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Effectiveness of Telepsychiatry Among Geriatric Participants with Age-Related Hearing Loss

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EFFECTIVENESS OF TELEPSYCHIATRY AMONG GERIATRIC PARTICIPANTS WITH AGE-RELATED HEARING LOSS

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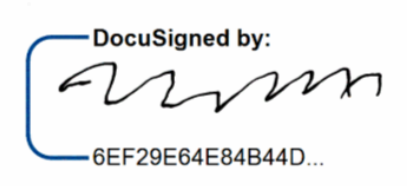

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Abstract

Presbycusis (hearing loss that occurs with age) affects 30% of adults aged 65 to 74, yet hearing loss is rarely considered when developing novel treatment deliveries. For example, research shows that telepsychiatry improves depression symptoms among geriatric patients similarly to traditional forms of therapy, however, there is no literature on effectiveness of telepsychiatry in geriatrics with presbycusis. The objective of this study is to assess whether, compared to face-to-face psychotherapy, telepsychiatry produces superior outcomes assessed by the Beck Depression Inventory II, among depressed geriatric patients suffering from presbycusis. We will conduct a randomized controlled trial among elderly individuals with depressive disorders and presbycusis who will be randomly allocated to 8 weekly, 60-minute manual sessions of Behavioral Activation Therapy for Depression either in the clinic or in the participants' home, using telepsychiatry. This study will help guide future therapies directed towards the growing geriatric population, many of whom suffer from presbycusis.

Chapter 1 – Introduction

Background

Telemedicine is the electronic transfer of medical and health information between distant sites and participants.[1] It has seen tremendous growth in the information age and has been successfully applied across various fields of medicine.[2-4] Technological advances that have made the relevant equipment less expensive and easier to use have stimulated so much interest and success in telemedicine that it is now a well-accepted method of diagnosis and treatment.[5]

Telepsychiatry—the delivery of healthcare and the exchange of healthcare information for the purposes of providing psychiatric services across distances[6]—has grown rapidly probably due to the easy adaptation of traditional talk therapy to delivery via telemedicine, specifically video-based telemedicine. Telepsychiatry review articles indicate that this form of medicine increases access to care, yields improved patient outcomes and leads to increased patient satisfaction.[7]

Many studies have examined the effectiveness, feasibility and acceptability of telepsychiatry, which has been successfully used in veterans with post-traumatic stress disorder,[8] Alzheimer's dementia,[9] and other mental health disorders.[10] However, more research is needed on clinical outcomes of telepsychiatry treatment models.[7]

Telepsychiatry has also been studied in various patient populations, but the geriatric population will likely benefit the most from the services. It is expected that 22% of Americans will be aged 65 or older by 2050, and the number of people who are 85 years and older is expected to nearly double by 2035.[9] Additionally, the geriatric population is at a higher risk of mood disorders such as depression – with as many as 49% of nursing home residents suffering from depression, 35% of those affiliated with in home health agencies and 25% in residential

care communities.[12] The elderly also make up a large portion of patients from rural and remote locations and often have multiple chronic conditions, a situation which limits their ability to access specialized care.[19] Even though depression is prevalent and the geriatric population is growing, access to geriatric psychiatrists is decreasing.[5] These factors have created a need for telepsychiatry to bridge the gap between patients and providers.[10] Telepsychiatry has the ability to connect psychiatrists to older adults in underserved or remote areas who would otherwise be unable to travel to the psychiatrist for treatment.

Statement of Problem

Telepsychiatry is a mainstream form of treatment used to address mood disorders in adult populations. Hearing loss affects 30% of adults aged 65 to 74, and 47% of adults over the age of 74.[13] Several studies have evaluated the effectiveness of telepsychiatry in the elderly population, but none has measured presbycusis and its impact on treatment outcomes in elderly patients with mood disorders such as depression.

Objective

The purpose of our study is to assess whether telepsychiatry is superior to traditional face-to-face therapy among depressed geriatric patients suffering from presbycusis.

Hypothesis

We hypothesize that Beck Depression Inventory II scores in depressed geriatric participants suffering from presbycusis will decrease from baseline to post-treatment clinically significantly more in the telepsychiatry group compared to the face-to-face group.

Definitions

Telemedicine: Electronic transfer of medical and health information between distant sites and participants.[1]

Telepsychiatry: The delivery of healthcare and the exchange of healthcare information for the purposes of providing psychiatric services across distances.[6]

Presbycusis: A progressive, bilateral and symmetrical sensorineural hearing loss due to age related degeneration of inner ear structures.[21]

Depression: Depressed mood and/or loss of interest or pleasure in life activities for at least two weeks and at least five of the following symptoms that cause clinically significant impairment in social, work, or other important areas of functioning almost every day: Depressed mood most of the day, diminished interest or pleasure in all or most activities, significant unintentional weight loss or gain, insomnia or sleeping too much, agitation or psychomotor retardation noticed by others, fatigue or loss of energy, feelings of worthlessness or excessive guilt, diminished ability to think or concentrate, or indecisiveness, recurrent thoughts of death.[20]

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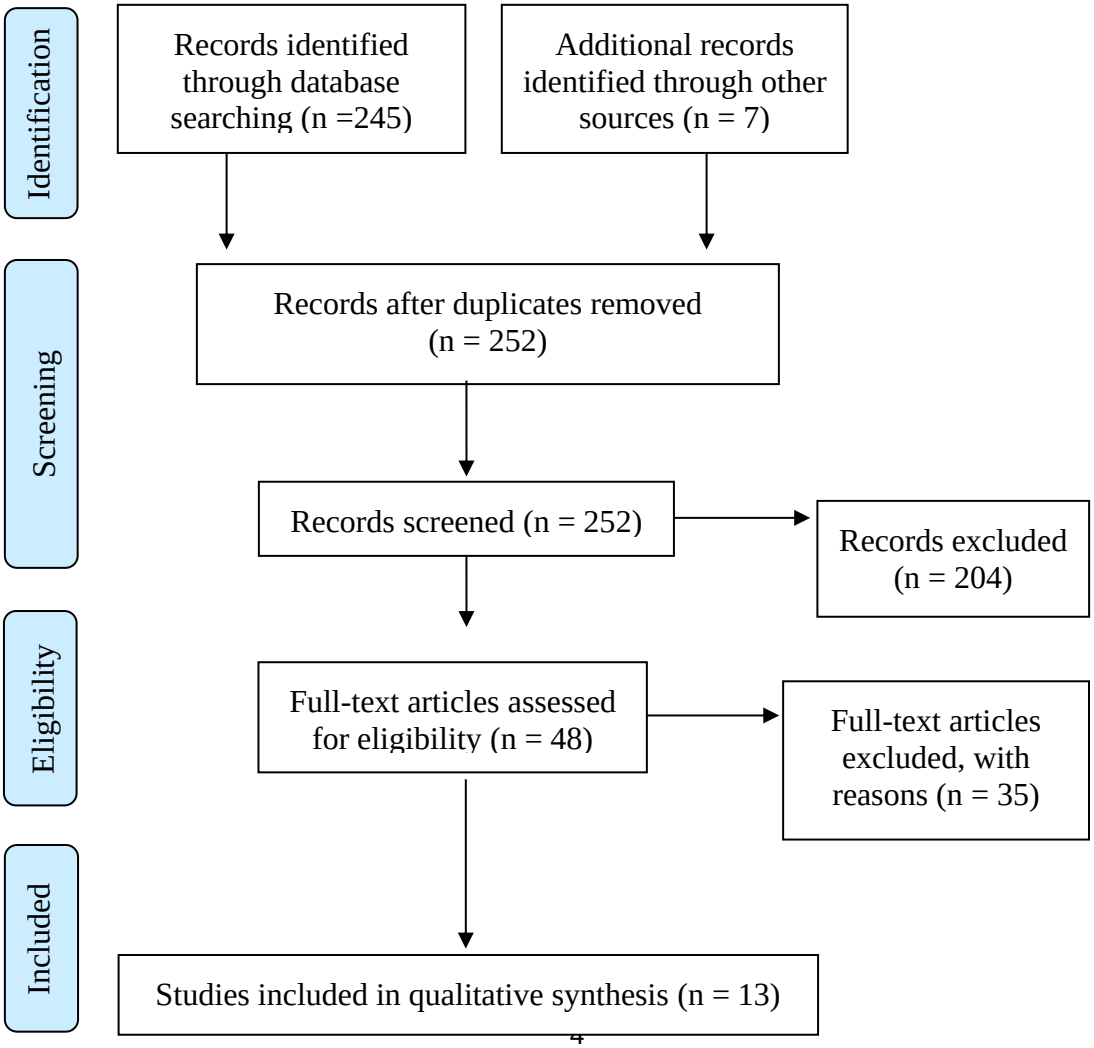
Chapter 2 – Review of Literature

Introduction

To assess the current status of telemedicine in the geriatric population, we performed a review of the literature in the English language from January 2003 to December 2018 using Scopus and PubMed. The following search terms were used: (((telemedicine OR tele mental health OR telehealth OR tele-psychology OR tele psychology)) AND (older adults OR geriatrics OR veterans)) AND (depression) OR hearing loss) OR (presbycusis)))). We also performed a manual search of references from review articles.

Figure 1. Literature Review Flow Diagram



Inclusion criteria were as follows: the article had to test the outcomes of a video-based form of telepsychiatry. The interventions had to include an accepted form of depression treatment (e.g. psychotherapy, medication management, etc.) in adult populations over the age of 18. Exclusion criteria included review articles, studies using telephone-based or automated interventions, deaf populations, and studies that did not assess patient outcomes as the main outcome variable.

Once duplicates were removed a total of 252 articles remained and were screened for relevance using titles and abstracts. After screening articles based on titles and abstracts, 48 remained and were screened for the inclusion and exclusion criteria stated above. Thirteen articles remained for review. Of these, two papers described pilot studies prior to their subsequent randomized controlled trials (RCT); we focused only on the paper describing the final RCT. Two articles were excluded based on their inclusion of deaf individuals for telepsychiatry treatment interventions[1,2] and no there were no articles that explicitly examined patients with hearing loss. Therefore, we focused on the available studies investigating the utilization of telepsychiatry for the treatment of depression in adults.

The next section will briefly summarize the study designs and methods used followed by a more detailed analysis broken down by study design topic.

Study Design

Within the telepsychiatry literature, individual psychotherapy was examined in 13 studies, including 6 randomized controlled trials,[3-8] one randomized, open-label trial,[9] three pilot studies[3,10,11] and three observational studies.[12-14] Among the randomized trials,

3 were superiority designs,[6,7,15] 2 were non-inferiority designs[8,9] and 2 were equivalence designs.[3-5]

Randomized Controlled Trials

Superiority Randomized Controlled Trials

Ruskin et al.[6] were the first authors to perform a large scale RCT in 2004 comparing telepsychiatry to in-person treatment of psychiatric illnesses in which they found no difference between treatment conditions. They recruited 119 participants from the Maryland Veterans Association. The treatment consisted of eight, 20-minute sessions with a psychiatrist over a 6-month period. Sessions addressed antidepressant medication management, psychoeducation and brief supportive counseling.

In 2006, De Las Cuevas et al.,[7] performed a RCT of 130 participants recruited from the Community Mental Health Centre of San Sebastian de la Gomera, in the Canary Islands and found no difference in outcome measures between face-to-face and telepsychiatry groups. The intervention was similar to that of Ruskin's,[6] consisting of eight, 30-minute sessions over 24 weeks and also required patients in both the face-to-face and telepsychiatry groups to report to the same location for their care. But the authors[7] differ by using a single provider for both the intervention and treatment as usual groups. This method allowed for more control of the patient-provider relationship, an important determinant for health outcomes, and also increased the internal validity of the study. However, using the same provider also introduces bias as the provider may favor one method over the other and unconsciously alter his/her interactions with patients.

