Multimodal Intervention Trial for Cognitive Deficits in Neurofibromatosis Type I: Efficacy of Computerized Cognitive Training and Stimulant Medication

NCT02944032

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Children's National

Consent/Parental Permission to Participate in a Clinical Research Study and Authorization to Use Protected Health Information

TITLE OF STUDY: Multimodal Intervention Trial for Cognitive Deficits in Neurofibromatosis Type 1: Efficacy of Computerized Cognitive Training and Stimulant Medication

PRINCIPAL INVESTIGATOR: Kristina K. Hardy, PhD

Throughout this document, "You" always refers to the person (you or your child) who takes part in the study.

We are inviting you to be part of a multicenter research study at Children's National Health System. Before you decide if you would like to participate, we want you to know why we are doing the study. We also want you to know about any risks and what you will be expected to do in the study.

This form gives you information about the study. Your study doctor or a member of the research team will talk to you about the study and answer all of your questions. We encourage you to discuss this study with your family and anyone else you trust before making your decision. You must sign this form if you agree to take part in the study. We will give you a signed copy of this form to keep.

Your participation in this research is voluntary.

This means that:

- You do not have to join the study;
- You may change your mind and stop your being in the study any time;
- We will tell you if we make any important changes to the study or if there are any important new findings so that you can decide if you still want to be in the study.

Why is this research study being done?

You are being asked to be in this study because you have neurofibromatosis type 1 (NF1) and may have problems with thinking skills such as attention and working memory. Working memory is the ability to keep information in mind while problem-solving.

We want to see if a computer program called Cogmed[RM] helps children with NF1 and working memory problems. In studies with children and adults without NF1, using the computer program has improved working memory and other thinking skills, but we do not yet know if it will be helpful to children and adolescents with NF1. We also want to find out if there are changes in your thinking skills after completing the computer program.

The study will involve up to 100 participants from 5 sites around the world. Thirty-three participants will be recruited at Children's National Health System.

The United States Department of Defense is paying for this research to be done.

What will happen in this research study?

Screening Visit

If you take any regular medications for attention problems, we will ask that you take the medication as usual on the day of the visit. At this visit, a member of the study team will measure some of your thinking and learning skills. We will ask you to complete tasks such as define words, solve puzzles, pay attention, and remember things.

A study doctor will also do a brief physical examination, including measurement of height, weight, heart rate, and blood pressure, and ask you questions about your medical history and current health. The testing and examination will last approximately 2 to 2 ½ hours with breaks. Based on the results of this visit, you may or may not be asked to participate in the computer program part of the study.

Home Training

If you are asked to participate, you will be randomly assigned to one of two groups (like flipping a coin, so you will have an equal chance of being in either group). One group will be assigned to receive a computer program called Cogmed[RM], which is designed to help children improve their working memory skills by doing activities requiring them to remember things. The other group will be assigned to use a different computer program, called MobyMax. MobyMax is a program designed to help children improve their reading skills by reading stories and answering questions about the stories. A member of the study team will teach you how to use the computer program he/she was assigned.

If you do not already have a computer at home, a laptop computer will be provided for the time you are enrolled in the study. If you borrow a laptop, we will ask that you return the laptop at the Follow-up Visit. You will be doing computer exercises three to five times a week for five to nine weeks. We ask that a responsible adult be present in, or close by, the room while you do the exercises. We ask that these adults not help you do the exercises, just watch over you.

Study Team Follow-up Phone Calls

A study member will be contacting you approximately once per week throughout the home training. The phone calls are to check in about how the training is going and answer any questions you have. The phone calls will last approximately 15 minutes.

Follow-up Visit

Within two weeks of completing the computer program, you will come back to Children's National Health System to complete some of the same tests you did during the screening visit. This will help the study team know if the programs helped to improve your working memory or reading skills. A member of the study team will ask you about any changes in your medical history and any adverse events (illnesses, injuries, or other undesirable experiences) that you have experienced since your last visit. The study team will also collect any changes in your medications. This visit will take approximately 1 to 1 ½ hours.

Is it O.K. to take other medications, dietary supplements, or alternative medicines while I am in this research study?

Tell the study doctor about all of the medications and supplements you are currently taking. The study doctor will review all of these with you and decide if you can participate in the study. Also, you should not take any new medications or dietary supplements without discussing it with the study doctor first.

How long will my participation in the research study last?

You will be in the study for up to 11 weeks. You will have two visits at Children's National Health System, one before the home training and one after the home training.

You should tell us if you decide to stop being in the study.

In rare cases we may ask you to drop out of the study if:

- There are any unexpected side effects
- Your study doctor and/or the Sponsor of the study thinks it is in your best interest

What are the risks and possible discomforts from being in this research study?

There may be risks we don't know about. Some children may find the testing or the computer program boring or frustrating at times. There is also a risk of unwanted persons being able to look at your private information. We will follow all research standards to best protect your private information, as described below in the "Confidentiality" section.

