RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Activity and Recreation in Communities for Health (ARCH)

Sponsor(s): National Institutes of Health (NIMHD)

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent (permission) form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to compare two outreach programs that are designed to help people reduce symptoms of depression and meet any exercise or weight loss goals they may have. One outreach program focuses on connecting people to healthcare services and providing social support, and the other focuses on encouraging people to engage in rewarding activities thought to help reduce depression.

If you agree to participate in this study, your participation may last up to 4.5 months, and you

will be asked to complete three brief study visits. During these visits, you will be asked to answer questions about your symptoms of depression, have your height and weight measured, and wear a small physical activity monitor on your waist for 7 days. You will also be asked to complete some surveys about your background, your mental and physical health, and the kinds of activities you like to do.

There are risks to you for participating in this study. In this study, there is a risk that your study information or identity may be seen or used by someone other than the investigators working on this study, but we will do our best to prevent this from happening. Also, some of the survey questions you will be asked to complete may make you uncomfortable. If this happens, you can skip these questions.

You may benefit from taking part in this study. Based on experience with the kinds of outreach programs we are testing, researchers believe it nay help people reduce their symptoms of depression, and for those interested in doing so, become more physically active or lose weight. Both of the programs are expected to help people like you, but researchers do not know if one approach is better than the other. Because individuals respond differently to therapy, no one can know in advance if it will be helpful for you.

There are other options available to you if you decide not to participate in this study. You may choose another form of treatment or care for your symptoms of depression, or for weight loss if you are interested in losing weight, without being in a study. Other treatments for depression include medications, psychotherapies, and even regular exercise. Existing treatments for weight loss include behavioral programs, medications, and weight loss surgeries. Talk to your health care provider if you would like to try a different treatment for symptoms of depression or weight loss outside of this study.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?

You are being asked to participate in this study because you have reported that you have elevated symptoms of depression, and are interested in being more physically active, losing weight, or both.

How many participants will take part in this study?

About 102 participants are expected to take part in this study.

What are the activities you will be doing if you participate in this study?

If you agree to be in this study, you will be asked to complete the following activities at three study visits, which will happen at the beginning, month 2, and month 4 of the study:

- Have your height, weight, and distance around your waist measured
- Wear an activity monitor for 7 days
- Complete questionnaires about your physical and mental health, your background, and the kinds of activities you do

During the study, you will be randomly assigned to either a referral-focused outreach program, or an activity-focused outreach program. Participants are twice as likely to be assigned to the activity-focused program; that is, two people will be assigned to the activity-focused program for every one person assigned to the referral-focused program. In both programs, you will receive regular phone calls from an outreach worker at Equal Hope, an organization that is partnering with us on this study. The outreach worker will ask you questions about symptoms of depression, your medical care, and any unmet social needs you may have (e.g., needs for housing or food assistance). You will also be asked about your interest in losing weight or increasing your physical activity level.

People who are randomly assigned to the referral-focused outreach program will:

- Be connected to healthcare providers and community resources that can address any needs they may have, including treatment for symptoms of depression. But, any care you receive is NOT part of this study.
- Receive support during calls from the outreach worker, which will happen at least every three weeks

People who are randomly assigned to the referral-focused outreach program will:

- Be able to meet with an outreach worker in person (if they choose), either at their home or in community locations such as recreation centers or libraries
- Receive guidance and support on finding rewarding activities that can help reduce depression

Will your information be used for research in the future?

Information collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, you will not be asked for additional consent.

Will you be contacted about participating in future research?

If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?

Side effects, risks, and/or discomforts from participation in this study may include:

- Loss of confidentiality. It is possible that people other than the investigators will obtain your medical information, but precautions will be taken to prevent this from happening.

- Injuries from exercise. When people become more physically active, there is a risk that they can injure themselves. In very rare circumstances, people can have a heart attack or stroke when they begin exercising.
- There may be other risks that may happen that we cannot predict.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Can you leave or be removed from this 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 leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps. The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

Please note that the following section, "What about confidentiality of your medical information?", is required in this consent/authorization form. Although we will not access your medical records in this study, the following section describes the information that we will collect about you, which may include information that can identify you. It also explains how that information will be used and protected in this study.

What about confidentiality of your medical information?
This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold (keep back) or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Appelhans, his study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information (the personal information we collect about you) that identifies you for the study described in this document.

