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

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

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Executive Summary

The COVID-19 pandemic and continued lockdown measures have led to social isolation that is likely disproportionately affecting community-dwelling seniors. This social isolation of seniors is expected to cause detrimental health effects especially in those who have an ongoing or new onset late life depressive episode. The COVID-19 pandemic has also made accessing formal psychotherapy services increasingly difficult due to an increased demand for these services and a limited number of trained professionals available to deliver these interventions. We plan to conduct an open label, pilot, randomized controlled trial (RCT), comparing a virtually delivered (telephone) student led mental health supportive initiative, Student Senior Isolation Prevention Partnership (SSIPP) (n=15) compared to a telephone delivered standard psychotherapy intervention, problem-solving therapy (PST) (n=15) versus a wait list control (n=15) in community-dwelling seniors suffering from late life depression. Participants in this study will be blinded to the hypothesis, while those performing data analysis will be blinded to treatment allocation. Both SSIPP and PST will be delivered via telephone as a weekly session for 12-weeks. Feasibility measures of recruitment, retention and costs will be collected as primary outcome measures. Self-rated measures of depression, anxiety, isolation and resilience will comprise secondary exploratory outcomes. We anticipate that it will be feasible to conduct an RCT of these telephone interventions, SSIPP and PST, in socially isolated community-dwelling seniors. Data from this study will be critical to plan a subsequent confirmatory large-scale RCT. It could be that telephone delivered medical student led supportive intervention, SSIPP and/or a telephone delivered psychotherapy initiative, PST, can be feasibly applied in the current pandemic to a high-risk population, isolated seniors suffering from depression.

Background

The rapid spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus responsible for the current coronavirus disease 2019 (COVID-19) outbreak, has led to strict social distancing and social isolation recommendations from the World Health Organization (1). As the elderly are most susceptible to critical illness and fatality due to infection with SARS-CoV-2, they have also been subjected to the most stringent social isolation guidelines in Canada as an attempt to prevent death in this population (1,2). While these public health measures are necessary to prevent the spread of SARS-CoV-2 among our vulnerable geriatric populations and to protect our over-burdened healthcare systems, social isolation has had a detrimental impact on the mental health of this population and has been deemed a mental health crisis (1,3). It is well established in the literature that social disconnection and isolation places older adults at a particularly great risk of anxiety and depressive symptoms (4). As strict lockdown and social distancing measures remain in effect and community-dwelling seniors are encouraged to avoid social contact with friends and family, it is crucial that accessible and effective mental health interventions be implemented to mitigate the negative consequences of social isolation on their mental health.

The Student-Senior Isolation Prevention Partnership (SSIPP) is a national initiative that partners medical students with older adults in the community to provide social support and connection through regular phone calls. The goal of SSIPP is to reduce rates of anxiety, depression, and loneliness, while fostering resilience among seniors in our communities. SSIPP was initially launched in March 2020 and has expanded to include ten university chapters nationwide with over 500 student volunteers. This student-led initiative has been particularly important during the current COVID-19 pandemic as resultant social isolation has led to higher self-reported rates of anxiety and depressive symptoms among seniors (5). Social isolation and lack of social supports has also led to higher rates of loneliness among community-dwelling seniors, demonstrated to be associated with the development of numerous physical health conditions, increased all-cause mortality, and decreased quality of life in the elderly (5,6). While no qualitative or quantitative data about the effectiveness of SSIPP in reducing late-life depression and anxiety currently exists, informal feedback from senior community members about their experiences with their matched medical students through SSIPP indicates the formation of meaningful relationships and social supports, critical issues impacted in the precipitation and maintenance of late life depression. This is thought to be particularly beneficial during times of increasing social isolation disproportionately affecting senior members of our communities during COVID-19 (5).

