A Pilot Study of the Effectiveness of Symptom Targeted Intervention (STI) for Post-Liver

Transplant Patients Focusing on Anxiety, Depression, Stress, and Alcohol Use.

Regina M. Miller

A Dissertation

In

Social Work

Chair of Dissertation
Phyllis Solomon, Professor of Social Policy & Practice

Dissertation Committee
Robert Weinrieb, MD
Department of Psychiatry
University of Pennsylvania Hospital

Table of Contents

Dedication

I dedicate this work to the patients and caregivers touched by liver transplant.

Acknowledgements

Abstract

Objective: The purpose of this exploratory pilot social work telemedicine study was to assess feasibility and preliminary outcomes as to whether Symptom Targeted Intervention (STI) was more effective in decreasing the symptoms of anxiety and depression, stress and alcohol use than social work monitoring and care coordination (SWCC) for the early liver transplant population (< 6 months). Assessing stress as an outcome measure is unique in the early post liver transplant research.

Methods: Twenty-seven early post liver transplant patients at Penn Medicine prescreened into the pilot randomized control trial and twenty-one were subsequently randomized into two groups, STI versus SWCC. Twenty-one completed pre and post measures, including Demographics, Quick Drinking Screen (QDS), Depression Anxiety Stress Scale (DASS-21) and Hospital Anxiety and Depression Scale (HADS). Due to the small sample size, and an inability to control for differences in higher screening scores in the treatment group, an exploratory analysis was conducted. This exploratory analyses utilized repeated measures t-tests to assess changes in the treatment and control group separately on DASS and HADS measures. Alcohol was not analyzed due to the lack of positive cases. Feasibility was measured by recruitment and attrition rate, completed sessions, patient engagement, along with social work fidelity and engagement.

Results: Feasibility measures were indicative of a promising pilot study, with ability to recruit a sample and 100% retention, 21 participants completing at least three and 17 completing six consecutive sessions, along with the posttests. Random observations matched weekly theme at 100% with 42.5 hours of total patient engagement. Evidence for the effectiveness of STI versus SWCC in the early liver transplant period to decrease stress and depression was found in the patterns of differences between groups at pre-test and post-test. The treatment group ($n=10$) but not the control group ($n=11$) showed a significant reduction in stress at post-test, with the treatment group's mean stress score ~4 points lower at post-test than it was at pre-test [$t(10)=3.58$, $p=0.003$] while the control group's post-test score was 2.36 points lower than at pre-test [$t(11)=1.90$, $p=0.09$]. Additionally, the control group *increased* in depression between pre and post while the treatment group *decreased* in depression, demonstrating a trend. Decreases in anxiety occurred in both groups measured by DASS. HADS anxiety results not significant, although arguably promising for STI group.

Conclusion: This pilot study demonstrates promising preliminary results in decreasing stress and depression. The feasibility findings of this study demonstrate the ability to implement STI for early post liver transplant patients by Master's degree prepared transplant social workers and being delivered with encouraging results.

Chapter 1. Background and Significance

Statement of the Problem

In the US, deceased solid organ donors increased 38% since 2014 (United Network Organ Sharing [UNOS], 2020). In 2019, the numbers of deceased donors increased 10.7%, and although the increase is welcome, it is barely closing the gap. In 2019 transplants performed in the US were 39,718 with over 100,000 patients waiting on the national list (UNOS, 2020). In the US, there are 12,139 patients awaiting a liver transplant (Organ Procurement and Transplantation Network [OPTN], 2020). In 2019, Penn Medicine transplanted 135 liver patients (OPTN, 2020). This unfortunate organ shortage highlights the ethical dilemmas inherent in all transplant programs. Transplant programs respond to resource allocation by creating policies around transplant fitness to improve positive outcomes. A failed transplant is very unfortunate, since re-transplant criteria is more highly scrutinized. Liver transplant recipients requiring a second transplant are held to higher standards based on past risk behaviors. The best survival benefit is from the *first* liver transplant compared to a second or third transplant (Marudanayagam, et al., 2010). Re-transplanted liver recipients suffer worse outcomes (Kasiske, 2020, p. 51). Social workers share responsibility for transplant outcomes (Morris, 2020; Pilch, 2020; Williams et al., 2016).

Social work is a mandated role on each transplant team (The Centers for Medicare and Medicaid [CMS], 2008; UNOS, 2020). Transplant patients require a formative set of skills from trained social workers to prepare and care for them throughout the transplant continuum (CMS, 2008; Society for Transplant Social Work [STSW], 2020; UNOS, 2020). The transplant social workers engage in discharge planning, concrete resources, and supportive care, with a high value

placed on attending to the emotional needs of the patients. Transplant social workers are met with the challenge of working with a patient population suffering from a variety of mental health and substance abuse issues. Mental health issues should be mitigated to improve long-term physical health outcomes in the transplant population (Dew, 1998). In liver transplantation, there is not one psychiatric disorder considered an absolute contraindication (Mahmud, 2020; Martin, 2014).

Mental health issues confound the transplant process and threaten positive outcomes (Bhogal et al., 2019; Corbett et al., 2013). Transplant social workers lack specific evidence-based practices in reducing symptoms of psychological distress in the transplant patients. Front-line interventions targeting anxiety, depression, and stress are unavailable, with most referrals for psychological care being sent to outside mental health providers. Referrals made to mental health providers outside the system create additional burden for patient and caregivers due to the complex medical routines and expectations of the transplant program in the early post- liver transplant phase. Schmajuk et al. (2019) recognize the gaps in the psychological care of transplant patients and encourage psychotherapies that span emotional wellness, physical symptoms, and adherence to treatment recommendations.

Liver transplant recipients demonstrate high rates of depression (Bhogal et al., 2019; DiMartini, Dew, & Trzepacz, 2011; DiMartini, Crone, & Dew, 2011; Rosenberger et al., 2012). Liver transplant recipients experience substantial elevation of anxiety and depression compared to the general population (Dew et al., 2015). Despite comprehensive pre-transplant assessment and screening, liver transplant recipients experience some of the highest rates of psychiatric disorders among all solid organ transplant patients (DiMartini et al., 2019). At three- months post-liver transplant, recipients experience higher depressive symptoms resulting in higher risk

of long-term mortality (Corruble et al., 2011). Moreover, depression is concurrent with alcohol use and impairment and future alcohol use and impairment (Conner, 2009). This combination of depression and alcohol use contributes to poor overall liver transplant outcomes (DiMartini, Crone & Dew, 2011). It is imperative to begin "risk- reduction activities" to mitigate anxiety and depression early in the post-liver transplant population (Bhogal et. al, 2019; Dew et al., 2015).

Enforcing a psychotherapeutic model of care throughout the transplant continuum is an effective approach to decrease psychological distress around the emergent crises that arise in this population (McKie et al., 2020; Zilberfein et al., 2008). Dew et al.'s (2015) qualitative review of psychosocial assessments and outcomes in organ transplantation points to the need for more carefully targeted interventions to address the areas of concern to promote improved outcomes (p. 252). Interventions comprised of service components derived from evidence- based practices, such as Symptom Targeted Intervention (STI), with the goal to decrease anxiety, depression, and improve coping in transplant patients, could feasibly fit in medical settings seem to meet the essential elements (Sledge et al., 2011). Symptom Targeted Intervention is based on evidence-based principles of Cognitive Behavioral Therapy, Mindfulness, Motivational Interviewing, and Solution Focused Therapy. Symptom Targeted Intervention (STI) provides staff education and patient assessment measures. In addition, the brief time requirements (20-30 minutes) per session make it most feasible in a medical setting (Stellicare.com). In 2016, at the STSW conference, preliminary results of Symptom Targeted Intervention (STI) were presented and findings demonstrated significant effects in a one group pretest-posttest for both anxiety and depression across liver, kidney, heart and lung recipients (Greene et al., 2020).

.   Given that STI shows promise, this pilot research utilized this intervention at Penn Transplant Institute (PTI) in the post-liver transplant population to examine its preliminary effectiveness using a stronger design by examining the following questions:

1) Can medical social workers feasibly implement Symptom Targeted Intervention (STI) via Telemedicine with fidelity to post-transplant liver patients? To what extent can these patients be recruited and fully engaged in STI?

2) Is Symptom Targeted Intervention (STI) using Telemedicine in the early post- liver transplant phase preliminarily more effective in decreasing depression, anxiety, stress, and alcohol relapse than usual social work monitoring and care coordination (SWCCS)?

Background and Significance

Physical illness is associated with higher rates of psychological distress (Cassem, 1995; Hamer et al., 2019; Schneiderman, et al., 2005). Rates of specific psychiatric disorders can be up to 8.5% higher for those suffering a physical illness compared to those in the community without a physical illness. In addition, the "physical illness-psychiatric condition" increase appears to vary in strength depending upon the specific illness (Dew, 1998, p. 196). Transplantation can be viewed as trading a life-threatening physical illness for a lifetime of medical care and surveillance. Solid organ transplant introduces new concerns that can contribute to psychological distress (Pascazio et al., 2010; Rogic, 2019).

Liver transplant is the only treatment for patients with terminal liver disease (Goel et al., 2019; Nickel et al., 2002). Liver transplant recipients with high rates of depression and anxiety experience poor quality -of -life in all dimensions (Nickel et al ., 2002). Findings on the prognostic value of pre-liver transplant (LT) depression or anxiety on post-LT outcomes are mixed, though depression appears to predict lower quality- of -life (QOL), and psychological

measures unrelated to alcohol or drug use during the pre-LT phase does not support or deny the influence of outcomes post- liver transplant (Fineberg et al., 2016). Psychiatric morbidity in post- liver transplant recipients is higher than that of the general medical patient population (Collis et al., 1995) and compared to other solid organ transplant recipients, liver transplant recipients have some of the highest prevalence of mental health disorders (DiMartini, et al., 2019).

Anxiety

Anxiety in the transplant population is influenced by liver diagnosis, sleep patterns, medication side effects and alcohol use. For example, anxiety is found in liver transplant recipients' who suffer a decrease in sleep quality that may result in an impaired recuperation during the post-liver transplant phase (Mendes et al., 2014). Liver transplant recipients are at risk of experiencing poor sleep patterns due to hospitalizations, medications, and other confounding reasons that may result in an increase in anxiety levels (Mendes et al., 2014). Anxiety- related disorders can reach 33% of post-liver transplant patients (Annema et al., 2015).

Post-liver transplant anxiety was measured in the ICU and this study split patients between high and low anxiety levels and both groups were followed up at one- year post transplant. A high level of anxiety early post- transplant surgery had a negative long-term influence on the health of patients (Perez-San-Gregorio et al., 2006, p. 2407). In a meta-analysis of thirty-one studies (N=16,922), an increase in medical symptoms were reported by patients when they suffered from anxiety and/or depression, along with chronic medical illness compared to those with chronic medical illness without anxiety and/or depression (Katon et al., 2007). In liver transplantation, thirty-three percent of liver transplant recipients experienced psychological problems, especially within the first two years and after ten years (Annema et al., 2015). Anxiety

in the transplant literature demonstrated a modest association with increased mortality risk post-transplant but did not show significance in a systemic review and meta-analysis (Dew et al., 2015). Dew et al. (2015) denotes that there are less precise and fewer studies on the effects of anxiety on morbidity and mortality post transplantation. Regardless, there is a need to further investigate anxiety post transplantation to learn how to mitigate its effects.

A descriptive study measured the post- liver transplant timeline and its association with mental health, or more specifically, anxiety. The population was split into groups based on a timeline that differentiates short-term (0-2 years), intermediate short-term (2-5 years), intermediate term (5-10 years), intermediate long term (10-15 years), and long term ($\geq$15 years). In each group, anxiety was reported as being associated with two variables: 1) number of side effects from immunosuppressant medications and 2) Viral hepatitis diagnosis (Annema et al., 2015, p. 530). Moreover, anxiety symptoms were highly correlated in the short- term group among those suffering from alcoholic liver disease (Annema et al., 2015). This study's findings differ from a previous controlled study denoting no difference in psychiatric outcomes in relationship to the diagnosis of alcoholic liver disease to transplant compared to those undergoing liver transplant diagnosed with a non-alcohol related liver diagnosis (Gledhill et al, 1999). Anxiety in liver transplant populations compared to the general populations demonstrates that anxiety levels decrease from pre -to post liver transplant, although anxiety remains higher than in the general population (Benzing, et al., 2015).

In Pelgur et al. (2009) descriptive study of anxiety and depression, sixty-four patients received a liver transplant at least one month prior to the interview. Thirty-three percent were female and 34.4% of the overall population were between ages 16 and 20 years, with 18.8% receiving a liver transplant < 1-year prior; 25%, 1 to 2 years prior; 12.5%, 3- years prior; 14.1%,

4 -years prior; and 4.7% > 4 years prior. The HADS was more sensitive to depression than anxiety among liver transplant patients. The anxiety subscale and depression subscale were related since 89.5% of anxious patients were depressed and 44.4% of patients who were not anxious were depressed. The highest mean score on the HADS and the highest percentage of anxious patients were found in those who had undergone transplantation 4 years prior. Seventy-five percent of patients were depressed who had undergone transplant 1- year prior and "according to the time elapsed after transplantation, no significant difference was observed in the distribution of patients who were and were not depressed" (p. 1745). The mean scores on the anxiety subscale, depression subscale, and the HADS were higher among those 46 years and older compared to other ages. In a more recent European study, researchers concluded that older age should not be a contraindication for liver transplant after it was found that those 70 or older recipients experienced fatigue, depression, anxiety, and reduced life satisfaction at comparable or improved rates to their younger counterparts (Krenzien et al., 2017). Notably, women demonstrate increase anxiety levels over men in the post liver transplant population (Pelgur et al., 2009; Yildiz & Kilinc, 2017). More specifically, women receiving liver transplant versus heart transplant report a significantly higher grade of global psychological stress (Langenbach, et al., 2008).

Depression

In the liver transplant population, thirty- percent of recipients suffer from depression (DiMartini, Dew, & Trzepacz, 2011). Depression- risk is higher than anxiety- risk in the liver transplant population (Yildiz & Kilinc, 2017). Recognizing and treating depression correlates with increased survivability. In a 2015 systematic meta-analysis, depression was associated with a 65% increased risk of post- transplant mortality, regardless of study-related characteristics

(Dew et al., 2015). Patients who sought treatment and received antidepressants had a forty - percent lower risk of dying in relation to others in the transplant sample, when controlling for age and sex (Meller et al., 2017). Rogal et al. (2013) found that treating depression early in the post-liver transplant course was associated with improved long-term mortality compared to those with depression symptoms either undertreated or not treated; and Corruble et al. (2011) found a relationship between the severity of depressive symptoms as measured by BDI and mortality, with patients suffering depressive symptoms three -months post-liver transplant. A surprising discovery was those same participants with depression at three months' post -transplant were facing a "higher risk of mortality if they did not have depressive symptoms while on the waiting list," (p. 34).

Demographics in this population illustrate additional complexities. Social support promotes good outcomes (Maldonado, et al., 2012), although a specific type of support raises interesting questions. The causes behind the finding that married patients are significantly more inclined to depression than single patients in post-liver transplantation (Pelgur et al., 2009) have not been studied. Moreover, gender plays a role in some studies, with the percentage of depressed male patients being higher than that of depressed female patients (Pelgur et al., 2009). Currently, treating depression in transplantation focuses primarily on pharmacological interventions, particularly a prescription for a Selective Serotonin Uptake Inhibitors (SSRI) as the drug of choice (Sebaaly et al., 2016; Krahn & DiMartini, 2005). To date, alleviating depression has not been at the fore of standard post- liver transplant care. Provider concerns are different in the post-transplant phase, with a strong focus on rejection or immunosuppressant medication effects on mortality. Pharmacological protocols inadequately address depression in the post-liver transplant population (Sebaaly

et al., 2016). There are very few studies that illustrate effects of non-pharmacological interventions in this population (Mullish et al., 2014). Gorevski et al.'s (2013) cross-sectional study of both liver and kidney recipients demonstrates the effects of depression in post liver and kidney transplant populations and reports both groups had minimal to mild depression, or 52% and 60%, respectively, with only one-fifth of all patients per group reporting no depressive symptoms. Depressive trajectories suggest it to be the strongest predictor of survival conferring a two- time higher risk for death (DiMartini, Dew, Chaiffetz, et al., 2011, p1292). Depression studies in the liver transplant population identify risk but lack concrete solutions other than recommending providers pay closer attention to psychopharmacology.

Stress

Overall, post solid organ transplant recipients demonstrate equal stress responses, regardless of organ type (Baranyi et al., 2013). Transplantation recipients may face major transplantation and treatment related overall mental distress and impairments to their health-related quality of life. Further, overall mental distress is a high-risk factor in intensifying impairments to patients' overall quality of life (Baranyi et al., 2013) and physical health (Hamer et al., 2019). Liver transplant patients are admitted to the Intensive Care Units post operatively until stable. Researchers report medical related stress in ICU admissions and find "a potent independent association with increased severity of not only Post Traumatic Stress Disorder (PTSD) symptoms but also depressive symptoms over the course of the year post-ICU, and these psychological risks are considerably modifiable" (Davydow et al., 2013, p. 229).

Alcohol Abuse and Relapse

Alcohol is the main cause for liver failure and subsequent transplantation in the United States (EASL, 2018; Lee et al., 2019). Alcohol can cause cirrhosis by itself or can contribute to the development of cirrhosis in other conditions, such as Hepatitis C (Yates et al., 1998). Five-year mortality for those patients with cirrhosis who cease drinking is 10% compared to 30% for those who continue to drink (DiMartini, 2015). Liver transplant is the only option for those decompensating from alcohol -related liver diagnoses. Yates et al. (1998) argue it is detrimental to prevent or delay liver transplant listing without consideration of both an estimate of alcoholism severity and duration of sobriety versus the patient's duration of sobriety alone. Complicating treatment in this liver transplant population is the consideration that those suffering from Alcohol Use Disorders (AUDs) with varying severity typically present with a depression and anxiety scenario (Yates, 2007). A study comparing alcoholic liver disease to non- alcoholic liver disease demonstrates that patients with AUDs remain vulnerable, but they do not show evidence of increased psychiatric morbidity in the liver transplant population (Howard et al., 1994). An earlier univariate and multivariate logistic regression identified independent predictors of relapse points to family history of Alcohol Use Disorders as an independent factor in relapse post liver transplant (Jauhar et al., 2004). Moreover, Gledhill et al.'s (1999) study refutes the idea that those suffering from alcoholism and subsequently receive a liver transplant will go on to suffer worse mental health and quality- of -life issues compared to their non-alcoholic liver transplant cohort.

In the general population, studies demonstrate the relationship between alcohol use and psychological issues. A substance abuse meta-analysis of seventy-four studies supports the hypothesized association between depression and concurrent alcohol use, and more specifically,

shows that depression correlates with 1) future alcohol use and impairment 2) an earlier age of

onset of an alcohol use disorder, and 3) higher treatment participation (Conner et al., 2009). This

study confirms the finding of an earlier study demonstrating higher participation in help- seeking

behaviors in the comorbid alcohol group, defined as those diagnosed with either alcohol abuse or

alcohol dependence, plus, at least one comorbid diagnosis of anxiety, affective or drug use

disorder in the previous 12 months versus the 'pure alcohol-(l) use disorder group' (Burns &

Teesson, 2002). The CIDI assessment tool excludes the possibility of an alcohol use disorder

when a lifetime diagnosis of alcohol dependence is present. This study reports that those meeting

criteria for the group labeled 'severe alcohol dependence' had a significantly stronger effect on

the persistence of depression and/or anxiety disorders than those meeting criteria for the group

labeled 'alcohol abuse'. The severity of alcohol dependence (meeting six or seven criteria) and

severity of alcohol abuse (one or more criteria) were defined by the number of criteria met in

each category. Severe alcohol dependence had the most significant unfavorable course of

depressive and/or anxiety disorders and comorbid alcohol dependence was more likely to be

secondary than primary to anxiety or depressive disorders (Boschloo et al., 2011, p 240).

Boschloo et al. (2011) differentiated alcohol dependence through the Short Form Composite of

International Diagnostic Interview (CIDI). Alcohol abuse was defined in this study with the

DSM-IV requiring one or more of the four abuse criteria, while dependence was defined by three

or more of the seven dependence criteria.

    Dew et al. (2008) reports a post liver transplant relapse rate defined as any alcohol use at

six per 100 patients per year (PPY) compared to heavy alcohol use at three cases per 100 PPY,

with the most worrisome trend being the cumulative rates, reaching 28 PPY by the fifth post

liver transplant year. Lee et al. (2018) reports relapse rates and harmful rates at 23.5% measured

at 1.5 years' post-liver transplant, with rates of any alcohol use increasing to 34% and sustained alcohol use at 17% by 3 years, and higher mortality rates for those with sustained alcohol use. The myth that patients are too sick to drink in the early phase post- liver transplant is refuted in Lee et al.'s (2017) retrospective three-year pilot for Severe Alcoholic Hepatitis (AH) study. Group 1 (severe AH) was compared to Group 2 (alcoholic cirrhosis and > 6- months abstinence prior to liver transplant) and the groups were similar in rates of alcohol relapse in the early transplant phase, or 23.5 vs. 29.2 (P>.099). Survival rates were 100% (Group 1) compared to 88% (Group 2) at 6 -months post- transplant. Group 2 exhibited relapses defined as 'slips' rather than sustained drinking. Conversely, three patients in Group 1 relapsed within three months and this group exhibited more harmful drinking patterns early post- transplant, resulting in early death due to sustained alcohol relapse for two of them (Lee et al., 2017).

Chronic, alcohol dependence reinforces stress hormones and chronic, heavy use of alcohol products contributes to an altered set point below that associated with normal mood states. There are physical and emotional costs associated with physiological corrections related to the effects of having a prolonged course of an alcohol Use Disorder (Anthenelli, 2012). Alcohol use contributes to developing malignancies, cardiovascular disorders, liver damage and reduced survival, with some patients experiencing cirrhosis unable to reach transplantation (Chak & Saab, 2010). A review in the *Journal of Hepatology* explains a new classified syndrome, or Acute-On-Chronic Liver Failure, creating keener insight into the acute trajectory of some suffering from cirrhosis. Acute-On-Chronic Liver Failure afflicts mostly young patients suffering from alcoholism and untreated Hepatitis B cirrhosis that presents with an exaggerated inflammatory response characterized by acute decompensation, organ failure and high short-term mortality (Arroyo et al., 2015). Liver transplant is a useful intervention to treat Acute-On-

Chronic Liver Failure (Finkenstedt et al., 2013). Regardless, alcohol use assessment is integral both pre- and post- transplant. Moreover, an alcohol intervention plan to address emotional well-being and alcohol relapse has been recommended to be instituted and adopted by the transplant team in the post-operative plan of care and continued for at least one-year post transplant (Dom et al., 2015; Winder et al., 2020).

Mental Health Practice in Medical Settings

Assessment and screening by social workers for mental health issues are standard practice in the pre-transplant setting (Maldonado et al., 2012). A prospective study design implementing the first known internet-based psychosocial transplant intervention for all solid organ populations used heart transplant recipients and respective caregivers by Dew et. al (2004) demonstrated significant depression and anxiety symptoms of patients pre to post with recipients (N=24) and associated caregiver anxiety and hostility symptoms (N=20) experienced decreased symptoms in the intervention group. Recent recommendations in the literature emphasizes the need to re-assess depression post- transplant and to intervene in a timely manner (Sebaaly et al., 2016). The early post-liver transplant phase is a time of opportunity for mental health practitioners to encourage the use of evidence-based interventions and tools in their practice. Evidence -based practices are showing promise in this population. Cognitive-Behavioral Therapy (CBT) compared to those receiving conventional treatment demonstrated a reduction in the level of anxiety and stable vital signs (Su et al., 2014). This limited study differs from a pilot study of post -heart transplant patients being offered 8 phone delivered CBT sessions for sixty minutes per session with a psychology student supervised by a psychologist, followed by a multidisciplinary case conference discussing the implications for longer term psychological treatment. A pilot randomized controlled trial and low recruitment of thirteen participants were

limitations in this study. The researchers concluded that those most benefiting from phone CBT were not accepting the telephone-based intervention and that face- to- face or video telemedicine may be more acceptable. In addition, a two-step screening process is recommended to confirm participants' intentions prior to randomization due to the number of drop outs after the initial contact (Conway et al., 2016).

Thus, responding to some of their suggestions in the study design, Sidhu et al. (2015) found that 56% (110/195) of lung transplant participants opted into telemedicine visits. Ninety-seven percent of the telemedicine sample rated telemedicine as equal or superior to face-to-face clinic visits. Furthermore, the proposed study differs from Conway et al. (2016) in its initial screening process, population focus, average age of transplanted organ, use of brief intervention and the use of a telemedicine video portal.

`   Mindfulness is being used across multiple non-transplant medical settings. Pre-existing mindfulness traits in individuals are shown to experience decreased plasma inflammation rates reaching novel states (Gusev, 2015). Gross et al.'s (2010) three-group randomized study tested the effectiveness of a Mindfulness Based Stress Reduction (MBSR) program to reduce symptoms of depression, anxiety or sleep disturbances. The MBSR program was compared to two Control groups: an active Health Education program and a usual care waitlist that was later re-randomized to MBSR or Health Education. Mindfulness-Based Stress Reduction (MBSR) was compared to Health Education classes. Recruitment took place via clinician referrals, direct mailing from patient advocacy groups, and brochures placed in medical clinics and pharmacies. The patients were at least six-months post -transplant. Mindfulness-Based Stress Reduction (MBSR) and Health Education classes were conducted in parallel, or 8- weekly 2.5-hour classes, and mostly populated by kidney transplant patients. In addition, the MBSR group had a two-day

booster and Health Education provided an equivalent amount of care. In three and one-half years, one-hundred and fifty patients were enrolled. The outcomes compared between MRSB and Health Education showed better outcomes in the MRSB experimental group. The waitlist group enabled the researchers to confirm that treatment effects (from either MBSR or Health Education program) exceeded usual care. Home practice of MRSB averaged 29 minutes, or 75% of recommended time up until week eight, and more home practice correlated with greater reduction in anxiety symptoms (Gross et al., 2010).

