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Development and validation of the Pressure Injury after Hospital Admission (PIAHA) screening tool for early assessment of hospital-acquired pressure injuries: a multiphase multicentre study protocol in acute care settings

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ABSTRACT

Introduction Early prediction of hospital-acquired pressure injuries (HAPIs) is crucial for delivering prompt therapeutic interventions and personalised preventive measures to hospitalised patients. However, existing pressure injury (PI) assessment tools often lack transparency, objectivity, comprehensiveness and reliability. This study protocol aims to identify risk factors, develop a screening tool (Pressure Injury after Hospital Admission – PIAHA), and conduct a two-step validation for the early prediction of PI after hospital admission.

Methods and analysis This multiphase, multicentre, sequential research design comprises five phases. The first phase involves an umbrella review to synthesise comprehensive information on PI risk factors in hospitalised patients from published review studies. The second phase will use conventional content analysis and qualitative interviews with national and international experts to identify context-specific predictors of HAPIs. The third phase will employ a three-round E-Delphi method to integrate findings and establish a structured list of potential predictors. In the fourth phase, a cross-sectional study will evaluate the predictive value of identified risk factors for HAPI development among hospitalised patients, contributing to the development of the PIAHA screening tool. The final phase consists of a two-step validation: (1) a cross-sectional comparison of the PIAHA tool against the gold standard and (2) a cluster randomised controlled trial to compare the effectiveness and cost-effectiveness of the novel 'IDEAL SKIIN CARES' prevention bundle, administered by trained wound specialist nurses, vs routine standard care.

Ethics and dissemination Ethical approval was granted by Baqiyatallah University of Medical Sciences (IR.BMSU.REC.1402.059) covering all study phases. Written informed consent will be obtained from participants or their legal representatives. The study follows the Declaration of Helsinki. Results will be disseminated via peer-reviewed publications, conferences, webinars, policy briefs and public engagement through social media, educational videos and podcasts.

Implications for clinical practice The PIAHA tool promises to enhance early detection of HAPI risk, facilitating individualised prevention and optimising clinical resource allocation. Implementation of the IDEAL SKIIN CARES bundle may improve patient outcomes and reduce healthcare costs by standardising evidence-based preventive care.

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Trial registration number NCT06369688.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The multiphase, multicentre sequential design integrates diverse research methods to comprehensively identify and validate risk factors for hospital-acquired pressure injuries.
⇒ Purposive sampling and expert engagement through a structured E-Delphi process enhance the rigour and relevance of predictor selection.
⇒ The cluster randomised controlled trial phase incorporates rigorous blinding and standardised protocols to minimise bias and contamination.
⇒ Potential challenges include patient attrition during longitudinal phases, which will be mitigated through proactive retention strategies and intention-to-treat analyses.
⇒ Variability across participating hospitals and wards may affect the external validity of findings, despite efforts to include diverse clinical settings.

BACKGROUND AND RATIONALE

Pressure injuries (PIs), commonly known as pressure ulcers, bedsores or decubitus ulcers,

are a significant healthcare challenge, especially among aged hospitalised patients[1 2] as the proportion of individuals aged 60 years and over is predicted to increase from 9.3% in 2020 to 16% in 2050, and expected to double to 2.1 billion by 2050.[3] Global data indicates that hospital-acquired PIs (HAPIs) occur at a rate of approximately 5.4 per 10 000 hospitalised patients daily.[4] Among adult hospital patients worldwide, PIs affect around 12.8%, with HAPIs specifically ranging from 7% to 9%.[4 5] HAPIs are globally regarded as 'never events',[6] for being largely preventable (up to 95%)[7] and reducible in their severity by using a multifaceted approach.[6 8] The costs of preventive measures are lower than the expenses incurred for treatment.[7]

PIs develop from prolonged pressure on the skin and/or underlying tissues, typically over bony areas, due to intense pressure, shear forces or medical device usage.[9 10] Of all health conditions, PI currently ranks among the highest in terms of cost.[6] They not only cause physical discomfort and pain but also carry substantial health risks, impacting quality of life through issues like hospital-acquired infections, prolonged recovery times and increased morbidity and mortality rates.[11 12] The economic burden associated with managing HAPIs is substantial, with costs related to treatment, extended hospital stays and long-term care placing strain on healthcare systems worldwide.[13 14]

In the hospital setting, PI development is a complex, multifactorial process shaped by a variety of intrinsic factors—including age, nutritional status,[15] unfavourable skin microclimate,[16] chronic illnesses, immobility, duration of intensive care unit stay, immune function, radiation therapy and mental health status—and extrinsic factors (pressure, friction, duration of pressure/friction, skin moisture, tension, temperature and humidity, trauma, oedema, infection, quality of nursing care, patient positioning and invasive interventions or medical devices usage and bed configuration).[17–20] Additional studies have identified other predictive factors like emotional stress and tissue hypoxia.[21–24] Systematic reviews highlighted eight domains of risk factors: mobility, perfusion, skin status, nutrition, age, haematology, skin moisture and overall health.[25 26] Recent research has even identified localised oedema as a predictor of PIs in specific anatomical areas like the sacrum and heels.[27] In a recent review study, 37 risk factors were classified into 14 groups, introducing four main risk factors: diabetes, length of stay in intensive care or surgery, use of vasopressors[28] and low haemoglobin levels.[17] Furthermore, inadequate prevention strategies, suboptimal wound care practices and limited healthcare provider awareness can increase the risk of PIs development in hospital settings. Various contextual factors also impact their clinical efficacy, including staffing constraints, time limitations, staff competence, nursing skills in critical thinking and decision-making, the influence of prior knowledge on clinical judgement and limited applicability across different clinical settings.[29 30] Therefore, it is essential to use a valid and reliable screening tool to predict PIs development in hospitalised patients because data demonstrate that PIs can develop within a period of 1–6 hours.[6] The prompt and accurate identification of at-risk individuals is therefore paramount so that preventive measures can be implemented.[20 31]

Identification of the predictive, personalised and patient-centred risk factors to reduce the pressing problem of developing PI has not yet been definitively established[32] despite the existence of more than 50 risk of developing PI scales in global literature[33 34] including Braden,[35 36] Norton,[37] Waterlow,[38] Ramstadius,[39] COMHON,[40] Cubbin & Jackson,[41] as well as newer tools such as the Shape Risk Scale,[42] InterRAI Pressure Ulcer risk,[43] Prevent Pressure Injury[44] and Bates-Jensen.[45] Existing research does not appear to exhibit that any given tool is superior to the others; the Braden and Norton risk assessment tools appear to be more accurate than nurses' clinical judgement in predicting PI risk.[43] Often, these tools provide a general assessment without considering specific patient characteristics and multiple risk factors influencing PI development.[46] Over three decades of using these risk assessment tools and despite the fact that these tools are comprehensive and assess various dimensions, these existing tools are fraught with recognised limitations because most of these dimensions are qualitative and cannot precisely determine the risk of each factor leading to PIs. Their reliance on necessitating nurses' subjective clinical judgement and applicability to limited patient populations potentially leading to imprecise risk evaluations across diverse groups.[46 47] It is while that some patients may have various risk factors and comorbidities; each risk factor and comorbidity has a specific weight to occur PI that is not measured by these tools. Therefore, it seems that existing risk assessment tools and conceptual frameworks do not fully explain the complex and variable interactions between risk factors. Given these limitations and the evolving understanding of risk factors, there is a clear need for a new screening tool that considers a specific score for each risk factor in the multifaceted factors involved in the development of PIs in hospital settings. To address this issue, this protocol study aims to identify risk factors, develop a screening tool (Pressure Injury After Hospital Admit – PIAHA), and conduct a two-step validation for early prediction of PIAHA.

METHODS AND ANALYSIS

Multiphase study design

To ensure a comprehensive identification of evidence-based risk factors that specifically predict the development of HAPIs, to develop a screening tool for HAPIs and as well as to conduct a validation of this screening tool, this study will use a multiphase multicentre sequential research design.[48] This design involves five distinct phases: an umbrella review (Phase 1), a conventional content analysis (Phase 2), a three-round Delphi method (Phase 3), a cross-sectional study (Phase 4) and

