Official Trial Title
Assessing a Novel Virtual Environment That Primes Individuals Living With AD/ADRD to Accomplish Activities of Daily Living

NCT05418296

Documents Combined
Informed Consent Form Staff
Informed Consent Form Residents

Document Date
05/11/2022

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant, you have the following rights. These rights include, but are not limited to, the Participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the study and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits;
- be given opportunities to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the study may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

_____ _____

Signature Date

_____

Print Name

PARTICIPANT INFORMATION AND CONSENT FORM FOR STAFF AND AUTHORIZATION TO DISCLOSE PERSONAL INFORMATION

INTRODUCTION

The information in this form describes the research study and your role as a prospective participant in the study. It is important that you read this information. This form describes the purpose, procedures and potential benefits and risks of the study. A member of the study staff will read through this consent with you and explain all the information. Study staff will also answer your questions about the study.

This Consent Form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. When you don't have any other questions, you will then be asked if you agree to take part. If you agree to participate in this study, you will sign this Consent Form on paper or electronically.

Throughout this consent, "Participant" is referring to the resident participant.

PURPOSE AND BACKGROUND

What is the problem our researchers want to study?
We are looking at new ways to assist people in completing daily tasks collectively called 'activities of daily living' (ADLs). These include brushing teeth, taking medication, getting dressed in the morning, and preparing for bed. These tasks are essential to maintain well-being. However, as people get older, they can become challenging or tedious, confusing or stressful.

We've developed an activity game that we think can help. It's called DevaWorld, and it's played on a touchscreen tablet, such as an iPad or Galaxy. We are asking you to take part in our study to see if playing DevaWorld makes completing your Participant's ADLs easier.

By participating, you may be helping the research team to develop new ways for older adults receiving care to express their preferences in undertaking everyday activities and feel more empowered and confident to make those decisions.

Why do we think DevaWorld might work?
Playing DevaWorld can help a person prepare for their ADLs because it's a bit like rehearsing before they do it.

DevaWorld depicts a home with two rooms, a bedroom and a bathroom. It looks a bit like a cartoon, but when you tap on objects inside the home, they come to life. The friendly characters that live inside DevaWorld could do with some help with ADLs themselves. Participating residents (Participants) can have fun giving DevaWorld characters a helping hand. They can go at their own pace, step-by-step, and you, as a member of the care team, will be with them to help, if needed.

Don't worry if you've never done anything like this before – DevaWorld is primarily for people living in communities like yours, and we've won awards for making it easy to use.

What are we hoping to learn from this study?
Our company, Mentia DTx, won a grant funded by the National Institutes of Health (NIH) to advance caregiving using new technologies. This study wants to see if a DevaWorld session makes ADLs easier. We also want to learn about the feasibility of using it in assisted living settings.

GENERAL INFORMATION ABOUT THE STUDY

Why am I being asked to participate?
We've chosen this community for our study because the staff and community welcome innovative well-being projects. In our discussions with Directors, and the care team, your name came up as someone who might be interested in helping us.

It's entirely your choice to take part in the study, and you can opt-out (withdraw) at any time should you feel our study is not right for you.

STUDY PROCEDURES:

The study is split into two parts – usual care for 2 weeks, and then usual care with intervention for 6 weeks.

During the 2-week Baseline (usual care without intervention), you will do usual care activities with your Participants to establish the baseline.

At the start of Baseline you will be required to complete a number of surveys (assistance and training will be provided as needed).

Survey about the resident-Participants you care for (time to complete – about 3 minutes):

- **ADL capacity**
  Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory (ADCS-ADL) 19-item inventory to assess activities of daily living for clinical trials in Alzheimer's disease.

About you (time to complete – about 20 minutes):

- **Demographics:** Age, gender, race, ethnicity, number of years of schooling and highest degree obtained, US or foreign born; languages spoken/language preference, marital status, currently or previously the primary informal caregiver of a person with dementia
- **Job Background:** Years as a professional care staff, years working for this employer, employed full or part time.
- **Burnout:** Copenhagen Burnout Inventory.
- **Sense of Competence:** Sense of Competence in Dementia Care Staff (SCIDS).
- **Attitudes towards People with Dementia:** Approaches to Dementia Questionnaire.

- **Job Satisfaction:** Minnesota Satisfaction Questionnaire, Short-form.