A clinically, exploratory six-week pilot intervention based on in -person mindfulness training classes were constructed for pre-transplant (n=10), post -transplant patients (n>6months=7 &/ n<6months=14), and caregivers (n=18) (Stonnington, et al., 2016). The class incorporated mindfulness practice, yoga, and neuroscience of stress and resilience provided to 31 heart, liver, kidney/pancreas, and stem cell transplant patients and 18 caregivers at Mayo Clinic in Arizona in three rounds over the course of one year. Study measures were completed at baseline, six weeks, and then, three months' post intervention and 80% attended three or more sessions with significant improvements in pre- and post- transplant patients over time (6 weeks and 3 months) from baseline measures of perceived stress, depression, anxiety and negative affect. Caregivers attending with patients did improve on the same outcome measures, although not enough for statistical significance. Classes were led by a psychologist and a yoga therapist experienced in mindfulness practices, with CDs provided for practice. The limitation to this study was its lack of a control group. The inclusion of a diverse transplant populations, including pre, post, and stem cell transplant patients, was meant to develop a larger program at this clinic in the future. The study suggests MRBT has an impact on improving severe mental health components of the health- related quality of life (HRQOL) measures. Recruiting efforts were

targeted at pre-existing support groups and the researchers indicate this could affect

generalizability (Stonnington et al., 2016). Regardless, patients seemed to have benefited from

the mindfulness practices in this study.

Motivational Emotional Therapy (MET) was used in Weinrieb et al. (2011) randomized

controlled design study and showed promise in decreasing both amount and frequency of alcohol

consumption.   Motivational Emotional Therapy (MET) is a psychotherapy approach for

addiction treatment used to overcome the ambivalence and resistance to behavior changes

(Rollnick & Miller, n.d.). Motivational Interviewing (MI) principles are used to strengthen

motivation and build a plan for change in MET (NIH, 2018). Motivational Interviewing is

employed in STI techniques (McCool et al., 2014).

Main components of Solution-Focused Therapy (SFT) is used in STI and its success in

the medical- behavioral setting is reported. For example, clients who received either Solution

Focused Group Therapy (SFGT) or a traditional addictions treatment approach for Level I

alcoholism both demonstrated overall improvement with screening tools, although clients who

received SFGT improved to a significantly greater degree on comorbid factors, unlike the

traditional approach group (Smock et al., 2008, p. 171). Arvand et al. (2012) published a case

presentation of two patients suffering from both depression and Hepatitis B, concomitantly. After

five- weekly 50- minute SFT sessions, relief of depressive symptoms was evident in both cases.

Solution Focused Therapy (SFT) can easily be implemented by clinicians who do not view

themselves as 'experts' (Bannink, 2007). The social workers' ethical standards (Hobdy et al.,

2017) span commitment to clients (1.01), self-determination (1.02), and informed consent (1.03)

and the concepts merge seamlessly with SFT's theoretical strength's perspective frame. The

essential social work ethical principal of placing human relationships at the fore to provide a

vehicle for positive change creates unique opportunities in the more problem-focused medical systems. The use of STI embedded with SFT components affords both transplant social worker and patient enhanced opportunities to work toward common goals in a more solution- based manner.

Symptom Targeted Intervention (STI) was being implemented and studied at multi-sites and forty-eight post-transplant participants (30- kidney, 9- liver, 6- heart, and 3- lung) demonstrated significance in renal transplantation for pre-test post-test anxiety in females. In addition, depression was significant at pretest- follow -up comparison in the renal population only. This current study of early post liver transplant patients differs from the Greene et al. (2020) study by focusing only on the post liver transplant population, measuring (di)stress, and scheduling telemedicine visits, along with tailoring the skills and materials to a specific transplant population.

In the early post-liver transplant phase, there is a need to introduce social work strategies to alleviate psychological symptoms to improve outcomes (Langenbach et al., 2008; Rainer et al., 2010). There are recommendations proposed in the literature to provide interventions to target symptoms of depression, since data suggests that depression and personality traits are associated with non-adherence to immunosuppressant medications (Gorevski, et al., 2013). Transplant social workers are proficient at assessment, although lack adequate skill training to deliver evidence-based intervention that may be useful in addressing outcomes of depression, anxiety, and substance use to this patient population.

Symptom Targeted Interventions (STI) delivered using Penn Telemedicine portal enables participants increased flexibility, confidentiality, and ability to engage in a more familiar space. Telemedicine is easily accessible and encouraged at Penn Medicine through the

VidYo/BlueJeans portal. "Nearly all studies affirmed the feasibility and acceptance of TMH [Telemedicine], involving children/adolescents, adults, and elderly patients with different disorders (migraine, attention-deficit disorders, bipolar disorders, anxiety, depression, substance abuse, and post discharge for somatic problems), rural and urban residents, and different technologies (telephone, Internet, and video)" (Bashshur et al., 2016, p. 109).

Applicability

Symptom Targeted Intervention (STI) provides a brief focused intervention that incorporates these evidence-based therapies and adopts tools to efficiently and practically implement them in a medical setting (McCool et al., 2011; McCool, 2015). STI is also a feasible intervention to use in medical settings (Greene et al., 2020; McCool et al., 2011) and targets symptoms associated with anxiety, depression and stress, along with other psychological stressors known to complicate the post-liver transplant trajectory. Post-transplant care requires a standardized social work intervention to meet the needs of this population. Currently, there is a shortage of brief interventions that can be efficiently integrated in a medical setting. In STI training, medical social workers easily attain skills to work effectively with patients (McCool et al., 2014; Greene et al., 2020). Brief intervention (20-30 minutes), along with a manualized approach tailoring a patient-centered curriculum that combines Mindfulness, Cognitive Behavioral Therapy (CBT), Motivational Interviewing (MI), and Solution-Focused Therapy (SFT) shows evidence of promise in transplant and dialysis populations.

Hypotheses

Based on the review of the literature, the study will examine the following hypotheses:

1) Symptom Targeted Intervention (STI) is a feasible social work intervention to implement in hospital systems in the early post -liver transplant phase.

2) Symptom Targeted Intervention (STI) will be preliminarily more effective in decreasing symptoms of depression, anxiety, stress and alcohol use in the early post-liver transplant phase compared to Social Work Monitoring and Care Coordination (SWCC).

. Objective: Assessing the feasibility of adopting Symptom Targeted Intervention to supplement social work case management in the liver transplant population at the Penn Transplant Institute (Penn Medicine).

The COVID 19 pandemic created unforeseen barriers, including the inability to meet with patients face-to-face and a pause on research unrelated to COVID 19. Moreover, social work resources became more restricted due to coverage issues, staff resignations, clinical prioritization, and increased staff workload. The ability to recruit and engage patients became increasingly difficult, which resulted in a lower number of participants than initially proposed. The lower N resulted in a design shift from an RCT to a pilot investigating preliminary assessment of feasibility and effectiveness of the STI intervention.

Chapter 2. Methods

Design

To explore the research questions, the researcher conducted a pretest post-test design by condition. All participants engaged with transplant social workers via phone app, iPad, or computer by using VidYo/Blue Jeans platform. The study implemented STI to mitigate symptoms of depression, anxiety, stress and decrease alcohol use in the early post-liver

transplant population for six consecutive weeks via HIPPA compliant Penn Medicine telemedicine technology through identified and secured staff computers. In addition, this study employed a control group, or enhanced treatment-as-usual, providing social work coordination and case management, also using telehealth, although the barriers and gaps during this study to enroll participants forced a change to the design at analysis from a desired Randomized Control Trial (RCT) to an exploratory analysis with a pre/post -test design by condition.   Brief initial screening tools were used to determine potential participants' eligibility. At the time of consent, HADS and DASS scores determined eligibility for study inclusion. Outcomes were measured at baseline, termination, and three months' post- transplant. The second post-test assessed the maintenance of any gains of the STI intervention. This methodology determined both feasibility and effectiveness of a brief, targeted follow-up intervention in the early post-liver transplant phase in a medical setting as compared to control condition of social work monitoring and care coordination via VidYo/Blue Jeans telemedicine portal.

Departmental Support and Administrative Arrangements

Penn Medicine Transplant Institute (PTI), the Penn Medicine Transplant Psychiatrist, Gift of Life (GOL) Organ Procurement Agency, and the Department of Social Work were provided a formal written proposal and presentation and remained supportive throughout the research study. All University of Pennsylvania Policy on conflicts of interest related to research was followed. The transplant social workers on the team were trained across populations and were voluntarily assigned to deliver either intervention or control conditions. The procedures documented in this proposal were sponsored by the Penn Medicine Health System and there was no additional patient billing or additional staff resources required to complete this study. The liver transplant advanced practitioners (APPs) welcomed the study and reported that they were

impressed by the level of engagement of patients in this study. Social workers were newly

trained to deliver interventions to reduce symptoms and to integrate individual telemedicine

sessions into the daily workflow which was met with enthusiasm. Telemedicine's trajectory into

the mainstream grew quickly to meet the needs of the patients and caregivers during the

pandemic and the workflow became more seamless in terms of tech support and education for

both staff and patients. This study was supported by the Penn Medicine IT support staff and help

desk.

Setting and Sample Size

This study included early post-liver transplant patients who were being followed at the

Penn Medicine Transplant Institute (PTI).   In FY 2020, PTI transplanted 125 deceased donor

livers and seven living donor livers. COVID-19 pandemic slowed the living donor program and

decreased the living liver donor volume by more than half compared to FY 2019, although the

donor after cardiac death (DCD) volume remained stable. The study sample was one of

convenience, specifically consecutive sampling was employed. Participants were randomized

into treatment or control group. Twenty -four participants were consented to screen via telehealth

after COVID-19 restrictions.

Rolling participant recruitment began in spring 2019. The goal was to reach N=50,

although the COVID19 outbreak and its effects on staff and workflow in March 2020 created

research gaps that affected the ability to consent, recruit and actively engage the participants.

However, at the University of Pennsylvania Hospital, senior leadership in transplant, social

work, nursing, psychiatry, pharmacy, and telemedicine continued to be supportive of this study.

Face- to -face recruitment occurred at post-transplant outpatient clinic visits until the COVID-19

pandemic changed workflow and IRB approved recruiting and consenting virtually for non -

Covid -19 related research in summer 2020. Patients were screened at the time of their post-

visits and a referral was made by a member of the multidisciplinary team and then it was

determined if the patient met the initial screening criteria, or age ($\underline{18}$ >), time of transplant (≤ 6

months), alcohol use documented in medical record within two years prior to transplant surgery,

competency to sign consents, access to phone and/or computer technology, and English as the

primary language. In clinic or virtually, the researcher approached the patient to consent and

screen by REDCap IPad computer collection of demographic information, QDS, HADS, and

DASS. HADS and DASS were used to determine if inclusion criteria were met, and if so,

participant were then enrolled.

Recruitment & Consent. Recruitment took place in the post liver transplant clinic setting or

virtually once COVID- 19 clinic restrictions were implemented. The team was aware of the

study and its inclusion criteria, and card reminders with inclusion criteria were supplied to the

providers and nurse coordinators. Participants were referred to the researcher by the liver

transplant team members. If the patient met eligibility criteria, they were approached and, if

appropriate, moved to prescreen and engaged with the REDCap online screens for Alcohol use,

HADS and/or DASS in the presence of this investigator. Once it was determined that the patient

reached the score threshold, an introduction to the telemedicine platform was explained. The

initial visit was used to assist patients in downloading the VidYo/Blue Jeans telemedicine

connection app on the phone. Eventually, with the advent of COVID -19 enhancements, Blue

Jeans replaced VidYo and the patients were not required to upload an app to access, only to click

on a HIPPA secure link. All virtual procedures and policies were followed with the guidance of

the director at Penn Medicine Telemedicine.

Inclusion criteria. Those meeting inclusion criteria also had to be able to participate in a pretest screening assessment, weekly scheduled interventions lasting 20-30 minutes for six weeks, post - testing at completion of intervention, and additional post- testing three months after the last intervention. Finally, all participants met one or more of the following pre-test baseline scores for anxiety or depression screening at their initial clinic visit:

- HADS -D $\geq$ 8 for Depression Subscale Scores.

- HADS -A $\geq$ 8 for Anxiety Subscale Scores.

- HADS-T $\geq$ 12 for combined Depression and Anxiety Subscale Scores

- DASS Depression Subscale Score $\geq$ 8.

- DASS Anxiety Subscale Score $\geq$ 8.

- DASS Stress Subscale Score $\geq$8.

Exclusion criteria

Liver transplant patients who met the above criteria but were working weekly with a psychotherapist or placed in inpatient psychiatry were not eligible for the study. Participants who volunteered to prescreen into the study, although they did not meet the baseline initial screening criteria for HADS or DASS to advance, but consented to the use of their demographics and medical record data (Appendix A).

Power

STI and Alcohol Use. Although no studies of the effect of STI on alcohol use were found in the medical literature, meta-analyses of the effect of CBT on alcohol use suggests that overall CBT has a small effect on alcohol use in various populations (Magill & Ray, 2009; Riper et al., 2014; Tanner- Smith & Lipsey, 2015). However, another primary component of STI that has

been found in randomized trials to have a large effect on alcohol use is mindfulness (Crescentini et al., 2015; Garland et al., 2010; Wupperman, et al., 2015). Taken together, these studies suggest that STI, which combines components of both CBT and mindfulness may have an average medium effect on alcohol use.

STI and Affect. The effect of Solution Focused Brief Therapy (SFBT), an intervention integrated in STI on affect (depression, anxiety, and behaviors), has been investigated in two meta- analytic reviews and found to have a small to medium effect (Kim, 2008; Stams et al., 2006). However, Gingerich and Peterson's (2013) analyses provided evidence for a large effect of Solutions Focused Behavioral Therapy across a range of fields of practice, particularly in the field of mental health. Kramer et al. (2014) used an SFBT web- based implementation and reported that while there were only small differences between groups at 9-weeks, participants showed a clinically significant change in depression that was significantly larger for the SFBT intervention compared to the control group at 4.5 months, with the SFBT group showing further improvements at 7.5 months. These findings suggest that STI may have a smaller effect in the short term and a large effect on over time. Greene et al. (2020) multisite, multi-post transplanted populations N=48 completed pre-test and posttest assessments with a paired t test analysis demonstrating a non-significant difference for depression, however anxiety decreased significantly based on the GAD-2 ($p<0.05$) and women reported a significant decrease ($p<0.01$).

A computerized cognitive behavioral intervention study of older community adults to decrease anxiety and depression implemented CBT versus TAU reported significant results in both categories in the treatment group (McMurchie et al., 2013). Finding a mean difference between groups at $p<0.05$ with *n*=37 per group suggests a large effect size (Cohen, 1992) of CBT delivered via telehealth methods on the effect of older adults.

In the lung transplant population, a brief, eight-week, telephone-based psychosocial intervention of supportive counseling combined with CBT techniques delivered by psychology students, proved more effective than routine care in reducing distress and increasing health-related quality of life in patients (Napolitano et al., 2002). Finding a mean difference between groups at p<0.05 with *n*=37 per group again suggests a large effect size (Cohen, 1992) of CBT delivered via telehealth methods on the effect of transplant patients.

Finally, DuHamel et al. (2010) found a significant difference between their stem-cell transplant and control groups on depression after a telehealth intervention with *n*=47 in the treatment group and *n*=34 in the control group. Finding a mean difference between groups at *p*<0.05 with an average *n*=40 per group suggests medium-large effect size (Cohen, 1992).

Affect and Alcohol Use. Studies of depression and anxiety on alcohol use have found "persons with current, but not remitted, depressive or anxiety disorders were at an increased risk of a first incidence of alcohol dependence, but not first incidence of alcohol abuse" (Boschloo et al., 2013, p.1233). Although this association was not conditional on the type of disorder, first incidence rates of alcohol dependence gradually increased with the number of depressive and anxiety disorders. A meta- analysis of the relationship reports Odds Ratios for alcohol use disorders and major depression and for alcohol use disorders and any anxiety disorder (Lai et al., 2015) at sizes roughly equivalent to a medium effect size (Chen et al., 2009).

STI, Affect, and Alcohol Use. Using Fritz and MacKinnon's (2007) power table and assuming a medium effect size for STI on alcohol use for *path τ,* a large effect size of STI on affect (i.e., depression and anxiety) for *path a*, and a medium effect size of affect (i.e., depression and anxiety) on alcohol use for *path b*, a sample size of *N*=60 was identified as necessary for the power to detect a mediated effect on the relationship between STI and alcohol use. However, due

to COVID -19 the proposed sample size was unable to be obtained, resulting in needing to make

changes in the analyses.

Randomization

This is a feasibility pilot study with a sample size of N=22, but N=21 for analysis. Ten

participants were randomly assigned to intervention group and twelve to the control group. (see

Consort Table 2.0). Randomizer.com was utilized by the same non- transplant, non-biased social

work manager throughout the duration of the study with no patient contact. No one else was

involved in the randomization of the participants. The grouping for randomization was a rolling

assignment in groups of four. Social workers were assigned to each participant on a rolling basis.

Approached, Drop Outs, Missing Sessions, Missing Data, and Refusals (Consort Table 2.0)

Approached. Eighty-four patients were approached based on inclusion/exclusion criteria and

sixty- two patients moved forward with consenting (Appendix B) and initial screening in

REDCap. Twenty-seven patients met baseline screening criteria for the next phase of this study,

although one female and four males were not randomized due to medical complexity or

disinterest in study soon after initial prescreen. Reasons for medical complexity included

readmission to hospital or rehab unit or overwhelmed with appointments. Thirty-five patients

were interested in the study and chose to prescreen, although they did not meet the baseline

screening criteria. Four patients were unable to be randomized, or ruled out, due to a

professional psychotherapy relationship on a regular basis.

Dropouts. In this study, the rate of attrition or dropout is defined as the inability to complete at

least three sessions or not completing the initial post survey. Dropout rate in this study was 10%

which was lower than the rate experienced by Hickman et al.'s (2021) liver transplant 12 week RTC via telemedicine, or 22.8%.

Missing sessions. Three female participants completed less than six sessions, or between three and five sessions, due to work responsibilities, moving out of state, or feeling overwhelmed due to other caretaking issues, although all three completed both post intervention and three- months post screens. One male completed four sessions and then he stopped responding, although he completed his post survey. One male was randomized but did not complete any sessions due to ensuing medical complexity and physical deconditioning.

Missing screens. One male missed one screen at the post intervention follow- up and another missed the three- month post screens. A third male was deceased prior to completing the second, or three-month post screening. One female missed the three- month post survey.

Refusals. Sixteen patients refused consent/ initial screening for a myriad of reasons. Thirteen male patients refused initial prescreen. Seven of the males communicated disinterest due to reasons, including, "I don't have emotional needs, this study won't help;" "I am worried about HIPAA;" "I'm upset that the alcohol variable was included in this study;" "My wife wants this study more than me, and there are good people around me, or maybe later". Two males approached and refused due to feeling "too old" to engage in telemedicine, one in fifth and the other in his seventh decade, and finally, four males felt "too sick". Three females approached and refused initial prescreen for reasons including, "I do not have anxiety or depression, I am feeling poorly, or I am not interested".

Consort Table 2.0

Participation and Disposition
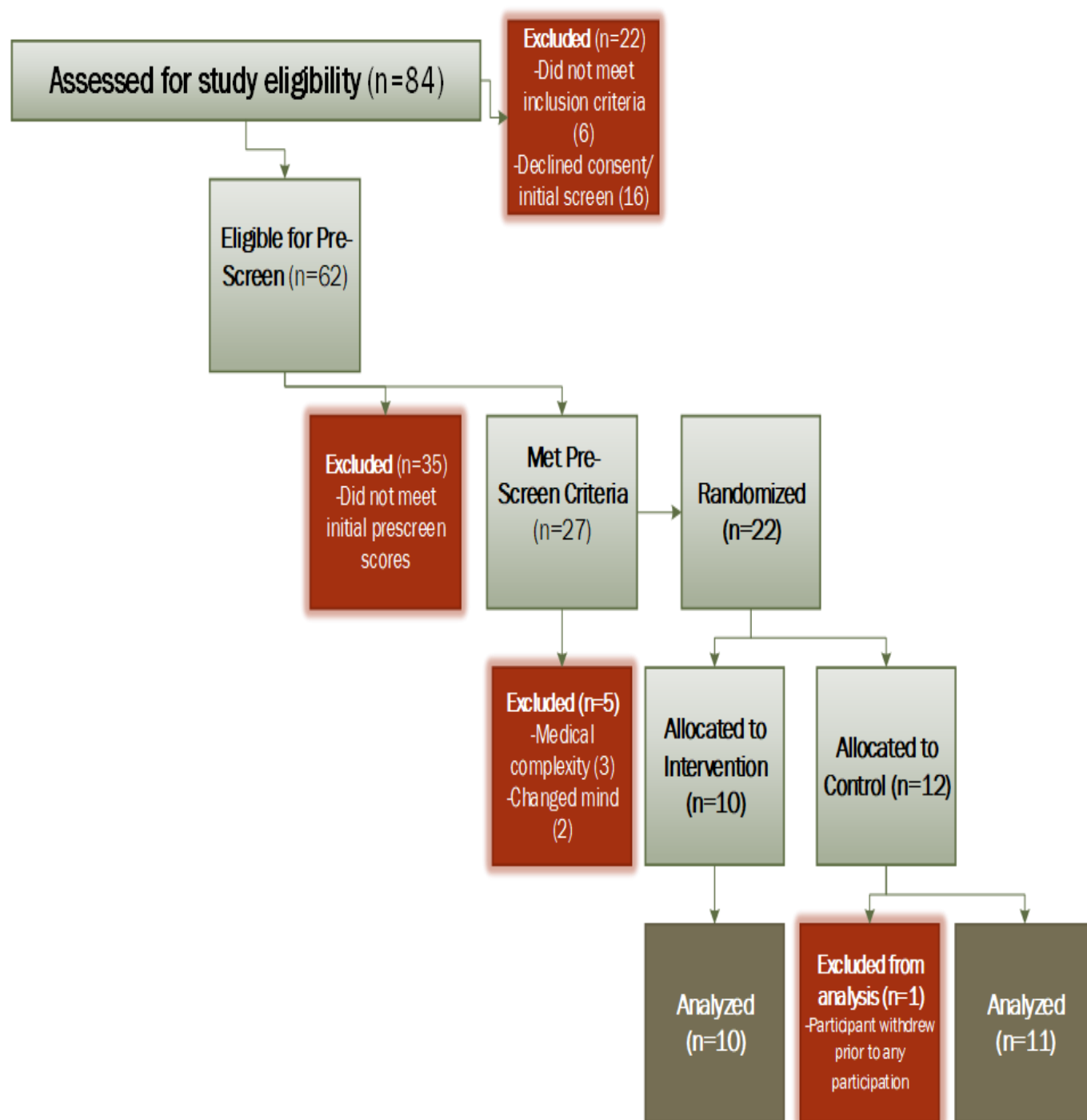
Interventions

The study employed a STI as the treatment condition and Social Work Monitoring

and Care Coordination (SWCC) for the control condition. Both STI and SWCC were

planned for six consecutive weeks for 20 minutes each session via HIPPA compliant

Penn Medicine telemedicine technology through VidYo/Blue Jeans. The initial sessions

were allotted thirty minutes for introductions and to complete the session. Appointment

flexibility was necessary to engage participants who were juggling medical appointments

or tending to many other commitments to encourage completion of the sessions. Each

study social worker had the ability to access and schedule sessions on telemedicine or to

request assistance from the front desk scheduler.

Treatment: Symptom Targeted Intervention (STI)

"Symptom Targeted Intervention (STI) is a focused, active approach that helps clinicians

manage symptoms of emotional distress in patients. The clinician identifies emotional distress in

the patient and teaches the patient how to cope better with difficult thoughts, feelings and

behaviors using an evidence-based selection of cognitive, behavioral and mindfulness

interventions which are often combined with relevant patient-centered topics. The patient and

clinician focus their efforts on the issue or symptom that is most bothersome to the patient. This

ensures that STI is patient driven. STI utilizes evidence-based cognitive, behavioral and

mindfulness techniques and strategies that have been modified and simplified for use by a wider

audience with limited time. Symptom Targeted Intervention contains strong elements of

Motivational Interviewing and Solution Focused Therapy (SFT), while maintaining a Rogerian,

patient-centered philosophy" (Stellicare.com). STI can be dosed face-to-face, telephone, or via

telemedicine and handouts or written reinforcements can be shared on the screen. Virtual

platforms are being embraced in hospital settings, and in most cases, there is little concern for a

weaker provider-patient relationship. In Pihlaja et al.'s (2017) review of 1658 relevant internet-

based Cognitive Behavioral Therapy studies, a total of six focus on therapeutic alliance and they

demonstrate promising results for future innovations around this theme.

The STI intervention was implemented for six consecutive weeks for 20-30 minutes per

session (McCool et al., 2014). In between sessions, a participant received "homework" or

educational reinforcements of concepts electronically. The sessions were thematic and tailored to

post liver transplant patients to address anxiety, depression, stress, and alcohol use with

evidence-based practices, including cognitive behavior therapy, mindfulness, and solution

focused therapy. Session themes (Weeks 1-6) (see Appendix C).

1. Goal Work: Solution-focused orientation by identifying positive directions for change in

   their life bring small successes into the participant's awareness, identifying positive

   directions for change and developing goals using Miracle questions, Exception questions and

   Coping questions.

2. Worry stories: Identify thought, examine evidence, and communicate: developing worry time

   of day (30 minutes) at same time, same place, observing daily worrying and delay it to the

   "worry period", attention to present moment with distractions, lists, routines and challenging

   thinking during worry period by differentiating and categorizing worries into controllable

   versus uncontrollable.

3. Self-care and daily routines: Narrative or log of daily routines, highlight strategies to conserve energy, optimize adherence routines, and guided imagery to build in image of low stress routines.

4. Mood management: Cognitive-behavioral focus: Psychoeducation (CBT Triangle), identifying mood, thoughts, and behaviors and record; identifying and challenging negative self -talk and track.

5. Triggers, self- management, and solutions: Identifying cravings and triggers, developing a change plan, strengthening commitment to change.

6. Managing Emotions: Pressing the 'reset' button - Mindfulness and meditation techniques: teaching and engaging in a mindfulness exercise, developing and use a breathing technique, promoting the use of daily mindfulness applications.

Control Group: Social Work Monitoring and Care Coordination

As previously noted, a recent study confirms that case management is "effective in optimizing evidence-based aftercare" in post living donor renal transplant patients (Schmid et al., 2017). The control group was provided 20-30 minutes of social work monitoring and care coordination weekly to assess emotional well-being, reviewed the treatment plan, and problem-solved any issues in the usual scope of transplant social work practice through the same telemedicine VidYo/Blue Jeans platform as STI (Appendix D). This differs from standard of care with early post liver transplant patients, which entails social workers called to provide consultation or support reactively versus proactively. Social work telehealth was not standard of care at the start of the study, and currently, is used more frequently to access patients for psychosocial assessment, case management, family meetings, or follow-up due to COVID-19 practice changes.

