PROTOCOL

Feasibility and acceptability of the Smart Eating and Nutrition Supports solving Amputations, Toe loss and Exudate (SENSATE) Trial: protocol of a pilot study

Hailey R Donnelly[1,2], Clare E Collins[1,2], Erin D Clarke[1,2], Diane White[3], Keisha Phillips[4], Chris Sankoorikal[5], Jye Hawkins[6], Michelle Kriss[5], Peta E Tehan[1,2,3,7]*

[1]School of Health Sciences, University of Newcastle, NSW, Australia
[2]Food and Nutrition Research Program, Hunter Medical Research Institute, Rankin Park, NSW, Australia
[3]High Risk Foot Service, John Hunter Hospital, Hunter New England Local Health District, New Lambton Heights, Australia.
[4]High Risk Foot Service, Tamworth Hospital, Hunter NE Local Health District, North Tamworth, Australia.
[5]Department of Endocrinology, John Hunter Hospital, Hunter NE Local Health District, New Lambton Heights, Australia.
[6]Greater Newcastle Sector Diabetes Service, Hunter NE Local Health District, Newcastle, Australia.
[7]School of Clinical Sciences, Monash University, Victoria, Australia.

*Corresponding author email peta.tehan@monash.edu

Abstract

Aims The aim of this pilot randomised controlled trial (RCT) is to evaluate feasibility and acceptability of a personalised medical nutrition therapy (MNT) intervention on wound healing in individuals with diabetes-related foot ulceration (DFU) attending high risk foot clinics in New South Wales. It's hypothesised that the personalised MNT intervention will be more acceptable and will improve diet quality compared to standard care.

Methods A six week superiority pilot multicentre, parallel-group two arm RCT for individuals (n=40) with type 1 and 2 diabetes, living with active DFU classified as VL or L as per WIfI grading and recruited from two-high risk foot clinics. The primary outcome is feasibility and acceptability, assessed by a process evaluation. The intervention group will receive MNT delivered by a dietitian at baseline, and weeks 2 and 4, with nutrient-dense food boxes provided at MNT consultations. The control group will receive a healthy eating brochure. Both groups received standardised podiatry care.

Discussion The results from this pilot study will enhance understanding of feasibility and acceptabilty of MNT for those with DFU and its potential for impact on wound healing. Results will inform future fully powered RCTs investigating effectiveness of MNT in individuals with DFU.

Keywords diabetic foot, diet, intervention, medical nutrition therapy, nutrition.

For referencing Donnelly R, et al. Feasibility and acceptability of the Smart Eating and Nutrition Supports solving Amputations, Toe loss and Exudate (SENSATE) Trial: protocol of a pilot study. Wound Practice and Research 2024;32(4):174-182.

DOI https://doi.org/10.33235/wpr.32.4.174-182

Submitted 22 April 2024, Accepted 10 June 2024

Introduction

Lower limb amputation as a result of diabetes complications is a devastating and costly outcome which is mostly avoidable, with foot ulceration preceding lower extremity amputation in most cases.[1,2] Individuals with active diabetes-related foot ulceration (DFU) are a highly vulnerable population who are at the highest risk of undergoing lower limb amputation.[2] These individuals are more likely to have greater levels of socioeconomic disadvantage, be a First Nations person, have multiple co-morbidities and suffer numerous complications of diabetes due to prolonged periods of sub-optimal blood glucose control.[3-9] This population therefore face additional barriers and are in urgent need of effective interventions aimed at improving both wound healing capacity and optimising blood glucose control in order to avoid lower extremity amputation.

Previous research has described poor diet quality, micronutrient deficiencies and malnutrition as highly prevalent

in individuals with DFU,[10-13] with one cohort study indicating up to 62% of individuals with DFU are malnourished.[13] It is well established that nutrition is critical for wound healing, with certain nutrients playing key roles in tissue repair.[14] In addition to wound healing, optimal dietary intake is also crucial in regulating blood glucose control and overcoming malnutrition. Long term dietary change can also support appropriate weight loss, and optimise cardiovascular risk factors, such as hypertension and hyperlipidaemia.[15,16] However, the addition of medical nutrition therapy (MNT) for individuals with DFU has not yet been assessed in clinical trials. MNT refers to the evidence-based use of the Nutrition Care Process (nutrition assessment, nutrition diagnosis, nutrition intervention, and nutrition monitoring and evaluation) to prevent, delay progression or manage diabetes/conditions.[17]

It is increasingly important that the views of the consumer are taken into consideration when designing resarch trials. Research has demonstrated that including patient perspectives increases the potential acceptability, effectiveness of, and adherence to the intervention.[18] The views of health professionals involved in the delivery of care is also equally important to capture. Therefore, we co-designed this trial with the participant group and wound care clinicians. Recent qualitative research demonstrated that many individuals with DFU do not engage with dietitians, with most not having seen a dietitian since their time of diagnosis. This can be up to 20 years.[19] Furthermore, many individuals with active DFU highlighted that nutrient supplementation was not preferable and most were seeking a personalised approach to medical nutrition therapy.[19] Health professionals have reported that nutrition assessment and management for DFU is not routine practice. Furthermore, health professionals lack confidence in nutrition assessment and management (unpublished data).

