DOI: 10.35279/jowm2023.24.01.02

Understanding frailty and pre-frailty to improve chronic wound management in older people: A study protocol

Duygu Sezgin, PhD, School of Nursing and Midwifery, University of Galway, Galway, Ireland; Alliance for Research and Innovation in Wounds, University of Galway, Galway, Ireland
Aaron Liew, PhD, School of Medicine, University of Galway, Galway, Ireland; Portiuncula University Hospital, Galway, Ireland
Georgina Gethin, PhD, School of Nursing and Midwifery, University of Galway, Galway, Ireland; Alliance for Research and Innovation in Wounds, University of Galway, Galway, Ireland

Correspondence: Duygu Sezgin, duygu.sezgin@universityofgalway.ie
Conflict of interest: None

Keywords
Chronic leg ulcers, chronic wounds, diabetes, frailty, pre-frailty, study protocol

ABSTRACT

Background

Frailty is a geriatric syndrome associated with limited function, reduced quality of life and premature death. Chronic conditions, such as diabetes and vascular disease leading to chronic ulceration, may increase the risk of frailty. If chronic wounds are a strong predictor of frailty, researchers and practitioners should proactively and effectively manage both the wound and the potential underlying frailty issues. However, there is a paucity of research evidence in this area.

Aim

We aim to identify the prevalence of frailty and pre-frailty in older adults with chronic leg ulcers and/or diabetes, and investigate the associations between having diabetes and chronic leg ulcers and being pre-frail or frail.

Design

Descriptive and cross sectional study protocol.

Data collection

Frailty and pre-frailty status will be identified using two separate tools: the Groningen Frailty Indicator (self-reported) for multidimensional frailty screening, and the five criteria of the Physical Frailty Phenotype for physical frailty assessment.

Sample

Patients aged ≥65 years with chronic leg ulcers and/or diabetes will be recruited from two hospitals in the west of Ireland.

Data analysis

Associations between the frailty and pre-frailty prevalence and wound aetiology and duration, age, gender and co-comorbidities will be explored using descriptive and comparative analyses.

INTRODUCTION

As the population ages, more older adults with chronic conditions, such as diabetes and vascular diseases, are vulnerable to developing chronic wounds [1,2] and are at high risk of adverse outcomes related to wound care interventions [1]. Chronic wounds in older individuals are among the most overwhelming and difficult-to-treat age-related conditions. They are strongly associated with a decreased quality of life (QoL) [1]. Chronic wounds in older adults are usually linked with declines in multiple domains ▶

of function, in contrast to younger individuals [1], and they cause significant morbidity [3]. Therefore, chronic wounds in older adults require attention as part of a comprehensive assessment [1].

'Frailty' is a geriatric syndrome that manifests as a decline in physiological reserve that compromises the ability to cope with stressors [4–6]. It is associated with older age [5] and functional impairments [6]. There are also conceptual definitions of frailty indicating that it is a multi-domain and multi-dimensional state, deficit or decline [6]. Despite several consensus definitions [7,8], frailty has been operationalised using different screening and assessment tools, such as the Physical Frailty Phenotype [9]; the deficit accumulation model, also known as Frailty Index [10]; and many other methods, including multidimensional frailty screening tools such as the Groningen Frailty Indicator [11,12]. The choice of instrument may depend on the setting, person using it, local policies and time constraints [6]; however, the use of standard and widely accepted instruments helps in making comparisons with available findings [5]. A prodromal stage of frailty, so-called 'pre-frailty', can be detectable before older adults are seriously impacted by their chronic condition [13]. Pre-frailty can be reversed by timely interventions [13] and may not necessarily lead to frailty. Early identification of frailty in older adults with chronic wounds could enable the prevention of adverse outcomes such as reduced QoL [14,15], reduced function and disability [15,16], increased hospital re-admissions [17] and mortality [15,18].

Chronic diseases and comorbidity affect the frailty status of older adults [9], and it has been reported in many studies that diabetes is associated with an increased risk of frailty [19–22]. The mechanism leading to the development of frailty in people with diabetes is complex [23], and it is still unclear whether frailty leads to diabetes and affects HbA1c levels [24,25]. However, diabetes and frailty often occur together [26]. Furthermore, the treatment and management of diabetes in older populations is challenging [27], and diabetes is associated with disruption in wound healing [28]. We hypothesise that the presence of chronic wounds, together with diabetes, significantly increases the risk of pre-frailty and frailty.