Social Workers' Tasks

Social workers collected demographics and location of patient at the time of session and documented in medical chart. Social workers investigated participant' location at time of each session and if discovered to be outside the PA/NJ states the sessions did not engage them due to licensure restrictions. Social workers knew the local county crisis numbers and/or call local 9-1-1 with psychological emergencies. Social workers assigned to the intervention were provided STI overview, education, and were to follow the STI thematic sessions as proscribed weekly. Social workers reviewed agenda and homework with the patients prior to the end of the session and referenced them during the following session. Social workers referred to the STI manual and face-to-face VidYo/Blue Jeans supervision to supplement education, as needed. Social workers were available to provide additional social work case management services, outside the STI session, via telephone or face-to-face and they were trained on the escalation process when clinical issues arose or how to respond to participants who were missing appointments

Qualifications and Training of Social Workers

All the social workers participating in the study were Collaborative Institutional Training Initiative (CITI) trained. In addition, they are experienced in solid organ transplant and possess licensure (LSW/LCSW) in PA and NJ for purposes of out-of-state STI telemedicine. Clinical supervisor holds LCSW licensures in PA and NJ. Social workers conducting the STI intervention groups completed VidYo/Blue Jeans and STI training. All the Social workers conducting the control groups also completed VidYo/Blue Jeans Training. The social workers were assigned to one of the two conditions throughout the entirety of the study, so as to control for any possible contamination by training and contact.

Weekly STI supervision sessions were available for one hour via live webinar for the social workers assigned to the intervention group to engage in best practices and consultation, consistently led by Melissa McCool, LCSW, (Stellicare.com), as a feature of STI. The STI Training Guide and Manual was available for reference along with a web- based educational version which provided additional social work teaching tools and support (McCool, et al., 2014). Initially, intervention transplant social workers were trained to use this intervention in a four-hour CEU event and certificates were allocated. Supervision for the intervention group was an essential part of the work. Supervision was provided by Melissa McCool, STI founder LCSW, and this occurred weekly. Once training was established, the intervention and control social work groups were provided supervision separately, scheduled at different times, to avoid contamination and investigator were blinded to assignments during supervision. The PI provided supervision to each separate group monthly and only names were disclosed through patient medical records when escalation required it. Staff were asked of participants not to use names or identifying information during supervision. This investigator does not work directly with the liver transplant population, nor were the two liver transplant social workers involved in STI training, study supervision, or research activities. There was no cross over and no one in the control group was provided education associated with STI training.

Telemedicine in Social Work

The terms telemedicine and telehealth are used interchangeably in this study, as well as in the literature. In some studies, the use of audio or the telephone is defined as either one. In this study, telehealth is defined as live, front facing, video and audio remaining on for both staff and participants throughout the sessions. It has been noted in the literature that telehealth

interventions prove effective in the treatment of psychological conditions. A meta-review (19 reviews) of high methodological quality Internet computer-based psychological treatments for a full spectrum of anxiety disorders with an average treatment time of seven weeks support the use of online interventions, regardless of many studies reporting high attrition rates. The benefits of internet computer-based treatment (ICT) were superior to those of waitlist groups or placebo treatments and the efficacy was mainly equal or superior to face-to-face treatments. Penate and Fumero's (2016) meta-review results show that providing even very brief face-to-face support from a therapist to users of computer- based psychotherapy could be extremely useful and demonstrates improved efficacy. Telehealth proves beneficial in the literature, with a meta-analysis study reporting the benefits of the therapeutic relationship when treating depression and anxiety in telehealth over face-to-face (Pihlaj et al., 2017). Thus, telehealth was provided for each condition with the realization prior to COVID-19 that some patients are required to travel to far to engage face-to-face treatment. It was originally deemed an innovative strategy to reach patients for this study and provided a measure of patient interest.

Data Collection & Measures

The study included demographic and clinical measures obtained directly from medical records. The screening/outcome measures were scheduled to be completed pre and post intervention/control and three months after the last session.

Data Collection

Data collection was only completed by this investigator, due to the limited nature of the study. This study was meant to assess feasibility and the funding would not cover a research assistant to provide data collection. Social workers did not collect data. Study data were

collected and managed using REDCap (Research Electronic Data Capture), an electronic data capture tool hosted at Penn Medicine. REDCap is a secure, web-based application designed to support data capture for research studies, providing: 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources (Harris et al., 2009). REDCap provided a consistent technical support person and video clips to review the platform.

Assessments and Measures

A total of three tools HADS (3 subscales, anxiety, depression, and total of anxiety and depression), DASS (3 subscales, anxiety, depression, and stress), and QDS (one drinking assessment measure) were used to assess the primary outcome variables of interest: depression, anxiety, stress, and alcohol use. Each assessment tool via REDCap was used for all participants' screening, at post sessions, and lastly, at 3 months' post sessions for both experimental intervention and control groups. Participants were asked demographic questions. Finally, a series of screening questions were used to determine eligibility for the study (as discussed previously). Depression was measured via HADS and DASS depression subscales, anxiety was measured via HADS and DASS anxiety subscales, and stress was measured via a DASS subscale. The Quick Drinking Screen (QDS) was used both pre and post and to statistically determine if alcohol use is mediated by the three key psychological outcome measures. Once it was determined the patient met the anxiety and depression criteria for inclusion through the prescreen HADS and/or DASS, the Quick Drinking Screen (QDS) was collected on the computer with a 14- day look back at the time of all measurement points.

Hospital Anxiety and Depression Screen (HADS). The HADS measures anxiety and depression in medical settings where comorbid physical conditions tend to be complicated by mental health. The screen is meant to be used in outpatient settings and repeated administration of the scale at subsequent visits provides useful information (Zigmond & Snaith, 1983).

The HADS is a widely used screening versus a diagnostic tool. Its period of recall for the patient is one week. The HADS consists of seven anxiety related questions and seven depression related questions, with good psychometric properties, including internal consistency, 0.76-0.80; retest reliability 0.70; sensitivity and specificity for anxiety disorders, 0.85 (Rose & Devine, 2014, p. 202).

The HADS-A and HADS-D subscales consists of 7 items each. Each item is rated on four choices ranging from a possible 0 to 3 score per item which means that a total score of 21 can be reached for anxiety and/or depression. Responses are based on the relative frequency of symptoms over the preceding week (Julian, 2011). The HADS -D measures depression and Cronbach Alpha has been found to be between 0.67 to 0.90 with a mean of 0.82, comparable to the HADS-A measuring anxiety. Coarseness is defined by a score of 8 or above for both HADS -A and HADS-D, or 8/21 for either. HADS combines the HADS-A and HADS-D, or a 14-item questionnaire with score of 0-3 per item (Bjelland, 2002). "The optimal cut-off values for HADS [(HADS -T)] is $\geq$ 12 (sensitivity: 81.0; specificity: 90.2)," (Loosman et al., 2010, p. 513). Cronbach's alpha value for depression and anxiety on the HADS scale (seven items each) in intensive care survivors at 3 months is 0.92 (depression) and 0.92 (anxiety) (Sukantarat et al., 2007).

HADS scores are sensitive to changes that occur following transplant as reported in a cluster analysis study (Goetzmann, et al., 2008). HADS is effective for use over longitudinal

studies to monitor effectiveness (Palmer, 2020). The HADS screens for significant anxiety and depression symptoms in medically ill patients and can be administered as self-report or individual interview. The concurrent validity of the HADS is noted as "good" to "very good" in a comprehensive review and the HADS-A is sensitive to change with sensitivity and specificity of 88% and 81%, respectively (Julian, 2011).

The HADS is an accurate, simple, and useful tool for transplant multidisciplinary teams to identify depression in the liver transplant patient candidates (Mohamed et al., 2014). The HADS takes 2-5 minutes to complete and best predicts how the respondent has felt in the past week (Snaith, 2003). Screening tools for anxiety disorders provide less favorable results than depression measures since various types of anxiety disorders have more heterogeneous symptoms than different types of depressive disorders (Rose & Devine, 2014). Anxiety is not fully studied in transplant populations.

Depression Anxiety Stress Scale (DASS). The central aim developing the DASS scale was to "generate measures of general negative affective syndromes, guided by existing conceptions but ultimately determined on empirical grounds" (Lovibond & Lovibond, 1996, p. 336). DASS has excellent clinimetric properties and few limitations, such as administering it with those diagnosed with developmental delay. DASS measures the extent to which the participant experienced the symptom in the past week. It is not intended to diagnose discrete mood disorders, and if scores fall in the high range, Parkitny and McCauley (2010) suggest a more comprehensive psychological assessment is necessary.

The clinimetric properties of DASS questionnaire have been examined in both general and clinical populations (Parkitny & McAuley, 2010). "The DASS is a 42-item questionnaire which includes three self-report scales designed to measure the negative emotional states of depression,

anxiety and stress. Each of the three scales contain 14 items, divided into subscales of 2-5 items with similar content. The Depression Scale assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/involvement, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect. The Anxiety scale assesses autonomic arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxious affect" (Lovibond & Lovibond, 1995, p.1).

The cutoff values used by Lovibond and Lovibond (1995) differ from one subscale to another. DASS was developed to measure the constructs of depression and anxiety and to address the failure of earlier emotional measures in discriminating between anxiety and depression (Lovibond & Lovibond, 1996). Cronbach's alpha value for depression and anxiety on the DASS Scale (14 items each) at three months is 0.82 (depression), 0.83 (anxiety) and 0.866 at nine months for both (Sukantarat et al., 2007, p. 240).

A Dutch study of an online version of DASS (long version) of the psychometric properties of an internet -administered version of the DASS scales finds high alpha coefficients (0.94-0.98) indicating very good internal consistency and the high average inter-item correlation (0.55-0.74) suggesting the DASS scales were homogenous in the coverage of depression. The results show that the internet version of DASS has good classical psychometric properties, contains sets of similar item-functioning, and is most suitable in the measurement of mild-moderate depression severity levels (Wardenaar, 2017).

Beaufort et al.'s (2017) pilot study determined timing of the DASS discriminates depression best in an alcoholic inpatient detoxification hospital in the post detoxification phase and not at the time of an alcohol intake assessment for detoxification purposes. For predicting depression using the DASS-21 total score after detoxification, the best results were obtained with

the highest sensitivity in this study (89%), a negative predictive power of 96% and specificity of

71%. General distress as a common symptom of depression and anxiety disorders is

conceptualized and measured in both long and short versions of the DASS scale (Lovibond &

Lovibond, 1995). The correlations between the three factors were: Depression-Anxiety r=0.42;

Anxiety-Stress r=0.46; and Depression-Stress r=0.39 (Lovibond & Lovibond, 1996, p. 19).

The differences between the Depression Anxiety Stress Scale (DASS) and the

Hospital Anxiety and Depression Screen (HADS) is that the DASS measures general

psychological distress, while still maintaining some distinction between the three separate

constructs, of anxiety, depression, and stress (Henry & Crawford, 2005). The HADS does

not measure somatic symptoms, thus avoiding over-estimations of psychological stress

related to physical illness (Jay et al., 2009). Moreover, the HADS has been validated

across somatic and psychiatric populations. The HADS focuses on non-physical

symptoms in primary or secondary health settings so that it can be used to diagnose

depression in people with significant physical illness-health problems (Stern, 2014; Covic

et al., 2012). The DASS measures an additional construct, or stress, while the HADS has

been the "gold standard" used among medical populations in clinical settings and

research. The HADS and DASS, "provide a good indication of possible depression and

anxiety and may be used for regular screening of psychological distress," although the

measure of psychological distress differs in both level and aspects, especially in terms of

anxiety (Covic et al., 2012, p. 8). Suicide risk or self-harm assessments are not measured

by either screen and it would be necessary for the interventionist to use standard of care if

harm to self or harm to others is suspected.

Quick Drinking Screen (QDS). In addition to psychological screens, alcohol use screens were completed three times throughout this study. Alcohol use is common in liver transplant populations and social workers routinely screen for substances in their psychosocial assessments as standard of care (STSW.org).

The Quick Drinking Screen (QDS) was used to measure alcohol use (see Appendix G). The QDS provides a brief three -question screen that is psychometrically sound (Roy et al., 2008). A post hoc data analysis study compared two retrospective alcohol use screening tools including both the QDS and the AUDIT-C (three -question screen) (Letourneau et al., 2017). The Quick Drinking Screen does not require the researcher to use a specific time frame. In addition, researchers point to QDS's language precision in question three as capturing additional binge drinking (Letourneau et al., 2017). In effect, QDS differentiates male versus female to better define and capture binge drinking (≥ 5, ≥ 4, respectively) compared to a lack of gender differences in the AUDIT-C tool (Bush et al., 1998). Participants reported higher levels of alcohol use on the QDS compared to the three questions on the AUDIT-C. In addition, the QDS is recommended for use in settings where it is desirable for a screening measure to also provide information on problem severity (Letourneau et al., 2017).

NIAAA Alcohol Education Pictogram. Screening tools in conjunction with an addiction consult provide best methods to identify drinking in this population (Donnadieu-Rigole et al., 2017). The National Institute on Alcohol Abuse and Alcoholism (NIAAA) supplies a pictogram for educational purposes to measure alcohol use accurately and was used in this study during the pre-post alcohol assessment and is encouraged to be used for measurement (Appendix G). In the United States, a "standard" drink is any drink that contains about 0.6 fluid ounces or 14 grams of "pure" alcohol, or:

12 ounces of regular beer (5% ethanol), 5 ounces of table wine (12% ethanol), or one shot

of spirits (40% ethanol) (NIAAA, Rethinking Drinking, n.d.). A pictogram is integrated

into the QDS tool for more accurate reporting.

Demographics. Upon consent**,** the following demographics and other data were extracted

from patient's medical record: name, street, address, city, country, and zip code or equivalent

geocodes, telephone numbers, medical record numbers, age in number of years, gender, marital

status, race, educational level, and employment (Appendix A).

Miscellaneous Data. Upon consent, the following medical record data points were

extracted from the patient's medical record: date of liver transplant, mental health history,

substance abuse history, mental health/substance abuse treatment, current smoking, time on wait

list in days, diagnosis codes, dual organ, second organ type, number of meds for

depression/anxiety post-transplant, number of readmissions for the first 90 days, active or

passive suicidality or homicidality. AST, ALT, and Alk Phos (liver function blood tests), and

alcohol blood or urine tests (Appendix A).

Analysis

Data Analysis Strategy

Descriptive statistics were used to describe the sample as a whole. Frequency

distributions were created for categorical and binary variables, including gender, race, education,

employment, mental health history, mental health treatment history, substance abuse history,

substance abuse treatment history, and alcohol use in the past 14 days. Means, standard

deviations, minimum and maximum scores, and correlations were calculated for continuous

variables, including age, pre-test levels of DASS Depression, DASS Anxiety, DASS Stress,

HADS Depression, and HADS Anxiety; time on waitlist, number of prescribed psychiatric medications, and AST, ALT, and ALK Phos levels. Inconsistencies in the alcohol use variables made it apparent that respondents were unclear about what the items were asking, therefore the following variables were not included in descriptive summaries and were dropped from equivalence testing, and analysis: number of days per week in the past 14 days respondents had any alcoholic beverage, number of days out of the past 14 days in which respondent had any alcohol, number of standard drinks in a day over the past 14 days, total number of drinks (days per week*number of drinks) in the past 14 days, and the number of times respondent had 4+ (females) or 5+ (males) standard drinks in a day.

Equivalence of Groups at Randomization

To test the equivalence of treatment and control groups at pre-test, 2-tailed independent t-tests were conducted to assess mean differences between groups on continuous variables: age; time on waitlist; number of medications taken for mental health; AST, ALT and Alk Phos levels; scores on DASS depression, DASS anxiety, and DASS stress; HADS depression and HADS anxiety.

As depicted in Table 2.1, there were no significant mean differences between groups in age, number of medications taken for depression, or baseline liver enzyme levels. Although the treatment group had higher mean scores on every continuous outcome variable (DASS Depression, DASS Anxiety, DASS Stress; HADS Depression, HADS Anxiety), only HADS Anxiety was significant [$t\ (20) = 2.33$, $p=0.03$].

Table 2.1

Comparisons of Continuous Variables at Randomization: Treatment v. Control

	Treatment		Control			2-tailed
	Mean	SD	Mean	SD	t-value	p-value
Age	53.10	12.16	53.25	11.87	-0.03	0.98
Days on Waitlist	82.00	136.12	95.58	114.19	-0.26	0.80
Psychiatric Meds	0.60	0.52	0.75	0.75	-0.53	0.60
AST	116.50	117.20	66.92	39.69	1.38	0.18
ALT	48.90	24.53	38.50	24.75	0.99	0.34
ALK_Phos	142.00	71.90	133.50	49.27	0.33	0.75
DASS Depress	5.20	3.49	3.25	4.62	1.10	0.29
DASS Anx	8.50	2.22	7.83	4.11	0.46	0.65
DASS Stress	10.30	3.86	7.33	4.74	1.59	0.13
HADS Depress	4.80	3.05	4.42	2.19	0.34	0.74
HADS Anxiety	10.00	3.43	6.67	3.26	2.33	0.03

Chi-Square Tests of Independence were used to test equivalence between groups on categorical variables: gender, race, education, employment, mental health history (yes/no), mental health treatment (yes/no), substance abuse history (yes/no), substance abuse treatment (yes/no). There were no significant differences found between groups on gender, race, or education. While the relationship between group assignment and employment was significant, the distribution of counts across categories violated the Chi Square assumption of fewer than 20% of cells with expected counts less than five. Therefore, to avoid a Type I error, it was assumed that there was no difference between groups in employment categories (see Table 2.2).

Table 2.2 Comparisons *of Demographic Variables: Treatment v Control*

			Group Assignment	
			Control	Treatment
Gender	Female	Count	5	5
		Std Res	-0.20	0.20
	Male	Count	7	5
		Std Res	0.20	-0.20
	ChiSquare (1, 22)=0.15, p=0.70			
Race	Asian	Count	1	2
		Std Res	-0.50	0.50
	Latino	Count	1	1
		Std Res	-0.10	0.10
	White	Count	10	7
		Std Res	0.20	-0.30
	ChiSquare (2, 22)=0.69, p =0.71			
Education	Associate degree	Count	1	0
		Std Res	0.60	-0.70
	Bachelor's degree	Count	2	5
		Std Res	-0.90	1.00
	High school degree or equiv	Count	3	0
		Std Res	1.10	-1.20
	Less then high school diploma	Count	1	0
		Std Res	0.60	-0.70
	Master's degree	Count	2	2
		Std Res	-0.10	0.10
	Some college no degree	Count	3	3
		Std Res	-0.20	0.20
	ChiSquare (5, 22)=6.12, p =0.29			
Employment	Disabled (SSI or SSDI)	Count	7	1
		Std Res	1.30	-1.40
	Retired	Count	0	3
		Std Res	-1.30	1.40
	Unemployed by choice	Count	0	2
		Std Res	-1.00	1.10
	Unemployed due to doctors appointments, illness	Count	3	0
		Std Res	1.1	-1.2
	Working full -time	Count	1	2
		Std Res	-0.50	0.50
	Working part- time	Count	1	2
		Std Res	-0.50	0.50
	ChiSquare (5, 22)=13.09, p =0.02			

As shown in Table 2.3, no significant differences were found between groups at pre-test in rates of previous mental health or substance abuse diagnoses or treatment.

Table 2.3

Comparisons of Mental Health and Substance Abuse: Treatment v Control

			Group Assignment	
			Control	Treatment
Mental Health History	No	Count	5	2
		Std Res	0.60	-0.70
	Yes	Count	7	8
		Std Res	-0.40	0.50
ChiSquare (1, 22)=1.18, p=0.28				
Mental Health Treatment	No	Count	8	5
		Std Res	0.30	-0.40
	Yes	Count	4	5
		Std Res	-0.40	0.40
ChiSquare (1, 22)=0.63, p=0.43				
Substance Abuse History	No	Count	6	2
		Std Res	0.80	-0.90
	Yes	Count	6	8
		Std Res	-0.60	0.60
ChiSquare (1, 22)=2.12, p=0.15				
Substance Abuse Treat	No	Count	9	6
		Std Res	0.30	-0.30
	Yes	Count	3	4
		Std Res	-0.40	0.50
ChiSquare (1, 22)=0.57, p=0.45				

Final Treatment and Control Groups Included in Analysis. Of the 22 participants who were randomized into the treatment or control group, 21 completed both the pretest and the post-test and were thus included in the final analysis of intervention effects. Although the attrition rate was only 10%, with the single participant dropping out of the control group, equivalence testing was once again conducted with the final 21 participants to assure that there was no change in equivalency between groups at pretest. As shown in Table 2.4, HADS Anxiety continued to be the only continuous variable that was significantly different, with the treatment group scoring higher at pretest than the control group.

Table 2.4

Comparisons of Continuous Variables at Randomization: Final Treatment v. Final Control

| | Treatment | | Control | | | 2-tailed |
	Mean	SD	Mean	SD	t-value	p-value
Age	53.10	12.16	53.18	12.45	-0.02	0.99
Days on Waitlist	82.00	136.12	102.55	117.06	-0.37	0.71
Psychiatric Meds	0.60	0.52	0.64	0.67	-0.14	0.89
AST	116.50	117.20	68.64	41.16	1.27	0.22
ALT	48.90	24.53	39.36	25.77	0.87	0.40
ALK_Phos	142.00	71.90	133.27	51.67	0.32	0.75
DASS Depress	5.20	3.49	3.18	4.83	1.09	0.29
DASS Anx	8.50	2.22	7.55	4.18	0.64	0.53
DASS Stress	10.30	3.86	7.45	4.95	1.46	0.16
HADS Depress	4.80	3.05	4.18	2.14	0.54	0.59
HADS Anxiety	10.00	3.43	6.27	3.10	2.62	0.02

Similar to findings in the overall sample, the only significant difference between the final treatment and control groups on demographic variables was on employment. However, similar to the overall sample, the distribution of counts across employment categories again violated the Chi Square assumption of fewer than 20% of cells with expected counts less than five.

Therefore, it was again concluded that no significant differences were found between groups on gender, race, education, or employment (see Table 2.5).

Table 2.5

Comparisons of Demographic Variables: Final Treatment v. Final Control

			Group Assignment	
			Control	Treatment
Gender	Female	Count	5	5
		Std Res	-0.10	0.10
	Male	Count	6	5
		Std Res	0.10	-0.10
		ChiSquare (1, 21)=0.04, p=0.84		
Race	Asian	Count	1	2
		Std Res	-0.50	0.50
	Latino	Count	0	1
		Std Res	-0.70	0.80
	White	Count	10	7
		Std Res	0.40	-0.40
		ChiSquare (2, 21)=1.82, p=0.40		
Education	Associate degree	Count	1	0
		Std Res	0.70	-0.70
	Bachelor's degree	Count	2	5
		Std Res	-0.90	0.90
	High school degree or equiv	Count	3	0
		Std Res	1.10	-1.20
	Master's degree	Count	2	2
		Std Res	-0.10	0.10
	Some college no degree	Count	3	3
		Std Res	-0.10	0.10
		ChiSquare (5, 21)=5.25, p=0.26		
Employment	Disabled (SSI or SSDI)	Count	6	1
		Std Res	1.20	-1.30
	Retired	Count	0	3
		Std Res	-1.30	1.30
	Unemployed by choice	Count	0	2
		Std Res	-1.00	1.10
	Unemployed due to doctors appointments, illness	Count	3	0
		Std Res	1.1	-1.2
	Working full -time	Count	1	2
		Std Res	-0.50	0.50
	Working part- time	Count	1	2
		Std Res	-0.50	0.50
		ChiSquare (5, 21)=12.22, p=0.03		

As summarized in Table 2.6, there were no significant differences between the final treatment and control groups in mental health or substance abuse diagnoses or treatment.

Table 2.6

Comparisons of Mental Health and Substance Abuse: Final Treatment v. Final Control

| | | | Group Assignment | |
			Control	Treatment
Mental Health History	No	Count	5	2
		Std Res	0.70	-0.70
	Yes	Count	6	8
		Std Res	-0.50	0.50
ChiSquare (1, 21)=1.53, *p*=0.22				
Mental Health Treatment	No	Count	8	5
		Std Res	0.50	-0.50
	Yes	Count	3	5
		Std Res	-0.60	0.60
ChiSquare (1, 21)=1.15, *p*=0.28				
Substance Abuse History	No	Count	6	2
		Std Res	0.90	-0.90
	Yes	Count	5	8
		Std Res	-0.70	0.70
ChiSquare (1, 21)=2.65, *p*=0.10				
Substance Abuse Treat	No	Count	9	6
		Std Res	0.40	-0.40
	Yes	Count	2	4
		Std Res	-0.60	0.70
ChiSquare (1, 21)=1.22, *p*=0.27				

Exploratory Analysis

Although tests indicated that the two groups were equivalent at pretest on all variables except anxiety as assessed by HADS, there was an overall pattern across the rest of the variables wherein the treatment group scored higher than the control group. This pattern included all of the dependent variables other than HADS anxiety, as well as all of the mental health and substance abuse history variables including the number of participants having a history of mental health

diagnoses, mental health treatment, substance abuse diagnoses, and substance abuse treatment. Although these differences can often be controlled for in analyses, the sample size in this case was too small to do so. Therefore, an exploratory analysis rather than hypothesis testing was conducted using repeated measures t-test to assess changes in the treatment group and changes in the control group separately.

Fidelity

First, all telemedicine times can be reviewed or pulled into a report to audit standards of the study sessions, or 20-30 minutes. Second, individual study sessions were documented in the respective participant chart under a research tab and a research social work note standard template confirmed location of the patient as either in PA or NJ. Third, the Electronic Health Record (Research Tab), or Penn Chart, tracks registration, scheduling, location, and other session documentation, along with missed appointments and schedule changes with documented reasons.

In the intervention group, proscribed themes were consecutively followed associated with the week (Appendix C), along with the respective psychoeducational weekly sheets to intervention participants to reinforce learning.

In the Social Work Monitoring and Care Coordination group, the questions were proscribed for the social worker as a starting point in each weekly session (Appendix D). Both groups were monitored for fidelity, as follows:

Once per month, the investigator made attempts to attend a group with very little notice to record: time spent per session with each participant, theme, resources/emotional support/psychoeducation, scheduling, location, missed appointments and schedule changes with reasons (Appendix E). Social workers were cognizant that this was a possibility at any point in

the study. This was completed throughout the duration of the study twelve times and became increasingly difficult due to clinic caseloads, scheduling or participant's comfort level.

