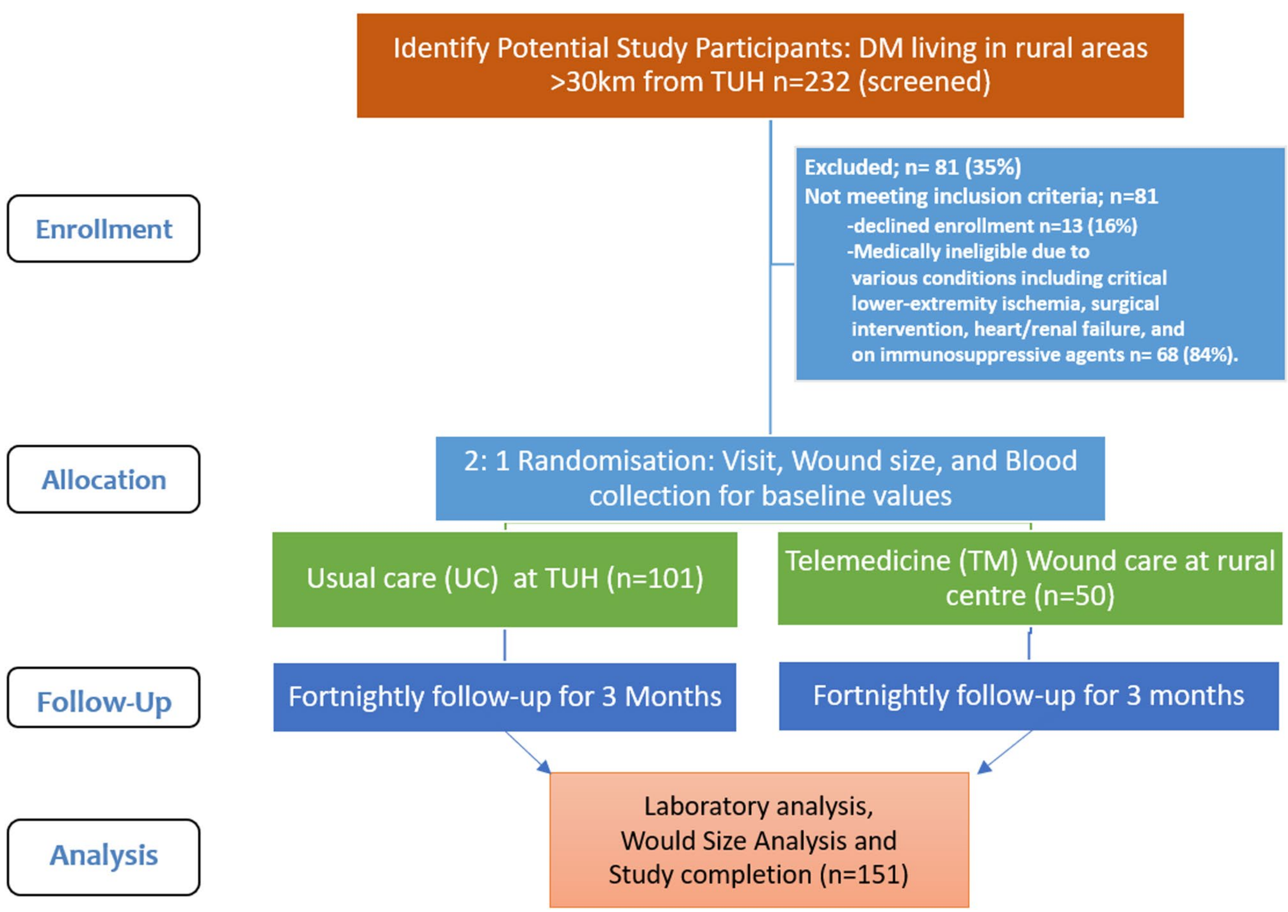

Fig. 2 Consort diagram- study design

review of 3D images and electronic forms. A standardized protocol, aligned with International Working Group on the Diabetic Foot guidelines, ensured consistent debridement, dressing, and offloading practices across groups. The 3D imaging measurements were performed by trained nurses in the TM group and podiatrists in the UC group, with all staff trained by the same certified podiatrist to ensure consistency.