Concurrently, other strategies to mitigate the detrimental impact of social isolation on seniors' mental health are formal psychotherapy interventions including problem-solving therapy (PST) (7,8). PST has been shown to reduce depression and rates of suicidal ideation, while improving disability, in adults aged 60 or older (7,8). PST is a psychotherapeutic intervention that teaches community members to identify and clarify problems at hand, set clear, achievable goals, brain-storm solutions to the problem, select their preferred solution,

implement this solution, and evaluate the outcomes (9). Unfortunately, in the midst of the COVID-19 pandemic, there is limited access to formal psychotherapy due to the public's increased need for these services (5) and the limited number of trained professionals available to deliver these services (9). There have been additional difficulties such as finding strategies to provision care in light of current public health restrictions (10), and an increased uptake in the use of telehealth services to provide mental health support (11).

Due to this increased need for social support resulting from the COVID-19 pandemic, increasing social isolation among seniors, and the increased risk of deteriorating physical and mental health that this imposes (5), it is crucial to find an easily accessible and effective intervention available to these senior members of our community to mitigate the detrimental impacts of social isolation. A student-led initiative, such as SSIPP, is a program that could fill this need within our community to improve the mental health of community-dwelling seniors and prevent the negative downstream health effects that result from social isolation. SSIPP is also delivered via telephone, which allows for public safety during COVID-19, and can be delivered without the presence of highly trained health professionals. These factors make this program more accessible than formal psychotherapy to seniors in our community.

The aim of this study is to assess the feasibility of delivering SSIPP in London, Canada, as compared to an active control, PST, as well as a wait list control. Such a study would also allow to collect effect size estimates on the efficacy of SSIPP on self-rated depression, anxiety, isolation and resilience among community-dwelling seniors. Data from this study will help inform the design of a future large, multi-center RCT which may help determine if SSIPP could be as effective as the structured psychotherapy PST at reducing self-rated depression, anxiety, and isolation, while improving self-rated resilience among community-dwelling seniors.

Objectives

Objective 1: To determine if it is feasible to conduct an RCT of telephone SSIPP in comparison to PST delivered to community-dwelling seniors during the current constraints imposed by COVID-19 and the need for telephone delivery of these services.
Objective 2: To determine the extent of change in self-rated depression, anxiety, isolation and resilience measures in a telephone delivered SSIPP as compared to telephone delivered PST and wait list control among community dwelling seniors.

Hypotheses

Hypothesis 1: It will be feasible to conduct an RCT of telephone SSIPP in comparison to telephone PST and a wait list control, under the current constraints imposed by COVID-19 and the need for telephone delivery of these services.
Hypothesis 2: It will be possible to collect effect size estimates of SSIPP compared to PST and a wait list control on symptoms of depression, anxiety, isolation and resilience in community dwelling seniors.

Study Design

This study will be open label, randomized~~,~~ controlled trial comparing 12-week telephone delivered SSIPP and PST in a total of 45 participants, randomized in a 1:1:1 ratio to one of three groups. The three study groups that participants could be randomized to, include SSIPP, PST, or a waitlist control (WLC). The WLC participants will self-select participation in either SSIPP or PST at the end of the 12-week waiting period. They will not complete study assessments following week 12. This study will plan to enroll n=45 with 15 participants randomized to each of the three groups. Participants will be asked to complete brief surveys, with online in REDCap or over the phone with a Research Assistant at weeks 0 and 12 of the study. REDCap will be used to achieve randomization and its concealment. Statistical analysts will be blinded to group allocation during data analysis.

Randomization

Participants will be randomized after they have:

1. Provided verbal informed consent.
2. Signed and returned their letter of information (LOI) by mail to the Division of Geriatric Psychiatry (in a return envelope provided) or signed the electronic LOI in REDCap.
3. The PI has confirmed eligibility.

Due to the COVID-19 pandemic, and the remote nature of this study, written paper consent cannot be witnessed by a study team member. Verbal consent will be obtained and documented for all participants. A randomization list will be generated using sealedenvelope.com and uploaded into REDCap. Randomization will be generated in random block sizes of 3, 6, and 9. REDCap will be used to perform randomization and allocation concealment. REDCap is widely used by health researchers worldwide to reduce errors in data entry and study management while improving confidentiality. All study participants will be blinded to the study hypotheses to prevent expectation bias. The study coordinator, Emily Ionson, will randomize participants using REDCap and inform the participant as well as their assigned PST or SSIPP counsellor as applicable of their intervention allocation. Participants will be assigned a screening code at time of expressing interest in the study e.g. SC001, SC002, SC003 etc. Upon confirmation of eligibility by the PI participants will be assigned a study code e.g. TEL001, TEL002, TEL003. Only the study coordinator will have access to the randomization list in REDCap.