Although it is estimated that chronic wounds, especially diabetic foot ulcers (DFU) and venous leg ulcers (VLU), are directly associated with an increased risk of frailty, there is a paucity of research evidence in this area: one small study from Brazil [29] identified moderate frailty in 42% of patients with DFU. Similarly, VLU are reported to be a predictor of frailty [30]. Studies reporting the prevalence of frailty or pre-frailty in patients with chronic wounds are very limited, and we will address this research gap. Frailty is not routinely assessed in chronic leg ulcer patients, and there are no standard recommendations for pre-frailty or frailty screening or assessment in patients with chronic leg ulcers. Furthermore, existing wound-specific clinical guidelines do not provide specific guidance on managing frail patients [3]. For these reasons, it is necessary to develop specific guidelines based on research evidence that support clinical decisions. This study will illustrate the importance of routine frailty assessment in patients with chronic leg ulcers and inform practitioners and policy-makers. Our study aims to identify the prevalence of frailty and pre-frailty in older adults with chronic leg ulcers and/or diabetes and to investigate the associations between having diabetes and chronic leg ulcers and being pre-frail or frail. It will also have a specific focus on both physical and multidimensional frailty, separately, to understand their connections with chronic leg ulcers.

METHODS

We hypothesise that chronic leg ulcers may be considered a determinant of frailty, and diabetes could be another factor contributing to this outcome when it co-occurs with a chronic leg ulcer. Therefore we expect that:

Hypothesis 1- Participants with chronic leg ulcers will have a higher rate of frailty, compared to those with diabetes only.

Hypothesis 2- Participants with chronic leg ulcers and diabetes will have a higher rate of frailty, compared to those with a chronic leg ulcer only or with diabetes only.

Objectives

Primary objectives: (1) To identify and compare the prevalence of frailty and pre-frailty in older adults with chronic leg ulcers and/or diabetes; (2) To identify the association between diabetes, chronic leg ulcers, pre-frailty and frailty.

Secondary objectives: (1) To compare physical frailty

and multidimensional frailty status measured using relevant tools and their association with chronic leg ulcers; (2) To provide evidence for a larger project on the development of interventions for early identification of pre-frailty in older adults with chronic leg ulcers.

Design, sample and sampling

This is a research protocol for a descriptive, cross-sectional study comprising three patient groups: Group 1, those with diabetes and a chronic leg ulcer; Group 2, those without diabetes but with a chronic leg ulcer; and Group 3, those with diabetes but without a chronic leg ulcer (reference group). Since the study data will be collected from a not very densely populated geographic area, the convenience sampling method will be used, which is a common type of non-probability sampling [31]. To minimise bias, sampling criteria will be used (i.e., patients who meet the inclusion criteria below and agree to take part in the study). To achieve an understanding of the interest area and obtain data to test the study's hypotheses, a sample of 150 patients will be targeted, with 50 participants in each group. Prior to commencement of the full study, data has been collected from 15 participants attending two clinics as part of a pilot study to test the feasibility of the data collection tools.

Inclusion and exclusion criteria

Patients who meet the following criteria will be included: aged ≥65 years; currently have a chronic leg ulcer, such as VLU, or have had one in the last 6 months (except Group 3 patients); have diabetes (Groups 1 and 3); able to walk; a community-dweller/not living in a long-term care facility; able to provide informed consent. Patients who are not able to walk independently, those living in a long-term care facility or who are currently hospitalised and those unable to give informed consent will be excluded.

Setting

The sample will be recruited from two hospitals in the west of Ireland.

Data collection

The data collection will be performed in two steps, to allow comparisons between physical frailty assessment and multidimensional frailty screening results and their association with chronic leg ulcer occurrence. The data collection will be completed by the lead investigator, who is a registered nurse and familiar with frailty identification tools, and research assistants will support this process after being trained by the lead investigator. Two commonly used, well validated [5,32] frailty assessment and screening instruments will be used for the identification of frailty status.

Groningen Frailty Indicator

An initial screening of pre-frailty and frailty will be completed using the multidimensional, self-reported Groningen Frailty Indicator (GFI) [12]. The self-reported GFI provides an assessment including physical, psychological, social and cognitive domains of frailty. It contains 15 questions, and a score of 4 or higher represents moderate to severe frailty. We choose to use the GFI since it has previously been used in other studies focusing on community-dwelling populations [32].

