PARTICIPANT INFORMED CONSENT FORM

STUDY TITLE: Testing Conversational Agents as a Digital Companion

PROTOCOL NO: 5R44MH134719

STUDY INVESTIGATOR: Chantal Kerssens, PhD

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SPONSOR: Friendi.fi Corporation

KEY INFORMATION

Things you should know:

- The purpose of the study is to test a coaching program that is designed for autistic young adults.
- If you choose to participate, you will be randomized to one of two groups, like tossing a coin. In one group, the program is delivered by conversational agents together with human staff. In the other group, the program is delivered entirely by humans.
- One of the conversational agents is a tablet-based avatar for at home. The other is chat-based and works through standard short message service (SMS) texts on a mobile phone. Both are supervised by humans.
- You will be asked to complete questionnaires and surveys, participate in brief interviews and engage with the coaching program for 10 weeks.
- The program includes setting goals that you would like to reach and reviewing them with a professional coach.
- Risks or discomforts from this research include discomfort or frustration using the technology or not reaching goals.
- Potential benefits to you from participating in this study may include improved health including your mood and ability to think, improved ability to reach your goals, and feeling less lonely or isolated. You may also not experience any direct benefit as a result of participating.
- The study was designed to be entirely remote whenever possible. This means you will not be required to travel to one of the research sites. You will meet with research staff in real-time ("in-person") using telecommunication tools such as phone and video conferencing calls. Links to secure online meeting rooms will be shared by us for this project.

ABOUT THIS RESEARCH

You are being asked to participate in a research study. The study is done to answer questions that may change or improve the way we do things in the future. This consent form will give you information about the study to help you decide if you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study and may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty. It will not affect your relationship with your Health Insurance Plan or Care Providers.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test a coaching program designed for autistic young adults, and a technology that speaks naturally with people.

The technology has two user products or “agents”: One is a virtual companion, called an “Avatar”, shown on a tablet device. The avatar is an animated pet, in the form of a dog or a cat, that responds to human voice and touch. The second agent is a chatbot, called “Fara”, that works on mobile phones through standard SMS texting. Both Fara and Avatar engage in conversations and check in several times per day to chat and see how people are doing. They may encourage people to engage in healthy habits and activities that make them feel good and stay healthy and well.

The agents are available around the clock and supported by a global team of trained staff. The staff can follow conversations and tell the Avatar or Fara what to say or do. Sometimes, what the agents say is decided by software or artificial intelligence (AI), and sometimes it is decided by the staff to ensure that the agents speak with you in a sensible and pleasant manner.

We hope that in the future this technology will help many autistic people. It may also help adults without autism as conversational agents are becoming more and more common.

You were selected as a possible participant because you (1) are between 18 and 35 years old, (2) have been diagnosed with autism, and (3) hold a job, volunteer, or attend college.

This study is being conducted by Dr. Chantal Kerssens and a team of researchers. It is funded by the National Institute of Mental Health (NIMH) at the National Institutes of Health (NIH). The technology to be used in this study is provided by two companies, called care.coach and Friendi.fi.

HOW MANY PEOPLE WILL TAKE PART AND HOW LONG WILL I BE IN THE STUDY?

If you agree to participate, you will be one of 38 people aged 18 to 35, inclusive, in this study.

You will participate for 10 weeks.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, you will do the following things:

- You will sign this informed consent form using electronic procedures (for example, Adobe Sign).
- You will answer questions in the form of questionnaires using an online survey platform (for example, Qualtrics).
  - Some questionnaires will ask about your overall health and wellbeing, including your mood and ability to think, your living environment, sources of information and support, and your technology experience, comfort level, and interests.
  - Other questionnaires will ask about your personal goals, strengths, and challenges as well as the strengths and challenges in your environment.
- You will be interviewed over video conferencing software (for example, Microsoft Teams, "Teams") about how and where you like to spend your time, what is enjoyable or difficult about these places and activities, and define 3 goals for the near future that you would like to achieve in consultation with a coach. At the end, we will ask for your opinions of this interview and activity.
- We will ask about your experiences with conversational technologies and agents, and your opinions about their usefulness.
- Participants in the group using the conversational agents will see two brief video demonstrations of the agents. The avatar will be shipped to your home by care.coach and Fara will be set up on your mobile phone via a simple opt-in code texted to Friendi.fi. Active participation for a few minutes per day is expected. You are free to engage more if you want.
- Participants in the non-technology coaching group will receive paper forms and worksheets to shape and track their goals.
- After 5 weeks, you will meet with a coach to review your goals and set new ones depending on progress.
- After 10 weeks, you will fill out some of the same questionnaires that you completed at the beginning of the study. You will also participate in an exit interview about your program experience that lasts about 20 minutes.

Recordings

With your permission, we will record meeting sessions.