Once per month, the investigator made attempts to attend a group with very little notice to record: time spent per session with each participant, theme, resources/emotional support/psychoeducation, scheduling, location, missed appointments and schedule changes with reasons (Appendix E). Social workers were cognizant that this was a possibility at any point in the study. This was completed throughout the duration of the study twelve times and became increasingly difficult due to clinic caseloads, scheduling or participant's comfort level.

Contamination

Each participant was assigned to the same social worker throughout the duration of the study. Each study condition was assigned two solid organ transplant trained social workers. Both groups met separately for supervision with transplant psychiatry regularly, either in a group, or one-on-one, as requested. The psychiatrist was not STI trained, although was readily available for cases that required supervision or escalation for issues such as alcohol use or severe symptoms reported or screening concerns in either group. There was no crossover of social workers' attendance between groups for training or supervision with psychiatry or the clinical social work supervisors for case discussion.

The following questions were asked to the treatment-as-usual social workers at the initiation of the study 1) Do you know about Symptom Targeted Intervention (STI)? If so, please describe what you know 2) Do you know the CBT triangle or mindfulness? (Appendix F). The control social workers focused on their assigned template questions and were not educated on the

tools or strategies around mindfulness or CBT, nor were these tools implemented in sessions during observations. One social worker knew about the CBT triangle but stated no specifics related to practice in this regard.

Participants who reported at least weekly therapy sessions with an established provider were not included in the study. This was necessary to avoid contamination of the therapeutic transplant social work relationship in this study and to avoid a break in a pre-established therapy relationship with an outside provider.

Human Subjects

Participants were at minimal risk in this study. The study was approved by both the University of Pennsylvania Institutional Review Board and the Penn Medicine Institutional Review Board prior to enrolling participants. Ethic principles and guidelines were followed. The participants were regularly engaged with the liver transplant multidisciplinary team as a requirement of their care. If issues arose around increasing depression, anxiety or there were concerns including harm to self or others, the issue was escalated to the appropriate provider. Potential risks were explained in detail in the informed consent. In addition, if the patient was readmitted to the hospital, the researcher determined the feasibility of continuing in the study face-to-face as an inpatient, delaying, or discontinuing the study. Forty-one percent of liver transplant patients are readmitted within thirty days of discharge, most commonly for renal insufficiency, vomiting/diarrhea, and pulmonary edema/effusion (Paterno et al., 2014). Three participants were too medically complex to complete the study due to readmission, rehab stay, or feeling overwhelmed by too many appointments.

Enrollment occurred behind closed doors in the privacy of the liver transplant clinic between the researcher, patient and support person (s) or over telemedicine due to COVID-19 restrictions. Initially, thirty -eight patients were consented and prescreened in person in the post liver clinic prior to telemedicine consenting commenced due to Penn Medicine clinic restrictions related to COVID- 19 safety standards. Support persons were welcome to be present when research was being discussed and questions answered, although they were asked to provide privacy by leaving the room while the participant was screening to avoid contamination. There was no recording, no one other than the researcher, patient, and patient's support team was able to enter the room when face-to-face or on telemedicine during enrollment phase. Only information to determine if the patient was a reasonable and safe candidate for study participation was sought. Study participants were identified in REDCap by study ID. Data was de-identified for study purposes after the initial screening, as much as possible, although accessible by this researcher in the case of need to escalate severe symptoms in screens and/or alcohol use. One person screened positive for alcohol use and this was reported to the transplant psychiatrist as standard of care, along with two others for severe symptoms. In this study, missed appointments did not become a factor in their healthcare appointment attendance score.

Handling and Protection of Data

The investigator collected the data through REDCap via an IPad initially, while sitting with the patients in the clinic, until COVID-19. Once the pandemic restrictions commenced, the IRB was modified for approval to use an email link for consent and the initial screen to be delivered and completed in the presence of this investigator through REDCap. This was the only data collector for the research project and REDCap collected and tracked all data. The data was

time stamped. For analysis, the analyst was able to go into REDCap and had the ability to export data. Excel sheets or analysis was stored in Penn Box, a HIPPA secure, password protected, storage system.

This investigator was not engaged in the delivery of the social work sessions. The investigator had completed CITI Human Subject Research training. Confidentiality was protected as best as possible, since the potential participants were approached in the clinic during the first few weeks after discharge from the hospital and the medical record captures research sessions. Each subject was assigned a number and data was collected and stored in a HIPPA generated Penn Medicine server or on REDCap platform when data are collected electronically. Medical records were not printed for purposes of this study and data were screened and collected by this researcher only. Prescreening data and medical record review was collected electronically in a password protected online account, or Penn Chart [EPIC]. Symptom Targeted Intervention (STI) is a product of Stellicare.com and was used for training, not to capture data or records.

Privacy. Recruitment of subjects took place in the early post liver transplant clinic setting or virtually. The team was aware of the study and its inclusion criteria. Participants were referred to the researcher by the nurse coordinators or physicians. If the patient met all eligibility criteria, including ruling in for HADS and/or DASS scores, an introduction to the telemedicine platform was explained; this visit was used to assist patients in downloading the VidYo/Blue Jeans telemedicine connection app on the phone. At any juncture, concern for each patient's emotional and/or physical wellbeing took precedent. The screening, pre, post, and follow-up data measures remained confidential to staff, unless a mandatory reporting situation arose, and the social workers followed social work protocol as outlined by law. If the potential participants did

not screen into the study, this was immediately communicated to the participants. In addition, the informed consent described the study and it was clear that the participants could choose to opt-out at any point in the study without repercussion. It was emphasized to the patient that non-participation in the study would not affect their overall transplant treatment.

There was no treatment advice unless suicidality or severe psychiatric symptoms including relapse with loss of control were found. All social workers participating in the study were trained in suicidality. Transplant psychiatry was approached three times during the study to comment on a high screening score or a report of alcohol use. No participants experienced homicidality or suicidality during the study time. Mandated reporting was discussed in the consent, along with additional limitations to confidentiality, such as communication with the multidisciplinary team if psychiatry was consulted and the study psychiatrist determined there was a need to communicate with the transplant team.

The following protected health information (PHI) was collected and used for research purposes.

- o Name
- o Street address, city, county, and zip code or equivalent geocodes
- o Telephone numbers
- o Medical Record Numbers
- o Psychosocial history related to anxiety, depression, distress, substance use issues, including corresponding diagnoses
- o Results of HADS, DASS and QDS throughout the study
- o Medical record information and Penn Chart documentation

The screening procedure documentation and follow-up outcome measures' documentation was de-identified and located on a research specific computer that is password protected and its location is both password protected and requires a key for entry into the research computer. In addition, the storage of the electronic generated data was stored on REDCap or in the HIPPA compliant Penn Box for the additional data measures obtained from the EHR. All information from individuals not recruited, due to negative screen or declined research participation, was stored in REDCap. All research data collected was assigned a code number for purposes of the study and a key was secured to identify participant's name. Once consents were signed, a social worker was assigned and VidYo/Blue Jeans telemedicine was uploaded on all participants iPhones. Access to VidYo/Blue Jeans was obtained through the App store or by a link sent from the subjects' My Penn Medicine HIPPA compliant patient portal. In addition, this link afforded the participant to download the VidYo/Blue Jeans platform onto a laptop or iPad, until recently, when a link can be sent to email versus downloading the app. Privacy standards are met with the use of Penn Medicine's telemedicine laws and regulations. Confidentiality around mandatory reporting was described and reinforced and informed consent included consent for use of technology, and when appropriate, offered reasonable alternatives to participate in the research (Hobdy et al., 2017, p. 25).

The study was approved by both the University of Pennsylvania Institutional Review Board and the Penn Medicine Institutional Review Board prior to enrolling participants. Ethical principles and guidelines were followed.

Inclusion of Women, Minorities & Children

Women and minorities were included in the study. No one under age 18, no prisoners, or pregnant women were included in the study.

Subject Payment

A Gift of Life (GOL) grant from the nation's leading organ procurement organization (OPO) provided compensation for this study. Compensation was offered to the consented participants. Payments were made through a secure web-portal that allows for authorized study researchers to transfer funds to participate in real time via a reloadable prepaid MasterCard and it worked like a bank debit card. The money was added to the card after each completed visit (schedule below). The debit card system is administered by an outside company. Participants were mailed a *Clincard and incremental payments up to a total of $40 were added to the card at each phase as follows:

Payment Schedule: First Phase or visit (recruitment)=$5.00

Second Phase A (completion of three sessions) =$5.00

Second Phase B (completion of six sessions) =$10.00

Third Phase (post intervention test completion) =$10.00

Fourth Phase (three months' post- intervention test completion) =$10.00

Five participants declined any compensation.

Chapter 3: Results

Sample

Due to COVID-19 restrictions, access to liver transplant patients was limited and the final sample consisted of 22 people, all of whom had undergone a liver transplant within (180 days) of study participation. As seen in Table 3.1 slightly more than half of the sample (55%) reported their gender as male ($n=12$), while a large majority (77.3%) reported their race as White ($n=17$), with the remainder of the participants identifying as Asian ($n=3$) or Latina/o ($n=2$). Almost 32%

of the participants indicated having a Bachelor's degree (*n*=7), 27% reported some college but no

degree (*n*=6), 18% reported having earned a Master's degree (*n*=4), 14% having a High School

degree or equivalent (*n*=3) and the remaining two participants had either an Associate degree

(4.5%) or less than a high school diploma (4.5%).

The demographic screening data noted that over 36% of participants categorized their

employment status as disabled on SSI or SSDI (*n*=8) and three participants each reported being

retired (13.6%), unemployed due to doctor's appointments from their illness (13.6%), working

full-time (13.6%), or working part-time (13.6%). Two participants indicated being unemployed

by choice (9.1%).

A chart review found almost 70% of participants had a recorded mental health diagnoses

(68.2%, *n*=15) and only 41% of participants had a record of previous mental health treatment

(*n*=9). Over 60% of participants had a documented history of substance abuse (63.6%, *n*=14),

while only 32% were noted to have previous substance abuse treatment (*n*=7).

Table 3.1 *Categorical Demographics in the Overall Sample and by Study Group*

	Total		Treatment		Control	
	N	%	N	%	N	%
Gender						
Female	10	45.5	5	50.0	5	41.7
Male	12	54.5	5	50.0	7	58.3
Race						
Asian	3	13.6	2	20.0	1	8.3
Latino	2	9.1	1	10.0	1	8.3
White	17	77.3	7	70.0	10	83.3
Education						
Less then high school diploma	1	4.5	0	0.0	1	8.3
High school degree or equivalent	3	13.6	0	0.0	3	25.0
Some college no degree	6	27.3	3	30.0	3	25.0
Associate degree	1	4.5	0	0.0	1	8.3
Bachelor degree	7	31.8	5	50.0	2	16.7
Master's degree	4	18.2	2	20.0	2	16.7
Employment						
Disabled (SSI or SSDI)	8	36.4	1	10.0	7	58.3
Retired	3	13.6	3	30.0	0	0.0
Unemployed by choice	2	9.1	2	20.0	0	0.0
Unemployed due to doctor appointments/illness	3	13.6	0	0.0	3	25.0
Working full -time	3	13.6	2	20.0	1	8.3
Working part- time	3	13.6	2	20.0	1	8.3
Mental Health History	15	68.2	8	80.0	7	58
Mental Health Treatment	9	40.9	5	50.0	4	33.3
Substance Abuse History	14	63.6	8	80.0	6	50.0
Substance Abuse Treatment	7	31.8	4	40.0	3	25.0

As shown in Table 3.2, participants ranged in age from 25 to 65, with an average age of 53 years (SD =11.71). The average number of days' participants spent on the waiting list for a liver was 89.4 days (SD=121.73) with a range of 2 to 412 days. Liver enzymes measured at baseline included AST levels, which ranged from 13 to 404 (M=89.45, SD=85.74), ALT levels, which

ranged from 10 to 89 (*M*=43.23, *SD*=24.63), and ALK Phos levels, which ranged from 32 to 256

(*M*=137.36, *SD*=59.21).

Mental Health Outcomes

Table 3.2 also summarizes baseline levels of the dependent variables: depression,

anxiety, and stress. Depression scores ranged from 0 to 15, with a mean of 4.14 (*SD*=4.17) when

assessed by the DASS and ranged from 0 to 9 with a mean of 4.59 (*SD*=2.56) when assessed by

the HADS. Anxiety scores ranged from 3 to 18 with a mean of 8.14 (*SD*=3.33) when assessed by

the DASS and ranged from 3 to 16 with a mean of 8.18 (*SD*=2.56) when assessed by the HADS.

Stress scores, as assessed by the DASS, ranged from 2 to 18 with a mean of 8.68 (*SD*=4.52). As

discussed in Chapter 2 (*Equivalence of Groups at Randomization),* the groups were not

significantly different in these baseline scores except for *HADS Anxiety,* in which the treatment

group had a significantly higher average score than the control group.

Table 3.2

Mean and Standard Deviations of Continuous Variables by Total Sample and Study Group

	Total		Treatment		Control			2-tailed
	Mean	SD	Mean	SD	Mean	SD	t-value	p-value
Age	53.18	11.71	53.10	12.16	53.25	11.87	-0.03	0.98
Days on Waitlist	89.41	121.73	82.00	136.12	95.58	114.19	-0.26	0.80
Psychiatric Meds	0.68	0.65	0.60	0.52	0.75	0.75	-0.53	0.60
AST	89.45	85.74	116.50	117.20	66.92	39.69	1.38	0.18
ALT	43.23	24.63	48.90	24.53	38.50	24.75	0.99	0.34
ALK_Phos	137.36	59.21	142.00	71.90	133.50	49.27	0.33	0.75
DASS Depress	4.14	4.17	5.20	3.49	3.25	4.62	1.10	0.29
DASS Anx	8.14	3.33	8.50	2.22	7.83	4.11	0.46	0.65
DASS Stress	8.68	4.52	10.30	3.86	7.33	4.74	1.59	0.13
HADS Depress	4.59	2.56	4.80	3.05	4.42	2.19	0.34	0.74
HADS Anxiety	8.18	3.67	**10.00**	3.43	**6.67**	3.26	2.33	0.03

As seen in Table 3.3, there were three significant correlations among the demographic and dependent variables. Levels of ALT enzymes were positively associated with levels of AST enzymes ($r=0.57$, $p<0.01$), DASS Depression was positively associated with DASS Anxiety ($r=0.65$, $p<0.01$), and DASS Stress was positively associated with HADS Anxiety ($r=0.48$, $p<0.05$).

Table 3.3

Correlations Among Continuous Variables

	Days Waitlist	Depress Meds	*AST*	ALT	ALKPhos	Age	*DASS Depres*	DASS Anxiety	*DASS Stress*	HADS Depress	HADS Anxiety
Days on Waitlist	1.00										
Psychiatric Meds	-0.29	1.00									
AST	-0.24	0.19	1.00								
ALT	-0.03	0.04	**0.57****	1.00							
ALK Phos	0.13	0.32	-0.29	-0.07	1.00						
Age	0.39	-0.30	-0.16	-0.13	0.10	1.00					
DASS Depression	0.14	0.21	0.12	0.40	0.08	-0.21	1.00				
DASS Anxiety	-0.12	0.29	-0.01	0.29	-0.04	-0.24	**0.65****	1.00			
DASS Stress	0.10	-0.20	-0.01	0.29	-0.11	-0.01	0.19	0.52*	1.00		
HADS Depression	-0.05	0.06	0.35	0.09	-0.10	0.01	0.14	-0.17	-0.01	1.00	
HADS Anxiety	-0.19	0.37	0.36	0.15	-0.03	-0.25	0.14	0.31	**0.48***	0.30	1

** $p<0.01$ level   * $p< 0.05$ level

Exploratory Findings

As shown in Table 3.4, the treatment group but not the control group showed a significant reduction in stress at post-test, with the treatment group's mean stress score ~4 points lower at post-test than it was at pre-test [$t(10)=3.58$, $p=0.003$] while the control group's post-test score was 2.36 points lower than at pre-test [$t(11)=1.90$, $p=0.09$]. Both groups had significant decreases in anxiety as measured by DASS, suggesting that the intervention was not the source of reduced anxiety at post-test in the treatment group. However, the two groups, which were significantly different at pretest on HADS anxiety, no longer had significantly different mean scores at post-test. The treatment group's mean score was 1.60 points lower at post-test and the control group's mean score was ½ of a point lower than at pre-test. While neither within group pre/post difference was significant, given the size of the difference in the treatment group compared to the control group, it is plausible that the significant difference between the two

groups at pre-test was no longer significant (i.e., the two were now equivalent) due to a real reduction in the treatment group obscured by the larger variance that comes with smaller samples (see Table 3.4).

Table 3.4

Differences between Pre-test and Post-test Scores within Treatment and Control Groups

	Treatment				Control			
	Mean Difference	SD	t-value	2-tailed p-value	Mean Difference	SD	t-value	2-tailed p-value
DASS Depression	1.50	3.54	1.34	0.21	-1.27	3.95	-1.07	0.31
DASS Anxiety	**3.90***	3.14	3.92	0.003	**3.36***	3.50	3.19	0.01
DASS Stress	**3.90***	3.45	3.58	0.006	2.36	4.13	1.90	0.09
HADS Despression	1.50	3.06	1.55	0.16	-0.10	4.15	-0.08	0.94
HADS Anxiety	1.60	3.31	1.53	0.16	0.50	3.89	0.41	0.69

Finally, the patterns of differences in depression between the treatment and control groups at post-test are worth noting. While not significant, the differences in mean scores between the pre- and post-tests on depression occurred consistently in opposite directions (see Table 3.5). The control group *increased* in depression between pre- and post-test as measured by both the DASS (M_{Pre}=3.18; M_{Post}=4.45) and HADS (M_{Pre}=4.10; M_{Post}=4.20) while the treatment group *decreased* in depression on both the DASS (M_{Pre}=5.20, M_{Post}=3.70) and the HADS (M_{Pre}=4.80, M_{Post}=3.30).

Table 3.5

Mean Scores at Pretest And Post-Test for Treatment and Control Groups

	Treatment				Control			
	Mean Pre	SD	Mean Post	SD	Mean Pre	SD	Mean Post	SD
DASS Depression	5.20	3.49	3.70	3.89	3.18	4.83	4.45	5.35
DASS Anxiety	8.50	2.22	4.60	2.63	7.55	4.18	4.18	4.12
DASS Stress	10.30	3.86	6.40	3.03	7.45	4.95	5.09	3.33
HADS Depression	4.80	3.05	3.30	3.80	4.10	2.23	4.20	3.97
HADS Anxiety	10.00	3.43	8.40	3.37	6.00	3.13	5.50	4.70

Feasibility Measures

Session Treatment Workload: The total sessions completed in the study equals 118. Seventy-seven percent (n=17) completed all six sessions scheduled or 102 sessions. Four additional participants completed at least three sessions to bring total to 118 sessions (n=21).

Patient Engagement: Twenty-one participants completed the post- test via REDCap email with 17 participants completing the final survey at three months' post intervention. One three- month post survey remains outstanding at the time of this publication due in September 2021. There were no reports of patients wanting to leave the sessions early, and sessions that were missed were rescheduled. Only 13/21 participants were able to complete the first three sessions within one month after initial social work contact due to various starting delays, although, once the participant reached session three, or 17/21 participants, the data demonstrates it was four weeks or less to complete the last three sessions. The CONSORT 2.0 points to the level of interest in this study, or 73.8% of participants hoping to move forward with this study. Only 43.5. % were able to move forward after meeting prescreen and 35.4% moved on to be randomized.

Social Work Fidelity Observations. Six monthly random observation of experimental sessions demonstrated the correct weekly theme corresponding to the correct treatment session number (Appendix C) were met at 100%. In addition, six random observation of control group found that social workers covered questions 1-6 at 100% (Appendix D). This investigator observed and documented that all points were met, as expected, in both groups. All fidelity observations by the investigator were unscheduled and participants were receptive to investigator attendance.

Social Work Engagement: Twenty-one participants completed the first 30-min sessions and approximately 10.5 hours and 97 sessions lasting 20- minutes, and 30- participant hours for a total of 42.5 total hours of participant engagement.

Chapter 4: Discussion and Conclusions

The results of this exploratory pilot study demonstrates that there was a preliminary

finding of a significant reduction in stress with the treatment group compared to the control

group. Both groups had a decrease in anxiety as measured by DASS which suggests the

experimental treatment per se did not reduce anxiety. However, the decrease in HADS anxiety

on posttest was most likely a result of the intervention. Additionally, a finding that is interesting,

but not significant, demonstrates the control group's increase in depression between pre and

post- test as measured by both DASS (Appendix H) and HADS (Appendix I).

For twenty years, researchers have identified a need to alleviate anxiety and

depression in the liver transplant population (Nickel et al., 2002). Schulz et. al (2007)

found in the population of 146 post liver transplant patients up to 44.5% expressed a

need for psychological services either at the time of the screening (38-month average) or

at an earlier time post liver transplantation. A call for measures to reduce psychological

symptoms in the post liver transplant population have been highlighted in the research,

although specific intervention studies and workflows within the transplant community

are lacking.

The stress finding and targeted intervention in the liver transplant population is

unique. Overall, stress, or distress, research is lacking, although one aforementioned

study recognized the correlation between personal and transplant-related stress at six and

12 months during the post liver transplant phase (Stilley et al., 2012) using an interview.

Another study recognized the level of perceived stress in the liver transplant recipients,

or 37.78% reported stress, correlating with poor sleep patterns (Marudanayagam, et al.,

2014). In this STI study, the DASS-21 scale discretely measures stress and is adaptable

for electronic use. Moreover, this study addresses stress measures in the early post liver transplant phase, plus interventions to reduce the stress. Keyes et al. (2012) study concludes that "exposure to stress in many forms is related to subsequent alcohol consumption and AUDs [Alcohol Use Disorders]". In liver transplant research, direct measurements of stress along with an intervention to mitigate stress has not been studied. Decreasing stress in early liver transplant through STI seems to be the right approach to promote best outcomes.

The HADS is considered a premier choice of a measure for medical populations, as it does not include physical symptomology. The DASS screens include a question addressing physical symptomology that highlights a common side effect of immunosuppressant medication, or trembling. The statement, "I experienced trembling (e.g.in the hands)", is a common feature in this population. A common side effect of early post liver transplant populations is trembling of the hands, resulting from medications (Paul et al., 2004). Some participants did acknowledge this question as difficult to answer. Given their comments, it is possible that participants made attempts to interpret this question as a physical symptomology only, unrelated to anxiety, thus minimizing the score.

In the Greene et al. (2020) multi-center STI study, forty-eight transplant participants (30 kidney, 9 liver, 6 heart, and 3 lung) completed the pretest and posttest assessment for anxiety with the GAD-2 and the paired samples *t* tests yielded significance. The Green et al. (2020) study did not incorporate telemedicine. The limitations to this study were the small number of liver patients enrolled and no control group. Similar to this study, the Greene et al. (2020) study did not show a significant difference in depression with the same sample measured by the PHQ-2.

In this study, the means of both the experimental and control groups followed opposite trajectories between the pre and post- test measured by both the DASS and HADS. The control group depression mean increased and the experimental depression mean decreased. Although not significant, this finding is peculiar because the small number of participants may be pointing to a neglected issue that requires closer attention, especially the question of "why" or "how" depression became worse in the control group.

In order to avoid potential cases of depression, Wu et al.'s (2021) recent study, speaks to a lower cutoff for HADS-D than used in this study. The HADS-D, or depression measure, required a cutoff of 8 to be accepted into this STI study, or a combined HADS-A and HADS-D of 12 as recommended in the literature. This is higher than validated by Wu, et al.'s (2021) results suggesting "a HADS-D score of 7 as the cut off to avoid false negatives". In this STI study, no additional participants would have been captured by lowering the score to 7 for HADS-D since a combined score of 12 between HADS-A and HADS-D met the prescreen measure to enter this study and there was no stand -alone score of 7 in HADS-D.

The correlation between depression and alcohol use is strong in the literature and remains one of the foremost concerns in this population (Kitajima et al., 2020). Psychiatric comorbidities predicted alcohol relapse in Alcohol Liver Transplant (ALD) and one-fifth of the participants diagnosed with ALD returned to alcohol (Chuncharunee et al., 2019). This study did not demonstrate a return to alcohol in any quantity, other than one participant, who was not diagnosed with either ALD or AUD.

Alcohol use was identified by one participant in this study, therefore, no statistical analysis was performed. An alcohol equivalent pictogram accompanied the Quick Drinking Screen (QDS) NIAA (2004) and a fourteen- day lookback screen was used. The alcohol-free

results of the study appear hopeful, although for study purposes, the self-reports could not be

confirmed with an alcohol blood or urine test and may not be entirely accurate through self-

report surveys alone. Many participants at this center do not have alcohol tests routinely ordered

post liver transplantation. Alcohol self-reports are limiting. The PEth is a promising alcohol use

biomarker for this population. This study grant could not support this high cost of Phosphatidyl

Ethanol (PEth) testing, or serum, urine or breath alcohol testing. Direct measurement of alcohol

in blood, exhaled breath, or urine is considered as the gold standard (EASL, 2018). The PEth

concentration correlates well with past weeks' alcohol intake (Helander et al., 2019). Any

alcohol use discovered in a post liver transplant patient with any AUD diagnosis sets off a

cascade of concerns and worries on the part of the caregivers and transplant teams and is

considered a psychosocial crisis. Hence, staff hypervigilance and resources are poured into these

critical cases.

An alternative to costly blood testing in this study, or breathalyzer testing, could have

included the researcher speaking to a family member for collateral information about alcohol use

at time of the post testing. This is a sensitive practice, although quite acceptable among

psychiatrist and mental health providers working in substance abuse and mental health

disordered treatment (Fong, 2021 & Petrik et al., 2015). Commonly, this includes family,

although collateral information could be elicited from unrelated relationships, too (Petrik et al.,

2015).

A hypothetical explanation to support this low use of alcohol in the early transplant phase

may be the high level of hypervigilance to physical needs or convalescence. In addition, a state

of euphoria or decreased craving with the addition of steroids and/or pain medications may have

alleviated the need for alcohol consumption (Swift, 1999). Moreover, at Penn Medicine patients

are attending appointments at least weekly and being monitored regularly with labs, and thus may have further discouraged participants from using alcohol, especially with enhanced engagement between the team and the support persons at the early post-transplant phase.