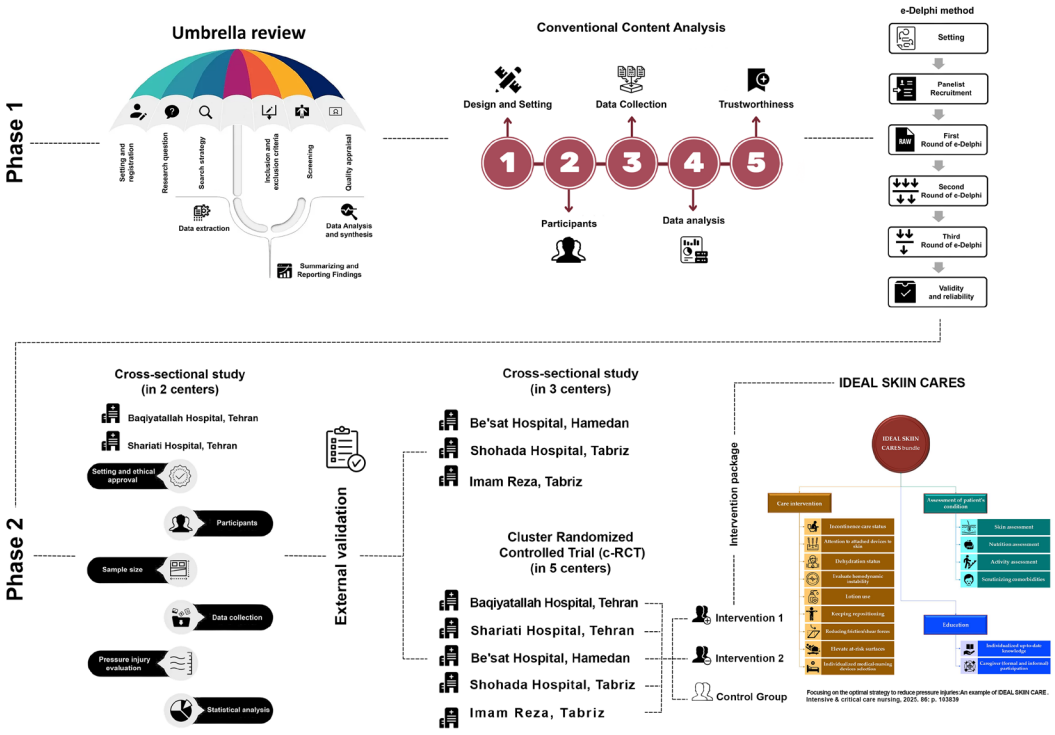


Figure 1 The multiphase multicentre sequential research design.

a two-step validation study (Phase 5) as a cross-sectional and a cluster randomised controlled trial (c-RCT). By integrating these five separate research designs, each representing a complete study, into one comprehensive investigation, this design facilitates a thorough examination of the topic[48] (figure 1). This study has received ethical approval from the Ethics Committee of Baqiyatallah University of Medical Sciences, Tehran, Iran (IR.BMSU.REC.1402.059), covering all phases of the research including the umbrella review, qualitative interviews, Delphi consensus process, cross-sectional studies and the c-RCT.

Patient and public involvement

Patients and the public were not directly involved in the design, conduct or recruitment phases of this study. However, to ensure the relevance and applicability of our findings, we plan to engage patient representatives and relevant community stakeholders during the dissemination phase. Study results will be communicated to participants and the wider public through accessible formats such as informational leaflets, webinars and social media platforms. This approach aims to enhance transparency and foster broader understanding and uptake of the research outcomes.

Umbrella review (Phase 1)

Setting and registration

Considering the significant increase in systematic review publications on HAPI predictive risk factors in recent decades, an overview summarising and synthesising the findings of these studies is necessary.[49 50] Therefore, for a comprehensive identification of evidence-based risk factors predicting the development of HAPIs, an umbrella review will be employed.[51] The process would entail defining a clear research question focused on identifying risk factors associated with HAPIs, establishing stringent inclusion and exclusion criteria to select relevant studies, conducting a thorough search across various databases to gather evidence from different review typologies, synthesising data on risk factors, evaluating the quality of included studies and reporting results.[52 53] This approach will provide a holistic overview of the current evidence landscape, facilitating a comprehensive understanding of the factors contributing to HAPIs and guiding the creation of effective preventive strategies. The umbrella review's protocol was registered in the international prospective register of systematic reviews (PROSPERO) (Identifier code: CRD42024532133) on 14 April 2024.

Research question

The main research question for this umbrella review will be 'What are the risk factors for HAPIs in adult patients, and how—to what extent—do various factors contribute to their development?' This central question will guide the review process and will be complemented by several specific questions, including: (1) which demographic and clinical characteristics of hospitalised patients influence the development of HAPIs? (2) Which socioeconomic and cultural characteristics of hospitalised patients influence the development of HAPIs? (3) How do the care

behaviours of hospital medical and nursing staff impact the development of HAPIs? (4) How do environmental-related risk factors contribute to the development of HAPIs? (5) What role do risk factors associated with medical equipment and devices play in the development of HAPIs? (6) How do treatment-related risk factors contribute to the development of HAPIs? and (7) What other related risk factors are involved in the development of HAPIs in adult patients? These focused questions will help to structure a review and facilitate a comprehensive exploration of various factors contributing to HAPIs in hospital settings.

Search strategy

To ensure a comprehensive and systematic identification of relevant literature, we will conduct an extensive search across multiple electronic databases from their inception through 1 June 2025. The databases selected for this umbrella review include Scopus, MEDLINE/PubMed, Web of Science, Embase, ProQuest, Cochrane Library, MagIran, Iran Medex and the Scientific Information Database (SID). This broad selection covers both international and regional sources, ensuring wide coverage of published studies related to PIs. Our search strategy will employ a carefully constructed combination of keywords and Medical Subject Headings (MeSH) terms tailored to each database's indexing system. To enhance transparency and reproducibility, we explicitly distinguish between keywords and controlled vocabulary terms (MeSH or Emtree), marking MeSH terms with '(MH)' throughout the search documentation. Boolean operators (AND, OR) will be systematically used to combine search terms related to PIs, risk and prediction factors, and review types, reflecting the scope of our umbrella review.

Search terms and conceptual framework

The search terms are organised into three main conceptual categories:

Pressure Injury Terms: This category includes keywords such as "pressure sor*," "pressure ulce*," "pressure injur*," "bed sor*," "decubit* ulce*," "decubit* sor*," "decubit* injur*," "skin sor*," "skin ulce*," "skin injur*," "skin defect," "bed injur*," "bed ulce*," "decubit* wound*," and "decubit* damage*." Corresponding MeSH terms include "Pressure Ulcer" (MH). The use of truncation (*) captures variations in word endings to maximise retrieval.

Risk and Prediction Terms: To capture studies focused on risk factors and predictive elements, we include terms such as "predic*," "at risk," "early," "risk," "risk factors," "predictors," "prognostic factors," "association," and "prediction." Relevant MeSH terms include "Risk Factors" (MH) and "Predictive Value of Tests" (MH).

Review Type Terms: Given the umbrella review design, it is crucial to identify systematic reviews, meta-analyses and narrative reviews. Keywords include "review," "systematic review," "narrative review," "meta-analysis," and various combinations thereof. Corresponding MeSH terms are "Systematic Review" (MH) and "Meta-Analysis as Topic" (MH).

Search strategy example for medline/pubmed

Below is an example of the search syntax for MEDLINE/PubMed, demonstrating the integration of keywords and MeSH terms with Boolean operators: text (("Pressure Ulcer"[MH] OR pressure sor* OR pressure ulce* OR pressure injur* OR bed sor* OR decubit* ulce* OR decubit* sor* OR decubit* injur* OR skin sor* OR skin ulce* OR skin injur* OR skin defect OR bed injur* OR bed ulce* OR decubit* wound* OR decubit* damage*) AND ("Risk Factors"[MH] OR "Predictive Value of Tests"[MH] OR predic* OR "at risk" OR early OR risk OR "risk factors" OR predictors OR "prognostic factors" OR association OR prediction) AND ("Systematic Review"[MH] OR "Meta-Analysis as Topic"[MH] OR review OR "systematic review" OR "narrative review" OR meta-analysis)). This structured approach ensures the retrieval of comprehensive and relevant literature on PI risk prediction within review articles. The search strategies used in the other databases are detailed in online supplemental file 1.

Database-specific adaptations

Recognising that each database uses different indexing systems and search interfaces, the search terms will be adapted accordingly: MEDLINE/PubMed: Uses MeSH terms combined with keywords in title and abstract fields. Embase: Employs Emtree terms analogous to MeSH, combined with keywords. Scopus, Web of Science, ProQuest: These databases do not use controlled vocabulary; therefore, searches will rely on keywords within titles, abstracts and subject fields. Cochrane Library: Supports MeSH terms and keywords with specific syntax. MagIran, Iran Medex, SID: Regional databases primarily support keyword searches in Persian and English. Grey Literature (EThoS, OpenGrey): Searches will focus on keywords to capture theses, dissertations and reports to minimise publication bias. Additionally, we will employ supplementary strategies such as handsearching relevant conference proceedings, contacting experts in the field and screening reference lists of included studies to further reduce the risk of missing pertinent unpublished or difficult-to-locate research. To maximise comprehensiveness and minimise language bias, we will not impose language restrictions during the initial search phase. Studies published in languages other than English and Persian will be identified and screened based on their titles and abstracts. For potentially relevant non-English/Persian studies, we will use online translation tools and, where necessary, seek assistance from colleagues with relevant language skills or professional translators to assess eligibility and extract pertinent data. This approach aligns with best practices in systematic reviews to ensure inclusion of all relevant evidence regardless of language, thereby reducing the risk of language bias.