<u>During the 2-week Baseline</u>

- You will be required to fill out a 3-4 minute online survey each day, for each resident-Participant, before the end of your shift. The survey asks about your resident-Participant's ADL activities and attitude that day.

DevaWorld Training (will take place at the end of Baseline)

- You will participate in a group training session to prepare you for the Study with DevaWorld (the intervention). The session will take approximately 2 hours.
- After the training session, you will complete a 5-minute interview with research staff to discuss any potential barriers to participation in, or adherence to, clinical trial requirements.

<u>During the 6-week Study</u> (with intervention)

- You will run a DevaWorld session of about a 5-minute duration, prior to the Mouth care / Teeth Cleaning ADL. You will do this twice a week for each resident on a schedule provided to you.
- You will be required to fill out a 3-4 minute online survey each day, for each resident-Participant, before the end of your shift. The survey asks about your resident-Participant's ADL activities, the DevaWorld session, and attitude that day.

<u>At the end of the 6-week Study</u>

You will be required to complete some of the surveys that you completed at the start of Baseline:

About the resident-Participant you care for (time to complete – about 3 minutes):

- **ADL capacity**
  Alzheimer's Disease Cooperative Study Activities of Daily Living Inventory (ADCS-ADL) 19-item inventory to assess activities of daily living for clinical trials in Alzheimer's disease.

About you (time to complete – about 15 minutes):

- **Burnout:** Copenhagen Burnout Inventory.
- **Sense of Competence**: Sense of Competence in Dementia Care Staff (SCIDS).
- **Attitudes towards People with Dementia:** Approaches to Dementia Questionnaire.
- **Job Satisfaction:** Minnesota Satisfaction Questionnaire, Short-form.

You will also do a 5-minute exit interview with research staff to provide other reflections and insights about your experiences during the study.

If you decide to participate in this study, the study personnel will meet with you. You will be asked to sign your consent to this consent form. You have the right to refuse completing any of the above surveys that are about you and your work; but if you do, you cannot participate in the study.

What kind of data will be collected?

- DevaWorld sessions will be recorded using the touchscreen tablet's internal camera and microphone.
- At the end of each DevaWorld session, resident-Participants will have the opportunity to indicate how they are feeling by clicking on a happy, sad, or neutral face. If needed, you can help them add comments about the session.
- You may also make some notes about the communication between you both during the session.
- The app automatically captures the time of day and duration of the session.
- Occasionally, a qualified researcher will take iPhone photos or videos of the DevaWorld session to document you and the resident playing together.

Following the DevaWorld session, you or another care team member will assist the Participant with their actual ADLs, noting changes such as ease, interest, or time taken. The researcher will compare your observations to notes from the beginning of the study ("baseline"), looking for meaningful changes.

Your name will be removed and we will assign an ID number instead so that you or sensitive information about you is hard to identify.

Who has an interest in this study?
The NIH's National Institute on Aging has funded this study to support the innovation of new approaches to dementia care. This research study is designed to test DevaWorld, a product made by Mentia. The person running this study (Principal Investigator) has an investment in Mentia, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that the person running this study could gain or lose money depending on the results of this study. The Principal Investigator has taken concrete steps to avoid possible conflicts of interest by involving independent external entities to oversee the study process and analysis of results. If you would like more information, please ask the Principal Investigator, Dr. Mandy Salomon, Ph.D.

Mentia may use information resulting from the study to develop products from which it may make a profit, and there are no plans to pay you or provide you with any products developed from this study. Also, Mentia will own all products that are developed using information from the study.

RISKS AND BENEFITS:

What are the possible risks of taking part in this study?
There are no physical risks associated with this study.

Data and personal information are protected with passwords and Internet security protocols. Any paper-based data collected is entered into a secure database, then destroyed, but there is always a slight risk that an unauthorized user could access your data (notes and observations) and personal information.

What are the possible benefits if I take part in this study?
The benefits which you may reasonably expect from your participation:

- Participants may have more interest and confidence in undertaking everyday tasks
- You may become more aware of any stresses that Participants may feel when completing ADLs
- You may have more strategies to assist Participants
- You may have less job stress by finding it easier to complete ADLs with Participants

We cannot and do not guarantee that you or the Participants will receive any direct benefits from this study. Your alternative is to not take part in this study.

Your decision whether to participate or to withdraw will not affect your employment in any way.

The data we collect from this study may help develop better ways to help people complete their daily tasks.

