

Lublin Pilot Study: Prediction, Monitoring, and Personalized Recommendations for the Prevention and Management of Dementia and Frailty

Introduction to the Department of Neurology, Medical University of Lublin, and Its Role in the COMFORTage Project

Established in 1948, the Chair and Department of Neurology at the Medical University of Lublin has grown to become the largest and most specialized neurological center in the Lublin region of Poland. It is internationally recognized as a leading academic and clinical institution, maintaining active collaborations with renowned European centers such as the Institute of Neurology at University College London (UCL), UK.

The department has developed recognized expertise in areas including multiple sclerosis, neurodegenerative diseases, and epilepsy. Currently, it operates with 57 beds and includes several specialized units: a General Neurology Ward, Stroke Unit, Video-EEG Monitoring Unit, Electrophysiology Unit (covering EP, EMG, neurography, EEG, ultrasonography), Neuropsychology Unit, Neurochemistry Laboratory, and an outpatient clinic.

The Dementia Research Group has been particularly active in national and EU-funded scientific initiatives. We are proud to be a partner in the COMFORTage consortium. Our primary goal in this project is to **create a healthcare model** tailored for individuals with dementia or at risk of developing dementia. This model is intended to be both universally applicable and adaptable to the practical realities of clinical practice in Poland, addressing the rising demand for neurological care associated with aging and lifestyle changes.

The Frailty and Dementia Challenge in Poland

Poland is facing a growing demographic challenge as its population ages. In 2022, nearly 20% of the population was aged 65 or older. This proportion is projected to rise to 30% by 2060, with the number of individuals aged 85 and above expected to more than double (an increase of over 1 million people). With aging, the risk of cognitive impairment and dementia significantly increases.

Whatever the scale used, Poland is the European country with the highest frailty incidence rate. While the recent more complex scales evaluate this rate to be around 40% for the population aged 50+, simpler scales such as the SHARE scale provide estimates between 15 and 20%.¹

There were over 525,000 dementia patients in Poland in 2018, which accounted for 1.38%² of the Polish population. Despite the decreasing overall population in Poland, it is expected that the number of patients suffering from dementia will exceed one million in 2050 (3.23%

¹ <https://www.sciensano.be/sites/default/files/ocaoimh2023comparing.pdf>

² https://www.alzheimer-europe.org/dementia/prevalence-dementia-europe?language_content_entity=en

of the population). Poland has one of the highest dementia prevalence rate in Europe, especially for the population aged 70+.

One major issue is under-diagnosis—only about 25% of people with dementia are formally diagnosed. Many affected individuals remain outside the healthcare system, making it difficult to assess the true scope of the problem.

Dementia has a long preclinical phase, during which the disease is progressing even though symptoms are not yet noticeable. This stage presents the best opportunity for intervention. To make a meaningful impact, these interventions must be implemented at the systemic level—embedded within national healthcare practices. This is why we are developing **a care model for individuals at risk of dementia, aiming to integrate it into everyday clinical practice in Poland**. Preventing or delaying the onset of dementia would alleviate the substantial social and economic burden it places on patients, families, and society at large.

What will the Polish pilot concretely do?

This is a **non-randomized, observational**, non-interventional study that will examine the progression of **early cognitive impairment**. We will assess clinical, cognitive, imaging, biomarker, and genetic data across three cohorts, all within the scope of standard neurological care.

The main objective of the pilot is to identify risk factors for the development of dementia problems over time in subjects aged over 50 years in Poland. We also aim to identify the biomarkers which are the most specific and sensitive to assess dementia progression. The COMFORTage prediction algorithm supported by the Virtual Twin will also be instrumental in this perspective.

The results of the study are meant to feed a proposal to create a new model of care using digital solutions in order to improve standards of care on population levels in Poland.

Participant Recruitment and Timeline

Participants aged 50 and above will be recruited from our neurological ward, outpatient clinic, research registries, or through advertising campaigns. Recruitment for the baseline cohort will occur from January to September 2025. All participants will provide written informed consent before undergoing any procedures.

We aim to enroll **100 patients without serious comorbidities** affecting general health status.

Inclusion and exclusion criteria

Inclusion criteria

- Patients able to provide informed consent to participate
- Age equal or older than 50 years.
- Clinical status fulfilling criteria of
 - Subjective Cognitive Decline (SCD)
 - Mild Cognitive Impairment (MCI)
 - Mild AD dementia
- Available medical records: laboratory results (blood, CSF); imaging (MRI/PET); comorbidities.

Exclusion criteria

- Concomitant diseases which, in the opinion of the attending physician, prevent the patient from participating in the study, such as: decompensated cirrhosis, active ulcer disease, epilepsy and symptomatic convulsions, untreated angle-closure glaucoma determined on the basis of the patient's interview and / or medical documentation. In addition, immunocompromised patients (solid organ transplant, BMT, AIDS, renal failure (patients with renal impairment may develop drug poisoning) or other diseases not mentioned and other diseases treated with biological, immunological and / or steroids in high doses will not be eligible for the study. doses (> 20 mg prednisone daily).
- Other neurological conditions with agitation or confusion, delirium syndromes or severe, unstable depression or psychoses.