Eligibility Criteria

Inclusion Criteria

1. Community-dwelling senior 65 years of age or older.
2. Meeting criteria of suffering from an episode of major depression, mild to moderate, as assessed by an experienced psychiatrist (DSM 296.21, 296.22, 296.31, 296.32), with the following applicable specifiers including anxious distress, mixed features, melancholic features, atypical features and seasonal pattern
3. Willing to receive services via telephone.
4. Have sufficient hearing to converse via telephone.
5. Have an adequate understanding of written and spoken English.
6. Answer yes to the question “do you perceive that you are either lonely or isolated?”

Exclusion Criteria

1. Pre-existing dementia or other neurodegenerative disorder as confirmed by a Montreal Cognitive Assessment (MoCA) score, telephone version, 17 or below
2. History of schizophrenia
3. History of bipolar disorder
4. History of substance use disorder
5. History of personality disorder as per previous clinical documentation
6. History of suicide attempts or threats as per previous clinical documentation or endorsement of any of the questions from item 2-6 of the Columbia- Suicide Severity Rating Scale.

Study Outcomes

Feasibility Outcomes

The following feasibility outcomes will be measured: (1) rate of participant recruitment, (2) rate of retention, (3) completeness of data entry, (4) cost of interventions, and (5) unexpected costs. These measures will be collected throughout the study and totaled at the end of the study.

Intervention Outcomes

Depression – PHQ-9

The Patient Health Questionnaire (PHQ-9) is a 9-item, self-rated measure of depression which has been validated for screening a major depressive episode in adults. Total scores indicate level of depression: 0–4, no depression; 5–9, mild depression; 10–14, moderate depression; 15–19, moderately severe depression; 20–27, severe depression (12, 13).

Anxiety – GAD-7

The Generalized Anxiety Disorder 7-item scale (each scored 0–3) is a self-rated measure of anxiety that has been validated for the diagnosis of Generalized Anxiety Disorder in the adult population. The scale is scored from 0 to 21. Higher scores indicate greater anxiety symptoms (5–9, mild anxiety; 10–14, moderate anxiety; 15–21 severe anxiety) (14).

Isolation – Lubben Social Network Scale-6 –LSNS6

The Lubben Social Network Scale 6 is a self-rated assessment scale comprised of 6 items, each rated on a 6-point likert scale (0 = none, 1 = one, 2 = two, 3 = three or four, 4 = five thru eight, 5 = nine or more). Higher scores indicate a lower level of isolation. The LSNS6 has demonstrated high levels of internal consistency (15).

Resilience – Connor-Davidson Resilience Scale (CD-RISC)

The Connor-Davidson Resilience Scale (CD-RISC) is a self-rated assessment scale comprised of 10 items, each rated on a 5-point Likert scale (0 = not true at all to 4 = true nearly all the time). Higher scores reflect greater resilience, indicating one's ability to cope with stressful situations. The scale has demonstrated strong reliability and validity in a variety of populations (16).

Study Procedures

Recruitment

Participants will include community-dwelling seniors (*n*=45) recruited from the Division of Geriatric Psychiatry at Parkwood Institute and from the Geriatric Mental Health Program at London Health Sciences Center, both located in London, Ontario. Participants to these two programs receive referrals from family doctors serving the city of London and

surrounding Middlesex County. The study will recruit via existing relationships and referrals established by the study PI and co-investigator. The PI and co-investigator will make initial contact with potential participants, providing two copies of the letter of information (LOI) with a return postage envelope to return one copy of the LOI by mail to the Division of Geriatric Psychiatry. The other copy of the LOI will be retained by patients for their records.

