



**is a multi-centre, multi-national
prospective, observational biomarker
study of premanifest and early stage
HD with no experimental treatment.**



Description

What is TRACK-HD?

TRACK-HD is a major new multi-national prospective, observational biomarker study of pre-manifest and early stage Huntington's disease (HD) with no experimental treatment. TRACK-HD is part of the worldwide collaborative Huntington Project (<http://www.huntingtonproject.org/>) funded by the CHDI Foundation, Inc. (<http://www.chdi-inc.org/>).

What are the aims of TRACK-HD?

As a comprehensive study of pre-manifest and early HD, TRACK-HD aims to measure the sensitivity of individual and combined assessment tools to detect subtle changes in disease progression. The ultimate goal is to establish what combination of measures is the most sensitive for detecting change over the natural course of HD. This would lay the foundations to develop the much-needed methodology to undertake future clinical trials of disease-modifying agents in HD.

Why is TRACK-HD important?

TRACK-HD is unique as it uses the most cutting-edge assessment techniques available to date, such as 3T MRI (3 tesla magnetic resonance imaging) and a range of computerized assessments that allow objective measurement of cognitive and motor functioning. In addition, the study is dynamic, in that it will incorporate promising new measures and refine its existing measures over time. These steps ensure that the final measures will be the most sensitive to subtle changes related to HD progression.

Enrolment

Who is eligible to participate in TRACK-HD?

Individuals who:

- are between 18 and 65 years of age
- are able to undergo a brain MRI scan
- are willing to donate a sample of blood
- have genetic confirmation of carrying the HD gene, and who have recently started showing clinical symptoms (early HD)
- have genetic confirmation of carrying the HD gene, and who have no clinical symptoms (pre-manifest)
- have family members with HD, and who have had genetic confirmation that they do not carry the HD gene (control)
- spouses of individuals who carry the HD gene (control).

How many participants are currently enrolled?

There are four sites involved in TRACK-HD: London, Leiden, Paris and Vancouver. Each site will recruit 90 subjects (30 pre-manifest, 30 early HD, 30



controls) between December 2007 and June 2008, with a total of 360 subjects worldwide. The baseline assessments will be conducted between January and July 2008.

What does participation involve?

Subjects participating in TRACK-HD attend a baseline assessment day, which tends to last from 9:30 am to 5:00 pm. Following the baseline measure, participants are invited to attend follow-up assessments one year (first half of 2009) and two years (first half of 2010) afterwards.

The assessment day consists of:

- a biosample donation
- collection of demographic details, medical history, current medications, HD family history, occupational and educational attainment, and activities of daily living
- a cognitive assessment
- a quantitative motor assessment
- a brief neurological evaluation and oculomotor assessment
- a psychiatric interview with self-report questionnaires
- a brain 3T MRI scan.

What are the benefits of participating in TRACK-HD?

There are no financial benefits for participants in TRACK-HD, but all costs incurred relating to transport and meals associated with a participant's visit will be reimbursed. Most importantly, individuals participating in TRACK-HD will be contributing uniquely to furthering the understanding of the natural progression of HD.

Data protection and confidentiality

Assessments are only performed once the participant has given a written informed consent. Following this, a nine-digit numerical code (pseudonym) is generated, and any identifiable details of the individual are stored in a secure location separate from the data collected. The identity of participants is only known to the study site staff who deal directly with the participant. These staff are bound by medical confidentiality. Data that are collected are then entered onto a secure web-based portal that is only accessible to authorised personnel. These data will only be associated with the pseudonym, ensuring individuals' confidentiality.

Organisation

Four sites are involved in TRACK-HD:
London, United Kingdom
Leiden, The Netherlands
Paris, France
Vancouver, Canada.



Each site has an investigation team comprising a clinical fellow, a psychologist and a research assistant under the supervision of a principal site investigator (PI). They carry out all of the assessments and data collection. The global PI is Dr Sarah Tabrizi. She heads a central coordination team consisting of a full-time clinical trial manager, project manager and study administrator, in addition to working with her co-investigators from Europe, Australia, Canada and the USA. The central coordination team is responsible for the study protocol and liaising with sites and all the other teams involved (data repositories, data monitors and expert advisors). The data monitoring team and IT team who manage the TRACK-HD electronic database are based at the EHDN headquarters in Ulm (Germany) and work closely with the central coordination team in running the study.

Contacts

How to obtain further information about TRACK-HD?

Further information can be obtained from the TRACK-HD administrator:

Ms Saiqah Munir
TRACK-HD
Box 104
Institute of Neurology
University College London
Queen Square
London WC1N 3BG
Phone: + 44 (0) 207 905 2944
Email: trackhd_admin@ion.ucl.ac.uk

TRACK-HD Global Principal Investigator

Dr Sarah Tabrizi
Dept of Neurodegenerative Disease
and National Hospital for Neurology and Neurosurgery
Institute of Neurology
Queen Square
London WC1N 3BG
Phone: +44 (0) 207 905 2952
Email (PA): k.perry@ion.ucl.ac.uk

Current TRACK-HD Steering Committee

David Craufurd (University of Manchester, UK)
Alexandra Dürr (Hopital de la Salpetriere, France)
Nick Fox (Institute of Neurology, UCL, London, UK)
Chris Frost (UCL, London, UK)
Hans Johnson (University of Iowa, USA)
Christopher Kennard (Imperial College, London, UK)
Bernhard Landwehrmeyer (University of Ulm, Germany)
Doug Langbehn (University of Iowa, USA)
Blair Leavitt (University of British Columbia, Canada)



Ralf Reilmann (University of Münster, Germany)
Raymund Roos (Leiden University, The Netherlands)
Diana Rosas (MGH Dept of Neurology, Charlestown, USA)
Julie Stout (Indiana University, USA, and Monash University, Australia).