Are there any costs or payments if you decide to participate in the study?
There is no cost to you and there are no payments to participate in this study.

What happens afterward?
The results of this study may be presented at scientific or professional meetings or published in scientific journals. However, if the results of this study are published, your identity will not be disclosed.

If we find that some images or video include you, and that would be publicly available because it is of broader scientific interest, we will ask you if you are willing to consent to their use. We will then provide a release of media agreement for your review.

Registration of this study on clinicaltrials.gov
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.

CONFIDENTIALITY
The risk of breaching confidentiality will be minimized by using unique ID numbers and password protected, secure on-line databases. Data collected within DevaWorld is stored on Health Insurance Portability and Accountability Act (HIPAA)-compliant servers. The identification number helps assure your confidentiality. Only one master log of study participant name, address, telephone number, and study identification assignment will be maintained. This log will be stored in a locked filing cabinet separate from other identifying information on site at Mentia's office, as well as encrypted on a server.

As data capture primarily occurs through on-line DevaWorld sessions using a tablet, there is a minimization of paper copies with identifying information. Paper may be used to collect baseline, midpoint, and endpoint ADL-related data and staff survey data. Paper-based data

will be digitized and stored as above. The original papers will be destroyed by shredding 24 months after the completion of the study.

If caregiver abuse or elder abuse is disclosed or observed, it will be reported, per the State of California regulations.

AUTHORIZATION TO USE YOUR PERSONAL INFORMATION FOR RESEARCH PURPOSES

Because information about you is private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form's purpose is to tell you how your information will be used or disclosed in the study. Please read it carefully before signing it. Your information will only be used according to the authorization form and the consent form and as required or allowed by law.

How will the photos and video recording be used?
To help us understand the relationship between Participants' changing mood and their various interactions within DevaWorld, the tablet's internal camera and microphone will record voice and facial expressions. Recording only occurs while the app is open. This means that conversations occurring between you and the participant during the session will be recorded. Although the camera’s focus is on the participant, your face or part of your face may be picked up by the internal camera. This data will assist in developing a speech-emotion recognition system for future product upgrades. These recordings will not be seen publicly and your identity will not be disclosed.

Occasionally, research staff will make iPhone recordings of sessions for added insights, and education and training, you may be identifiable. If you prefer not to be recorded for these purposes or on these occasions, you may decline at the time. There are no consequences or repercussions for declining.

What is the purpose of this research study, and how will my information be used in the study?
The purpose of this study is to see if DevaWorld is accepted by Supporters and Participants and see how well it fits into daily care routines, especially noting if it improves the completion of ADLs. In addition, the study will observe the effect of DevaWorld sessions on mood and engagement. Data collected by the DevaWorld app during sessions will measure these aspects. During the study, you will fill out online and paper surveys. Your diligence with completing these surveys is critical to the study's success. At the end of the study, we will provide you with our results in a summary form. We intend to publish the results of this study in peer-reviewed journals. Any study data we use will not identify you in any way. After the study, study data and any video recordings and photos that may prove useful for further research, education or training purposes will be stored indefinitely. Mentia will hold all rights to this material. All other data and material will be deleted 24 months after the study’s conclusion.

Do I have to sign this consent/authorization form?
You do not have to sign this form. Your participation in this study is voluntary. You do not have to take part, or you may discontinue your involvement at any time without penalty or loss of benefits to which you are otherwise entitled. Whether you sign the form or not, your

employment will not be affected in any way. The only consequence of *not* signing this form is that you opt-out of participating in this research study.

If I sign this form, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your information and session recordings (and to discontinue any other participation in the study) at any time. After any revocation, your information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain the integrity of research). Session recordings already collected will be used anonymously for data analysis purposes and possibly for education and training purposes. If you wish to revoke your authorization for the research use or disclose your information in this study, you must write to Mandy Salomon, the Principal Investigator. Mandy is also Mentia's CEO.

What personal information will be obtained, used, or disclosed?
Your information related to this study may be used or disclosed in connection with this research study, including, but not limited to, your demographic information; for example, your location, DevaWorld session observations, and personal details: your age, gender, and professional background.

Any surveys you complete for this study – such as job satisfaction or attitudes about care – will remain anonymous and the results will only be presented in aggregate/summary form.