A recent systematic review further highlighted that the majority of research in nutrition and DFU is focused on dietary supplementation of specific nutrients, rather than supporting long term behaviour change in dietary intake (unpublished data).

In line with patient preferences, there is a need to determine if a food-first, personalised MNT intervention in individuals with active DFU is feasible and acceptable, and can result in enhanced wound healing and optimisation of cardiovascular risk factors.

Therefore, the overall aim of this trial is to evaluate the feasibility, acceptability and preliminary efficacy of a personalised MNT intervention on wound healing in individuals with DFU in regional and rural Australia. The key pilot trial objectives are to:

- Assess recruitment and retention rate of individuals living with a diabetes-related foot ulceration to the trial.
- Evaluate the personalised MNT intervention acceptability including satisfaction and appropriateness.
- Determine the preliminary impact of the personalised medical nutrition therapy intervention on wound depth, size, and width, diet quality, weight, HbA1c, cholesterol, random blood glucose and kidney function.

Methods

The 2013 Standard Protocol Items: Recommendations for Interventional Trials guidance on clinical trials was utilised for this protocol.[20] This trial has been registered with the Australian New Zealand Clinical Trials Registry (ANZCTR), reference ACTRN12623001111662p.

Trial design

The study will be a six week superiority pilot multicentre, parallel-group two-arm randomised controlled trial for individuals with type 1 and 2 diabetes, with active DFU. Feasibility and acceptability of the MNT intervention will be assessed by process evaluation questionnaire. See Appendix A for flow diagram summarising the study protocol flow.

Public Involvement

This study was co-designed with patients[19] and clinicians through conducting interviewing and completing surveys, in combination with a systematic review recently completed by the research team (unpublished data).

Study setting

Two hospitals in regional and rural areas of the Hunter New England Local Health District, New South Wales, Australia that run estabilished high risk foot services, that share models of care.

Eligibility criteria

Inclusion criteria for the study will include individuals:

- Aged 18 years and over;
- With a diagnosis of type 1 or 2 diabetes mellitus and an active foot ulceration classified Stage VL or L as per WIfI grading[21];
- Stage 1 or 2 chronic kidney disease;
- Able to provide written informed consent;
- Those on active weekly insulin titration will be included;
- Those taking oral nutrition supplements or vitamin/mineral supplements will be included however participants must ensure they keep the dose stable throughout the trial intervention phase.

Exclusion criteria:

- Foot ulceration classified as stage M or H as per WIfI[21];
- Current acute or chronic osteomyelitis or active Charcot neuroarthropathy;
- Malabsorptive background (bariatric surgery and inflammatory bowel disease);

- Currently receiving personal dietetic support/intervention;
- Those with food allergies/intolerances;
- History of cognitive disorders impacting their ability to consent or communicate effectively;
- Stage 3–5 chronic kidney disease or on dialysis;
- Pregnant or breastfeeding;
- Individuals with wounds located on the heel.

Stage 3 to 5 chronic kidney disease has been excluded due to nutrient requirements being quite varied depending on the individual for protein, fluid, potassium, sodium and phosphate.[22,23] Heel wounds were excluded due to the higher associated risk of non-healing and amputation, and the greater variation in clinical management that is required. In order to have a more homogenous group, these wounds were excluded.

Demographics, diabetes history and medical history

Data collected prior to baseline can be seen in Table 1. Information will also be retreived from participants medical records.

Sample Size

Feasibility and acceptability pilot trials do not use a sample size calculation,[29] rather a pragmatic target of 40 participants (20 per group) was determined to be consistent with pilot interventions.

Recruitment, sample size and enrolment

Participants will be recruited from two high-risk foot clinics in the Hunter New England Region of New South Wales, Australia, including the Tamworth and John Hunter Hospitals. One senior podiatrist from John Hunter Hospital (DW) and one senior podiatrist from Tamworth Hospital (KP) will provide eligibile individuals who attend these clinics with an invitation to participate. The primary intervention is expected to recruit between February 2024 and December 2024 with the waitlist control intervention conducted up until February 2025.

The participant information statement will inform participants of the requirements of participation, as well as the potential risks and benefits. Those willing to participate will provide written informed consent prior to enrolment in the study.

Allocation: Sequence generation/Allocation concealment mechanism/Implementation

A researcher (EDC) external to the active intervention will randomise enrol participants in the trial and assign them to their intervention by using a computer-generated block randomisation[30] with a block of 6 and a 1:1 ratio. EDC will conceal the sequence generation and only inform the dietitian conducting the intervention (HRD) assignment of the intervention once participants have been randomised.