To facilitate the practical assessment of DFUs, we utilized a Silhouette® 3D camera as part of the TUH telehealth network to obtain data on wound size. Complete healing was defined as 100% wound closure, confirmed by 3D imaging showing no measurable ulcer depth or surface area, validated by podiatrist review. In addition to wound size, we evaluated biochemical evidence of wound healing and compared it between the two groups. For this purpose, 10 ml of whole blood was collected at week 1 and 12 for biochemical analyses. We specifically examined inflammatory markers, including tumour necrosis factor-alpha (TNF-alpha), c-reactive protein (CRP), globulin, neutrophils, and platelet counts. Furthermore, we measured wound healing markers such as adiponectin and fibrinogen. To assess diabetes control, we utilized the HbA1c test. These markers were selected due to their established roles in wound healing: TNF-α and CRP reflect inflammation, which delays healing, while adiponectin and fibrinogen indicate tissue repair and clotting processes critical to ulcer resolution [13].

Statistical analysis

Analyses were conducted using an intention-to-treat (ITT) approach, including all randomized participants as allocated.

For the inflammatory marker analysis and patient history data, analyses were conducted using all available data from participants who completed the respective assessments. Specifically, laboratory data for inflammatory and wound healing markers (e.g., TNF-α, CRP, adiponectin, fibrinogen) and chart data (e.g., wound measurements, clinical outcomes) were subject to missingness due to logistical challenges, such as incomplete blood sample collection or data not available for the time point of interest. No imputation methods were applied, as the missing data were considered missing at random. The intention-to-treat approach ensured that all randomized participants were included in the primary analyses, with available data used to assess secondary outcomes like inflammatory markers.

Clinical data of the subjects were represented as absolute numbers and percentages while chi-square test was performed to test for association between the two groups. Tests for normality were performed based on the outcome to determine differences between the groups. The results were given as mean ± standard deviation (SD). Student T test was carried out for continuous variables for parametric data using SPSS version 28 (Chicago, IL, USA). Results were considered statistically significant at a p-value less than 0.05.

Results

A total of 232 participants underwent screening, of which 151 met the inclusion criteria and were included in the study. The remaining 81 participants were excluded due to not meeting the criteria as shown in Fig. 2. Among the enrolled participants, 50 were randomly allocated to the telemedical treatment (TM) group, while 101 were assigned to the usual care (UC) group.

Baseline characteristics for both groups demonstrated high similarity, as indicated by the data presented in Table 1. The average age of the TM group was 62.4 years, while the UC group had an average age of 65.8 years. Both groups exhibited comparable diabetic characteristics and comorbidities, including microvascular and macrovascular problems, hypertension, and osteomyelitis ($P > 0.05$; Table 1).

Table 2 presents DFU measurements and amputation counts at the end of the study. After a 12-week therapy, the measurements of the ulcers were comparable in both the TM and UC groups, i.e., in the TM group, 16 out of 50 individuals (32%) achieved complete wound healing, while in the UC group, 28 out of 101 individuals (28%) achieved the same outcome ($P = 0.58$). Similar results were observed regarding the amputations, where these adverse events occurred in 23% and 25% of the TM and UC patients, respectively ($P = 0.80$). The absolute risk difference in healing rates was 4% (95% CI: -11.5–19.5%), with a risk ratio (RR) of 1.15 (95% CI: 0.68–1.95), suggesting telemedicine is equivalent to UC.

Finally, we analysed various circulating inflammatory and wound-healing markers in the TM and UC groups. The findings indicated no statistically significant differences between the two groups at the end of the study, as presented in Table 3. Furthermore, it is noteworthy that diabetes control, as measured by the HbA1c, remained similar in both the TM and UC groups at the end of the study ($P = 0.88$; Table 3). Subgroup analyses by ulcer severity (e.g., size, ischemia, osteomyelitis) were not performed due to sample size limitations but could reveal differential effects.

Discussion

In this randomized controlled clinical trial of treatment of DFU in rural/remote areas using telehealth by trained nurses versus podiatrist's face to face care in a tertiary referral hospital, we showed no statistically significant difference between TM and UC. Baseline characteristics between the two groups were similar and there were no confounders that were statistically significant. Indeed,