Lee et al.'s (2017) retrospective three-year pilot for Severe Alcoholic Hepatitis calls for validated models to predict alcohol relapse and to use extreme caution in selection of patients to move to liver transplantation, as both the AUD (first liver decompensation related to alcohol) and ALD (six months of sobriety) demonstrate equal amounts of relapse (10-30%). Moreover, Lee et al. (2018) found sustained alcohol use after liver transplant was infrequent but associated with increased mortality.

The Penn Medicine liver transplant multidisciplinary team is using their best clinical skills to predict outcomes at the time of evaluation and work to prevent relapse by promoting strategies to optimize sobriety prior to liver transplantation. In the current study, the diagnosis spans more broadly than ALD and AUD, or included liver transplant candidates who only had one or more alcoholic beverages within two years of the transplanted date. This was to increase the pool of participants and to correlate alcohol use and depression, although this was not a finding in this study. The correlation between depression and alcohol use is strong in the literature and remains one of the foremost concerns in this population (Kitajima et al., 2020). Psychiatric comorbidities predicted alcohol consumption in Alcohol Liver Transplant (ALD) and one-fifth of the participants diagnosed with ALD returned to alcohol (Chuncharunee et al., 2019).

Although not significant, depression increased in the control group and decreased in the experimental group between the pre-and post-test measurements by both DASS and HADS. Dew et al.'s (2015) systematic meta-analysis study showed significant effects of depression on

poor outcomes in transplant populations and depression is considered the strongest predictor of survival (DiMartini, Dew, Chaiffetz, et al., 2011). Attention to depression scores is valuable when following the trajectory throughout the transplant continuum. In this population, treatment is complicated due to concerns in relation to depression and co-occurring alcohol abuse history (Yates, 2007, p. 374). Symptom Targeted Intervention (STI) established a therapeutic relationship over time that promoted coping skills and strategies to address psychological symptoms.

Symptom Targeted Intervention (STI) played a role in engaging participants who may have otherwise been lost in the gaps in the system, such as difficult transitions to a community treatment program or therapeutic milieu. Some participants were recommended for IOP due to history of excessive alcohol use and chose to delay treatment for a variety of reasons; STI captured some of these participants, and although not a replacement for IOP, System Targeted Intervention (STI) introduced the value of therapeutic models of psychological care while concomitantly embedded in the health system. The benefits of working with social workers in STI on a weekly basis was reinforced by the providers on the team and acted as a monitoring system for any participants using alcohol or presenting with severe psychiatric symptoms. Approaching the patients in the early phase of care promotes the concept of emotional wellness throughout the continuum. This individualized STI study supported a patient's emotional wellness was well received, as indicated by the large number of patients interested in moving forward (Consort Table).

This study investigation of STI implemented by transplant social workers in a virtual environment demonstrated positive patient engagement during a vulnerable time

for patients, or post liver transplant (<6 months). Eighty-four patients meeting inclusion criteria receiving early liver transplantation (<6 months) were approached with the intention to move forward with the study if they met the screening criteria. Twenty-seven met the screening criteria to move forward (Consort Table). The low attrition rate in this psychosocial study may be related to the additional time placed in the first session to provide time for the social workers to develop a relationship with the participant by adding an extra ten minutes. In addition, patient compensation was offered in small amounts at different points in the study, which could arguably have influenced retention, although the topic of participant compensation did not appear to be a motivating factor, and some participants initially or fully declined compensation.

This STI study boasts an unusually low drop-out rate at 10% compared to the Fernandez et al (2015) meta-analysis CBT treatment study publishing a dropout weighted average of 26.2% or Swift and Greenberg's (2012) meta-analysis of psychotherapy dropout averaging 19.7%. Drop- out rates for psychosocial interventions are similar across treatment modalities, although a number of variables for higher participant dropout rates include, but are not limited to, students-in-training and interventions lacking session endpoints (Swift, & Greenberg, 2012).

Telemedicine

Telemedicine

Telemedicine is a highly utilized and acceptable method of delivering health care services. The recommendation to engage on telemedicine for all transplant social workers within appropriate parameters and with safety escalation policies in place will enhance the social work practice. Telemedicine is an extension of the in-person therapeutic relationships social workers

enjoy. COVID-19 has created innovative opportunities, such as embedding the telemedicine service into the patient charts, where data can easily be collected, such as time spent in the appointment and messaging with patients in real-time. We have illustrated that telemedicine offers an effective modality to integrate behavioral and medical treatments. In this study, only two percent of the entire patients approached did not have access to a cell phone or know someone to lend them one for the study. Connectivity was an issue for participants during some sessions, although the social workers devised plans to reschedule the session or connect them with technology support.

As mentioned, the initial session is imperative to begin to form a therapeutic alliance and for the social worker to communicate the session structures, for both groups. "Attention to patient engagement principles can facilitate confidence in the security and confidentiality of a telemedicine encounter" (Talal et al., 2020, p. 12). The World Health Organization (WHO) published telemedicine guiding principles with a phased approach that stresses patient engagement and access to care (WHO, 2020). This type of telemedicine standardization has been adopted at Penn Medicine and prepares clinicians to provide optimum care and contributes to good outcomes. The participants remained with their respective social worker in each group and no one requested a change in social worker. The highly structured sessions, with attention to the therapeutic relationship, proved beneficial.

In Child et al.'s (2021) study of a population diagnosed with psychiatric needs, telehealth outperformed in person group-based Intensive Outpatient Program (IOP) services for adults, regardless of program type and among the dually diagnosed patients, which highlights the importance of reaching the patients. Telehealth was linked to increased attendance rates for

group-based IOP psychotherapy services for adults regardless of clinical program type (Childs et al., 2021).

Some of the group characteristics in the literature influencing telemedicine outcomes were not measured in this STI study, for example, poverty and health literacy, both important in telemedicine service (Chew et al., 2004; Nouri et al., 2020). Interestingly, the population in the STI study boasts a high education rate, or over 80% with some college or more. Nicol Turner Lee & Roberts (2020) highlight four barriers to the full engagement of telemedicine, or: reimbursement, licensure, existing health disparities, and rural broadband gaps. Talal et al. (2020) raises the specific issue of poverty as a variable in telemedicine success, which was confirmed in Sadiq et al.'s (2021) large COVID-19 telemedicine study investigating demographic shifts in use of telemedicine compared to pre pandemic rates. Further, many researchers raise connectivity issues as barriers to telemedicine in rural versus urban areas.

Retention and Training of Social Workers

The transplant social workers joined the study on a voluntary basis. An incentive for the social worker to participate in the study was a social work departmental- wide ladder system that encourages "leveling up" to gain clinical expertise. At the start of COVID- 19, both groups lost one social worker through attrition to work outside the health system. As a result, there were two trained STI social workers and one control social worker remaining throughout the duration of the study. At this point, it was difficult to replace them due to the clinical pressures on the staff resulting from the pandemic. The remaining social workers did not express feeling overburdened or indicate a wish to leave the study.

The social workers were able to be CITI trained at no individual cost, which was required by the IRB. In addition, grant monies were used to reimburse for licensure costs in NJ in order to

have at least one social worker per group with a traditional NJ license (non COVID-19 waiver).

All of the social workers attended a full day of registration class and were required to pass a

written and computer- based test offered by Penn Medicine Registration group. In addition, the

social workers obtained telemedicine certificates through education offered by the Director of

Telemedicine at Penn Medicine.

The intervention social workers were required to attend an STI CE event offered for four

hours over two sessions. Training manuals and training materials were made available. Weekly

supervision sessions were scheduled by Melissa McCool at Stellicare online and via virtual

connection on a weekly basis until social workers became proficient in the delivery of the STI. In

addition, the Stellicare platform was provided to the social workers to enhance learning, along

with a proscribed weekly theme tailored to the liver transplant population and social work tip

sheets to enhance learning and standardization (Appendix C). The Gift of Life Organ

Procurement Organization grant helped reimburse for the supervision time and resources

provided by Stellicare.com.

The control group social workers were given six basic assessment questions to be

addressed with the participants at each session (Appendix D) and there were no other proscribed

resources besides the aforementioned registration and telemedicine trainings. This group

engaged in "enhanced –treatment-as-usual" and provided similar support that would mimic a

clinic visit, although on telemedicine. The research social workers remained assigned as the

primary social worker with their study participants until the end of the study.

The social workers in the control group had three and 14 years of experience and only

worked in medical social work. The experience noted was at the start of the study. The social

worker who remained in the control group had 14 years' experience. It was a concern that her

contributions to the study as a very experienced social worker may tip the outcome in favor of the control, although this did not play out.

Both groups of social workers were highly engaged in the work, attended all supervisions, or were available to make up any misses. Each social worker came to supervision with good questions. These groups were separated to avoid contamination and individual supervision was available upon request for LCSW or psychiatry, at the request of the social worker.

Treatment Engagement

Treatment engagement was measured by attendance in this study. The ease and flexibility of scheduling on the part of the patient encouraged attendance. The social worker took ownership of scheduling their own participants and only requested assistance from central registration with more difficult patient schedules.

Participants completing at least three sessions were sent post surveys. Twenty-seven patients met prescreen criteria and five dropped out prior to randomization. One dropped out after randomization. The reasons for the five drop outs included very medically complex, timed out ($\leq$ 6 months), disinterest, and change of mind (2). Three females completed between 3-5 sessions and then left for reasons including work schedule, moving to another state, and feeling overwhelmed. They were all willing to complete the post tests. The drop- out rate was low in this study when defined by three sessions. Seventy-seven percent (17/22) completed all six sessions, and posttest. The engagement number reaches 100% with pre/posttest for at least three sessions with 21 participants. The total number of sessions in this early post-liver transplant phase of care study is an impressive commitment to the research, although attrition rates for studies with

longer intervention sessions in liver transplant populations prove trickier. Hickman et al.'s (2021) randomized telemedicine feasibility study of twelve sessions, along with group sessions, had a dropout of 22.8% (n = 8) for 35 participants, and overall session attendance rate was 60% for twelve sessions, although the researchers concluded this intervention was feasible. In Weinrieb et al.'s (2011) pre -liver transplant Motivations Enhancement Therapy (MET) intervention study with seven sessions compared to waitlisted participants (TAU) at two sites (N=91) found that 49% dropped out of the study in the MET group and 63% dropped out of the TAU group, with no statistical significance between the groups.

The prescreen was completed either face- to- face or on telemedicine. The results appear automatically through the REDCap portal to the investigator email through a link that was HIPPA compliant. The ease of scheduling the follow up emails and the alert to the investigator was followed up immediately to screen for concerning survey scores. The investigator was the only staff monitoring the screens and providing appropriate escalation. There was one escalation for alcohol use in a non-alcohol related diagnosis and two for severe psychological symptoms with appropriate follow –up scheduled with transplant psychiatry for a check in.

Fidelity

The investigator periodically attended telemedicine sessions to document fidelity (Appendix E) for both groups. The participant had to agree to this arrangement and the investigator remained out of the telemedicine video frame. The social worker knew that the time is stamped on the telemedicine record and they were able to remain within the time frames

allotted. There were no shortened sessions reported, other than technical difficulties, which then became rescheduled. There was some inherent fidelity due to the proscriptive nature of STI and its accompanying homework to match the session. The investigator noticed very engaged patients and social workers in sessions. Supervision of the groups remained separate throughout the study and was provided by psychiatry and an LCSW working in transplant.

Feasibility and STI

Patients

Symptom Targeted Intervention (STI) was successfully implemented in the hospital setting with transplanted patients and in dialysis units (Greene et al., 2020; McCool, 2011). A majority of the patients approached were interested in both learning about the study and pre-screening to determine eligibility. Most patients had the support of a loved one or caregiver in the early liver transplant phase. Patients were receptive to the study providing a consistent level of support by the social worker, along with the providers' support.

STI offered a unique experience at the Penn Transplant Institute (PTI) and proved a positive combination. Transplant teams and patients quickly adopted telemedicine into their practices with patients welcoming the technology, which grew exponentially during COVID-19.

Social Work Staff

Medical social workers have feasibly implemented STI with fidelity to post-transplant patients. This pilot study with a targeted population seemed to keep the social workers engaged in the process. The social workers' contributions to the study were on a voluntary basis, and attrition was only related to two social workers leaving Penn Medicine.

At the study's commencement, social workers were not using telemedicine in their daily workflow. As the entire Penn Transplant Institute (PTI) community was scrambling to pivot and implement telemedicine with their patients, the social workers had been at the fore of this training pre COVID-19 on the telemedicine platforms. Social workers did not cancel any appointments with their participants and participant rescheduled for various reasons with the social workers. The social workers expressed positivity toward the interventions explaining it provided a measurable and concrete guide for their work. The only attrition of social work researchers in this study was experienced when two staff left the transplant population for other opportunities. COVID-19 pandemic forced a pivot from the face-to-face clinical work to an increase in telemedicine workflows, thus, a lot of multidisciplinary team efforts were required to transfer appointments to the virtual platform and support patients and caregivers. In addition, replacing the two research social workers at this time would have been a disconnect from the focus of the rest of the health system. Social workers were being asked to volunteer for many services to support the larger hospital community which were struggling with both concrete resources and psychological wellbeing and non COVID-19 research efforts were paused.

The Penn Medicine Pavilion opened its doors in October 2021 with access to unique and progressive technology. The large, single, inpatient rooms allow for increased confidentiality and the room is equipped to deliver and project medical information, identifiable staff, and family video calls onto a wall- sized screen. This enables all of the members of the team to engage with innovative technology for education and treatment. This cohort of patients could be engaged in the future to increase the numbers of participants enrolled in telemedicine studies.

Challenges

The small sample size limits the generalizability of the results to other transplant populations or centers. Increased recruitment and participation may demonstrate effectiveness. Moreover, the sample was not represented by black race. Originally, this 2- group pre-test posttest design study was submitted as a randomized intervention pilot study with a three -month follow -up (N=50). Due to the effects of COVID- 19 on the hospital system and staff, along with the ability to concentrate on recruitment for this study, the participation rate became limited. In addition, staff recruitment was not ethical during a pandemic when a lot of attention in the department was expected for COVID-19 workflows and concerns about COVID-19 dominated the hospital culture in both the clinical and research arenas.

The rate of completion of the three- month post survey required additional attention. Reminder calls by the investigators to ensure the email was delivered may have increased participation on the last survey. An additional challenge was the recruitment effort since this investigator was the only available staff for the effort. Each visit took approximately 30-40 minutes per participant and the topic of alcohol and/or mental health elicited emotional responses for some of the patients and/or caregivers. Recruitment was labor intensive, although a very important aspect of the study that required tremendous effort and skill.

Limitations

Sixty -four patients were screened with twenty –seven participants meeting scores to prescreen into the study. Data on those unable to proceed with screening due to inability to secure WiFi or phone/computer/IPAD equaled three potential prescreens and the ability to offer an alternative could have been considered at the time of the study protocol. An alternative to this problem may have been to lend a temporary cell phone or secure a clinic room and set up telemedicine sessions on computers within the clinic, at least until pandemic restrictions. Social

work licensure outside of NJ and PA became limiting for our patients residing in DE and MD. Licensure restriction continues to be a barrier for both research and clinical work when engaging via telemedicine (Nicole et al., 2020).

COVID-19 created both logistical and psychological barriers for the staff, thus, research for psychosocial interventions was not prioritized. The Mini Cog paper and pencil test was used for all participants who this investigator met face –to-face and this assessment tool could not be implemented online, therefore, the collected data was incomplete. The use of the self-report Quick Drinking Screen (QDS) was limiting in this study. More importantly, the low N in this study forced an analysis shift from a RCT to pilot study producing preliminary effectiveness results, so the research required additional participants to buttress the STI preliminary findings. Also, given that the study took place at only one site further limits the generalizability of results.

Future Research

A larger scale social work study could prove the usefulness of Symptom Targeted Interventions (STI). Once significance is confirmed in a larger cohort, broadening the study population to other transplant populations should be considered. If conducting the study in the early post liver transplant population ($\leq$ 6 months), removing alcohol use as a variable would likely increase participation, since alcohol use in this very early phase did not surface as a measurable variable. A move to increase the post- transplant duration of follow-up to one or two years may result in a more robust alcohol measure (Lee et al., 2019), although participants further out from transplant are theoretically less engaged with the transplant team making them less apt to participate in an intervention study. In addition, those with an alcohol -related diagnosis may become increasingly embedded in alcohol- related community supports that may interfere with this type of study.

Future telemedicine RCT should make attempts to collect and measure poverty and health literacy as participant characteristics in solid organ transplantation. During the pandemic, Nouri et al.'s (2020) commentary highlighted the inverse relationship between health disparities and access to telehealth with a call to advocate at the local, state, and national level for improved access.

The interactions with the support person by this investigator at the time of recruitment identified a caregiver gap, as many support persons expressed an interest in obtaining a similar intervention as that being provided to the participants. Community agencies, such as Gift of Life (GOL), an Organ Procurement Agency (OPO), provides resources and amenities to transplant patients and families, such as housing, transportation, meals, and activities. Opportunities to collaborate and learn best strategies to care for our caregivers has developed from this study. Caregivers require education and support from the transplant teams. Caregivers play an important role in their loved ones' transplant outcomes (Maldonado, 2012). Solid organ transplant caregiver research is limited.

Implications

This study illustrates the additional value that Master's prepared transplant social workers offer to this vulnerable population after achieving certifications and trainings in STI.   More recently, most university-based hospital social workers are required to hold initial licensure at the time of hire, or LSW. After clinical hours are obtained, they are able to sit for the clinical license. The Licensed Clinical Social Worker (LCSW) in community agencies can bill for services at a provider level, and moreover, the Licensed Social Worker (LSW) is able to provide clinical interventions with the direct supervision of an LCSW. The availability of STI with the transplant patient populations could potentially work in favor of staff satisfaction and retention

among transplant social workers. At Penn Medicine, social work participation in this STI study met a clinical ladder metric toward professional portfolio development within the social work department.

Hospital social workers are well versed in discharge planning and crisis management, although not specifically trained to implement psychotherapeutic skills in this setting. Social workers trained in specific brief modalities, such as Motivational Interviewing, or aspects of CBT, are not encouraged or expected to practice these skills in a hospital setting. Contrarily, LCSW's in the community setting have the ability to practice independently in practice as a result of insurance contracting and the ability to practice "up to the level of one's license" with additional psychodynamic training. The LCSW practicing STI in the hospital or transplant clinic offers additional interventions and tools to enhance therapeutic skills with patients and caregivers.

Conclusion

Transplant social workers should feel encouraged that interventions providing patients relief of symptoms can be accomplished on telemedicine in the early phases of transplantation. Training STI can be accomplished via Stellicare.com and through direct supervision with trained clinical supervisors. Providing social workers a thematic weekly outline reinforces learning and a frame to work and increases engagement with this patient population. Psychoeducation was a strong component of STI to reinforce learning and promote coping longer term.

Most medical or transplant social workers do not engage patients with psychological interventions, however, they are focused mostly on concrete resources, family work, discharge planning, and group support services. Symptom Targeted Intervention (STI) is a transferable skill that is easily taught to the patients, thematically based, and can be delivered weekly. For

these reasons, STI can benefit all social workers faced with populations exhibiting symptoms of anxiety, depression, or stress, throughout the transplant continuum.

Transplant social workers are expected to be highly trained and effective in working with their patients, and this includes focusing on psychological wellbeing. Social workers must adopt their own creative practices that are supportive and meet the needs of the population in their system in order to pave a path that addresses patients' psychological wellbeing in a more holistic way. STI provides short sessions (20-30 minutes) to initiate goals with a trajectory toward better coping, motivation, and adherence. Without the ability to deliver an intervention such as STI, transplant social workers tend to refer patients out to community providers when their patients present with poor adjustment to illness. These skills when provided by transplant social workers in a hospital environment can provide a bridge to community resources and were found in this trial to be well received by the transplant team, patients, and caregivers. The patient and caregivers heightened interest in an intervention study was refreshing, especially so close to transplant surgery. In addition, it appears the study design promoted a strong rate of retention and resulted in positive engagement by both the participants and the social workers.

References

Annema, C., Roodbol, P.F., Stewart, R.E., Porte, R.J. & Ranchor, A.V. (2015).

Prevalence of psychological problems and associated transplant-related variables

at different time periods after liver transplantation. *Liver Transplantation*, 21,

524-538.

Anthenelli, R.M. (2012) Overview: stress and alcohol use disorders revisited. *Alcohol Research Current Reviews,* 34(4), 386.

Arroyo, V., Moreau, R., Jalan, R., & Ginès, P. (2015). Acute-on-chronic liver failure: a new syndrome that will re-classify cirrhosis. *Journal of Hepatology*, *62*(1), S131-S143.

Arvand, J., Shafiabadi, A, Falsafinejad, M.R., & Naderi, N. (2012). Depression in patients with chronic hepatitis B: an experience on individual Solution-Focused Therapy. *Gastroenterology and Hepatology from Bed to Bench,* 5 (3), 166.

Bannink, F.P. (2007). Solution-focused brief therapy. *Journal of Contemporary Psychotherapy*, 37(2), 87-94.

Baranyi, A., Rothenhausler, H.B. & Krauseneck, T. (2013). Overall mental distress and health-related quality of life after solid-organ transplantation: results from a retrospective follow-up study. *Health and Quality of Life Outcomes*, 11(1), 15. https://hqlo.biomedcentral.com/articles/10.1186/1477-7525-11-15.

Bashshur, R.L., Shannon, G.W., Bashshur, N., & Yellowlees, P.M. (2016). The empirical evidence for telemedicine in mental disorders. *Telemedicine and e-Health*, 22(2),

Beaufort, I. N., De Weert-Van Oene, G. H., Buwalda, V. A., de Leeuw, J. R. J., & Goudriaan, A. E. (2017). The depression, anxiety and stress scale (DASS-21) as a screener for depression in substance use disorder inpatients: a pilot study. *European addiction research*, *23*(5), 260-268.

Benzing, C., Krezdorn, N., Hinz, A., Glaesmer, H., Brähler, E., Förster, J., Wiltberger,

G., Frenzies, F., Schmelzle, M., & Michael Bartels (2015). Mental status in

patients before and after liver transplantation. *Annals of Transplant,* 20, 683-693.

doi: 10.12659/AOT.894916.

Bjelland, I., Dahl, A.A., Haug, T.T., & Neckelmann, D. (2002). The validity of the

 Hospital Anxiety and Depression Scale: an updated literature review. *Journal of*

Psychosomatic Research, 52(2), 69-77.

Bhogal, N., Dhaliwal, A., Lyden, E., Rochling, F., & Olivera-Martinez, M. (2019).

Impact of psychosocial comorbidities on clinical outcomes after liver

transplantation: Stratification of a high-risk population. *World Journal of*

Hepatology, *11*(8), 638–645. https://doi.org/10.4254/wjh.v11.i8.638

Boschloo, L., Vogelzangs, N., Smit, J. H., van den Brink, W., Veltman, D. J., Beekman,

A.T., & Penninx, B. W. (2011). Comorbidity and risk indicators for alcohol

use disorders among persons with anxiety and/or depressive disorders:

findings from the Netherlands Study of Depression and Anxiety

(NESDA). *Journal of Affective Disorders*, *131*(1), 233-242.

Boschloo, L., Vogelzangs, N., van den Brink, W., Smit, J. H., Veltman, D. J., Beekman,

A. T., & Penninx, B. W. (2013). Depressive and anxiety disorders predicting first

incidence of alcohol use disorders: results of the Netherlands Study of Depression

and Anxiety (NESDA). *The Journal of clinical psychiatry*, *74*(12), 0-0.

Burns, L. & Teesson, M. (2002). Alcohol use disorders comorbid with anxiety,

depression and drug use disorders: Findings from the Australian National Survey

of Mental Health and Well Being. Drug & Alcohol Dependence, 68, (3), 299-307.

Bush, K., Kivlahan, D., McDonnell, M.B., Fihn, S.D., Bradley, K.A. (1998). The

AUDIT Alcohol consumption questions (AUDIT-C): An effective brief

screening test for problem drinking. *Archives of Internal Medicine,* 158, 1789-

1795.

Cassem, E.H. (1995). Depressive disorders in the medically ill: an overview.

Psychosomatics, 36(2), S2-S10.

Chak & Saab (2010). Risk factors and incidence of de novo malignancy in liver

transplant recipients: a systematic review. *Liver International*, *30*(9), 1247-1258.

Chen, H., Cohen, P., & Chen, S. (2009). How Big is a Big Odds Ratio? Interpreting the

Magnitudes of Odds Ratios in Epidemiological Studies. *Communication in Statistics –

Simulation and Computation*, 39 (4), 869-864.

Chew, L.D., Bradley, K.A., Boyko, E.J. (2004). Brief questions to identify patients with

inadequate health literacy. *Family Medicine*. 36(8):588-94. PMID: 15343421.

Childs, A. W., Bacon, S. M., Klingensmith, K., Li, L., Unger, A., Wing, A. M., & Fortunati, F.

(2021). Showing Up Is Half the Battle: The Impact of Telehealth on Psychiatric

Appointment attendance for hospital-based intensive outpatient services during COVID-

19. *Telemedicine and e-Health*.

Chuncharunee, L., Yamashiki, N., Thakkinstian, A., & Sobhonslidsuk, A. (2019). Alcohol

relapse and its predictors after liver transplantation for alcoholic liver disease: a

systematic review and meta-analysis. *BMC Gastroenterology*, *19*(1), 1-17.

(CMS) Centers for Medicare and Medicaid (2008). *Organ Transplant Program

Interpretive Guidelines*. https://www.cms.gov/Medicare/Provider-Enrollment-

and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter08-25.pdf.

Cohen, J. (1992). A power primer. Psychological Bulletin, 112(1), 155.

Collis, I., Burroughs, A., Rolles, K., & Lloyd, G. (1995). Psychiatric and social outcome of liver transplantation. *British Journal of Psychiatry*, 166, 521–523.

Conner, K.R., Pinquart, M., & Gamble, S.A. (2009). Meta-analysis of depression and Substance use among individuals with alcohol use disorders. J*ournal of Substance Abuse Treatment, 3*7(2), 127-137.

Conway, A., Sheridan, J. Maddicks-Law, J., & Fullbrook, P. (2016). Pilot testing a model of psychological care for heart transplant recipients. *BMC Nursing*, 15(1), 62. doi.org/10.1186/s12912-016-0183-1.

Corbett, C., Armstrong, M.J., Parker, R., Webb, K., & Neuberger, J. (2013). Mental health disorders and solid-organ transplant recipients. *Transplantation*, 96(7), 593-600. doi: 10.1097/TP.0b013e31829584e0.