Additional search procedures

To further enhance the robustness of our search strategy, the following steps will be undertaken: (1) The entire search strategy will undergo Peer Review of Electronic Search Strategies by an expert information specialist to ensure accuracy, comprehensiveness and adherence to best practices; (2) Grey literature databases such as EThoS and OpenGrey will be systematically searched to identify unpublished or difficult-to-locate studies, thereby reducing publication bias; (3) Forward citation searching will be performed using citation tracking tools to identify newer studies citing the eligible papers; and (4) Backward citation searching will involve screening the reference lists of included studies to locate additional relevant publications.

Inclusion and exclusion criteria

To ensure a comprehensive coverage of relevant review studies on risk factors for HAPIs, we will employ the PICO framework to establish clear inclusion and exclusion criteria. Our inclusion criteria will encompass various review study designs such as narrative reviews, scoping reviews, critical reviews, mapping reviews, rapid reviews, systematic reviews with/without meta-analysis and umbrella reviews. For the umbrella review, the following criteria are established; population: adult hospitalised patients aged 18 years or older with hospital stays exceeding 24 hours. Intervention/exposure: no specific intervention or exposure is required. Comparison: no specific comparison is needed. Outcome: The outcomes of interest will include any stage of HAPIs as defined by the International Pressure Injury Guideline.[54] We will selectively include studies conducted in English or Persian languages with full-text availability, without imposing restrictions on the publication year. However, we will exclude duplicate studies, review studies lacking sufficient data to address the research question, reviews concentrating solely on specific medical conditions or patient populations and subset data of hospitalised patients that cannot be extracted from the review due to combined analytic results (eg, merging hospital and nursing home data).

Screening

To streamline the search results and screening process, we will transfer the retrieved records to EndNote software (V.20.2.1) primarily for efficient data management and referencing. Duplicate removal will be conducted within Rayyan software, which supports this feature even in its free version. Following this, two independent researchers (AV-A and FB) will perform the initial screening of titles and abstracts using Rayyan to identify studies relevant to the research questions. In the subsequent phase, the same researchers will conduct a thorough evaluation of full-text articles to select studies that align with the inclusion criteria. Full-text articles meeting the criteria will be retrieved, while those that do not meet the criteria will be excluded, with reasons for exclusion detailed in the final report. Inter-rater reliability between the two researchers will be assessed to ensure consistency, with any discrepancies resolved through discussion or consultation with third researchers (SP and AP). To maintain quality standards, a blind review method will be employed to conceal journal names and author identities. The final search results will be presented in a flow diagram following the guidelines outlined in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) 2020 statement (figure 2).

Quality appraisal

The quality of systematic reviews will be measured using the AMSTAR-2 (Assessment of Multiple Systematic Reviews) tool,[55] which will evaluate the methodological quality of systematic reviews, including the transparency of the review process, the validity of study selection criteria and the appropriateness of data synthesis methods (online supplemental table S1). Furthermore, the credibility of evidence from various types of review studies will be evaluated using the GRADE (Grading of Recommendations Assessment, Development and Evaluations) framework.[56] This framework assesses evidence by taking into account factors such as risk of bias, imprecision, inconsistency, indirectness and other considerations. Initially, the studies included will be viewed as high-quality evidence and will be adjusted downwards according to the criteria mentioned. The evidence will be graded into different levels: high quality, moderate quality, low quality and very low quality, reflecting the degree of uncertainty surrounding the estimated impact.

Data extraction

Two researchers (AV-A and FB) will independently extract data and consult with third researchers when necessary for adjudication (SP and AP). The data extraction process will adhere to the methodology outlined by the Joanna Briggs Institute (online supplemental table S2).[57] The extracted data will include authors' names, publication year, analytical methods used in the reviews, number of primary studies included, population or clinical settings, summarised risk factors, sample size, participant demographics (such as gender and age) and key findings. In cases of missing information or inconsistencies in reported data, review authors will be contacted for clarification.

Data analysis and synthesis

Initially, the data will be analysed to identify all pertinent risk factors that could potentially predict the development of HAPIs in hospitalised patients. Subsequently, the findings will be sorted inductively into categories based on the demographic, clinical, socioeconomic and cultural features of patients, the care practices of medical and nursing staff, the equipment used for patients, the types of treatments administered, environmental related risk factors and other risk factors.

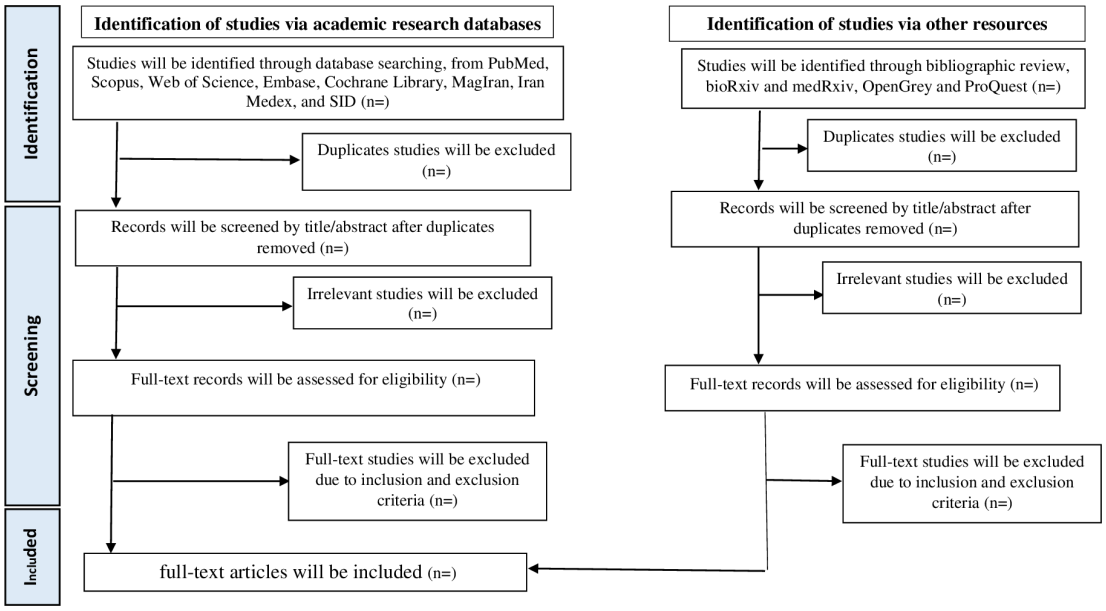


Figure 2 Flowchart of umbrella review process which includes searches of academic research databases and other resources according to PRISMA 2020. The flow diagram presented follows the PRISMA 2020 guidelines and was created using the official PRISMA 2020 flow diagram template available from the PRISMA website (www.prisma-statement.org). This template is distributed under the Creative Commons Attribution (CC BY 4.0) licence, which permits use and adaptation with proper citation. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; SID, Scientific Information Database.

Summarising and reporting findings

We will plan to systematically summarise, review and present the collected data. Visual representations such as tables or charts will be created to highlight the key discoveries from the review. Finally, we will compile a formal report detailing the outcomes for each aspect after consulting with relevant stakeholders.

Conventional content analysis (Phase 2)

Design and Setting

A qualitative approach using conventional content analysis, as described by Lindgren *et al*,[58] will be employed to identify risk factors associated with HAPIs in hospitalised patients. This method aims to provide a thorough understanding of participants' experiences and to aid in developing culturally sensitive interventions. Data will be organised to offer a succinct yet comprehensive depiction of the observed occurrences.[59 60]

Participants

Participants will be selected using a purposeful sampling technique to ensure diverse representation. The selection criteria for expertise will include national and international PI experts with recognised academic or clinical credentials, wound care nursing specialists with certification or extensive clinical experience, general surgeons actively involved in managing PIs, nursing service managers and supervisors with leadership roles in wound care programmes and nurses possessing practical, hands-on experience in PI prevention (PIP) and treatment. Additional key stakeholders involved in PI care and research may also be included. To achieve maximum variation sampling, factors such as gender, years of professional experience, clinical specialties and age groups will be considered during selection to ensure data saturation and capture a broad spectrum of perspectives.

Data collection

In-depth data will be gathered through face-to-face semi-structured interviews that will be conducted in a suitable and quiet environment. The interviews will be recorded and guided by an interview script. Participants will be questioned about their experiences regarding risk factors for HAPI development in hospitalised patients, the influence of demographic, clinical, socioeconomic and cultural characteristics on HAPI development, the impact of care practices by medical and nursing staff, the role of medical equipment in HAPI development, the contribution of treatment factors to HAPI development, the role of environmental related factors in HAPI development and other relevant risk factors. Exploratory questions will be used to delve deeper into participants' responses. Data collection and analysis will be conducted concurrently with the interviews and will continue until data saturation is achieved. Recognising that achieving saturation with a limited number of experts can be challenging, we will employ purposive sampling to ensure a diverse range of perspectives and expertise. Additionally, we will monitor saturation rigorously by documenting emerging themes and will consider extending the sample size or conducting follow-up interviews if new information continues to arise.

