

C-Path's CPAD Database Drives Insights into Alzheimer's Disease

C-Path's Critical Path for Alzheimer's Disease (CPAD) Consortium is thrilled to share how Novo Nordisk A/S utilized the CPAD Alzheimer's disease database in their latest research presented at the Alzheimer's Disease and Parkinson's Disease Conference (#ADPD2025) in Vienna.

Novo Nordisk used C-Path's CPAD database, which holds data from 12,811 patients across 36 clinical trials of Alzheimer's disease (AD) and mild cognitive impairment, to study how BMI changes over time in early AD patients and examined how BMI affects trial dropout. All data in CPAD database has been remapped to a common data standard so that all the data can be analyzed across all studies. By leveraging our CPAD database, Novo Nordisk answered a question that would have been tough to solve with a single study or across separated datasets. This research highlights the importance of public-private partnerships and the power of a well-curated, aggregated, regulatory-grade clinical trial database in accelerating drug development and bringing effective treatments to patients faster.

Novo Nordisk's commitment to developing new therapies to help people with Alzheimer's disease and their families is clear. A big thank you to Novo Nordisk A/S for conducting this research and to all our CPAD member organizations and collaborators for sharing important patient-level clinical trial data that makes progress like this possible. Apply for access to the CPAD database [here](#). View the poster utilized during the presentation below or download it [here](#).

Insights from the Critical Path for Alzheimer's Disease (CPAD) consortium

Teresa León Colombo^{1*}, Sharon Cohen², Nils Skjæra³, Alex Mourer¹, Alice Clark¹, Masaru Mimura⁴

In this sample of clinical trial participants with early Alzheimer's disease, BMI increased slightly over time up to 2.5 years of follow up. BMI appears to have no influence on trial dropout.

19.8%
(95% CI, 17.3–22.4)
18-month cumulative incidence for the entire population for the composite outcome (trial dropout or mortality)

Aim

- There is considerable evidence to support that body mass index (BMI) is related to the risk of developing Alzheimer's disease (AD).
- Understanding the natural weight evolution among patients with early AD may provide insights into the impact of changes on this population's health and well-being.
- However, there are few studies investigating change in weight following an AD diagnosis.
- Moreover, evidence is lacking regarding the weight trajectory of early AD patients and whether this impacts dropout from clinical trials.
- Using the Critical Path for Alzheimer's Disease (CPAD) repository, we investigated the natural BMI trajectory over time in early AD clinical trial participants and examined the impact of BMI on trial dropout.

Methods

- The CPAD database contains patient-level data from 12,811 patients across 36 clinical trials of AD and mild cognitive impairment.
- We included participants aged 55–85 years with a documented AD diagnosis (limited data on amyloid status), Non-Mental State Examination (NMSE) score of 21–30 and 12 BMI measurements.
- The percentage BMI change over time was computed and analyzed with linear mixed-effects models and in patient subgroups (sex, BMI class at baseline, and concomitant use of acetylcholinesterase inhibitors for AD).
- Adjusted cumulative incidence curves using a Cox proportional hazards model and the G-formula were used to determine the association between baseline BMI on trial dropout or mortality (composite outcome). The follow-up period for this analysis was set to 18 months because of incomplete information regarding patients with longer follow-up times.

Key results

- Data from 1908 participants were included: 55% were women, median age was 71 years, median BMI was 24 kg/m² and 83% had an MMSE score of 21–25 (Table 1).
- Participants generally gained weight over 2.5 years of follow-up (20 months). Those gaining weight were more likely to be women, under or normal weight, and concomitantly using acetylcholinesterase inhibitors for AD (Figure 1).

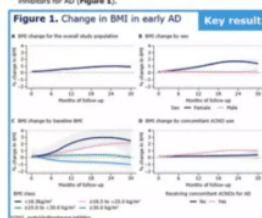


Table 1. Baseline characteristics

Characteristic	Total population (N=1,908)
Female, n (%)	1,051 (54.9)
Median (min, max) age, years	71 (55, 85)
Race, n (%)	
White	1,641 (86.0)
Asian	171 (9.0)
American Indian or Alaska Native	63 (3.3)
Black or African American	30 (1.6)
Other	3 (0.1)
BMI, kg/m ² , n (%)	
<18.5	45 (2.4)
≥18.5 – <25	888 (46.3)
≥25 – <30	757 (39.7)
≥30	268 (14.0)
Median BMI, kg/m ²	24.2
Non-mental state examination score, n (%)	
21–25	1,546 (81.0)
26–29	362 (19.0)
Acetylcholinesterase inhibitors, n (%)	
Yes	1,550 (81.2)
No	358 (18.8)

- For those with follow-up information, the 18-month cumulative incidence for the entire population for the composite outcome was 19.8% (95% CI 17.3–22.4) (Figure 2).
- The cumulative incidence, adjusted for baseline characteristics (age, sex, race, MMSE, use of acetylcholinesterase inhibitors), revealed no statistically significant association between baseline BMI groups and trial dropout (Figure 3).
- Given the low number of deaths (n=5; 0.3%), death should not impact the interpretation of results.

Figure 2. Cumulative incidence of dropout over months of follow-up

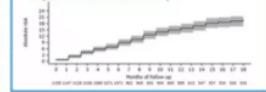
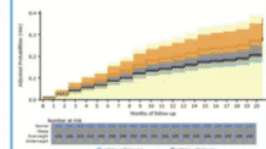


Figure 3. Adjusted cumulative incidence of dropout by BMI groups over months of follow-up



Limitations

- Post hoc analyses are considered exploratory and should be validated with further research.
- Few datasets and hence few patients on the CPAD database had information on biological AD criteria, such as consistent amyloid positivity measurements.
- Standardization across different trials is uneven, leading to difficulties in merging and analyzing data.
- Limited information on the CPAD database regarding BMI, hence the low number of cases included in the analysis (less than 13% of the available CPAD database patients).
- 40% of the final subset of 1,908 patients lacked dropout information.
- Lack of information on any dietary / exercise interventions during trials.

Conclusion

- In this sample of clinical trial participants with early AD, BMI increased slightly over time up to 2.5 years of follow up.
- BMI appears to have no impact on trial dropout in this CPAD repository data analysis, although analyses were underpowered for such assessment.
- Additional research is necessary to investigate changes in BMI among individuals in the early stages of AD.

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[1] Qorbani M et al. *Lancet Diabetes Endocrinol* 2015;3:411–418. [2] Gu Y et al. *Ann Alzheimer Dis* 2014;1:109–120. [3] O'Brien J et al. *Ann Neurol* 2019;105:1115–1125. [4] <https://cpi-path.org/publications/cpi-path-for-alzheimers-disease-cpad-database>