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The impact of pressure injury on quality of life in adults: Protocol for a systematic review

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ABSTRACT

Background

Pressure injuries are a common healthcare problem and are associated with impaired quality of life.

Objective

To investigate the impact of pressure injuries on the quality of life of adults aged 18 years and older.

Design

Systematic review.

Eligibility criteria

Both quantitative and qualitative studies that report on quality of life in adults with a pressure injury from acute care, rehabilitation, long-term care and community settings will be included.

Methods

Studies conducted between January 2009 and July 2022 and found in the Ovid Medline, Ovid Embase, CINAHL EBSCO, Scopus and Central Register of Controlled Trials databases will be identified. Two independent review authors will perform the study selection and data extraction. Methodological quality will be appraised using the Critical Appraisal Skills Programme checklists. A thematic synthesis will be used to analyse qualitative evidence. A meta-analysis will be conducted for quantitative data if no significant heterogeneity is detected. Where statistical pooling is not possible, findings will be reported narratively. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) and the GRADE-Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) tools will be used to determine confidence levels of findings from quantitative and qualitative studies.

INTRODUCTION

1.1 Description of the condition

A pressure injury (PI), also referred to as pressure ulcer, pressure sore, bed sore or decubitus ulcer, is defined as 'localised damage to the skin and/or underlying tissue, as a result of pressure or pressure in combination with shear (1) and is a common healthcare problem (2, 3). In adults, PIs most commonly occur at the bony prominences of the hips and sacrum (4). Other locations, such as the ischial tuberosity, greater trochanter, heel and lateral malleolus, are also common sites for PIs (4). The National Pressure Injury Advisory Panel (NPIAP) categorises PIs into four stages: non-blanchable erythema, partial-thickness skin loss with exposed dermis, full-thickness skin loss, full-thickness skin and tissue loss. For a PI that is obscured by slough or eschar, the depth of wound is unknown, so it is classified as an unstageable PI: obscured full-thickness skin and tissue loss. A deep tissue PI is staged as persistent with a non-blanchable deep red, maroon or purple discoloration (1). The latest review (5) and recent studies (6, 7) have reported

that the risk factors for PIs in adult patients include physiological factors (advanced age, body mass index (BMI) < 18.5, malnutrition, incontinence, impaired mobility, poor perfusion, dehydration and comorbid conditions such as diabetes), extrinsic factors that affect skin integrity (friction/shear, interface pressure and turning and repositioning) and mental status/ neurological disorders (traumatic brain injury, dementia or other cognitive disorders). The European Pressure Ulcer Advisory Panel (EPUAP) and the NPIAP collaboratively published the first edition of the Prevention and Treatment of Pressure Ulcers/ Injures: Clinical Practice Guideline-The International Guideline (The International Guideline) (1) in 2009. It was later updated in 2014 and 2019 (1, 8) to ensure supporting resources are in place for healthcare professionals, patients and informal caregivers to manage and prevent PIs (1). PIs remain a significant problem in hospitals and long-term care facilities, with the prevalence ranging from 13% to 15% (4). PIs are often associated with a long healing period, severe pain, exudate, odour, sleep and mood disturbances and infection (9, 10). A PI can also lead to a reduced quality of life (QoL), impaired mobility, high cost for patients and healthcare systems and increased morbidity and mortality (4, 9, 10).

Quality of life refers to 'the functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient' (11). QoL can be affected by an individual's physical, social and psychological states (12) and is generally recognised as a valid indicator for unmet needs. It has also been used for monitoring the efficacy of health services, evaluating the effectiveness of interventions, and analysing cost-utility as a supplementary objective clinical measure (13, 14). Measuring QoL can provide a deep understanding of the impact of disease on individuals (15). There are two primary instruments developed for QoL measurement; these include either generic or disease-specific instruments. Generic instruments, such as the 36-Item Short Form Survey (SF-36), can be used to assess the outcome of health status across multiple diseases, interventions or populations. In contrast, disease-specific instruments, such as the Pressure Ulcer Quality of Life Scale (PU-QOL), are used for QoL measurements related to specific conditions or diseases (15, 16). The International Guideline reports on the complex relationship between QoL and its contributory factors, such as comorbidities, coping ability and knowledge, all of which interact with one another (1).

1.2 Why it is important to undertake this review

We conducted a preliminary search of MEDLINE and the Cochrane Database of Systematic Reviews. A systematic review (17) published in 2009 and one literature review (18) published in 2014 on this topic were identified. The previously published systematic review identified the impact of PI on QoL in older adults (17); however, it was published before the first edition of the International Guideline (1). The previously published literature review (18) demonstrated the impact of PI on QoL, but it was not a systematic review, and the cited studies were published in or before 2010. In this study, we address this gap and systematically review the evidence on the impact of PI on QoL of adults aged 18 years and older. We include studies on the QoL of people with PI published after the first edition of the International Guideline published in 2009 and the evidence-based recommendations implemented into practice.