Corruble, E., Barry, C., Varescon, I., Falissard, B., Castaing, D., & Samuel, D. (2011). Depressive symptoms predict long-term mortality after liver transplantation. *Journal of Psychosomatic Research,* 71 (1), 32-37. http://proxy.library.upenn.edu:2146/10.1016/j.jpsychores.2010.12.008.

Covic, T., Cumming, S. R., Pallant, J. F., Magnolias', N., Emery, P., Conaghan, P. G., & Tennant, A. (2012). Depression and anxiety in patients with rheumatoid arthritis: prevalence rates based on a comparison of the Depression, Anxiety and Stress Scale (DASS) and the hospital, Anxiety and Depression Scale (HADS). *BMC Psychiatry*, *12* (1), 6. http://www.biomedcentral.com/1471-244X/12/6.

Crescentini, C., Matiz, A., & Fabbro, F. (2015). Improving personality/character traits in individuals with alcohol dependence: The influence of mindfulness-oriented meditation. *Journal of Addictive Diseases,* 34:1, 75-87.

Davydow, D.S., Zatzick, D., Hough, C.L., & Katon, W.J. (2013). A longitudinal investigation of posttraumatic stress and depressive symptoms over the course of the year following medical- surgical intensive care unit admission. *General Hospital Psychiatry,* 35(3), 226-232.

Dew, M.A. (1998). Psychiatric illness in the context of physical illness. P.B. Dohrendwend (Ed)*, Adversity, Stress, and Psychopathology*. New York: Oxford University Press.

Dew, M.A., DiMartini, A.F., Steel, J., De Vito Dabbs, A., Myaskovsky, L., Unruh, M. & Greenhouse, J. (2008), Meta-analysis of risk for relapse to substance use after transplantation of the liver or other solid organs. *Liver Transplantation*, 14: 159-172. https://doi.org/10.1002/lt.21278.

Dew, M.A., Goycoolea, J.M., Harris, R.C., Lee, A., Zomak, R., Dunbar-Jacob, J., Rotondi, A., Griffith, B.P. & Kormos, R.L. (2004). An internet-based intervention to improve psychosocial   outcomes in heart transplant recipients and family caregivers: development and evaluation. *The Journal of Heart and Lung Transplantation*, 23(6), 745-758. https://doi.org/10.1016/j.healun.2003.07.002.

Dew, M.A., Rosenberger, E.M., Myaskovsky, L., DiMartini, A.F., Dabbs, A.J.D., Posluszny, D.M., Steel, J., Switzer, G.E., Shellmer, D.A.&, J.B.   (2015). Depression and anxiety as risk factors for morbidity and mortality after organ transplantation: A systematic review and meta-analysis. *Transplantation,* 100(5), 988-1003. http://doi.org/10.1097/TP.0000000000000901.

DiMartini, A., Crone, C., & Dew, M. A. (2011). Alcohol and substance use in liver transplant patients. *Clinics in Liver Disease*, *15*(4), 727-751.

DiMartini, A., Dew, M.A., Chaiffetz, D., Fitzgerald, M.G., deVera, M.E. & Fontes, P. (2011), Early trajectories of depressive symptoms after liver transplantation for Alcoholic Liver Disease predicts long-term survival. *American Journal of Transplantation,* 11: 1287-1295. https://doi.org/10.1111/j.1600-6143.2011.03496.x

DiMartini, A.F., Dew, M.A. & Trzepacz. P.T. (2011). Organ transplantation. J. Levenson (Ed.), *The American Psychiatric Publishing Textbook of psychosomatic medicine; psychiatric care of the medically ill* (775-803). American Psychiatric Publication.

DiMartini, A. F., Golden, E., Matz, A., Dew, M. A., & Crone, C. (2019). Post-transplant psychosocial and mental health care of the liver recipient. In *Psychosocial Care of End-Stage Organ Disease and Transplant Patients* (pp. 181-191). Springer, Cham.

Dom, G., Wojnar, M., Crunelle, C.L., Thon, N., Bobes, J., Preuss, U.W., Addolorato, G., Seitz, H.K. & Wurst, F.M. (2015). Assessing and treating alcohol relapse risk in liver transplantation candidates. *Alcohol and Alcoholism*, *50*(2), 164-172.

Donnadieu-Rigole, H., Olive, L., Nalpas, B., Winter, A., Ursic-Bedoya, J., Faure, S, Georges-Phillipe, P. & Perney, P. (2017). Follow-up of alcohol consumption after liver transplantation: Interest of an addiction team? *Alcoholism: Clinical and Experimental Research*, 41(1), 165-170.

DuHamel, K.N., Mosher, C.E., Winkel, G., Labay, L.E., Rein, C., Meschian, Y.M., Austin, J., Greene, P.B., Lawsin, C.R., Rusiewicz, A. & Grosskreutz, C.L. (2010). Randomized clinical trial of telephone-administered cognitive-behavioral therapy to reduce post-traumatic stress disorder and distress symptoms after

hematopoietic stem-cell transplantation. *Journal of Clinical Oncology*, *28*(23), 3754.

[EASL] European Association for the Study of the Liver. (2018). EASL Clinical Practice Guidelines: Management of alcohol-related liver disease. *Journal of Hepatology*, *69*(1), 154-181.

Fernandez, E., Salem, D., Swift, J. K., & Ramtahal, N. (2015). Meta-analysis of dropout from cognitive behavioral therapy: Magnitude, timing, and moderators. *Journal of Consulting and Clinical Psychology*, *83*(6), 1108.

Vineberg, S.K., West, A., Na, P.J., Oldham, M., Schilsky, M., Hawkings, K.A., & Lee, H.B. (2016). Utility of pretransplant psychological measures to predict posttransplant outcomes in liver transplant patients: a systematic review. *General Hospital Psychiatry*, 40, 4-11.

Finkenstedt, A., Nachbaur, K., Zoller, H., Joannidis, M., Pratschke, J., Graziadei, I. W. and Vogel, W. (2013), Acute-on-chronic liver failure: Excellent outcomes after liver transplantation but high mortality on the wait list. *Liver Transplantation,* 19: 879–886. doi:10.1002/lt.23678.

Fritz, M. S., & MacKinnon, D. P. (2007). Required sample size to detect the mediated effect. *Psychological science*, *18*(3), 233-239.

Garland, E. L., Gaylord, S. A., Boettiger, C. A., & Howard, M. O. (2010). Mindfulness training modifies cognitive, affective, and physiological mechanisms implicated in alcohol dependence: results of a randomized controlled pilot trial. *Journal of psychoactive drugs*, *42*(2), 177-192.

Gingerich, W.J., & Peterson, L.T. (2013). Effectiveness of solution-focused brief therapy: A systematic qualitative review of controlled outcome studies. *Research on Social*

Work Practice, 23(3), 266-283.

Gledhill, J., Burroughs, A., Rolles, K., Davidson, B., Blizard, B. & Lloyd, G. (1999).
Psychiatric and social outcome following liver transplantation for alcoholic
liver disease: A Controlled study. *Journal of Psychosomatic Research*, 46,
359-368.

Goel, A., Siddique, O., & Ahmed, A. (2019). End-Stage Liver Disease and Indications for Liver
Transplantation. In *Psychosocial Care of End-Stage Organ Disease and Transplant
Patients* (pp. 139-146). Springer, Cham.

Goetzmann, L., Ruegg, L., Stamm, M., Ambühl, P., Boehler, A., Halter, J., Muellhaupt, B., Noll,
G., Schanz, U., Wagner-Huber, R. & Spindler, A. (2008). Psychosocial profiles after
transplantation: a 24-month follow-up of heart, lung, liver, kidney, and allogeneic bone-
marrow patients. *Transplantation*, 86(5), 662-668.

Gorevski, E., Succop, P., Sachdeva, J., Cavanaugh, T.M., Volek, P., Heaton, P., Chisholm-
Burns, M. & Martin-Boone, J.E. (2013). Is there an association between
immunosuppressant therapy medication, adherence and depression, quality of life, and
personality traits in the kidney and liver population*? Patient Preference and
Adherence*, 7, 301-301.

Greene, G. M., Merighi, J. R., Voorhes, P., & McCool, M. (2020). A multisite study on
 using symptom-targeted interventions to improve mental health outcomes of
solid organ transplant patients. *Progress in Transplantation*, *30*(2), 132-139.

Gross, C.R., Kreitzer, M.J., Thomas, W., Reilly-Spong, M., Cramer-Bornemann, M.,

Nyman, J.A., Frazier, P. and Ibrahim, H.N. (2010). Mindfulness-based stress reduction for solid organ transplant recipients: a randomized controlled trial. *Alternative Therapies in Health and Medicine*, *16*(5), 30.

Gusev, A. (2015). Mindfulness as a Predictor of IL-6 Response to a Repeated Stressor. (Doctoral dissertation).

Hamer, M., Kivimaki, M., Stamatakis, E., & Batty, G. D. (2019). Psychological distress and infectious disease mortality in the general population. *Brain, Behavior, and Immunity*, *76*, 280-283.

Harris, P.A., Taylor, R., Thielke, R., Payne, J., Gonzalez, N., & Conde, J. (2009). Research electronic data capture (REDCap). A metadata-driven methodology and workflow process for providing translational research informatics support. *Journal of Biomedical Informatics,* 42(2), 377-381.

Helander, A., Hermansson, U., & Beck, O. (2019). Dose–response characteristics of the alcohol biomarker phosphatidylethanol (PEth)—a study of outpatients in treatment for reduced drinking. *Alcohol and Alcoholism*, *54*(6), 567-573.

Henry, J. D., & Crawford, J. R. (2005). The short-form version of the Depression Anxiety Stress Scales (DASS-21): Construct validity and normative data in a large non-clinical sample. *British Journal of Clinical Psychology*, *44*(2), 227-239.

Hickman, I.J., Hannigan, A.K., Johnston, H.E., Elvin-Walsh, L., Mayr, H.L., Staudacher, H.M., Barnett, A., Stoney, R., Salisbury, C., Jarrett, M. & Reeves, M.M. (2021). Telehealth-delivered, Cardioprotective Diet and Exercise Program for Liver Transplant Recipients: a randomized feasibility study. *Transplantation Direct*, *7*(3).

Hobdy, D., Barsky, A., & Reamer, F. (2017). The official national training of the new

    NASW Code of Ethics [PowerPoint slides]. Retrieved from

    https://www.socialworkers.org/includes/newIncludes/homepage/PRA-BRO-

    33617.TechStandards_FINAL_POSTING.pdf.

Howard, L., Fahy, T., Wong, P., Sherman, D., Gane, E., & Williams, R. (1994). Psychiatric

    outcome in alcoholic liver transplant patients. *Quarterly Journal of Medicine*, 87(12)

    731-736.

Jauhar, S., Talwalkar, J.A., Schneekloth, T., Jowsey, S., Wiesner, R.H., & Menon, K.V. (2004).

    Analysis of factors that predict alcohol relapse following liver transplantation.

    Liver Transplantation, 10(3), 408-411.

Jay, C. L., Butt, Z., Ladner, D.P., Skaro, A.I., & Abecassis, M. M. (2009). A review of

    quality of life of instruments used in liver transplantation. Journal of Hepatology, 51(5),

    949-959.

Julian, L. J. (2011). Measures of anxiety: State-Trait Anxiety Inventory (STAI), Beck Anxiety

    Inventory (BAI), and Hospital Anxiety and Depression Scale-Anxiety (HADS-A).

    Arthritis Care & Research, 63(S11).

Kasiske, B. (2020). OPTN/SRTR 2018 Annual Data Report: Liver. *American Journal of*

    Transplantation., 20(s1), 193–299. https://doi.org/10.1111/ajt.15674

Katon, W., Lin, E.H., & Kroenke, K. (2007). The association of depression and anxiety

    with medical symptom burden in patients with chronic medical illness. *General*

    Hospital Psychiatry, 29(2), 147-155.

Keyes, K. M., Hatzenbuehler, M. L., Grant, B. F., & Hasin, D. S. (2012). Stress and

    alcohol: epidemiologic evidence. *Alcohol Research: Current Reviews* [Abstract].

Kim, J.S. (2008). Examining the effectiveness of solution-focused brief therapy: A meta-analysis. *Research on Social Work Practice*, 18, 107-116.

Kitajima, T., Nagai, S., Segal, A., Magee, M., Blackburn, S., Ellithorpe, D., Yeddula, S., Qadeer, Y., Yoshida, A., Moonka, D., Brown, K. & Abouljoud, M.S. (2020). Posttransplant complications predict alcohol relapse in liver transplant recipients. *Liver Transplantation*, 26: 379-389. https://doi.org/10.1002/lt.25712

Krahn, L.E., & DiMartini, A. (2005). Psychiatric and psychosocial aspects of liver transplantation. *Liver Transplantation*, 11(10), 1157-1168.

Kramer, J., Conijn, B., Oijevaar, P., & Riper, H. (2014). Effectiveness of web-based solution-focused brief chat treatment for depressed adolescents and young adults: randomized control trial. *Journal of Medical Internet Research*, 6(5),

Krenzien, F., Krezdorn, N., Morgan, M.H., Wiltberger, G., Atanasov, G., Hau, H.M., Hinz, A., Schmelzle, M., Bartels, M. & Benzing, C. (2017). The elderly liver transplant recipients: anxiety, depression, fatigue, and life satisfaction. *Zeitschrift fur Gastroenterologie*, 55(06), 557-563.

Lai, H.M.X., Cleary, M., Sitharthan, T., & Hunt, G.E. (2015). Prevalence of comorbid substance use, anxiety and mood disorders in epidemiological surveys, 1990-2014: a systematic review and meta-analysis. *Drug & Alcohol Dependence,* 154, 1-13.

Langenbach, M., Schmeisser, N., Albus, C. & Decker, O. (2008). Comparison of social support and psychosocial stress after heart and liver transplantation. *In Transplant Proceedings* (Vol. 40, No. 4, pp. 938-939). Elsevier.

Lee, B.P., Chen, P.H., Haugen, C., Hernaez, R., Gurakar, A., Philosophe, B., Dagher, N., Moore,

S.A., Li, Z. & Cameron, A.M. (2017). Three-year results of a pilot program in early liver

transplantation for severe alcoholic hepatitis. *Annals of Surgery*, 265(1), 20-29.

Lee, B.P., Mehta, N., Platt, L., Gurakar, A., Rice, J.P., Lucey, M.R., & Im, G.Y. (2018).

Outcomes of early liver transplantation for patients with severe alcoholic

hepatitis. *Gastroenterology*, *155*(2), 422-430.

Lee, B.P., Vittinghoff, E., Dodge J.L., Cullaro, G. & Terrault, N.A. (2019). National trends and

long-term outcomes of liver transplant for alcohol-associated liver disease in the United

States. *JAMA Intern Medicine,* 179(3):340–348. doi:10.1001/jamainternmed.2018.6536.

Letourneau, B., Sopel, L.C., Sobell, M.B., Agrawal, S., & Gioia, C.J. (2017). Two brief

measures of alcohol use produce different results: AUDIT-C and Quick Drinking Screen.

Alcoholism: Clinical and Experimental Research, 41(5), 1035-1043.

Loosman, W.L., Siegert, C.E.H., Korzed, A., & Honig, A. (2010). Validity of the Hospital

Anxiety and Depression Scale and the Beck Depression Inventory for the end-stage renal

disease patients. *British Journal of Clinical Psychology*, 49(4), 507-516.

Lovibond, S.H.& Lovibond, P.F. (1996). *Manual for the Depression Anxiety Stress Scales*. (2nd.

Ed.) Sydney: Psychology Foundation.

Lovibond, P.F. & Lovibond, S.H. (1995). The structure of negative emotional states:

Comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression

and Anxiety Inventories, *Behaviour Research and Therapy*, 33(3), 335-343.

Magill, M., & Ray, L. A. (2009). Cognitive-behavioral treatment with adult alcohol and illicit

drug users: A meta-analysis of randomized controlled trials. *Journal of Studies on

Alcohol and Drugs*, *70*(4), 516-527.

Mahmud, N. (2020). Selection for liver transplantation: Indications and

evaluation. *Current Hepatology Reports*, 1-10.

Maldonado, J.R., Dubois, H.C., David, E.E., Sher, Y., Lolak, S., Dyal, J. & Witten, D.

(2012). The Stanford Integrated Psychosocial Assessment for Transplantation

(SIPAT): A new tool for the psychosocial evaluation of pre-transplant candidates,

Psychosomatics, 53 (2), 123-132. doi: 10.1016/j.psym.2011.12.012.

Martin, P., DiMartini, A., Feng, S., Brown, R., & Fallon, M. (2014). Evaluating for liver

transplantation in adults: 2013 practice guidelines by the American Association for the

Study of Liver Diseases and the American Society of Transplantation. *Hepatology*,

59(3), 1144-1165.

Marudanayagam, R., Shanmugam, V., Sandhu, B., Gunson, B.K., Mirza, D.F., Mayer, D.,

Buckels, J. & Bramhall, S.R. (2010). Liver retransplantation in adults: a single-centre,

25-year experience. *HPB*, *12*(3), 217-224.

Marudanayagam, R., Shanmugam, V., Sandhu, B., Gunson, B.K., Mirza, D.F., Mayer, D.,

Buckels, J. & Bramhall, S.R (2014). Relevance of anxiety and stress levels on sleep

quality after liver transplantation. *Transplantation Proceedings*, 46(6), 1822-1826.

McCool, M. (2015). Symptom Targeted Intervention (STI): The Complete Training Guide.

Los Angeles, CA

McCool, M., Boyd, S., Aebel-Groesch, K., Gonzalez, T., & Evans, D. (2014).

Symptom targeted intervention webinar trainings: feedback from participants.

Nephrology News & Issues, 28(7), 23-26.

McCool, M., Johnstone, S., Sledge, R., Written, B., Contillo, Aebel-Groesch, K., & Hafner.

(2011). The promise of symptom-targeted intervention to manage depression in dialysis

patients. *Nephrology News and Issues*, 25(6), 32-37.

McKie, P., Webzell, I., Tavabie, O., Loewenthal, D., & Heaton, N. (2020). An exploratory study of the experiences of deceased-donor liver transplant recipients and their need for psychotherapeutic support. *Journal of Clinical Nursing*.

McMurchie, W., Macleod, F., Power, K., Laidlaw, K., & Prentice, N. (2013). Computerised Cognitive Behavioural Therapy for depression and anxiety with older people: a pilot study to examine patient acceptability and treatment outcome. *International Journal of Geriatric Psychiatry,* 28(11), 1147-1156).

Meller, W., Welle, N., Sutley, K., & Thurber, S. (2017). Depression and liver transplant survival. *Psychosomatics,* 58(1), 64-68.

Mendes, K.D.S., Lopes, A.R.F., Martins, T.A., Lopes, G.F., Ziviani, L.C., Rossin, F.M., Castro-e-Silva, O. & Galvão, C.M. (2014, July). Relevance of anxiety and stress levels on sleep quality after liver transplantation. In *Transplantation proceedings* (Vol. 46, No. 6, pp. 1822-1826). Elsevier.

Mohamed, S., Sabki, Z.A., & Zainal, N.Z. (2014). Depression and psychosocial correlates of liver transplant candidates: A systematic review. *Asia-Pacific Psychiatry*, 6(4), 447-453.

Morris E.D. (2020) Psychosocial Considerations of Heart Transplant: Keeping Apace with the Revolution in Cardiac Care. In: Bogar L., Stempien-Otero A. (eds.) *Contemporary Heart Transplantation*. Organ and Tissue Transplantation. Springer, Cham. https://doi.org/10.1007/978-3-319-58054-8_5.

Mullish, B.H., Kabir, M.S., Thursz, M.R., & Dhar, A. (2014). Review article: Depression and the use of antidepressants in patients with chronic liver disease or liver transplantation. *Alimentary Pharmacology and Therapeutics,* 40, 880-892.

Napolitano, M.A., Babyak, M.A., Palmer, S., Tapson, V., Davis, R.D., & Blumenthal, J.A.

(2002). Effects of a telephone-based psychosocial intervention for patients awaiting

lung transplantation, *Chest*, 122(4), 1176-1184.

NIAAA: National Institute on Alcohol Abuse and Alcoholism. *Drinking Defined*.

https://www.NIAAA.nih.gov/alcohols-effects-health/overview-alcohol-

consumption/what-standard-drink.

NIAAA: National Institute on Alcohol Abuse and Alcoholism (2004). *Recommended Alcohol*

Questions. https://www.NIAAA.nih.gov/research/guidelines-and-

resources/recommended-alcohol-questions.

NIH: National Institute of Drug Abuse (2018). P*rinciples of Drug Addiction Treatment: A*

Research Based Guide (3rd Ed).

https://d14rmgtrwzf5a.cloudfront.net/sites/default/files/podat_1.pdf

Nickel, R., Wunsch, A., Egle, U., Lohse, A., Otto, G. (2002). The relevance of anxiety,

depression, and coping in patients after liver transplantation. *Liver Transplantation*,

8(1), 63-71.

Nicol Turner Lee, J.K. & Roberts, J. (2020) Removing regulatory barriers to telehealth before

and after COVID-19. *Brookings Institution*.

Nouri, S., Khoong, E.C., Lyles, C.R., & Karliner, L. (2020). Addressing equity in telemedicine

for chronic disease management during the COVID-19 pandemic. *NEJM Catalyst*

Innovations in Care Delivery, 1(3).

OPTN (Organ Procurement Transplantation Network) (2020). Data reports. Retrieved from

https://optn.transplant.hrsa.gov/data/organ-datasource/liver/?type=state&display=Liver.

Palmer S.C. (2020) Hospital Anxiety Depression Scale. In: Gellman M.D. (eds.)

Encyclopedia of Behavioral Medicine. Springer, Cham. https://doi.org/10.1007/978-3-030-39903-0_962.

Parkitny, L., & McAuley, J. (2010). The Depression Anxiety Stress Scale (DASS). *Journal of Physiotherapy*, 56(3), 204.

Pascazio, L., Nardone, I.B., Clarici, A., Enzmann, G., Grignetti, M., Panzetta, G.O., & Vecchiet, C. (2010). Anxiety, depression and emotional profile in renal transplant recipients and healthy subjects: A comparative study. *Transplant Proceedings*, 42, 3586-3590.

Paterno, F., Wilson, G.C., Wima, K., Quillin III, R.C., Abbott, D.E., Cuffy, M.C., Diwan, T.S., Kaiser, T., Woodle, E.S. & Shah, S.A. (2014). Hospital utilization and consequences of readmissions after liver transplantation. *Surgery*, 156(4), 871-879.

Paul, F., Müller, J., Christe, W., Steinmüller, T., Poewe, W., & Wissel, J. (2004). Postural hand tremor before and following liver transplantation and immunosuppression with cyclosporine or tacrolimus in patients without clinical signs of hepatic encephalopathy. *Clinical Transplantation*, *18*(4), 429-433.

Pelgur, H., Atak, N., Kose, K. (2009). Anxiety and depression levels of patients undergoing liver transplantation and their need for training. *Transplantation Proceedings*, 41, 1743-1748.

Penate, W., & Fumero, A. (2016). A meta-review of Internet computer-based psychological treatments for anxiety disorders. Journal of Telemedicine and Telecare, 22(1), 3-11.

Perez-San-Gregorio, M.A., Martin-Rodriguez, A.M., Diaz-Dominguez, R., & Perez-Bernal., J. (2006). The influence of posttransplant anxiety on the long-term health of patients. *Transplant Proceedings*, 38, 2406-2408. doi:

10.1016/j.transproceed.2006.08.069.

Pihlaja, S., Stenberg, J.H., Joutsenniemi, K., Mehik, H., Ritola, V., & Joffe, G. (2017).

Therapeutic alliance in guided internet therapy programs for depression and anxiety

disorders –A systematic review. Internet Interventions.

https://doi.org/10.1016/j.invent.2017.11.005.

Pilch N.A. (2020) Regulatory Agencies. In: Bogar L., Stempien-Otero A. (eds).

Contemporary Heart Transplantation. Organ and Tissue Transplantation. Springer,

Cham. https://doi.org/10.1007/978-3-319-58054-8_28.

Rainer, J. P., Thompson, C. H., & Lambros, H. (2010). Psychological and psychosocial aspects

of the solid organ transplant experience–A practice review. *Psychotherapy: Theory,*

Research, Practice, Training, *47*(3), 403.

Riper, H., Andersson, G., Hunter, S. B., de Wit, J., Berking, M., & Cuijpers, P. (2014).

Treatment of comorbid alcohol use disorders and depression with cognitive-behavioural

therapy and motivational interviewing: A meta-analysis. *Addiction*, *109*(3), 394-406.

Rogal, S. S., Dew, M. A., Fontes, P., & DiMartini, A. F. (2013). Early treatment of

depressive symptoms and long-term survival after liver transplantation. *American*

Journal of Transplantation, 13(4), 928-935.

Rogic, C. (2019). The Renal Transplant Experience. (MSW Thesis).

http://hdl.handle.net/11375/24902.

Rollnick, S., & Miller, W.R. (n.d.). What is MI? Retrieved from

http://www.motivationalinterview.net/clinical/whatismi.html.

Rose, M., & Devine, J. (2014). Assessment of patient-reported symptoms of anxiety. *Dialogues*

in Clinical Neuroscience, *16*(2), 197–211.

Rosenberger, E.M., Dew, M.A., Crone, C., DiMartini, A.F. (2012). Psychiatric disorders as risk

factors for adverse medical outcomes after solid organ transplantation. *Current Opinion Organ Transplantation, 17, (188-192).*

Roy, M., Dum, M., Sobell, L. C., Sobell, M. B., Simco, E. R., Manor, H., & Palmerio, R. (2008). Comparison of the Quick Drinking Screen and the alcohol Timeline Follow back with outpatient alcohol abusers. *Substance Use & Misuse, 43*(14), 2116-2123.

Sadiq, Y., Patel, A.M., Huskamp, H., Uscher-Pines, L., Gangull, I., & Barnett, M.L. (2021) Variations in telemedicine use and outpatient care during the Covid-19 pandemic in the United States. *Health Affairs*, 40:2, 349-358. https://doi.org/10.1377/HLTHAFF.2020.01786.

Schmajuk M., DeGuzman E., & Allen N. (2019) Psychotherapy in Transplant Patients. In: Sher Y., Maldonado J. (eds) Psychosocial Care of End-Stage Organ Disease and Transplant Patients. Springer, Cham. https://doi.org/10.1007/978-3-319-94914-7_43.

