Letter of Information and Consent

Project Title

Naturalistic pilot study comparing the feasibility of applying a Student Senior Isolation Prevention Partnership vs. problem-solving therapy vs. waitlist control in patients suffering from late-life depression during the COVID-19 pandemic: A randomized controlled trial

Document Title

Letter of Information and Consent

Principal Investigator (PI) + Contact

Dr. Akshya Vasudev MD
Associate Professor of Psychiatry and Neuroscience
Division of Geriatric Psychiatry, Department of Psychiatry, Western University
Email: akshya.vasudev@lhsc.on.ca
Phone: 519-685-8500 ext. 75504
Address: #A2-607, Victoria Hospital, London Health Sciences Centre (LHSC)
800 Commissioners Road East,
London, ON N6A 5W9

Additional Research Staff + Contact

Study coordinator: Emily Ionson
Phone: 519-685-8500 ext. 74912
Email: emily.ionson@lhsc.on.ca

Emergency contact between the hours of 7am to 4pm:
Dr. Akshya Vasudev MD
Phone: 519-685-8500 ext. 75504
Email: akshya.vasudev@lhsc.on.ca

Emergency contact outside of business hours:
Canadian Mental Health Association (CMHA) crisis line:
519-433-2023 or 1-866-933-2023 (toll-free)
CMHA web chat: http://reachout247.ca/

1. Invitation to Participate

You are being invited to participate in this research study that aims to determine if it will be possible to compare the effectiveness of two intervention methods on reducing the negative consequences of social isolation on senior's mental health because of the coronavirus disease 2019 (COVID-19) restrictions. This study will include seniors with depression who live in the community. This letter will explain the study in detail and what you can expect if you are eligible and choose to participate in the study. This information will help you make an informed decision regarding your participation in this research.

2. Why is this study being done?

Older adults are facing an unprecedented challenge of strict COVID-19 pandemic restrictions. The disruption of usual daily routines and the social isolation imposed by public health measures place older adults at particularly great risk of anxiety and depression. As strict lockdown and social distancing measures remain in effect, accessible and effective mental health interventions are especially important to reduce the negative consequences of social isolation on their mental health. Unfortunately, it has been shown that even before the strict COVID-19 pandemic restrictions, older adults are at a higher risk of developing anxiety and depression than other age groups in the general population.

The purpose of this study is to evaluate the feasibility of comparing the Student-Senior Isolation Prevention Partnership (SSIPP) to the Problem-Solving Therapy (PST) and a waitlist control in community-dwelling older adults suffering from depression before or during the COVID-19 pandemic. Both interventions (SSIPP and PST) will be delivered by telephone. Results from this study will help inform the feasibility and design of a future large, multi-center study to compare the effect of SSIPP and PST at reducing symptoms of depression and anxiety in community-dwelling older adults.

SSIPP is a national initiative partnering health professional students to call older adults weekly during the pandemic providing social support and connection. The goal is to reduce rates of anxiety, depression, and loneliness while fostering resilience among seniors in our communities.

PST is a formal psychotherapeutic intervention that teaches community members to identify and clarify problems at hand, set clear, achievable goals, brainstorm solutions to the problem, select their preferred solution, implement this solution, and evaluate the outcomes.

3. How long will you be in this study?

If you are interested, eligible, and agree to participate in this study, you will be offered a 30-60-minute session (either SSIPP or PST) delivered by telephone weekly over 12 weeks or be put on a waitlist to later receive SSIPP or PST. It is expected that you will be in the study for 12 weeks. You will be asked to complete brief surveys when you join the study and 12 weeks after you join the study. You can complete the surveys online independently or over the telephone with one of our trained research assistants who will document your responses, if this is more comfortable for you.

4. What are the study procedures?

This study plans to recruit 45 participants with 15 participants randomized to three groups: SSIPP, PST, or waitlist control (WLC).

What happens before the study period?

Consent and Screening

Before being enrolled in this study, you will be provided with this letter in your preferred format either an electronic copy by email or a hard copy by regular mail with a return envelope. You will be asked to read this letter and a research team member will follow up with a phone call. During this call, the research team member will review this letter and answer any questions you have. If you are willing to participate, you will be directed to electronically sign this letter and submit it using a secure web platform called REDCap. After that, you will immediately be provided with the contact information form. You will be asked to fill out your contact information including your email address and phone number. A member of the research team will contact you by phone to confirm your eligibility for the study. If it is determined that you are eligible and you are interested in participating, the research team will email you a link to complete surveys in REDCap. The surveys will take about 45 minutes to complete and will be reviewed by a research team member.

