Official Title:	Scaling Up Science-based Mental Health Interventions in Latin America (DIADA)
NCT number:	NCT03392883
Document Type:	Informed Consent Form (Patient)
Date of the Document:	May 3, 2019

CONSENT TO PARTICIPATE IN RESEARCH – PATIENT FORM

Study Title: Scaling Up Science-based Mental Health Interventions in Latin America

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Introduction: You are being asked to take part in a research study. Your participation is completely voluntary.

You are being asked to take part in this study because you have shown symptoms of depression and/or problematic alcohol use at a visit to your medical provider.

Taking part in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information to help patients in the future. And you may also experience benefits of research participation, as described below.

Your decision to participate in this study will not affect your ability to receive treatment at [name of clinic inserted here]. You may say "no" to answering any questions. If you agree to participate, you may stop being a participant in the study at any time without affecting your treatment at [name of clinic inserted here].

Before you decide to be in this study, please read the following information carefully. Feel free to ask your provider or a member of the research team about what being in the study means. Please ask questions if there is anything about this study you do not understand.

What is the purpose of this study?

The purpose of this study is to test a new way to offer care for depression and problematic alcohol use to patients in primary care health care systems in Colombia. This study will be conducted in multiple health care systems in urban, semi-urban, and rural areas of Colombia. We expect to enroll approximately 2,000 people in this study across all participating health care sites in Colombia.

Will you benefit from participating in this study?

Being a participant in the study may help you change your depression and/or problematic alcohol use and may improve your quality of life and your health. Being in the study and sharing information with us will also help us learn more about effective ways to offer care for depression and problematic alcohol use to patients in primary care health care systems.

We hope to gather information that may help people like you in the future.

What does this study involve?

Your participation in this study may last up to one year. We will ask you to come to the clinic five times to answer questions for research purposes during the next 12 months.

Some participants in this study may have depression, others may have problematic alcohol use, and others may have problems with both depression and alcohol use. This was determined in your communications with your medical provider earlier today or at a previous appointment. If you agree to participate in this study, you will be offered a new treatment for your depression and/or problematic alcohol use. All participants in the research study will receive this same model of treatment.Your providers at this health care site have received training on effective ways to care for depression and problematic alcohol use. Some components of this care will be provided to you from your medical provider outside the context of this research and may include additional visits, referral to specialty care for depression and/or problematic alcohol use, or medications. These additional components are not considered part of this research study.

The research portion of this treatment will involve access to a computer-based program called Laddr. Laddr helps you learn new skills and strategies you can use to help change your depression and/or problematic alcohol use. The skills and content offered in this program have been shown to be effective in prior scientific research. You will be asked to use Laddr outside of your medical appointments to help you make these changes.

This computer program is web-based, which means you can access it anytime and anywhere on your smartphone. If you do not have a smartphone, you can access it on any computer or tablet that has Internet access. Your health care site can also provide access to this web-based program on one or more computers located at the health care facility if you do not have access at home.

You will be asked to answer questions to help us better understand how helpful this treatment is. You will be asked questions about your depression symptoms, alcohol use, quality of life and overall functioning. You may also be asked to provide feedback on the care you are receiving for your depression and/or alcohol use.

You will be asked to answer these questions on a computer (or on paper if a computer is not available). You will be asked to answer these questions at the time you first join the study and every 3 months thereafter for 12 months (or as long as the study is being conducted at your health care site). So, we expect that you will be asked to answer these questions a total of 5 times during the next 12 months. It should take about 60 minutes to complete these questions each time you are asked to complete them.

We may also obtain information from your medical record at your health care program, including your frequency of visits to the health care program and your clinical status on depression and/or alcohol use (as documented by your health care team). We will also obtain the answers from some screening forms you completed that identified your depression or alcohol use symptoms.

You will also be asked to periodically meet with your health care provider so they can continue to monitor your care and your clinical status. These visits will be part of your regular clinical care, but are not considered part of this research.

What are the options if you do not want to take part in this study?

You do not have to participate in this study. If you elect not to participate in this study, you will receive care as usual from your health care provider.

If you take part in this study, what activities will be done only for research purposes?

