Informed Consent Document

A Randomized Controlled Trial of Visual Cues, Signage, and Spaced Retrieval Education within Long Term Care Communities to Assist with Wayfinding

NCT03537729
Dr. Rebecca Davis

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This research protocol has been approved by the Institutional Review Board at Grand Valley State University. Study No. 18-039-H

Research Informed Consent Form

Study Title: A Randomized Controlled Trial of Visual Cues, Signage, and Spaced-Retrieval Education within Long Term Care Communities to Assist with Wayfinding

Principal Investigator: Rebecca Davis, RN, PhD, Grand Valley State University

Other Study Investigators: Margaret Calkins, M. Arch, PhD; Jennifer Brush, MS, CCC/SLP

Study Sponsor: The National Institutes of Health, National Institutes on Aging

1. Introduction and Key Information

Key Information for You to Consider

- **Voluntary Consent. You are being asked to take part in a clinical research study.** It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose to participate or continue participation.
- **Purpose. The purpose of this study is to find out if certain types of cues (pictures, wall hangings, etc.), signs, and education can impact how well older adults find their way from one place to another within a senior community**.
- **Duration. If you choose to participate, you will be asked to meet with researchers at your community 5- 17 times for 30 minutes to an hour throughout a one year period**.
- **Risks. Risks or discomforts from this research are similar to what you may experience in your normal daily activities and include; frustration, anxiety, fatigue, or falling**
- **Benefits. There are no direct benefits to you for participating, however, you might learn to find your way more often in your community**
- **Alternatives.** Participation is voluntary, and the only alternative is not to participate.

We are looking for men and women who are 62 years or older, who want to join us in this research study. We are looking for people who sometimes have problems finding their way within the community, even if it is to places they do not go to all of the time. The participants must be able to communicate in English. Also, participants must be able to get around by themselves, with or without mobility aids such as scooters or walkers.

You may want to take part in this study if you would like to help us determine if our ideas to improve how people find their way work or not. You might not like to take part in this study if you think this study is not worthwhile.

2. Length of Your Participation

This study takes place over a period of a year. We would be asking you to meet with our researchers for about an hour six times over the year. Some participants will be asked to participate in twelve thirty-minute educational sessions in addition. The total time commitment is between 6-12 hours over the year.

3. Where the Study is Being Done and Number of People Participating

We are conducting this study in twelve senior communities, and we are planning to recruit 137 men and women. All of the study testing will occur within the senior communities in which our participants live.

4. Study Procedures

If you join the study, we will ask some questions about your health and activities and ask you to complete some memory exercises. We may ask you for permission to ask caregivers who help you about your activities or abilities. We will be assigning by chance the senior communities into one of three groups - Group 1 (control – we won't change anything within your community); Group 2 (We will add some special pictures, wall hangings, and signs to certain areas within the community) and Group 3 (Cues, Signs, and Education – the same as Group 2 but with added educational sessions). You will not know which group your community is in until after the study starts.

After the study starts, you will be asked to find your way to three places within the community five times over the year (at the beginning of the study, 1, 3, 6, and 12 months). In addition we will ask some questions about how much you get out and about. Participants in Group 3 will also be asked to be present for twelve additional education sessions. These sessions are one-on-one with our research staff members and take about 30 minutes each.

Some participants may be asked to wear a wrist band that tracks their movement within the community for five one-week sessions during the study time period. These wrist bands are similar to "fitness trackers" that many people wear. You can wear them in the shower or bath and not worry about them. They tell us how far you get out and about.

We will also ask to collect some minimal medical information about your health history, and will ask you to sign an authorization to allow us to have access to this information. You may still participate in the study if you do not wish to share this information.

5. Possible Risks or Side Effects of Taking Part in this Study

This study has very few risks, similar to what you would have in your normal daily events. You might have some frustration or anxiety if you feel you cannot find your way. But we will be with you the whole time, and will help you find your way back. There is also a chance that while finding your way, you might get tired; but we want you to take rest periods whenever you need them. Finally, there is a small chance you might fall, just as there is any time you are walking. We will be walking along side you and will encourage you to stop if we feel you are not steady. We also will ask you to tell us anytime you feel you need to rest or stop for any reason.

6. Costs for Taking Part In this Study

There is no cost to be in this study.

7. Payment for Taking Part in this Study

You will receive a store gift card for $10 for each day that we ask you to find your way (at baseline, 1, 3, 6, and 12 months) in this study. In addition, we will give an extra $10 gift card at the end of the study to those who complete the year-long study. Payment will be in the form of a gift card to a local store. If you attend all of the sessions, you would receive a total of $60 in store cards. Since we are giving you a gift card, it is required that we ask you for your social security number. We will keep the social security number locked up and not share it with anyone except our business office for tax purposes if they ask for it.

If you do not wish to share your social security number, you may still receive gift cards for visits at 1, 3, 6 and 12 months of $10 each, totaling $40. GVSU requires that any person who receives payment over $49 must give their social security number due to tax purposes, but you may receive this lesser amount without giving you social security number; or you may refuse a gift card.