Data analysis

The collected data from face-to-face semi-structured interviews will be thoroughly analysed using the methodology

outlined by Lindgren *et al* in 2020.[58] The process will begin with the verbatim transcription of the interview recordings. Subsequently, the data will undergo multiple readings to gain a deep understanding of the content. Meaning units within the data will be identified, followed by coding to assign labels to these units. These codes will then be categorised based on similarities and differences, leading to the formulation of overarching themes that capture the essence of the data. This systematic approach ensures a comprehensive and structured analysis of the information gathered during the interviews, allowing for nuanced insights into the experiences and perspectives shared by the participants regarding risk factors for HAPIs in hospitalised patients.

Trustworthiness

In terms of trustworthiness in the research process, maximum variation sampling will be used to enhance the credibility of the collected data. This sampling technique involves intentionally selecting participants with diverse backgrounds, characteristics or experiences to ensure a comprehensive understanding of the phenomenon under study. Furthermore, to strengthen the validity of the findings, the researchers will conduct independent analyses of the data. Peer-checking, where colleagues review and provide feedback on the analysis process, and member-checking, which involves sharing a summary of the interviews with participants to validate the accuracy and authenticity of the interpretations, will also be carried out as a part of the validation process.[58 61] By involving participants in the validation process, researchers can confirm that their perspectives and experiences have been accurately captured and represented in the analysis, thereby enhancing the overall trustworthiness and credibility of the research findings.

E-Delphi method (Phase 3)

Setting

We will use the standard E-Delphi method across three consecutive rounds to develop a screening tool for predicting the development of HAPIs in patients at admission to hospital.[62] The Delphi method will be conducted over three rounds to balance thoroughness with efficiency. To mitigate the time-intensive nature of multiple rounds, we will employ several strategies: clear scheduling with predefined deadlines, concise and focused questionnaires and regular communication with panellists to encourage timely responses. Additionally, we will use an online platform to facilitate easy access and completion of surveys, reducing logistical barriers. These measures aim to streamline the process while maintaining the rigour and validity of the consensus-building exercise. The E-Delphi method was selected for its capacity to refine concepts and viewpoints from a broad group of experts to achieve a consensus, defined as having a minimum of ≥75% agreement on a core set of attributes.[63] The level of agreement among panellists in each session will be assessed using Kendall's coefficient of concordance.

Panellist recruitment

Panellists will be recruited from diverse professional backgrounds, including specialists in emergency care, wound experts, highly experienced university faculty members, wound care nursing specialists, general surgeons, nursing service managers, supervisors, nurses with practical experience or knowledge in the field of PIs and other key stakeholders. Panellists will be purposefully selected based on predefined inclusion criteria, and invitations will be sent well in advance of the study's commencement. To promote consistent participation across multiple Delphi rounds, we will maintain regular communication, provide clear timelines and reminders and offer flexibility in response deadlines to accommodate panellists' schedules. The inclusion criteria for specialists include: (1) a professional background of more than 5 years in the relevant field, (2) the capacity to provide comprehensive and informed suggestions based on their expertise and (3) demonstrated motivation and willingness to participate in the study, which will be assessed through an initial screening process involving direct communication. Specifically, potential participants will be contacted via email or phone, during which their interest, availability and commitment to engage actively in the study will be confirmed before enrolment. Exclusion criteria for specialists include: (1) unwillingness to continue participation, (2) poor participation in meetings and (3) missing scheduled appointments in one or more meetings.

First round of E-Delphi

In the initial round of the E-Delphi process, the experts will be presented with the risk factors identified for the development of HAPI from the umbrella review and qualitative phases. They will be asked to prioritise these factors based on their importance and necessity. Each factor will be evaluated on two criteria: 'necessity' and 'importance', with a scoring range from 1 (lowest) to 10 (highest). Factors scoring ≤5 will be eliminated. In cases of score discrepancies, discussions within the research team will continue until a consensus with a minimum agreement of ≥75% is achieved. Additionally, an open-ended question will be included to gather insights from the experts on factors that could contribute to HAPI development but may not have been listed. Following this stage, the research team will review the experts' responses and modify the initial checklist of variables for the subsequent round.

Second round of E-Delphi

In the second round, experts will be asked to re-evaluate the modified list of potential predictors based on importance and necessity ratings. Once this round is completed, the revised list will undergo another review by the research team to finalise the factors for the next stage.

Third round of E-Delphi

Experts will be provided with the third version of the factors list and will be prompted to review and discuss

these items based on their expertise and the assigned importance and necessity scores. Discussions within the research team will continue until a consensus of ≥75% is reached, leading to the preparation of the final version of potential predictors.

Validity and reliability

For content validity, we will engage 10 experts to assess the assessment tool items based on relevancy, clarity, simplicity and necessity. The Content Validity Ratio (CVR) will be computed based on responses related to question necessity (nE), using the formula CVR = (nE − N/2) / (N/2). We will refer to Lawshe's table to establish the CVR cut-off point.[64] As per Lawshe's guidelines, each item should possess a minimum CVR of 0.62 from 10 professionals. Additionally, we will employ the Content Validity Index (CVI) following Waltz and Basel's index.[65] The CVI for each item will be determined by dividing the number of professionals who rated items as compatible or fully compatible across relevancy, clarity and simplicity by the total number of professionals. The average of these three criteria will form the total CVI for each item, with a minimum required CVI of 0.79 for each item.[66] In evaluating the reliability of the assessment tool items, we will use test–retest and intraclass correlation coefficient (ICC) for quantitative variables, and Cohen's Kappa coefficient for qualitative variables. An ICC or Kappa value exceeding 0.6 will be deemed acceptable.[67]

Cross-sectional study (Phase 4)

Setting and ethical approval

During this phase, a cross-sectional study will be conducted to evaluate the potential risk factors identified in the preceding three phases associated with the development of HAPIs among hospitalised patients. The primary objective will be to create a screening tool called PIAHA, designed to enable early prediction of HAPI development. Prior to participation in the study, all participants or their legal guardians will provide written informed consent. The research will strictly adhere to the principles set forth in the Declaration of Helsinki,[68] and the findings will be reported in accordance with the STROBE (Strengthening Reporting of Observational Studies in Epidemiology)[69] guidelines.

Participants

The eligible participants for this cross-sectional study will be chosen from two university hospitals: Baqiyatallah Hospital of Baqiyatallah University of Medical Sciences and Shariati Hospital of Tehran University of Medical Sciences. Patients will be eligible if they meet all the inclusion criteria as follows: (1) adults aged 18 years or older, (2) hospitalised for a minimum of 24 hours and (3) absence of PIs or vascular ulcer on hospital admission (PIs defined by the National Pressure Ulcer Advisory Panel).[70] However, the exclusion criteria will include: (1) patients with pre-existing serious skin diseases or injuries that hinder accurate assessment of skin integrity; (2) individuals with significant immobility at hospital admission, defined as those unable to reposition themselves without assistance for more than 12 hours; (3) patients with severe or uncontrolled urinary or faecal incontinence at the time of hospital admission; (4) individuals with documented mental illness or severe cognitive impairment at admission, as determined by review of medical and nursing records or validated cognitive screening tools routinely used in the hospital (eg, Mini-Mental State Examination); (5) critically ill patients requiring admission to the intensive care unit; and (6) those unwilling to participate in the research.

Sample size

The sample size for this cross-sectional phase will be determined by considering the development of HAPIs in hospitalised community patients and the number of potential risk factors for HAPI identified in the previous three phases of the study. To calculate the sample size, we will use the Cochran sample size determination equation: $N = (Z_{1-\alpha 2} \times p \times (1-p) / d2)$, with α=5%, z=1.96, p (expected proportion of PIs in population) = 0.5, and d (margin of error) = 0.05. This calculation yields a minimum of 384 individuals, serving as the sample size floor according to the Cochran formula.[71 72] Additionally, considering the inclusion of multiple risk factors and their varying significance in relation to HAPI, we will follow the methodology outlined by Perduzzi *et al*,[73] which recommends having at least 7–10 individuals per variable (risk factor) to accurately estimate the sample size. Therefore, the sample size will be 384, and 7 to 10 patients will be added for each variable according to the development of Pls.

Data collection

To gather information, a comprehensive four-part questionnaire will be used. The first segment will focus on sociodemographic characteristics, encompassing details such as age, sex, weight, height, body mass index (BMI), marital status, socioeconomic status (education, housing, income and health insurance),[74] incontinence, smoking habits, substance addiction and disability status. The second section of the questionnaire will delve into the patients' clinical history, covering comorbidities (anaemia, cardiovascular disease, diabetes, renal disease, dialysis, respiratory disease, spinal trauma, limb paralysis, stroke and malignancy), admission history, surgical history, PI history and medication history. Moving on, the third part of the questionnaire will centre on the clinical characteristics post-hospital admission. This will include the cause of hospitalisation, level of consciousness at admission, use of medical devices/ventilation and vital signs (body temperature, heart rate, blood pressure, respiratory rate, oxygen saturation and pain level). Additionally, laboratory test results for creatinine, albumin and haemoglobin will be included. Lastly, the fourth part will assess the identified risk factors for HAPIs based on the preceding three phases.