If you take part in this study, the answers that you provide to the questions mentioned above will be collected for research purposes only. We will also collect data from your use of the Laddr program. Any other treatment you receive as part of the program will be provided for your benefit through your provider and will not be considered part of the research study. Your visits to your health care provider will continue to be paid for by your insurance carrier.

What are the risks involved with taking part in this study?

There are no anticipated physical, social or economic risks associated with participation. However, you may find some of the questions uncomfortable, and one of the questionnaires does ask about any illicit drug use (please see the section on confidentiality for details on how we will keep this information private and secure). You do not have to answer any questions that make you feel uncomfortable. You may also experience possible fatigue and frustration in discussing sensitive and/or personal information. You should understand that you can choose to not answer a question. And you can choose to discontinue your participation in the study at any time without loss of benefits to which you are otherwise entitled.

You may also feel concerned about using the Laddr web-based program on your smartphone because another person may see you using it. You should understand that you can choose to use the program at a time of your choosing. Also, the name of the program is intentionally vague and does not directly refer to depression or alcohol use.

You may also find that some of the topics that Laddr addresses, including depression and/or alcohol use, may be sensitive topics and you may be uncomfortable with some of this content. It is also possible that you may find that this content does not help you. You should understand that the components of Laddr have been shown to be effective in prior scientific research. And you can choose to discontinue your participation in the study at any time without loss of benefits to which you are otherwise entitled.

If at any time during this study you have any concerns or if you experience any worsening of symptoms or any problems from using the Laddr program, you can choose to discontinue participation. You can also contact your doctor and the research directors for this study, Dr. Sergio Castro, at 320-8320 ext. 2812 or by email at sergiomariocastro@gmail.com and/or Dr. Magda Cepeda at 57-301-362-1356 or by email at mccepedag@gmail.com.

There is a small chance that your private information may be seen by people who are not members of the research team (individuals who are conducting or who oversee the research). We do everything we can to safeguard your information. We describe our efforts to protect your information in the section below called, “How will your privacy be protected?”.

Other important items you should know:

• **Leaving the study:** You will have the freedom to withdraw or leave the study at any time, without any penalty and without affecting your relationship with the health center. If you become suicidal or

otherwise require a higher level of treatment than this research or model of care can reasonably and safely provide, your participation in this research will be terminated.

If you choose to stop participating in the study, you will no longer have access to the Laddr computer-based program. If you choose to stop taking part in this study, you may cancel permission for the use of your research information. You should let your provider or a member of the research team know if you want to cancel your permission. The research team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

• **New Information:** New information related to this research will be made known to you when it becomes available. This may affect your decision to stay in this study.

• **Funding:** The U.S. National Institute of Mental Health at the National Institutes of Health is the sponsor of this research.

One of the Principal Investigators of this project (Dr. Marsch) has an affiliation with Square2 Systems, Inc., the company that developed the Laddr mobile intervention. Dr. Marsch's affiliation with this company is extensively managed by her academic institution, Dartmouth College in the U.S.

How will your privacy be protected?

The information collected as data for this study includes information on your depression and/or alcohol use problems, the treatment you receive for those problems, your use of the Laddr program, and questions that help us understand the helpfulness of this new model of care (mentioned above).

We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential, except as ruled by law (such as if you express suicidal intent, intent to physically harm another person or indicate that someone is physically harming you) .

Your name will never appear in documents, publications, or presentations that come out of the study. The information will be used only for scientific purposes by the persons responsible for this research and will never be shared with your name or other details that may identify you.

The persons responsible for this research include a team of researchers at Javeriana University, Dartmouth College in the U.S., and the National Institute of Mental Health in the U.S.

We will keep all information you give us in our secure, encrypted databases under a study number, not your name. The name-number code will also be kept secure so that no one outside of the research team can find out how you answered the questions. We will NOT disclose the information you provide to anyone outside the research team.

Your information will be transferred in encrypted form to the researchers at Javeriana University. This information will not include your name, and will be sent via secure electronic data transfer to protect your privacy.