In 2013, Lichstein et al.[10] underwent a pilot study which eventually led to the 21-participant RCT completed by Scogin et al.[16] in 2018. The authors assessed whether

treatment of comorbid depression and insomnia by therapists through telepsychiatry resulted in better clinical outcomes than usual care with a primary care practitioner (PCP). There was no difference between experimental and control groups on a depression and sleep outcome measures.

None of these three superiority RCTs found statistically significant differences between the face-to-face and telepsychiatry groups. Even though these studies are powered to detect statistically significant differences between treatment groups based on comparative methods rather than equivalence methods, often their authors incorrectly conclude that non-significant differences between groups implies equivalence. In order to address this issue, two subsequent authors present equivalency RCTs.

Equivalence Randomized Controlled Trials

O'Reilly et al.[5] specifically designed and powered an equivalence study to determine whether telepsychiatry consultations for depression, which included optional monthly follow-up sessions for up to 4 months, were not inferior to face-to-face delivered sessions. 286 participants completed the study; equivalence was demonstrated between the telepsychiatry and face-to-face groups.

Similarly, Choi et al.[4] presents two studies, a preliminary efficacy trial and a subsequent equivalence RCT with 116 participants. Both studies report on the same experiment at different time points. The study design is a three-arm randomized control trial where the control group received 30 minute "support calls" from social workers, while the two treatment groups received six 60-minute face-to-face or telepsychiatry sessions focusing on problem solving therapy. This method differs from the previous studies in that a "true" control group is used in addition to the face-to-face comparison

group. The authors found that at follow-up, the telepsychiatry group had improved more than face-to-face and control groups on depression and disability measures. Although the difference was not statistically significant, the authors were unable to reject the null hypothesis of equivalence between telepsychiatry and face-to-face groups.

The previous two studies used equivalence methods to determine whether the telepsychiatry intervention is neither worse nor better than face-to-face treatment or control condition. Equivalence trials are often confused with non-inferiority trials, whose main goal is to determine whether a new intervention is inferior to another or established intervention. Inferiority trials use a defined non-inferiority margin, based on clinical judgement and statistical considerations, which defines the limit of acceptable inferiority. Often non-inferiority designs are implemented for novel approaches to current successful therapies but may be beneficial or superior in other ways. For example, telepsychiatry has been shown to be as effective as face-to-face therapy, but it may also provide additional benefits such as decreased travel time, costs and increased accessibility. The following two studies implement a non-inferiority design.

Non-inferiority Randomized Controlled Trials

Egede et al.[9] performed a non-inferior RCT in 2015 to assess telepsychiatry amongst older veterans suffering from depression compared to face-to-face treatment. They randomized 241 participants to either telepsychiatry or face-to-face therapy; 204 participants completed the study. Using a non-inferiority margin of 15%, they found the telepsychiatry treatment to be non-inferior to face-to-face treatment.

The following year, Luxton et al.[8] published a non-inferior RCT in which they randomized 121 military service members and veterans into home tele-therapy or face-to-

face therapy (82 completed the study). Authors found slightly better results for in-person visits, but the difference was not statistically significant and based on the non-inferiority analysis, the null hypothesis could not be rejected. Thus, the study concluded that in-home telepsychiatry was no worse than face-to-face psychotherapy.

Observational Studies

While RCTs are the "gold standard" of trials, they are often expensive, timely and difficult to achieve. Researchers can also draw valid conclusions from observational studies especially when an such a study is well designed and may even better reflect the "real world" than some RCTs. The following authors performed observational studies.

Kennedy et al.[12] recruited 124 participants who were referred for mental healthcare through telepsychiatry and compared them to those being seen face-to-face in rural Queensland. Participants were not randomized in this observational study and the effect of treatment was evaluated using the Mental Health Inventory (MHI)[17]—a 38-item self-reported measure of mental health issues—completed by participants, and Health of the Nation Outcome Scales (HoNOS)[17]—a 12-scale, clinician-rated measurement of health and social functioning, completed by practitioners. They found an improvement in both groups from baseline to post-treatment, but the groups did not differ statistically significantly.

Griffiths et al.[13] performed an observational study among 18 participants with depression and/or anxiety in Queensland that tested the effects of 6 to 8 weekly telepsychiatry CBT sessions had on clinical outcomes. They found statistically significant improvements from baseline to post-treatment among 48 participants. No control or comparison group was used.

Urness et al.[14] measured patients' satisfaction and patient outcomes in an observational study of patients receiving either face-to-face mental health or telepsychiatry care (not randomized). The telepsychiatry group showed a statistically significant improvement in pre- and post-intervention scores, while the face-to-face group did not. These difference between groups was not analyzed.

The results obtained from these observational studies have limitations. For example, even though Urness et al.[12] found improvements in the telehealth group and not in the face-to-face group, there may be some confounding factors between the groups that were not neutralized because of the study design. Furthermore, Kennedy et al.[12] found improvements from baseline but it is not known whether these improvements were due to the intervention or may have occurred by chance given the lack of a control group.

Case Studies

Lastly, Lazzari et al.[11] performed a small pilot study examining the effectiveness of Behavioral Activation Treatment for Depression (BATD) in older adults. In this study two out of the three patients improved sufficiently and no longer met the criteria for depression by post-treatment. All patients reported satisfaction with treatment by videoconferencing. Since the pilot study included only 3 participants, it is limiting in its ability to extrapolate findings to the general population.

Patient Selection

In general, recruitment of participants for the eleven studies occurred through the use of new or existing referrals for outpatient treatment of depression or self-referrals through print and radio advertisements,[5,6,8,12,14] electronic medical records,[7,9,15] case manager referrals[3,4] and purposive sampling.[11]

Several studies recruited participants from the Veterans Affairs Medical Center.[6,8,9] One study recruited participants by mailing postcards to a mailing list, requesting that patients contact study coordinators if they felt that they were sad or depressed and were interested in participating in a clinical trial.[9]

While the structure of the VA system provides easier avenues for patient recruitment, study trial participants are often homogeneous, leading to sample bias. For example, the majority of the VA participants in the Ruskin et al.[6] trial were male (88%) and Caucasian (61%). Similarly, Egede et al.[9] and Luxton et al.[8] had comparable participant characteristics: 98% and 82% of their sample was male, and Caucasian (60% and 70%, respectively). Thus, women and minorities were vastly underrepresented in these samples and there were likely other characteristics within these groups that may present confounding factors.

Another popular method of recruitment was through referrals from other health agencies or systems[5,7,11-14,16] resulting in a participant pool already being seen in an existing healthcare system. This method of recruitment does not allow researchers to include patients who have not sought treatment for their mental health due to inability to access care or fear of stigmatization.

In contrast, Choi et al.[4] recruited patients through referrals from "Meals on Wheels" and other agencies serving low income seniors in Texas. Only older adults who were both low income and homebound were referred. This unique method targeted populations most in need of telehealth services – low income, homebound elderly adults who were not necessarily already being seen in the healthcare system.

Although we believe that older adults will benefit most from telehealth services, many of the studies included in this review excluded them. Specifically, a few studies consisted of adult populations with ages ranging from eighteen to sixty-five,[5,8] eighteen to sixty[14] or eighteen to fifty.[6] Only two authors did not cap the upper age limit,[7,12] and only three studies focused on the older population by including ages over 50, 58 and 65.[4,11,15] One study did not supply information about the age of participants.[13] In Luxton's et al.[8] study, a large portion of participants were employed and were required to leave work in the middle of the day to go home for their therapy session, which presents an obstacle for an employed adult. In short, it is clear that further studies with more diverse populations and a focus on older adults is warranted.

Table 1. Summary of Studies

Author	Study Design	Sample Size	Objective	Method	Findings
Kennedy et al. (2003)[12]	Observational	124	To compare telepsychiatry to face-to-face psychiatry among rural, depressed patients	CBT sessions followed by in-person reinforcement with case managers	Improvements in both MHI and HoNOS scores from baseline to post-treatment (p<0.01) but no difference between groups in MHI (p=0.7) or HoNOS (p=0.4)
Ruskin et al. (2004)[6]	Superiority RCT	119	To compare face-to-face psychiatry to telepsychiatry among depressed patients	8 20-minute sessions addressing psychoeducation, supportive counseling, medication management of over the course of 6 months	Both groups had improvement in depressive symptoms (p<0.001). No difference between groups
De Las Cuevas et al. (2006)[7]	Superiority RCT	140	To compare face-to-face psychiatry to telepsychiatry among depressed patients	8 30-minute sessions of CBT and medication management over 24 weeks delivered	Improvement in both CGI and SLC-90R scores from baseline to post-treatment in both groups (p<0.001). No difference between groups ($\chi 2$= 0.4, df=1)

Griffiths et al. (2006)[13]	Observational	15	To compare face-to-face psychiatry to telepsychiatry among patients with depression and/or anxiety	6-8 weekly CBT sessions (type of CBT depended on diagnosis) followed by in-person reinforcement with case managers	Improvements in both MIH and HoNOS scores from baseline to post-treatment ($p<0.05$, $p<0.05$, respectively)
Urness et al. (2006)[14]	Observational	48	To compare face-to-face psychiatry to telepsychiatry	Traditional psychotherapy sessions. No specific type was described by authors	Telepsychiatry group showed improvement from baseline to post-treatment in MCS measure ($p=0.001$) but not PCS ($p=0.28$). Face-to-face group did not show improvement in either score.
O'Reilly et al. (2007)[5]	Equivalence RCT	286	To compare face-to-face psychiatry to telepsychiatry among depressed patients	Psychiatric consultation with recommendations provided to PCP with optional month follow-up	Both groups showed improvements in BSI score at follow-up and per protocol analysis revealed equivalence of telepsychiatry to in-person psychiatry
Lazzari et al. (2011)[11]	Uncontrolled Pilot Study	3	To compare face-to-face psychiatry to telepsychiatry among depressed elderly	Five 1-hour BATD sessions at psychiatric clinic	Two out of three patients no longer met criteria for depression by post-treatment
Choi et al. (2014)[4]	3-arm Equivalence RCT	158	To compare telepsychiatry to face-to-face psychiatry and control support calls among low-income, depressed elderly	Six 60-minute PST session via video conferencing or in-person and control group received 30-minute support calls from social workers	Both in-person and tele-PST were more effective than control support calls based on HDS scores ($p=.001$, $p=.001$, respectively)
Egede et al. (2015)[9]	Non-inferiority RCT	241	To compare telepsychiatry to face-to-face psychiatry among depressed veterans	60-minute weekly BATD sessions over 8 weeks	No evidence for non-inferiority of telepsychiatry to face-to-face therapy. Both continuous and dichotomous outcome measures show non-significant differences in GDS ($p= .4058$) and BDI ($p=0.5169$)
Luxton et al. (2016)[8]	Non-inferiority RCT	121	To compare telepsychiatry to face-to-face	50 to 60-minute BATD sessions for	No evidence of inferiority of

			psychiatry among depressed veterans		telepsychiatry to face-to-face therapy. Non-significant reductions in BDI-II and BHS in the ITT sample
Scogin et al. (2018)[16]	Superiority RCT	21	To compare usual care with PCP to telepsychiatry among patients with comorbid depression and insomnia	10 sessions of integrated CBT-D and CBT-I performed by graduate students	Non-significant decrease in HDS scores from baseline to post-treatment (p=0.14)

Abbreviations: CBT: Cognitive Behavioral Therapy, MHI: Mental Health Inventory, HoNOS: Health of the Nation Outcome Scale, CGI: Clinical Global Impression, SLC-90R: Symptoms Checklist-90-Revised, MCS: Mental Component Score, PCS: Physical Component Score, BSI: Brief Symptom Inventory, BATD: Behavioral Activation Therapy for Depression, PST: Problem Solving Therapy, GDS: Geriatric Depression Score, BDI: Beck Depression Inventory, BDI-II: Beck Depression Inventory-II, BHS: Beck Hopelessness Scale, ITT: Intention to Treat, PCP: Primary Care Provider, CBT-D: Cognitive Behavioral Treatment for Depression, CBT-I: Cognitive Behavioral Treatment for Insomnia, HDS: Hamilton Depression Scale

Inclusion Criteria

Five of the eleven articles had inclusion criteria consisting of major depression disorder (or other similar diagnosis such as dysthymic disorder or generalized anxiety disorder) as diagnosed by DSM-IV criteria.[6,8,9,11,13] Two studies based their inclusion criteria on the Hamilton Depression Scores (HDS):[18] Ruskin et al.[6] included participants who scored a 16 or higher on the HDS while Choi et al.[4] included those who scored a 15 or higher on the HDS. O'Reilly et al.[5] used a score above 63 on the Brief Symptom Inventory (BSI)[19] to determine participant eligibility.

