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Development of a guideline for the early detection of psychosis in long-term care facilities

Submission date
10/10/2025

Recruitment status
Recruiting

Registration date
16/10/2025

Overall study status
Ongoing

Last Edited
16/10/2025

Condition category
Mental and Behavioural Disorders

[ ] 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
This study develops a practice-oriented clinical guideline for the care of nursing home residents with psychotic symptoms. Psychosis is frequent yet often underestimated in this population, leading to missed care and unnecessary suffering. It is characterized by delusions, hallucinations, and profound disruption of identity and reality. The study aims to map the prevalence, characteristics, and correlates of psychotic symptoms and related needs, identify organizational and experiential barriers, and develop evidence- and expert-based recommendations to improve care and quality of life.

Who can participate?
The study includes three groups of participants from participating care facilities: nursing home residents, healthcare professionals, and family members. Healthcare professionals and family members are included based on their professional or personal involvement with the residents.

What does the study involve?
Residents are assessed using standardized behavioral scales (NPI-NH, BEHAVE-AD, Cornell Depression Scale, Doloplus-2), the Montreal Cognitive Assessment (MoCA), and a structured DSM-5-based interview for psychotic symptoms, anxiety, and depression. Residents with significant psychotic symptoms undergo a multidisciplinary needs-based analysis and pharmacological review involving a geriatrician, psychiatrist, neurologist, and pharmacist. Healthcare professionals and family members participate in focus groups to capture organizational and experiential barriers in daily care.

What are the possible benefits and risks of participating?
Participants may benefit from a better understanding of their or residents' needs, improved awareness among staff, and contributions to a guideline that may enhance future care. Risks are minimal and mainly involve the time required to complete assessments or participate in interviews and focus groups; all data are handled confidentially.

Where is the study run from?
University College Odisee (Belgium)

When is the study starting and how long is it expected to run for?
June 2025 to April 2027

Who is funding the study?
University College Odisee (Belgium)

Who is the main contact?
Hilde Lahaye, hilde.lahaye@odisee.be

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Unmet care needs among residents of long-term care facilities with moderate to severe psychotic symptoms

Acronym

PHARE

Study objectives
Psychotic symptoms such as delusions and hallucinations affect up to one in five residents in long-term care facilities, yet they are often overlooked, normalized, or misattributed to dementia or psychiatric history. This normalization results in care gaps, as psychotic symptoms are rarely acknowledged as indicators of unmet needs requiring appropriate and tailored interventions. Instead, psychotropic medication is frequently prescribed, despite well-documented concerns regarding appropriateness, side effects, and limited effectiveness. General practitioners themselves report insufficient knowledge and uncertainty in managing these symptoms, further contributing to inadequate care. Previous research has shown that a needs-based care approach can significantly improve outcomes in residents, but psychotic symptoms have remained largely underexplored. When recognized, they reveal profound distress, fear, and existential disruption for residents and their caregivers. This study therefore aims to close a critical gap by mapping missed care, conducting medication reviews, and developing a practical guideline to improve early detection and appropriate support for residents with psychotic symptoms.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/05/2025, Committee of Ethics Antwerp University Hospital (Drie Eikenstraat 655, Edegem, 2650, Belgium; +32 (0)38213897; ethisch.comite@uza.be), ref: B3002025000079

Study design
Multicentre cross-sectional study

Primary study design
Observational

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Older adults in nursing homes with moderate and severe psychotic symptoms