8. Possible Benefits to You for Taking Part in the Study

Although we cannot promise that you will gain anything from being in this study, you might learn how to find your way more often if our ideas in this study work. This study will provide some very good data about how our ideas help (or not) persons find their way from one place to another which may help others.

9. About Participating in this Study

Whether or not you take part in this study is up to you. You may stop being in this study at any time. If you decide to stop taking part in this study, this decision will not affect your medical care or any benefits that you have. If you decide to stop taking part in this study, you should tell the researcher. The researcher and/or the Sponsor may stop you from taking part in the study at any time if they decide that it is in your best interest. They may also do this if you do not follow instructions. If you have other medical problems or side effects, the researchers will decide if you may continue in the research study.

10. Sharing of Results

We will not share the results of your personal test results with you in this study. However, we will share the results of the study as a whole with you once it is done if you provide us with your residential or email address.

11. What happens if I am injured?

If you are hurt as a result of taking part in this research, the researchers will assist you to find emergency care. If you have health insurance, your insurance carrier will be billed in the ordinary manner. As with any health insurance, any costs that are not covered or are more than what is paid by your insurance will be up to you to pay. By signing this consent form, you will not giving up any legal rights. You also do not release the parties who are doing this study from liability for negligence.

12. Confidentiality of Study Records and Medical Records

Your name will not be used in any reports on this research project. We will be downloading your data into a secure, password protected computer network. The surveys and written data will have any information that says who you are removed from them. We will report this data as group data only – your name will not be attached. We will have a list of all names and codes kept in our locked file drawer in our research office. All hard copies of data will be kept locked up in a file cabinet, and we will destroy them within 7 years of end of the study.

To further protect your privacy, the National Institutes of Health has issued a Certificate of Confidentiality to the research study. Most people outside the research team will not see your name on any research forms. This includes people who try to get your information using a court order. If you agree that we can give out research information with your name on it, then that would be an exception. Other exceptions are information about child abuse or neglect and harm to yourself or others. The National Institutes of Health may also use your information for an audit or program evaluation.

The Confidentiality Certificate does not prevent you or a member of your family from sharing that you are involved in this research study.

We will keep your taking part in this research study private to the extent allowed by law. However, it is possible that other people may learn of your taking part in this study. For example, the following people or groups may inspect and copy records from this research:

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- The Grand Valley State University Human Research Review Committee *(a committee that reviews and approves research studies)* and
- The Grand Valley State University Human Subjects Protection Office
- The National Institutes of Health, the study sponsor

Some of these records could contain information that identifies who you are. We will make strong efforts to keep your identifying information in your research record private and confidential but we cannot promise for sure that we will be able to do so.

We might use your research data and in future studies. These future studies might be done by us or by other investigators. Before we use your data or samples, we will remove any information that shows your identity. There still may be a chance that someone could figure out that the information is about you.

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 the web site at any time.

13. Release of Personal Information

We will do our best to make sure that your private information is kept confidential and private to our best ability required by law. We cannot promise absolute confidentiality and privacy. Your personal information may be told to others if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

14. Names of Contacts for Questions About the Study

If you have any questions about taking part in this study, or in the event of a research related illness or injury, contact *Rebecca Davis at 616-331-3079*. If you have any questions about your rights as a research participant, you may contact: Office of Research Compliance and Integrity at Grand Valley State University, Allendale, MI Phone: 616-331-3197; e-mail: rci@gvsu.edu.

DOCUMENTATION OF INFORMED CONSENT

By signing this consent form, you certify you have read this form, you have had the chance to ask questions about this study and this form, and you have received answers that fully satisfy those questions. You are voluntarily signing this consent form as evidence of your decision to participate in this research study and you are giving authorization for release of all your private health information relative to this research.

You have been told that you may withdraw your consent in writing at any time without harming your future medical care or losing any benefits to which you might be otherwise entitled. You have been advised that the investigator in charge of this study may discontinue your participation in this study if it is felt to be in your best interest, if you do not follow the study requirements or if the study is stopped.

You will receive a signed copy of this Research Informed Consent Form.

By signing this consent form, you have not waived any of your legal rights or released the parties involved in this study from liability for negligence.

_____ _____

Signature of Study Participant Date

_____

Printed Name of Study Participant

_____ _____

Signature of Person Obtaining Informed Consent Date

_____

Printed Name of Persons Obtaining Informed Consent

Signature Block for Adult Unable to Consent

Your signature below documents your permission for the participant named below to take part in this research and to the use and disclosure of this person's protected health information. You will receive a signed copy of this complete form.

Printed name of participant

Signature of legally authorized representative | Date

Printed name of legally authorized representative | Relationship to participant

Signature of person obtaining consent | Date

Printed name of person obtaining consent

Assent

❑ Verbal Assent Obtained

Signature of person obtaining assent | Date

Printed Name of person obtaining assent

Verbal Consent

❑ Verbal Consent Obtained

Signature of person obtaining Verbal Consent | Date

Printed Name of person obtaining Verbal Consent