



2013

Dear _____,

You have expressed interest in the Deep Brain Stimulation for Treatment Resistant Depression Research Study. The following provides you with some general information:

What is DBS?

Deep brain stimulation (DBS) is a surgical treatment that uses small pulses of current from a pair of electrodes implanted in the brain to stimulate targeted areas that control mood and anxiety. Stimulation is continuous and personalized for each patient. DBS is not a cure. It may help symptoms in some people. A DBS system looks and operates much like a pacemaker for the heart. The DBS electrodes are surgically positioned in the brain, and the pulse generator is placed under the skin in the chest. A health care professional uses a programmer to program the pulse generator.

About the CRIO-DBS Research Study

This research study has been funded by Alberta Innovates Health Solutions (AIHS) Collaborative Research and Innovation Opportunities (CRIO). Our ultimate objective is to learn which people with severe depression will respond to DBS, which electrical parameters are best, whether Cognitive Behavioural Therapy (CBT) will further improve quality of life, and how DBS works in the subcallosal cingulate (SCC) region of the brain.

In order to qualify for this study and have DBS implanted into the brain, patients in this study must:

- Meet the inclusion/exclusion criteria
- Have neurosurgery to have the DBS system implanted
- Participate in Cognitive Behavioural Therapy for 3 months in Calgary
- Be available for monthly follow-up visits for 15 months in Calgary
- Continue to take current medications

Do I Qualify?

You may be eligible for this study if you are:

- between the ages of 20 and 60
- Have a diagnosis of major depressive disorder (MDD) or bipolar disorder (BP)
- Have failed to respond to four different classes of antidepressants, evidence-based psychotherapy, cognitive behavioural therapy (CBT) or electroconvulsive treatment (ECT) despite adequate dosage, duration and compliance
- Have a minimum score of 20 (out of 52) on the 17 item Hamilton Depression Rating Scale (HDRS)
- Are a good candidate for surgery and

- Are available in Calgary for follow-up for at least 15 months

If you meet these criteria and would like more information, contact the study centre at the University of Calgary at 403-210-6905.

Time Commitment

Consideration should be given to the time commitments required:

- 3 initial medical appointments, two with psychiatrists and one with the neurosurgeon. Each visit will take about 1 to 2 hours each.
- An appointment with a neuropsychologist, about 4 to 5 hours.
- Pre-surgical testing and imaging:
 - Blood work
 - MRI scan
 - PET scan
- About 5 days in the hospital to have the device implanted; the electrodes implanted on day one under local anaesthetic and the power generator implanted in a second surgery under general anaesthetic several days later.
- Clinic visit for suture removal and initial programming, one week after surgery, about 4 hours
- Monthly visits with the study psychiatrist and study nurse for 15 months, about 1-2 hours
- A CT scan 3 months after surgery
- A PET scan 6 months after surgery
- 12 weeks of once weekly individual sessions of cognitive behavioural therapy beginning 6 months after surgery

Additional information is available, including Frequently Asked Questions, Research Journal Articles, Informed Consent, and What to Expect after your Implant Procedure. Please contact the study centre at the University of Calgary at 403-210-6905 or email sgolding@ucalgary.ca.

Best regards,

Sandra Golding BN, RN, MSCHA
CRIO-DBS Research Coordinator
403-210-6905
sgolding@ucalgary.ca

CRIO-DBS RESEARCH STUDY
ELIGIBILITY SCREENING TOOL

Date of Screening: _____

Screening completed by: _____

How do you know about this study? _____

Name: _____

Address: _____

Home Phone: _____

Work Phone: _____

Cell Phone: _____

Email Address: _____

Date of Birth: _____ Age: _____

Alberta Health Card #: _____

Referred by: _____

Phone: _____

Psychiatrist Name: _____ Phone: _____

Family Doctor Name: _____ Phone: _____

Psychologist/Counsellor Name: _____ Phone: _____

Psychiatric Diagnosis: _____

Date of Diagnosis: _____

Are you experiencing a current major depressive episode of greater than one (1) year?

Yes: _____ Dates: _____

No: _____ Dates of last episode: _____

What kind of symptoms are you dealing with?

If confused/unsure, ask the following questions:

- In the last 2 weeks, has there been a period of time when you were feeling depressed or down most of the day, nearly every day? What was it like? _____

- Have you lost interest or pleasure in things you usually enjoy?

- How is your energy level? Do you feel tired or fatigue most of the time?

- How is your appetite? Did you lose or gain any weight?

- How was your sleep?

- Were you so fidgety or restless that you were unable to sit still? Or maybe you were talking or moving more slowly than is normal for you?

- Did you have trouble thinking or concentrating? _____
- Was it hard to make decisions about everyday things? _____

- Were things so bad that you were thinking a lot about death or that you would be better off dead? What about thinking of hurting yourself? Did you do anything to hurt yourself?