Blinding (masking)

Trial participants, and the senior podiatrists (KP and DW) who assess the primary outcome will be blinded after assignment of interventions and throughout the intervention phase of the trial. The dietitian (HRD) who provides the intervention and will also complete data analysis will not be blinded as it is not feasible due to the nature of a medical nutrition therapy intervention. Unblinding of researchers or participants will be

Table 1. Baseline data collection

Participant characteristics and medical history	• Age • Sex • Postcode • History of previous ulceration • Ulcer grade as per WIfI21 • Diabetes type and duration • Diabetes medication and other relevant medications • Antibiotic use • Diabetes-related complications • Comorbidities • History of previous surgical intervention • History of hospital admissions
Ethnicity	Defined as per the Australian Standard Classification of Cultural and Ethnic Groups[24]
Smoking	A two-item questionnaire will be used to measure smoking status: "Do you currently smoke any tobacco products?" and "Would you have smoked 100 or more cigarettes or equivalent tobacco in your life?"[25] Additionally, abstinence will be measured at weeks 2, 4 and 6 by asking, "Have you smoked at least part of a cigarette in the last 7 days?"[26] Participants will also be asked, "Do you vape or smoke e-cigarettes?"
Alcohol consumption	A validated 3-item Alcohol Use Disorders Identification Test Consumption will be utilised to indicate typical weekly alcohol consumption (grams).[27]
Physical activity	The validated Active Australia Survey will be utilised. Eight questions will quantify participation in activity and five statements will determine awareness of contemporary public health physical activity messages.[28]

permissible, if there is risk to a participant's overall wellbeing. Participants will be blinded using limited disclosure. They will be informed they will receive one of two nutrition interventions, however will not be told what each nutrition intervention involves.

Retention and discontinuation/deviation from intended intervention

Participants will discontinue their assigned intervention at participant request or if an amputation needs to be performed during the intervention phase of the trial. Even if higher than expected attiriton occurs, we still expect the sample to be large enough to complete a sample calculation for a larger trial.

Participants can withdraw from the intervention at any time. Data from withdrawn participants will only be removed if a participant requests so. Intention to treat analysis will be used to account for withdrawals using the last observation carried forward.

Intervention - Personalised Medical Nutrition Therapy intervention + food box

Participants in the intervention group will be provided with one initial dietitian MNT consultation (duration of 30 minutes) and two review sessions (30 minutes) with the dietitian. The initial consult will be conducted at baseline of the intervention phase, with the review sessions occurring in weeks 2 and week 4. The personalised MNT dietitian consults include use of the the Personalised Nutrition Questionnaire (PNQ) with motivational interviewing, based on the Capabilities, Opportunities, Motivation and Behaviour Model (COM-B) model. The intervention group will also receive two intervention food boxes containing foods rich in nutrients important for wound healing (Supplementary file 1), at baseline (1 box) and week 4 (1 box), and a A$25 grocery voucher at baseline, week 2, week 4 and week 6, at their podiatry appointments to compensate them for their time and to assist with food costs. All participants will be provided standardised podiatry care which will include debridement, wound dressing and pressure offloading (standard care). Intervention participants will be required to attend the baseline, week 4 and week 6 appointments face-to-face with the dietitian, however participants will be given the option to utilise telehealth for the week 2 dietitian appointment. The My Virtual Care secure telehealth virtual consultation platform developed by NSW Health will be utilised for participants opting in to telehealth.[31]

Waitlist Control Group

Participants in the waitlist control group will be provided with a leaflet on healthy eating for wound healing, a A$25 grocery voucher will be provided during the intervention phase at each point of contact. At the end of the six week intervention, the waitlist group will be provided the personalised MNT intervention, including the food box at baseline and week 4, and MNT at baseline, week 2 and week 4.

Outcomes

Questionnaires will be completed either by hard copy or in an online version, depending on their preference at baseline and end of the intervention phase.

Primary outcome – feasibility and acceptability

A process evaluation questionnaire (Supplementary file 2) will be utilised to examine satisfaction and appropriateness of the intervention after the intervention.

Satisfaction: Participants will be asked to rate their satisfaction with the personalised MNT intervention on a Likert scale (1=strongly agree, 5=strongly disagree).

Appropriateness: Participants will be asked to rate the relevance and usefulness of the personalised MNT intervention on a Likert scale (1=strongly agree, 5=strongly disagree).

The questionnaire will also involve open-ended questions to assess what they liked and did not like about the MNT intervention and to allow for participants to express their perspectives in a comment box. Participants will also be asked for recommendations for future trials in this population. Objective measures such as recruitment, retention rate and appointment attendance will also be measured.