Screening

After receiving the LOI, potential participants will be given a minimum of 24 hours to review this information. Potential participants will then receive a phone call from a trained Research Assistant (RA) to further explain the study and answer questions participants may have prior to enrolment. During this phone call, the RA will obtain verbal consent for those willing to participate, and document this. If participants are willing to electronically sign the LOI and submit via REDCap they will immediately be provided with the contact information form requesting contact information including email address and phone number. Alternatively, potential participants can elect to sign the paper copy of the LOI provided to them at initial contact with the study PI or co-investigator, and return by mail with the return envelope included.

Prior to calling potential participants to review the LOI and obtain verbal consent, a trained RA will access the participant's chart, either paper or electronic charts, to perform pre-screening for eligibility. The RA will contact the potential participant's psychiatrist to clarify any information that is unavailable or unclear after reviewing the patient's chart. Pre-screening eligibility will be documented by the RA. Once completed pre-screening forms and signed LOI's are reviewed by the PI or co-investigator, patients will be enrolled in the study.

Study Interventions

Both SSIPP and PST will be delivered via telephone. Telephone PST will be 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. These health professionals will receive a one-hour review training course delivered by a trainer within the Division of Geriatric Psychiatry prior to delivering PST to participants.

PST will be delivered to study participants once a week for a 30–60-minute session over a 12-week period. PST therapists will administer the PHQ-9 during each of the 12 PST sessions as part of the standard PST program. SSIPP is a pre-existing initiative at the Schulich School of Medicine and Dentistry in London, Ontario where medical students are matched with a

community-dwelling senior to provide social support via weekly phone calls. This intervention will be delivered to participants by a medical student in compliance with SSIPP's pre-existing protocol. Phone calls will be made by medical students once a week on a schedule negotiated by the medical student and matched participant. Medical students will be required to complete a weekly call log to ensure completion of these calls, as per SSIPP protocol. Medical students will receive a one-hour training session, provided by SSIPP according to their standard procedure, prior to beginning calls with their matched senior participant. Both PST and SSIPP counsellors will take attendance for each planned session and notate any negative or positive comments provided by participants about the program. Any suspected adverse events (AE) will be reported by the counsellors to the PI within 24 hours.

Study Assessments

Assessment		**Date of Administration**		
Name of Assessment	**Variables**	**Screening**	**Week 0**	**Week 12**
Informed consent	Consent	X		
Contact information form	Name, phone number, e-mail address, mailing address	X		
Inclusion/exclusion	Eligibility	X		
Telephone MoCA	Objective neurocognitive impairment	X		
C-SRSS	Suicidal Ideation or Intent	X		X
Demographics questionnaire	Age, gender, past year substance use, religious and spiritual affiliation, frequency of religious practice, previous history of mental health disorders, physical health status using CIRS-G		X	
GAD-7	Anxiety		X	X
PHQ-9	Depression		X	X
LSNS6	Isolation		X	X
CD-RISC-10	Resilience		X	X
Medication Assessment			X	X

Abbreviations: Generalized Anxiety Disorder-7 scale (GAD-7), Patient Health Questionnaire-9 scale (PHQ-9), Lubben Social Network Scale 6 (LSNS6) and Connor-Davidson Resilience Scale-10 (CD-RISC-10).

Once enrolled, demographic data including age, gender, substance use history, religious and spiritual affiliation, frequency of religious practice, and previous history of mental health disorders will be collected. The telephone MoCA will also be administered by a trained research assistant at this time to ensure potential participants have a minimum score of 18. This tool is a valid measure to screen for mild cognitive impairment in a variety of patient populations (25).

As this is a naturalistic study, psychiatric medications will be assessed at week 0 and week 12 through participants' psychiatrist/s at the Division of Geriatric Psychiatry and /or the Geriatric Mental Health Program to assess for medication changes made during the 12-week study period. Physical health status of patients will be screened for using the Cumulative Illness Rating Scale for Geriatric patients (CIRS-G). This scale has been validated to compute ratings of chronic illness burden in medically and psychiatrically impaired elderly subjects (21). Finally, the Columbia Suicide Severity Rating Scale (C-SRSS) will be used to screen patients for suicidal ideation or intent prior to enrolment. This scale is a reliable and valid measure to screen for suicidal ideation, behaviour, and intent (24).

The following well validated, self-rated scales will be administered to participants. Completion of the self-rated scales can be completed online (for participants who are comfortable with this format and have access to a computer) or by a trained research assistant over the phone with the participant (for participants who are not comfortable with the use of computer-based technology). The RA will ask the patient the scale questions verbally over the phone, and document all participant responses on a paper form. The paper copy of participant responses will be stored in a locked cabinet, until responses can be entered into the REDCap database. The Generalized Anxiety Disorder-7 scale (GAD-7) will be used to screen for anxiety and the Patient Health Questionnaire-9 scale (PHQ-9) will be used to screen for depression, with no cut-off scores necessary as participants will have received a diagnosis by a psychiatrist. The Lubben Social Network Scale 6 (LSNS6) will be used to assess isolation (15). The Connor-Davidson Resilience Scale-10 (CD-RISC-10) will be used to screen for resilience (U.S.A. general population mean =32.1 and standard deviation = 5.8). Data from the electronic surveys and paper surveys completed over the telephone with participants will be entered to REDCap by a trained Research Assistant.

All self-rated scales will be administered at week 0 before beginning interventions, and at week 12, following delivery of the last intervention session. Although PHQ-9's will be collected during each PST session only the PHQ-9 collected from session 1 and session 12 will be utilized as outcome data. Participants in SSIPP will only complete pre and post intervention PHQ-9's. If a participant drops out for any reason, the reason for drop out will be collected by a telephone call performed by an RA.

Statistical Considerations

Primary outcome measures will be calculated using rates, percentages and costs. For exploratory purposes, the secondary outcome measures will be subject to the following analyses. A Multivariate Analysis of Variance (MANOVA) will be conducted to detect differences between the two interventions, i.e. SSIPP and PST as the independent variables and scores on GAD-7, PHQ-9, and CD-RISC-10 scale as the dependent variables. Multivariate F value (Wilks' λ or Hotelling's trace or Pillai's trace) will be used with a statistical significance set at $p < 0.05$. Demographic measures will be described using either calculations of means or percentage as required. As there is no consensus or current evidence recommending an appropriate sample size for feasibility studies, it is advised that feasibility study samples sizes not be

attempted a priori (17). Pilot studies investigating the comparable psychotherapies cognitive behavioural therapy (CBT) and mindfulness-based cognitive therapy (MCBT) were able to demonstrate reductions in self-reported anxiety and depression with a sample size of n=52 and n=30, respectively (22,23). Given these effect sizes, the desired sample size is n=45. Attrition and retention rates will be calculated as feasibility measures as part of this pilot study to help inform required sample size for a future large, multi-center RCT.

IBM SPSS ® (v26) will be used for the conduction of data analysis (18). Contingent on final sample size, either the Kolmogorov-Smirnov or the Shapiro-Wilk test will be used to assess normality of the data. The Expectation-Maximization (EM) algorithm will be used to account for missing data (19, 20). Analysis will first be carried out using an Intent to Treat (ITT) approach, followed by per protocol (PP) analyses for the participants who completed the study only. The differences in anxiety, depression, and resiliency outcomes between the groups at week 0 and week 12 will be analyzed using a repeated MANOVA test, in both ITT and PP analysis groups.