Who may use, disclose or receive the information and study records?
The following parties are authorized to use or disclose your information in connection with this research study:

- The Principal Investigator,
- Community Executive Director
- This study's Research Staff, including Mentia employees and academic consultants

These parties may disclose your information to the following persons and organizations for their use in connection with this research study:

- Government or regulatory authorities, including The U.S. Food and Drug Administration (FDA) and The Office for Human Research Protections in the U.S. Department of Health and Human Services
- National Institute on Aging, NIH
- The Sponsor, Mentia (the maker of DevaWorld)
- The Institutional Review Board (IRB) overseeing this study.

Your information may be re-disclosed by the recipients described above if they are not required by law to protect the privacy of the data.

When will my authorization expire?
Your authorization to use and disclose your information will end on August 31, 2022, or when the research project ends, whichever is later. We reserve the right to use short video clips and photos to demonstrate and support the further development of our product.

You can also revoke this authorization at any time by writing to Dr. Mandy Salomon.

WITHDRAWAL FROM STUDY

If you decide to withdraw it will impact the data we collect for this study. At a minimum, we will need to replace you on very short notice. The study data will be affected by the change. Losing any participants from the study will affect the analytical significance of our results, we calculate your input represents about one-quarter of all the data collected at the community. Please consider your availability and interest in this study before agreeing to take part.

If you wish to withdraw from the study, please inform Dr. Mandy Salomon.

Your Resident-Participant may also opt to withdraw from the study. However, due to their cognitive decline, they may find it hard to express this wish. You will use the following process to determine when that is the case: If a resident-Participant decides that they no longer want to be involved in the study, not just the DevaWorld session for the day, they will be offered DevaWorld sessions daily. After 7 consecutive days of refusals, they will be withdrawn from the study.

The Principal Investigator may also withdraw you from the study without your consent for one or more of the following reasons:

- The study is canceled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION

If you have any questions, concerns, complaints, or input to offer about this research study, its procedures, risks, and benefits, or alternative approaches, you should ask the Principal Investigator: Dr. Mandy Salomon, Mentia, Cell: nnn; Email: mmm. You should also contact her at any time if you feel you may have been hurt by being a part of this study.

If you have any general questions about your rights as a study participant, or if you would like to speak with someone not directly involved in the study, you may contact the Institutional Review Board (IRB): Ethical & Independent Review Services (E&I). You can contact them by phone at 1-800-472-3241 or by email at subject@eandireview.com. Please reference study 22053.

E&I IRB is a committee that independently reviews research with the safety, welfare, and rights of research participants in mind.

CONSENT

By signing this form, I consent to be part of this study and do not give up any of my legal rights. I authorize the use and disclosure of my protected information. The extra copy of this signed and dated consent form is for me to keep.

__ I agree to be photographed, video and audio recorded for research purposes knowing they will not identify me in any way. If you do not agree, you **cannot** take part in this study.

__ I agree that I may be asked to be photographed, video and audio recorded for education and training purposes knowing I may be identifiable. If you do not agree, you **can** still take part in this study.

_____ _____

Signature Date

_____

Print Name

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant, you have the following rights. These rights include, but are not limited to, the Participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the study, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits;
- be given opportunities to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the study may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form;
- be given the opportunity to decide to consent or not to consent without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

_____ _____
Signature Date

_____
Print Name

ONLY if applicable: The participant is unable to sign. I, as the Legally Authorized Representative (LAR), guardian or conservator of the participant, sign on behalf of the participant.

_____ _____
Signature of Guardian / Conservator / LAR Date

_____
Printed Name of Guardian / Conservator / LAR

_____
Authority to act for Participant

RESIDENT - PARTICIPANT INFORMATION AND CONSENT FORM AND AUTHORIZATION TO DISCLOSE PERSONAL INFORMATION

INTRODUCTION

The information in this form describes the research study and your role as a prospective participant in the study. It is important that you read this information. This form describes the purpose, procedures and potential benefits and risks of the study. A member of the study staff will read through this consent with you and explain all the information. Study staff will also answer your questions about the study.

Some of the people we are looking for to take part in this study may not be able to give consent because of their medical condition. Because of this, we will ask the person's authorized representative, called their Legally Authorized Representative (LAR), to give consent for them. However, throughout the consent form, "you" always refers to the "Participant," the person who takes part in the study.