Table 1 Baseline characteristics of the study population

Characteristics	Telemedicine (TM) *N* = 50 Mean ± SD or *n* (%)	Usual Care (UC) *N* = 101 Mean ± SD or *n* (%)	*P* value
Age (years)	62.4 ± 10.4	65.8 ± 10.3	0.22
Male/Female (n)	45/5	62/39	0.001
Caucasian/First Nations (n)	44/6	95/6	0.11
Insulin treatment, n (%)	15 (31%)	34 (36.6%)	0.50
HbA1c (%)	8.3 ± 1.7	7.8 ± 1.7	0.10
GFR (ml/min/1.73 m2)	66.4 ± 17.8	66.3 ± 21.0	0.99
Duration of diabetes (years)	22.4 ± 8	16.3 ± 9	0.20
Weight (kg)	100.3 ± 20.5	100.5 ± 22.8	0.96
BMI (kg/m2)	38.9 ± 8.6	39.4 ± 8.9	0.82
Cholesterol (mmol/L)	4.1 ± 1.3	4.2 ± 1.2	0.84
LDL (mmol/L)	2.1 ± 1.2	2.1 ± 1.0	0.95
HDL (mmol/dL)	1.0 ± 0.3	1.1 ± 0.3	0.41
TG (mmol/L)	2.3 ± 1.4	2.1 ± 1.4	0.71
Nephropathy, n (%)	10 (20%)	15 (15%)	0.42
Retinopathy, n (%)	11 (22%)	13 (13%)	0.15
Neuropathy, n (%)	13 (26%)	25 (25%)	0.87
CAD, n (%)	7 (14%)	13 (13%)	0.85
Stroke, n (%)	2 (4%)	4 (4%)	0.99
HTN, n (%)	36 (75%)	62 (66.7%)	0.30
Peripheral vascular disease n (%)	11 (22%)	12 (12%)	0.10
Osteomyelitis, n (%)	9 (18%)	15 (15%)	0.62

Table 1: Baseline characteristics of the study population. Data presented as mean ± SD or n (%). P-values derived from chi-square tests (categorical variables) or Student's t-test (continuous variables). Abbreviations: TM = Telemedicine, UC = Usual Care, HbA1c = Glycated hemoglobin, GFR = Glomerular filtration rate, BMI = Body mass index, LDL = Low-density lipoprotein, HDL = High-density lipoprotein, TG = Triglycerides, CAD = Coronary artery disease, HTN = Hypertension

Table 2 Wound characteristics at the end of 12 weeks of treatment

Characteristics	Telemedicine (TM) *N* = 50 Mean ± SD or *n* (%)	Usual Care (UC) *N* = 101 Mean ± SD or *n* (%)	*P* value
Ulcer Width (mm)	5.0 ± 0.7	5.8 ± 0.5	0.30
Ulcer Length (mm)	6.4 ± 0.9	7.0 ± 0.6	0.50
Ulcer depth (mm)	0.8 ± 0.2	1.4 ± 0.2	0.07
Ulcer surface area (mm^2)	62.4 ± 14.00	73.6 ± 9.8	0.51
Completely healed (n)	16 (32%)	28 (28%)	0.58
Amputation (n)	11 (23%)	23 (25%)	0.80

Table 2: Wound characteristics at 12 weeks. Data presented as mean ± SD or n (%). P-values from chi-square tests (categorical) or Student's t-test. Abbreviations: TM = Telemedicine, UC = Usual Care

Table 3 Assessment of inflammatory and wound healing markers after 12-week treatment

Characteristics	Telemedicine (TM) *N* = 50 Mean ± SD or *n* (%)	Usual Care (UC) *N* = 101 Mean ± SD or *n* (%)	*P* value
TNF-α (pg/ml)	26.0 ± 0.3	26.6 ± 0.2	0.10
CRP (mg/dL)	150.0 ± 75.3	57.2 ± 13.8	0.24
Globulin (g/dL)	33.0 ± 1.0	34.0 ± 0.6	0.35
Neutrophils (c/uL)	16.0 ± 1.0	14.7 ± 0.8	0.51
Platelets (c/uL)	280.0 ± 14.3	267.0 ± 11.0	0.50
Adiponectin (ng/ml)	12.1 ± 1.0	14.3 ± 0.6	0.08
Fibrinogen (mg/dL)	7.3 ± 2.0	6.3 ± 0.7	0.70
HbA1c (%)	7.6 ± 1.6	7.7 ± 1.9	0.88

Table 3: Inflammatory and wound healing markers after 12 weeks. Data presented as mean ± SD. P-values from Student's t-test. Abbreviations: TM = Telemedicine, UC = Usual Care, TNF-α = Tumor necrosis factor-alpha, CRP = C-reactive protein, HbA1c = Glycated hemoglobin

ulcer healing was similar in both settings, as demonstrated by objective physical measurements of the ulcers and circulating biomarkers; the latter proved to be a reliable marker of wound healing [10, 11]. Thus, our findings further support evidence of the beneficial role of telemedicine in managing DFU, particularly in underserved populations in rural/remote areas. Our findings agree with previous studies [14–17]. The lack of assessor blinding may introduce detection bias, though this was mitigated by objective wound measurements via 3D imaging and consistent evaluation protocols. After monitoring for 12 months, Rasmussen et al. reported no significant difference in ulcer healing or amputation between the two groups but showed an increased risk of mortality in the remote monitoring group [14]. It is important to note that our study was for a short period of 12 weeks and was not meant to assess mortality as an outcome of the study. The observed high mortality in the telemedicine group was a surprising finding that was not reported by other investigators [15–18]. However, there is a need for further studies to determine the excess deaths that were reported in the telemedicine group [14]. The lack of statistically significant differences in healing and amputation rates may reflect the standardized treatment protocols and robust training provided to rural nurses, ensuring care quality comparable to UC. Alternatively, the 12-week follow-up may be insufficient to detect differences in chronic wound outcomes, or the sample size, while powered, may not capture smaller effect sizes. The analysis confirms TM as comparable to UC, aligning with its goal of equitable care delivery.

On the other hand, besides having comparable wound healing parameters among the 2 groups, Smith-Strom [15] and co-workers noted significantly fewer amputations in the telemedicine group [15]. In contrast, our current report and previous work by others found similar amputation occurrence in both groups [14, 18, 19]. Unlike Smith-Strom et al. [15], who reported fewer amputations with telemedicine, our study found no no statistically significant difference, possibly due to differences in patient populations (e.g., ulcer severity) or intervention intensity. The variations could be due to differences in the study by Smith-Strom et al. [15] which used a cluster-randomized design with less frequent telemedicine consultations (monthly vs. our fortnightly) and focused on urban-adjacent rural settings with better access to specialists, potentially explaining their observed reduction in amputations. Our study, conducted in more remote Australian settings with nurse-led care and 3D imaging, prioritized frequent specialist oversight via real-time teleconsultations. These differences may account for the lack of amputation rate differences in our study. This study uniquely contributes by demonstrating nurse-led telemedicine with 3D imaging as a feasible model in rural Australia, addressing a gap in region-specific evidence. However, Khan et al. [20] and Chen et al., [3] in their meta-analyses, concluded that the incidence of amputation is lower in patients assigned to the telemedicine group than in patients in the control group. In contrast, the outcome efficacy of wound healing around one year and three months was not significantly different between TM and UC [18]. Studies during the COVID-19 pandemic have shown TM's effectiveness in managing DFU. Using a virtual triage regime and consultations for a group of patients and comparing the outcomes with UC from before the pandemic, Rastogi et al. [18] concluded similar ulcer and limb outcomes in both groups. A randomized control trial (RCT) by Téot et al. [16]. during the COVID-19 pandemic reported an insignificantly slower healing rate in the TM group [16]. In Australia, as in most developed countries, foot care specialists are concentrated in urban areas, with rural health centres having a relatively higher nurse-to-doctor ratio [21, 22]. This study builds on prior telemedicine research by evaluating nurse-led DFU care with 3D imaging in rural Australia, offering a practical extension of established approaches. It may benefit patients in rural areas or who do not have easy access to seeing a healthcare professional in person. The popularity of the internet and smart devices has made it possible to adopt telemedicine to improve the management of DFUs, where it would not previously have been possible. Increases in the use of telemedicine during the COVID-19 pandemic have shown that it can play an essential role in healthcare, particularly in rural/remote areas where access to specialist care is lacking.

It is important to emphasize that the quality of care provided through telemedicine in our study was not compromised, even in the face of staffing challenges often encountered in rural or remote areas. The rural nurses responsible for delivering the care received comprehensive support from diabetes and diabetic foot ulcer specialists. This support was facilitated through real-time consultations and the sharing of stored images. Our results provide evidence that the level of care provided through telemedicine was comparable to in-person consultations. This finding highlights the effectiveness of telemedicine in extending specialized care to remote areas where access to healthcare professionals may be limited.

In addition to physical wound outcomes, our study evaluated inflammatory and wound healing markers, reflecting the broader systemic impact of diabetes on DFU progression. Recent research highlights the role of inflammation and oxidative stress in diabetic complications, with Mohammadpour Fard et al. (2024) demonstrating that interventions targeting these pathways, such as melatonin supplementation, may reduce inflammatory markers like TNF-α and CRP in diabetic patients [23].

Similarly, Bahreiny et al. (2024) identified Galectin-3 as a potential biomarker linking diabetes severity to tissue damage, suggesting its relevance in chronic wound contexts like DFU [24]. While our trial found no statistically significant differences in these markers between TM and UC groups, these findings underscore the need to explore adjunctive therapies or biomarkers that could enhance telemedicine's impact on rural DFU care, particularly given the high burden of comorbidities in these populations.