What are the possible benefits from being in this research study?

We cannot promise that participating in this research study will help you. Your participation in this study may help us find out if using the computer program improves thinking or working memory skills in children and adolescents with NF1. It is possible that you will see an improvement in your working memory.

What other choices do I have if I don't want to take part in the study?

You do not have to take part in this study. There are other ways to get help for problems with thinking, including problems with attention and working memory, but there are no computer programs that we know are helpful. If your study doctor thinks that any treatment other than what you will get in this study would be better, your study doctor will tell you that and will not ask you to be in this study.

Will it cost me anything to take part in the study?

There are no costs to you or to your insurance company for taking part in this study. You or your insurance company will have to pay for the costs of any routine or standard medical care that is not part of the study. This may include, but is not limited to, visits to the clinic or other tests not part of the study. If your insurance company does not pay for the routine or standard care, you will be responsible for paying for it.

Will I be paid for taking part in this study?

You may receive up to a total of $100 in gift cards after finishing this research study. The payment will be made based on your completion of the visits and home-training sessions. You will receive $30 in gift cards for completing the screening visit. You will receive $10 in gift cards for completing the first 8 home-training sessions. You will receive $10 in gift cards for completing 8 more home-training sessions. You will receive $10 in gift

cards for completing 2 more home-training sessions. You will receive $10 in gift cards for completing the next 2 home-training sessions. You will receive $30 in gift cards for completing the follow-up visit. We will also pay for your parking at Children's National Health System when you are here to take part in the study.

ClinicalTrials.gov

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.

How will you protect my privacy if I take part in this study? Who will see the information that I give you?

There are some government agencies or other groups that may check records that identify you without your permission. They might review the records of this study and your medical records to make sure we are following the law and protecting the children in the study. The agencies or groups who might see these records are the people working on the study at Children's National Health System, the Coordinating Center managing the study, the US Department of Defense, and the ethics committee that reviewed and approved this research study.

The results of this research may be presented at meetings or in publications. You will not be personally identified.

Certificate of Confidentiality

Sometimes people tell us some very personal information about themselves when they participate in a study and it becomes part of their research record. To help us protect your privacy, the investigators have obtained a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by a court order or subpoena) to give information that may identify you in any federal, state or local civil or criminal court, or in any administrative, legislative, or other proceedings. At some time, however, DHHS might request this information as part of a review of the study records and medical records to make sure we are following the law and protecting the people in the study, and to make sure our results are correct. If this happens, we are required to give DHHS all of the information they request for their review.

It is important that you know that a Certificate of Confidentiality does not stop you or a member of your family from voluntarily giving information to others about yourself or your taking part in this research. You should also know that if an insurer or employer learns about your participation and you give them permission to receive research information about you, we cannot use the Certificate of Confidentiality to keep your information private from them. This means that you must also actively protect your own privacy.

Finally, it is important that you know that we are not prevented from taking steps to prevent serious harm to you or to others. For example, if you or anyone else might be in danger, we will have to report this to the authorities and get emergency help if it is needed.

What happens if I get hurt or sick because of taking part in this research study?

Children's National Health System cannot promise that the risks we have told you about or other unknown problems will not happen. If you think that you are hurt, sick, or otherwise harmed because of something to do with the study, please call the Principal Investigator, Kristina K Hardy, PhD, at (202) 476-2514.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA). This privacy law protects your individually identifiable health information (Protected Health Information or PHI). The privacy law requires you to sign an agreement so researchers can use or share your PHI for research purposes. This describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully and ask a member of the research team to explain anything you do not understand.

I authorize the Principal Investigator, Kristina K Hardy, PhD, and her research staff to create, access, use, and disclose my PHI for the purposes described below.

Protected Health Information that may be used and shared includes:

- Information that identifies you such as date of birth
- Information that relates to your health or medical condition from your medical records
- Information obtained from the study procedures outlined in this consent form, for example: things done to see if you can join the study such as physical exams and any other medical information we learn from you about your health history and family history
- Interviews conducted with you by members of the research team

The researchers may use and share my protected health information with:

- The Principal Investigator, other Investigators, Study Coordinators, and all administrative staff in charge of doing work for the study;
- Government agencies that have the right to see or review your PHI including, but not limited to, the Office of Human Research Protections, the Food and Drug Administration; and the Department of Defense;
- Children's National Health System ethics board;
- Audit Committee of the Children's National Health System ethics board;

In addition to the above people and organizations, the researchers may also use and share my protected health information with:

- Doctors and staff at other places that are participating in the study.
- The Sponsor of the study and people that the Sponsor may contract with for the study. The study was funded by a grant from the US Department of Defense.
- Members of the Coordinating Center.

Should your health information be disclosed to anyone outside of the study, your information may no longer be protected by HIPAA and this Authorization. However, the use of your health information will still be regulated by applicable federal and state laws.