Some studies did not narrow their inclusion criteria to any mental illness but rather included all patients who were referred by any source and identified by a practitioner as having a mental disorder, requiring mental health services.[12,14,16] Such broad inclusion criteria with no specific diagnosis increases the generalizability of the study, but decreases the internal validity making it difficult to identify the effect treatment had on participants with a depression diagnosis.

In addition, one study did not implement a systematic way to evaluate participants for their inclusion diagnosis – Scogin et al.[16] limited participants to those who had both depression and insomnia, but the participants were not required to have an official diagnosis of depression or insomnia. Instead they were required to have symptoms that were severe enough to require ongoing treatment from their primary care practitioner. Because participants were not diagnosed with depression or insomnia through the study protocol, it is arguable that this inclusion criterion is not robust and possibly led to bias in patient selection.

Exclusion Criteria

Authors excluded participants who met criteria for bipolar disorder,[3,6] substance abuse or dependence,[4,6,8,9,16] psychosis, [4,6,8,9,11,16] suicidal ideation or self-harm,[4,9,11,13,14,16,20] or if they were currently receiving psychotherapy[8,11,16,21] or pharmacotherapy for depression.[6]

Two authors excluded participants who demonstrated visual or hearing impairment (impairments were not operationalized or measured directly).[4,11] Furthermore, most authors did not take into account common disabilities in the elderly (such hearing loss, vision loss or decreased fine-motor skills) that impact their capability to use telehealth services. By failing to take into account confounding factors such as disabilities commonly found in certain patient populations, it is difficult for authors to draw accurate conclusions in their data.

Table 2. Recruitment and Inclusion and Exclusion Criteria

Author	Age	Population/Recruitment	Inclusion Diagnosis	Exclusion Diagnosis
Kennedy et al. (2003)[12]	>18	Consecutive sampling of patients being seen by practitioners for	Any psychiatric disorder requiring mental health services	None

		mental healthcare in rural Queensland		
Ruskin et al. (2004)[6]	18-50	Veterans referred for outpatient treatment	MDD, Dysthymia, adjustment disorder, depressed mood, not otherwise specified (DSM-IV) HDS >15	Bipolar, schizophrenia, substance abuse or dependence in past year, current pharmacological treatment for depression for > 1 month before initial visit
De Las Cuevas et al. (2006)[7]	>18	Consecutive psychiatric outpatients referred from PCP	Substance abuse, psychosis, mood d/o, somatoform d/o, adult personality and behavior d/o (ICD-10)	None
Griffiths et al. (2006)[13]	N/A	Recruited through case managers	MDD or mixed anxiety and depressive d/o, GAD, panic d/o with agoraphobia (ICD-10)	Severe comorbid conditions, high risk of self-harm, poor English skills
Urness et al. (2006)[14]	18-60	Recruited from existing patients from 11 sites offering tele- or in-person psychiatric treatment in Alberta, CA	No specific diagnosis but no psychotherapy for at least 6 months before initial consultation	Referred urgently, unable to consent, physically aggressive, agitated or suicidal
O'Reilly et al. (2007)[5]	18-65	Referrals from PCP in Ontario, CA	BSI >62	If PCP believed them unable to consent, or if patients were referred for medico-legal issues
Lazzari et al. (2011)[11]	>64	Purposive sampling of patients from psychiatry clinic	MDD or dysthymia (DSM-IV)	Psychosis, SI, cognitive impairment, currently receiving psychological treatment, audio or visual impairments
Choi et al. (2014)[4]	>50	Homebound, served by senior agencies	HDS>14	Psychosis, dementia, SI, bipolar, substance addiction, audio or visual impairments
Egede et al. (2015)[9]	>58	Veterans from VA hospital and four associated outpatient clinics	MDD (DSM-IV)	Psychosis, dementia, SI, current substance use or dependence
Luxton et al. (2016)[8]	18-65	Active duty members, reserve, national guard	MDD (DSM-IV)	Psychosis, SI, current substance use or dependence, currently enrolled in psychotherapy for depression
Scogin et al. (2018)[16]	>50	Patients were recruited from primary care clinics in mid-western Alabama	Agreement of PCP of the presence of depression and insomnia with symptoms significant enough to warrant treatment	Psychosis, SI, current substance use or dependence, cognitive impairment or currently receiving psychological treatment

Abbreviations: MDD: Major Depressive Disorder, DSM-IV: Diagnostic and Statistical Manual of mental disorders, 4th edition, HDS: Hamilton Depression Scale, ICD-10: International Classification of Disease, GAD: Generalized Anxiety Disorder, BSI: Brief Symptom Inventory, PCP: Primary Care Provider, SI: Suicidal Ideation

Outcome Measures

Depression was the primary outcome measure in all the studies included in the review. There are numerous validated outcome measurement tools for depression in the literature which include short assessments made by the provider, extensive self-reported surveys/questionnaires and clinician-delivered interviews, to name a few.

Within our literature review, authors used the Hamilton Depression Scale (HDS),[3,4,6,10,15] Geriatric Depression Score (GDS),[9,11,22] Clinical Global Impression (CGI) ratings, Short Form Health Survey (SF-12),[9,14,22] Brief Symptom Inventory (BSI),[5] Beck Depression Inventory-II (BDI-II),[6,8,9,22] Beck Hopelessness Scale (BHS)[8], Symptom Checklist-90 Revised (SCL-90R)[7], Structured Clinical Interview for Depression (SCID),[9,22] Patient Health Questionnaire (PHQ-9),[15] Mental Health Inventory (MHI)[12,23] and Health of the Nation Outcome Scale (HoNOS).[12,13]

The most commonly used outcome measure of depression is the Hamilton Depression Score (HDS).[4,6,16] Ruskin et al.[6] used this 24-item scale in addition to measures of treatment adherence, patient satisfaction, psychiatrist satisfaction and resource consumption. Choi et al.[4] used a modification of the Hamilton scale which included three additional items measuring hopelessness, helplessness and worthlessness.

The efficacy of treatment in De Las Cuevas et al.'s[7] study was measured with the Symptom Checklist-90 Revised (SCL-90R)[24] global distress indexes and the Clinical Global Impression (CGI)[25] ratings. The CGI is administered in approximately 2-minutes by the study psychiatrist and uses a 7-point Likert scale to assess severity of illness and global improvement. The CGI also does not assess for depressive symptoms but rather

relies heavily on the subjective evaluation of the clinician to assess for improvement in symptoms. Because the scale does not use more concrete markers for improvement and is performed by the patients' psychiatrist, it is highly susceptible to bias because it cannot be assessed blindly. The SCL-90R is a self-reported, 5-point Likert scale measure, encompassing a broad range of psychological problems. While gathering data on such a broad range of issues is advantageous for assessing the psychological health of a patient, it may not be specific enough for evaluating depression-specific symptoms, which is the primary outcome of interest.

Table 3. Outcome Measures

Author	Primary Outcome
Kennedy et al. (2003)[12]	MHI[17]: 38-item self-reported survey measuring distress and well-being HoNOS[17]: 12-item survey completed by clinicians, measuring behavior, symptoms and social functioning
Ruskin et al. (2004)[6]	HDS[18]: 17-item questionnaire administered by clinician on a Likert scale to assess severity of depression.
De Las Cuevas et al. (2006)[7]	SCL-90R[22]: Self-reported measure of psychological improvement based on 5-point Likert scale CGI[25]: Assesses treatment response in all categories of psychiatric patients; administered in 2-minutes by clinicians
Griffiths et al. (2006)[13]	MHI:[17] 38-item self-reported survey measuring distress and well-being HoNOS:[17] 12-item survey completed by clinicians, measuring behavior, symptoms and social functioning
Urness et al. (2006)[14]	SF-12:[27] 12-item self-reported survey of health
O'Reilly et al. (2007)[5]	BSI[5]: 53-item self-report of psychological symptoms and measures distress from these symptoms.
Lazzari et al. (2011)[11]	GDS[26]: 30-item self-report assessment used to identify depression in the elderly PANAS:[27] A self-report questionnaire that consists of two 10-item scales to measure both positive and negative affect based on 5-point Likert scale Q-LES-Q:[28] A self-report measure designed to enable investigators to easily obtain sensitive measures of the degree of enjoyment and satisfaction experienced by subjects in various areas of daily functioning

Choi et al. (2014)[4]	Modified HDS: 17-item questionnaire administered by clinician on a Likert scale to assess severity of depression. Modification included three additional items measuring hopelessness, helplessness and worthlessness SF-12:[29] 12-item self-reported survey of health
Egede et al. (2015)[9]	SCID:[30] Diagnostic exam used to determine psychological disorders BDI-II:[31] 21-question multiple-choice self-reported inventory of depression GDS:[26] 30-item self-report assessment used to identify depression in the elderly
Luxton et al. (2016)[8]	BHS:[32] 20-item self-report inventory used to assess hopelessness BDI-II:[33] 21-question multiple-choice self-reported inventory of depression
Scogin et al. (2018)[16]	HDS:[18] 17-item questionnaire administered by clinician on a Likert scale to assess severity of depression ISI:[34] 7-item self-reported questionnaire based on 7-point Likert scale used to assess the nature, severity, and impact of insomnia in adults

Abbreviations: MHI: Mental Health Inventory, HoNOS: Health of the Nation Outcomes Scale, HDS: Hamilton Depression Scale, BSI: Brief Symptom Inventory, SLC-90R: Symptoms Checklist-90 Revised, CGI: Clinical Global Impression , SF-12: Short Form-12, BSI: Brief Symptoms Inventory, GDS: Geriatric Depression Scale, PANAS: Positive Negative Affect Schedule, Q-LES-Q: Quality of Life Enjoyment and Satisfaction Questionnaire , SCID: Structured Clinical Interview for DSM-IV, BDI-II: Beck Depression Inventory-II, ISI: Insomnia Severity Index

Sample Size

Studies vary in their sample sizes from 3 participants[11] to 286 participants[5] with an average of 100 participants (excluding case studies). Of the RCTs, drop-out rates varied from 7% to 48%, with an average drop-out rate of 27%. In the only RCT limited to elderly patients, most of the drop outs were due to hospitalizations, patients moving to nursing facilities or death.[4]

Randomization and Blinding

Neither the three observational studies nor the case study in this review were randomized or blinded. However, all the RCTs were randomized and often were further stratified by baseline characteristics such as age,[7] depression severity,[7] race/ethnicity[9,16] and recruitment site.[8,16] Blinding of the RCTs occurred at baseline interviews[9,16] and outcome measures.[5,8,9,16] In some cases, the assessors were not blinded to the treatment

condition because questions were included that were specific to subject method – such as the ease and accessibility of telemedicine technology – which did not apply to the face-to-face treatment groups. Nevertheless, assessors were blinded to the study hypothesis.[4]

Telemedicine Technology

The devices and equipment used for the transmission of telepsychiatry services differed among the studies reviewed here. The most common method was through a computer[6,7] that had videoconferencing software installed and often included a camera,[6,8,13,16] headphones,[4,16] or speakers.[13] A majority of the studies provided the telehealth sessions at a location other than the participants home such as at the local hospital or mental healthcare facility.[5-7,11-13,16] This design allows authors to control for variables such as lighting, audio and privacy while also supporting on-sight technicians to aide in issues with connectivity. However, it does not allow authors to assess some positive effects of remote treatment such as convenience, reduced cost, reduced travel.