Pressure injury evaluation

All patients will be closely monitored for the development of HAPI within 24 hours of hospital admission. Two independent and experienced wound specialist nurses will conduct separate examinations of patients to assess the presence or absence of PIs, following the guidelines provided by the European Pressure Ulcer Advisory Panel (EPUAP), National Pressure Injury Advisory Panel (NPIAP), Pan Pacific Pressure Injury Alliance (PPIA) and National Pressure Ulcer Advisory Panel (NPUAP).[70] These assessments will be performed three times a day during the morning, evening and night shifts to ensure comprehensive monitoring for at-risk patients and a daily assessment in patients without PI risk factors. To ensure consistency and accuracy in PI evaluation, the inter-rater reliability between the two assessors will be evaluated using the Kappa agreement test. A substantial agreement will be defined as a Kappa value falling within the range of 0.61 to 0.80.[75] This rigorous evaluation process aims to maintain the high standards of assessment reliability and to minimise the likelihood of errors in identifying and documenting HAPI development in the study participants. Wound specialist's nurses in this phase are different from selected wound specialist's nurses in the c-RCT phase. Here, we will invite working high-experience wound specialist's nurses in hospital.

Statistical analysis

Categorical variables will be presented as counts (percentage), while continuous variables will be expressed as mean±SD. Demographic and clinical characteristics will be evaluated using Student's t-test for variables with a normal distribution, or the Mann-Whitney U test for variables with a skewed distribution. For continuous variables, the χ^2 test will be employed, and for categorical variables, either the χ^2 or Fisher's exact test will be used as appropriate.

The study will employ χ^2 automatic interaction detector decision tree analysis to identify risk factors associated with HAPI. The development of PI will be the dependent variable, while various risk factors will be considered as independent variables. Univariate and multivariate binary logistic regression analyses will be conducted to assess the impact of these variables on the likelihood of developing PI. Each variable will undergo univariate analysis separately, and those with a significance level of $p<0.05$ will be included in a multivariate backward stepwise Wald model. The results of the regression analysis will be presented as ORs with corresponding 95% CIs.

To evaluate the predictive accuracy of the identified risk factors in predicting PI, receiver operating characteristic (ROC) curves and the corresponding area under the curve (AUC) will be calculated using the final multivariate model. AUC values will be interpreted based on established criteria: AUC between 0.9–1.0 indicates excellent discriminative power, 0.8–0.9 indicates good power, 0.7–0.8 indicates fair power and 0.6–0.7 indicates poor power. Sensitivity, specificity, positive likelihood ratio, negative likelihood ratio and Youden index will also be assessed to determine optimal cut-off points.

Additionally, an internal cross-validation will be performed using 1000 bootstrap samples to further evaluate the predictive accuracy of the screening tool. Model calibration will be assessed by plotting observed PI risk against predicted risk across 20% risk strata. The study will examine the combined effects of the final variables on PI development by calculating interactions on both multiplicative and additive scales. Multiplicative interactions will be directly determined from the binary logistic regression model,[76] while the effects of additive interactions will be assessed using the relative excess risk due to interaction (RERI), the attributable proportion (AP) due to interaction and the synthetic index (S). Specific values of RERI, AP or S not equal to 0 or 1, respectively.[77 78]

The statistical analysis will be conducted using Stata V.17 (Stata Corp, Texas, USA, RRID: SCR_012763), SPSS software V.21 from SPSS (Illinois, Chicago, USA), GraphPad Prism V.9 from GraphPad Software (La Jolla, California, USA) and MedCalc software. A significance level of <0.05 will be used for all analyses.

External validation (Phase 5)

External validation of the PIAHA screening tool will be conducted through two steps. Step one will be a cross-sectional and step two will be a c-RCT.

External validation: Cross-sectional

To validate the PIAHA screening tool, external validation will be applied by running the PIAHA in different populations and settings. This process aims to determine if the screening tool can effectively identify individuals with a specific risk score for developing PI. In order to externally validate the PIAHA, the tool will be assessed in adult hospitalised patients without pre-existing PIs, vascular ulcers, serious skin issues and who have been hospitalised for a minimum of 24 hours. Data will be collected using a comprehensive four-part questionnaire covering sociodemographic characteristics, clinical history, post-hospital admission clinical features and the PIAHA to gather predictive risk factors for HAPI like fourth phase. Data collection will be conducted in three university hospitals: Be'sat Hospital of Hamadan University of Medical Sciences, and Shohada and Imam Reza Hospitals of Tabriz University of Medical Sciences. To evaluate the predictive accuracy of PIAHA in predicting HAPI, ROC curves and the corresponding area under the AUC will be calculated using the final multivariate model. This validation phase will provide crucial insights into the tool's accuracy, sensitivity, specificity and overall predictive ability in new population and setting, ensuring that it remains effective and applicable beyond its initial development population.

External validation: Cluster Randomised Controlled trial

Trail design and ethical approval

The study will be a multicentre, triple-blinded, c-RCT conducted with a three-arm parallel design and a 1:1:1 allocation ratio. The experimental groups will consist of two arms: the intervention group (group A), where patients will receive training in relevant PI care bundles, and the placebo group (group B), where patients will receive training in an irrelevant topic like respiratory care. Both intervention and placebo groups will receive specialised PIP care bundle from trained wound specialist nurses (WSNs). The third arm will be the control group (group C) comprising patients who do not undergo any training course and will receive only routine standard care for PIP care bundle. The aim of the c-RCT phase will be to compare the incidence of HAPI in the three study groups and to provide detailed evidence on the effect of the developed PI care bundle, administered by WSNs on the development of HAPI in trained hospitalised patients, as opposed to those receiving routine standard care without training. The methodology for c-RCT has undergone scrutiny and approval by the Ethics Committee of Baqiyatallah University of Medical Sciences in Tehran, Iran. The c-RCT was registered in the USA Registry of Clinical Trials; https://clinicaltrials.gov/ (Identifier code: NCT06369688) on 17 April 2024, and written informed consent will be obtained from each patient. The study will adhere to the guidelines of the CONSORT (Consolidated Standards of Reporting Trials) statement (figure 3) and the ethical principles outlined in the Helsinki Declaration.[79 80] Conducting a c-RCT in a hospital setting presents operational challenges such as participant dropout and non-adherence to protocols. To address these, we will implement comprehensive retention strategies including thorough informed consent, regular communication and flexible scheduling. Adherence will be monitored through routine audits and feedback, supported by extensive training and detailed operational manuals for healthcare staff. Intention-to-treat analyses will be applied to maintain validity despite protocol deviations. Reasons for dropout and non-adherence will be documented to inform interpretation. These measures collectively ensure the feasibility and rigour of the c-RCT within the complex hospital environment.

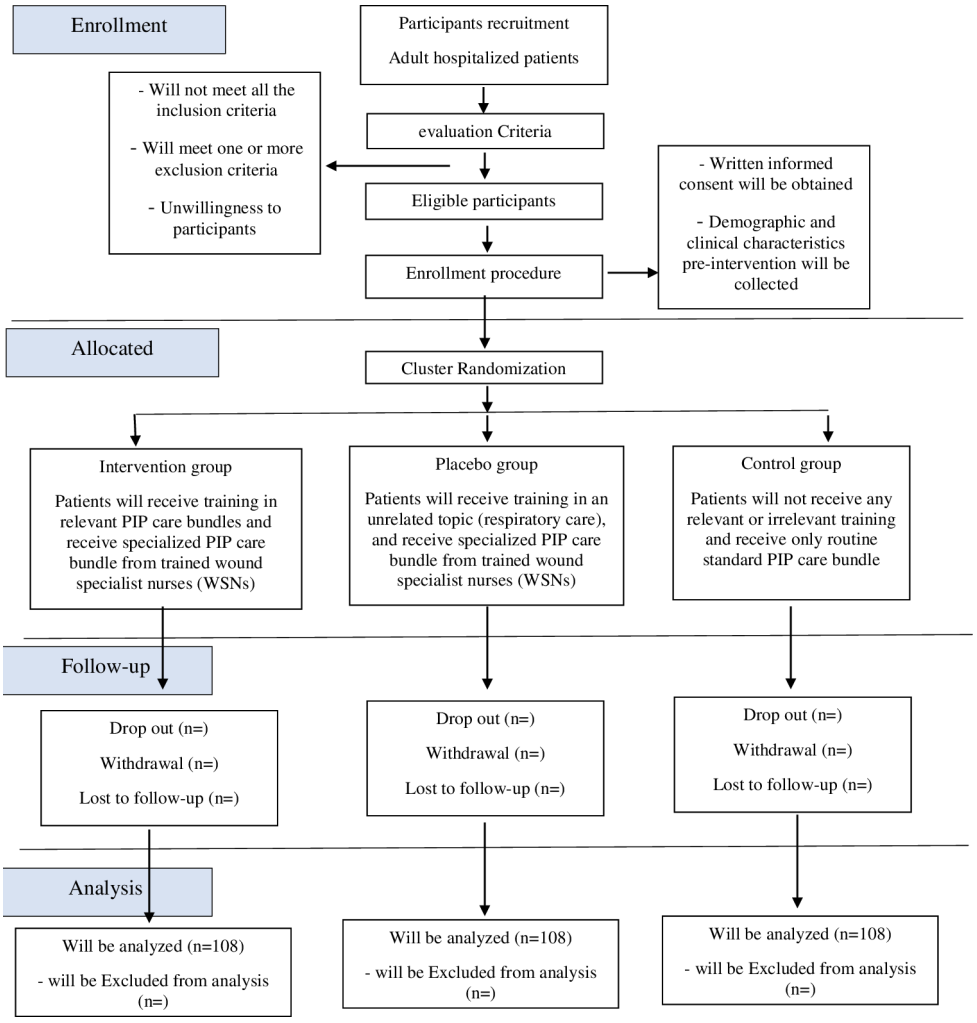


Figure 3 The CONSORT flowchart of Trial participants. CONSORT, Consolidated Standards of Reporting Trials; PIP, pressure injury prevention.

