

PREVENT-AD study description

1. Data description

The first release includes longitudinal data from 232 participants either in the observational cohort or from INTREPAD, the main clinical trial of PREVENT-AD.

INTREPAD (Investigation of Naproxen as a TREatment for Prevention of Alzheimer's Disease) is a double-blind, placebo controlled, randomized trial of naproxen sodium 220 mg or placebo twice daily.

Population

Participants were 60 years of age or older, excepting with the exception of those persons between 55 - 59 years old who were eligible if their age was within 15 years of symptom onset of their youngest-affected first-degree relative.

For detailed inclusion/exclusion criteria of the PREVENT-AD cohort, please visit the PREVENT-AD website (http://prevent-alzheimer.net).

Trial inclusion/exclusion criteria are specified in a publication describing results from INTREPAD (Meyer, Tremblay-Mercier et al, 2019) which has been uploaded in the LORIS Document Repository.

Available data includes:

- MRI/fMRI: See document in the 'Document Repository' for MRI protocols and parameters
- ❖ Age at MRI: Participant's age in months at the time of the MRI session
- Gender: Sex of the participant (Male or Female)
- Test Language: Language in which the participant performed the tests in the research project (French or English)
- Handedness Interpretation: The Edinburgh Handedness Inventory test results interpretation establishing hand dominance (right handed, left-handed or ambidextrous)
- ❖ Handedness Score: The Edinburgh Handedness Inventory test score results

Additional handedness fields from the handedness instrument are available in the database through the API (see instructions on how to use the API for more details). See table next page for the description of those fields.

Handedness field	Description
Date_taken	Not used (a.k.a. always NULL)
Candidate_Age	Not used (a.k.a. always NULL)
Window_Difference	Not used (a.k.a. always NULL)
Examiner	Not used (a.k.a. always NULL)
test_done	Was the handedness test done at this visit?
test_done_no_reason	Not used (a.k.a. always NULL)
test_done_no_reason_status	Not used (a.k.a. always NULL)
1_writing	1. Writing handedness degree (LL, L, R, RR)
2_drawing	2. Drawing handedness degree (LL, L, R, RR)
3_throwing	3. Throwing handedness degree (LL, L, R, RR)
4_scissors	4. Scissors handedness degree (LL, L, R, RR)
5_toothbrush	5. Toothbrush handedness degree (LL, L, R, RR)
6_knife	6. Knife (without fork) handedness degree (LL, L, R, RR)
7_spoon	7. Spoon handedness degree (LL, L, R, RR)
8_broom	8. Broom (upper hand) handedness degree (LL, L, R, RR)
9_match	9. Striking match (match) handedness degree (LL, L, R, RR)
10_box	10. Opening box (lid) handedness degree (LL, L, R, RR)
left_total	Left total (Sum of the L)
right_total	Right total (Sum of the R)
difference	Difference (Left Total - Right Total)
cumulative_total	Cumulative Total (Left Total + Right Total)
result	Final Handedness Score (x=Difference/Cumulative Total*100)
interpretation	Interpretation (x<-40: Left-handed; -40 <x<40: 40<x:="" ambidextrous;="" right-handed)<="" td=""></x<40:>
Validity	Not used (a.k.a. always NULL)
Administration	Administration for handedness test (None, Partial or All)

2. PREVENT-AD visit label explanation

Simplified PREVENT-AD timeline



LEGEND: EL: Eligibility; EN: enrolment; BL: baseline; FU: follow-up; 00, 03, 12, 24, 36, 48: number of months after BL.

* Additional time point, for the INTREPAD trial only. This time point represents the 'run-in' period of the trial. Reaching that time point, on study drug, was required to be part of INTREPAD trial.

Visit label description

NAPFU12 or PREBL00

♣ NAP: (Naproxen subproject): INTREPAD trial participants*.

This acronym in front of the visit label means that the participant was part of INTREPAD trial at this specific time point. Note that the study drug (active or placebo) was started after BL00. After the 24 months duration of the trial, participants were followed annually (off study drug) and their visits remained being labelled with NAPFU* (ex.: NAPFU36, NAPFU48).

❖ PRE: (PREVENT-AD subproject): participants in the observational cohort.

These participants were never enrolled in INTREPAD <u>or</u> were initially enrolled in INTREPAD (and had initial visits labelled with NAP at the beginning) but were unable to adhere to the study protocol until the 3-month follow-up (FUO3) and were then switched back to the observational cohort (and had their follow up visits labelled as PREFU* for further visits).

NOTES about NAP and PRE subprojects:

- All PREVENT-AD participants' eligibility visits were identified as PREEL00
- Participants enrolled in INTREPAD had their visits named NAP at the enrolment visit (EN) and remained in the NAP subproject or switched back to the PRE subproject (if unable to follow INTREPAD protocol until the 3-month follow-up).

*For more details about the trial and main outcomes, please refer to the recently published INTREPAD results paper (Meyer & Tremblay-Mercier et al., 2019) which has been uploaded in the document repository.