

# Deep brain stimulation for addiction

<b>Submission date</b> 09/07/2024	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/08/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/05/2026	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Alcohol and opioid addiction are major public health issues with significant personal and social costs and risks of physical and mental illness and early death. The disorders are associated with high relapse rates with many remaining refractory (not responding) to conventional therapies. Deep brain stimulation (DBS) acts like a brain pacemaker to normalise abnormal brain activity. It is effective for severe Parkinson's disease and other neurological disorders and for obsessive-compulsive disorder. DBS has been approved for use in tremor since 2002. More than a quarter of a million people worldwide have DBS devices implanted. A small randomised controlled trial and at least four pilot studies suggest both safety and potential effectiveness in alcohol and opioid use disorders. This study aims to use DBS to treat refractory alcohol and opioid addiction. Addictions can be considered an imbalance of excessive acceleration and lack of braking. DBS will stimulate the nucleus accumbens involved in the drive of motivation and reward for addictions and the ventral internal capsule white matter tracts involved in braking and decision-making to balance function.

### Who can participate?

Adults (aged 18-60 years) with alcohol or opioid use disorder of at least 5 years duration, with at least three relapses, and who have failed conventional therapies

### What does the study involve?

This is a 10-month study. DBS involves a neurosurgical procedure under general anaesthesia. The participant will stay in hospital for 7 to 10 days. The participant will be followed to optimise stimulation for 6 months then enter a 4-month randomised cross-over trial. They will also take part in brain recording studies to understand the disorder and to help optimise treatment. The DBS team will continue to follow the participant for as long as they have the device in place.

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

Severe untreated chronic addiction that is not responding to the usual treatments is at high risk of comorbid medical illness and early death. DBS has been approved since 2002 and has been shown to be relatively safe and effective in other neurological disorders and obsessive-compulsive disorder. More than a quarter million individuals have undergone DBS for other disorders. Specific to addictions, a small randomized controlled trial and several pilot studies also has shown DBS to be relatively safe and potentially effective. The risks of the neurosurgery can include infection, bleeding and seizure. The neurosurgical team are highly experienced

functional neurosurgeons with the lead neurosurgeon having completed more than 500 DBS surgeries. Risks of stimulation include hypomania which can be managed by changing stimulation parameters.

Where is the study run from?

1. Cambridge University Hospital, University of Cambridge (UK)
2. Kings College Hospital, Kings College London (UK)

When is the study starting and how long is it expected to run?

January 2018 to October 2027

Who is funding the study?

The Medical Research Council (UK)

Who is the main contact?

1. Prof. Valerie Voon, vv247@cam.ac.uk
2. Dr David Okai

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2024-000621-40

**Integrated Research Application System (IRAS)**  
316169

**Central Portfolio Management System (CPMS)**  
56678

## Study information

### Scientific Title

Deep brain stimulation for disorders of addiction: mechanisms and a pilot blinded randomized cross-over placebo-controlled trial

### Acronym

Brain-Pacer

### Study objectives

Deep brain stimulation of the nucleus accumbens and ventral internal capsule is more effective than sham stimulation on alcohol and opioid use outcomes in alcohol and opioid use disorder.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 30/06/2023, Yorkshire and the Humber: Sheffield Research Ethics Committee (NHS Blood and Transplant Blood Donor Centre Holland Drive, Newcastle, NE2 4NQ, United Kingdom; +44 (0)207 104 8282; sheffield.rec@hra.nhs.uk), ref: 23/YH/0110

### Study design

Multicenter interventional double-blind randomized controlled crossover trial

### Primary study design

Interventional

### Study type(s)

## Treatment

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

Alcohol and opioid use disorder

### **Interventions**

Following neurosurgical implantation, deep brain stimulation (DBS) will be delivered at chronic high frequency (~130 Hz; 2-4 V) in the nucleus accumbens and ventral internal capsule. The stimulation protocol parameters will be optimized over the 6-month open-label stimulation optimization period. At postoperative month 6, participants will undergo a single-blind randomized cross-over controlled trial (order randomized) of four arms: dual stimulation, single stimulation and sham with each arm, lasting for 1 month.

### **Intervention Type**

Device

### **Phase**

Phase II

### **Drug/device/biological/vaccine name(s)**

Deep brain stimulation

### **Primary outcome(s)**

Alcohol and opioid use is measured using Timeline Followback during randomised control cross-over trial at baseline and months 1, 2, 3 and 4

### **Key secondary outcome(s)**

Alcohol and opioid use is measured using Timeline Followback during open-label stimulation optimisation at baseline and months 1, 2, 3, 4, 5, 6

### **Completion date**

31/10/2027

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosis of treatment-refractory opioid use disorder (OUD) or alcohol use disorder (AUD) (DSM-5 diagnosis)
2. Comorbid nicotine dependence, other psychoactive use disorder permissible as long as OUD or AUD is the primary diagnosis
3. At least 5 years duration
4. 3+ failed abstinence attempts
5. Failed psychotherapy and standard pharmacotherapy
6. Age 18 to 60 years old
7. MRI compatible
8. Capable of informed consent

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

60 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. Deep brain stimulation or neurosurgical contraindication (e.g. unable to tolerate general anaesthesia, risk of bleeding)
2. History of repeated falls
3. Other major psychiatric (e.g. schizophrenia, bipolar disorder or severe major depression) or neurologic disorder
4. Major head injury
5. Marked cognitive impairment or cortical atrophy

**Date of first enrolment**

31/08/2023

**Date of final enrolment**

30/09/2027

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

United Kingdom

England

**Study participating centre**

**Cambridge University Hospitals NHS Foundation Trust**

Cambridge Biomedical Campus

Hills Road

Cambridge

England

CB2 0QQ

**Study participating centre**  
**Kings College London, IoPPN**  
16 De Crespigny Park  
London  
England  
SE5 8AB

**Study participating centre**  
**Humber Teaching NHS Foundation Trust**  
Trust HQ, Block A, Ground Floor  
Beverley Road  
Willerby Hill  
Hull  
England  
HU10 6FE

**Study participating centre**  
**Turning Point**  
Suffolk Recovery Network  
Sanderson House  
17-19 Museum Street  
Ipswich  
England  
IP1 1HE

## **Sponsor information**

**Organisation**  
Cambridge University Hospitals NHS Foundation Trust

**ROR**  
<https://ror.org/04v54gj93>

**Organisation**  
University of Cambridge

**ROR**  
<https://ror.org/013meh722>

# Funder(s)

## Funder type

Research council

## Funder Name

Medical Research Council

## Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request following publication from Prof. Valerie Voon (vv247@cam.ac.uk).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version 2.01	12/01/2024	11/07/2024	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes