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Diagnostic accuracy of a nursing assessment meta-tool (VALENF Instrument) in adult inpatients units

Submission date
21/07/2023

Recruitment status
No longer recruiting

Registration date
25/07/2023

Overall study status
Completed

Last Edited
16/04/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Different studies have shown that the registry of nursing assessments does not meet adequate standards of quantity and quality of information, including studies that analyze the completion of information on functional capacity, falls or pressure injuries. In fact, the instruments used to assess functional capacity, risk of pressure injuries, and risk of falls are probably the most used by nurses in adult hospitalization units. In clinical practice, these instruments are used independently, but they share constructs, dimensions, and items related to mobility, hygiene, eating, or elimination, which implies that their items become redundant and are duplicated. It has been seen how the use of redundant assessment instruments generates skepticism and a perception of wasting time, making it difficult for them to be accepted and implemented in nursing. Therefore, nursing assessments can become an automatic and imprecise task without much input from nurses, affecting not only their validity, but also the task of detecting patients at risk.

Recently, a meta-tool composed of only 7 items has been developed with a more parsimonious approach to nursing assessment in adult hospitalization units (VALENF Instrument). The results of this research are pending publication and were funded by the Universitat Jaume I (UJI-A2020-08). This meta-tool integrates the assessment of functional capacity, the risk of pressure injuries and the risk of falls. The VALENF Instrument is good at predicting outcomes on the Barthel, Braden, and Downton indices, with high agreement between different observers (inter-observer reliability). It also shows good accuracy in measuring what it intends to measure (construct validity) and consistency in its results (internal consistency). However, we still need to find out how well it can identify patients at risk of functional loss, pressure injuries, or falls, as this information is yet to be determined. Consequently, the main objective of this project is to estimate the diagnostic accuracy of the VALENF Instrument, which integrates the assessment of functional capacity, the risk of pressure injuries, and the risk of falls, with a more parsimonious approach to nursing assessment. compared to the instruments habitually used by nursing in adult hospitalization units.

Who can participate?
The study population will be made up of users admitted to the adult hospitalization units of the University Hospital of La Plana.

What does the study involve?
The developed assessment instrument is expected to have at least the same diagnostic validity as the original instruments, but be more agile, so that it is accepted by nurses, reducing bureaucracy, increasing direct care time and improving the safety of the patient.

What are the possible benefits and risks of participating?
The benefits are to improve the quality of care and patient safety with an adequate nursing assessment of functional capacity, the risk of pressure injuries and the risk of falls. There is no risk to participating in the study.

Where is the study run from?
The Universitat Jaume I (Spain)

When is the study starting and how long is it expected to run for?
October 2022 to December 2024

Who is funding the study?
Valencian generalitat (Spain)

Who is the main contact?
Víctor M. González Chordá, vchorda@uji.es (Spain)

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CIGE/2022/150

Study information

Scientific Title
Diagnostic accuracy of a nursing assessment meta-tool (VALENF Instrument) that collapses assessment of functional capacity, pressure injury risk, and fall risk in patients admitted to adult inpatient units

Acronym
VALENF-DS

Study objectives

Justification: Different studies have evidenced that the recording of nursing assessments does not meet adequate standards of quantity and quality information including studies analyzing the completion of information on functional capacity, falls or pressure injuries. Indeed, instruments used to assess functional capacity, pressure injury risk, and falls risk are probably the most commonly used by nurses in adult inpatient units. In clinical practice, these instruments are used independently, but share constructs, dimensions, and items related to mobility, hygiene, feeding or elimination, which implies that their items become redundant and duplicated.

The use of redundant assessment instruments has been seen to generate scepticism and a perception of wasted time, making their acceptance and implementation in nursing difficult. Therefore, nursing assessments can become an automatic and inaccurate task without much involvement of nurses, affecting not only their validity but also the task of detecting patients at risk.

