Informed Consent Form

TITLE: A Pragmatic Trial of HOme Based Self-management & COgnitive Training CHanges Lives (HOBSCOTCH) in Georgia

NCT NUMBER: NCT04639206

IRB APPROVAL DATE: May 18, 2023

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of approximately 100 people who are being studied at Emory.

Why is this study being done?

This study is being done to answer the question: Will a home-based self-management program, HOBSCOTCH, be effective in improving quality of life and perceived difficulties in cognitive abilities by teaching problem-solving strategies? The research team is also looking at a new mobile application that was developed to go with the program, and looking at extra booster sessions to improve long-term outcomes.

In order to learn about the effectiveness of the program, half of the people in this study will be randomly assigned to be in the intervention immediately. The other half will be randomly assigned to a 6-month waitlist period before getting the intervention. All participants will receive the program at some point during the study.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for at least 3 months. We expect it will take about 12 months for you to complete the study (8 study visits within a 3-month period, with assessments at baseline, 3 months, 6 months, 9 months, and 12 months). The researchers will ask you to do the following: 1) take baseline and follow-up testing of memory, quality of life, mood, and healthcare use, and 2) HOBSCOTCH self-management intervention. ALL of these procedures will be paid for by the study.

How is this study going to help you?

While it is not guaranteed, you may benefit from participating in this study by learning new tools for your memory and thinking problems. It is also possible that you will not personally benefit from being in this research study. If you are in this study, you will be helping the researchers answer the study question: Can HOBSCOTCH improve quality of life and perceived difficulties in cognitive abilities by teaching problem-solving strategies?

What are the risks or discomforts I should know about before making a decision?
The study will take time. The risks of this study are low. The most common risk would include the time burden of the intervention and surveys, boredom, or frustration.

This program does ask questions about your mental health and symptoms of depression. This information will be strictly confidential, but will be discussed in the event that you screen positive for suicidal thoughts or behaviors. If you screen positive for suicidal thoughts or behaviors, the following will happen:

- A clinician from our study team will contact you to discuss your answers on the questionnaire and make sure your participation in the study should continue.
- If the clinician believes it is necessary and appropriate, we may contact your primary care doctor to alert them and make sure you are receiving care for mental health.
- For safety reasons, we may provide you with information on the National Suicide Prevention Lifeline (1-800-273-8255).

You should report any problems to the director of this study: Dr. Cam Escoffery [redacted].

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
The HOBSCOTCH program and all materials will be supplied free of charge.

All additional tests/visits/procedures as described in, “What do I have to do if I choose to participate in this study?” will be paid for by the Centers for Disease Control and Prevention (CDC).

The procedures in this study are no part of usual care and nothing will be billed to your insurance.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: A Pragmatic Trial of HOBSCOTCH in Georgia

Principal Investigator: Cam Escoffery, PhD, MPH, CHES
Professor of Behavioral, Social and Health Education Sciences
Rollins School of Public Health

Co-Investigator: Katie Bullinger, MD, PhD
Assistant Professor, Epilepsy Division
Emory Department of Neurology
Staff physician/Epileptologist, Grady Memorial Hospital

Funding Source: Centers for Disease Control and Prevention (CDC)

Introduction

You are being asked to be in a research study because you have indicated that you have epilepsy and memory or cognition problems. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form, you will not give up any legal rights.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

Study Overview

The purpose of this study is to learn if a program called HOBSCOTCH can improve the quality of life and perceived difficulties with memory and thinking. HOBSCOTCH is a home-based self-management program where you will meet with a coach and have one-on-one sessions in-person or over the phone.

Your participation in the study will last approximately 12 months. You will be paid $15 each time you complete a set of surveys, and can be paid up to $75 if all surveys are completed.

The risks of this study are low. The most common risks would include the time burden of the intervention and surveys, boredom, or frustration.

It is possible that you will not personally benefit from being in this research study. We hope to gather information that may help people with epilepsy in the future. While it is not guaranteed, you may benefit from participating in this study by learning new tools for your memory and thinking problems.