This Consent Form may contain words that you do not understand. Please ask the study staff to explain any words or information that you do not clearly understand. When you don't have any other questions, you will then be asked if you agree to take part. If you agree to participate in this study, you will sign this Consent Form on paper or electronically.

PURPOSE AND BACKGROUND

What is the problem our researchers want to study?
We are looking at new ways to assist people to complete daily tasks, collectively called 'activities of daily living' (ADLs). These include brushing teeth, taking medication, getting dressed in the morning, and preparing for bed. These tasks are essential for well-being. However, as people get older, they can become challenging or tedious, confusing or stressful.

We've developed an activity game that we think can help. It's called DevaWorld, and it's played on a touchscreen tablet. We are asking you to take part in our study to see if playing DevaWorld makes completing your ADLs easier.

By participating, you may be helping the research team to develop new ways for older adults receiving care to express their preferences in undertaking everyday activities and feel more empowered and confident to make those decisions.

What is DevaWorld?
DevaWorld depicts a home with two rooms, a bedroom and a bathroom. It looks a bit like a cartoon, but when you tap on objects inside the home, they come to life. The friendly characters that live inside DevaWorld could do with a bit of help with ADLs themselves; your job is to help them. You can go at your own pace, step-by-step, and a staff member from your community will be with you to help, if needed.

Don't worry if you've never done anything like this before; DevaWorld is especially for people living in communities like yours. We've won awards for making it simple to use.

What are we hoping to learn from this study?
We want to see if a DevaWorld session makes ADLs easier to do. We also want to see what the staff member who usually helps you thinks of DevaWorld.

GENERAL INFORMATION ABOUT THE STUDY

Why am I being asked to participate?
We've chosen this community for our study because the staff and community welcome new well-being programs. In our discussion with Directors and the Wellness Team, your name came up as someone who might be interested in helping us. The Principal Investigator has reviewed your health and care records with staff and determined that you meet the eligibility criteria to participate.

It's entirely your choice to take part in the study, and you can opt-out (withdraw) at any time should you feel our study is not right for you.

STUDY PROCEDURES:

The study will last for 6 weeks. You will receive all the usual care that you receive today. In addition, twice a week you will play a DevaWorld session with your care partner. This play, an exploration of DevaWorld, will last about 5 minutes; after which your usual care activities will resume. You can decline the DevaWorld session anytime. If you do, your care partner will check in with you again in 3-5 minutes, and then again the following days. Please know that if you decline for 7 consecutive days, we will interpret that as a request to withdraw from the study. See “Withdrawal from Study” section below.

If you decide to participate in this study, the study personnel will meet with you. You will be asked to review and sign your consent to this consent form.

Before the study starts, we will add a picture of you into the DevaWorld. This picture can be one you already have or if you’d like, you or your care partner can take a new picture of you. This photo you will see on the start page of DevaWorld. You will tap on your photo to start the DevaWorld session.

You will be seated at a table in a quiet and calm place, where you will play DevaWorld sessions twice a week over six weeks. Each session takes about 5 minutes. If you don't feel like playing DevaWorld for any reason, you can take a break, or you may even decide to stop altogether. If you decide to take a break you may be asked to participate at a later time. If you decide to stop all together, please refer to the “Withdrawal from Study” section below for instruction on what to do.

What kind of data will be collected?

- Your DevaWorld sessions will be recorded using the iPad's internal camera and microphone.
- At the end of each DevaWorld session, you will have the opportunity to indicate how you are feeling by clicking on a happy, sad, or neutral face, and you can add comments about the session with or without help from your care partner.
- Your care partner may make some notes about the communication between you both during the session.
- The app automatically captures the time of day and duration of the session.
- Occasionally, a qualified researcher will take iPhone photos or videos of the DevaWorld session to document you and your care partner playing together.

Following the DevaWorld session, your care partner will assist you with actual ADLs, such as mouth care and grooming, noting any changes such as ease, interest, or time taken. Their notes will be compared to notes made at the beginning of the study, before you started your DevaWorld sessions.

Your name will be removed and we will assign an ID number instead so that you or sensitive information about you is hard to identify.

Who has an interest in this study?
The NIH's National Institute on Aging has funded this study in order to support the innovation of new approaches to dementia care. This research study is designed to test DevaWorld, a product made by Mentia. The person running this study (Principal Investigator) has an investment in Mentia, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that the person running this study could gain or lose money depending on the results of this study. The Principal Investigator has taken concrete steps to avoid possible conflicts of interest by involving independent external entities to oversee the study process and analysis of results. If you would like more information, please ask the Principal Investigator, Dr. Mandy Salomon, Ph.D.