Data Collection and Patient Engagement

This two-year observational study involves continuous contact with participants.

Baseline data—such as demographics, dietary habits, and cognitive assessments—will be collected shortly after consent, with MRI scans completed within the same month.

Regular neuropsychological assessments will track cognitive function, and patients will benefit from free consultations. Based on each participant's demographic and medical profile, **personalized recommendations will be offered** to modify lifestyle and medical treatment to reduce dementia risk. In essence, participants will receive a tailored "life plan" aimed at preserving cognitive health. Those recommendations are however not to be considered as interventions.

Each participant will have a secure, individual medical data account accessible to both the patient and the clinical team. Anonymized data will be used for scientific analysis, forming the basis for future publications and insights.

Project Timeline and Development

We have developed a comprehensive clinical observational protocol. Although each partner developed a customized version of the protocol, all COMFORTage pilots will contribute to a shared dataset for AI-based analysis, aiming to develop predictive models and decision-support tools.

Our protocol was carefully designed by neurologists and public health experts to align with the needs and realities of the Polish healthcare system. We are honoured to include a representative from the Polish Ministry of Health on our project team, ensuring the protocol also supports national health priorities in dementia care.

In November 2024, we submitted our clinical trial documentation to the Bioethics Committee at the Medical University of Lublin and received full approval in December 2024. By March 2025, we began the clinical phase of the project with a public information and promotional event. Patients interested in participating are now being invited for consultations.

It's important to note that this is a non-interventional study—no treatments will be imposed. Instead, our specialists will offer suggestions and personalized recommendations, which participants may choose to adopt or not. The clinical phase is expected to continue for three years.

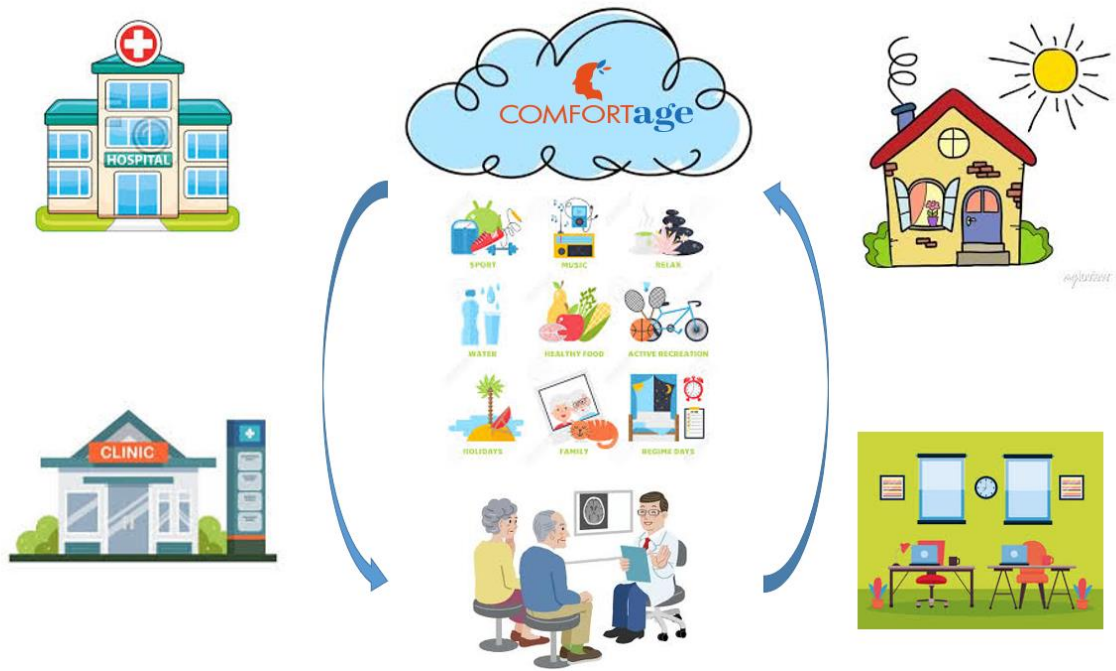
Impact of COMFORTage at the Medical University of Lublin

COMFORTage brings together 39 partners from 12 European countries to combat dementia using integrated health data, AI-driven predictive modelling, and Digital Twin technology. By enabling earlier detection and personalized intervention, the project aims to revolutionize dementia prevention and care.

Through this collaboration, we aim to generate high-quality, reliable data on dementia progression. Participation in this expert international network marks an important step forward in our institution's scientific development and offers invaluable experience for our researchers and clinicians.

Conclusion

The outcomes of the COMFORTage project will not only advance scientific understanding but also directly benefit the population of the Lublin region and beyond. Thanks to the close collaboration with the Polish Ministry of Health, we hope to support the development of new methods for diagnosing and managing dementia in the general population.



Promoting Comfortage project and ideas- Lublin Clinical Kick-off meeting (Lublin; 07.03.2025).