Secondary outcomes

Wound healing size reduction

A senior podiatrist at both sites will complete the WIfI grading and measure the wound using VISITRAK® technology (digital planimetry) at baseline, week 2, week 4 and week 6. This will provide a cross-sectional area in cm2. Wound depth will be measured with a probe in mm and wound location will also be documented by the senior podiatrist. The WIfI classification system is a risk stratification and prediction system based on the severity across three domains; wound, ischaemia, and foot infection.[21]

These assessors will be blinded to participant group allocation. Wound healing measurements will be conducted twice to increase reliability of the measurement, and if discrepancies arise, a third measurement will be taken. Both senior podiatrists have adequate training to complete these assessments and commonly complete these assessments on a daily basis in their clinic practice. A 50% reduction in wound size at 4 weeks is predictive of healing at 12 weeks, and will be considered as part of the primary outcome.[33]

Change in dietary intake

Dietary intake of participants will be self-reported at baseline and on conclusion of the six week intervention phase using the Australian Eating Survey (AES) — Heart (AES-Heart), validated food frequency questionnaire (FFQ). The AES assesses an individual's usual food intake over specified time periods and has been valiadted related to other methods and dietary biomarkers.[34,35] The AES-Heart is a 177-item FFQ,

Table 2. Summary of data collection at each time-point of the intervention

	Prior to baseline	Baseline	Week 2	Week 4	Week 6
Eligibility screening	X				
Informed consent and randomisation	X				
Medical and demographic questionnaire	X	X	X	X	X
Smoking questionnaire		X	X	X	X
Alcohol questionnaire		X	X	X	X
Smoking questionnaire		X	X	X	X
Wound healing measures	X	X	X	X	X
AES-Heart FFQ	X				X
PNQ	X				X
PAM-10	X				X
Anthropometric measures		X			X
Blood sample	X				X
EQ-5D	X				X
Acceptability (Process evaluation)					X
SHS	X				X
Food security	X				X
MST		X			X
SGA		X			X
Compliance monitoring: Recording of uneaten food from the food box			X		X
Adverse event reporting			X		X

X represents this data will be collected at the corresponding timepoint.
AES-Heart FFQ = Australian Eating Survey – Heart version Food Frequency Questionnaire
PNQ = Personalised Nutrition Questionnaire
PAM = Patient Activation Model
EQ-5D = EuroQOL five-dimension questionnaire
SHS = Subjective Happiness Scale
MST = Malnutrition Screening Tool
SGA = Subjective Global Assessment

including 111 unmodified AES items and an additional 27 items that are important sources of nutrients relevant to heart health.[35] Participants will be asked at baseline to report their intake based on the previous 3 to 6 months, while at the end of the trial, they will be asked to report their intake during the previous 6-week intervention period.

Given the high rates of CVD in those with diabetes, and that CVD is the main cause of mortality among those with DFU,[36] AES-Heart was deemed most appropriate assessment tool for this population. The proportion of total energy derived from core (nutrient-dense) and non-core (energy-dense, nutrient-poor) food groups (confectionary, takeaway foods, sweetened drinks) will be compared pre- and post-intervention.

Patient Activation

The Patient Activation Model (PAM) is a validated patient-reported outcome measure.[37] The PAM 10 survey takes three to five minutes to complete which requires participants to express their degree of agreement or disagreement with each statement.[37] Once the survey is completed, the scoring algorithm provides a PAM level ranging from one to four, with level one being “disengaged and overwhelmed”, level two “becoming aware but still struggling”, level three “taking action and gaining control, and level four “maintaining behaviours and pushing further”[37]. This survey will be available in phone, email, and paper format to ensure suitability for all participants pre- and post- intervention.

Anthropometric measures

One researcher (HRD) will measure participants' height and weight, and subsequently calculate their Body Mass Index (BMI) at baseline and week 6. Participants will be asked to remove any items out of their clothing pockets, remove heavy clothing and shoes if appropriate. Height and weight will be measured twice to increase reliability. If discrepancies arise between measurements, participants will be measured a third time. Age will be considered when classifying a participant into the BMI categories.[38]

Biochemistry measures

Non-fasting biochemistry will be measured at commencement and conclusion of the trial including:

HbA1c (%), random BGL (mmol/L), total cholesterol (mmol/L), triglycerides (mmol/L), LDL cholesterol (mmol/L), HDL cholesterol (mmol/L), the total/HDL cholesterol ratio, eGFR (mL/min), albumin (g/dL), a full blood count, and urine Albumin/Creatinine ratio (mg/mmol).

To evaluate intervention impact on glycaemic control, participants will be provided an Abbott Freestyle Libre 2 continuous glucose monitor in the initial 2 weeks and the final 2 weeks of the intervention phase. Continuous glucose monitors provide data on an individual's interstitial glucose level over time and estimate an individual's HbA1c based on one to two weeks of interstitial glucose data by taking a glucose reading every single minute. This technology will allow the dietitian to further personalise their dietary advice provided to the participants, particularly in regards to supporting patients in minimising blood glucose peaks and troughs, and reducing dysglycaemia.[39]

Quality of life

The EuroQOL five-dimension questionnaire (EQ-5D) will measure study participants health-related quality of life by assessing the following domains: mobility, self-care, usual activities, pain-discomfort and anxiety-depression.[40] A Visual Analogue Scale (VAS) ranging from 0–100 (0 being worst imaginable health state and 100 indicating best imaginable health state), accompanies the questionnaire, with participants undertaking an assessment of their own health.[40] The EQ-5D will be completed prior to commencement and at completion of the intervention phase.