Mentia may use information resulting from the study to develop products from which it may make a profit, and there are no plans to pay you or provide you with any products developed from this study. Also, Mentia will own all products that are developed using information from the study.

RISKS AND BENEFITS:

What are the possible risks of taking part in this study?
There are no physical risks associated with this study. Other risks are minor distresses similar to those that might accompany a typical one-to-one recreation activity, disinterest, eyestrain, being unsure about the process, and interactivity of the session.

Data and personal information are protected with passwords and Internet security protocols. Any paper-based data collected is entered into a secure database, then destroyed, but there is always a slight risk that an unauthorized user could access your data and personal information.

What are the possible benefits if I take part in this study?
The benefits which you may reasonably expect from your participation:

- You may have more interest and confidence in undertaking everyday tasks.
- Staff may become more aware of any stresses you may feel when completing your ADLs.
- Staff may have more strategies to assist you.
- You may be on a path to better health because your ADLs are easier to complete.
- You and your care partner may have greater enjoyment across the day.
- Your mood may improve, and you may feel less isolated.
- Your self-esteem may improve.
- You may improve in your communication with your environment.

We cannot and do not guarantee that you will receive any direct benefits from this study. Your alternative is to not take part in this study.

Your decision to participate or to withdraw will not affect the quality of care you receive.

The data we collect from this study may help develop better ways to help people complete their daily tasks.

Are there any costs or payments if you decide to participate in the study?
There is no cost to you and there are no payments to participate in this study.

What happens afterward?
The results of this study may be presented at scientific or professional meetings or published in scientific journals. However, if the results of this study are published, your identity will not be disclosed**.**

If we determine some images or video that include you and would be publicly available because it is of broader scientific interest, we will ask you if you are willing to consent to their use. We will then provide a release of media agreement for you (and your LAR, if applicable) to review.

After the conclusion of the 6-week study, you will no longer have access to the DevaWorld program.

Registration of this study on clinicaltrials.gov
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.

CONFIDENTIALITY

The risk of breaching confidentiality will be minimized by using unique ID numbers and password protected, secure on-line databases. Data collected within DevaWorld is stored on

Health Insurance Portability and Accountability Act (HIPAA)-compliant servers. The identification number helps assure your confidentiality. Only one master log of study participant name, address, telephone number, and study identification assignment will be maintained. This log will be stored in a locked filing cabinet separate from other identifying information on site at Mentia's office, as well as encrypted on a server.
As data capture primarily occurs through on-line DevaWorld sessions using a tablet, there is a minimization of paper copies with identifying information. Paper may be used to collect baseline, midpoint and endpoint ADL-related data and staff survey data. Paper-based data will be digitized and stored as above. The original papers will be destroyed by shredding after 24 months following the conclusion of the study

If caregiver abuse or elder abuse is disclosed or observed, it will be reported, per the State of California regulations.

WITHDRAWAL FROM STUDY

If you decide to withdraw it will impact the data we collect for this study. Due to the short duration of the study, we will not be able to replace you. The study data will be affected by the change. The number of participants is small and losing any participants from the study will affect the analytical significance of our results, as we will need to remove all their data and analyses from the study. Please consider your availability and interest in this study before agreeing to take part.

If you wish to withdraw from the study, you, or your LAR if applicable, will inform Dr. Mandy Salomon.

The Principal Investigator may also withdraw you from the study without your consent for one or more of the following reasons:

- You have declined DevaWorld sessions for 7 consecutive days.
- The study is canceled.
- Other administrative reasons.
- Unanticipated circumstances.

CONTACT INFORMATION:

If you have any questions, concerns, complaints, or input to offer about this research study, its procedures, risks, and benefits, or alternative approaches, you should ask the Principal Investigator: Dr. Mandy Salomon, Mentia, Cell: nnn; Email: mmm You should also contact her at any time if you feel you may have been hurt by being a part of this study.

If you have any general questions about your rights as a study participant, or if you would like to speak with someone not directly involved in the study, you may contact the Institutional Review Board (IRB): Ethical & Independent Review Services (E&I). You can contact them by phone at 1-800-472-3241 or by email at subject@eandireview.com. Please reference study 22053.

E&I IRB is a committee that independently reviews research with the safety, welfare, and rights of research participants in mind.

CONSENT

By signing this form, I consent to be part of this study and do not give up any of my legal rights. I authorize the use and disclosure of my protected information.

__ I agree to be photographed, video and audio recorded for research purposes knowing they will not identify me in any way. If I do not agree, I **cannot** take part in this study.

__ I agree that I may be asked to be photographed, video and audio recorded for education and training purposes knowing I may be identifiable. If you do not agree, you **can** still take part in this study.

The extra copy of this signed and dated consent form is for you to keep.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

ONLY if applicable:

The participant is unable to give consent. I, as the Legally Authorized Representative (LAR), guardian or conservator of the participant, give consent for their participation in this study.

_____ _____
Signature of Guardian / Conservator / LAR Date

_____
Printed Name of Guardian / Conservator / LAR

_____
Authority to Act for Participant

AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH PURPOSES

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the consent form and as required or allowed by law. Please read it carefully before signing it.

How will the photos and video recording be used?
To help us understand the relationship between your changing mood and your various interactions within DevaWorld, the tablet's internal camera and microphone will record voice and facial expressions during the session. Recording only occurs while the app is open. Your face or part of your face will be picked up by the internal camera. This data will assist in developing a speech-emotion recognition system for future product upgrades. These recordings will not be seen publicly and your identity will not be disclosed.

Occasionally, research staff will make iPhone recordings of sessions for added insights, and education and training. In these videos, you may be identifiable. If you prefer not to be recorded for these purposes or on these occasions, you may decline at the time.

What is the purpose of this research study, and how will my health information be utilized in the study?
This study aims to assess the ease of use and effectiveness of DevaWorld to improve the completion of ADLs. In addition, the study will observe the effect of DevaWorld sessions on mood and engagement. Video, audio recordings, and DevaWorld usage data collected during DevaWorld sessions will be used to create improvements to DevaWorld. After the study, recordings may be used for education and training purposes. At the end of the study, we will provide you with our results in a summary form. We intend to publish the results of this study in peer-reviewed journals. Any data we use will not identify you in any way.

After the study, study data and any video recordings and photos that may prove useful for further research, education or training purposes will be securely stored indefinitely; Mentia will hold all rights to this material. All other data and material will be deleted 24 months after the study’s conclusion.

Do I have to sign this consent/authorization form?
You do not have to sign this authorization form. Your participation in this study is voluntary. You do not have to take part, or you may discontinue your involvement at any time, without penalty or loss of benefits to which you are otherwise entitled.

Whether you sign the form or not, the care you receive outside of this study will not be affected.

If I sign this form, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information and session recordings (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain the integrity of research). Session recordings already collected will be used anonymously for data analysis purposes and possibly for education and training purposes. If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Mandy Salomon, CEO, Mentia.

What Personal Information Will Be Obtained, Used, or Disclosed?
Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, your health and demographic information. This includes things like your activity level, cognitive ability, location, use of DevaWorld, completion of ADLs, and personal details: your age, gender, living situation, background, and medical history.

Who may use, disclose or receive the Information and study records?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Principal Investigator
- Community Executive Director
- This study's Research Staff, including Mentia employees and academic consultants

These parties may disclose your health information to the following persons and organizations for their use in connection with this research study:

- Government or regulatory authorities, including The U.S. Food and Drug Administration (FDA) and The Office for Human Research Protections in the U.S. Department of Health and Human Services
- National Institute on Aging, NIH
- Mentia (the maker of DevaWorld)
- The Institutional Review Board (IRB) overseeing this study.

Your information may be re-disclosed by the recipients described above if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization to use and disclose your information will end on August 31, 2022, or when the research project ends, whichever is later. We reserve the right to use short video clips and photos to demonstrate and support the further development of our product.

You can also revoke this authorization at any time by writing to Mandy Salomon at email: mandy@mentia.me.

By signing this Authorization form, I am authorizing the disclosure and use of my Protected Health Information as described above.

_____ _____
Signature Date

_____
Print Name

ONLY if applicable: The participant is unable to sign. I, as the Legally Authorized Representative (LAR), guardian or conservator of the participant, sign on behalf of the participant.

_____ _____
Signature of Guardian / Conservator / LAR Date

_____
Printed Name of Guardian / Conservator / LAR

_____
Authority to Act for Participant