

# Impact of amyloid PET on diagnosis, treatment, and adverse health outcomes

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### Publishable Summary

**Background.** Amyloid-PET allows the direct assessment of amyloid deposition, one of the main hallmarks of Alzheimer's disease. However, this technique is currently not widely reimbursed due to the lack of appropriately designed studies demonstrating its clinical impact.

**Methods.** AMYPAD-DPMS is a prospective, multicenter, randomized controlled study assessing the clinical impact of amyloid-PET in memory clinic patients. Patients with subjective cognitive decline plus (SCD+), mild cognitive impairment (MCI) or dementia from 8 European memory clinics were randomized (using a minimization method) into three study arms: ARM1, amyloid-PET performed early in the diagnostic workup (within 1 month); ARM2, late in the diagnostic workup (after 8±2 months); or ARM3, if and when the managing physician chose to. The primary endpoint was the difference between ARM1 and ARM2 in the proportion of participants receiving an etiological diagnosis with a very high diagnostic confidence (i.e. ≥ 90% on a 50-100% visual analogue scale) within 3 months. To assess the primary endpoint, we performed an intention-to-treat analysis, focusing on participants who underwent both baseline and 3-month visit.

**Findings.** Participants were recruited from April 16<sup>th</sup>, 2018, to October 30<sup>th</sup>, 2020. Among them, 272 ARM1 and 260 ARM2 underwent both baseline and 3-month visits. After 3 months, we observed a higher frequency of participants with very high diagnostic confidence in ARM1 and ARM3 versus ARM2.

**Interpretation.** This study supports the implementation of amyloid-PET early in the diagnostic workup, as its use is associated with a greater proportion of highly confident etiological diagnoses 3 months after initial clinical visit. The manuscript on the primary endpoint is submitted, and results will be publicly presented at AAIC in July 2022.

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