Physical Frailty Phenotype

A further assessment of physical frailty will be performed using the well-validated Physical Frailty Phenotype [5,9], which has been widely used in previous studies employing frailty assessment in various settings, including community-dwellers [5,32]. It defines frailty by five criteria: weakness, slowness, exhaustion, low physical activity and unintentional weight loss. Participants are considered robust (0), pre-frail (1–2), or frail (≥3) depending on the number of criteria they score. Weakness will be measured using a handgrip strength dynamometer [33,34]; slowness by gait speed (the Timed 'Up and Go' test with ≥12s cut-off) [35,36]; unintentional weight loss (≥5%) with the Malnutrition Universal Screening Tool (Step 2) [37]; exhaustion using the question 'In this last month, do you feel that you have less energy to do the things you want?' (0=no exhaustion, 1=exhaustion); [38] and low physical activity by the question 'How often do you practice a physical activity such as dancing, walking, farm work or gardening?' [39](≥once a week=active, ≤three times a month=not active) [38].

Case report form

A case report form developed by the researchers based on the relevant literature will be used to record participants' age, gender, wound type, duration of wound and co-morbidities.

Data analysis

Data analysis will be performed using Statistical Package for the Social Sciences (SPSS). Descriptive statistics will be applied, and comparisons will be

made considering group differences and covariates. These comparisons will include frailty and pre-frailty status, the presence of diabetes and chronic leg ulcer status to describe differences between Groups 1, 2 and 3. Comparisons will also be made based on age, gender, wound aetiology, wound duration and co-morbidities. Sub-group analyses will be performed based on ulcer status (i.e., currently open or not) and type of frailty (physical versus multidimensional). Outcome measures will be the variables related to frailty status (pre-frail, frail and robust, assessed by the Physical Frailty Phenotype and GFI score 4 and over). The independent variables will be the participants' age, gender, chronic leg ulcer status, ulcer aetiology, ulcer duration, diabetes status and co-morbidities. Parametric or non-parametric tests will be applied based on the distribution of data. Logistic regression analyses will be performed to identify factors contributing to frailty status.

Ethics

Ethics approval has been obtained from the Galway Clinical Research Ethics Committee (Reference number C.A. 2715). The study protocol conforms to the ethical guidelines of the Declaration of Helsinki (2013) and the General Data Protection Regulation (GDPR) (European Union) 2016/679. Written information (patient information leaflets) will be provided to each potentially eligible participant explaining the nature of the study. The recruitment will be opt-in; potential participants will express their interest by contacting the researcher directly. The researcher will provide detailed information about all assessment procedures. Written consent will be obtained prior to data collection. All participants will have the capacity to give informed consent. All data will be collected, processed and stored anonymously.

IMPLICATIONS FOR CLINICAL PRACTICE

This will be the first European study to understand frailty and pre-frailty prevalence in older adults with chronic leg ulcers. It will open new ground in a promising area by explaining the connections between frailty and wound management. The results of this study will also provide evidence for the association between chronic leg ulcers and physical and multidimensional frailty. This study will determine the functional impact of chronic wounds on community dwellers and illustrate the importance of frailty screening in older adults with chronic wounds. Therefore, it will inform practitioners and policy-makers about considering frailty when evaluating and treating such patients. It will also motivate future studies about simple self-screening tools for the early identification of pre-frailty in adults with chronic leg ulcers. Consequently, in line with the current gaps in this area of research, this study highlights the potential for future studies targeting the effective management of frailty and pre-frailty in people with chronic wounds to enhance patients' capacity and self-management, to enable them to continue taking part in society and to contribute to reducing healthcare costs.

Key messages

- Studies reporting the prevalence of frailty or pre-frailty in patients with chronic wounds are very limited.
- We hypothesise that the presence of chronic wounds, together with diabetes, significantly increases the risk of pre-frailty and frailty.