Luxton et al.[8] performed one of the only studies with in-home treatment. However, there were several limitations: the participants were middle-aged, employed and were expected to leave work to return home to attend the session, which negates many of the advantages that telehealth may offer in terms of accessibility and less fear of stigmatization. Most problematically, participants also experienced substantial technical difficulties in this study - out of all sessions, 36.3% were unable to initiate a webcam connection and 35.7% required a phone call to resolve a technical issue**.**

All but one study[9] connected to the Integrated Services Digital Network (ISDN) line, providing a 384 kilobit per second transmission in most cases.[5-7,14] In instances where a slower bandwidth was used, the result was delays in both speech and

movement.[12,13] Participants in the Egede et al.[9] trial used a videophone which was connected via a standard telephone service that was simple and easy to use.

Table 4. Telemedicine Technology

Author	Technology	Transmission	Location
Kennedy et al. (2003)[12]	Venue 2000 and Swiftsite systems, PictureTel	ISDN at 128 kbit/s	Local mental healthcare facility
Ruskin et al. (2004)[6]	VTEL software with cameras mounted on the monitors	ISDN at 384 kbit/s	Clinic
De Las Cuevas et al. (2006)[7]	Viewstation 512 polycom	ISDN at 384 kbit/s	University hospital
Griffiths et al. (2006)[13]	PC-based desktop with speakerphones and camera	ISDN at 128 kbit/s	Mental health service facility
Urness et al. (2006)[14]	videoconferencing equipment	ISDN at 384 kbit/s	In home
O'Reilly et al. (2007)[5]	Polycom 512 View Station and a Sony Trinitron screen	N/A	Local mental healthcare facility
Lazzari et al. (2011)[11]	videoconferencing technology and headsets provided by the university	N/A	University psychology clinic
Choi et al. (2014)[4]	Provided with laptops and headsets and used *Skype* software	N/A	In home
Egede et al. (2015)[9]	Videoconferencing via analogue videophone (KMEA TV500SP)	Standard telephone service at 18 frames per second	In home
Luxton et al. (2016)[8]	Provided with Dell M6500 laptop and video camera and used Jabber video software (a Cisco Systems product	N/A	In home
Scogin et al. (2018)[16]	*Skype* Technologies combined with web cameras, a headset and microphone	N/A	Primary care office

Abbreviations: ISDN - Integrated Services Digital Network

Intervention

The interventions used in the studies include problem solving therapy,[4] Behavioral Activation Treatment for Depression,[8,9,11] medication management, psychoeducation, supportive counseling referrals to short-term psychotherapy programs,[5,6,12] telepsychiatry consultations provided to primary care practitioners[7] and

Cognitive Behavioral Therapy.[10,13] The number of sessions varied from five sessions[11] to ten session,[16] lasting anywhere from 20 minutes[7] to 60 minutes.[4,8,9,11] Several studies had follow-up periods ranging from 8 weeks[16] to 12 months.[9]

One of the most commonly known and used forms of psychotherapy is Cognitive Behavioral Therapy (CBT) which has been shown to be an effective treatment for many psychological disorders including depression.[35] The treatment involves the patient recognition of unhelpful or distorted ways of thinking resulting in the modification of these thoughts and behaviors.

In some studies, a remote certified psychologist delivered CBT sessions to participants while case managers observed and then reinforced the intervention while face-to-face with participants, following the session.[12,13] The type of CBT delivered was based on the participants diagnosis. Those with depression focused on problem-solving, sleep, increasing activity and good eating behaviors.[13] De Las Cuevas et al.[7] incorporated eight, 30-minute CBT and medication management sessions over a 24-week period.

In contrast, participants in the Scogin et al.[16] study received CBT from graduate students in clinical psychology who had 4 days of didactic and experiential instruction. The limited training of graduate students providing psychotherapy is in contrast to other studies who delivered treatment through trained and experienced therapists, often with several years of experience with psychotherapy.

Only one study used problem solving therapy (PST),[4] which focuses on improving coping skills for high stress situations through instruction in specific problem-solving steps. PST was delivered over six, 60-minute weekly sessions. Trained social workers provided both telehealth and in person visits.

Psychiatric consultations were used in another study.[5] The consultations were administered to participants and a report was provided to the participants' primary care provider. Consultations included follow-up appointments with the psychiatrist for up to 4 months at monthly intervals if deemed clinically appropriate. The consultations themselves consisted of medical management, psychoeducation, supportive counseling and referrals to other local services such as psychotherapy. Psychiatrists were required to travel by plane and stay overnight in hotels while consulting face-to-face. Because of these travel commitments, psychiatrists may have been less likely to follow-up with face-to-face consultations given the vast difference in time commitment required, thus increasing bias in treatment between the two groups. Furthermore, treatments varied between patients resulting in perhaps a more generalizable study, but one that may lack internal validity.

Along with CBT, Behavioral Activation Therapy for Depression (BATD) was among the most popular intervention used in our review and has similar efficacy as CBT.[35] It was more likely to be implemented among Veterans – both Egede et al.[9] and Luxton et al.[8] recruited participants from the VA and used BATD. Egede et al.[9] reported their study was "the first randomized control trial of manualized evidence-based psychotherapy for depression in older adults with telemedicine" and differs from past studies in that it focuses on a robust model of psychotherapy (as opposed to medication management). Subsequent studies have taken this approach, using forms of psychotherapy like CBT as discussed above. In Egede's study, participants all received behavioral activation for depression for weekly 60-minute sessions over 8 weeks.[9] Patients also used daily planners and activity lists to reinforce scheduling of behaviors

that were of value to the patient. Much like the Egede study,[9] participants in Luxton's[8] study were provided with 50 to 60-minute behavioral activation treatment for depression every week for 8 weeks.

Data Analysis

Across all the papers reviewed, mixed effects models were the most common analytic technique. In order to test for the significance of the difference between treatment and control groups, most studies used mixed effects models with a repeated measure design and used the significance of the interaction between treatment condition and time as the key outcome.[4,6,9,21,36] This statistical method is well suited to the answering the key research question as it allows for significance testing of the treatment condition as well as allows the researchers to account for the change in effect of treatment condition over time. Mixed effects models also allow researchers to control for confounding factors such as initial depression severity or demographics like gender and age. One limitation of this method is that compared to simpler statistical methods it usually requires larger samples sizes.

We also found that chi-squared tests were a popular method: to use this method researchers dichotomized the outcome measure (typically splitting patients into those who experienced clinical remission and those who did not). The chi-squared test allows researchers to test whether the proportion of patients experiencing remission differed between the treatment and control groups; this method was often used as a complement to mixed effects models.[6,7,12,16] Finally, several studies also used T-tests as the primary statistical test.[5,13,14,21]

Results

Most studies revealed improvements in outcome measures of depression from baseline to follow-up, whether treated with telepsychiatry or face-to-face therapy,[4-8,11-13] however, differences between groups were not statistically significant.[5-9,12] Several studies were able to conclude non-inferiority[8,9] or equivalence[4,5] of telepsychiatry to face-to-face treatment but no superiority study was able to conclude superiority of telepsychiatry over face-to-face psychiatry.[6-8]

One possibility for these non-significant findings among the superiority studies could be due to their utilization of remote locations for their treatment sessions, thus negating the positive effects of remote sessions. The patients most in need of remote telepsychiatry are often those who are homebound, chronically ill with comorbid diseases and have difficulty ambulating and traveling to appointments. It is likely that this study design did not allow for homebound individuals to take part in the study. Similarly, the patient selection of all but one study[4] did not allow for patient selection from the population of homebound adults—rather, selection was limited to those who had previously sought out and received healthcare services.

Other confounding factors found in our review included recruitment exclusively from the VA healthcare system, resulting in a largely male and Caucasian participant population.[6,8,9] Furthermore, most studies did not focus on the elderly population, often including participants over the age of 18 – only one study included participants over the age of 65.[11] Inclusion criteria was too broad in several cases[12,14,16] or not operationalized.[16]

The most common interventions were psychotherapy (BATD[8,9,11] or CBT[10,13]) which were delivered by trained and experienced providers in all but one study, which used graduate students with minimal training and no experience.[16] Outcome measures were varied, with HDS being the most commonly used.[3,4,6,10,15] The technology was similar in most studies, utilizing computer-based teleconferencing equipment connected to the internet in all but one study which implemented an analogue phone.[9]

There are many studies in the literature focusing on patient satisfaction with telepsychiatry. Although not the purpose of this review, some of the studies included in the review did report satisfaction measurements as a secondary analysis. One study found that homebound adults had higher approval rates of telepsychiatry than the face-to-face treatment groups,[4] another reported moderate satisfaction,[5] and one study had no difference in satisfaction.[6] All three participants in the Lazzari et al.[11] study reported satisfaction with treatment by videoconferencing.

Conclusion

Based on a review of the literature, telepsychiatry is at least as effective as face-to-face therapy. However, more research on depression outcome measures targeted specifically at older, homebound adults is needed. When studying older patient populations, methods should be employed that will be most accessible to this population, such as delivering treatments in the participant's home as opposed to a clinic or off-site study location. In addition, recruiting a more diverse population in both age, race and gender is important to the external validity of the study.

Most importantly, our literature review concluded that there have been no studies that specifically account for the physical abilities and limitations that are commonly

encountered in older age. Controlling for hearing loss, impaired mobility and lack of familiarity with technology is important since these variables all impact the effectiveness of telepsychiatry delivery. In general, clinical studies tend to attract young and healthy adults and often exclude those with disabilities. It is important to include participants with disabilities so that interventions may be optimized to the complex populations they are designed to treat. In particular, late-life psychiatric conditions tend to be more complex and often co-morbid with other serious impairments, and it would be short-sighted to investigate the effectiveness telepsychiatry in elderly populations without accounting for hearing loss, a common ailment found in this population.

Due to the limitations found in the literature, we propose a study aimed towards the depressed, elderly population, who often suffer from presbycusis. We will to take this disability into account when the designing study methodology by directly measuring hearing loss and incorporating hearing devices into the remote treatment technology.

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Chapter 3 – Study Methods

Study Design

We will conduct a single-blind, randomized controlled trial powered to assess superiority of telepsychiatry over traditional, face-to-face psychotherapy. The groups will be assessed for depression using the Beck Depression Inventory II (BDI-II)[1] at baseline (week 0), mid-treatment (week 4) and post-treatment (week 8). The primary outcome is clinical improvements in depression and the secondary outcome is patient satisfaction, assessed using the Charleston Psychiatric Outpatient Satisfaction Survey (CPOSS)[1] at post-treatment.

Outcome Measures

Primary Outcomes

The primary outcome measure will be the numerical change in BDI-II scores from baseline to post-treatment for each participant. BDI-II is a 21-item, self-reported, multiple-choice inventory that is a widely used indicator for the severity of depression. Each answer is scaled on a range of 0 to 3. Sum scores range from 0 to 63 with higher scores indicating increased depression severity. A score of 0 to 10 is categorized as "normal," 11 to 16 as "mild mood disturbance," 17 to 20 as "borderline clinical depression," 21 to 30 as "moderate depression," 31 to 40 as "severe depression" and over 40 is considered "extreme depression." The BDI-II has good internal consistency ($a=0.91$)[2] and high validity and is sensitive to change.[3]

Changes in BDI-II scores in the telepsychiatry group will be compared to the face-to-face group. We hypothesize that there will be a clinically significant difference in pre-treatment to post-treatment scores between the experimental and control groups.

