Informed Consent to Participate in a Research Study

Art Intervention: A community-based study of the impact of visual art on the cognitive and other aspects of healthy aging

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Marshall University IRB

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Key Information

You are invited to participate in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You may or may not receive any benefit from being part of the study. One of the potential benefits is improvements in some aspects of health and well-being by engaging in visual art activities in the workshop provided in this study. However, the effectiveness of this workshop for enhancing health has not been evaluated scientifically, and assessing it is the main purpose of this study. In addition, even if it is found effective in general, some individuals may not benefit from this workshop. Your participation is voluntary. Please take your time to make your decision, and ask your research investigators or research staff to explain any words or information that you do not understand. The following is a short summary to help you decide why you may or may not want to be a part of this study. Information that is more detailed is listed later on in this form.

The purpose of the study is to assess the effectiveness of our multiweek visual art workshop named "Life Bouquet" for promoting multiple areas of health and well-being. You will be asked to participate in this art workshop and complete four sets of assessments related to different areas of health and well-being. We expect that you will be in this research study for a total of eight to ten months. However, you will not need to be actively involved in this study for the whole period. More specifically, you will be asked to (1) participate in eight weekly or biweekly workshop sessions for approximately two months and (2) receive four sets of assessments that will be conducted approximately bimonthly and will typically take 30 to 60 minutes to complete each set. The primary risk of participation is possibly having some uncomfortable experiences due to interacting with other participants in the workshop or doing new activities particularly if you do not have previous experience creating visual art products. However, we expect that such experiences will be similar to those one would encounter in their daily life.

How Many People Will Take Part In The Study?

About 60-70 people (at two senior centers) will take part in this study. A total of 72 participants are the most that would be able to enter the study.

What Is Involved In This Research Study?

(1) The visual art workshop provided in this study will consist of eight sessions, including six workshop sessions (two hours each) in addition to introductory and concluding sessions, that will be held weekly (or biweekly if there is a holiday). In the workshop facilitated by our teaching artist (who is a Marshall University art alum), participants will engage in various activities such as creating paintings, drawings, collages, and assemblages. You will be asked to participate in this workshop at either the Barboursville Senior Center or the Ceredo Senior Wellness Center.

(2) In addition to participating in the art workshop, you will be asked to receive four sets of assessments that aim to measure levels of cognitive functioning, depressive symptoms, perceived stress, pain, social connections, and loneliness before or after you participate in the workshop. The four sets of assessments will be conducted approximately biweekly at the senior center where the workshop will be provided for you.

What about Alternative Procedures?

You have an alternative option to engage in visual art activities by yourself without participating in this study, which may have similar potential health benefits to those expected by participating in this study (though the potential benefits of such an alternative method need to be investigated in different studies). However, the workshop of this study will be facilitated by an experienced teaching artist, who will expose participants to various forms of visual art and help them learn to create art products in a structured manner. This can be considered an advantage of participating in this workshop over the alternative option.

What Are Your Rights As A Research Study Participant?

You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first.

The study investigators may stop you from taking part in this study at any time if they believe it is in your best interest; if you do not follow the study rules; or if the study is stopped.

Detailed Risks Of The Study

As mentioned above, for participating in the art workshop of this study, we expect no more than minimal risks one would encounter in their daily life. Similarly, we expect only minimal risks for completing the sets of assessments. As the assessments will

include health-related questions, you may experience some discomfort when responding to some assessment items, but such discomfort can also be experienced in everyday settings. If you have an uncomfortable experience or discomfort in any part of this study, we encourage you to communicate with our teaching artist or staff members so that we will address it to improve the situation.

What About Confidentiality?

We will do our best to make sure that your personal information is kept confidential. However, we cannot guarantee absolute confidentiality. Federal law says we must keep your study records private. Nevertheless, under unforeseen and rare circumstances, we may be required by law to allow certain agencies to view your records. Those agencies would include the Marshall University IRB (Institutional Review Board), Office of Research Integrity (ORI) and the federal Office of Human Research Protection (OHRP). This is to make sure that we are protecting your rights and your safety. In addition, if we determine that you are threatening to harm yourself or others, we will notify Emergency Medical Services and/or your emergency contact (e.g., next of kin) you are listing in your sign-up sheet in order to keep you and others safe. If we publish the information we learn from this study, you will not be identified by name or in any other way.

What Are The Costs Of Taking Part In This Study?

There are no costs to you for taking part in this study. All the study costs, including any study tests, supplies and procedures related directly to the study, will be paid for by the study.

Will You Be Paid For Participating?

You will receive no payment or other compensation for taking part in this study.

Who Is Sponsoring This Study?

This study is being sponsored by the Huntington Foundation. The sponsor is providing money or other support to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

What About Identifiable Private Information?

For privacy protection, we will use a coding system in which a unique code will be assigned to you in a way that the code will not indicate your name or any other "identifiers" or information that identifies you. The code will be used for our data collection, including assessments, and data entry without including your name or other identifiable information. The study investigator will store participant lists, including the

code and your name, and your contact information separately from the collected data (including the code but excluding your name and other identifiers) in secure locations. Thus, identifiers will be excluded from the private information collected in our assessments. The information, from which identifiers are excluded, could be used for future research studies or distributed to another investigator for future research studies without additional consent from you.

Whom Do You Call If You Have Questions Or Problems?

For questions about the study, contact the study investigator Masa Toyama at (304) 696-2777 or (304) 696-2785. In the event of a research-related injury, contact Co-Investigator/physician Cindy Pinson at (304) 638-9747 or (304) 529-7004. You should also call the investigator (Toyama) if you have a concern or complaint about the research.

For questions about your rights as a research participant, contact the Marshall University Office of Research Integrity (ORI) at (304) 696-4303. You may also call this number if:

- You have concerns or complaints about the research.
- The research staff cannot be reached.
- You want to talk to someone other than the research staff.

You will be given a signed and dated copy of this consent form.

SIGNATURES

You agree to take part in this study and confirm that you are 18 years of age or older. You have had a chance to ask questions about being in this study and have had those questions answered. By signing this consent form you are not giving up any legal rights to which you are entitled.

_____

Subject Name (Printed)

_____ _____

Subject Signature Date

_____

Person Obtaining Consent (Printed)

_____ _____

Person Obtaining Consent Signature Date

Participant's Initials _____