Happiness

The Subjective Happiness Scale (SHS), a 4-item 7-point Likert measure of global subjective happiness will be utilised prior to baseline and at week 6 to assess changes in mean SHS scores in response to the personalised MNT intervention.[41] An average of the scores will be conducted (the fourth will be reverse-coded) to determine the final score from one to seven, with the higher the score indicating greater happiness.[41]

Food security

Food security refers to an individual's ability to access enough food in order to live an active and healthy life.[42] Food security is important to consider in this population due to research identifying that those living with diabetes had a higher level of food insecurity, and those with food insecurity had a higher prevalence of diabetes.[43] Therefore, the United States Department of Agriculture 6-item Food Security Module will be utilised to determine study participants level of food security prior to baseline and at week 6, with a raw score of 0–1 indicative of high/marginal food security and a raw score of 5–6 suggesting a very low food security.[44]

Malnutrition screening and assessment

Study participants will be screened for malnutrition using the validated Malnutrition Screening Tool (MST),[45] and a malnutrition assessment will be completed by using the validated Subjective Global Assessment (SGA)[46] at baseline and week 6, as those living with DFU presenting with malnutrition or those at risk of malnutrition have additional requirements.[14] The MST is a 2-item questionnaire, with a score of 0–1 indicating a low risk of malnutrition, a score of 2 signifying an individual may be at risk of malnutrition and a score of 3–5 suggesting a high risk of malnutrition.[45] The SGA consists of four areas of medical history including weight, dietary intake, gastrointestinal symptoms and functional capacity, and a physical examination section aimed to identify subcutaneous fat loss, muscle wasting and fluid accumulation.[46] An overall SGA score of A indicates an individual is well nourished while an overall B score indicates moderation malnutrition, and an overall C score signifies severe malnutrition.[46]

Food Box compliance

To assess compliance of participants consuming food provided, participants will be asked to take a picture of the remaining food they have not consumed prior to their week 2 and week 6 podiatry appointments. If participants are unable to take a photo, alternatively they will be asked to complete a checklist of the food remaining they have not consumed from the food box.

Statistical Analysis

Data analysis will be conducted by using StataBE 17 software.[47] Acceptability and feasibility will be measured using a process evaluation questionnaire as outlined by methods described previously.[48,49] The tool will be administered at the completion of the intervention, and includes open and closed questions. The closed questions are Likert based and as such will be pooled and presented as frequencies and percentages. The open questions will be coded using a conventional content analysis. Cohen's D will be utilised to measure the effect size.

For the secondary outcome of wound healing, data collected will be assessed for normality. If the data is normally distributed, we will use parametric tests to present means

and SDs. If the data is not normal distributed, we will present medians and IQR's for descriptive information. Paired t-tests will be utilised to compare the wound healing between the intervention and control groups, as well as other secondary outcomes.

Participant safety

Data collection and recruitment will adhere to the pre-specific plan or standard procedures by trained research investigators. Should any adverse events be reported these will be recorded.

Data monitoring/Unexpected findings during examination

A monthly meeting will be held among the study governance team (HRD, PET, EDC and CEC) to discuss unexpected clinical findings to determine whether these findings need to be escalated and the participant's general practitioner will be informed to provide care needed. Where required, study participants will be contacted by the chief investigator and their participation in the trial will be terminated, if directed by the general practitioner.

Discussion

Optimal nutrition underpins overall health, including providing nutrients essential for wound healing. Previous trials have demonstrated preliminary effectiveness of supplementation of nutrients such as zinc, magnesium, vitamin C, D, E or amino acids on wound healing outcomes in those with DFU.[50-53] While specific supplementation may have some effectiveness in the short term, long term behaviour change is required to reduce recurrence of DFU, effectively manage weight and cardiovascular risk, and optimise blood glucose levels. This would save both limbs and lives. Therefore, a holistic personalised MNT intervention that targets one aspect of the underlying pathophysiology, poor diet quality, is required.

This is the first pilot randomised controlled trial to assess acceptability and feasibility of a personalised MNT intervention in individuals living with diabetes-related foot ulceration, and investigate the role of personalised MNT in supporting improvements in wound healing, diet quality, glycaemic control and biomarkers. The authors anticipate that study results will identify personalised MNT as a feasible and acceptable nutrition intervention that can support wound healing in conjunction with standard wound care. The primary strength of this study is the utilisation of co-design, encompassing the patient and health practitioner's views to develop the nutrition intervention. Numerous randomised and non-randomised experimental studies have explored the role of nutrient supplementation or brief nutrition education, however most have not explored the role of MNT in those with DFU and do not report overall diet quality. Therefore, a validated food-frequency questionnaire, the AES-Heart is being utilised to assess diet quality in this trial.