Secondary Outcome

The secondary outcome measure is treatment satisfaction measured at mid-treatment and post-treatment using the CPOSS. The CPOSS is a 16-item Likert-scale response format that measures a patient's satisfaction with his or her treatment. Scores range from 13 to 65, with higher scores representing increased satisfaction with treatment. We hypothesize that participants in the telepsychiatry group will have higher scores than those in the face-to-face group at both mid-treatment and post-treatment. We will also assess how the level of presbycusis affects clinical outcomes and patient satisfaction by correlating the level of presbycusis (discussed under "Hearing Loss" in "Study Variables and Measures" section) to BDI-II scores and CPOSS scores.

Study Population and Sampling

Study participants are male and female veterans and non-veterans. Veterans will be recruited from the VA mental health and primary care clinics; non-veterans are referred from healthcare professionals, self-referred via posted fliers in the community, or through agencies serving seniors in their homes. Inclusion criteria are as follows: participants aged 60 or older who—based on the Structured Clinical Interview (SCL) for the *DSM-IV* Axis I Disorders[4]—meet the *Diagnostic and Statistical Manual of Mental Disorders IV* (*DSM-IV*)[5] criteria for the following mood disorders: major depression disorder (MDD), mood disorder due to a general medical condition, adjustment disorder with depressed mood, dysthymic disorder (DD) or depression disorder not otherwise specified (NOS). Participants must score a 11 or greater on the Beck Depression Inventory II, indicating a depression severity of mild and above.[6] They also must have age-related hearing loss as assessed using pure tone audiometry[7] as well as have access to high speed internet in their home. Participants will be excluded if they have a *DSM-IV* diagnosis of psychosis, dementia, suicidal ideation with clear intent, substance dependence,

cognitive impairment (Montreal Cognitive Impairment Assessment[8] score of less than 26), if their living situation does not permit a private area for sessions to take place or if their corrected hearing in both ears does not allow them to hear below 90 dB, measured with pure tone audiometry.

Recruitment

We will use three methods for recruitment for eligible subjects. The first method will be an IRB approved sampling method in which we will systematically identify patients with any of the following diagnosis: MDD, mood disorder due to a general medical condition, adjustment disorder with depressed mood, dysthymic disorder or depression disorder not otherwise specified using the Veterans Affairs Connecticut Health Care (VACT) clinic billing records over the previous 12-months. We will contact providers of eligible patients in order to request permission to contact their patients regarding study enrollment. We will mail invitation letters to eligible patients. The letter will specify our interest in recruiting individuals with hearing loss and depression. The recruitment letter will include the following: information about the study, eligibility requirements, an addressed, stamped postcard that potential participants can return to indicate interest or decline participation in the study, and a phone number that participants can contact to obtain more information about the study, to make an appointment for study assessment or to decline the invitation. The letter will also inform the subject that they will receive a follow-up phone call in two weeks if they have not returned the post-card or have not called to accept or decline the invitation. Once patients agree to participate, they will be asked to provide written consent and will be scheduled for a screening assessment.

The second method will be a convenient sampling through self and provider referrals. IRB approved fliers will be placed at prominent locations outside of VA primary care clinics,

primary care health clinics in CT and at senior centers throughout New Haven and surrounding communities. The fliers will describe the study and its eligibility requirements, as well as provide an email and phone number for subjects to contact if interested. The fliers will also be provided to clinicians who may refer patients to the study at their discretion. Clinicians may also obtain verbal consent from patients for study personnel to contact them. Furthermore, we will present the study, its aims and subject requirements at physician and clinic staff meetings at the VACT and community primary care sites to encourage referral of eligible subjects.

The final method of recruitment will be through the senior agencies such as Meals on Wheels, Senior Dine Program and "My Ride" transit. We will use IRB approved methods to systematically identify potential participants who meet the age criteria through the agencies records and send invitations to participate in our study. Participants interested in participating can then contact researchers who will answer any additional questions and schedule participants for an initial screening session.

Screening and Baseline Questionnaires

Once participants have agreed to participate, they will complete a written informed consent and undergo a baseline screening for depression, cognitive impairment, other psychiatric comorbidities and hearing loss. The baseline interview at week 0 will include a demographic questionnaire, a Montreal Cognitive Assessment (MoCA) screen, a structured clinical interview for DSM-IV (SCID-IV), the Beck Depression Inventory II (BDI-II) assessment, and a pure tone audiometry test. We will also ensure that patients taking antidepressants will be stabilized for 4 weeks prior to initiating study treatment and will ask that providers maintain dosage, if possible, throughout the 8 weeks of the study.

Demographic Questionnaire

Demographic information will include age, race/ethnicity, occupation/work status, level of education, family income, living situation, marital status, branch of military service (if applicable), number of diagnosed chronic illnesses, number of diagnosed psychiatric illnesses, previous mental health treatment and number of medications including class of medications (e.g. antidepressants, sedative hypnotics, antipsychotics, mood stabilizers, stimulants, anti-anxiolytics).

Montreal Cognitive Assessment (MoCA)[8]

The MoCA is a widely used screening tool for detecting cognitive impairment by assessing short-term memory, visuospatial abilities, attention, language and orientation. The test is scored from 0 to 30, with a score of 26 or over considered normal. Scores below 26 indicate cognitive impairment. The MoCA has good convergent validity and was superior to its counterpart exam, the Mini Mental Status Exam, in this regard.[9]

Structured Clinical Interview for DSM-IV (SCID)[4]

The SCID is a semi-structured interview that is considered the "gold standard" in diagnosing psychiatric disorders. The interview is performed by clinicians and incorporates current and past major depressive episodes, manic and hypomanic episodes, delusions, hallucinations as well as substance use disorders. The interview has been shown to have excellent validity.[10]

Beck Depression Inventory II[6]

Participants must score an 11 or greater on the Beck Depression Inventory II, indicating a depression severity of mild and above.[6] Participants will complete the BDI-II questionnaire at the screening interview and at the end of their 4th and 8th sessions and will remain in the office or

online with the clinician until the questionnaire is screened by the clinician for suicidal ideations (SI). If a participant responds to the suicidal thoughts or wishes question (question #9) as either "I have thoughts of killing myself, but I would not carry them out," "I would like to kill myself," or "I would kill myself if I had the chance to," then researchers will inform the primary investigator (PI) who will speak with the patient via the phone, assess the subject's safety, and if indicated, activate the local emergency medical service (EMS) to bring the patient to the closest emergency room for further evaluation. If the subject is physically present and endorses a positive response on item #9 of the BDI-II, the PI will meet with the subject, assess the subject's safety and escort the patient to the onsite emergency room for further evaluation, if required.

Pure Tone Audiometry (PTA) Test

The PTA test is the "gold standard" hearing test used to identify the decibel threshold at which an individual is able to hear. Patients are asked to indicate when they hear the "beep" of the machine. The resulting shape of the audiogram gives an indication of the type of hearing loss. In our study, uncorrected and corrected hearing loss will be assessed as described in the "Study Variables and Measures" section below. Participants will be excluded if they are able to hear below 25 decibels without correction (considered "normal" hearing) or if they are unable to hear below 70 decibels with correction in both ears. PTA is a valid test among older adults even without the use of a sound-treated environment.[11]

Methodology

Randomization

A senior biostatistician will randomly assign participants into either control or experimental groups and provide the study coordinator with the assignments in individualized,

sealed envelopes. This information will remain confidential in order to provide the study with a single-blind design.

Blinding

Due to the nature of the study design, neither the participants nor the clinicians providing the intervention will be blinded to the intervention. However, the researchers collecting the outcome data and baseline assessments will not be aware of the treatment condition, making this a single blind study.

Data Collection

We will use a secure, password protected electronic database to document participants' medical and psychiatric diagnosis', hearing assessments and questionnaires. In addition to baseline questionnaires and assessments, participants will repeat the BDI-II assessment at mid-treatment and post-treatment. The CPOSS survey will be completed at mid-treatment and post-treatment.

Table 5. Data Collection Protocol

	Demographic Questionnaire	SCID Interview	MoCA	PTA	BDI-II	CPOSS
Baseline (week 0)	X	X	X	X	X	
Mid-Treatment (week 4)					X	X
Post-Treatment (week 8)					X	X

Participant Protection and Confidentiality

This proposal will be submitted for review to the VA and Yale Institutional Review Board (IRB) before proceeding with the protocol described. In addition, we will submit an application and supporting documents to the Human Subjects Committee (HSC) at the Yale School of Medicine. Following submission of all material, all study personnel will undergo

Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy training and provide documentation of completion. Furthermore, all participants will be required to provide informed consent in order to participate in the study. Participants will be provided with detailed information regarding study protocols and any anticipated risks and benefits. They will be informed that their participation is voluntary and may be terminated at any point if they choose and their withdrawal will not affect their eligibility for future studies. Participants will not be considered for the study if they are unwilling or unable to provide consent. Finally, in accordance with state and federal law, all protected patient information will be securely stored and accessed via a password-protected electronic database. No physical participant records will be stored. All study personnel and clinicians will sign a confidentiality agreement.

Study Variables and Measures

Hearing loss

The Center for Disease Control (CDC) defines the degree of hearing loss as a specific range of decibels (dB) that one can hear with their better ear. The CDC provides the following widely accepted ranges of defined hearing loss:[7]

Table 6. Degree of Hearing Loss

Hearing Ability	Range (decibels)
Normal hearing	0-25
Mild hearing loss	26-40
Moderate hearing loss	41-55
Moderately severe hearing loss	56-70
Severe hearing loss	71-90
Clinically deaf	91+

We will exclude normal hearing adults and condense the classifications into two groups as defined as mild/moderate hearing loss ranging from 25 to 55 dB, and severe hearing loss ranging from 56 to 90 dB. Participants will be assessed for corrected hearing loss with the use of their own hearing aids or those provided to them through the study. They will be excluded if their corrected hearing loss does not allow them to hear below 90 decibels.

Corrected Hearing Loss

Participants in the experimental group will be provided with Sony - ZX Series Wired On-Ear Headphones.[12] The headphones are designed to fit comfortably over existing hearing aids and will allow for further sound amplification of the clinician during telepsychiatry sessions, while also reducing unwanted ambient noise. The control group will not use headphones since they will be receiving treatment in-person, however they will be permitted to use their own hearing aids.

Psychotherapy Treatment

All participants will receive 8 weekly 60-minute depression treatment sessions. The experimental group will receive sessions via telepsychiatry in their homes and the control group will receive sessions face-to-face in the clinic. For the treatment of depression, we will use the Behavioral Activation Treatment for Depression (BATD)[13] method for both groups. The primary outcome will be effectiveness of the BATD treatment measured by the Beck Depression Inventory. The secondary outcome will be patient satisfaction with the treatment, measured by the Charleston Psychiatric Outpatient Satisfaction Survey.[1]

Treatment Integrity

Twenty percent of the sessions will be audio recorded and rated independently by an expert in BATD protocol to ensure treatment consistency and proper treatment administration.

The expert reviewer will use a 7-point Likert scale rating form to assess how well the clinician accomplished the various behavioral tasks throughout the session. In addition, clinicians will be asked to rate themselves after each session using the same Likert scale as the expert reviewer.

