

# A feasibility study of real-time displays of brain activity as a treatment for symptoms in Huntington's disease

<b>Submission date</b> 27/01/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/01/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/02/2023	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Huntington's disease (HD) is a condition that stops parts of the brain working properly over time. It's passed on (inherited) from a person's parents. It gets gradually worse over time and is usually fatal after a period of up to 20 years. The symptoms usually start at 30 to 50 years of age, but can begin much earlier or later.

Recent advances in brain imaging technology now provide us with the opportunity to not only monitor disease-related changes in HD, but to also develop non-invasive interventions, such as neurofeedback training using real-time functional MRI (rt-fMRI), aiming at helping patients better manage their disease symptoms. Participants learn to regulate their own brain activity in selected regions and networks.

The aim of the current study is two-fold: firstly it is to employ neurofeedback training using real-time fMRI in order to train early stage HD patients and pre-symptomatic gene carriers to regulate their brain activation and manage their disease symptoms. Secondly, it is to assess the effects of neurofeedback training using real-time fMRI in early stage HD patients and pre-symptomatic gene carriers.

### Who can participate?

Patients aged 18 years or above, with early stage HD or HD gene carriers without symptoms.

### What does the study involve?

Participants will be randomly allocated to receive actual or sham neurofeedback training for controlling symptoms of HD. The participants take part in one baseline visit, four training visits and three post-training follow-up visits. Participation will involve MRI scans at each visit.

### What are the possible benefits and risks of participating?

This study involves MRI. This is a painless, non-invasive and safe technique that can obtain detailed images of the brain structure and function. It uses strong magnetic fields to generate the images and, unlike X-ray techniques, there is no ionising radiation. MRI scans are not done on people with certain metal implants (such as pacemakers) and prior to enrolment in the study we

will go through a series of questions to ensure that a participant is safe to take part in the study. Neurofeedback training using MRI is non-invasive and only involves the use of advanced brain imaging equipment to accurately measure and present the participant's brain activation. Changes in brain plasticity are driven by each person's internal capacity to improve their behaviour through feedback. No side-effects have ever been reported in the literature and it can be used in combination with other medical treatments. The uniqueness of the proposed approach is that the feedback provided is the brain activity of each person, providing direct access to how the brain responds to disease-related changes and ultimately the ability to regulate this response in order to improve behaviour.

It is important to note that this intervention does not offer a cure for the disease. This is the first time this approach will be used in HD patients, so the degree of symptom improvement, if any, following this method is currently unknown.

Where is the study run from?  
University College London (UK)

When is the study starting and how long is it expected to run for?  
February 2016 to November 2019

Who is funding the study?  
Medical Research Council (UK)

Who is the main contact?  
Dr Marina Papoutsi  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

160463

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

05/N046, IRAS 160463

## **Study information**

**Scientific Title**

Evaluating the feasibility of real-time fMRI neurofeedback training as a treatment for cognitive symptoms in Huntington's disease

**Acronym**

HD-BrainTrain

**Study objectives**

The aim of our project is to develop and test neurofeedback training as a method to induce plasticity in Huntington's disease (HD), with the aim of improving cognitive and motor symptoms.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 05/11/2012, London - Queen Square Research Ethics Committee (Manchester HRA Head Office, 3rd Floor Barlow House  
4 Minshull Street, Manchester, M1 3DZ; +44 (0)207 104 8345; NRESCommittee.London-QueenSquare@nhs.net), ref: 05/Q0512/74

**Study design**

Single-centre interventional randomized controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Quality of life

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Huntington's disease

## **Interventions**

The study tests real-time fMRI neurofeedback training (NFT).

Participants are randomized into four groups, two treatment groups, one receiving neurofeedback derived from the activity of the Supplementary Motor Area (SMA), and another receiving neurofeedback based on the correlation of SMA and left striatum activity (connectivity NFT), and two sham control groups, matched to each of the treatment groups.

Participants are randomized into the four groups based on the UHDRS total motor score.

The participants take part in one baseline visit, four NFT visits and three post-training follow-up visits. The baseline and follow-up visits include advanced structural and functional MRI scanning up to two months post-training.

## **Intervention Type**

Other

## **Primary outcome measure**

Participants' ability to upregulate NFT target levels without feedback (near transfer) measured using fMRI at baseline and follow up (two months after training)

## **Secondary outcome measures**

Measures of cognitive and psychomotor function at baseline and follow-up (two months after training):

1. Stroop word reading
2. Symbol Digit Modalities Task
3. Emotion Recognition
4. Circle Tracing
5. Paced and Speeded Tapping

## **Overall study start date**

01/02/2014

## **Completion date**

18/11/2019

## **Eligibility**

### **Key inclusion criteria**

1. > 18 years old
2. Pre-symptomatic gene-carriers, i.e. they will carry the HD gene, but will not have been clinically diagnosed (UHDRS diagnostic score of 4 or less) at the time of enrolment, OR
3. Early-stage 1 HD patients, i.e. patients with Total Functional Capacity (TFC) score between 11-13

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

32 HD gene-carriers (pre- and manifest)

**Key exclusion criteria**

Cannot be scanned in the MRI scanner

**Date of first enrolment**

12/02/2016

**Date of final enrolment**

15/06/2017

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****University College London**

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**Sponsor information****Organisation**

University College London Hospitals NHS Foundation Trust

**Sponsor details**

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+44 (0)20 3447 5124  
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**Sponsor type**

Research organisation

**Website**

<https://www.uclh.nhs.uk/Pages/home.aspx>

**ROR**

<https://ror.org/042fqyp44>

**Funder(s)****Funder type**

Research council

**Funder Name**

Medical Research Council

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Results and Publications****Publication and dissemination plan**

Publication in peer-reviewed journals and presentation in international and national conferences related to neuroscience and Huntington's disease.

## Intention to publish date

01/02/2020

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2018	28/01/2020	Yes	No
<a href="#">Results article</a>		23/04/2020	28/02/2023	Yes	No