Overall, findings from the current trial and learnings from the implementation of the personalised MNT intervention in the high-risk foot setting will inform design of feasibility and acceptability randomised trials exploring nutrition interventions for prevention and management of diabetes-related foot ulcers, with trial data assisting with sample size calcuations and identifying a standardised method to measure diet quality for future nutrition intervention trials in those with DFU.

Acknowledgements

We would like to thank Abbott Australia and New Zealand who provided Freestyle Libre 2 continuous glucose monitors for this research. HRD is undertaking this RCT as part of her PhD (Nutrition and Dietetics) at the University of Newcastle and is supported by a University of Newcastle research training program scholarship. CEC is supported by an NHMRC Leadership Research Fellowship (L3, APP2009340).

Conflict of interest

The authors declare no conflicts of interest.

Ethics statement

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 2023/ETH02331. This trial has been registered with the Australian New Zealand Clinical Trials Registry (ANZCTR), reference ACTRN12623001111662p.

Funding

This trial is supported by small grants from the Hunter New England Allied Health Advisory Group, the John Hunter Hospital Research Committee and Research Training Program funding as part of PhD support (for HRD) provided by the University of Newcastle.

Author contribution

All authors designed the randomised controlled trial protocol. HRD submitted the trials protocol to the Australian New Zealand Clinical Trials Registry. HRD, CEC, EDC and PET developed the ethics application. PET, CEC and EDC are supervisors for HRD.

References

1. Lazzarini PA, O'Rourke SR, Russell AW, Clark D, Kuys SS. What are the key conditions associated with lower limb amputations in a major Australian teaching hospital? J Foot Ankle Res. 2012;5(1):12. doi:10.1186/1757-1146-5-12
2. Tehan P, Linton C, Norbury K, White D, Chuter V. Factors contributing to wound chronicity in diabetic foot ulceration. Wound Practice and Research. 2019;27(3):111–115.
3. Diabetes: Australian Facts. Australian Institiute of Health and Welfare.; 2008. https://www.aihw.gov.au/getmedia/cf278981-8242-45c0-90d0-97dbac891bfb/daf08-c05.pdf.aspx
4. Bergin SM, Brand CA, Colman PG, Campbell DA. The impact of socio-economic disadvantage on rates of hospital separations for diabetes-related foot disease in Victoria, Australia. J Foot Ankle Res. Jun 20 2011;4:17. doi:10.1186/1757-1146-4-17

