Work Chat: An Interactive Virtual Workday

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WORK CHAT: AN INTERACTIVE VIRTUAL WORKDAY

Consent to Participate in a Research Study

Principal Investigator:
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KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

You are invited to take part in a research study. This form contains information that will help you decide whether to join the study.

Things you should know:

- The purpose of the study is to see if a virtual reality computer program (Work Chat) can help people who have autism spectrum disorder improve their social skills.
- If you choose to participate, you will be asked to complete surveys, assessments, and to use the Work Chat program or continue services as usual.
- Risks or discomforts of your participation are: boredom completing the surveys, boredom using the computer programs, or a confidentiality breach.
- If you get to use the Work Chat program, you may improve your social skills.

Taking part in this research study is up to you. You do not have to participate in this research. If you choose to take part, you can change your mind at any time. The researcher and your teachers will not be upset or treat you any differently.

PURPOSE OF THE STUDY

Students may have a hard time keeping a job. We created a virtual reality computer program to improve social skills for students with a form of autism. We want to test the virtual reality computer program, called “Work Chat: An Interactive Virtual Workday”, to see if it helps students to become more socially skilled at work.

The **National Institute of Mental Health** funded this study.

WHO CAN PARTICIPATE IN THE STUDY?

You are being asked to participate in the study because of the following:

1) You are at least 18 years old
2) You have a diagnosis on the autism spectrum
3) You are English-speaking

INFORMATION ABOUT STUDY PARTICIPATION

If you agree to take part in this study, your participation will last about 1 year. Once we make sure you are eligible and that you agree to participate, you will be asked to complete some assessments (computer assessments and surveys) over a few days. These assessments will be done over the computer or in-person at your school.

These assessments will be about your background, employment history, your mood and feelings, autism spectrum symptoms, cognition, and other things. Some assessments will be audio and/or video recorded. In total, you might spend up to three hours completing assessments at two time-points. We will split these into different days.

Next, you will be randomized to the intervention group, where you will use the Work Chat program, or the control group, where you will receive services-as-usual at your school. Randomization will be like flipping a coin to see which group you are in.

Once your group is determined, you will use either the Work Chat program for about 6-weeks or services-as-usual for about 6 weeks.

We will then follow up with some more assessments, similar to the ones you completed before, over a one to three day period. This time, you might spend up to one and a half hours completing assessments.

Afterwards, we will follow up with you for 9 months to collect employment information. We will do this by phone or by email. This follow up should last about 10 minutes per month. At the 3-month, 6-month, and 9-month time point, we will also ask you to complete some short surveys about your mood and feelings and anxiety. After about 9 months, your participation in the study is complete.

We would also like you to know that throughout the study, teachers or other staff will provide information about you or complete surveys about you and your performance during the study. They also might provide us with your educational records, such as an Individual Education Placement (IEP) or 504 Plan. If you do not agree to this, you may not participate.

INFORMATION ABOUT STUDY RISKS AND BENEFITS

There is a rare confidentiality risk that the University of Michigan computer server system could be broken. We will tell you how we manage these risks down below. Spending 45 minutes using the virtual computer program could cause boredom. Please tell your teacher or a research staff member if you need a break. It can also be hard to sit still in order to complete the study assessments. Please let research staff know at any time if you need a break. We will also offer breaks between each assessment.

Since the computer-training program was created to improve social skills with other people, you may receive some direct benefit from participating. We hope that what we find out in this study will help us to create better training for other students or people who need to improve their social skills.

ENDING THE STUDY

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 9. “Contact Information”. If you choose to tell the researchers why you are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis it will not be possible to remove your information.

FINANCIAL INFORMATION

If you participate, you will receive:

- $25.00 for completing the Eligibility Assessments
- $25.00 for completing the Pre-Visit 1 Assessments
- $25.00 for completing the Pre-Visit 2 Assessments
- $25.00 for completing the Post-Visit 1 Assessments
- $25.00 for completing the Post-Visit 2 Assessments

You will receive $30.00 for completing the follow ups at the 3 month, 6 month, and final 9-month time period.

Students will not be paid to use the intervention. At most, you can earn up to $215 participating in the study. If you choose to no longer participate in the study, you will be paid whatever part(s) of the study you have completed.