Recently, VALENF Instrument has been developed as a meta-tool composed of only 7 items with a more parsimonious approach for nursing assessment in adult inpatient units. This meta-tool integrates the assessment of functional capacity, risk of pressure injuries, and risk of falls. Thus, VALENF Instrument has a high predictive ability on the Barthel (R2adj = 0.938), Braden (R2adj = 0.926) and Downton (R2adj = 0.921) indices, with high inter-observer reliability (ICC > 0.9), good construct validity (RMSEA = 0.0726; TLI = 0.968) and internal consistency (Ω = 0.864), although its sensitivity, specificity and predictive values for detecting patients at risk of functional loss, pressure injuries or falls remain to be determined.

Consequently, the main objective of this project is to estimate the diagnostic accuracy of the VALENF Instrument, which integrates the assessment of functional capacity, the risk of pressure injuries, and the risk of falls, with a more parsimonious approach to nursing assessment, compared to the instruments usually used by nurses in adult hospitalization units.

Specific objectives:
1. Estimate the cumulative incidence and period incidence of pressure injuries, falls and functional loss in the sample studied.
2. Analyze the evolution of functional capacity, the risk of pressure injuries and the risk of falls during the care process
3. To determine the sensitivity, specificity, and predictive values of the VALENF Instrument in detecting patients at risk of pressure injuries, falls, and functional loss using the original assessment instruments as reference tests.
4. Classify patients according to their functional capacity, risk of pressure injuries, and risk of falls.
5. Determine the cut-off points of the meta-tool for the detection of patients at risk of pressure injuries, falls and functional loss

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/06/2023, Ethics and Research Committee of the Hospital Universitario de la Plana (Vila-real - Burriana km. 0,5, Villarreal, 12540, Spain; +34964399775; laplana@gva.es), ref: version 1.0. code VALENF

Study design
Observational longitudinal prospective randomized study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Diagnostic accuracy of the VALENF Instrument compared to instruments commonly used by nurses in adult inpatient units to assess functional capacity, pressure injury risk, and fall risk.

Interventions
Current interventions as of 03/05/2024:

This is an observational, longitudinal, prospective and randomized study to estimate the diagnostic accuracy of a meta-tool that collapses other assessment instruments used by nurses in adult medical-surgical hospitalization units for the assessment of functional capacity, risk of pressure injuries and falls in a public hospital in the province of Castellón. The estimated duration period is 12 months.

The study population will be made up of users admitted to the hospitalization units. Special services will not be part of the study. The study will include nursing assessments that meet the following inclusion criteria: users subject to assessment over 18 years of age; assessment carried out within the first 24 hours after admission; expected hospital stay of more than 48 hours; acceptance to participate in the study and to sign the Informed Consent; nursing assessments that include the use of the instruments under study. Users coming from transfers from other units or from other hospitals will be excluded.

A sample size of 362 participants has been calculated.

Variables and instruments. Test to be evaluated: VALENF Instrument; reference tests: functional capacity on admission measured with the Barthel index; risk of pressure injuries on admission measured with the Braden index; risk of falls on admission measured with the Downton scale. Outcome variables sensitive to nursing care, related to the care process and sociodemographic variables will also be collected.

Sociodemographic variables and variables related to the care process will only be collected on admission. While evaluation tests (VALENF Instrument) and baseline tests (Barthel, Braden and Downton) will be collected at admission, every five days and at discharge. Outcome variables sensitive to nursing care will be collected at discharge.

Data collection will be performed with Research Electronic Data Capture (REDCap) software. First, a descriptive analysis of the sample will be performed. After this initial analysis, the cumulative and period incidence of pressure injuries and falls and patients with functional loss will be estimated. A survival analysis will be performed. Next, the sensitivity, specificity and positive and negative predictive values of the VALENF Instrument will be analyzed using the Barthel, Braden and Downton indices as reference tests. Finally, the cut-off points of the VALENF Instrument will be established.
The project has been approved by the Ethics and Research Committee of the Hospital Universitario de La Plana.

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Previous interventions:

This is an observational, longitudinal, prospective and randomized study to estimate the diagnostic accuracy of a meta-tool that collapses other assessment instruments used by nurses in adult medical-surgical hospitalization units for the assessment of functional capacity, risk of pressure injuries and falls in a public hospital in the province of Castellón. The estimated duration period is 12 months.

