

# Eye-tracking parameters as biomarkers of frontotemporal dementia

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Structural brain disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON51509

### Source

ToetsingOnline

### Brief title

Eye-tracking in FTD (FTDEYE)

### Condition

- Structural brain disorders

### Synonym

Alzheimer's disease, Frontotemporal dementia

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Neurologie

**Source(s) of monetary or material Support:** NWO/ZonMw,Stichting Dioraphte;Alzheimer Nederland;Bluefield;JPND

## Intervention

**Keyword:** Alzheimer's disease, Biomarkers, Eye-tracking, Frontotemporal dementia

## Outcome measures

### Primary outcome

Eye movement features derived from the eye-tracking test battery.

### Secondary outcome

Not applicable

## Study description

### Background summary

Frontotemporal dementia (FTD) is a clinical, pathological and genetically heterogeneous neurodegenerative disorder. In up to 30% of cases FTD is inherited in an autosomal dominant inheritance pattern, with the most common mutations occurring in the microtubule-associated protein tau (MAPT), progranulin (GRN), and chromosome 9 open reading frame 72 (C9orf72) genes. As a result, we can define mutation carriers in the presymptomatic phase. Since 2009, a large cohort of at-risk mutation carriers are being followed in the Erasmus MC, called the FTD Risk Cohort (FTD-RisC). Research in familial FTD has demonstrated that disease pathology already emerges years before symptom onset, and is associated with subtle cognitive changes as measured by neuropsychological examination. For upcoming medication trials, sensitive biomarkers to assess disease stage and track progression are crucial. Cognitive measures could serve as biomarkers, however, standard neuropsychological assessment lacks sensitivity. We hypothesize that eye movement features could serve as a sensitive biomarker for FTD.

### Study objective

The objective is to identify which eye movement features are sensitive biomarkers for FTD. To answer this question, we will assess which eye movement features dissociate best between healthy controls, patients with FTD (familial and non-familial), patients with Alzheimer's dementia (AD), and presymptomatic FTD mutation carriers.

### Study design

This is an observational study. A range of eye-tracking tests that have been related to FTD and AD in previous research will be administered, including pro-/anti-saccade, oculomotor capture, smooth pursuit, self-paced eye movements, Brixton spatial anticipation, and free viewing. Clinical data will be retrieved from the FTD Risk Cohort study (FTD-RisC; MEC-2009-409) study, and dementia biobank (MEC-2016-069).

### **Study burden and risks**

Patients with FTD and AD will be assessed in a single research session lasting 2-3 hours. Presymptomatic mutation carriers and healthy controls will be assessed on a (two) yearly basis, in combination with their FTD-RisC follow-up appointment. A (non-invasive) eye-tracking test battery is administered during which gaze position is recorded. Eye-movements are made frequently in daily life, without any conscious effort. Making eye movements in the suggested test battery will not cause discomfort, as we will investigate participants\* normal viewing behaviour. It might occur that eye fatigue is experienced, as the tests take part in a dimly lit room. This burden is, however, minimal. To minimize burden, breaks are provided during and in between tests.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- 1) Patients with FTD referred to our referral center and diagnosed with use of International Consensus Criteria. The dementia symptoms have to be mild (clinical dementia rating  $\leq 1$ ). Patients with all variants of FTD (behavioural frontotemporal dementia, semantic variant PPA, non-fluent variant PPA) will be included.
- 2) Patients with mild Alzheimer's dementia diagnosed according to International Consensus Criteria. The dementia has to be mild (clinical dementia rating  $\leq 1$ ).
- 3) Asymptomatic, first degree relatives of dementia patients due to genetic mutations. They have 50% chance of having the mutation and developing FTD. DNA status is determined in a related study (MEC-2009-409) in a double-blind design. Participation is possible from 18 years and over.

### Exclusion criteria

Subjects with a previous stroke or other (neurological) conditions that may affect cognitive functions (brain tumour, multiple sclerosis, use of psycho-active medications) will be excluded from participation in this study.

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated):	31-10-2022
Enrollment:	136
Type:	Actual

## Ethics review

Approved WMO	
Date:	28-10-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL80727.078.22