

Mock Case Study - MCI

by Jinesh Shah

Disease Background

Mild cognitive impairment (MCI) is a condition characterized by a noticeable decline in cognitive abilities, including memory and thinking skills, which is greater than expected for an individual's age but not severe enough to interfere significantly with daily life. This condition can be a precursor to more serious neurological disorders such as Alzheimer's disease. MCI is complex and does not have a cure to-date; the underlying molecular mechanisms and pathogenesis are not well understood and many possibilities exist.

Objective:

In prior studies the team noticed an increase in Acetylcholine (A) levels in some patients administered with a drug (D) was administered, however, the data is highly variable and is from a different population compared to the target population.

The team would like to test the hypothesis that drug D tested will enhance cognitive function by targeting specific neurotransmitter systems in the brain. The leading hypothesis is that D targets Acetylcholinesterase (AChE) which modulates acetylcholine levels, a neurotransmitter crucial for learning and memory processes. By increasing acetylcholine (A) levels and improving synaptic plasticity, the drug aims to restore cognitive functions and slow down the progression of cognitive decline in patients with MCI.

Study Design

The trial enrolled 200 participants diagnosed with mild cognitive impairment (MCI) based on standardized clinical criteria. The participants were randomly assigned to either the treatment group, receiving the new cognitive-enhancing drug (D), or the control group, receiving a placebo (P). The trial duration was six months.

Outcome Measures

The primary outcome measure was cognitive function, assessed using the Mini-Mental State Examination (MMSE) score, a widely used test of cognitive ability. MMSE is used as a continuous measure, the score ranges from 0 to 30, allowing for a wide range of values representing different levels of cognitive function.

Questions:

- How would you communicate the problem of interest to a non-statistical collaborator?
- Draw a causal diagram to communicate your problem with your collaborators.
- How would you formally define this estimand in potential outcomes notation?
- How would you identify the mechanism of action for this drug?
- What analysis method or model would you propose?
- How might the results of such an analysis look in a table?
- How would you go about communicating the relevant assumptions to collaborators?
- How would you interpret the results of such an analysis to a non-statistical collaborator?

When you're done, please email a picture of your results to iscb.causal.symposium@gmail.com and feel free to cc your team members to share the work.