Trial participants

To be eligible to participate in the trial, patients must meet the following criteria: (1) be adults aged 18 years or older; (2) have been hospitalised for a minimum of 48 hours; and (3) be willing to participate. Exclusion criteria will include: (1) patients with significant pre-existing skin conditions or injuries that make it difficult to observe skin integrity; (2) having existing PIs or vascular ulcers on admission to the hospital (PIs defined by the National Pressure Ulcer Advisory Panel)[70]; (3) being at risk of PIs due to limited mobility (requiring physical or mechanical assistance to reposition or move); (4) patients with severe or uncontrolled urinary or faecal incontinence, mental illness or severe cognitive impairment on hospital admission; (5) patients who are hospitalised in day-surgery, critical care, emergency, maternity, paediatrics, mental health and dialysis units; (6) admitted to the hospital for>28 days; and (7) those with prior experience of PIs or training in PIs care and prevention. The eligible patients for this c-RCT will be enrolled from five university hospitals: Baqiyatallah Hospital of Baqiyatallah University of Medical Sciences, Shariati Hospital of Tehran University of Medical Sciences, Be'sat Hospital of Hamadan University of Medical Sciences and Shohada and Imam Reza Hospitals of Tabriz University of Medical Sciences. At each hospital, a senior researcher and six groups of research assistants will be assigned distinct roles: (1) patient recruitment; (2) WSN training; (3) patient training; (4) intervention delivery; (5) daily data collection to assess HAPI incidence and compare the effect of training and PIP care bundle among the three study groups; and (6) data collection for cost evaluation.

Recognising that differences between hospitals and wards may affect the generalisability of our findings, this study is conducted across multiple centres representing diverse healthcare settings. Participating hospitals and wards vary in size, location and patient demographics, allowing for a comprehensive assessment across different contexts. Subgroup analyses will be performed to examine the influence of contextual variables on outcomes. Detailed descriptions of each site will be provided to facilitate interpretation and applicability of results. These strategies collectively enhance the external validity of the study while transparently acknowledging potential limitations.

Sample size

To calculate the sample size for a c-RCT with a three-arm parallel design and a 1:1:1 allocation ratio, we will use the formula for sample size calculation in clinical trials.[81]

In this formula, we consider the following parameters: ($Z_{1-\alpha}$) = confidence level, ($Z_{1-\beta}$) = Power of study, (δ) = SD deviation of the outcome measure (incidence of PIs), (S) = minimum clinically significant difference to be detected. Given that the incidence of PIs in hospitalised Iranian patients ranges from 3% to 22%,[82 83] we will use a conservative estimate and assume a SD of around 10% (0.10). Assuming a minimum clinically significant difference of 5% (0.05), a 95% confidence level, 90% power and accounting for a 20% dropout rate, we calculate the values as follows: ($Z_{1-\alpha}$) = 1.645 (for 90% power), ($Z_{1-\beta}$) = 1.282 (for 90% power), (δ) = 0.10, (S) = 0.05 and dropout rate=0.20. Based on the formula and these parameters, a sample size of 324 adult hospitalised patients per hospital, with 108 in each arm, will be sufficient to detect the incidence of HAPI using a two-tailed Z-test of proportions between three groups with a 90% power and a 5% level of significance, considering a 20% dropout rate. Therefore, the total sample size required across five hospitals will be 1620 patients. To address potential patient attrition, we will implement proactive retention strategies including regular follow-up contacts, flexible scheduling and participant engagement efforts. Intention-to-treat analysis will be applied to include all enrolled patients in the analysis, regardless of dropout. Attrition rates will be monitored continuously, and sensitivity analyses will be conducted to evaluate the impact of missing data. Additionally, reasons for dropout will be documented, when possible, to inform mitigation strategies. These measures will help preserve the validity and reliability of the study findings.

Sampling method, randomisation and blinding

In the process of blocked randomisation for a three-arm parallel design c-RCT, participants will be enrolled using convenience sampling. An allocation sequence with random 1:1:1 block allocation and variable block sizes (eg, 6 or 12) will be generated, stratified by hospitals (based on HAPI rates), BMI (<30/≥30), gender (male/female) and age (<60/≥60). To prevent between groups contamination and attrition due to substantial patient movement between wards, hospitals will be the unit of randomisation. Central randomisation will be carried out by an independent statistician to assign participants to intervention, placebo or control groups, with allocation based on clusters kept concealed until intervention assignment. A statistician, blinded to groups (A, B and C) and not involved in recruitment, will create the allocation sequence using computer-generated random numbers. This process will be repeated for each new participant enrolled, ensuring a validity and a reliability of the study results. In this placebo-controlled trial, patients will be blinded to their group allocations. Additionally, WSNs, who are trained for delivering special PIP care bundles, as well as nursing staff who are responsible for measuring wounds and collecting data, and data analysts, will also be blinded. This blinding approach is implemented to maintain impartiality and reduce bias across all stages of the study.

Introducing IDEAL SKIIN CARES Bundles

We developed a specialised PIP care bundle, named IDEAL SKIIN CARES, through extensive review of literature and expert insights,[84–88] which will be used for training WSNs and patients in the intervention group (Group A). This comprehensive bundle comprises 15 key components aimed at effectively preventing PIs: (1) **I**ncontinence care

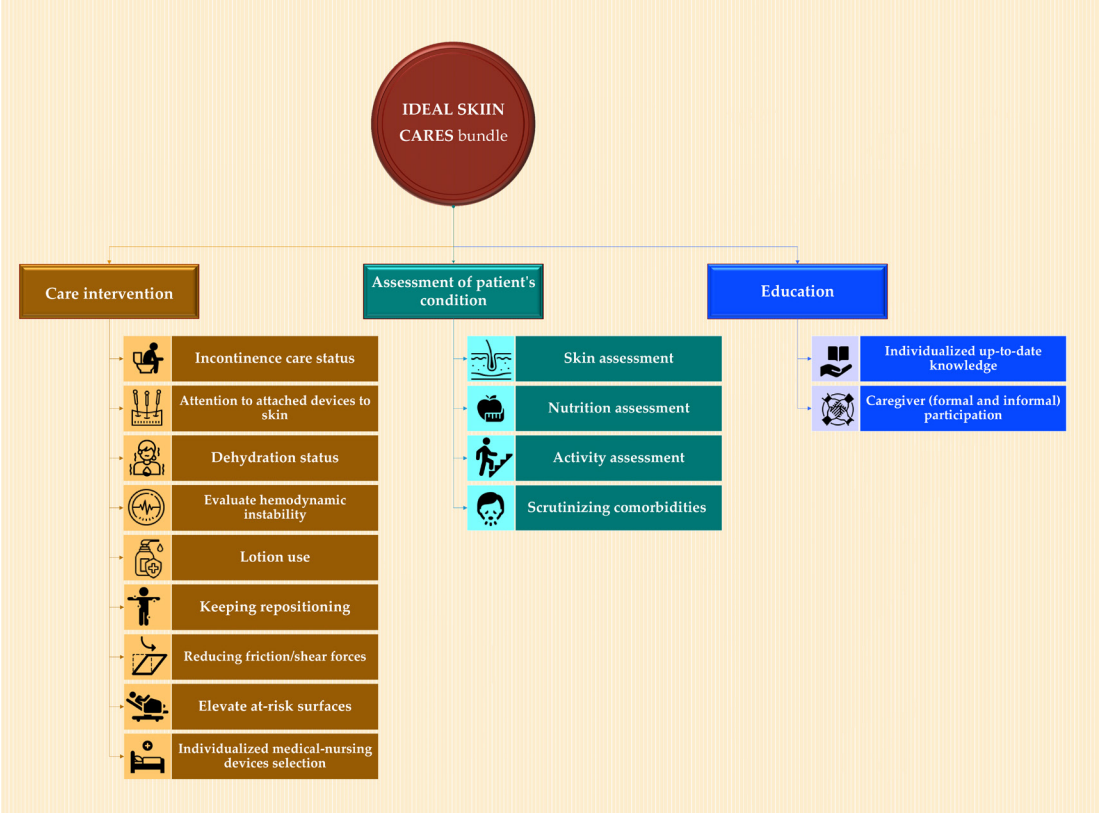


Figure 4 IDEAL SKIIN CARES bundle.