Procedures

If you decide to enroll into this research study a computer will assign you by chance to one of the following groups:

- **Group 1** – receives the HOBSCOTCH self-management intervention immediately
- **Group 2** – following a waitlist period of 6 months, receives the same HOBSCOTCH self-management intervention

If you are assigned to **Group 1**, we will ask you to participate in the HOBSCOTCH program, which includes multiple sessions with a HOBSCOTCH Coach by video, telephone, or in-person. Your first and last session may occur in-person, over the telephone, or through video chat. **In Group 1**, your visits will include the following:

Visit	Description
Enrollment 30-60 minutes	You will meet with the Study Coordinator either in-person or through a video chat. You will sign the informed consent, be randomized to Group 1 or Group 2, and will complete baseline assessments after the visit (online or by mail and return).
HOBSCOTCH Introduction 30-60 minutes (video)	Video session with your HOBSCOTCH Coach to get to know each other. Your Coach may ask you about your epilepsy journey and certain questions about your life.
HOBSCOTCH Session 1 60 minutes (video)	Video or in-person session with your HOBSCOTCH Coach where you will learn about epilepsy and cognition.
HOBSCOTCH Sessions 2-7 45-60 minutes (telephone)	Telephone sessions with your HOBSCOTCH Coach where you will use Problem Solving Therapy and learn a memory strategy.
HOBSCOTCH Session 8 45-60 minutes (video or telephone)	Video, telephone, or in-person session with your HOBSCOTCH Coach where you will use Problem Solving Therapy and wrap-up the program.
3-month Assessments 30-45 minutes	Complete assessments online or by mail and return – no visit with study staff.
HOBSCOTCH Booster Sessions 1-3 45 minutes each (video or telephone)	Video or telephone session with your HOBSCOTCH Coach where you can check-in and use Problem Solving Therapy.
6-month Assessments 30-45 minutes	Complete assessments online or by mail and return – no visit with study staff.
9-month Assessments 30-45 minutes	Complete assessments online or by mail and return – no visit with study staff.
12-month Assessments 30-45 minutes	Complete assessments online or by mail and return – no visit with study staff.

If you are assigned to **Group 2**, we will ask you to participate in the HOBSCOTCH program, which includes multiple sessions with a HOBSCOTCH Coach by video, telephone, or in-person, *however you will not begin HOBSCOTCH for 6 months after enrollment*. You will be contacted at month 3 and month 6 to complete assessments prior to starting your sessions. **In Group 2**, your visits will include the following:

Visit	Description
Enrollment 30-60 minutes (video)	You will meet with the Study Coordinator either in-person or through a video chat. You will sign the informed consent, be randomized to Group 1 or Group 2, and will complete baseline assessments after the visit (online or by mail and return).
3-month Assessments 30-45 minutes	Complete assessments online or by mail and return – no visit with study staff.
6-month Assessments 30-45 minutes	Complete assessments online or by mail and return – no visit with study staff.
HOBSCOTCH Introduction 30-60 minutes (video)	Video session with your HOBSCOTCH Coach to get to know each other. Your Coach may ask you about your epilepsy journey and certain questions about your life.
HOBSCOTCH Session 1 60 minutes (video)	Video or in-person session with your HOBSCOTCH Coach where you will learn about epilepsy and cognition.
HOBSCOTCH Sessions 2-7 45-60 minutes (telephone)	Telephone sessions with your HOBSCOTCH Coach where you will use Problem Solving Therapy and learn a memory strategy.
HOBSCOTCH Session 8 45-60 minutes (telephone or video)	Video, telephone, or in-person session with your HOBSCOTCH Coach where you will use Problem Solving Therapy and wrap-up the program.
9-month Assessments 30-45 minutes	Complete assessments online or by mail and return – no visit with study staff.
HOBSCOTCH Booster Sessions 1-3 45 minutes each (telephone or video)	Video or telephone session with your HOBSCOTCH Coach where you can check-in and use Problem Solving Therapy.
12-month Assessments 30-45 minutes	Complete assessments online or by mail and return – no visit with study staff.