1.3 Objective

In this protocol for a systematic review, we present a transparent process, listing every step of the review in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P) statement (19). The objective of the planned systematic review was to investigate the impact of PI on the QoL of adults aged 18 years and older.

Research question: *How do pressure injuries impact the quality of life of adults aged 18 years and older?*

METHODS

In this protocol, we present a transparent process of the planned methods for our systematic review guided by the PRISMA 2020 statement (20). This protocol is registered with the PROSPERO (CRD42022350983) and has been deposited in Open Science Framework (OSF) repository (21).

2.1 Eligibility criteria

2.1.1 Types of studies

This review will include both quantitative and qualitative research studies on the impact of PI on the QoL of adults aged 18 years and older.

Quantitative studies, including:

- Randomised controlled trials
- Quasi-randomised trial

- Non-randomised studies
- Cross-sectional studies
- Cohort studies
- Before and after evaluation studies
- Case-control studies

Qualitative studies, including:

- Studies that use qualitative methods to collect data, such as group or individual interviews, focus group discussions and observations

- Studies that use qualitative methods of data analysis, such as thematic analysis, grounded theory, qualitative content analysis and phenomenological analysis

Studies not focused on QoL or the impact of QoL will be excluded, as will studies that merely report the measurement properties of QoL instruments. Further, any studies that report the impact of a specific product or drug on the QoL will be disregarded. Conference abstracts, all kinds of reviews, letters to the editor, abstract-only publications, editorials and comments will also be excluded from this review, as will animal studies.

2.1.2 Types of participants

Adults aged 18 years and older with a PI from acute care, rehabilitation, long-term care and community settings will be included in this systematic review. Participants younger than 18 years old, or those with ulcers/injuries other than PI will be excluded.

2.1.3 Outcome measures

The outcome in this review will be an assessment of the QoL of adults with PI. Quantitative studies usually measure QoL with generic and disease-specific instruments, and the QoL is reported as the score or scores on different subscales of the QoL instruments, such as subscale scores ranging from 0–100 in the SF-36. In qualitative studies, the outcome measures will be participants' descriptions of how the PI affects their QoL, including physical symptoms, social and psychological functioning, financial status and other aspects of life and wellbeing.

2.1.4 Report characteristics

This systematic review will consider studies published between January 2009, the year when the first edition of the International Guidelines was published, and July 2022. Only studies published in English will be included, but no geographical limitations will be imposed.

2.2 Information sources

The electronic databases searched in this review will include Ovid Medline, Ovid Embase, CINAHL EBSCO, Scopus and the Central Register of Con-

Figure 1: Search strategy

#	Medline OVID	
1	Pressure Ulcer/	13,267
2	(pressure ulcer* or pressure sore* or pressure injur* or bed sore* or bed ulcer* or heel ulcer* or heel sore* or deep tissue injur* or deep tissue ulcer* or deep tissue sore* or decubitis ulcer* or decubitus sore* or decubitis injur*).mp.	16,691
3	1 or 2	16,691
4	"Quality of Life"/	247,975
5	"Activities of Daily Living"/	70,935
6	(quality of life or QoL or HRQoL or life qualit* or wellbeing or well-being or activities of daily living or daily living activit* or wellness or healthiness or health level or health status or happiness or health index* or health indices or health profile*).mp.	647,188
7	4 or 5 or 6	647,188
8	3 and 7	1,204
9	limit 8 to yr="2009 -Current"	720

trolled Trials. Grey literature will be searched through Open Grey, Greylit.org, clinicaltrials.gov and Google Scholar for works' first ten pages. The reference lists of the included studies will be screened for potentially eligible studies. Studies' authors will be contacted in cases of missing data, or for additional data for clarification, if necessary. If no data are found, the study will be excluded.

2.3 Search strategy

The Patient/population, Intervention, Comparison and Outcomes (PICO) model was used to build the initial search terms. An expert research librarian was also consulted to support the development of the search strategy. An initial search of Ovid Medline (Figure 1) was conducted in July 2022, focused on keywords and subject headings contained in the relevant papers to develop the search strategy of this systematic review. All keywords and index terms of the search strategy were modified for the different databases by using phrase searching, wildcards, Boolean operators and quotations. The keywords in the search strategy were 'pressure injury', 'pressure wound', 'pressure ulcer', 'pressure sore', 'bed sore', 'decubitus ulcer' and 'quality of life'.

2.4 Study records

2.4.1 Data management

All studies will be imported into Endnote 20 to remove duplicate citations and then imported to Covidence for the management of the review process.