Behavioral Activation Therapy for Depression (BATD)[13]

BATD is an efficient and effective depression treatment method which encourages patients to identify activities and individuals that bring them joy, and to therefore maximize contact with these sources. The therapy focuses on self-reflection through daily monitoring worksheets, life areas assessment worksheets, life activities checklists and identification of supportive people. It has good internal consistency, reliability and validity.[14]

BATD was developed as a shorter form of behavioral activation (BA) after seminal work done by Lewinsohn (1974)[15] found that the behavioral aspects of cognitive behavioral therapy (CBT) performed as well as CBT as a whole.[15] Additionally, BATD has been shown to be an efficient and effective treatment for depression in adults[13] and has been used in many telepsychiatry studies to compare the effect of telepsychiatry BATD to in vivo BATD.[16-19] The fundamental aim of BATD therapy is to monitor daily activities in order to identify those activities which bring the greatest joy and maximize time spent engaged in those pursuits.

In a meta-analysis of BADT consisting of 16 studies and 780 subjects, authors found a large effect size of 0.87.[20] When compared to cognitive behavioral therapy (CBT)[21] and antidepressants (paroxetine), it was found to be superior to CBT and comparable to antidepressants.[22] Studies have also shown that older adults prefer counseling over antidepressants for the treatment of depression.[23] Another form of depression psychotherapy is Acceptance and Commitment Therapy (ACT)[24] which is a based on the concept that a patient will have sad feelings and should accept these feelings while continuing to live their life. ACT

therapy does not focus on a functional assessment like BATD but places more value more on acceptance of feelings. Compared to ACT, BATD is more action-focused and thus may be better suited for the large portion of veterans in our sample size, the majority of which are men. It has been demonstrated that men who suffer from depression are less likely to communicate problems verbally and more likely to act out by working more, engaging in risky behaviors and/or turning to alcohol or drugs.[25] These action-oriented behaviors suggest that veterans may respond better to action-oriented therapy compared to cognitive-oriented therapy. Lastly, compared to other forms of psychotherapy, BATD is relatively simple, time-efficient and does not require complex skills from the patient nor does it require intensive training of the therapist. For these reasons, we concluded that BATD would be the best treatment modality for our study.

The revised manual of BATD consists of 5 treatment sessions with an additional 5 sessions to review concepts and engage in post-treatment planning. Although there has been no formal systematic comparison of BATD treatment length and its efficacy, 10 sessions is a standard length, with even shorter protocols producing benefits.[26,27] Our study will use 8 sessions.

Beck Depression Inventory II (BDI-II)[6]

The BDI-II consists of 21 questions scored on a scale of 0 to 3 with higher scores indicating more severe depression. It is the most widely used self-reported depression inventory tools in use. It has a Pearson r of .71 correlation with the Hamilton Depression Rating Scale and a one-week test-retest rating of Pearson r of .93, making it a very effective tool among self-reported measurement instruments.[6] The internal consistency was rated high (a=0.89) among geriatric patients as well.[28]

Although the BDI-II measurement has good reliability and consistency, it is still vulnerable to patient exaggeration or minimization because it is a self-reported measure. However, we expect this confounding factor to be minimized since our study will be comparing scores from pre-treatment to post-treatment among the same individuals.

Charleston Psychiatric Outpatient Satisfaction Survey (CPOSS)[1]

The CPOSS is a 16-item Likert-scale response survey that measures a patient's satisfaction with their treatment. Scores range from 13 to 65, with higher scores representing increased satisfaction with treatment. In a sample population, Egede et al. (2009), found that this measure had excellent reliability (Cronback's alpha = 0.96) and good validity with relevant anchor items ("would you recommend this treatment to a friend or family member?") among elderly veterans treated for depression through telepsychiatry.[29] Although some of the items on the scale are only relevant to clinic-based practices, there is an "Not Applicable" option and scores will be calculated by blinded researchers in order to take these answers into account.

Sample Size Calculation

We would like to demonstrate superiority of telepsychiatry compared to face-to-face psychotherapy among geriatric participants with presbycusis. The primary outcome measure is the numerical difference in the BDI-II score from baseline to post-treatment. In order to calculate the sample size required for this continuous outcome superiority trial, we used the previously identified clinically significant effect size of 5 for the BDI-II[30] with a standard deviation of ten.[31] To achieve 80% power on a one-sided test to detect this difference with a significance level of 5%, it is estimated that 113 subjects per group would be required. After accounting for a 20% drop-out rate, 137 subjects per group or a total of 274 subjects will be recruited (see Appendix I for sample size calculation).

Analysis

Inferential statistics will be used to compare the baseline characteristics of each group to ensure adequate randomization. We will also report baseline characteristics as proportions for the dichotomous variables and as means and standard deviations for the continuous variables. Prior to analysis, we will implement a last observation carried forward (LOCF) method to compare patients who dropped out to those who persisted in the study to ensure that there are not significant differences between the groups.

Our null hypothesis is that depression treatment delivered via telepsychiatry is superior to treatment delivered face-to-face among geriatrics patients suffering from presbycusis. The primary outcome will be change in depression score, measured by the BDI-II, between baseline and post-treatment. Using a univariate method, we will compare the differences in baseline and post-treatment depression scores between treatment and control groups using a T-test. Additionally, following the design of similar studies in the literature, the primary outcome measure will be analyzed using a linear mixed effects model. This is often preferable to univariate analysis because it allows us to control for potential confounding factors and to better understand the trajectory of depression scores over multiple measurements (baseline, mid-treatment and post-treatment).

To model this, we will consider the baseline, mid-treatment and post-treatment measures as “repeated measures” and construct a mixed effects model to assess the effect of treatment group on depression score. In this model the dependent variable is depression score, and the key independent variables are (1) treatment group, (2) time (measured in weeks since patient intake) and (3) the interaction of treatment group and time. This will allow us to test both whether treatment versus control group assignment impacted the final depression score, as well as

whether patients in the treatment group improved at the same or different rate compared with patients in the control group. This analytic method is well suited to this problem because we can use patient background characteristics as covariates (including age, initial severity of depression and severity of hearing loss) and because it allows us to investigate the trajectory of depression scores over time.

Timeline and Resources

Timeline

Study personnel will be recruited four months before initiation of the start of subject recruitment and will undergo personnel-specific training as described below. We expect participant recruitment to commence in October of 2019 and continue until October of 2020. Participants will begin the 16-week study treatment on a rolling basis, with the last treatment scheduled to end by March 2020. Data entry will be completed on a rolling basis, and analysis is expected to be completed by June 2020. Completion of the study, which includes study personnel training, recruitment, therapeutic intervention and data analysis will take 24 months in total.

Research Assistants

Research assistants (RA) will be volunteer senior psychology majors or graduate psychology students recruited by the psychology department at Yale University through fliers and student interest group postings. We will recruit 5 to 6 RA's and their responsibilities will include placement of fliers as directed by the study coordinator, as well as receiving calls from potential participants, providing them with information about the study, directing calls to the PI or Co-PI when necessary and inputting data into our database.

Senior Biostatistician

This role will be filled by a volunteer biostatistician who will have a minimum of two years of experience as a biostatistician with experience working in a research setting. The biostatistician will provide randomized participant assignments to the study coordinator in a blinded fashion. He/she will also be available to the PI for statistical consultation during the analysis phase.

Study Coordinator

The study coordinator will be the Principle Investigator (PI) and will be responsible for ensuring all study personnel complete their required training and will be available to support their responsibilities. They will not be involved in data gathering or treatments and will remain blind to the conditions throughout the study. The PI will be a licensed independent practitioner, qualified to assess a participants' physical health, psychological status and suicidality.

Treatment Clinicians

Four to five board certified clinical psychologists with at least three years of clinical experience will be recruited from clinicians working at the VA or in the community through fliers and emails. They will undergo a two-week training course on BATD as well as training on the remote software. Their main responsibility will be to provide BATD to study participants.

Outcome Measures Clinicians

Three to four board certified clinical psychologists with at least three years of clinical experience will be recruited from clinicians practicing at the VA or in the community to complete all initial SCID and MoCA evaluations. Initial screening and baseline measurement will be completed in the clinic for all participants, thus blinding clinicians to treatment conditions. The mid-treatment and post-treatment measurements (BDI-II and CPOSS) will be

completed by participants after their 4th and 8th sessions while clinicians remain on-line or in the clinic. Clinicians will review the BDI-II question number 9 (assessing for suicidality), before ending the session with the participant, and will take further action by informing the PI if the study participant screens positive for SI. All study personnel will be required to complete HIPAA training and to sign a confidentiality agreement.

Videoconferencing Equipment

Google's Duo videoconferencing system will be used for telepsychiatry sessions. The system is optimized for low bandwidth networks and provides high-definition video calls. It also offers default end-to-end encryption for safety and privacy.[32] Inclusion criteria includes access to a computer in the home as well as high speed-internet (defined as having an Integrated Services Digital Network (ISDN) or Digital Subscriber Line (DSL) connection). Therefore, set-up for Google's Duo's videoconferencing system will only require participants to navigate to the website, enter their phone number, and enter the system-provided verification code sent to the participant's phone.

Sound Amplifiers

The experimental group will be provided with Sony - ZX Series Wired On-Ear Headphones[12] which will amplify the telepsychiatry sessions. Participants will be able to wear their own hearing-aides simultaneously.

Research Staff Workroom

Several private rooms in VACT or Yale Medical School will be designated for clinical outcome measure interviews, questionnaires and telepsychiatry sessions.

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Chapter 4 – Conclusion

Telepsychiatry is an expanding field but many studies have focused on patient satisfaction rather than outcome measures. Furthermore, of those that investigate outcome measures, few include the geriatric population, even though this population is growing and may be particularly in need of remote treatment for chronic illnesses such as depression. Geriatric patients have more difficulty coordinating transportation to appointments, may be geographically isolated, and have age-related physical impairments which may make the delivery of healthcare more accessible when provided remotely. Our study focuses on outcomes among this disadvantaged population of older adults with age related hearing loss.

Advantages and Disadvantages

Our study specifically measures hearing loss as a confounding variable using pure tone audiometry, a method that has not been used before and will be vital in providing information on the impact hearing loss has on the success of telepsychiatry among geriatric patients. We have chosen to exclude patients who are clinically deaf as this population requires a different set of interventions such as American Sign Language (ASL) interpreters; fortunately, there is another set of literature addressing this population.[1,2] Furthermore, to ensure patient diversity, we have recruited subjects from the VA hospital, connunity primary care clinics and senior agencies with the goal of expanding our study population to elderly who are homebound and may not be currently receiving medical care. We also plan to provide our telepsychiatry intervention in the participants home. While this design does not allow for a carefully controlled setting, it will allow us to appreciate the effectiveness of the intervention in vivo.

There are several limitations in our study. First, although our sample size is large enough to detect superiority of telepsychiatry to face-to-face therapy, it may be too large to recruit and

complete the study in a two-year timeframe and more time may be needed to recruit patients. Second, the sample size also may not be large enough to detect the association between levels of presbycusis and outcome measures. Third, a third arm ideally would be added to the design, representing a "true" control that would allow us to not only compare telepsychiatry to face-to-face depression treatment but also to compare it to a placebo-like interaction such as support calls. However, adding a third arm dramatically increases the sample size required to detect significance between groups and would not be feasible within our limited timeline and resources. Since we do not want to confound any treatment of depression with the specific remote intervention we are implementing, we have chosen to compare our intervention to the standard treatment protocol as opposed to a placebo treatment.

Fourth, our study is a single-blind study because it is not possible to blind the participants to the intervention of telepsychiatry or face-to-face psychiatry. While a double-blind study is ideal, our intervention presents limitations in this regard. Nevertheless, we have blinded assessors and researchers to treatment conditions at all other data collection points. A fifth limitation is the lack of follow-up. Ideally, a lengthy follow-up period would allow us to determine the long-term outcomes of telepsychiatry treatment.