5. Hurst JE, Barn R, Gibson L, et al. Geospatial mapping and data linkage uncovers variability in outcomes of foot disease according to multiple deprivation: a population cohort study of people with diabetes. Diabetologia. Mar 2020;63(3):659–667. doi:10.1007/s00125-019-05056-9
6. World Health Organization. Diabetes. World Health Organization. Accessed October 9, 2022. https://www.who.int/news-room/fact-sheets/detail/diabetes
7. Ouyang W, Jia Y, Jin L. Risk factors of diabetic foot ulcer in patients with type 2 diabetes: a retrospective cohort study. Am J Transl Res. 2021;13(8):9554–9561.
8. Tai CH, Hsieh TC, Lee RP, Lo SF. Prevalence and medical resource of patients with diabetic foot ulcer: a nationwide population-based retrospective cohort study for 2001-2015 in Taiwan. Int J Environ Res Public Health. 2021;18(4):1891. doi:10.3390/ijerph18041891
9. West M, Chuter V, Munteanu S, Hawke F. Defining the gap: a systematic review of the difference in rates of diabetes-related foot complications in Aboriginal and Torres Strait Islander Australians and non-Indigenous Australians. J Foot Ankle Res. 2017;10:48. doi:10.1186/s13047-017-0230-5
10. Basiri R, Spicer MT, Munoz J, Arjmandi BH. Nutritional intervention improves the dietary intake of essential micronutrients in patients with diabetic foot ulcers. Curr Dev Nutr. 2020;4:8.
11. Lauwers P, Dirinck E, Van Bouwel S, et al. Malnutrition and its relation with diabetic foot ulcer severity and outcome: a review. Acta Clin Belg. Jul 29 2020:1–7. doi:10.1080/17843286.2020.1800315
12. Pena G, Kuang B, Cowled P, et al. Micronutrient status in diabetic patients with foot ulcers. Adv Wound Care (New Rochelle). Jan 1 2020;9(1):9–15. doi:10.1089/wound.2019.0973
13. Zhang SS, Tang ZY, Fang P, Qian HJ, Xu L, Ning G. Nutritional status deteriorates as the severity of diabetic foot ulcers increases and independently associates with prognosis. Exp Ther Med. Jan 2013;5(1):215–222. doi:10.3892/etm.2012.780
14. Armstrong DG, Mills JL, Molina M, Molnar JA. Nutrition interventions in adults with diabetic foot ulcers. Guideline Central. 2021. Accessed 21/04/2024. http://eguideline.guidelinecentral.com/i/1428995-nutrition-in-dfu-guidelines-advisory-pocket-guide/0?
15. Asif M. The prevention and control the type-2 diabetes by changing lifestyle and dietary pattern. J Educ Health Promot. 2014;3:1. doi:10.4103/2277-9531.127541
16. Sami W, Ansari T, Butt NS, Hamid MRA. Effect of diet on type 2 diabetes mellitus: A review. Int J Health Sci (Qassim). Apr–Jun 2017;11(2):65–71.
17. Academy of Nutrition and Dietetics. Medical Nutrition Therapy. Accessed 12 Sep 2023, https://www.andeal.org/topic.cfm?menu=5284
18. Noorbergen T, Teubner T, Collins C, Adam M. Using Co-Design in mHealth Systems Development: A qualitative study with experts in Co-design and mHealth System Development. MIR mHealth and uHealth.2021;9(11):e27896.
19. Donnelly HR, Collins CE, Haslam R, White D, Tehan PE. Perceptions of diet quality, advice, and dietary interventions in individuals with diabetes-related foot ulceration; a qualitative research study. Nutrients. Jun 14 2022;14(12):2457. doi:10.3390/nu14122457
20. Butcher NJ, Monsour A, Mew EJ, et al. Guidelines for reporting outcomes in trial protocols: The SPIRIT-Outcomes 2022 Extension. JAMA. 2022;328(23):2345–2356.
21. Mills JL Sr, Conte MS, Armstrong DG, et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: risk stratification based on wound, ischemia, and foot infection (WIfI). J Vasc Surg. Jan 2014;59(1):220–234.e1–2. doi:10.1016/j.jvs.2013.08.003
22. Fiaccadori E, Sabatino A, Barazzoni R, et al. ESPEN guideline on clinical nutrition in hospitalized patients with acute or chronic kidney disease. Clin Nutr. Apr 2021;40(4):1644–1668. doi:10.1016/j.clnu.2021.01.028
23. Ikizler TA, Burrowes JD, Byham-Gray LD, et al. KDOQI Nutrition in CKD Guideline Work Group. KDOQI clinical practice guideline for nutrition in CKD: 2020 update. Am J Kidney Dis. 2020;76(3)(suppl 1):S1–S107.
24. Australian Standard Classification of Cultural and Ethnic Groups (ASCCEG). Australian Bureau of Statistics. 2019.
25. Mullins R, Borland R. Changing the way smoking is measured among australian adults: a preliminary investigation of victorian data. Quit Evaluation Studies. 1998;9:163–173.
26. Hughes JR, Keely JP, Niaura RS, Ossip-Klein DJ, Richmond RL, Swan GE. Measures of abstinence in clinical trials: issues and recommendations. Nicotine Tob Res. Feb 2003;5(1):13–25.
27. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. Ambulatory Care Quality Improvement Project (ACQUIP). Alcohol Use Disorders Identification Test. Arch Intern Med. Sep 14 1998;158(16):1789–95. doi:10.1001/archinte.158.16.1789
28. The Active Australia Survey: a guide and manual for implementation, analysis and reporting. Australian Instituite of Health and Welfare. 2003. Cat. no: CVD 22.
29. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. Pilot Feasibility Stud. 2016;2:64. doi:10.1186/s40814-016-0105-8
30. Sealed Envelope Ltd. Create a blocked randomisation list. Accessed 12 Sep 2023, https://www.sealedenvelope.com/simple-randomiser/v1/lists
31. eHealth NSW. myVirtualCare. NSW Government. Accessed 26 October, 2023. https://www.ehealth.nsw.gov.au/solutions/virtual-care/consultations/myvirtualcare
32. Robinson WP, Loretz L, Hanesian C, et al. Society for Vascular Surgery Wound, Ischemia, foot Infection (WIfI) score correlates with the intensity of multimodal limb treatment and patient-centered outcomes in patients with threatened limbs managed in a limb preservation center. J Vasc Surg. 2017;66(2):488–498. doi:https://doi.org/10.1016/j.jvs.2017.01.063
33. Coerper S, Beckert S, Küper MA, Jekov M, Königsrainer A. Fifty percent area reduction after 4 weeks of treatment is a reliable indicator for healing – analysis of a single-center cohort of 704 diabetic patients. J Diabetes Complications. Jan–Feb 2009;23(1):49–53. doi:10.1016/j.jdiacomp.2008.02.001
34. Collins CE, Boggess MM, Watson JF, et al. Reproducibility and comparative validity of a food frequency questionnaire for Australian adults. Clin Nutr. Oct 2014;33(5):906–914. doi:10.1016/j.clnu.2013.09.015
35. Schumacher TL, Burrows TL, Rollo ME, Wood LG, Callister R, Collins CE. Comparison of fatty acid intakes assessed by a cardiovascular-specific food frequency questionnaire with red blood cell membrane fatty acids in hyperlipidaemic Australian adults: a validation study. Eur J Clin Nutr. 2016/12/01 2016;70(12):1433-1438. doi:10.1038/ejcn.2016.144
36. McDermott K, Fang M, Boulton AJM, Selvin E, Hicks CW. Etiology, epidemiology, and disparities in the burden of diabetic foot ulcers. Diabetes Care. Jan 1 2023;46(1):209–221. doi:10.2337/dci22-0043
37. Patient Activation Measure® (PAM®). Insignia Health. https://www.insigniahealth.com/pam/