If you are not comfortable with the use of technology or do not have access to a computer, you will be provided with a hard copy of this letter with a return envelope in regular mail. A follow-up call will be delivered to review this letter and answer any questions you have. Upon receipt of your signed copy of this letter in the mail a member of the research team will contact you by phone to confirm your eligibility. Once it is determined you are eligible, you will complete the surveys via telephone with one of our study team members.

Randomization

If you decide to participate and you are eligible, you will be "randomized" into one of the groups described below by using a computer program. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have a 1 in 3 chance of being placed in one of the three groups. Neither you, the study staff, nor the study doctors can choose what group you will be. You will be informed about which group you have been assigned to over the phone.

What happens during the study period?

You will be invited to complete a demographics questionnaire including age, gender, substance use history, religion and spiritual affiliation, frequency of religious practice, and previous history of mental health disorders. You will continue with your current treatment while participating in this study.

Study interventions

If you are assigned to SSIPP or PST, you will be asked to attend a 30-60 minute either SSIPP (for SSIPP) or PST (for PST) study interventions weekly over 12 weeks. Both study interventions will be delivered by telephone.

If you are assigned to the PST, you will receive the weekly telephone PST delivered by a trained healthcare professional from the Division of Geriatric Psychiatry and/or the Geriatric Mental Health Program which may include a psychologist, a social worker, a nurse, or an occupational therapist. If you are assigned to the SSIPP, you will receive weekly telephone calls from a medical student from the Schulich School of Medicine and Dentistry, Western University, to provide social support. It is important to note that medical students will not be providing you with any medical advice during these phone calls.

Study Assessments

You will be asked to complete questionnaires at week 0 when you join the study and 12 weeks after you join the study. Depending on your preference you can complete these questionnaires online or by phone with a research team member. These questionnaires will help us assessthe effect of the study interventions on anxiety, depression, and resilience. This information will be important for designing future research studies to determine how we can best provide mental health support to older adults in the community like yourself. We will also ask you demographic questions and questions about the medications you take. Your physical health status will be assessed by using a validated rating scale. The surveys will take about 45 minutes to complete.

If you are assigned to the WLC, you will select whether you would like to participate in SSIPP or PST at the end of the 12-week waiting period. You will be able to choose only one of these two interventions. No study assessment following week 12 will take place.

5. What are the risks and harms of participating in this study?

There are no known or anticipated risks or discomforts associated in participating with SSIPP and PST telephone interventions.

The questionnaires used in the study carry little risk. You may feel uncomfortable, sad, embarrassed, or anxious as some of the questions you will be invited to answer are personal. Some of the questions in this study ask about suicide and mood. You may find these questions trigger negative thoughts, feelings or emotions. If you have any concerns about your mental health, you may contact the study lead at 519-685-8500 X 75504 during business hours. If you prefer to contact the study lead by email, you can contact akshya.vasudev@lhsc.on.ca. This email will be checked regularly on weekdays between the hours of 7am to 4pm. If you experience any deterioration in your mental health or have any mental health concerns outside of business hours you should immediately contact the Canadian Mental Health Association (CMHA) crisis line at 519-433-2023 or 1-866-933-2023 (toll-free), or web chat at http://reachout247.ca/ If you are concerned for immediate risk to yourself outside of business hours and require in-person support, you should visit your local Emergency Department immediately. Any indication of a change in your overall mental health and/or risk of suicide will be reported immediately to the Principal Investigator for further clinical assessment and management. If you are considered of imminent risk you will be referred to the Centralized Emergency Psychiatry Services (CEPS) at Victoria Hospital, London Health Sciences Centre.

6. What are the benefits of participating in this study?

Your participation will help to determine if it is feasible to conduct a larger randomized controlled clinical study comparing the ability of SSIPP and PST to reduce symptoms of anxiety or depression in older adults. If you are in either the SSIPP or PST group, you may experience reductions in anxiety and depression, improved ability to cope with mental health problems.

There is also a possibility that you will receive no personal benefit from this study.

7. Can participants choose to leave the study?

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions, or withdraw from the study at any time for any reason with no effect on your future care.

If you withdraw from the study, any information that was collected before when you leave the study will still be used for the study unless you request otherwise. No new information will be collected from you. The study Principal Investigator may choose to withdraw you from the study at any time for reasons including but not limited to your safety and/or health.