status; (2) **D**ehydration status; (3) **E**levate at-risk surfaces; (4) **A**ttention to attached devices to skin; (5) **L**otion use; (6) **S**kin assessment; (7) **K**eeping repositioning; (8) **I**ndividualised up-to-date knowledge; (9) **I**ndividualised medical-nursing devices selection; (10) **N**utrition status; (11) **C**aregiver (formal and informal) participation; (12) **A**ctivity assessment; (13) **R**educing friction/shear forces; (14) **E**valuate haemodynamic instability; (15) and **S**crutinising comorbidities. These components are categorised into three groups to facilitate understanding and enhancing patient engagement in PIP care bundles: (1) Education; (2) assessment of patient's condition; and (3) Care intervention (figure 4).[89]

WSNs training

The comprehensive training programme for WSNs will be meticulously developed based on the IDEAL SKIIN CARES bundle and predictive risk factors for HAPI (online supplemental file 3, page 1–2). Prior to the recruitment phase of the study, eligible nurses who express willingness to participate in specialised training on PIs will undergo a rigorous 3-month training process supervised by the principal investigator. The training curriculum will encompass formal teaching supplemented with educational materials, a blend of lectures, case studies, hands-on training, interactive sessions and both formal and informal discussions post-training to actively engage with the nursing staff. This approach aims to ensure WSNs grasp the significance of the IDEAL SKIIN CARES bundle in supporting wound management, in addition to their routine standard PIP care bundle and nursing procedures. To qualify for the training, nurses must meet specific criteria: (1) hold a bachelor's degree or higher, (2) have a minimum of 10 years of patient care experience and (3) clinical qualifications and competence validated by expert panels. Following the training course, 10 nurses who demonstrate proficiency in both theoretical knowledge and clinical skills with high grades will be selected and appointed as WSNs to participate in the study. These designated WSNs will be assigned to work in rotating shifts (morning, evening and night) with patients in both intervention and placebo groups. They will oversee all aspects of care related to the IDEAL SKIIN CARES bundle and predictive risk factors for HAPI, under the direct supervision of an experienced steering team.

Research assistant training and ensuring treatment consistency

To maintain uniformity in protocol implementation and data collection across all clusters (hospitals), all research assistants will receive customised training based on their research roles. Research coordinators and WSNs will be equipped with standardised data collection forms and strategies to address any fidelity issues related to the interventions. This tailored approach aims to enhance the accuracy and reliability of the research outcomes.

Intervention

Intervention group: The intervention group will be provided with a comprehensive educational package, including an educational pamphlet, brochure and visual

poster that outlines the three key components of the IDEAL SKIIN CARES bundle: 'Education', 'Assessment of patient's condition' and 'Care intervention', along with specific details on subitems. These materials will be explained in detail by a trained research assistant to ensure that patients fully understand them. In addition to the educational materials, patients will be encouraged by the research assistant, acting as an interventionist, to actively participate in PIP self-care activities following the IDEAL SKIIN CARES approach. The research assistant will deliver the IDEAL SKIIN CARES bundle to patient's shortly after recruitment and will continue to provide patient education throughout the study period. This training will begin before data collection and will be maintained as needed, especially considering staff turnover. Each hospital's study investigator will oversee the training activities at their site to guarantee consistency and adherence to the intervention protocol (online supplemental file 3, page 3–4). In addition, patients in the intervention group will receive the IDEAL SKIIN CARES bundle from WSNs.

Placebo group: The placebo group will receive training in an unrelated topic, specifically respiratory care (online supplemental file 3 page 3, page 5). This training will involve the distribution of educational pamphlets, brochures and visual posters outlining key aspects of respiratory care, mirroring the approach taken with the intervention group. Despite the focus on respiratory care education, patients in the placebo group will also benefit from specialised PIP care through the IDEAL SKIIN CARES programme, administered by trained WSNs. These WSNs will provide interventions focused on PIP strategies based on the IDEAL SKIIN CARES bundle, ensuring that patients in the placebo group receive comprehensive wound care support throughout the study period.

This approach in the intervention and placebo groups aims to ensure consistency in care provision across both study groups and to evaluate the impact of the IDEAL SKIIN CARES package on PIP outcomes. Additionally, this evaluation will involve assessing the combined effect of the IDEAL SKIIN CARES bundle and patient education within the intervention group, comparing it with the placebo group which will not receive relevant training (only the effect of the IDEAL SKIIN CARES bundle).

Control group

The control group will not receive any relevant or irrelevant training or educational materials. They will only receive routine standard care for the PIP care bundle, following the care plans as routine by the hospital.

Data collection

For the purpose of data collection, we will have two questionnaires. The PIAHA screening questionnaire and a three-part questionnaire. The initial section of the three-part questionnaire will focus on sociodemographic factors, encompassing information such as age, gender, weight, height, BMI, marital status, socioeconomic status (education, housing, income and health insurance), incontinence, smoking habits, substance use and disability status. The subsequent segment of the questionnaire will explore the patients' medical background, including any coexisting conditions (anaemia, cardiovascular disease, diabetes, renal disease, dialysis, respiratory disease, spinal trauma, limb paralysis, stroke and malignancy), admission details, surgical history, PI history and medication records. Lastly, the third part of the questionnaire will focus on the clinical aspects following hospital admission. This will involve the reason for hospitalisation, utilisation of medical equipment/ventilation, level of consciousness on admission, vital signs (body temperature, heart rate, blood pressure, respiratory rate, oxygen saturation and pain assessment) and laboratory findings (creatinine, albumin and haemoglobin levels).

Primary outcome

The primary outcome measured will be the incidence of HAPI among study participants, along with a comparative analysis across the three groups.

Secondary outcomes

The secondary outcomes will be as follows: (1) PI stage: assessing the stage of PIs among patients and monitoring the progression of PI stages (increased severity in PI stages) in all three study groups; (2) patient participation in care: focusing on evaluating the level of patient engagement and involvement in their care plans for PIP; and (3) healthcare costs: analysing and comparing healthcare costs associated with managing PIs across the three study groups.

Outcome measures

Incidence of HAPI and PI stage: All patients in the three groups will be closely monitored for the development of HAPI within 48 hours of hospital admission until they reach the trial endpoints of hospital discharge or 28 days. Two independent and experienced WSNs will oversee the intervention and placebo groups, while two independent and experienced research assistants will supervise the control group. They will conduct separate examinations of the patients to assess the presence or absence of PIs, following the NPUAP guidelines.[70] These assessments will occur three times a day during morning, evening and night shifts to ensure comprehensive monitoring of at-risk patients, and with daily evaluations for patients without PI risk factors. The occurrence time of PIs will be recorded for each patient based on the day. Furthermore, WSNs and experienced research assistants will determine the stage of PIs among patients and monitor the progression of PI stages (increased severity in PI stages) in all three study groups. Accurate staging of PIs is essential for appropriate assessment, management and prevention.[76 90] The six-category staging system is widely used by the NPUAP according to the EPUAP and the Pan-Pacific Pressure Injury Alliance.[76] Stage 1 is characterised by mild to non-blanchable erythema that progresses to

severe tissue loss and exposure of underlying structures (stage 4). The presence of slough or eschar can prevent accurate staging (unstageable PI), and deep discolouration indicates damage at deeper tissue levels (deep tissue PI or multiple stage).[6] The assessment of PI stages will involve evaluating factors such as skin integrity, tissue involvement and the presence of necrosis. Any changes in the stage of a PI will be carefully documented to track the progression of the injury over time.[70] To ensure consistency and accuracy in PI assessment and stage determination, the agreement between the two assessors will be evaluated using the Kappa agreement test for inter-rater reliability on both the primary outcome (incidence of PI) and the secondary outcome (stage of PI). A substantial agreement will be defined if the Kappa value falls within the range of 0.61 to 0.80.[75]

Patient participation in care: The outcome assessor will collect data using a structured process. When patients reach the trial endpoint, the assessor will use the Patient Participation Scale as a secondary outcome measure, following the guidelines outlined by Weingart *et al*.[91] This scale evaluates patient engagement in inpatient care through seven questions that assess patients' knowledge and understanding of their medical conditions and procedures, their ability to interact with healthcare professionals, participate in decision-making processes and their overall hospital experiences. Lastly, patients will be asked to self-report their level of participation in preventing PI by providing a score from 0 to 10. This self-report assessment will offer insights into the patient's perception of their involvement in their care plan. Furthermore, the research assistants and WSNs involved in the study will be requested to rate the level of cooperation exhibited by the patients. Their input will provide an additional perspective on patient engagement and collaboration throughout the care process.