Interventions
This multicentre, observational study combines cross-sectional and mixed-methods approaches over 1.5 years to inform the development of a practice-oriented clinical guideline for nursing home residents with psychotic symptoms. In the preparatory phase, residents are assessed using standardized behavioral scales, including the NPI-NH, Cornell Depression Scale, and Doloplus-2, alongside the Montreal Cognitive Assessment (MoCA) and a structured clinical interview based on DSM-5 criteria for psychotic symptoms, anxiety, and depression, conducted by trained psychologists. Quality of life is evaluated using the WHOQOL-8 questionnaire and semistructured interviews. Residents with significant psychotic symptoms (NPI-NH score ≥6 on delusions and/or hallucinations) will undergo a detailed needs-based analysis to identify missed care and care priorities, as well as a multidisciplinary pharmacological review involving a geriatrician, psychiatrist, neurologist, and pharmacist to evaluate the appropriateness of treatment. Focus groups with professionals, residents, and family members will capture organizational and experiential barriers in daily care. Findings from these assessments will

inform the identification of key clinical and organizational questions, guide evidence-based recommendations, and support the development of a practical guideline aimed at improving care and quality of life.

Intervention Type
Other

Primary outcome(s)
Prevalence and characteristics of psychotic symptoms measured using the Neuropsychiatric Inventory-Nursing Home version (NPI-NH) and a structured DSM-5-based clinical interview at baseline

Key secondary outcome(s))
1. Quality of life measured using the WHOQOL-8 questionnaire and semi-structured interviews at baseline
2. Cognitive status measured using the Montreal Cognitive Assessment (MoCA) at baseline
3. Depressive symptoms measured via the NPI-NH, the Cornell Depression Scale and a structured DSM-5-based clinical interview at baseline
4. Pain levels measured using the Doloplus-2 scale at baseline
5. Anxiety symptoms measured via the NPI-NH and a structured DSM-5-based clinical interview at baseline
6. Prevalence and description of missed care identified through a detailed multidisciplinary needs-based analysis and focus groups with professionals, residents, and family members at baseline
7. Prevalence and appropriateness of pharmaceutical care evaluated through a multidisciplinary medication review involving a geriatrician, psychiatrist, neurologist, and pharmacist at baseline

Completion date
30/04/2027

Eligibility

Key inclusion criteria
The study includes nursing home residents, healthcare professionals, and family members from participating care facilities. There are no specific inclusion criteria beyond residency or professional/family involvement in the care of the residents.

Participant type(s)
Health professional, Carer, Resident

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Sex

All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/09/2025

Date of final enrolment
30/04/2027

Locations

Countries of recruitment
Belgium

Study participating centre
Nursing Home Heilig Hart
Tereken 14
Sint-Niklaas
Belgium
9100

Study participating centre
Nursing Home Het Hof
Hofstraat 134
Sint-Niklaas
Belgium
9100

Study participating centre
Nursing Home Hoevezavel
Jan Davidlaan 11
Lommel
Belgium
3920

Study participating centre
Nursing Home Kapittelhof
Kapittelhof 1
Lommel
Belgium
3920

Study participating centre
Nursing Home Villa Hugardis
Maagdenblokstraat 21
Hoegaarden
Belgium
3320

Study participating centre
Nursing Home Sint-Franciscus
Kwaremontplein 41
Kluisbergen
Belgium
9690

Study participating centre
Nursing Home Huize Roborst
Kloosterstraat 1
Zwalm
Belgium
9630

Study participating centre
Nursing Home Haagwinde
Hasselstraat 7
Maarkedal
Belgium
9680

Study participating centre
Nursing Home Betlehem
Wilselsesteenweg 70
Herent
Belgium
3020

Study participating centre
Nursing Home Ocura
Havenlaan 7

Beringen-Koersel
Belgium
3582

Study participating centre
Nursing Home Ocura
Trompetplein 1
Herk-de-Stad
Belgium
3540

Study participating centre
Nursing Home Ocura
Hellebronstraat 8
Montenaken
Belgium
3890

Study participating centre
Nursing Home Ocura
Kloosterstraat 21
's Gravenvoeren
Belgium
3798

Sponsor information

Organisation
University College Odisee

ROR
https://ror.org/02c89h825

Funder(s)

Funder type
University/education

Funder Name
University College Odisee

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Hilde Lahaye (hilde.lahaye@odisee.be).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes