Title: A Mobile Informatics Solution to Aid in Memory; NCT04700540

Care Partner Consent

This consent version (V6) was IRB approved on 9/29/2023.

Consent Form

Title of Research Study: Evaluation of the Smartwatch Reminder System for People with Memory Concerns and Their Families (Phase II)

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Jude P. Mikal, PhD Investigator Departmental Affiliation: University of Minnesota, School of Public Health Phone Number: 385-212-4185 Email Address: jpmikal@umn.edu	Study Staff: Ashley Millenbah University of Minnesota, School of Public Health Phone Number: 612-626-9576 Email Address: memoryaid@umn.edu

If you choose to enroll in the study, a copy of this completed consent form will be emailed to you. This study is being conducted by: Dr. Jude Mikal at the University of Minnesota School of Public Health, Dr. Lauren Mitchell, Emmanuel College, Dr. Jessica Finlay, University of Michigan and Dr. Eric Jutkowitz, Brown University. The contact information for Dr. Mikal as well as Ashley Millenbah (Research Coordinator) are listed at the top of the consent form.

Supported By: This research is supported by the National Institutes of Health.

Key Information About This Research Study

The following is a summary to help you decide whether or not to be a part of this research study.

What is research?

The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being invited to take part in this research study?

We are asking you to take part in this research study because we are interested in learning how a new technology, the Smartwatch Reminder System, can help people with memory concerns who desire social interaction but struggle to remember names and relationships. The Smartwatch System is a wristwatch with a display connected to a smartphone, and the wristwatch can show names, photos, and information about people the person with memory concerns is physically near. We hope that the Smartwatch System can help improve the person with memory concern's social connections, communication, and quality of life. You were selected as a possible participant because you are a family care partner of someone with a memory concern. We ask that each family care partner joins the person with memory concerns to participate in this study as a pair.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this study to evaluate whether the Smartwatch System has positive benefits on persons with memory concerns' social connections, communication, and quality of life.

How long will the research last?

We expect your participation to last for about 6 months.

What will I need to do to participate?

You will be asked to verbally consent to be a part of the project today. If you decide to be a part of the study, we would ask you to complete 3 surveys over the next 6 months (one at the time of enrollment, then 3 months and 6 months later). Surveys are typically completed online, but can be sent via mail if requested.

Following the initial survey the research team will randomly assign you to a study group. If you are randomly assigned to receive the Smartwatch System (intervention group), we will schedule an appointment to help you set up the system so that you and your relative can use it over the next 6 months. If you are randomly assigned to the control group, you will receive 2 calls over the next 6 months from study staff to check in with you and the person with memory concerns. Lastly, if you are in the intervention group you and the person with memory concerns may be selected for an interview at the end of the 6-month study period. If the person with memory concerns living situation changes throughout the course of the study (such as they pass or move to a long term care or similar setting), you may continue to participate but receive shorter survey options.

Is there any way that being in this study could be bad for me?

Since the study involves no invasive procedures, we do not anticipate any physical risks to you or the person with memory concerns. There may be times you become upset with study questions prompting you to think about current and future care situations, or thinking about the person with memory concerns. If assigned to the trial of the new technology, you and your care recipient may experience stress during use of the new technology.

The potential social or legal risks for you or the person with memory concerns relate only to possible violations of confidentiality. Given our data security procedures, we believe such risks are highly unlikely (we would estimate the likelihood of these risks at 5% or under).

Will being in this study help me in any way?

We cannot promise any benefits to you or others by taking part in this research.

What happens if I do not want to be in this research?
Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Detailed Information About This Research Study

How many people will be studied?
We expect about 100 pairs of persons with memory concerns and their care partners to be in this research study.

What happens if I say "*Yes, I want to be in this research*"?
If you agree to be in this study, we would ask you to do the following things:

- Review the consent form with the University of Minnesota research staff and agree to participate in the research study (this is what we are completing now).
- If you agree to participate after we finish reviewing the details of the study, the research assistant will administer the UCSD Brief Assessment of Capacity to Consent to determine if the person with memory concerns is capable of providing consent for themselves. Those who are not able to provide consent personally will be asked to assent to participate. If either of you refuse at any time, then neither of you will be part of the study any longer.
- If you and the person with memory concerns both agree to participate after we finish reviewing the details of the study, the research assistant will send you and your relative the first surveys within two weeks. You will then be randomly assigned to receive the Smartwatch System or not.
- Approximately three and six months after the first surveys, we will send you and the person with memory concerns surveys to complete. The surveys take between 20-30 minutes to complete. A staff member will contact you and the person with memory concerns before each survey to obtain verbal assent or consent from the person with memory concerns to ensure their agreement to continuing participation.
- At the end of the six months, you and the person with memory concerns may be selected to participate in an interview so we can learn more about your experiences with the Smartwatch System. The interview may last up to one hour, and if you allow, will be recorded for data analysis.

What happens if I say "Yes", but I change my mind later?
You can leave the research study at any time and no one will be upset by your decision. It will not affect your relationship with the University of Minnesota. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting your relationship.

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?
The records of this study will be kept private. Research records will be stored securely and only researchers will have access to the records. Study data will be encrypted according to current University policy for protection of confidentiality. Audio recordings will be similarly kept private, and only Dr. Mikal, Dr. Mitchell, Dr. Finlay, Dr. Jutkowitz, and the research staff will have access to these recordings. We will erase these recordings once we have completed disseminating any scientific findings from this project, which will be in around 24 months.

The business entity responsible for designing and creating the Smartwatch System will collect some data about your use of the system, such as the frequency and duration of the use of the system, and your location when the app is in use. They will not collect any other data on your smartphone (outside of data used by the app). The collected data from the app will be shared with the University of Minnesota researchers to analyze in combination with your research records.

Organizations that may inspect and copy your information include the National Institutes of Health, and the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance. In any sort of report we might publish, we will not include any information that will make it possible to identify a participant.

Additionally, if we learn of any vulnerable adult abuse or neglect, we are required to report this information to authorities.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of

the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Whom do I contact if I have questions, concerns or feedback about my experience?
This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, contact the Research Participants' Advocate Line. Their phone number and website will be provided to you (612-625-1650; https://research.umn.edu/units/hrpp/research-participants/questions-concerns). You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Data Collected
Hard-copy data collected as part of this study will be stored in Dr. Mikal's research office at the University of Minnesota in locked file cabinets. All data collected online or entered will be stored on a secure Academic Health Center-Information Systems data server.

Except for the audio recordings which will be destroyed within 24 months of study completion, your data will be maintained for approximately 2-3 years after the study is completed. At that time, we will remove all identifiable private information collected during this research. Please note that the de-identified data collected as part of this study could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Will I have a chance to provide feedback after the study is over?
The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous. If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP.

Will I be compensated for my participation?
If you agree to take part in this research study, we will pay you up to $100 at the conclusion

of the study for your time and effort. If selected for an additional interview, you will receive an extra $50.

Please note: Compensation is for both you and your relative's participation.

Payment will be made using an Amazon gift card. This card is anonymous, so Amazon will not have any information related to your name, health status, or study in which you are participating.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 being issued to you and a copy sent to the IRS.

Do you have any questions about the study? (Only included on telephone consent form)

[Study team to write notes about any questions addressed]

Would you like to participate in the study?

_____***Yes***

_____***No***

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. I will read each statement and would like you to tell me whether you agree or disagree with each. [Research staff to select based on participant response].

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may audio record my interview to aid with data analysis.
_____	_____	I accept the use of unencrypted email as a way to communicate with the research team members. I understand that unencrypted email

communication is not secure and can be intercepted.

The following participant has provided verbal consent to participate in: Evaluation of the Smartwatch Reminder System for People with Memory Concerns and Their Families (Phase II)

_____

Printed Name of Participant

_____ _____

Signature of Study Staff Obtaining Consent Date

_____

Printed Name of Study Staff Obtaining Consent

Participant will be emailed a copy of this completed consent form to keep for their records.

Title: A Mobile Informatics Solution to Aid in Memory; NCT04700540

Person with Memory Concerns Consent

This consent version (V5) was IRB approved on 9/29/2023.

Title of Research Study: Evaluation of the Smartwatch Reminder System for People with Memory Concerns and Their Families (Phase II)

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Jude P. Mikal, PhD Investigator Departmental Affiliation: University of Minnesota, School of Public Health Phone Number: 385-212-4185 Email Address: jpmikal@umn.edu	Study Staff: Ashley Millenbah University of Minnesota, School of Public Health Phone Number: 612-625-9576 Email Address: memoryaid@umn.edu

If you choose to enroll in the study, a copy of this completed consent form will be emailed to you. This study is being conducted by: Dr. Jude Mikal at the University of Minnesota School of Public Health, Dr. Lauren Mitchell, Emmanuel College, Dr. Jessica Finlay, University of Michigan and Dr. Eric Jutkowitz, Brown University. The contact information for Dr. Mikal as well as Ashley Millenbah (Research Coordinator) are listed at the top of the consent form.

Supported By: This research is supported by the National Institutes of Health.

Key Information About This Research Study

The following is a summary to help you decide whether or not to be a part of this research study.

What is research?

The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being invited to take part in this research study?

We are asking you to take part in this research study because we are interested in learning how a new technology, the Smartwatch Reminder System, can help people with memory concerns who desire social interaction but struggle to remember names and relationships. The Smartwatch System is a wristwatch with a display connected to a smartphone, and the wristwatch can show names, photos, and information about people physically near. We hope that the Smartwatch System can help improve the persons with memory concern's social connections, communication, and quality of life. You were selected as a possible participant

because you are living with a memory concern. We ask that you participate in this study with your family care partner as a pair.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are doing this study to evaluate whether the Smartwatch System has positive benefits on persons with memory concerns' social connections, communication, and quality of life.

How long will the research last?

We expect your participation to last for six to seven months.

What will I need to do to participate?

You will be asked to verbally consent to be a part of the project today. Then, we would ask you to complete three surveys over the next six months, and you may be selected to be interviewed with your relative at the end of the six months. If you are randomly assigned to receive the Smartwatch System, we will create an appointment to help you set up the system so that you and your relative can use it over the next six months. If you are randomly assigned to the control group, you or your relative will receive about three calls over the next six months from study investigators to check in.

Is there any way that being in this study could be bad for me?

Since the study involves no invasive procedures, we do not anticipate any physical risks to you or your relative. There may be times you become upset with questions or thinking about your current and future situation. If assigned to the trial of the new technology, you and your relative may experience stress during use of the new technology. The potential social or legal risks for you or your relative relate only to possible violations of confidentiality. Given our data security procedures, we believe such risks are highly unlikely (we would estimate the likelihood of these risks at 5% or under).

Will being in this study help me in any way?

We cannot promise any benefits to you or others by taking part in this research.

What happens if I do not want to be in this research?

Participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University of Minnesota. If you decide to

participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Detailed Information About This Research Study

How many people will be studied?

We expect about 100 pairs of persons with memory concerns and their care partners to be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

If you agree to be in this study, we would ask you to do the following things:

- Review the consent form with the University of Minnesota research staff and agree to participate in the research study (this is what we are completing now).
- If either you or your relative refuse at any time, then you will no longer be part of the study.
- If you and your relative both agree to participate after we finish reviewing the details of the study, the research assistant will send you and your relative the first survey within two weeks. You will then be randomly assigned to receive the Smartwatch System or not.
- Approximately three and six months after the first survey, we will send you and your relative surveys to complete. The surveys will take about 20-30 minutes to complete.
- At the end of the six months, you and your care partner may be selected to participate in an interview so we can learn more about your experiences with the Smartwatch System. The interview may last up to one hour, and if you allow, will be recorded for data analysis.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision. It will not affect your relationship with the University of Minnesota. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting your relationship.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research?

The records of this study will be kept private. Research records will be stored securely and only researchers will have access to the records. Study data will be encrypted according to current University policy for protection of confidentiality. Audio recordings will be similarly kept private, and only Dr. Mikal, Dr. Mitchell, Dr. Finlay, Dr. Jutkowitz, and the research staff

will have access to these recordings. We will erase these recordings once we have completed disseminating any scientific findings from this project, which will be in around 24 months.

The business entity responsible for designing and creating the Smartwatch System will collect some data about your use of the system, such as the frequency and duration of the use of the system, and your location when the app is in use. They will not collect any other data on your smartphone (outside of data used by the app). The collected data from the app will be shared with the University of Minnesota researchers to analyze in combination with your research records.

Organizations that may inspect and copy your information include the National Institutes of Health, and the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance. In any sort of report we might publish, we will not include any information that will make it possible to identify a participant.

Additionally, if we learn of any vulnerable adult abuse or neglect, we are required to report this information to authorities.

Certificate of Confidentiality

To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains

your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, contact the Research Participants' Advocate Line. Their phone number and website will be provided to you (612-625-1650; https://research.umn.edu/units/hrpp/research-participants/questions-concerns). You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Data Collected

Hard-copy data collected as part of this study will be stored in Dr. Mikal's research office at the University of Minnesota in locked file cabinets. All data collected online or entered will be stored on a secure Academic Health Center-Information Systems data server.

Except for the audio recordings which will be destroyed within 24 months of study completion, your data will be maintained for approximately 2-3 years after the study is completed. At that time, we will remove all identifiable private information collected during this research. Please note that the de-identified data collected as part of this study could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous. If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you up to $100 at the conclusion of the study for your time and effort. If selected for an additional interview, you will receive an extra $50.

Please note: Compensation is for both you and your relative's participation.

Payment will be made using an Amazon gift card. This card is anonymous, so Amazon will not have any information related to your name, health status, or study in which you are participating.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 being issued to you and a copy sent to the IRS.

Do you have any questions about the study? (Only included on telephone consent form)

[Study team to write notes about any questions addressed]

Would you like to participate in the study?

_____***Yes***

_____***No***

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. I will read each statement and would like you to tell me whether you agree or disagree with each. [Research staff to select based on participant response].

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may audio record my interview to aid with data analysis.
_____	_____	I accept the use of unencrypted email as a way to communicate with the research team members. I understand that unencrypted email communication is not secure and can be intercepted.

The following participant has provided verbal consent to participate in: Evaluation of the Smartwatch Reminder System for People with Memory Concerns and Their Families (Phase

II)

_____ Printed
Name of Participant

_____ _____
Signature of Study Staff Obtaining Consent Date

_____
Printed Name of Study Staff Obtaining Consent

Participant will be emailed a copy of this completed consent form to keep for their records.

Title: A Mobile Informatics Solution to Aid in Memory; NCT04700540

Person with memory concerns assent

This assent version (V1) was IRB approved on 6/9/2022.

VERBAL ASSENT FORM

Project Title: Evaluation of the Smartwatch Reminder System for People with Memory Concerns and Their Families (Phase II)
Principal Investigator: Jude P Mikal, PhD
Supported by: National Institutes of Health

Hi, my name is _____. If you have any questions about what I am telling you, you can ask me at any time.

I want to tell you about a research study we are doing. In this study, we will test a new technology called the Smartwatch Reminder System. When family and friends come near, a smart wristwatch shows their picture, name, and how you know them. We are asking you to join because we want to know whether this technology helps people in your situation to remember the names of family and friends, and if it is helpful to your family.

If it's okay with you, we will ask you to fill out three surveys. We are randomly picking half of the people in the study to try out the new technology for six months. You might get to try out the Smartwatch Reminder System, or you might not. If you are picked to use the Smartwatch Reminder System, we might ask you and your care partner to talk with us at the end of the study in six months. During that talk, we will ask questions to learn what you liked and didn't like about the Smartwatch Reminder System. We will use an audio recording device so that we don't miss any of your helpful comments.

Dr. Jude Mikal, Dr. Lauren Mitchell, Dr. Jessica Finlay, and Dr. Eric Jutkowitz, who are researchers at the University of Minnesota, Emmanuel College, University of Michigan, and Brown University, will have access to your survey and interview information. They will analyze your information for the research study to determine whether the Smartwatch Reminder System works or not. It is important for you to know that they will remove your name, address, and any other identifying information before they analyze your information. The data collected from the app, like your location and how much you use the app, will be shared with the University of Minnesota researchers to analyze in combination with your research records.

Your care partner said it is okay for you to be in this study. You can ask any questions that you have about this study. If you have a question later that you did not think of now, you can ask us later.
You do not have to be in this study. It is totally up to you. You will still be able to have the same services from the University of Minnesota if you say no to being in this study. You can say yes now and still change your mind later. No one will be mad at you if you change your mind. All you have to do is tell me.

If you are willing to be in this study you can tell me yes, that you would like to be in the study. If you do not want to be in this study, you can tell me no, that you do not want to be in this study. Do you have any questions? Would you like to be in this study?

End of verbal script.

To be completed by person obtaining verbal assent from the participant:

Participant's response: ☐Yes to participating ☐No to participating

_____

Participant's Name (printed)

_____ _____

Signature of Study Staff Obtaining Assent Date

_____

Name of Study Staff Obtaining Assent (printed)

Participant will be mailed a copy of this completed assent form to keep for their records.