Storage of PHI in a Database:

We would like to store personal health information collected from you in this study in a database for future research. The database is maintained by the Coordinating Center located at Children's National Medical Center

Please indicate your approval of any or all of the following by initialing next to the statement:

1. My personal health information may be stored in the above named database for future analysis related to this study.	☐ Yes ☐ No	_____ Initials
2. My personal health information may be stored in the above named database for future analysis related to NF1.	☐ Yes ☐ No	_____ Initials
3. My personal health information may be stored without any of my identifying information for use in other studies of other diseases.	☐ Yes ☐ No	_____ Initials

If you agree to participate in this research study, the research team, the research sponsor (when applicable) and the sponsor's representatives may use Personally Unidentified Study Data. The Personally Unidentified Study Data does not include your name. Instead, the researcher assigns a code to the Personally Unidentified Study Data. Personally Unidentified Study Data may include your date of birth, initials, and dates you received medical care. Personally Unidentified Study Data may also include the health information used, created, or collected in the research study. The research team or the research sponsor may share the Personally Unidentified Study Data with others to perform additional research, place it into research databases, share it with researchers in the U.S. or other countries, or use it to improve the design of future studies. They may also publish it in scientific journals, or share it with business partners of the sponsor and to file applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

You do not have to sign this Consent/Authorization. If you decide not to sign the Authorization, you will not be allowed to participate in the research study.

After signing the Consent/Authorization, you can change your mind and revoke this Authorization.

- If you revoke the Authorization, you will send a written letter to the Principal Investigator to inform her of your decision.

  Kristina K. Hardy, PhD (202) 476-2514

- If you revoke this Authorization, researchers may only use and disclose the PHI that was collected for this research study before you revoked the Authorization.
- If you revoke this Authorization, your PHI may still be used and disclosed if you should have an adverse event (unexpected side effect).
- If you change your mind and withdraw the Authorization, you will not be allowed to participate in the study

Whom can I call if I have questions about this research study?

We want you to ask questions about any part of this research study at any time,

- For questions about the study or the information in this informed consent/parental permission document, call the Principal Investigator, Kristina K. Hardy, PhD, at (202) 476-2514

Whom can I call if I have questions or concerns about my rights as a research study participant?

The Children's National Office for the Protection of Human Subjects is available to talk with you about:

- Your rights as a research participant
- Your concerns about the research
- A complaint about the research

This is the administration office for the Institutional Review Board, which is a group of doctors, nurses, and non-medical people who review research studies for safety and the protection of people who participate in research. You can call the Office for the Protection of Human Subjects at 301-565-8447.

Children's National has a research participant and family advocate. The advocate is here to answer your questions or concerns about taking part in this research. The advocate does not work for the doctors who are doing this research and is not paid by the researchers. The advocate is here only to help and protect you during any research.

You may contact the research advocate at any time. This can be done before you decide to take part in the research, during the study, or even after you finish the study. You can contact the research advocate at 202-476-5586 or by email at RSA@childrensnational.org. In urgent situations the research advocate and pediatric ethics program team can be reached at the pager number: 202-259-2082.

CONSENT/PARENTAL PERMISSION:

- I am the study participant or I am authorized to act on behalf of the participant.
- I have read this consent form or had it read to me.
- I have been invited to take part in a research study. I was told why the research is being done and how long my participation in the study is expected

to last. I was told about what will happen in the study and if there are any procedures or drugs that are experimental.

- I was told that taking part in this research is voluntary. I also was told that I can decide not to take part or stop being in it at any time without any penalty to me or any change to the quality of care I receive at Children's National.
- I was told about the risks and possible discomforts of taking part in this research study. I was also informed if there are any possible benefits to me if I am in this study.
- I have been given the chance to ask questions about the study, and my questions have been answered. If I have questions later, I can ask one of the people listed in this form.
- I agree to take part in this research study.
- I will receive a copy of this Informed Consent/Parental Permission form to keep.

Signature of Parent(s)/Guardian for participant under the age of 18 years

Printed Name of Participant: _____

Printed Name of Parent/Guardian: _____

Signature of Parent/Guardian: _____

Date: _____

AFFIDAVIT OF PERSON OBTAINING CONSENT / PARENTAL PERMISSION:

I certify that I have explained to the above individual(s) the nature and purpose of the study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised.

Printed Name of Person Obtaining Consent: _____

Research Role: _____

Signature: _____

Date: _____

AFFIDAVIT OF PERSON OBTAINING ASSENT FROM A 7-11 YEAR-OLD CHILD:

I have explained all aspects of the research study to the child participant to the best of his/her ability to understand.

I have answered all of the child participant's questions relating to the research study.

I believe the child participant's decision to enroll is voluntary.

The study doctors and study staff agree to respect the child participant's physical or emotional dissent at any time during this research study when that dissent pertains to anything being done solely for the purpose of the research.

Printed Name of Person Obtaining Assent: _____

Title: _____

Signature: _____

Date: _____