Healthcare costs: A trial-based economic evaluation will be conducted from the perspective of the healthcare system to compare the direct healthcare costs and outcomes associated with implementing an IDEAL SKIIN CARES bundle for PIP versus routine standard PIP care bundle. The costs linked to providing the IDEAL SKIIN CARES bundle, including time spent on patient education, training WSNs and developing educational resources like brochures, posters and pamphlets, will be gathered for all participants in the trial. Additionally, data on the length of hospital stays will be collected. Over a 28-day observational period (period of trial study for each patient), detailed micro-costing data will be collected by a dedicated research assistant. This data collection will enable the calculation of the direct costs incurred by the hospital for pressure-related assessment and prevention for each participant across all participating hospitals. Specifically, the number of repositioning episodes per participant, the clinical staff required for repositioning and the nurse time needed per repositioning will be determined. Other resources used for IDEAL SKIIN CARES or standard care bundles, such as special mattresses, skincare products and incontinence care, will also be documented. These resources usage data will be obtained through direct observation of study participants and auditing of medical records. The direct costs will then be allocated to each resource unit using established costing references. The data from the cost study will be combined with information on the intervention and length of hospital stay to estimate the total resource utilisation and direct healthcare costs per participant for the three study groups throughout the entire study duration.

Statistical analysis

We will implement an intention-to-treat analysis, meaning all subjects randomised to either the intervention, placebo or control groups will be analysed. The normality of data distribution will be evaluated with the Shapiro-Wilk test. In cases of normally distributed data, continuous variables will be presented as mean and SD, while categorical attributes will be shown as percentages (%). For non-normally distributed data, median and IQR will be used for reporting. Depending on the distribution of the data, comparisons of continuous variables will be conducted using either Student's t-test or Mann-Whitney U test, while categorical variables will be analysed using the χ^2 test or Fisher's exact test as deemed suitable. Other outcomes will be assessed between the three study groups using paired t-tests within each group, independent t-tests between the groups, analysis of covariance to adjust for covariates' effects and two-way analysis of variance with repeated measures to evaluate interactions between the groups and their individual impacts on the dependent variable.

The cumulative incidence of HAPI will be calculated by dividing the total number of new cases of PIs, multiplied by 100, by the total number of participants in the time period. The incidence rates between intervention, placebo and control groups will be compared at cluster level. Estimates of the HAPI incidence in each group, group differences as well as the 95% CIs and p values will be reported. Other outcomes will also be compared at the cluster levels between the interventions and control groups. Baseline variables and other covariates will be compared between the three groups to ensure the interventions and control groups do not differ in their baseline characters. The HRs, along with their 95% CIs, will be determined using a stratified univariate and multivariate Cox proportional hazards model for risk factors related to HAPI. If necessary, continuous variables will be dichotomised based on the median score to perform Cox regression analysis. In addition, Kaplan-Meier analysis will be performed to compare time to new HAPI events between three groups of study.

The duration for clinical improvement, defined as a two-point enhancement on the WHO scale, will be compared across groups using a competing risk analysis method. The Fine and Gray model will be applied, considering the escalation of PI as a competing event. Continuous and smooth improvement will be defined as

achieving a two-point advancement on the clinical WHO scale without necessitating any escalation of PI, such as a severity the stage of wound. The timeframe for this enhancement will be calculated from the date of enrolment to the moment when a two-point decline in the score is observed.

Micro-costing will be performed on a subsample of participants (n=324; 20% of the sample population) over a 28-day period or reaching the study endpoint to supplement cost data for the IDEAL SKIIN CARES bundle for PIP versus routine standard PIP care bundle based on the primary outcome measure (incidence of HAPI). This sample size will be 20% of the trial cohort and is deemed sufficient to represent the mean and distribution of resource use in the study population. Hierarchical modelling approaches and cluster-adjusted non-parametric bootstrapping techniques will be employed to compare mean difference in the total costs between three groups, and to estimate CIs around the mean.[92]

All statistical analyses will be conducted using SPSS software (V.21), Stata software (V.17) and GraphPad Prism 9. A significance level of <0.05 (two-tailed) will be used to determine statistical significance.

DISCUSSION

A multimethod multiphase approach will be used to develop and validate the PIAHA screening tool to predict PI development in hospitalised patients in mixed university hospitals. We will assess the relative contribution of well-recognised and described risk factors in relation to PI development through an umbrella review. Umbrella reviews achieve intuitive results by conducting systematic reviews with a consistent approach to variables, which allows for a comprehensive analysis that integrates previously published systematic reviews or meta-analyses.[93] However, the validity of findings and quality of evidence depend on the eligible retrieved papers.[51] The second phase will be a qualitative content analysis that will not only cover the context-based related risk factors to PI but also encompass some drawbacks of the first phase.

PIs are of great importance due to the significant patient outcomes and economic burden on hospitals[6] that depend on the country, setting, patient population and presence of PI care bundle strategies.[94] Low implementation of guidelines, in spite of long-term introducing national and international PI clinical prevention strategies, is an ongoing health service problem.[95 96] The complex hospital setting, with limited and prioritised resources, presents challenges in implementing guidelines even when a plan is established.[97] Here, we need to integrate the different results in a wide international geography that requires a method to have such characteristics. Delphi methods are the best selection as they have features like anonymity for unbiased responses, flexibility in geographical location, limited open discussion and cost-effectiveness for obtaining expert group opinion.[63 98] Then, the Delphi method will integrate the results of phase 1 and 2 and will prepare a draft of the PIAHA screening tool.

It has been discussed that the development of PI is a multifaceted and a multilayer phenomenon[99] that increases with the presence of multiple rather than single risk factors.[86] The first step of the cross-sectional phase will collect data of hospitalised patients in different settings, through univariate and multivariate logistic regression models, significant PI risk factors will be identified. The remaining PI risk factors in a multivariate logistic regression model will be used to create a risk score model. The contribution of each variable in the predictive screening tool will be based on its regression coefficient. To our knowledge, the PIAHA screening tool is the first development of a screening tool to enable healthcare staff to estimate the risk for subsequent PI development in admitted patients in hospital. To estimate the risk of patients for PI development, the presence of risk factors in the patients at the time of hospital admission will be collected. Each risk factor represents a risk score. The individual risk scores are added together to a total risk score. Healthcare staff will be able to allocate resources to hospital follow-up based on the risk estimation.

After developing the PIAHA screening tool, we need to validate the screening tool (phase 5) as validation studies help researchers to identify the errors that exist, so that these errors can be minimised or removed, and research studies can attain more accurate and valid results.[100] The PIAHA screening tool will be validated in two steps; one step is a cross-sectional study in different populations and settings. The purpose is to compare the accuracy of the PIAHA screening tool with PI development after hospital admission. The second step is a large multicentre c-RCT with three-arm in five university hospitals. The purpose is to compare effect size between intervention(s), placebo(s) and control(s) groups based on the PIAHA screening tool results. For c-RCT, we developed a novel PI prevention strategy, called IDEAL SKIIN CARES with 15 subitems (figure 1).

The c-RCT will provide significant knowledge on the impact of a personalised and a patient-centred PI prevention care bundles (IDEAL SKIIN CARES) to reduce the incidence and severity of HAPI, improve patient participation in their care and minimised associated healthcare costs among study participants, along with a comparative analysis across the three groups.

The study has several strengths from the perspective of study design, outcomes, research methodology, data collection, data analysis and intervention package. A multimethod multiphase design[101–103] will be employed for this study, consisting of five distinct phases. This design allows for the integration of five separate research designs, each representing a complete study, into one comprehensive investigation.[104] From an outcomes view, patient participation in healthcare leads to enhanced outcomes and response to interventions and is accelerated by pioneering healthcare organisations worldwide. The inclusion of an economic substudy will improve

the influence of the findings by providing meaningful cost analysis data and may provide recommendations regarding the adoption of the intervention for PI prevention in clinical practice.[94] For research methodology, throughout the study for data collection, at each hospital, we will have a senior researcher and six groups of research assistants that will be assigned distinct roles. The c-RCT will be three-blinded to prevent between groups contamination and attrition due to substantial patient movement between wards; hospitals will be the unit of randomisation. As we will use an international scheme in the first phase, the study has some degree of generalisability to other environments and populations. For data collection, the PIAHA screening tool after development will be assessed in two validation studies along with other research questionnaires. The golden standard tool in this study is PI development. We will use a comprehensive data analysis profile to show not only intervention effect across three groups of study but also to use accuracy profile to compare results of screening tool with golden standard. Finally, we developed a novel and comprehensive 15 PI prevention care bundles to cover important PI prevention care bundles called IDEAL SKIIN CARES. However, it is important to acknowledge potential limitations of this study regarding reaching recruitment target and preventing patients' attrition in phases 4 and 5. To prevent reducing the power of study, we calculated the adequate sample size in the two mentioned phases, including acceptable attrition rates. We recognise that implementing this study requires substantial resources, which may impact its progress and scope. To mitigate this, we have established a comprehensive project management framework focused on efficient resource utilisation and cost containment. The research team comprises experienced investigators with proven expertise in managing large-scale studies within budgetary limits. Preliminary funding and institutional support have been secured to provide necessary infrastructure and personnel. Additionally, the study design integrates pragmatic elements, such as embedding procedures within existing clinical workflows and employing electronic data capture, to reduce costs. Continuous monitoring and adaptive management will address resource challenges proactively, ensuring the study's successful completion without compromising quality or scope.

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