During the study, Dr. Appelhans and his study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. The health information that Rush may use or disclose for this research includes:

- Your mental health history and current symptoms
- Your height and weight measurements

Dr. Appelhans and his study team may share your health information with people outside of Rush who assist with the conduct and review of this study. The people who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- To the Researchers at Equal Hope and University of California at San Diego
- The study Sponsor, the National Institutes of Health
- Advarra Participants Payment System

While you participate in the study you will have access to your medical record, but Dr. Appelhans is not required to release study information to you that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Appelhans at 1700 W. Van Buren St., Suite 470, Chicago, IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety (the entire time) of this research study. It will expire when the study is completed or if you revoke (take back) the authorization. If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. Your identity will be separated from your medical information. All of the information you provide will be coded with a numeric identifier to protect your identity.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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. This research study can be found by searching for the following Clinical Trial Registry Number (NCT#): NCT06093282

Certificate of Confidentiality

To help us protect you and the information we will be collecting from you, this study has obtained a Certificate of Confidentiality by the U.S. government. This Certificate means that researchers cannot be forced, even by courts or the police, to disclose any information about you. The Certificate does not stop you from disclosing, or agreeing in writing to allow researchers to disclose, information about you. For example, if you would like an employer or insurer to know something about you that is documented in this study, you can write and sign a statement telling the researchers it is okay to give your employer or insurance company information.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research participants;
(4) for the purpose of auditing or program evaluation by the government or funding agency

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. Please contact the investigator for more information on how to provide this consent.

If you tell us about actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (such as the Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

What are the costs to participate in this study?

All costs for the required study visits, and the outreach programs that you will participate in, will be paid for by the National Institutes of Health (NIH). The following are some of the items and services that will be provided to you free of charge by the NIH: treatment for depression provided by your outreach worker, and screening and referrals for any medical, mental health, or social needs you may have.

As part of the outreach programs, you may be connected with different resources in your community. The types of resources you hear about will be based on your needs. For example, your outreach worker may connect you to recreational centers, food pantries, healthcare centers, or people who provide legal or financial advice. You do not have to use any of these resources, and most of them are free or low cost. However, if you choose to use a resource, you would be responsible for any costs associated with them.

Your outreach worker may encourage you to participate in programs at recreational centers, recreational activities that you can do on your own. The study will provide some funds for these activities. However, you would have to pay for any expenses beyond that covered by the money that is provided to you as part of this study.

You or your insurance will be responsible for paying for the cost of any routine medical care that you would receive whether you participate in this study or not, unless you are told that such item or service will be supplied at no cost.

Will you be paid for your participation in this study?

Yes, you will be paid for some of the activities you do in this study. As mentioned above, all participants will receive $200 that can be used to pay for programs at recreational centers, and another $200 to pay for recreational activities that you can do on your own (for example, buying art supplies, gardening tools, puzzles, etc). Participants who are randomly assigned to one outreach program will receive these funds soon after they begin the study. Participants who are randomly assigned to the other outreach program will receive these funds at the end of the 4-month outreach program.

In addition to the money you will get for recreational activities, you will also be paid $100 at each of the three study visits. These visits occur at the beginning of the study, after 2 months, and after 4 months. At each visit, you will wear a physical activity monitor for 7 days. You will receive the $100 payment when we receive the activity monitor back from you. All payments will be provided using a preloaded Visa debit card through Advarra Participants Payment Solution that you can use at almost any store or business, just like a debit card you would get from a bank. If you do not finish this study, you will be paid for the study visits you have completed. You will be paid the same day that you return the physical activity monitor, but occasionally, this payment could take a few extra days in unforeseen circumstances (e.g., electronic payment systems are not working, etc). We may need to collect your social security number or Taxpayer Identification Number (TIN) in order to pay you and for tax reporting purposes to the United States Internal Revenue Service (IRS).

What if you are injured as a result of your participation in this study?

If you get ill or injured from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Appelhans at telephone number 312-942-3477.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.
By signing this form, you are not giving up any legal rights to seek compensation of injury.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Dr. Brad Appelhans at 312-942-3477, or email him at brad_appelhans@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Appelhans in writing at the address on the first page. Dr. Appelhans may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT:
By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

_____
Name of Participant

_____ _____
Signature of Participant Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

_____
Name of Individual Obtaining Consent

_____ _____
Signature of Individual Obtaining Consent Date of Signature