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VALENF-HAD: optimizing nursing assessment in hospital-at-home units

Submission date
06/05/2025

Recruitment status
Recruiting

Registration date
09/05/2025

Overall study status
Ongoing

Last Edited
09/05/2025

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims
Performing an accurate nursing assessment is essential for identifying and stratifying individuals according to their characteristics in order to ensure they receive personalized care. This enables nurses to act precisely and professionally when addressing the diverse needs of their patients. Thus, considering that nursing assessment has a crucial impact on patient outcomes, it is essential to ensure optimal conditions for nursing records, including valid, reliable, and comprehensive information. Therefore, offering alternatives that enhance nursing assessment through an integrated and structured evaluation of patients presents a current challenge. From this perspective, the VALENF Instrument was developed—an algorithm capable of predicting scores for functional capacity, risk of pressure injuries, and risk of falls based on the analysis of the 21 items included in the Barthel, Braden, and Downton assessment tools, respectively. It offers a more parsimonious solution using only 7 items, while maintaining high predictive accuracy and reliability for the original instruments' scores, along with adequate psychometric properties. This project aims to develop and validate a competent meta-instrument for the assessment of functional capacity, risk of pressure injuries, risk of falls, frailty, nutritional and sleep status in subjects admitted to home hospitalization units based on the analysis of other validated measurement instruments used by nurses in nursing assessment.

Who can participate?
Adult patients admitted to the hospital-at-home units of the four public hospitals in the province of Castellón (Spain): La Plana University Hospital, General University Hospital of Castellón, Provincial Hospital, and Vinaròs Regional Hospital.

What does the study involve?
The developed nursing assessment meta-instrument is expected to have at least the same psychometric properties as the original instruments, while being more agile, in order to be accepted by nursing staff, reduce bureaucratic burden, increase direct care time, and enhance patient safety.

What are the possible benefits and risks of participating?
The benefits include improving the quality of care and patient safety through appropriate nursing assessment of functional capacity, risk of pressure injuries, risk of falls, nutritional status, frailty, suspected dysphagia, and sleep. Participation in the study is free of charge.

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

When is the study starting and how long is it expected to run for?
March 2024 to December 2027

Who is funding the study?
Jaume I University (Spain)

Who is the main contact?
Irene Llagostera Reverter, llagoste@uji.es (Spain)

Contact information

Type(s)
Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UJI-2024-06

Study information

Scientific Title
Development and validation of a comprehensive meta-instrument for assessing functional capacity, risk of pressure injuries, risk of falls, frailty, nutritional status, suspected dysphagia, and sleep quality in patients admitted to hospital-at-home units, based on the analysis of other validated nursing assessment tools

Acronym
VALENF-HAD

Study objectives
Conducting a proper nursing assessment is essential to identify and stratify individuals according to their characteristics, in order to ensure they receive personalized care. The development of assessment tools has grown exponentially in recent years, leading to an increase in the volume of information and duplication of items to be recorded.

Proposing alternatives that enhance nursing assessment through a comprehensive and structured evaluation of patients represents a current challenge. In this regard, the literature is beginning to present proposals for new meta-instruments. These can be understood as measurement tools that consolidate others by capturing related constructs and sharing dimensions or items. The aim is to achieve a more parsimonious assessment approach, while maintaining at least the same psychometric properties and diagnostic capacity as the original instruments.

Currently, in Spain, there are few studies that demonstrate the economic impact of nursing care, the time spent delivering care, and related adverse events. However, studies conducted in the United Kingdom and Brazil estimate that nursing professionals spend over one million hours per week on administrative tasks, including the completion of nursing assessments, which takes approximately 20 minutes per patient. The time devoted to administrative tasks reduces the amount of direct care nurses can provide to patients.

In the absence of specific studies on adverse events affecting patients admitted to hospital-at-home units, their prevention largely depends on the availability of risk assessment tools that are sensitive and accepted for use by nursing professionals. The economic benefits to the healthcare system from improving risk assessment and detection systems that help prevent adverse events are evident.

Therefore, the main objective of this project is to develop and validate a competent meta-instrument (VALENF-HAD) for the assessment of functional capacity, risk of pressure injuries, risk of falls, frailty, nutritional status, and sleep in patients admitted to hospital-at-home units, based on the analysis of other validated nursing assessment instruments.

Specific Objectives:
1. To describe the characteristics of patients admitted to hospital-at-home units.
2. To analyze the influence of sociodemographic and care process-related variables on the assessment outcomes using the original instruments.
3. To analyze the relationships between the selected assessment tools and items.
4. To develop the VALENF-HAD meta-instrument.
5. To determine the psychometric properties of VALENF-HAD.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 20/06/2024, Research Ethics Committee for Medicinal Products (CEIm) of the General University Hospital of Castelló (Benicàssim Avenue, s/n, Castellón de la Plana, 12004, Spain; +34964725000; ceim_hgucs@gva.es), ref: version 2, code VALENF-HAD

2. Approved 15/07/2024, 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: code VALENF-HAD

3. Approved 26/11/2024, Research Ethics Committee for Medicinal Products of the Provincial Hospital Consortium of Castellón (Avenue Dr. Clará, 19, Castellón de la Plana, 12002, Spain; +964376105; ceim@hospitalprovincial.es), ref: Approved by the Research Ethics Committee (Minutes No. 65)

Study design
Cross-sectional and multicenter study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Home, Hospital

Study type(s)
Screening

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

To develop and validate a comprehensive meta-instrument for the assessment of functional capacity, risk of pressure injuries, risk of falls, frailty, nutritional status, suspected dysphagia, and sleep in patients admitted to hospital-at-home units.