Public Health Significance

Overall, this study represents a novel contribution to the field through its focus on the provision of telepsychiatry in hearing impaired older adults and its recruitment of a diverse patient population. The evidence that the elderly population is accepting of a videoconferencing as a form of therapy[3] means that such a method is scalable to meet the needs of this population. As the field of telemedicine grows, the technology will be become cheaper and more accessible to both patients and providers. However, Medicare only reimburses for telepsychiatry when

delivered to designated rural-area residents.[4] Thus, the policies surrounding Medicare reimbursement for telemedicine services should be addressed and include disadvantaged populations such as the elderly and homebound individuals. The results of our study will impact future therapies directed towards older adults and contribute to the growing support of telepsychiatry and the populations it aims to serve.

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Appendix A

Form 1. Invitation to Potential Participants

Hi, my name is Stephanie Mock and I am a graduate from the Yale University Physician Associate program. I am conducting a research study to examine the impact of therapy (Behavioral Activation Treatment for Depression (BATD)) on older individuals suffering from depression and hearing loss. Our records indicate that you are a potential candidate for our study.

Participation in this study will involve completing baseline questionnaires, a complete hearing evaluation, and follow-up questionnaires at the end of the study. The majority of your time will be involve participating in either online (from your home) or in-person psychotherapy sessions with a licensed clinical psychologist. These will consist of 8 weekly 1-hour sessions and include weekly assignments, daily journals and thoughtful discussion with the clinician. Your involvement will require about 1 hour/week for 10 weeks. You will not be expected to pay for the therapy sessions, nor will you be compensated for your participation.

The ideal candidate for participation in this study is one who has access to high speed internet, has a private space in the home, has some trouble hearing in one or both ears, and suffers from depression.

If you are interested in finding out more about this study, please call one of our researchers at ###-###-####.

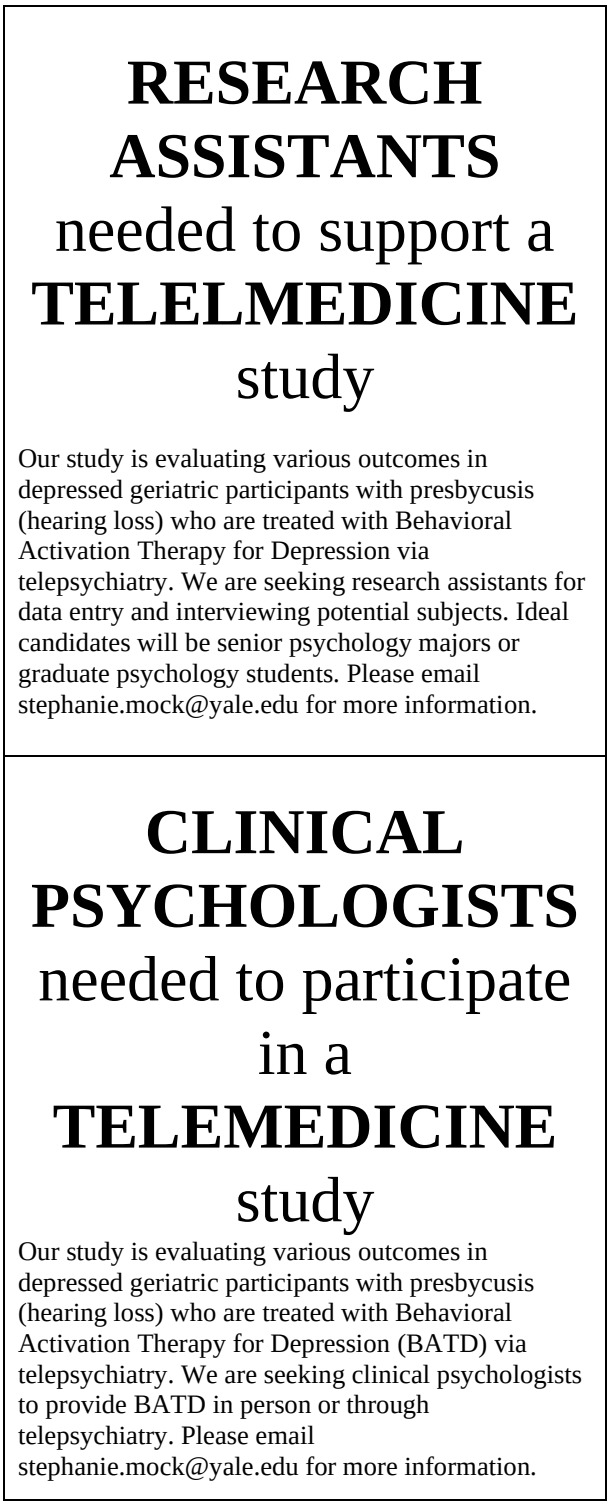
If you know whether or not you would like to participate in this study, please indicate so on the attached form and send using the pre-addressed and stamped post-card. You may also call the number above to indicate your interest or disinterest. If we do not receive a response within 2 weeks, we will call to confirm your response to the invitation.

Thank you for your consideration,

Stephanie Mock

Appendix B

Figure 1. Psychologist and Research Assistant Recruitment Fliers



Appendix C

Form 2. Informed Consent

Title: Effectiveness of Telepsychiatry Among Geriatrics with Age-Related Hearing Loss

Researcher(s): **Stephanie Mock, Yale Physician Associate Program**
Michelle Conroy, MD Yale School of Medicine

Researcher Contact Info: ###-###-####
stephanie.mock@yale.edu

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision about whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation. • **Purpose**. The purpose of this research is to assess effects that Behavioral Activation Treatment for Depression (BATD) has on older individuals suffering from depression and hearing loss. • **Duration.** It is expected that your participation will last 5 months. • **Procedures and Activities.** You will be asked to participate in 8 weekly online or in-person BATD sessions with a trained clinician, to complete all aspects of the treatment protocols, including but not limited to weekly assignments, daily journals and thoughtful discussion with the clinician. You will also be asked to complete questionnaires throughout the course of the study as well as complete one full audiometric assessment at the start of the study. • **Risks.** Some of the foreseeable risks or discomforts of your participation include discussion of topics that may cause emotional distress, suicidal ideations or thought of harming others or yourself. • **Benefits**. Some of the benefits that may be expected include receiving treatment for depression and learning how to cope with depression in the long-term. • **Alternatives.** Participation is voluntary and the only alternative is to not participate.

The researcher(s) Stephanie Mock and Michelle Conroy from Yale University are asking for your consent to this research.

The purpose of the research is to evaluate the effectiveness of depression therapy through telepsychiatry among older adults suffering from hearing loss and depression. You are being

asked to participate because you have met criteria for age, potential hearing loss and potential depression diagnosis. About 150 people will take part in this research.
If you agree to be in this research, your participation will include: assessment of hearing loss, baseline questionnaires to evaluate your physical and mental health, participate in depression treatment with a trained clinician through videoconferencing in your home or at the study headquarters.

We will tell you about any new information that may affect your willingness to continue participation in this research.

What happens to the information collected for this research?
Information collected for this research will be used to compare to other participants' information in order to discern how differences in treatment may affect depression symptoms and how differences in participant characteristics effect how they respond to treatment types.

How will my privacy and data confidentiality be protected?
We will take measures to protect your privacy including storing data in password protected database. Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected.

Individuals and organization that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information and electronic medical records. These individuals and organizations include: the primary research investigator, clinicians, staff biostatistician and research assistants. All study personnel will undergo Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy training and provide documentation of completion.

What if I want to stop participating in this research?
Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship with the researcher, Veterans Affairs, senior agencies or Yale University.

Who can answer my questions about this research?
If you have questions, concerns, or have experienced a research related injury, contact the research team at:

Stephanie Mock
###-###-####
stephanie.mock@yale.edu

If you would like to talk with someone other than the researchers to discuss problems or concerns, to discuss situations in the event that a member of the research team is not available, or to discuss your rights as a research participant, you may contact the Yale University Human Subjects Committee, 203-785-4688, human.subjects@yale.edu. Additional information is

available at https://your.yale.edu/research-support/human-research/research-participants/rights-research-participant

STATEMENT OF CONSENT

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

I consent to participate in this study.

Name of Adult Participant	Signature of Adult Participant	Date

Researcher Signature (to be completed at time of informed consent)

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

Name of Research Team Member	Signature of Research Team Member	Date

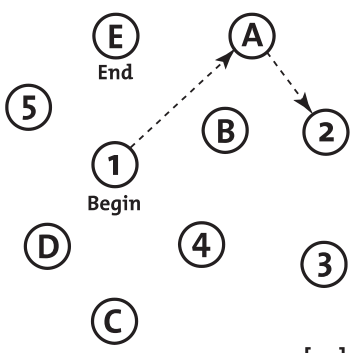
Appendix D

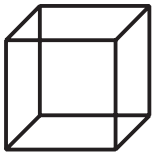
Form 3. Montreal Cognitive Assessment (MoCA)

MONTREAL COGNITIVE ASSESSMENT (MOCA)

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE — POINTS





Copy cube

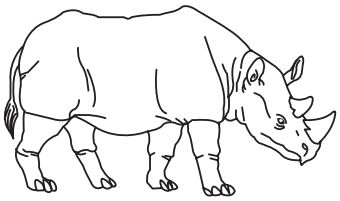
[ ] [ ]

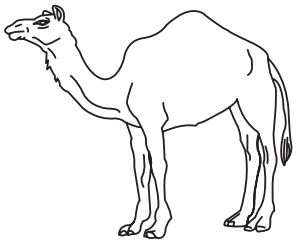
Draw CLOCK (Ten past eleven) (3 points)

[ ] Contour [ ] Numbers [ ] Hands

__/5

NAMING





[ ] [ ] [ ]

__/3

MEMORY — Read list of words, subject must repeat them. Do 2 trials. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION — Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 2 1 8 5 4

Subject has to repeat them in the backward order [ ] 7 4 2

__/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

__/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

__/3

LANGUAGE — Repeat : I only know that John is the one to help today. [ ]

The cat always hid under the couch when dogs were in the room. [ ]

__/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] ____ (N ≥ 11 words)

__/1

ABSTRACTION — Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler

__/2

DELAYED RECALL

	Has to recall words WITH NO CUE	FACE [ ]	VELVET [ ]	CHURCH [ ]	DAISY [ ]	RED [ ]	Points for UNCUED recall only
Optional	Category cue						
	Multiple choice cue						

__/5

ORIENTATION — [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

__/6

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Normal ≥ 26 / 30

TOTAL __/30

Add 1 point if ≤ 12 yr edu

Appendix E

Form 4. Demographics and Psychiatric Questionnaire

Patient's Name: _____

Date of Birth: ____/____/____ Patient's Birthplace:_____ Sex: __M __F

Race: __ African-American __ Caucasian __ Hispanic __ Asian __ Other _____

Who referred you this study? _____

Have you ever received outpatient mental health treatment? __ No __ Yes
If yes, please list in order:

Clinician/ Doctor	Date(s) of Evaluation or Treatment	Type of Evaluation or Treatment	Frequency of visits

Have you ever received inpatient mental health treatment? __ No __ Yes
If yes, please list in order:

Hospital Name	Dates of Treatment	Reason for hospitalization

If you have ever taken psychiatric medications, please list them below: ‰ Not applicable Rx

Name	Reason Given	Highest Dose	% Improvement	Side-effects	Dates Taken

Have you ever had any brain imaging or functional studies? (MRI, CAT scan, EEG, etc.)
__ No __ Yes

Substance Use History

Please describe your past or current use of any of the following substances:
__ Never tried any Substance

Substance	Age at 1st use	Frequency of use	Amount used	Last use	Problems (physical, legal, occupation, relationships, etc.)
ALCOHOL					
TOBACCO					
MARIJUANA					
COCAINE					
AMPHETAMINE					
ECSTACY					
LSD/ ACID					
OPIATES					
INHALANTS					
HALLUCINOGENS (mushrooms, PCP, etc)					

Have you ever received inpatient or outpatient substance abuse treatment? __ No __ Yes

Medical History

Who is your Internist or Family Doctor? __ Do not have a doctor
_____
When was your last physical examination?
_____

Current Medications (include Over-the-counter meds, Vitamins, Herbs, or Supplements)
__ None OR Please List:

Rx Name	Dosage	Frequency	Prescribing M.D.