The 3D camera enhanced wound assessment by providing precise, objective measurements, reducing human error compared to manual methods, and enabling accurate remote monitoring by specialists. While it did not directly improve healing rates, its utility lies in standardizing assessments and facilitating teleconsultations, potentially improving care consistency in rural settings. Telemedicine likely improved adherence by reducing travel burden, though patient satisfaction and quality of life (QoL) were not assessed. Future studies should incorporate patient-reported outcome measures (PROMs) to evaluate these benefits.

The strength of our study lies in its design as a prospective randomized controlled trial, where the same team was responsible for all clinical measurements and treatments. This approach eliminated any potential inter-investigator variation in multicentre trials with multiple investigators. As far as we know, this is the first RCT on telemedical care of DFU in rural/remote areas in Australia where telehealth has been in existence for a long time, yet no such study had been designed for management of DFU in the resource-deprived areas. However, it is essential to acknowledge the limitations of this study. The COVID-19 pandemic-imposed restrictions on travel and led to a significant period of suspension for clinical studies. This restriction affected the study and may have influenced the results. Furthermore, the study was not designed to assess mortality because of a short follow-up period of 12 weeks, which limited our ability to evaluate long-term outcomes. The sex imbalance (TM: 45/5 male/female, UC: 62/39) was statistically significant, Table 1 ($p = 0.001$) and is a potential factor affecting generalizability, particularly since DFU outcomes may vary by sex due to differences in wound healing or comorbidities. Furthermore, while this study is the first study to evaluate inflammatory markers as a component of telemedical monitoring of patients with diabetic foot ulcers. We acknowledge that the study was not specifically powered to detect differences in inflammatory and wound healing markers, which were secondary outcomes. With 50 TM and 101 UC participants, the study had limited power (~60%) to detect small-to-moderate differences (e.g., 0.5 SD) in markers like TNF-α or CRP. Additionally, we did not conduct a cost-benefit analysis in this report. Despite these limitations, we firmly believe that our study has successfully addressed the clinical utility of telemedicine in the care of DFUs in rural or remote areas. Our findings further support and build upon previous research [20, 25, 26].

Although a formal cost-benefit analysis was not conducted, telemedicine likely reduces patient travel costs (e.g., >1000 km to the tertiary health centre) and healthcare system expenses by leveraging local nurses rather than specialists. From our preliminary calculations we estimate a savings of USD $400–800 per patient over 12 weeks of reduced patient travel costs (e.g., fuel, accommodation for >1000 km round trips) and lower specialist consultation fees by leveraging local nurses [19, 27], though future studies should quantify direct and indirect costs, including equipment and training, to confirm cost-effectiveness.

In conclusion, this study demonstrates that nurse-led telemedicine with 3D imaging is as effective as Usual Care for DFU management in rural/remote areas over a comparison period of 12 weeks, offering a practical solution to reduce healthcare disparities. While not superior, its equivalence suggests telemedicine can enhance access without compromising outcomes. Future research should focus on long-term outcomes, including subgroup analyses to assess whether ulcer severity modifies treatment efficacy, cost-effectiveness, and patient-reported measures like quality of life to fully establish its role.

Author contributions
U.H.M, V.N.V, K.S.S.: Conceived and designed the study, contributed to data acquisition, data analysis and interpretation, drafted and critically revised the manuscript.J.G and J.B.: Contributed to data acquisition, critically revised the manuscript.E.B.: Contributed to data analysis and interpretation, critically revised the manuscript.H.D.: Contributed to interpretation, critically revised the manuscript.All authors reviewed the manuscripthttps://submission.springernature.com/submission/644871b0-a61a-4122-9f6c-fbc727a10ee0/declarations.

Funding
This study received funding support from BUPA Australia and THHS Study, Education and Research Trust Account (SERTA). It was also supported by in-kind resources from James Cook University and Townsville University Hospital (THHS).

Data availability
The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
The study was approved by the Townsville Hospital and Health Service Human Research Ethics Committee (HREC/14/QTHS/211 and SSA/15/QTHS/157) and registered with the Australian and New Zealand Clinical Trial Registry (ACTRN12615001215516). Written informed consent was obtained from all participants prior to enrollment.

Competing interests
The authors declare no competing interests.

Consent to publish

Not applicable, as no individual participant data are included in this publication.

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Received: 6 March 2025 / Accepted: 13 June 2025
Published online: 02 July 2025

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