REFERENCES

1. Gould LJ, Abadir PM, White-Chu EF. Age, frailty, and impaired wound healing. In: Rosenthal RA, Zenilman ME, Katlic MR, editors. Principles and Practice of Geriatric Surgery. New York: Springer Cham; 2020. p. 465-82.
2. Franks PJ, Barker J, Collier M, Gethin G, Haesler E, Jawien A, et al. Management of patients with venous leg ulcers: challenges and current best practice. J Wound Care. 2016 Jun 1; 25(Sup6):S1-7.
3. Ferris AE, Harding KG. Are chronic wounds a feature of frailty? Br J Gen Pract. 2020 May 1; 70(694):256-7.
4. Clegg A, Young J, Iliffe S, Rikkert MO, Rockwood K. Frailty in elderly people. Lancet. 2013 Mar 2; 381(9868):752-62.
5. O'Caoimh R, Sezgin D, O'Donovan MR, Molloy DW, Clegg A, Rockwood K, et al. Prevalence of frailty in 62 countries across the world: A systematic review and meta-analysis of population-level studies. Age Ageing. 2021 Jan; 50(1):96-104.
6. Sezgin D, O'Donovan M, Cornally N, Liew A, O'Caoimh R. Defining frailty for healthcare practice and research: A qualitative systematic review with thematic analysis. Int J Nurs Stud. 2019 Apr 1; 92:16-26.
7. Sezgin D, O'Donovan M, Woo J, Bandeen-Roche K, Liotta G, Fairhall N, et al. Early identification of frailty: Developing an international Delphi consensus on pre-frailty. Arch Gerontol Geriatr. 2022 Mar 1; 99:104586.
8. Rodríguez-Mañas L, Féart C, Mann G, Viña J, Chatterji S, Chodzko-Zajko W, et al. Searching for an operational definition of frailty: A Delphi method based consensus statement. The frailty operative definition-consensus conference project. J Gerontol: Bio Sci Med Sci. 2013 Jan 1; 68(1):62-7.
9. Fried LP, Tangen CM, Walston J, Newman AB, Hirsch C, Gottdiener J, et al. Frailty in older adults: Evidence for a phenotype. J Gerontol: Bio Sci Med Sci. 2001 Mar 1; 56(3):M146-57.
10. Mitnitski AB, Mogilner AJ, Rockwood K. Accumulation of deficits as a proxy measure of aging. Sci World J. 2001 Aug 8; 1:323-36.
11. Steverink N, Slaets JP, Schuurmans H, Lis M. Measuring frailty: Developing and testing the GFI (Groningen Frailty Indicator). Gerontologist. 2001; 41, 236-7.
12. Peters LL, Boter H, Buskens E, Slaets JP. Measurement properties of the Groningen Frailty Indicator in home-dwelling and institutionalized elderly people. JAMDA. 2012 Jul 1; 13(6), 546-51.
13. Sezgin D, Liew A, O'Donovan MR, O'Caoimh R. Pre-frailty as a multi-dimensional construct: A systematic review of definitions in the scientific literature. Geriatr Nurs. 2020 Mar 1; 41(2):139-46.
14. Crocker TF, Brown L, Clegg A, Farley K, Franklin M, Simpkins S, et al. Quality of life is substantially worse for community-dwelling older people living with frailty: Systematic review and meta-analysis. Qual Life Res. 2019 Aug; 28(8):2041-56.
15. Rivera-Almaraz A, Manrique-Espinoza B, Ávila-Funes JA, Chatterji S, Naidoo N, Kowal P, et al. Disability, quality of life and all-cause mortality in older Mexican adults: Association with multimorbidity and frailty. BMC Geriatrics. 2018 Dec; 18(1):1-9.
16. Hoogendijk EO, Afilalo J, Ensrud KE, Kowal P, Onder G, Fried LP. Frailty: Implications for clinical practice and public health. Lancet. 2019 Oct 12; 394(10206):1365-75.
17. Grana M, LopezÐGuede JM, Irazusta J, Labayen I, Besga A. Modelling hospital readmissions under frailty conditions for healthy aging. Expert Syst. 2020 Apr; 37(2):e12437.
18. O'Donovan M, Sezgin D, O'Caoimh R, Liew A. The Impact of and Interaction between Diabetes and Frailty on Psychosocial Wellbeing and Mortality in Ireland. International Journal of Environmental Research and Public Health. 2020 Dec;17(24):9535.
19. García-Esquinas E, Graciani A, Guallar-Castillón P, López-García E, Rodríguez-Mañas L, Rodríguez-Artalejo F. Diabetes and risk of frailty and its potential mechanisms: A prospective cohort study of older adults. JAMDA. 2015 Sep 1; 16(9), 748-54.
