VCU Parkinson's and Movement Disorders Center

PARKINSON'S AND MOVEMENT DISORDERS CENTER

I. TITLE: Detecting depression and anxiety in people with adult-onset idiopathic dystonia: a diagnostic accuracy study.

SHORT TITLE: Anxiety and Depression in Dystonia Screening (ADDS)

II. SPONSORS: Department of Clinical Neurosciences, Cumming School of Medicine, University of Calgary; Hotchkiss Brain Institute; Tourmaline Oil Chair in Parkinson's Disease

III. SITE PRINCIPAL INVESTIGATOR:

Dr. Brian Berman, MD, MS, FAAN
Professor of Neurology and Bemiss Endowed Chair
Director, VCU Parkinson's and Movement Disorders Center
Chair, Movement Disorders Section

P: (804) 628.5276
E: brian.berman@vcuhealth.org

IV. PRINCIPAL INVESTIGATOR:

Dr. Davide Martino
Associate Professor, Department of Clinical Neurosciences
Director, Movement Disorders Program
Cumming School of Medicine, University of Calgary
Health Sciences Centre
P: 403.210.8726 F: 403.210.9149
E: davide.martino@ucalgary.ca

CO-INVESTIGATORS:

- Zahra Goodarzi, PhD MD
  Department of Community Health Sciences
  Tourmaline Chair in Parkinson's Disease
  Hotchkiss Brain Institute

- Veronica Bruno, MD
  Assistant Professor, Department of Clinical Neurosciences

- Justyna Sarna, MD, PhD, FRCP(C)
  Clinical Assistant Professor, Department of Clinical Neurosciences

- Tamara Pringsheim, MD, PhD, FRCP(C)
  Director of the Tourette Syndrome and Pediatric Movement Disorders Program
  Associate Professor of Neurology

This consent form is only part of the process of informed consent. It will give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Please take the time to read the following pages carefully. You will receive a copy of this form.

V. BACKGROUND:

We are asking you to take part in this study because you have adult-onset idiopathic dystonia.

This is an observational study. If you agree to take part, the research team will first complete a clinical interview with you. After the interview, you will complete 8 self-administered questionnaires. The whole procedure will take place only once.

Participation is voluntary. You are completely free to choose whether to take part in this research study. You can change your mind and withdraw from the research study at any time. You are not required to give any reasons for your decision. Deciding not to take part or to withdraw will not affect your current or future clinical care in any way.

VI. WHAT IS THE PURPOSE OF THE STUDY?

Doctors often do not recognize depression and anxiety in people with dystonia. Because of this, depression and anxiety may remain untreated in people with dystonia. This study aims to select the best tests to assess depression and anxiety in people with dystonia. This will help doctors to treat depression and anxiety in people with dystonia better.

VII. WHAT WOULD I HAVE TO DO?

If you decide to take part in this study, you will have to sign this consent form. The research team will ask you to complete a few questionnaires.

PROCEDURES:

· Informed consent procedure

· A member of the research team will search the Parkinson's and Movement Disorders Center Registry for patients who have cervical dystonia. From the registry, they will obtain contact information for those patients who, through the registry, consented to be contacted about research opportunities and have cervical dystonia. The research team member will ask you about your age, sex, education level, and ongoing medications either in person or in a phone call. Researchers might review your records to learn more on your medical conditions and the medications you are taking. The same researcher will then interview you to understand if you suffer from any psychiatric condition.

· A member of the research team will explain to you the eight questionnaires that you will fill out during the study. These questionairres will ask about your mood, mental health, social and behavioral habits, and will ask about anxiety levels, depression, and suicidality. You will be able to choose whether to fill these out on paper or online. To fill them out online, you will receive an email from the research team with a secure link to the questionnaires. Filling out all these questionnaires should take no longer than

70 minutes. You will have to fill them out within 3 days from the interview with the research team. You will be able to take all the breaks you need while filling them out.

VIII. WHAT ARE THE RISKS?

Risks associated with clinical assessments: Neurologists or nurses will supervise all the interviews and questionnaires during the study. There are no known physical risks associated with these clinical assessments. In the course of doing questionnaires or tests you may feel tired and/or irritable. If this happens, please tell a member of the research staff and ask them to allow you time to rest.

There is a slight risk of loss of confidentiality. Private identifiable information such as phone number, email, and name will be collected from the participant to allow linkage in the electronic database. Only VCU research personnel will have access to this key, however, because it exists, there is a risk that someone could accidently view these records.