2.4.2 Selection process

Two review authors will independently screen all titles and abstracts based on the eligibility criteria. The full text of selected studies will be retrieved and imported in Covidence. The full-text studies will be independently screened by two review authors against the eligibility criteria, and the reason for any exclusion will be noted in Covidence. Any discrepancies of inclusion or exclusion will be resolved by discussion or consulting with a third author. The results of the selection process and reasons for exclusion will be presented in the PRISMA flow diagram (20) (Figure 2).

2.4.3 Data collection process

Data from included studies will be extracted independently by two review authors. A data extraction template developed by the author team will be used for data collection. The details of extraction templates are shown in Figures 3 and 4. Two review authors will extract data from the first three studies to ensure the consistency of data collection. Discrepancies that arise between the two review authors will be resolved by discussion or consulting with a third review author.

2.5 Data items

For quantitative studies, the following data will be extracted from the included studies:

- Author, publication year, country
- Age of participants
- Sex of participants
- Study design type
- Study size
- Study setting
- Aim of the study
- Main findings
- Stages of PI
- QoL score
- QoL assessment instrument: Generic or disease-specific instruments

For qualitative studies, the review authors will extract the following data:

- Author, publication year, country
- Age of participants
- Sex of participants
- Study design
- Study size
- Study setting
- Stages of PI (if reported)
- Aim of the study
- Participants' quotes related to the QoL
- Authors' descriptions or analyses of the participants' quotes

2.6 Risk of bias in individual studies

The methodological quality of eligible studies will be critically appraised by two independent review authors using the Critical Appraisal Skills Programme (CASP) checklists for evaluating different study designs, such as randomised controlled trials, cohort studies and qualitative studies (22). The CASP is the most commonly used appraisal tool used in healthcare-related qualitative evidence synthesis (23). Discrepancies between the two review authors will be resolved by discussion or consulting with a third review author, if necessary. The results of studies' methodological quality will be reported narratively. Studies that do not meet the quality threshold will not be excluded; however, quality will be considered when developing themes.