Do you have any drug allergies? …….__ No __ Yes (please list):
_____
Do you have any current medical problems? …….__ No __ Yes (please list):
_____
_____
_____

Social History
City of Residence: _____
Now Living with: __ Spouse __ Children __ Roommate __ Other:_____
Marital status: __ Single __ Separated __ Divorced __ Married (How long?)_____

Employment

Occupation:_____

Work Status:
___ Employed ___Retired ___Unemployed ___On disability ___Other

If "Other" please explain: _____

School History

Highest grade level completed: _____

Appendix F

Form 5. BATD Schedule of Treatment

1. Session 1
    a. Introduction
    b. Discussion of Depression
    c. Introduction to Treatment Rationale
        i. What about trauma and loss in your life?
        ii. Why is coming every week important?
    d. Introduce Daily Monitoring (Form 1)
        i. Importance and Enjoyment Ratings
    e. Introduce and Complete Contracts Part 1: Identifying Supportive People (Form 2: Top Part)
    f. Important Points about the Structure of This Treatment

2. Session Two
    a. Review Daily Monitoring (Form 1)
    b. Review Contracts Part 1: Identifying Supportive People (Form 2: Top Part)
    c. Introduce and Complete Life Areas and Values (Form 3)
3. Session Three
    a. Review Daily Monitoring (Form 1)
    b. Review and Edit Life Areas and Values (Form 3)
    c. Introduce and Complete Life Activities Checklist (Form 4)
4. Session Four
    a. Review Daily Monitoring (Form 1)
    b. Review Life Activities Checklist (Form 4)
    c. Introduce and Complete Activity Selection and Ranking (Form 5)
    d. Introduce and Complete Activity Hierarchy (Form 6)
5. Session Five
    a. Review Daily Monitoring (Form 1)
    b. Review and Edit Activity Selection and Ranking (Form 5)
    c. Review and Edit Activity Hierarchy (Form 6)
    d. Introduce and Complete Activity Planning (Form 1)
6. Session Six
    a. Review Daily Monitoring (Form 1)
    b. Review and Complete Activity Planning (Form 1)
    c. Introduce and Complete Contracts Part 2: Getting Help from Supportive People (Form 2: Bottom Part)
7. Session Seven
    a. Review Daily Monitoring with Activity Planning (Form 1)
    b. Review and Edit Contracts Part 2: Getting Help from Supportive People (Form 2: Bottom Part)
    c. Review and Complete Activity Planning (Form 1)

d. Review Daily Monitoring with Activity Planning (Form 1)
e. Review Concept and Edit Activities (Forms 4, 5, and 6)
f. Complete Activity Planning (Form 1)
g. Review Concept and Edit Contracts (Form 2: Top and Bottom Part)
h. Complete Activity Planning (Form 1)

8. Session Eight

    a. Review Daily Monitoring with Activity Planning (Form 1)
    b. Review Concept and Edit Life Areas and Values (Form 3)
    c. Complete Activity Planning (Form 1)
    d. Prepare for Termination: Continuation of Daily Monitoring with Activity Planning (Form 1)

List of Forms

Form 1. Daily Monitoring (with Activity Planning starting in Session 6)
- Therapist Manual: One copy
- Patient Manual: 84 copies (one for each day of treatment)

Form 2. Contracts
- Therapist Manual: One copy
- Patient Manual: 10 copies

Form 3. Life Areas Assessment
- Therapist Manual: One copy
- Patient Manual: One copy

Form 4. Life Activities Checklist
- Therapist Manual: One copy
- Patient Manual: One copy

Form 5. Activity Difficulty Assessment
- Therapist Manual: One copy
- Patient Manual: One copy

Form 6. Activity Hierarchy
- Therapist Manual: One copy
- Patient Manual: One copy

Appendix G

Form 6. BDI - II

Instructions: This questionnaire consists of 21 groups of statements. Please read each group of statements carefully. And then pick out the one statement in each group that best describes the way you have been feeling during the past two weeks, including today. Circle the number beside the statement you have picked. If several statements in the group seem to apply equally well, circle the highest number for that group. Be sure that you do not choose more than one statement for any group, including Item 16 (Changes in Sleeping Pattern) or Item 18 (Changes in Appetite).

1. Sadness
    0. I do not feel sad.
    1. I feel sad much of the time.
    2. I am sad all the time.
    3. I am so sad or unhappy that I can't stand it.
2. Pessimism
    0. I am not discouraged about my future.
    1. I feel more discouraged about my future than I used to.
    2. I do not expect things to work out for me.
    3. I feel my future is hopeless and will only get worse.
3. Past Failure
    0. I do not feel like a failure.
    1. I have failed more than I should have.
    2. As I look back, I see a lot of failures.
    3. I feel I am a total failure as a person.
4. Loss of Pleasure
    0. I get as much pleasure as I ever did from the things I enjoy.
    1. I don't enjoy things as much as I used to.
    2. I get very little pleasure from the things I used to enjoy.
    3. I can't get any pleasure from the things I used to enjoy.
5. Guilty Feelings
    0. I don't feel particularly guilty.
    1. I feel guilty over many things I have done or should have done.
    2. I feel quite guilty most of the time.
    3. I feel guilty all of the time.
6. Punishment Feelings
    0. I don't feel I am being punished.
    1. I feel I may be punished.
    2. I expect to be punished.
    3. I feel I am being punished.
7. Self-Dislike
    0. I feel the same about myself as ever.
    1. I have lost confidence in myself.
    2. I am disappointed in myself.

3. I dislike myself.

8. Self-Criticalness
    0. I don't criticize or blame myself more than usual.
    1. I am more critical of myself than I used to be.
    2. I criticize myself for all of my faults.
    3. I blame myself for everything bad that happens.
9. Suicidal Thoughts or Wishes
    0. I don't have any thoughts of killing myself.
    1. I have thoughts of killing myself, but I would not carry them out.
    2. I would like to kill myself.
    3. I would kill myself if I had the chance.
10. Crying
    0. I don't cry any more than I used to.
    1. I cry more than I used to.
    2. I cry over every little thing.
    3. I feel like crying, but I can't.
11. Agitation
    0. I am no more restless or wound up than usual.
    1. I feel more restless or wound up than usual.
    2. I am so restless or agitated, it's hard to stay still.
    3. I am so restless or agitated that I have to keep moving or doing something.
12. Loss of Interest
    0. I have not lost interest in other people or activities.
    1. I am less interested in other people or things than before.
    2. I have lost most of my interest in other people or things.
    3. It's hard to get interested in anything.
13. Indecisiveness
    0. I make decisions about as well as ever.
    1. I find it more difficult to make decisions than usual.
    2. I have much greater difficulty in making decisions than I used to.
    3. I have trouble making any decisions.
14. Worthlessness
    0. I do not feel I am worthless.
    1. I don't consider myself as worthwhile and useful as I used to.
    2. I feel more worthless as compared to others.
    3. I feel utterly worthless.
15. Loss of Energy
    0. I have as much energy as ever.
    1. I have less energy than I used to have.
    2. I don't have enough energy to do very much.
    3. I don't have enough energy to do anything.
16. Changes in Sleeping Pattern
    0. I have not experienced any change in my sleeping.
    1a I sleep somewhat more than usual.
    1b I sleep somewhat less than usual.
    2a I sleep a lot more than usual.

2b I sleep a lot less than usual.
3a I sleep most of the day.
3b I wake up 1-2 hours early and can't get back to sleep.

17. Irritability
    0. I am not more irritable than usual.
    1. I am more irritable than usual.
    2. I am much more irritable than usual.
    3. I am irritable all the time.
18. Changes in Appetite
    0. I have not experienced any change in my appetite.
    1a My appetite is somewhat less than usual.
    1b My appetite is somewhat greater than usual.
    2a My appetite is much less than before.
    2b My appetite is much greater than usual.
    3a I have no appetite at all.
    3b I crave food all the time.
19. Concentration Difficulty
    0. I can concentrate as well as ever.
    1. I can't concentrate as well as usual.
    2. It's hard to keep my mind on anything for very long.
    3. I find I can't concentrate on anything.
20. Tiredness or Fatigue
    0. I am no more tired or fatigued than usual.
    1. I get more tired or fatigued more easily than usual.
    2. I am too tired or fatigued to do a lot of the things I used to do.
    3. I am too tired or fatigued to do most of the things I used to do.
21. Loss of Interest in Sex
    0. I have not noticed any recent change in my interest in sex.
    1. I am less interested in sex than I used to be.
    2. I am much less interested in sex now.
    3. I have lost interest in sex completely.

Total Score: _____

Appendix H

Form 7. Charleston Psychiatric Outpatient Satisfaction Scale

Your opinions about us are very important. Please give your honest opinions on each question.

Please rate each item on the following scale: EXCELLENT, VERY GOOD, GOOD, FAIR, or POOR. If an item does not apply to you, circle DOES NOT APPLY (N/A).

	Very Good	Excellent	Good	Fair	Poor	Does Not Apply
1. Helpfulness of the secretary	5	4	3	2	1	N/A
2. Information provided about payment for services	5	4	3	2	1	N/A
3. Amount of time waiting to be seen	5	4	3	2	1	N/A
4. Amount of information given to you about your problem	5	4	3	2	1	N/A
5. Respect shown for your opinions about treatment	5	4	3	2	1	N/A
6. Matching of treatment plan to your individual needs	5	4	3	2	1	N/A
7. Helpfulness of the services you have received	5	4	3	2	1	N/A
8. Overall quality of care provided	5	4	3	2	1	N/A
9. Appearance of the waiting room	5	4	3	2	1	N/A
10. Appearance of the office	5	4	3	2	1	N/A
11. Office hours	5	4	3	2	1	N/A
12. Location of this outpatient service	5	4	3	2	1	N/A
13. Parking	5	4	3	2	1	N/A
14. Clear and correct monthly bill	5	4	3	2	1	N/A
15. Would you recommend this program to a friend or family member? (circle one)	Yes	No	Probably			Definitely
	Probably Not			Definitely Not		

How could we improve our services?
Other Comments:

Scoring the Charleston Psychiatric Outpatient Satisfaction Scale Items 1 through 14 are scored using the following 5-point scale: 5 = Excellent 4 = Very good 3 = Good 2 = Fair 1 = Poor

Item 15 is scored using the following 4-point scale. 4 = Yes, definitely 3 = Yes, probably 2 = No, probably not 1 = No, definitely not

The scale is scored by summing the scores of all individual items except the anchor items (items 8 and 15). The possible range is 13 to 65.

uses of the scale, the owner of the copyright should be contacted. Citation: Pellegrin KL, Stuart GW, Maree B, Frueh BC, Ballenger JC. A brief scale for assessing patients' satisfaction with care in outpatient psychiatric services. Psychiatric Services 2001; 52:816-81

Appendix I

Form 8. Sample Size Calculation

Our sample size was calculated using the GLIMMPSE software created by University of Colorado for sample size calculations for mixed effects models.[1] Using a power of .80 and a type 1 error rate of 0.1, a total sample size of 226 was recommended (113 each in treatment and control groups). The key assumption for this calculation was that over the course of the study telepsychiatry patients' improvements would be superior to face-to-face treatment by the minimal clinically significant amount (5 points on the 60-point scale[2)]. Furthermore, we assumed that BDI has a standard deviation of 10.[3]

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