Expected Results and Significance

We expect this pilot feasibility study will demonstrate that it is feasible to conduct an RCT of telephone-delivered PST versus SSIPP for community-dwelling seniors in the London area. It will also be feasible to deliver both of these services over the telephone. SSIPP is a current initiative at the Schulich School of Medicine and Dentistry that is currently delivered by medical students to community-dwelling seniors over the telephone. Delivering PST over the telephone will reduce participants' and healthcare providers' risk of exposure to COVID-19. Based on previous statements from community-dwelling seniors currently enrolled in SSIPP indicating their positive experience with the initiative, we expect that SSIPP will be as effective as the formal psychotherapy intervention PST for improving self-rated depression, anxiety, and resiliency. Overall, this study is necessary in light of the COVID-19 pandemic and continuing lockdown measures that further isolate community-dwelling seniors and limit access to formal psychotherapy interventions. Social isolation has disproportionately affected the mental health of seniors contributing to a detrimental impact on their quality of life and physical health, while increasing their mortality even prior to the COVID-19 pandemic and subsequent public health measures that placed them at an increased risk. The results from this study will be crucial for directing future initiatives with the goal of reducing social isolation and its sequelae among community-dwelling seniors. This study will inform if it is feasible to conduct a future RCT that may be able to determine if student-led initiatives, such as SSIPP, are as effective as the structured psychotherapy intervention PST. The results from this study may be used to direct a future RCT that may determine if student-led initiatives have the potential to fill the need for geriatric mental health supports resulting from the limited accessibility of and the increased demand for formal psychotherapy interventions as a result of the COVID-19 pandemic.

Limitations

One potential limitation of this study is that recruitment will be taking place from the Division of Geriatric Psychiatry, Parkwood and the Geriatric Mental Health Program at LHSC. This could lead to a disproportionately high representation of seniors with pre-existing mild to moderate depression, rather than those suffering from depressive and anxiety symptoms not meeting criteria for a major depressive episode. This could limit generalisability of our findings to the community. PST is currently used as an adjunctive therapy to pharmacotherapy in managing depression, anxiety, and other psychiatric concerns in seniors. As this is a naturalistic study, our interventions (ie. PST and SSIPP) will be implemented as adjuncts to current therapy participants are receiving. Differences in pre-existing extent of anxiety or depression, and differences in treatment modalities that participants are receiving prior to the start of the trial period will be mitigated by the randomization process. We will also collect data at the end of the 12-week study period to assess for psychiatric medication changes made by participants' psychiatrists during the study period.

Another potential limitation of our study is the delivery of email based LOIs, eligibility forms, demographic forms, and self-rated scales. Online forms may be difficult for our study population to navigate independently, or to access if they do not own a computer. This limitation will be overcome by offering participants the opportunity to complete these forms over the phone with a trained RA who will record and document their responses. Participants may feel more comfortable completing surveys by this method, leading to a better rate of retention. Our study has also included a low number of self-rated scales and brief questionnaires to also assist with participant retention.

Adverse Events

During the enrollment process, participants will be provided with contact information for the study PI and will be instructed to call the PI at 519-685-8500 ext. 75504 if they experience deterioration in their mental health or suicidality. Participants will be informed that this voicemail will be checked regularly during business hours. Participants will also be informed that they can reach the study PI by email at akshya.vasudev@lhsc.on.ca between the hours of 7am and 4pm. If participants experience a deterioration in their mental health or suicidality, at any time, they will also be provided with the phone number for the Canadian Mental Health Association crisis line, which is available 24/7, and be encouraged to visit their local Emergency Department for immediate support, at any time, if requiredParticipants will only be recruited to this study if they are capable and consenting. Study staff, PST counsellors, and SSIPP counsellors will report any suspected AE to the PI within 24 hours.

Study Personnel

Name	Role in Study	E-mail
Akshya Vasudev	Principal Investigator	akshya.vasudev@lhsc.on.ca
Lisa VanBussel	Co-Investigator	lisa.vanbussel@sjhc.london.on.ca
Emily Ionson	Research Coordinator	emily.ionson@lhsc.on.ca
Sarah Meulendyks	Student Research Assistant	smeulendyks2024@meds.uwo.ca
Taranah Adli	Student Research Assistant	tadli2024@meds.uwo.ca
Jia Zhang	Student Research Assistant	jzhang2023@meds.uwo.ca
Juanni Liu	Clinical Trials Management Student	jliu788@uwo.ca
Katy DAngelo	PST therapist	Katy.DAngelo@lhsc.on.ca
Susan Macdonald	PST therapist	Susan.Macdonald@sjhc.london.on.ca
Adriana Barel	PST therapist	Adriana.Barel@sjhc.london.on.ca
Patrick Flemming	PST therapist	Patrick.Fleming@lhsc.on.ca
Lisa Joworoski	PST therapist	Lisa.Joworski@lhsc.on.ca

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