No matter which group you are assigned to, you will also be asked to complete a series of questionnaires 5 times during your involvement in the study. These assessments will be done either by mail or over the internet – you can complete the surveys whichever way you prefer. In addition, you will also be asked to use a mobile phone application to enter data daily regarding seizures, medications, and mood. Please note that paper versions of these logs are available for people who do not have access to a mobile phone.

Risks and Discomforts

The study will take time. The risks of this study are low. The most common risk would include the time burden of the intervention and surveys, boredom, or frustration.

This program does ask questions about your mental health and symptoms of depression. This information will be strictly confidential, but will be discussed in the event that you screen positive for suicidal thoughts or behaviors. If you screen positive for suicidal thoughts or behaviors, the following will happen:

- A clinician from our study team will contact you to discuss your answers on the questionnaire and make sure your participation in the study should continue.
- If the clinician believes it is necessary and appropriate, we may contact your primary care doctor to alert them and make sure you are receiving care for mental health.
- For safety reasons, we may provide you with information on the National Suicide Prevention Lifeline (1-800-273-8255).

You should report any problems to the director of this study: Dr. Cam Escoffery [redacted] or Dr. Katie Bullinger [redacted].

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

While it is not guaranteed, you may benefit from participating in this study by learning new tools for your memory and thinking problems. It is also possible that you will not personally benefit from being in this research study. If you are in this study, you will be helping the researchers answer the study question: Can HOBSCOTCH improve quality of life and perceived difficulties in cognitive abilities by teaching problem-solving strategies? The study results may be used to help other people with epilepsy in the future.

Compensation

As part of this study, you will be given surveys to fill out on your own, either by hand or online, approximately every three months. There are a total of 5 time points during the study where we will ask you to complete surveys. These surveys and assessments can take anywhere from 3-45 minutes. You will be paid $15 each time you complete the required assessments, for a possible total of $75 over the course of the study. Payment will be in the form of a gift card that will be mailed to you each time you complete a set of assessments. We will record the number of the gift cards that you receive, and your name and address will be given to an office at Emory University that monitors payments.

Other Options Outside this Study

If you decide not to enter this study, you can ask your healthcare provider about other options available for helping with memory and cognition. You do not have to take part in this study to receive medical care or treatment. HOBSCOTCH is an educational skill-building program that does not replace regular clinical care including: visits with an epileptologist, neurologist, or another healthcare provider. It does not replace formal cognitive rehabilitation or other forms of therapy or rehabilitation.

Participation in the research study is optional.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include [the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Compliance]. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

This research study is part of the Managing Epilepsy Well (MEW) Network. Which means other institutions and Universities are also participating in a similar study. As a result, your de-identified data will be shared with institutions within the MEW Network, specifically, Dartmouth-Hitchcock, the institution that created this program.

[No results returned to participants]

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record

If you have been an Emory and/or Grady Health System patient before, then you already have an Emory and/or Grady Health System medical record. If you have never been an Emory and/or Grady Health System patient, you do not have one. An Emory and/or Grady Health System medical record will be made for you if an Emory Atlanta and/or Grady Health System provider or facility gives you any services or procedures for this study.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: baseline and follow-up surveys.

Tests and procedures done at non-Emory and/or Grady Health System places may not become part of your Emory and/or Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Emergency Care

We will give you emergency care if you are injured by this research. However, Grady Health System and Emory University have not set aside funds to pay for this care or to compensate you if a mishap occurs. If you believe you have been injured by this research, you should contact Dr. Katie Bullinger ([redacted]) or Dr. Cam Escoffery ([redacted]).

Patients' Rights

If you are a patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Demographics
- E-mail address for contact information
- Epilepsy diagnosis, treatment, seizure counts and frequency, and present/past medications
- Depression, wellbeing, quality of life, seizure severity, patient activation, medication adherence, epilepsy self-management, and health care utilization

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and

share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form. If you do not sign this form, you may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The Centers for Disease Control and Prevention (CDC) is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: Centers for Disease Control and Prevention and National Institute of Health.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

[redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr. Cam Escoffery, Principal Investigator, [redacted] or Dr. Katie Bullinger, Principal Investigator, [redacted]:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Name of Subject

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**