Schmid, A., Hils, S., Kramer-Zucker, A., Bogatyreva, L., Hauschke, D., De Geest, S., & Pisrski, P. (2017). Telemedically supported case management of living-donor renal transplant recipients to optimize routine evidence-based aftercare: A single-center randomized Controlled trial. *American Journal of Transplantation*, 17(6), 1594-1605.

Schneiderman, N., Ironson, G., & Siegel, S.D. (2005). Stress and health: psychological, Behavioral, and biological determinants. *Annual Review of Clinical Psychology*, 1, 607-628.

Schulz, K. H., Ewers, H., Rogiers, X., & Koch, U. (2007). Need and use of psychosocial care after liver transplantation. *PPmP Psychotherapy· Psychosomatics· Medical Psychology, 57*(05), 221-230. [Abstract Translated from German to English].

Sebaaly, J.C., Fleming, J., Pilch, N., Meadows, H., Finn, A., Chavin, K., Baliga, P.,

Bratton, C.F., McGillicuddy, J.W., Nadig, S. & Taber, D.   (2016). Depression resource utilization, and outcomes following liver transplant. *Progress in Transplantation,* 26(3), 270-276. doi: 10.1177/1526924816654641.

Sidhu, A., Chaparro, C., Binnie, M., & Chow, C. (2015). Outcomes of telehealth for lung transplant recipients. *The Journal of Heart and Lung Transplant*, 34(4), p. S173-S173.

Sledge, R., Aebel-Groesch, K., McCool, M., Johnstone, S., Witten, B., Contillo, M., & Hafner, J. (2011). Part 2. The promise of symptom-targeted intervention to manage depression in dialysis patients: improving mood and quality of life outcomes. *Nephrology News & Issues*, *25*(7), 24-8.

Smock, S.A., Trepper, T.S., Wetchler, J.L, McCollum, E.E., Ray, R., & Pierce, K. (2008). Solution-focused group therapy for level 1 substance abusers. *Journal of Marital and Family Therapy, 34*(1), 107-120. doi:10.1111/j.1752-0606.2008.00056.x

Snit, R.P. (2003). The hospital anxiety and depression scale. *Health and Quality of Life Outcomes,* 1(1), 29.

Stams, G.J., Dekovic, M., Buist, K., & De Vries, L. (2006). Efficacy of solution-focused brief therapy: A meta-analysis. *Gedragstherapie*, 39(2), 81-94.

Stern, A.F. (2014). The Hospital Anxiety and Depression Scale, *Occupational Medicine*, 64 (5), 393–394. https://proxy.library.upenn.edu:2101/10.1093/occmed/kqu024

Stilley, C.S., Flynn, W.B., Sereika, S.M., Stimer, E.D., DiMartini, A.F., & deVera, M.E. (2012). Pathways of psychological factors, stress, and health outcomes after liver transplantation. Clinical Transplantation, 26(2), 216-222. https://doi.org/10.1111/j.1399-0012.2022.01467.x.

Stonnington, C.M., Darby, B., Santucci, A., Mulligan, P., Pathuis, P., Cup, A., Hentz, J.G., Zhang, N., Mulligan, D. & Sood, A. (2016). A resilience intervention involving mindfulness training for transplant patients and their caregivers. *Clinical Transplantation*, 30(11), 1466-1472.

(STSW) Society for Transplant Social Workers. (2021). https://www.stsw.org/

Su, J. H., Wang, S. Y., Liang, X., Zhu, M. L., Qiao, S., & Yin, H. Y. (2014). Mode and effect of cognitive-behavioral therapy for liver transplant recipients waiting for a liver transplant. *Chinese Journal of Tissue Engineering Research*, 18, 687-692. 10.3969/j.issn.2095-4344.2014.05.006.

Sukantarat, K.T., Williamson, R.C.N., & Brett, S. J. (2007). Psychological assessment of ICU Survivors a comparison between the Hospital Anxiety and Depression scale and the Depression, Anxiety and Stress Scale, *Anaesthesia*, 62(3), 239-243.

Swift, J. K., & Greenberg, R. P. (2012). Premature discontinuation in adult psychotherapy: a meta-analysis. *Journal of Consulting and Clinical Psychology*, *80*(4), 547.

Swift, R. M. (1999). Medications and alcohol craving. *Alcohol Research & Health*, *23*(3), 207.

Talal, A.H., Sofikitou, E.M., Jaanimägi, U., Zeremski, M., Tobin, J., & Markatou, M. (2020). A framework for patient-centered telemedicine: Application and lessons learned from vulnerable populations. *Journal of Biomedical Informatics*, 112, 103622. https://doi.org/10.1016/j.jbi.2020.103622.

Tanner-Smith, E.E., & Lipsey, M.W. (2015). Brief alcohol interventions for adolescents And young adults: A systematic review and meta-analysis. *Journal of Substance Abuse Treatment,* 51, 1-18.

UNOS. Donation and Transplantation: Transplant Trends (2020). Retrieved from:

https://unos.org/data/transplant-trends/.

Wardenaar, K.J., Wanders, R.B.K., Jeronimus, B.F. & de Jonge, P. (2017).

    Journal of Psychopathology and Behavioral Assessment,

    https://doi.org/10.1007/s10862-017-9626-6.

Weinrieb, R. M., Van Horn, D. H., Lynch, K. G., & Lucey, M. R. (2011). A randomized,

    Controlled study of treatment for alcohol dependence in patients awaiting liver

    transplantation. *Liver Transplantation*, *17*(5), 539-547.

Williams, A., Low, J.K., Manias, E., & Crawford, K. (2016). The transplant team's support

    of kidney transplant recipients to take their prescribed medications: a collective

    responsibility. *Journal of Clinical Nursing*, 25(15-16), 2251-2261.

    https://doi.org/10.1111/jocn.13267.

Winder, G. S., Shenoy, A., Dew, M. A., & DiMartini, A. F. (2020). Alcohol and other substance

    use after liver transplant. *Best Practice & Research Clinical Gastroenterology*, 101685.

World Health Organization. (2020). Implementing telemedicine services during

    COVID-19: Guiding principles and considerations for a stepwise approach.

Wu, Y., Levis, B., Sun, Y., He, C., Krishnan, A., Neupane, D. (2021). Anxiety and

    Depression Scale Depression subscale (HADS-D) to screen for major depression:

    systematic review and individual participant meta-analysis. *BMJ*, 373: n972. doi:

    10.1136/bmj.n972.

Wupperman, P., Cohen, M., Haller, H., Flom, P., Litt, L., & Rounsaville, B. (2015). Mindfulness

    and Modification Therapy for Behavioral Dysregulation: A Comparison Trial Focused on

    Substance Use and Aggression. *Journal of Clinical Psychology, 71*, 964–978.

Yates, W.R. (2007). Psychiatric disorders in liver disease. Journal of Pharmacy Practice,

    20, 373-376. doi: 10.1177/0897190007304985.

Yates, W.R., Martin, M., LeBrecque, C., Hillebrand, D., Voight, M., & Pfab, D. (1998).

A model to examine the validity of the 6-month abstinence criterion for liver transplantation. *Alcoholism: Clinical and Experimental Research*, 22(2), 513-517.

Yıldız, E., & Kılınç, G (2017). The relationship between anxiety-depression status and psychosocial adjustments in the patients undergoing liver transplantation. *Perspectives in Psychiatric Care,* 1-9, doi: 10.1111/ppc.12226.

Zigmond, A.S., & Snaith, R.P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica,* 67(6), 361-370.

Zilberfein, F., Hutson, C., Snyder, S., & Epstein, I. (2008). Social work practice with pre-and post-liver transplant patients. *Social Work in Health Care,* 33, (3-4),91-104. doi: 10.1300/J010v33n03_07.

Appendix A:

I. **Demographics and Medical Chart Information in Consent.**
    - **Name**
    - **Street address, city, county, and zip code or equivalent geocodes**
    - **Telephone numbers**
    - **Medical Record numbers**
    - **Psychosocial history related to anxiety, depressions, distress, substance use issues, including corresponding diagnoses**
    - **Results of HADS, DASS, and QDS throughout the study**
    - **Age (open ended in years)**
    - **Gender (M/F)**
    - **Marital status (Y/N)**
    - **Race (Black/White/Hispanic/Other)**
    - **Educational Level (8th grad or less/some high school/completed high school or GED/some college/completed college/post graduate)**
    - **Employment at the time of evaluation (full time/part-time/disabled/unemployed**

II. **Medical Record Data:**
    - **Current Smoking (Y/N)**
    - **Time spent on the waiting list (open in months)**
    - **Diagnoses codes (ICD-10)**
    - **More than one liver transplant (Y/N)**
    - **More than one transplant surgery (Y/N)**
    - **Dual organ (Y/N)**
    - **History mental health disorder(s)**
    - **Current mental health disorder(s)**
    - **History alcohol treatment**
    - **Number of medications used for depression and/or anxiety post- transplant**
    - **Number of readmissions first 90 days post–transplant**
    - **Active or Passive Suicidality and/or Homicidality**
    - **AST, ALT, serum alcohol, urine alcohol, and PEth test.**

APPENDIX B: Combined Informed Consent and HIPPA Authorization Form Title of the Research Study: A Pilot Study of the Effectiveness of Symptom Targeted Intervention (STI) for Post-Liver
Transplant Patients Focusing on Anxiety, Depression, Stress, and Alcohol Use Protocol Number:
Principal Investigator: Robert Weinrieb, MD
Professor of Psychiatry
Corporate (UPHS)
Psychiatry Department of Behavioral Health
HUP Liver Transplant, 2 Dulles
Robert.Weinrieb@pennmedicine.upenn.edu
(215) 662-2858 (voicemail) or 4717 (Kathy Kratowicz, administrative assistant)
Social Work Dept. Gibson 1 Bldg.
3400 Spruce Street,
Philadelphia, PA 19104
Regina.Miller@uphs.upenn.edu
(215)490-6728
(215)662-3162
Emergency Contact: Patricia Meehan, LSW Social Work Dept. Gibson 1 Bldg.
3400 Spruce St.
Patricia.Meehan@uphs.upenn.edu (215)662-
3161 (215)662-4000
Consent Summary
Research is voluntary and contact information
Research is voluntary and a refusal to participate will be acknowledged and respected without any penalty. A few attempts to contact you will be made to determine your interest in continuing the study. If we do not hear back within three weeks, you will receive written notice of being disenrolled in the study. Participants will be dis-enrolled in the study if meeting weekly with a psychotherapist, admitted to an inpatient psychiatric facility, or at their request. This choice will not affect your care at Penn Medicine and we are grateful for any time you spent in the study.
Please contact with questions or concerns:
Regina "Jeannie" Miller, LCSW: (215) 490-6728 Regina.Miller@pennmedicine.upenn.edu
Study Purpose
Penn Transplant Institute (PTI) recognizes the importance of post-transplant psychosocial care in the immediate post-transplant phase. One aspect of psychosocial care includes being attentive to the psychological well-being of our liver transplant patients. Transplant research supports the concept of addressing psychosocial problems, although very little research concentrates on specific interventions or methods to promote it. The purpose of this study is to provide emotional support and/or psychological interventions during the immediate post- liver transplant phase with

IRB Approved From: 08/31/2020

trained transplant social workers. Depression, anxiety, and stress will be measured with the hypothesis that the intervention group will demonstrate evidence that there will be improvement

in symptoms after completion of the interventions compared to the enhanced treatment-as-usual group. The intervention is provided by a transplant social worker on telemedicine through your phone or IPad at your convenience. At the initial visit, a short cognition screen will be administered and data will be compared to your scores of depression, anxiety, and/or stress. In addition, the use of alcohol is explored in this study. Alcohol use complicates the post- transplant phase and can alter psychological wellness and transplant outcomes.

Study Procedures

The participants require access to a phone or IPad in order to participate. The research team will assist you in uploading the application required for the study. Additionally, there is free Penn Medicine IT support and information to enhance the experience. Once consents are signed, you will screen-in for depression, and/or anxiety, and/or stress. Once screened -in to meet minimum requirements of anxiety, depression, and/or stress, you will be randomized into the intervention or enhanced-treatment-as-usual group, both via telemedicine. Your assigned telemedicine social worker will remain with you throughout the duration of the study. If there are any concerns about severe symptoms of depression, anxiety, or stress, the psychiatrist on the study will be contacted for next steps. If there is alcohol use noted, the same procedure will be followed. The social workers are trained to respond in a crisis on telemedicine.

Patient compensation is available and will be presented on a ClinCard debit card. Confidentiality is maintained through safe storage of papers in locked files in a locked social work office, along with upload on HIPPA compliant, secure Penn Box. REDCap is the data survey and collection HIPPA compliant portal used in this study. If you do no screen-in for next steps on telemedicine, your data is still very important to us and this study.

Duration of Participation

The pilot study will be completed through the Blue Jeans platform for six consecutive weeks, with a time commitment of 20-30 minutes per week. The pilot study will be completed through the Blue Jeans platform for six consecutive weeks, with a time commitment of 20-30 minutes per week.

The HIPPA compliant REDCap portal will generate an email after the completion of the social work telemedicine sessions, and lastly, three months thereafter. After the final email screening, your participation is complete.

Risks and Benefits

The psychological risks could include intense thoughts or feelings being evoked during the study, which could worsen symptoms. Any severe or worrisome symptoms are reported and monitored by our social workers and psychiatry department. The study makes all attempts to maintain the highest integrity of confidentiality, although feelings of suicidality, homicidality, and/or severe anxiety, depression, stress and/or a positive alcohol test is reported to the psychiatrist on this study, Dr. Weinrieb, and then assessed. There are no benefits to the participants except to contribute to research.

You are being asked to take part in a research study. This is not a form of treatment or therapy. It is not supposed to detect a disease or find something wrong. Your participation is voluntary

IRB Approved From: 08/31/2020

which means you can choose whether to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled.

Before you decide, you will need to know the purpose of the study, the possible risks and benefits of being in the study and what you will have to do if you decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to decide now; you can take the consent document home and share it with friends, family doctor and family. Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

If you do not understand what you are reading, do not sign it. Please ask the researcher(s) to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy will be given to you. Keep this form, in it you will find contact information and answers to questions about the study. You may ask to have this form read to you.

What is the purpose of the study?

•The purpose of the study is to investigate and report on the effectiveness of brief, Symptom Targeted Interventions in the medical setting for the early post liver transplant population.

•Changes in levels and/or changes in symptoms of anxiety, depression, and/or stress will be measured. This study will capture how changes in depression, anxiety, and/or stress may affect alcohol use.

•The study will use Penn Medicine transplant social workers assigned to provide case management or providing Symptom Targeted Intervention via the Penn telemedicine platform, Blue Jeans Platform.

•This study is part of a doctoral dissertation through the University of Pennsylvania School of Social Policy and Practice (SP2) in the Doctor of Clinical Social Work (DSW)program.

Why was I asked to participate in the study?

•You are being asked to join this study because you have been identified as using any amount of alcohol two years prior to the date of your liver transplant. This is because we are exploring alcohol use in the early post -transplant phase. Each post liver transplant patient meeting this alcohol criterion will be approached to join this study.

•Second, a screening for anxiety, depression, and/or stress will identify you as being eligible for the study and randomly placed into one of two groups, either the intervention group or the enhanced treatment-as-usual group.

•The MiniCog, or a short cognition screening, will be administered at initial screening.

•If you do not meet minimum requirements for anxiety, depression, or stress, you will not be asked to join this study, although your demographic and screening data can be used in the study.

•In addition, you will be unable to participate in this study during any psychiatric or behavioral health inpatient admissions or if you are seeking psychotherapy at the time of the study.

IRB Approved From: 08/31/2020

•If you are admitted to a medical hospital or another level of medical care, other than home, you can remain as a participant in the study and attempts will be made to accommodate you, if

possible.

How long will I be in the study?

•The length of your participation in the study will be at least six weeks to complete all of the 20-30-minute weekly sessions. If there is a readmission, we will make attempts to reach you in the hospital, depending upon the severity of your illness.

•At the completion of both group's telemedicine sessions, there will be an additional post screening sent via email, or online, with the same screening tools after the last session.

•Lastly, there will be one additional screening with the same tools sent via email, or online, at three months post last session.

•We ask you to allow one 20-30 -minute session once per week for six weeks to participate in this study. The social worker you are assigned will be scheduling you and there will be reminders. The session will be timed.

•The initial session may be longer, or 30-40 minutes, to accommodate for testing of Blue Jeans platform and any unforeseen technological issues. You will be enrolled in the Blue Jeans platform at Penn Medicine or through a confidential online link either on your phone and/or laptop and you will have technology assistance by telemedicine IT or Penn Medicine support (866.614.7606) or https://www.pennmedicine.org/bluejeans.

It is a goal to enroll approximately fifty post liver transplant patients who meet eligible criteria over the span of twenty-four months.

Where will the study take place?

You will be asked to meet via telemedicine during a time arranged weekly between you and your social worker between 8am-9pm, Monday through Saturday, in a location comfortable to you with the most privacy where you have access to a strong Wi-Fi signal to engage via videoconferencing, or the Blue Jeans platform. **What will I be asked to do?**

•Initially, you will be identified and then eligibility determined once screenings completed.

•Second, you will be asked to spend time during a clinic visit to upload the Blue Jeans platform onto your phone with technical assistance.

•Uploading the Blue Jeans can be attempted outside the clinic, too, with no cost to the patient.

•You will be randomly assigned to either the treatment group (Symptom Targeted Intervention) or the control group (case management and transplant social work) upon completion of the screenings.

•From there, you will be assigned a transplant social worker who will remain with you for the duration of the study and the social worker will be engaging with you on the telemedicine platform for each session. If any unforeseen issues arise, the social workers are trained to respond in a safe and professional manner. Every effort will be made to continue your care with the same social worker while enrolled in this study both on and

IRB Approved From: 08/31/2020

off the telemedicine platform. You will be given their contact information at the time of the assignment. • Your social worker will contact you within a week to arrange your first session on

the Blue Jeans platform, or telemedicine, at a time convenient to both of you, and preferably, during work hours. Once six sessions are completed, we will ask you to answer three short questionnaires, the same screening questionnaires you completed to enroll in the study. • You will answer the three questionnaires at the time of the screening. • The last week of your sixth session. • Three months later.

What are the risks?

In general, there is a small level of risk involved with working with feelings that may be elicited or not expected, in either the treatment group or the enhanced-treatment-as usual group.

• Because either group could explore painful feelings, emotions and experiences, you may feel emotionally uncomfortable at times. You may cry, get upset or feel angry during a challenging session, or you may also feel physically drained.

• Targeting depressive, anxious, or stress symptoms can be positively impacted by engaging with trained transplant social workers and there should be minimal risk.

• If concerns should arise, the masters' prepared social workers are trained to assess and will consult and/or refer to a higher level of intervention or care within our social work department, transplant psychiatry, and/or the transplant team.

Mandatory Reporting:

Transplant and Psychiatry Emergency Services

A threat to self or others is reportable. The standards of clear and present danger may be met when a person has made a threat of harm to self or others; has made a threat to commit suicide; or has made a threat to commit an act of mutilation and has committed acts in furtherance of any such threats. Each social worker will have your county emergency crisis contact information available or 9-1-1 will be called if any of the above crisis occurs. If crisis or 9-1-1 is called, the social worker will report this to the transplant psychiatrist on call.

Child Welfare Law and Mandatory Reporting in PA

Licensed health care workers and providers are considered mandatory reporters in the state of PA and NJ. A person licensed or certified to practice in any health-related field under the jurisdiction of the Department of State in PA and NJ are mandatory reporters of child (under age 18). Mandatory reporting encompasses physical abuse, emotional abuse, or neglect of a minor. **How will I benefit from the study?**

There is no benefit to you. However, your participation could help us understand if Symptom Targeted Intervention (STI) is worthwhile to use in our post liver transplant populations to address symptoms of anxiety, depression, and/or stress.

IRB Approved From: 08/31/2020

This could potentially support better outcomes in the solid organ transplant populations, which

can benefit you indirectly. In the future, this may help other people by identifying their symptoms early on and using the resources already available on the transplant teams.

What other choices do I have?

Your alternative to being in the study is to not be in the study.

What happens if I do not choose to join the research study?

• You may choose to join the study, or you may choose not to join the study. Your participation is voluntary.

• There is not penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you or would come to you in the future. Your therapist, social worker, nurse, doctor, or psychiatrist will not be upset with your decision.

• If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

• You will continue to be followed by the transplant team and any decision to stop this study will not change this fact. You will continue to be cared for with the same care and concern by each member of the team, regardless of this decision.

When is the study over? Can I leave the study before it ends?

The study is expected to end after all participants have completed all visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

• The PI feels it is best for your safety and/or health-you will be informed of the reasons why.

• You have not followed the study instructions

• The PI, the sponsor or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care.

If you no longer wish to be in the research study, please contact Regina Miller, Transplant Social Work Supervisor, at (215) 490-6728 or 215-662-3161 and take the following steps:

IRB Approved From: 08/31/2020

1. Call and talk to Regina Miller and if unavailable, please leave a message with name and best contact method.

2. A return call will occur. A few questions will be asked:

a. Why do you want to leave the study?

b. Is there anything we can do to assist you or answer for you prior to leaving the study?

3. You will continue to have access to any member of the transplant team, regardless of study participation.

4. There will be no consequences to leaving the study.

5. If you begin to feel emotionally worse at any point in your care please contact your transplant team to discuss at (215) 662-4200

When does treatment effect enrollment in this study?

If you are placed in an inpatient facility for addictions or mental health, you will be unable to complete your telemedicine sessions. If you are in weekly treatment with a psychotherapist for anxiety and/or depression, you will discontinue the telemedicine sessions. You will continue to be enrolled in the study and receive study measures at the treatment termination phase and three months' post treatment phase.

How will confidentiality be maintained, and *my* privacy be protected?

The person recruiting and screening for eligibility will not be the same person collecting the outcome data. The data collector will collect and track all data. To protect your privacy in this research study we will label all the forms and data we collect for the study with a unique number and data will be collected and stored in a HIPPA generated Penn Medicine server. The unique number will be found on forms and Medical records and data will be screened and collected and matched with the Medical Record Number (MRN) and placed in a HIPPA protected Penn Box account.

Privacy. Recruitment of subjects will take place in the post liver transplant clinic setting or over the phone for the initial introduction. The screening, pre, post, and follow-up data measures will remain confidential to staff, unless a mandatory reporting situation arises, and the social workers will follow social work protocol as outlined by hospital policy and the law. If the potential

IRB Approved From: 08/31/2020

participants do not screen into the study, this will be immediately communicated to the participants in person or over the phone, dependent upon when the information is obtained.

What information about me may be collected, used or shared with others?

The following protected health information (PHI) will be collected and used for research purposes.

o Name

o Street address, city, county, and zip code or equivalent geocodes o Telephone numbers o Medical Record Numbers

o Psychosocial history related to anxiety, depression, distress, substance use issues, including corresponding diagnoses

o Results of HADS, DASS and QDS throughout the study

o MiniCog

o Age – open ended number o Gender (M/F) o Marital status (Y/N) o Race (Black/White/Hispanic/Other)

o Educational level (8th grade or less/some high school/completed high school or GED/come college/ completed college/post graduate) o Employment at time of evaluation (Full-time/Part-time/Disabled/Unemployed) o Medical Record Data: Current smoking (Yes/No); Time spent on the waiting list; Diagnosis codes; More than one liver transplant surgery; more than one transplant surgery; Dual organ; Mental Health; Alcohol Treatment; Number of medications used for depression and/or anxiety posttransplant; Number of readmissions first 90 days' post – transplant; Active or Passive Suicidality and/or Homicidality; AST, ALT ratio, serum alcohol, urine alcohol, and PEth test.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

• do the research

• oversee the research

• to see if the research was done right

• to evaluate and manage research functions.

• And to maintain the safest procedures and protocols for our Penn Medicine patients.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

• Robert Weinrieb, MD, Principle Investigator, Dr. Phyllis Solomon, PhD, Michelle EvansChase, PhD, John Schafhauser, LCSW, and Regina M. Miller, LCSW.

• The Psychiatry Department at Penn Transplant Institute.

IRB Approved From: 08/31/2020

• The Social Work Department at Penn Medicine-Hospital of the University of Pennsylvania.

• Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB.

Who, outside of the School of Medicine, might receive my information?

• Dr. Phyllis Solomon, PhD, University of Pennsylvania-Research Dissertation Chair

• Michelle Evans-Chase, PhD. University of Pennsylvania-Statistics

• John Schafhauser, LCSW, Penn Medicine-The University of Pennsylvania Hospital.

• Regina M. Miller, LCSW, Penn Medicine-The University of Pennsylvania Hospital.

Oversight organizations

• The Office of Human Research Protections

• The Office of Penn Telemedicine

• The study data and safety monitoring board at Penn Medicine.

Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your data could be stored and distributed for future research studies without additional informed consent

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

• You have given written authorization

• The University of Pennsylvania's Institutional Review Board grants permission

• As permitted by law

IRB Approved From: 08/31/2020

Can I change my mind about giving permission for use of my information? Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information? Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

• An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

• A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the conduct of the research.

• If you are receiving care or have received care within the University of Pennsylvania

Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

• Only patients already receiving a liver transplant at Penn Medicine Transplant Institute within six months or less will be involved in this study. Once data and information is placed in your medical record (EMR) or CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team.

• Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

What happens if I am injured from being in the study?

•We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

IRB Approved From: 08/31/2020

•There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

•If you think you have been injured because of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher(s)'s name and phone number are listed in the consent form.

Will I have to pay for anything?

•There will be no cost to you to participate in the study. Once enrolled, the study can be completed in your home except for participation with the lab test.

Will I be paid for being in this study?

•Payment for time is important. Payment will be made using a pre-paid debit card, or Clincard. Payments are made through a secure web-portal that allows for authorized study coordinators to transfer funds to participate in real time via a reloadable prepaid MasterCard and it works like a bank debit card. The money will be added to the card after each completed visit (schedule below).

•The debit card system is administered by an outside company. The company, Greenphire, will ask your name and social security number. They will use this information only as part of their payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

•You may use this card at any store that accepts credit cards or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals and inactivity. You will receive additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

IRB Approved From: 08/31/2020

•Participants will be receiving a Clincard and incremental payments up to a total of $40will be

added to card at each phase as follows.
Payment Schedule: First Phase or visit (recruitment)=$5.00
Second Phase A (completion of three sessions) =$5.00
Second Phase B (completion of six sessions) =$10.00
Third Phase (post intervention test completion) =$10.00
Fourth Phase (three months' post- intervention test completion) =$10.00

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

•If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215)898-2614.