- Audio may be recorded using a handheld device or using the Teams video conferencing software that is developed and maintained by Microsoft Corporation (Redmond, WA).
- Video is recorded in Teams, unless your camera is turned off.

Teams has measures in place that are designed to secure recordings from accidental loss and from unauthorized access, use, alteration or disclosure. Additionally, the software settings for this project are such that the recordings comply with HIPAA, a law to protect patient and participant protected health information from unauthorized use and disclosure. All recordings will be stored in a secure cloud folder and only members of the study team will have access to them.

Audio will be transcribed and transcripts analyzed. There will be no mention of your name or other identifiable information in the transcription. The research team may use information from your recording in transcribed form rather than as an audio clip in research presentations to other academics and the public. You will never be identified by name or voice.

Recordings will be erased 7 years after publication of the findings. Transcripts will be destroyed within 10 years after completion of the study.

WHAT ARE THE RISKS OR DISCOMFORTS OF TAKING PART IN THE STUDY?

Although this is a study with minimal risk, some questions and technology interactions may cause discomfort or frustration. The research personnel and technology support staff are trained to recognize and minimize any discomfort or frustration. You can tell the research or support staff that you feel uncomfortable or do not want to answer a question. You can also tell them when you are frustrated.

Loss of confidentiality is another possible risk. Our data management and quality assurance procedures have been effective in maintaining confidentiality and all study personnel have completed training in Human Subjects Research and HIPAA standards for protecting sensitive patient health information. The technology and conversational agents meet HIPAA and industry security standards, and the avatar is regularly used for ongoing health care by patients and healthcare providers.

You may feel sad giving up the technology or program after using it. To relieve such sadness, you will be given extra time to interact with the technologies or meet with the coach. We can also let you know when there are new research opportunities with the agents and this program.

Overall, measures have been put in place to minimize the risks of participating in this research.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

This research may improve socially assistive robots and digital companions based on conversational AI.

Potential benefits to you from participating in this study may include improved health including your mood and ability to think, improved ability to reach your goals, and feeling less lonely or isolated. You may also not receive any direct benefit from taking part in this study.

WHAT FINANCIAL INTEREST DO THE RESEARCHERS HAVE?

Dr. Kerssens receives compensation from Friendi.fi. We share this information so you can decide if this affects your willingness to participate in this study. If you would like more information, please ask a member of the research team at the university involved in this study.

HOW WILL MY INFORMATION BE PROTECTED?

All efforts will be made to keep your personal information confidential. No information which could identify you will be shared in publications or presentations about this study.

All data will be collected and stored on a secure server managed by care.coach. Access to the company systems is provided on a 'named user' password-protected basis.

Other study data, such as answers to questions, opinions, and ratings will be collected in a de-identified manner by the researchers. This means that it is unclear which participant gave the responses.

We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and their research associates, the Institutional Review Board (IRB) or its designees, the NIMH or NIH, and state or federal agencies who may need to access the research records (as allowed by law). State and federal agencies may include the Office for Human Research Protections (OHRP).

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

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

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

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

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

WILL I BE PAID FOR PARTICIPATION?

As a thank you for participating, you will receive a $50.00 gift card for completing the questionnaires and interview at the beginning of the study, a $75.00 gift card after completing the consultation session in the middle of the study (at 5 weeks), and a $75.00 gift card after completing the questionnaires and interview at the end of the study (10 weeks). You will only receive payment for the parts that you complete.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study. If you are worried about any costs, such as the cost of sending and receiving text messages on your mobile phone, please let us know. We may reimburse you for those costs.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, contact the lead researcher, Chantal Kerssens, PhD, at 404-849-8323 or chantal@friendi.fi during business hours.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about this research study, please contact Sterling Institutional Review Board (IRB) Regulatory Department at 888-636-1062 (Toll-Free) or 770-690-9491 during business hours or email at info@sterlingirb.com.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. This decision will not affect the services you receive through your health care or insurance program. If you decide to withdraw, please let the research lead know by calling 404-849-8323 or by telling a member of the research or support team.

No usual care or treatment is withheld from study participants, and therefore, there is no concern over transitioning back to usual care if you end your participation in the study.

You may also be withdrawn from the study by the study investigator due to safety concerns or failure to comply with study procedures. You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

(see next page)

PARTICIPANT'S CONSENT

I have read the Participant Informed Consent Form and I agree to take part in this research study. All my questions have been answered.

I have not waived any of my legal rights by signing this document.

I will be given a signed copy of this informed consent document to keep for my records.

_____
Printed Name

_____ _____
Signature Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

CONSENT TO RECORD (choose by signing one)

Option 1: I agree that my study sessions may be recorded and that my de-identified audio information/data may be stored for further analysis in this project.

SIGNATURE _____

Option 2: I do not allow my study sessions to be recorded.

SIGNATURE _____