Interventions

This is a multicenter, cross-sectional study aimed at developing and validating a meta-instrument that consolidates various nursing assessment tools used in hospital-at-home units to evaluate functional capacity, risk of pressure injuries, risk of falls, frailty, nutritional status, and sleep quality. The study will be conducted across the four public hospitals in the province of Castellón, with an estimated duration of three years.

The study population will consist of patients admitted to hospital-at-home units. Nursing assessments will be included if they meet the following inclusion criteria: patients over 18 years of age undergoing evaluation; assessment performed within the first 24–48 hours of admission; and informed consent provided for participation in the study. Assessments will be excluded if patients are not expected to remain in the unit for more than 48 hours, such as those frequently readmitted for recurrent treatments like transfusion support or medication administration under a day-hospital model. A sample size of 1,180 participants has been calculated.

The study will include sociodemographic variables and variables related to the care process. The assessment variables linked to hospitalization-related issues include: functional capacity (Barthel Index and Lawton & Brody Scale); risk of pressure injuries (Braden Scale); risk of falls (STRATIFY Scale); VALENF Instrument; frailty (FRAIL Questionnaire); nutritional status (Nutritional Screening Initiative tool); suspected dysphagia (Eating Assessment Tool); and sleep quality (Athens Insomnia Scale).

Data collection will be carried out using the Research Electronic Data Capture (REDCap) software following patient admission, based on routine nursing assessments and through consecutive sampling.

First, a descriptive and bivariate analysis of the sample will be conducted. Based on this initial analysis, conceptual and semantic relationships between the dimensions of the instruments will be examined. The items of each instrument will also be analyzed to detect similarities, duplications, and redundancies. Subsequently, the meta-instrument will be developed using linear modeling, treating each assessment tool as a dependent variable and assessing the influence of sociodemographic and care process-related variables as independent variables.

Once the meta-instrument is developed, initial validation tests will be carried out, including concordance analysis. Finally, psychometric properties will be evaluated, including content validity, construct validity, internal consistency, and inter-rater reliability.

The project has been approved by the Research Ethics Committees and the administrations of the participating hospitals.

Intervention Type

Other

Primary outcome measure

The nursing assessment meta-instrument will be developed by consolidating data collected by the following assessment tools within the first 24–48 hours after admission:
1. Barthel Index

2. Lawton and Brody Scale
3. Braden Scale
4. STRATIFY Scale
5. FRAIL Questionnaire
6. Nutritional Screening Initiative Tool
7. Eating Assessment Tool
8. Athens Insomnia Scale

Secondary outcome measures
The psychometric properties of the new meta-instrument will be examined, including content validity, construct validity, internal consistency, and inter-rater reliability using data collected during the study at one timepoint

Overall study start date
01/03/2024

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. The patient undergoing assessment must be over 18 years of age
2. Nursing assessments must be conducted within the first 24–48 hours after admission to the hospital-at-home unit
3. Patients who voluntarily agree to participate in the study and sign the Informed Consent Form, or in cases of disability, their primary caregiver

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
Both

Target number of participants
1180

Key exclusion criteria
1. Nursing assessments of patients who are not expected to remain in the hospital-at-home unit for more than 48 hours.
2. Patients who are frequently readmitted for the administration of recurrent treatments, such

as:
2.1. Transfusion support
2.2. Medication delivery under a day-hospital model

Date of first enrolment
01/02/2025

Date of final enrolment
31/01/2026

Locations

Countries of recruitment
Spain

Study participating centre
University Hospital La Plana
Road Vila-real - Burriana, Km. 0.5,
Villarreal, Castellón
Spain
12540

Study participating centre
General University Hospital of Castelló
Benicassim Avenue, s/n
Castellón de la Plana
Spain
12004

Study participating centre
Provincial Hospital Consortium of Castellón
Avenue Dr. Clará, 19
Castellón de la Plana
Spain
12002

Study participating centre
Vinaròs Regional Hospital
Avenue Gil de Atrocillo, s/n
Vinaròs
Spain
12500

Sponsor information

Organisation
Universitat Jaume I

Sponsor details
Av. Vicent Sos Baynat, s/n
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12071

Sponsor type
University/education

Website
https://www.uji.es/ujiapps/

ROR
https://ror.org/02ws1xc11

Funder(s)

Funder type
University/education

Funder Name
Universitat Jaume I

Alternative Name(s)
Universitat Jaume I de Castelló, Universitat Jaume I de Castellón, UJI

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

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
30/12/2027

Individual participant data (IPD) sharing plan
The data sets generated and/or analyzed will be available upon request to Irene Llagostera Reverter, llagoste@uji.es.
- The type of data to be shared: The anonymized database will be shared for future research.
- Timing for availability: 31/12/2027
- Whether consent from participants was required and obtained: Informed consent was required and was obtained from all participants.
- Comments on data anonymization: The data is anonymized.
- Any ethical or legal restrictions: The study was designed in accordance with current legislation.

IPD sharing plan summary
Available on request