Figure 2: PRISMA flow diagram

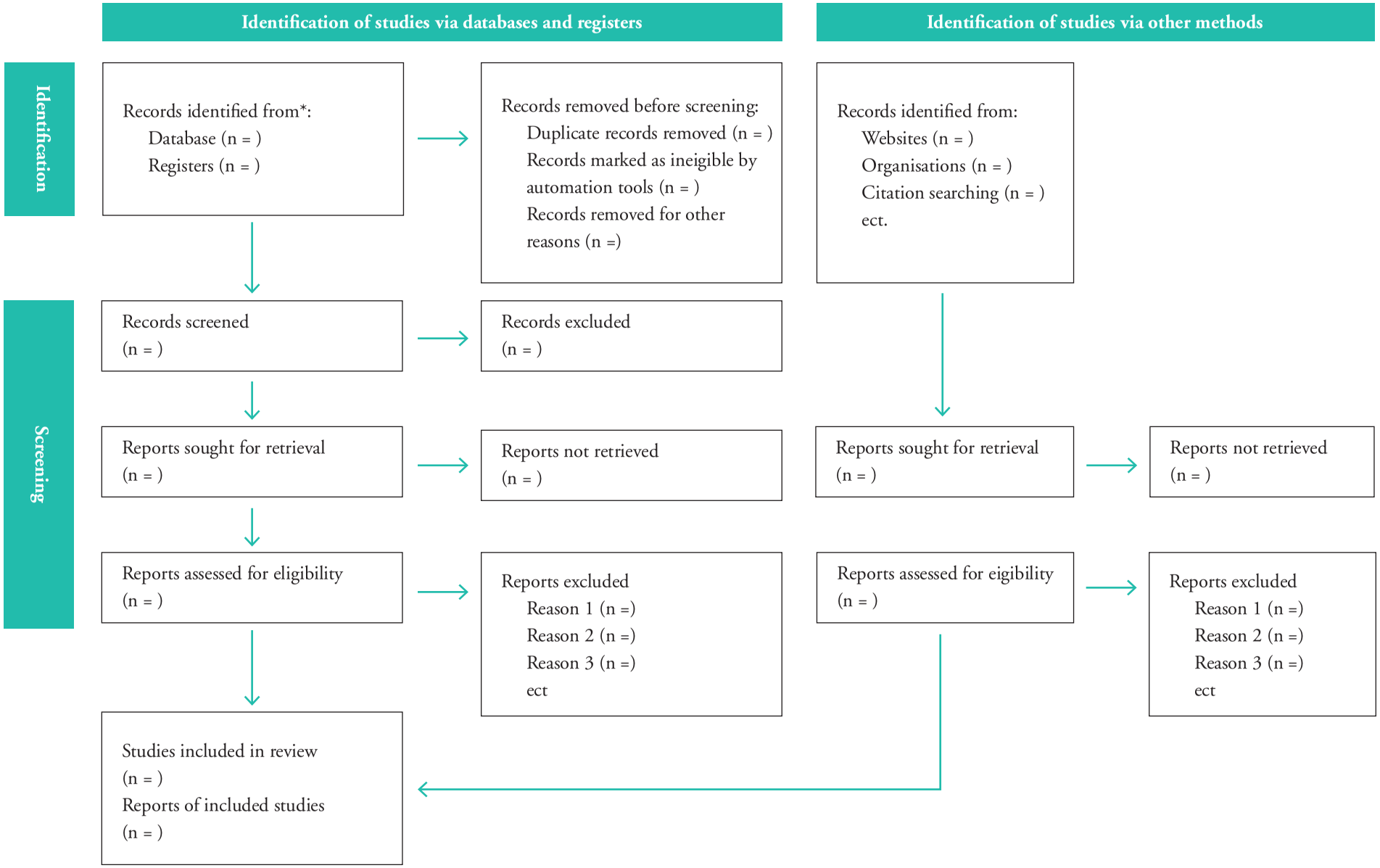

Figure 3: Data extraction instrument-Quantitative studies

Author, Year, Country	Age (years)	Sex (% male)	Study design	Study size	Study setting	Stages of PI	QoL instru-ments	QoL score	Main findings

Figure 4: Data extraction instrument - Qualitative studies

Author, Year, Location	
Age (years)	
Sex (% male)	
Study design	
Study size	
Study setting	
Stages of PI	
QoL	
Participant's quote	
Authors' description Or analysis	

2.7 Data synthesis

The qualitative and quantitative results will be reported separately. To evaluate the impact of PI on QoL, quantitative data will, where possible, be pooled for statistical meta-analysis. The heterogeneity will be examined using an inconsistency index (I2). If no significant heterogeneity is detected (I2< 75%), a meta-analysis will be performed using a random effects model.(24) Effect sizes of risk ratios (dichotomous data) or the mean difference (continuous data) will be calculated for analysis. Where statistical pooling is not possible, the findings of effectiveness will be reported narratively.

This systematic review will use a thematic synthesis as described by Thomas and Harden (25). This approach is recommended in the Cochrane Handbook for Systematic Reviews of Qualitative Evidence to investigate participants' perspectives and experiences (25, 26). NVivo software will be used for thematic synthesis.

The first stage in the process of thematic synthesis is coding (25). Two review authors will select a study for independent, line-by-line coding for themes. They will then discuss with each other to agree on themes. The first review author will continue the line-by-line

coding for the remaining studies. When a new theme is generated during the coding process, the second review author will be consulted. The second review author will review one third of the studies, to check the accuracy of the coding. Any discrepancies will be resolved by discussion or consultation with a third review author.

The second stage in the thematic synthesis is the identification of descriptive themes (25). Two review authors will work together to discuss the similarities and differences of coded themes and then group related themes to form the descriptive themes.

The third stage in the thematic synthesis is analytical themes. Comparing descriptive themes that are closely related to the original findings means analytical themes tend to 'go beyond' the findings to explore understanding or hypotheses (25). This review aims to develop analytical themes about the impact of different implications of PI on the QoL. If discrepancies arise between the two review authors, a third review author will be consulted.

2.8 Confidence in cumulative evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) methods will be used to assess the quality of quantitative evidence. Evidence will be graded as high, moderate, low or very low (27). The results of the GRADE assessments will be presented as tables. The GRADE-Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) (28) will be used to assess the confidence in the synthesis findings. The confidence will be judged as high, moderate, low or very low. These results will also be shown in tables.

DISCUSSION

Pressure injuries are an ongoing challenge for patients, caregivers and healthcare professionals. This protocol was developed following the PRISMA-P statement. Three independent review authors with experience in systematic review methodology will perform the screenings and data extraction to avoid bias in selecting studies. In this review, studies written in languages other than English will be excluded, due to the review team's language limitations. This is a limitation of the systematic review. Findings of this systematic review will be of interest to health planners in designing promotion programmes for improving the QoL of people with PIs. The findings will also enable healthcare professionals, patients and caregivers to gain a greater understanding of how PIs impact QoL. Finally, the findings of this review will play an important role in improving the prevention of PIs.

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Key messages

- Pressure injuries are associated with impaired quality of life.
- The study's aim is to investigate the impact of pressure injuries on the quality of life of adults aged 18 years and older.
- A systematic review, including both quantitative and qualitative studies, will be conducted.

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