20. Stout MB, Justice JN, Nicklas BJ, Kirkland JL. Physiological aging: Links among adipose tissue dysfunction, diabetes, and frailty. Physiology. 2017 Jan; 32(1):9-19.
21. Abd Ghafar MZ, O'Donovan M, Sezgin D, Moloney E, Rodríguez Laso Á, Liew A, et al. Frailty and diabetes in older adults: Overview of current controversies and challenges in clinical practice. Front Clin Diabetes Healthc. 2022 August; 3:895313.
22. Sinclair AJ, Abdelhafiz AH. Age, frailty and diabetes–Triple jeopardy for vulnerability to COVID-19 infection. EClinicalMedicine. 2020 May 1; 22:100343.
23. Aguayo GA, Fagherazzi G. Intricate relationships between frailty and diabetes: Where do we go from here? Lancet Healthy Longevity. 2020 Dec 1; 1(3):e92-3.
24. Veronese N, Stubbs B, Fontana L, Trevisan C, Bolzetta F, De Rui M, et al. Frailty is associated with an increased risk of incident type 2 diabetes in the elderly. J Am Med Dir Assoc. 2016 Oct 1; 17(10):902-7.
25. Jang HC. Sarcopenia, frailty, and diabetes in older adults. Diabetes Metab J. 2016 Jun 1;40(3):182-9.
26. O'Donovan M, Sezgin D, O'Caoimh R, Liew A. The relationship between frailty and diabetes: An investigation of self-rated health, depression symptoms and quality of life in the Study of Health Aging and Retirement in Europe. Arch Gerontol Geriatr. 2021 Sep 1; 96:104448.
27. Morley JE, Abbatecola AM, Woo J. Management of comorbidities in older persons with type 2 diabetes. JAMDA. 2017 Aug 1; 18(8), 639-45.
28. Blakytny R, Jude E. The molecular biology of chronic wounds and delayed healing in diabetes. Diabet Med. 2006 Jun; 23(6):594-608.
29. Bôas NC, Salome GM, Ferreira LM. Frailty syndrome and functional disability among older adults with and without diabetes and foot ulcers. J Wound Care. 2018 Jul 2; 27(7):409-16.
30. Hippisley-Cox J, Coupland C. Development and validation of QMortality risk prediction algorithm to estimate short term risk of death and assess frailty: Cohort study. BMJ. 2017 Sep 20; 358:j4208.
31. Gray JR, Grove SK, Sutherland S. Burns and Grove's the practice of nursing research-E-book: Appraisal, synthesis, and generation of evidence. 8th Edition. Missouri. Elsevier Health Sciences; 2016.
32. Bongue B, Buisson A, Dupre C, Beland F, Gonthier R, Crawford-Achour É. Predictive performance of four frailty screening tools in community-dwelling elderly. BMC Geriatr. 2017 Dec; 17(1):262. doi: 10.1186/s12877-017-0633-y.
33. Sousa-Santos AR, Amaral TF. Differences in handgrip strength protocols to identify sarcopenia and frailty-a systematic review. BMC Geriatr. 2017 Dec; 17(1):238. doi: 10.1186/s12877-017-0625-y.
34. Hoogendijk EO, Suanet B, Dent E, Deeg DJ, Aartsen MJ. Adverse effects of frailty on social functioning in older adults: Results from the Longitudinal Aging Study Amsterdam. Maturitas. 2016 Jan 1; 83:45-50.
35. Podsiadlo D, Richardson S. The timed "Up & Go": A test of basic functional mobility for frail elderly persons. J Am Geriatr Soc. 1991 Feb; 39(2):142-8.
36. Jung HW, Kim S, Jang IY, Shin DW, Lee JE, Won CW. Screening value of timed up and go test for frailty and low physical performance in Korean older population: the Korean Frailty and Aging Cohort Study (KFACS). Annals of geriatric medicine and research. 2020 Dec; 24(4):259-266.
37. Malnutrition Universal Screening Tool – The 'MUST' Toolkit. 2003. https://www.bapen.org.uk/pdfs/must/must-full.pdf Accessed: 30.05.2022.
38. Alves S, Teixeira L, Ribeiro O, Paúl C. Examining frailty phenotype dimensions in the oldest old. Front Psychol. 2020 Mar 26; 11:434.
39. Duarte N, Teixeira L, Ribeiro O, Paul C. Frailty phenotype criteria in centenarians: Findings from the Oporto Centenarian Study. Eur Geriatr Med. 2014 Dec 1; 5(6):371-6.