There is a slight risk of discovering that a participant may be at risk for harming themselves and/or others. In this case, the researchers will contact your neurologist or your family doctor and will then share this information with you. The research team will help you with arranging appropriate follow up and care.

IX. WILL I BENEFIT IF I TAKE PART?

You will not receive a direct health benefit from participating in this study. By taking part in the study, you will help us to understand the best way to assess depression and anxiety in people with dystonia. This may help future patients with dystonia.

X. DO I HAVE TO PARTICIPATE?

You do not have to take part in this study. Choosing not to take part will not affect your current or future medical care at VCU.

XI. WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

You will not receive any payment for taking part in this study. You will not have to pay anything to participate in this research study.

XII. WILL MY RECORDS BE KEPT PRIVATE?

We will not put your name, address or any other information that could identify you on the information you allow us to collect from you. Only the site research staff will be aware of your identity and will be able to link the information collected during your study visit to you. We will store the data collected in locked filing cabinets or on a secure University of Calgary server (REDCap), with access limited to the Research Team members from VCU and University of Calgary only. The information we upload into REDCap is de-identified, meaning that your data is linked to a study ID letter/number sequence and does not contain your name. Only the research team members at VCU will have the key that links your study ID to your name. This key will be destroyed once the study is closed. We will not share identifying information about participants with those outside the study.

In general, we will not give you any individual results from the study. However, during the study, the researchers could learn something about you that they or you didn't expect or know. For example, the researchers may find out that you could be suffering from a depressive or an anxiety disorder. In this case, the researchers will contact your neurologist or your family doctor and will then share this information with you. The research team will help you with arranging appropriate follow up and care.

I consent for the researchers to share findings with me:
__YES

__NO

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.
While we will make every effort to keep information we learn about you private, we cannot guarantee this.

Representatives from the University of Calgary and the Conjoint Health Research Ethics Board may look at your identifiable study records for quality assurance.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- Representatives of VCU and the VCU Health System/VCU Dental Care
- Representatives of the Dystonia Coalition Project Reliance and the University of Calgary Research team, who initiated the study and maintain the database where de-identified information is held
- Officials of the Department of Health and Human Services
- This research is also being conducted in foreign countries, so personal information pertaining to you may be shared or copied by authorized agents of governmental agencies in those countries.

We may present the results of the research at meetings or in publications, but we will never use your name or any other identifying information. For the purposes of this study, we will identify your data only through the use of a coded number.

The information collected as part of this study will not be used or distributed for future research studies, even if identifiers are removed.

HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?

As part of this research study, we will ask you to permit us to access existing information from your healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

What type of health information will be used or shared with others during this research?

The following types of information may be used for the conduct of this research:

☐ Complete health record	☒ Diagnosis & treatment codes	☐ Discharge summary
☐ History and physical exam	☐ Consultation reports	☐ Progress notes
☐ Laboratory test results	☐ Medical imaging reports	☐ Imaging films/scans/pictures
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☐ Information about drug or alcohol abuse	☐ Information about Hepatitis B or C tests	
☐ Information about mental health	☐ Information about sexually transmitted diseases	
☐ Other physical or mental health information (specify):		

Who will use or share protected health information about me?

VCU and VCU Health VCU Dental Care are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health or VCU] to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
-
- Data Coordinators
-
- Data Safety Monitoring Boards

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

When will this authorization (permission) to use my protected health information expire?

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

Statement of Privacy Rights

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator, Dr. Brian Berman at 1101 E Marshall Street Box 980539 Richmond, VA 23298..

XIII. CONTACT PERSONS:

For more information concerning this research, please contact:

The Principal Investigator:	Dr. Brian Berman	(804)-628-5276
The Study Coordinator:	Caileigh Dintino	(804)-220-0970

XIV. SIGNATURES:

Your signature on this form indicates that you have understood to your satisfaction the information about participation in this study research project and agree to take part. This does not waive your legal rights nor release the researchers, or involved institutions from their legal and professional responsibilities. You are free to withdraw from this study at any time without jeopardizing your health care. If you have any further questions on this research, please contact Dr. Brian Berman or Caileigh Dintino.

If you have any questions concerning your rights as a participant in this research, please contact The Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990 or the VCU IRB at

Virginia Commonwealth University Office of Research

800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298

Phone: (804) 827-2157
https://research.vcu.edu/human-research/hrppirb/research-participants/

Participant's Signature and Time | Printed Name | Date

Investigator/Person obtaining consent's Signature Date and Time | Printed Name

_____ _____

Principal Investigator Signature (if different from above) | Date