The data collected during the study will be stored at Javeriana University data servers. The Direction of Information Technology at Javeriana University complies with all national and international safety

standards for data protection including assistance in security informatics related to research projects. The procedures of the Direction of Information Technology are available at: http://www.javeriana.edu.co/dir-tecnologias-de-informacion/asistencia-de-seguridad-informatica. The protection of personal data collected in this project will follow the Colombian regulation laws on data protection: Law 1581 of 2012 and the regulation 1377 of 2013. The information collected for this study will be used only for the purposes of research as stated earlier in this form.

There may be other times when we cannot keep your information private. If we determine that you or someone else is in danger, we will tell someone who can help. If we think that a child or adult who cannot care for themselves is being exploited, abused, or neglected, we will tell someone who can help.

This study is reviewed by groups that are dedicated to the safety of the participants in research studies and also to ensure the study is being conducted correctly. These groups are permitted review of private information (if needed). In this study, those groups or agencies are:

- Javeriana University's Institutional Review Board
- Dartmouth College Committee for the Protection of Human Subjects
- U.S. National Institute of Mental Health's Data and Safety Monitoring Board

Who may use or see your health information?

By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study. You also permit any health care provider holding health information needed for this study to give copies of your information to the research team.

The information collected for this study may be used by researchers or officials of the following institutions:

- Javeriana University
- Dartmouth College
- U.S. National Institute on Mental Health
- Data and Safety Monitoring board overseeing the conduct of this study

Some of the information used in this study, called Protected Health Information ("PHI"), is protected by federal privacy laws in the U.S. By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. Your permission to use your health information for this study will not end until the study is completed.

To help us keep your information private, we will request a special certificate called a Certificate of Confidentiality (COC). The COC comes from the National Institutes of Health in the United States (U.S.) and can be used to legally refuse to disclose information that may identify you in any proceedings of the U.S. government (federal, state, or civil, criminal, administrative, legislative, or other proceedings). We will use the COC to further help keep your information private. A Certificate of Confidentiality only protects data stored in the United States.

Data Sharing: Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health to collect and share deidentified information with each other.

A data repository is a large electronic database where information from many studies is stored and managed. Deidentified information means that name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental health more quickly than before.

During and after the study, the researchers will send deidentified information about your health and behavior to NDA via secure electronic data transfer. Other researchers in the U.S. can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults with mental health challenges so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who are conducting this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available online at http://data-archive.nimh.gov.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your health information for this study, you may not take part in this study.

If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

Whom should you call about this study?

If you have questions about this study or need to report a study related injury, you can call your doctor or the research directors for this study: Dr. Sergio Castro at 320-8320 ext. 2812 or sergiomariocastro@gmail.com and/or Dr. Magda Cepeda at 57-301-362-1356 or by email at mccepedag@gmail.com.

If neither Dr. Castro nor Dr. Cepeda are available, other members of the research team will be available to answer your questions during normal business hours at 320-8320 ext. 2827.

If you have questions, concerns, complaints, or suggestions about human research at Javeriana, you may call the Institutional Review Board at 571 5946161 Ext 2741 or +571 2879227 during normal business hours.

What about the costs of this study?

There is no cost to you for participating in this study. You will not have to pay to access the Laddr web-based program. And, as stated above, your visits to your health care provider will continue to be paid for by your insurance carrier. Insurance companies will not be billed for any research activities.

Will you be paid to take part in this study?

You will not be provided any additional compensation for participating in this study.

What happens if you get sick or hurt from taking part in this study?

This study is being conducted by researchers at Javeriana University and Dartmouth College (U.S.) with funds from the U.S. National Institute of Mental Health at the National Institutes of Health. The researchers do not anticipate that you will get sick or hurt from taking part in this study, as none of the research being conducted is considered harmful to you.

If you are injured or become ill as a result of research procedures, you will be provided with medical treatment but the following organizations do not plan to pay for this treatment:

- Your health care clinic
- U.S. National Institute of Mental Health
- Javeriana University
- Dartmouth College

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

SIGNATURE OF INFORMED CONSENT

I have read the above information about "Scaling Up Science-based Mental Health Interventions in Latin America" and have been given time to ask questions. I agree to take part in this study and I will be given a copy of this consent form.

_____

Participant's Signature and Date / PRINTED NAME

_____

Researcher or Designee Signature and Date / PRINTED NAME

Witness Signature and Date	/	PRINTED NAME
Witness Relationship to Participant	/	Witness Address