The study population will be made up of users admitted to the hospitalization units. Special services will not be part of the study. The study will include nursing assessments that meet the following inclusion criteria: users subject to assessment over 18 years of age; assessment carried out within the first 24 hours after admission; expected hospital stay of more than 48 hours; acceptance to participate in the study and to sign the Informed Consent; nursing assessments that include the use of the instruments under study. Users coming from transfers from other units or from other hospitals will be excluded.

A sample size of 521 participants has been calculated.

Variables and instruments. Test to be evaluated: VALENF Instrument; reference tests: functional capacity on admission measured with the Barthel index; risk of pressure injuries on admission measured with the Braden index; risk of falls on admission measured with the Downton scale. Outcome variables sensitive to nursing care, related to the care process and sociodemographic variables will also be collected.

Sociodemographic variables and variables related to the care process will only be collected on admission. While evaluation tests (VALENF Instrument) and baseline tests (Barthel, Braden and Downton) will be collected at admission, every five days and at discharge. Outcome variables sensitive to nursing care will be collected at discharge.

Data collection will be performed with Research Electronic Data Capture (REDCap) software. First, a descriptive analysis of the sample will be performed. After this initial analysis, the cumulative and period incidence of pressure injuries and falls and patients with functional loss will be estimated. A survival analysis will be performed. Next, the sensitivity, specificity and positive and negative predictive values of the VALENF Instrument will be analyzed using the Barthel, Braden and Downton indices as reference tests. Finally, the cut-off points of the VALENF Instrument will be established.
The project has been approved by the Ethics and Research Committee of the Hospital Universitario de La Plana.

Intervention Type

Other

Primary outcome measure
Diagnostic accuracy will be analyzed through the sensitivity, specificity and positive and negative predictive values of the VALENF Instrument to detect patients at risk of pressure injuries, falls and functional loss using the Barthel, Braden and Downton indices as reference tests within the first 24 hours after admission

Secondary outcome measures
The cumulative incidence and the period incidence of pressure injuries, falls and patients with functional loss will be estimated by units and globally. A survival analysis will be carried out considering the appearance of pressure injury, falls or functional loss as dependent variables and the other study variables as independent variables.
Finally, the VALENF Instrument cut-off points will be established to detect the risk of pressure injuries, falls, and functional gain through simple linear regressions with the original instruments, cluster analysis to categorize patients, and analysis of the area under the ROC curve.

Overall study start date
01/10/2022

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Users are subject to nursing assessment over 18 years of age
2. Nursing assessment performed in the first 24 hours after admission
3. Expected hospital stay of more than 48 hours
4. Agree to participate in the study and sign the Informed Consent
5. Nursing assessments including the use of the instruments under study (Barthel index, Braden index, Downton scale and VALENF Instrument)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Both

Target number of participants

362

Total final enrolment
314

Key exclusion criteria
Users who come from transfers from other units of the same hospital and other hospitals will be excluded, since their care process is still in progress and their admission assessment does not correspond to that of the hospital.

Date of first enrolment
02/01/2024

Date of final enrolment
15/06/2024

Locations

Countries of recruitment
Spain

Study participating centre
University Hospital La Plana
Road Vila-real - Burriana, Km. 0.5,
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Organisation
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Sponsor type
University/education

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https://ujiapps.uji.es/

ROR
https://ror.org/02ws1xc11

Funder(s)

Funder type
Government

Funder Name
Generalitat Valenciana

Alternative Name(s)
Regional Government of Valencia, Generalitat, GVA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
It is expected that this project will result in at least 3 publications in journals in the Nursing category of the JCR. The first of these will be the research protocol that will be sent first, to the BMC Nursing journal. The other publications will address the results of the project and the Journal of Advanced Nursing is proposed as the first candidate. All publications will be in Open Access

Intention to publish date
30/07/2025

Individual participant data (IPD) sharing plan
The data sets generated and/or analyzed will be available upon request to: Víctor M. González Chordá, vchorda@uji.es.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		27/10/2023	30/10/2023	Yes	No