38. Nutrition Education Materials Online Team. Using Body Mass Index 2017. Queensland Government; 2024. Using Body Mass Index. NEMO (health.qld.gov.au)
39. Jangam S, Dunn T, Xu Y, Hayter G, Ajjan RA. Flash glucose monitoring improves glycemia in higher risk patients: a longitudinal, observational study under real-life settings. BMJ Open Diabetes Res Care. 2019;7(1):e000611. doi:10.1136/bmjdrc-2018-000611
40. Gusi N, Olivares PR, Rajendram R. The EQ-5D Health-Related Quality of Life Questionnaire. In: Preedy VR, Watson RR, eds. Handbook of Disease Burdens and Quality of Life Measures. Springer New York; 2010:87–99.
41. Lyubomirsky S, Lepper HS. A measure of subjective happiness: preliminary reliability and construct validation. social indicators research. 1999;46(2):137–155. doi:10.1023/A:1006824100041
42. Bowden, M. Understanding food insecurity in Australia. Australian Institute of Family Studies 2020: CFCA Paper No. 55.
43. Gucciardi E, Vahabi M, Norris N, Del Monte JP, Farnum C. The intersection between food insecurity and diabetes: a review. Curr Nutr Rep. 2014;3(4):324–332. doi:10.1007/s13668-014-0104-4
44. Economic Research Service. U.S. Household Food Security Survey Module: Six-Item Short Form. United States Department of Agriculture 2012. Accessed 10 September 2023. https://www.ers.usda.gov/media/8282/short2012.pdf
45. Department of Health. Malnutrition Screening Tool (MST). Tasmanian Government 1999. https://www.health.tas.gov.au/sites/default/files/2021-11/MST_DoHTasmania2020.pdf
46. Nutrition Education Materials Online Team. Subjective Global Assessment. Queensland Government; 2009. https://www.health.qld.gov.au/__data/assets/pdf_file/0030/143877/hphe_sga.pdf
47. StataCorp 2022. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC.
48. Hutchesson MJ, Callister R, Morgan PJ, et al. A targeted and tailored eHealth weight loss program for young women: The Be Positive Be Healthe Randomized Controlled Trial. Healthcare. 2018;6(2):39. doi:10.3390/healthcare6020039
49. Hutchesson MJ, Taylor R, Shrewsbury VA, et al. Be Healthe for Your Heart: a pilot randomized controlled trial evaluating a web-based behavioral intervention to improve the cardiovascular health of women with a history of preeclampsia. Int J Environ Res Public Health. 2020;17(16):5779. doi:10.3390/ijerph17165779
50. Afzali H, Jafari Kashi AH, Momen-Heravi M, et al. The effects of magnesium and vitamin E co-supplementation on wound healing and metabolic status in patients with diabetic foot ulcer: A randomized, double-blind, placebo-controlled trial. Wound Repair Regen. May 2019;27(3):277–284. doi:10.1111/wrr.12701
51. Halschou-Jensen PM, Sauer J, Bouchelouche P, Fabrin J, Brorson S, Ohrt-Nissen S. Improved healing of diabetic foot ulcers after high-dose vitamin D: a randomized double-blinded clinical trial. Int J Low Extrem Wounds. 2023;22(3):466–474. doi:10.1177/15347346211020268
52. Momen-Heravi M, Barahimi E, Razzaghi R, Bahmani F, Gilasi HR, Asemi Z. The effects of zinc supplementation on wound healing and metabolic status in patients with diabetic foot ulcer: A randomized, double-blind, placebo-controlled trial. Wound Repair Regen. May 2017;25(3):512–520. doi:10.1111/wrr.12537
53. Yarahmadi A, Saeed Modaghegh MH, Mostafavi-Pour Z, et al. The effect of platelet-rich plasma-fibrin glue dressing in combination with oral vitamin E and C for treatment of non-healing diabetic foot ulcers: a randomized, double-blind, parallel-group, clinical trial. Expert Opin Biol Ther. May 2021;21(5):687–696. doi:10.1080/14712598.2021.1897100

Supplementary data/files can be found by logging into the electronic version of the WPR Journal via the Wounds Australia website members' area (woundsaustralia.org).