•When you sign this document, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

Signature of Subject: _____

Print Name of Subject: _____

Date: _____

IRB Approved From: 08/31/2020

Appendix C: Interventions & Assignments Weeks (1-6)

STI INNOVATIONS

Post-transplant stress management: WEEK #1

1. What is going well?

- *Our brains are drawn to problems and often don't notice the good stuff. Research: if we teach our brains to notice what is going well, we are happier.*
- *What is going well right now in your life?*
- *What could you say to remind yourself about all the good things?*

(what do they want to remember?:_____)

- *What was your very best moment yesterday?*

2. Create a positive anchor

1. Educate: About associations and anchors:
- *Now that you feel good, we want to show you a trick you'll love*
- *90% of what we think is below our level of awareness. This is where we associate things. Songs are a good example.*
- *Let's create a gesture that you can start to associate with positive feelings so that down the road you can pull it up if you're ever feeling down or need it.*

2. Identify anchor: Pick unusual micro-gesture to be the anchor:
- Patient can use any gesture. To save time, propose either squeezing space between last two fingers or tapping twice on inside wrist with two fingers.

(What is their gesture?:_____)

3. Go back to the good feeling or have patient think of last time they felt really good:
4. Have patient do gesture while feeling good. Have them do during the week.

3. Identify a goal

Have patient pick a goal to work on:
- *What would you like to see or do more of? What is a goal you have?*

Identify Exception moments:
- *Are there times when you are doing that now? How?*

Miracle question:
- *Imagine that while you were sleeping tonight, a miracle happened.*
- *Your goal was accomplished but no one told you.*
- *How would you know that it had happened?*
- *What would you notice? What would other people notice?*

What has helped you in the past?

Week #1: A focus on what is working + goals

1. What is going well?

You are really making progress. How can you tell?

What was your "best moment of the day" yesterday?

What kind and encouraging thing would you like to remind yourself?

2. Use your positive gesture

3. Take one step toward your goal:

Your Goal:

What is one step you can take right now?

What has helped you in the past?

4. **Assignment:** *should you choose to accept it...*

YouTube.com video: *"Tony:* The BEST method to create an anchor & remove negative anchors"

Post-transplant stress management: WEEK #2

1. What is going well? + Anchor
- *What is going well? What was your very best moment yesterday?*
- *Think of how good you feeling. Do your "feel good" gesture (anchor)*

2. Worry thoughts
- **Normalize** *that post-transplant patients worry*
- **Education about thoughts:** *60K thoughts a day. Many untrue*
- *What kind thing could you say to yourself that would help you relax?*
(what do they want to remember?:_____)

3. Analyze worry thought
Logical analysis:

Worry Thought:	Predicted outcome:	Evidence for:	Evidence against:	Likelihood of prediction happening:

Worry Thought:	Predicted outcome:	Evidence for:	Evidence against:	Likelihood of prediction happening:
Pain in foot means that something is wrong with my transplant.	My transplant will fail	There is pain in my foot. It started after my transplant.	I didn't have a foot transplant so it might not be related to my liver transplant. I've had this foot pain before after I ran	It feels high but it is unlikely.

4. Stop and distract
- Notice the upsetting thought
- Say "stop"
- *(Just because you have a thought doesn't mean you need to think it.)*
- Distract yourself by doing something else
- Either change locations or do something else. *(What has helped in the past?)*

3. Container
Normalize: *Let me show you something to take a break from any negative stuff.*
Experiential exercise:
- *Close your eyes and imagine a container. What does it look like?*
- *Let's put everything you don't want or need a break from in the container.*
- *What should we put in there? Let's close it. Where do you want to keep it?*
- *If you think of those things, you can always put them back in your container.*
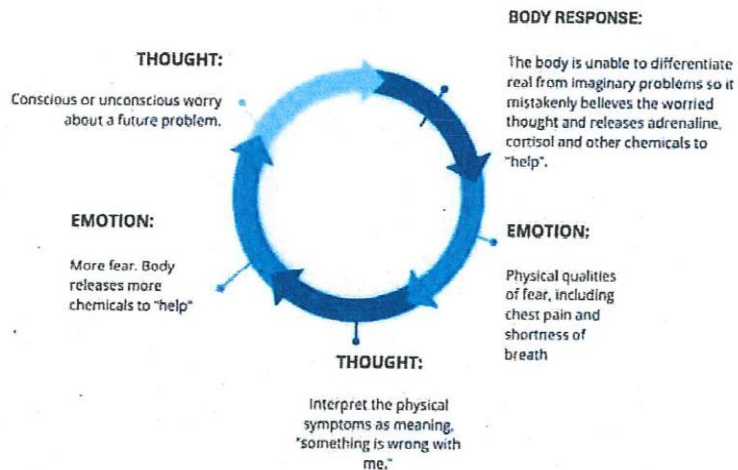
Week #2: Strategies for worry stories

1. What was your best moment of the day yesterday?
Remember to use your positive gesture when you have a good moment

2. Notice the impact of your worry thoughts:
The body response is the same whether your worry thoughts are true or false

THOUGHT:

Conscious or unconscious worry about a future problem.

BODY RESPONSE:

The body is unable to differentiate real from imaginary problems so it mistakenly believes the worried thought and releases adrenaline, cortisol and other chemicals to "help".

EMOTION:

More fear. Body releases more chemicals to "help"

EMOTION:

Physical qualities of fear, including chest pain and shortness of breath

THOUGHT:

Interpret the physical symptoms as meaning, "something is wrong with me."

>50,000 thoughts a day. 80% of thoughts are negative. 90% are unconscious.

3. Four steps to logically examining your thoughts:
1. WHAT IS YOUR WORRY STORY:
2. EVIDENCE THAT YOUR STORY IS TRUE:
3. EVIDENCE THAT YOUR STORY IS FALSE:
4. ANOTHER WAY OF LOOKING AT THE SITUATION:

4.Assignment: *should you choose to accept it...*You Tube Video:
Accepting the Present Moment; not the Life Situation! Eckhart Tolle

STI INNOVATIONS

Post-transplant stress management: WEEK #3

1. What is going well? + Anchor
- *What is going well? What was your very best moment yesterday?*
- *Think of how good you feeling. Do your "feel good" gesture (anchor)*

2. Post-transplant life can be stressful
- **Normalize:** *Stress is part of life. We all try to balance stressors with coping.*
- *What has helped you manage stress in the past?*
- **Educate:** *We know three things that can really help.*

3. Daily routine and structure
- **Educate:** *Routines and structure provide safety and consistency.*
- **Normalize:** *They often need adjustment post-transplant.* **What is schedule?**

What is your current schedule?

6am–9am/early morning

10am–12pm/late morning

1pm–4pm/afternoon

5pm–9pm/early evening

9pm–12am/late evening

12am–6am/night

4. Self–care and GRAPES
- **Educate:** *Doing a few things for you every day is best protection against stress.*
- **Normalize:** *We all struggle to make it a priority. We often feel guilty doing it.*
- **Create a self-care plan for tomorrow using GRAPES**

> **G**ENTLE: *What is something nice that you can remind yourself?*
> **R**ELAXING: *What will you do that is relaxing?*
> **P**LEASURABLE: *What could you do that will be fun and enjoyable?*
> **E**XERCISE: *What could you do that would exercise your body?*
> **S**OCIAL: *Who will you connect with? What will you do?*

(what is their GRAPES?:_____)

5. Calm place visualization
Normalize: *Let me show you something you can use to relax anytime.*
Experiential exercise: (do with them)
- *Close your eyes and just breath. (wait until they are really relaxed)*
- *Imagine you're in a calm, safe place. (pause)*
- *What do you see? What do you hear? What do you smell? How do you feel?*
- *What would you call this place? You can go here anytime to relax.*

Week #3: Daily routine + GRAPES self care

1. What was your best moment of the day yesterday?
Remember to use your positive gesture when you have a good moment

2. What is your daily routine?
External structure creates internal structure
- *What time do you wake up?*
- *What time do you eat meals?*
- *What time do you go to bed?*
- *What are your routines, structures, daily rituals?*

3. What is your GRAPES daily self-care routine?

G is for be Gentle to yourself
Say kind and loving things to yourself—you don't have to be perfect.

R is for Relaxation
Go to your calm place, try deep breathing, take a bath or read.

A is for Accomplishment
Water the plants, fold the laundry or take a shower—even small accomplishments feel good.

P is for Pleasure
Do something you enjoy every day: watch a movie, meet a friend.

E is for Exercise
Any kind of movement is good, including stretching or short walks.

S is for Social
Have a phone conversation or join an online group like Facebook.

Gentle:_____

Relaxing:_____

Accomplish:_____

Pleasurable:_____

Exercise:_____

Social:_____

4. Assignment: *should you choose to accept it...*
Create a GRAPES program for yourself and do it for one day: *Did you notice any benefit? What worked or didn't? How could you do it another day?*

Post-transplant stress management: WEEK #4

1. What is going well? + Anchor

- *What is going well? What was your very best moment yesterday?*
- *Think of how good you feeling. Do your "feel good" gesture (anchor)*

2. Managing moods can be challenging post-transplant

- **Normalize:** *Maintaining moods is an ongoing challenge for all of us.*
- *What is something that has helped you manage your mood in the past?*
- **Educate:** *The thought-mood-behavior connection helps manage moods.*
(what helped them in the past?:_____)

3. Thought-mood-behavior triangle

- *The story you tell yourself affects how you feel and what you do.*
  - *When we feel bad, our brain tries to figure out why. If life is 80% good and 20% bad, our brains will think about the 20%.*
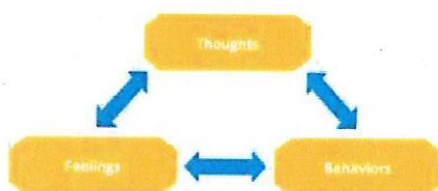
  - *The more we think about the bad (20%), the worse we feel.*

  - *When we feel bad, we pull away and spend more time alone.*

  - *This gives us more time to think about the bad stuff (20%).*

2. Keep busy. Do the opposite of how you feel

- **Educate:** *It's easy to isolate and avoid but it makes our moods worse.*
- **Normalize:** *All of us isolate, avoid, and think too much when get down.*
- Keep busy. Create a schedule and make sure there isn't too much time to think.
- **Opposite Day:** Do the opposite of how you feel when you start to feel down.

3. Do something creative

- **Educate:** *Creative activities helps people to be in the flow so they think less.*
Identify creative activity:
- *What do you like to do that is creative? What did you used to do? Options?*
- *The benefit comes from the process of doing the activity so it doesn't matter if you're "good" at it or not.*
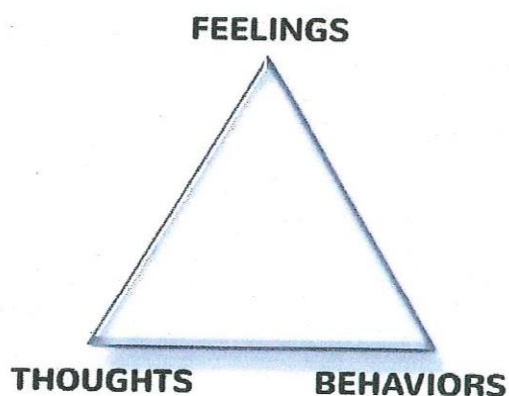**(what creative activity will they do?_____)**

Week #4: Mood management strategies

1. <u>**What was your best moment of the day yesterday?**</u>
Remember to use your positive gesture when you have a good moment

2. <u>**Thought- Mood- Behavior Triangle:**</u>
How you feel is impacted by what you're doing and thinking.

FEELINGS

THOUGHTS   **BEHAVIORS**

- When we feel bad, our brain tries to figure out why.
- If life is 80% good and 20% bad, our brains will think about the 20%.
- The more we think about the bad stuff (20%), the worse we feel.
- When we feel bad, we are tired and don't have energy so we isolate.
- This gives more time to think about the bad stuff (20%). we feel worse.
- **When you feel bad, thinking makes everything worse.**

3. <u>**Feel bad? No thinking. Keep busy + 15 minute "pity parties"**</u>
- Spend most of your time very busy--distract yourself with activities.
- Do "Opposite Day" since you won't feel like doing any of the activities.
- Have 15 minute Pity Parties. Cry, yell, write, exercise. Get the negative emotions out of your body. Then wipe your tears and move forward.

4. <u>**Assignment:**</u> *should you choose to accept it...*
Google: "The benefits of crying" : *What did you find most interesting? What messages did you received about crying as a child? What do you think now?*

STI INNOVATIONS

Post-transplant stress management: WEEK #5

1. What is going well? + Anchor
- *What is going well? What was your very best moment yesterday?*
- *Think of how good you feeling. Do your "feel good" gesture (anchor)*

2. What is the behavior patient is avoiding or quit?
- **Normalize:** *We all have "bad behaviors" that we're working on.*
- *What is the behavior you would like to avoid?*

3. Identify triggers: What might cause patient to relapse?
- ***What worked in the past?*** Use Trigger Diagram on recent success
- *What are triggers that might come up in the future?* Identify common triggers

TRIGGERING SITUATION OR EVENT	THOUGHT	EMOTION	ACTION	RESULT
Specific situations in which you feel compelled to do the behavior?	Are you aware of your thoughts or what you're telling yourself?	Do you feel the urge to do the behavior when you feel:	Once you start the "bad behavior, what makes you continue?	What happens as a result? How do you feel afterwards?

4. Plan for triggers

- *What will you do instead of the behavior?* Create a plan for each trigger:

TRIGGERING SITUATION OR EVENT	THOUGHT	EMOTION	ACTION	RESULT
Anticipated, future situations in which you feel compelled to do the behavior?	What kind, encouraging thing can you tell yourself?	What can you do to manage stress and difficult emotional situations?	What can you do instead? What can you do in the moment?	What will happen as a result? How will you feel afterwards?

5. Identify "hot spots" and create reset plan
Identify "hot spots":
- "When do notice you feel bad?"
- "What are you actually doing when you start to feel bad?"

Reset plan:
- *What will you tell yourself?*
- *What will you do?*

(what will they do and tell themselves?:_____)

Week #5: Identify + plan for your triggers

1. What was your best moment of the day yesterday?
Remember to use your positive gesture when you have a good moment

2. Identify your triggers:
What habit are you working on changing?

TRIGGERING SITUATION OR EVENT	THOUGHT	EMOTION	ACTION	RESULT
Specific situations in which you feel compelled to do the behavior?	Are you aware of your thoughts or what you're telling yourself?	Do you feel the urge to do the behavior when you feel:	Once you start the "bad behavior, what makes you continue?	What happens as a result? How do you feel afterwards?

Specific triggers:
-
-

3. Create a plan for your specific triggers:
What could you do instead?

TRIGGERING SITUATION OR EVENT	THOUGHT	EMOTION	ACTION	RESULT
Anticipated, future situations in which you feel compelled to do the behavior?	What kind, encouraging thing can you tell yourself?	What can you do to manage stress and difficult emotional situations?	What can you do instead? What can you do in the moment?	What will happen as a result? How will you feel afterwards?

Plan for triggers:
-
-

4. Assignment: *should you choose to accept it...*
Experiment with your plan to cope with your triggers. What did you find?
Watch this You Tube video: *"A Simple Way to Change a Bad Habit"*

Post-transplant stress management: WEEK #6

1. What is going well? + Anchor

- *What is going well? What was your very best moment yesterday?*
- *Think of how good you feeling. Do your "feel good" gesture (anchor)*

2. Understanding and managing emotions is challenging

- **Normalize:** *Most of us don't understand them so hard to know what to do*
- **Three tools:** 1. Letting go   2. Reset button   3. Being present

3. About emotions
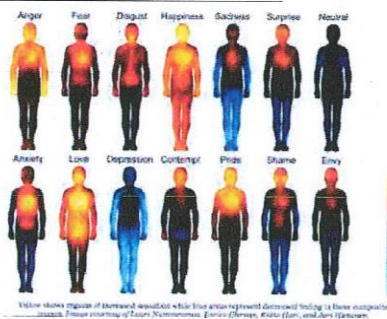
1. Emotions live in the body.

2. Emotions go up and down, often unexpectedly.

3. Emotions aren't always logical. No "shoulds" with emotions; they just are.

4. They need to be released so they don't harm the body or come out in other ways.

4. Let go of emotions

Since they live in the body, they need to be released through the body. Laughing, crying, talking, writing, exercising, manual labor all effective.

5. Journal or voice memo

- We have found talking into your phone (like you're talking to a friend) using a voice memo to be very therapeutic. *Even though you are talking to yourself, the act of holding a phone tricks the brain into thinking it's a conversation.*
- Write anything that comes to mind before bed or after waking up for 15 min.

6. Be in the present moment

- **Normalize:** None of us are really here. We are worrying about the future and thinking about the past.

  - **First minute:** Focus on the **sounds** you hear

  - **Second minute:** Focus on your **breath**

  - **Third minute:** Focus on your **body** sensations

  Educate: It's simple but not easy to train your brain to be here.

  Experiential exercise: 3 minutes.

(which one of the three did they like best ?:_____)

Week #6: Press the reset + stay present

1. What was your best moment of the day yesterday?
Remember to use your positive gesture when you have a good moment

2. Reset Plan Push the Reset Button on a bad mood or day:

> **My Reset Action Plan:**
> When I'm in a bad mood, I will take the following actions:
> 1.
> 2.
> And I will remind myself that...
> 1.
> 2.

3. Be here. (Three minute mindfulness exercise)

- We have 60k + thoughts a day. We are always thinking.
- Feeling bad about the past (=depression), planning and worrying about the future (=anxiety).
- When we bring our thoughts to the present moment, there is peace

> - **First minute:** Focus on the **sounds** you hear
>
> - **Second minute:** Focus on your **breath**
>
> - **Third minute:** Focus on your **body** sensations

4. Assigment *(should you choose to accept it...)*

- Go to: YouTube.com
- Search: 10 Minute Guided Body Scan Meditation from The Meditation Coach

Appendix D: Social Work Monitoring and Care Coordination

Questions (1-6):

1. How have you felt both physically and emotionally?

2. How are you coping with your transplant surgery?

3. Are you able to meet the expectations of the team?

4. Are there any concerns about medication routine?

5. Are there any concerns about your support system?

6. How are you coping and what has been going well for you?

Appendix E: Fidelity

Date:

Social Worker:

Participant Number:

Med record note review:

Location/state, missed appointment, other comments, schedule change

Time spent in session:

Weekly intervention themes (sessions 1-6) or social work case management questions/prompts

(questions 1-6) observed:

Intervention worksheets shared and matches respective week in session:

Appendix F: Contamination

Contamination Survey for Participants

1) Do you know what Symptom Targeted Intervention means? If so, please describe

2) Has anyone discussed or described what the social workers are doing with the control or experimental group? If so, please describe.

Contamination Survey for Control Social Workers

1) Do you know the components of STI? If so, please describe them and explain if you have used any of them with your clients?

2) How much time have you spent with your participants beyond the study on a) emotional support or b) resource allocation? If so, how much total time has been spent working with your participants on these two items?

Contamination Survey for Experimental Social Workers

1) Do you know the components of the case management and care coordination used in the control group? If so, please describe.

2) How much time have you spent with your participants beyond the study on a) emotional support or b) resource allocation? If so, how much total time has been spent working with your participants on these two items?

Appendix G: Drinking Defined (NIAAA)

What Is a Standard Drink?

| 12 fl oz of regular beer | = | 8–9 fl oz of malt liquor (shown in a 12 oz glass) | = | 5 fl oz of table wine | = | 1.5 fl oz shot of distilled spirits (gin, rum, tequila, vodka, whiskey, etc.) |

about 5% alcohol · about 7% alcohol · about 12% alcohol · about 40% alcohol
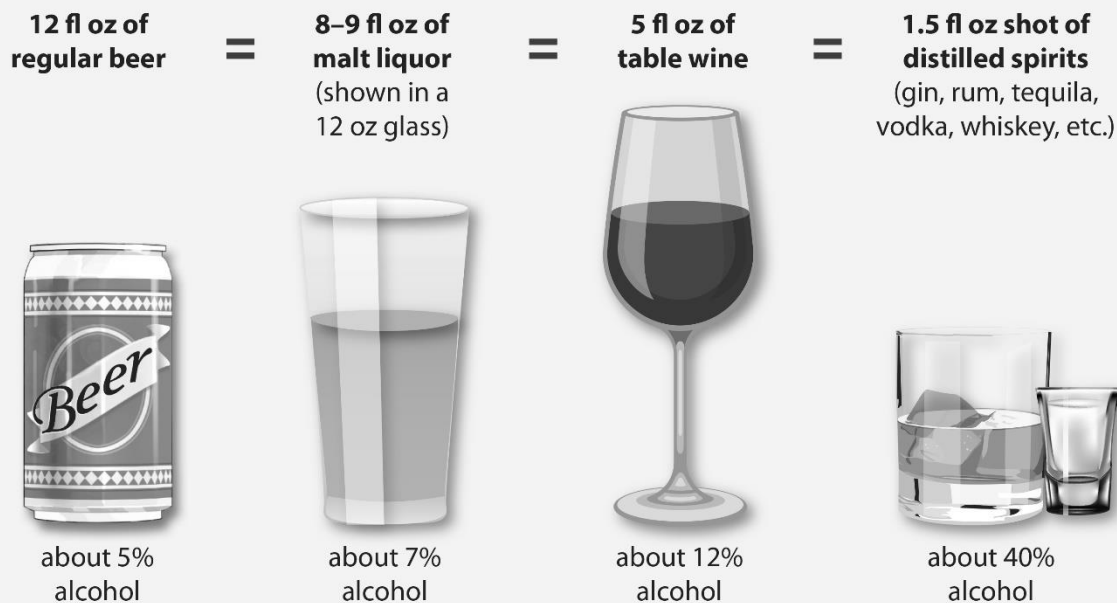
Each beverage portrayed above represents one standard drink (or one alcohol drink equivalent), defined in the United States as any beverage containing .6 fl oz or 14 grams of pure alcohol. The percentage of pure alcohol, expressed here as alcohol by volume (alc/vol), varies within and across beverage types. Although the standard drink amounts are helpful for following health guidelines, they may not reflect customary serving sizes.

QUICK DRINKING SCREEN (QDS) (NIAAA, 2004).

Question 1. In the past 14 days, did you drink ANY alcoholic beverages, even one drink? ____Yes ____No (Q1)
Question 2. In the past 14 days, on average how many days per week did you drink ANY alcoholic beverages? ** _____ days/week (Q2)

Question 3. ****INTERVIEWER:** If Q2 is answered as "0" days per week, that is, the person drinks, but not weekly, then ask: How many days out of the past 14 days did you drink any alcohol: _____ # days drank alcohol in past 14 days (Q3)

Question 4. On average, on days when you drank, how many standard drinks did you drink in a day? _____ drinks. (Q4)

Question 5. INTERVIEWER: MULTIPLY Q2 x Q4 to get: Drinks Per Week

_____drinks/week (Q5)

Question 6. In the past 14 days, on one occasion or day, how many times have you had 5 or more standard drinks (for men) or 4 more standard drinks (for women)? Number of binge drinking days (occasions) in the past 14 days? ___binge days (Q6).

APPENDIX H:

Depression, Anxiety and Stress Scale (DASS-21)

DASS 21   NAME _____ DATE _____

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.
The rating scale is as follows:

0 Did not apply to me at all - NEVER
1 Applied to me to some degree, or some of the time - SOMETIMES
2 Applied to me to a considerable degree, or a good part of time - OFTEN
3 Applied to me very much, or most of the time - ALMOST ALWAYS

FOR OFFICE USE

#	Statement	N	S	O	AA	D	A	S
1	I found it hard to wind down	0	1	2	3			
2	I was aware of dryness of my mouth	0	1	2	3			
3	I couldn't seem to experience any positive feeling at all	0	1	2	3			
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3			
5	I found it difficult to work up the initiative to do things	0	1	2	3			
6	I tended to over-react to situations	0	1	2	3			
7	I experienced trembling (eg, in the hands)	0	1	2	3			
8	I felt that I was using a lot of nervous energy	0	1	2	3			
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3			
10	I felt that I had nothing to look forward to	0	1	2	3			
11	I found myself getting agitated	0	1	2	3			
12	I found it difficult to relax	0	1	2	3			
13	I felt down-hearted and blue	0	1	2	3			
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3			
15	I felt I was close to panic	0	1	2	3			
16	I was unable to become enthusiastic about anything	0	1	2	3			
17	I felt I wasn't worth much as a person	0	1	2	3			
18	I felt that I was rather touchy	0	1	2	3			
19	I was aware of the action of my heart in the absence of physicalexertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3			
20	I felt scared without any good reason	0	1	2	3			
21	I felt that life was meaningless	0	1	2	3			
					TOTALS			

DASS Severity Ratings

The DASS is a **quantitative** measure of distress along the 3 axes of depression, anxiety[1] and stress[2]. It is not a categorical measure of clinical diagnoses.

Emotional syndromes like depression and anxiety are intrinsically dimensional - they vary along a continuum of severity (independent of the specific diagnosis). Hence the selection of a single cut-off score to represent clinical severity is necessarily arbitrary. A scale such as the DASS can lead to a useful assessment of **disturbance**, for example individuals who may fall short of a clinical cut-off for a specific diagnosis can be correctly recognised as experiencing considerable symptoms and as being at high risk of further problems.

However for clinical purposes it can be helpful to have 'labels' to characterise degree of severity relative to the population. Thus the following cut-off scores have been developed for defining mild/moderate/severe/extremely severe scores for each DASS scale.

Note: the severity labels are used to describe the full range of scores in the population, so 'mild' for example means that the person is above the population mean but probably still way below the typical severity of someone seeking help (ie it does not mean a mild level of disorder.

The individual DASS scores do not define appropriate interventions. They should be used in conjunction with all clinical information available to you in determining appropriate treatment for any individual.

[1]Symptoms of psychological arousal
[2]The more cognitive, subjective symptoms of anxiety

DASS 21 SCORE

DEPRESSION SCORE	ANXIETY SCORE	STRESS SCORE

	Depression	Anxiety	Stress
Normal	0 - 4	0 - 3	0 - 7
Mild	5 - 6	4 - 5	8 - 9
Moderate	7 - 10	6 - 7	10 - 12
Severe	11 - 13	8 - 9	13 - 16
Extremely Severe	14 +	10 +	17 +

APPENDIX I:

Hospital Anxiety and Depression Scale (HADS)

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

Please check you have answered all the questions

Scoring:
Total score: Depression (D) _____   Anxiety (A) _____
0-7   = Normal
8-10   = Borderline abnormal (borderline case)
11-21 = Abnormal (case)