RESEARCH FUNDING AND DISCLOSURES

The institution and investigators are receiving a grant from the National Institute of Health to support this research. Dr. Matthew Smith, the principal investigator and the person responsible for the conduct of this research study is an inventor of the Work Chat: An Interactive Virtual Work Day program. The program is sold by SIMmersion LLC and Dr. Smith has a financial interest in the program. SIMmersion LLC is a sponsor of this study. SIMmersion LLC and Dr. Smith may one day benefit financially from the results of the study. SIMmersion, LLC personnel will also have access to study data. Research can lead to new discoveries (e.g., tests, apps, software, devices). Researchers, their organizations, such as U-M, research sponsors, and other entities, including companies, may potentially benefit from the use of the discoveries or data. You will not have rights to these discoveries or any proceeds from them.

PROTECTING AND SHARING RESEARCH INFORMATION

We plan to share the results of this study with the public. We will not include any information that would identify you. We will protect your privacy by completing all research visits in a private or semi-private research room. To keep this information safe, the researchers will enter research data on a computer protected by a password. To protect your confidentiality, your name will not be in any written or published materials. Research data will be stored with an ID number. All research records that are reviewed, stored, and analyzed will be kept in a secured area at the University of Michigan School of Social Work. The researchers will keep this information for future research studies.

You will have the option to be contacted to see if you would like to share your name or other information with a news outlet or to complete an interview for a press release – this is not required to participate and is optional.

We will keep your participation in this research study confidential. However, it is possible that other people may become aware of your participation in this study. For example, the following people or groups may inspect and copy records pertaining to this research:

- The Office of Human Research Protections in the U.S. Department of Health and Human Services
- The University of Michigan Institutional Review Board
- The University of Michigan Human Subjects Protection Office
- The National Institute of Health, the study sponsor.

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private and confidential but absolute confidentially cannot be guaranteed.

A description of this study will be posted on a public website, http://ClincalTrials.gov , and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. No information that can identify you will be posted.

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means that we cannot be forced to disclose any research information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, except as described below.

As the researchers are mandatory reporters, we will report to the appropriate authorities in specific cases, such as if we learn of abuse, neglect or endangerment of any vulnerable person.

Please note 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, employer, or other person obtains your written consent to receive research information, then we will not use the Certificate to withhold that information.

More detailed information about Certificates may be found at the NIH CoC webpage: https://humansubjects.nih.gov/coc/index

We will store your data to use for future research studies as mentioned above. Your name and any other identifying information will be secured and stored separately from your research data at the School of Social Work. If you agree to be contacted for future research studies, we will keep your name and contact information until you tell us you would like it removed. Dr. Smith, the Principal Investigator, and research study team members will have access to your research data for future research studies. SIMmersion will have access to and keep your research data to improve future SIMmersion virtual interventions. Research data may be shared with other investigators but will never contain any information that could identify you.

CONTACT INFORMATION

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or another problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Matthew Smith
Email: mattjsmi@umich.edu
Telephone: 734-764-9322

Study Coordinator: Brittany Ross
Email: rossbrit@umich.edu
Telephone: 734-764-2368

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS)
2800 Plymouth Road
Building 520, Room 1169 Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933 Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111

YOUR CONSENT

Before making the decision to participate in this research you should have:

- Reviewed the information in this form
- Had the opportunity to ask any questions you may have
- Agree to have parents and/or teachers complete surveys about you
- Agree that you agree to be audio/video recorded for certain assessments
- Agree that your data will be kept for future research (if you would not like your data to be retained, you must write a letter to the Principal Investigator requesting so)

You will receive a copy of the signed and dated form to keep for yourself. You may contact the researcher or research staff if you think of a question later.

For the Participant: *By signing this consent form, I am voluntarily agreeing to participate in this research study.*

_____
Printed Name

_____ _____
Signature Date

OPTIONAL CONSENT

Optional - Consent to be contacted for Participation in Future Research

I agree to be contacted for participation in future research.

***YES*_____ *NO*_____**

Optional - Consent to be contacted for Press Release Purposes

I agree to be contacted for participation in a press or news release regarding this program.

***YES*_____ *NO*_____**

Optional - Consent for video recordings to be shared for training purposes

I agree to allow my research study video recordings to be shared with others for training purposes.

YES_____ NO_____