If you are participating in another study currently, please inform the study coordinator right away to determine if it is appropriate for you to participate in this study.

Representatives of the Western University Health Sciences Research Ethics Board and/or the Lawson Quality Assurance Education Program may contact you or require access to your study-related records to monitor the conduct of the research team and/or for quality assurance purposes.

8. How will participants' information be kept confidential?

Your research records will be stored in a secure office for up to 15 years past the end of the study. To further protect your confidentiality, your name will be replaced with a participant ID number in the study database. The master list linking your identity and participant ID number will be stored separately and electronically for 15 years past the end of the study on a secure database called REDCap. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published. Your results will remain de-identified and will be combined with those of other participants. No information that could reveal your identity will be released to anyone except for your doctor.

Study team members may access data on REDCap, download this data and store the data. Any such activities will be done under the direction and supervision of the study's Principal Investigator.

The rare exception to guaranteeing confidentiality is in cases where you indicate you may harm yourself or someone else. Then we are required to disclose this information as per current law.

If you withdraw your consent, the study team will no longer collect your information for research purposes. However, the PI and/or research staff will ask you whether you agree that the data collected so far can be used. In case you do not agree, these data will not be included in any analysis. However, data usage cannot be revoked for data that has already been published, anonymized, or has been processed or reported to comply with legal and/or regulatory requirements.

For this study, we will collect your contact information which may include your full name, phone number, e-mail address, or mailing address. We will also collect a variety of demographic information including:

- Age
- Gender
- Substance use history
- Religion
- Spiritual affiliation
- Frequency of religious practice
- Previous history of mental health disorders

9. Are participants compensated to be in this study?

You will be compensated for participating in this study. If you complete the study, you will be mailed a $20 gift card at the end of the study.

10. What are the rights of participants?

Your participation in this study is voluntary. You may decide not to be in this study. Even if you consent to participate you have the right to not answer individual questions or to withdraw from the study at any time. If you choose not to participate or to leave the study at any time it will not affect your care.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

You do not waive any legal right by signing this consent form.

11. Whom do participants contact for questions?

If you have any questions about the study, please contact:

Principal Investigator:
Dr. Akshya Vasudev: 519-685-8500 ext. 75504
Or send an email to akshya.vasudev@lhsc.on.ca

(Please note that email is not an entirely secure form of communication and caution is recommended with information included to protect your privacy).

If you have any questions about your rights as a research participant or the conduct of this study, you may contact the Patient Relations Office at LHSC at (519) 685-8500 ext. 52036 or access the online form at: https://www.lhsc.on.ca/patients-visitors/when-you-have-concerns.

If at any time during the research study you feel that your mental health has deteriorated and would need additional support outside of business hours, please call the Canadian Mental Health Association (CMHA) crisis line at 519-433-2023 or 1-866-933-2023 (toll-free), or web chat at http://reachout247.ca/.If you require additional support outside of business hours, you should visit your local Emergency Department immediately. During business hours, you can contact the PI by telephone at 519-685-8500 X 75504 or by email at akshya.vasudev@lhsc.on.ca This email will be monitored between the hours of 7am and 4pm.

Please keep one copy of this letter, marked 'copy' on the front page to keep for future reference. Please mail the other copy to the study team in the return envelope.

12. Consent

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Phone: 519-685-8500 ext. 75504
Address: #A2-607, Victoria Hospital, London Health Sciences Centre
800 Commissioners Road East, London, ON N6A 5W9

Additional Research Staff + Contact

Study coordinator: Emily Ionson
Phone: 519-685-8500 X 74912
Email: emily.ionson@lhsc.on.ca

Important note
If you have read this Letter of Information and have further questions, please contact the study research staff, either Emily Ionson at (519) 685-8500 X 74912 or Emily.Ionson@lhsc.on.ca. If you have no questions, please continue with this form.

I have read the Letter of Information, understand the nature of the study, and I agree to participate. All questions have been answered to my satisfaction.

Yes ☐ No ☐

If you have any questions about the study, please contact Emily Ionson at emily.ionson@lhsc.on.ca.

Please print your name:

_____

Please sign your name (in black or blue ink):

_____

Date (YYYY:MM:DD):

_____

Printed name of person obtaining consent:

_____

Signature of person obtaining consent (in black or blue ink):

_____

Date (YYYY:MM:DD):

_____