Has depression made it hard for you to do your work, take care of things at home or get along with other people? _____

Psychiatric Medication History:

List dates & dosages you have taken any of the medications listed below:

Trade Name	Generic Name
Combination Antipsychotic and Antidepressant Medication	
Symbyax (Prozac & Zyprexa) _____	fluoxetine & olanzapine
Antipsychotic Medications	
Abilify _____	aripiprazole
Clozaril _____	clozapine
Fanapt _____	iloperidone
fluphenazine (generic only) _____	fluphenazine
Geodon _____	ziprasidone
Haldol _____	haloperidol
Invega _____	paliperidone
Latuda _____	lurasidone
Loxitane _____	loxapine
Moban _____	molindone
Navane _____	thiothixene
Orap (for Tourette's syndrome) _____	pimozide
perphenazine (generic only) _____	perphenazine
Risperdal _____	risperidone
Seroquel _____	quetiapine
Stelazine _____	trifluoperazine
thioridazine (generic only) _____	thioridazine
Thorazine _____	chlorpromazine
Zyprexa _____	olanzapine

Trade Name	Generic Name
Antidepressant Medications (also used for anxiety disorders)	
Anafranil (tricyclic) _____	clomipramine
Asendin _____	amoxapine
Aventyl (tricyclic) _____	nortriptyline

Celexa (SSRI)	citalopram
Cymbalta (SNRI)	duloxetine
Desyrel	trazodone
Effexor (SNRI)	venlafaxine
Elavil (tricyclic)	amitriptyline
Emsam	selegiline
Cipralext (SSRI)	escitalopram
Ludiomil (tricyclic)	maprotiline
Luvox (SSRI)	fluvoxamine
Marplan (MAOI)	isocarboxazid
Nardil (MAOI)	phenelzine
Norpramin (tricyclic)	desipramine
Pamelor (tricyclic)	nortriptyline
Parnate (MAOI)	tranylcypromine
Paxil (SSRI)	paroxetine
Pexeva (SSRI)	paroxetine-mesylate
Pristiq	desvenlafaxine (SNRI)
Prozac (SSRI)	fluoxetine
Remeron	mirtazapine
Sarafem (SSRI)	fluoxetine
Sinequan (tricyclic)	doxepin
Surmontil (tricyclic)	trimipramine
Tofranil (tricyclic)	imipramine
Tofranil-PM (tricyclic)	imipramine pamoate
Vivactil (tricyclic)	protriptyline
Wellbutrin	bupropion
Zoloft (SSRI)	sertraline

Trade Name	Generic Name
Mood Stabilizing and Anticonvulsant Medications	
Depakote	divalproex sodium (valproic acid)
Eskalith	lithium carbonate
Lamictal	lamotrigine
lithium citrate (generic only)	lithium citrate
Lithobid	lithium carbonate
Neurontin	gabapentin
Tegretol	carbamazepine
Topamax	topiramate
Trileptal	oxcarbazepine

Trade Name
Anti-anxiety Medications
(All of these anti-anxiety medications are benzodiazepines, except BuSpar)

Generic Name

Ativan _____	lorazepam
BuSpar _____	bupirone
Klonopin _____	clonazepam
Librium _____	chlordiazepoxide
oxazepam (generic only) _____	oxazepam
Tranxene _____	clorazepate
Valium _____	diazepam
Xanax _____	alprazolam

Trade Name
ADHD Medications
(All of these ADHD medications are stimulants, except Intuniv and Straterra.)

Generic Name

Adderall _____	amphetamine
Adderall XR _____	amphetamine (extended release)
Concerta _____	methylphenidate (long acting)
Daytrana _____	methylphenidate patch
Desoxyn _____	methamphetamine
Dexedrine _____	dextroamphetamine
Dextrostat _____	dextroamphetamine
Focalin _____	dexmethylphenidate
Focalin XR _____	dexmethylphenidate (extended release)
Intuniv _____	guanfacine
Metadate ER _____	methylphenidate (extended release)
Metadate CD _____	methylphenidate (extended release)
Methylin _____	methylphenidate (oral solution and chewable tablets)
Ritalin _____	methylphenidate
Ritalin SR _____	methylphenidate (extended release)
Ritalin LA _____	methylphenidate (long-acting)
Strattera _____	atomoxetine
Vyvanse _____	lisdexamfetamine dimesylate

Have you ever had CBT (Cognitive Behavioural Therapy) or any other psychotherapy/counseling? And if yes, please list:

Dates/Duration: _____

Where: _____

Therapist Name: _____

Have you ever had ECT (Electroconvulsive Therapy)? And if yes, please list:

Dates: _____

Where: _____

Psychiatrist Name: _____ Phone: _____

Have you ever had rTMS (Transcranial Magnetic Stimulation): If yes, please list:

Dates: _____

Where: _____

Psychiatrist Name: _____ Phone: _____

Exclusion Criteria:

Do you have or have you ever had any other Psychiatric Disorders, including?

Schizophrenia: _____

Psychosis: _____

Active Suicidal Ideation over previous six (6) months: _____

Anorexia/bulimia: _____

Gender Identification Issues: _____

Panic disorder: _____

Social anxiety disorder: _____

Obsessive compulsive disorder: _____

Post traumatic stress disorder: _____

Borderline personality disorder or other personality disorders: _____

Somatoform disorder or hypochondrias: _____

Adult ADHD: _____

Alcohol or drug abuse (cannabis, cocaine, meth or other street drugs):

Other: _____

Do you have any cerebral vascular risk factors?

Previous stroke: _____

Head injury: _____

Neurodegenerative disorders: _____

Epilepsy: _____

Are you pregnant or planning on being pregnant in the near future?

Do you have any medical or general contraindications for DBS surgery?

Cardiac pacemaker: _____

Cardiac defibrillator: _____

Do you have Diabetes?

Type I: _____ Medications: _____

Type II: _____ Medications: _____

Do you have or have you ever had any medical illnesses? Please specify:

- Heart attack _____
- Angina _____
- COPD _____
- High Blood Pressure , controlled or uncontrolled _____
- Asthma _____
- Other _____

What other medications and supplements do you take?

MEDICATION	DOSAGE	REASON

What surgeries have you had?

SURGERY	DATE	WHERE	DOCTOR

Summary (Notes by person doing the screening):

Screening Decision:

Does not meet criteria, decline: _____

Meets basic criteria, refer to psychiatrist for assessment: _____

Unsure if meets basic criteria, discuss with psychiatrist: _____