RANDOMIZED CONTROLLED TRIAL OF SHAME-FOCUSED PSYCHOTHERAPY FOR ALCOHOL ABUSE

by

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Abstract

Prior studies have shown that mindfulness and acceptance therapies have reduced symptoms of substance abuse in affected populations. This proposed study builds on prior research regarding the relationship between substance abuse and feelings of shame by testing a shame-focused psychotherapy for alcohol abuse by comparing its effects on levels of shame and severity of symptoms relative to treatment as usual (TAU). The theory driving this treatment is that shame is a central experience of substance abuse, both a cause and effect. Thus, a psychotherapy focusing on patients experiencing and working through shame should be incredibly effective. The hypotheses are that: (1) the shame-focused treatment will reduce symptoms of alcohol abuse significantly more than TAU; (2) the treatment will reduce levels of shame significantly more than TAU; and that (3) the effects of the treatment on levels of shame will mediate the effects of the treatment on symptoms of alcohol abuse. Two hundred fifty participants with a DSM-V diagnosis of Substance Abuse - Alcohol will be recruited through targeted advertisements posted publicly, on social media, and at alcohol anonymous meetings. Recruited potential participants will undergo the Structured Clinical Interview of the DSM-V (SCID-V) to determine their eligibility for participation. Participants will be randomly assigned to either the shame-focused treatment or the TAU group. Participants will not be informed as to which treatment they are receiving. Sessions will be held once a week for 12 weeks, with a follow-up 8 weeks after treatment concludes. All therapists will follow a manualized structure for their respective forms of treatment. Their adherence to the manuals will be observed and rated three times by independent judges throughout treatment. Measures will include treatment attendance, levels of shame, and severity of alcohol abuse symptoms. The independent variable is the treatment condition, the dependent variable is the symptoms of alcohol abuse, and the mediating variable is

levels of shame. If the results support the hypotheses, it will indicate that the shame-focused treatment reduces symptoms of alcohol abuse significantly more than TAU because it targets and reduces the feelings of shame. The theoretical and clinical implications of this potential finding are discussed.

Randomized Controlled Trial of Shame-Focused Psychotherapy for Alcohol Abuse

The development of shame, conceptually defined as the painful feeling arising from the consciousness of something dishonorable, improper, or ridiculous done by oneself or another, is dependent on an individual possessing sufficient cognitive capacity, having an awareness of social rules and expectations, and an understanding of their behavior in comparison to those expectations, as well as adequate theory of mind (Rahim & Patton, 2015). Research has shown that shame is a master emotion of everyday life but remains invisible in society due to it being taboo, resulting in denial and silence (Scheff, 2003). Since there is shame about shame, we behave as though shame does not exist (Kaufman, 1989), which only hinders any attempt to heal or overcome those feelings. Shame is felt by everybody, although its effects differ in depth across the population, and when people start healing shame, we will be moving toward humanity, humility, autonomy, and competence (Potter-Efron & Potter-Efron, 1989). Previous research attributes shame-proneness with decreased cognitive functioning and suggests that shame may lead to psychopathology and early-onset substance use (Rahim & Patton, 2015). There is a distinctive association between substance use as a result of shame-proneness and shame-proneness as a result of substance use. Shame has a significant impact on mental and physical health, showing neurophysiological influences (Thomas, 1995).

Shame is a seminal experience in alcohol abuse. As will be shown, shame is both a cause of abuse (self-medicate shame with alcohol) and a consequence of the abuse. Thus, if treatment is to be effective – and have lasting effects – it must focus on underlying feelings of shame in the lives of those who abuse alcohol. The current study builds on prior research, developing and testing a new form of psychotherapy that targets the aforementioned underlying feelings of shame. Measures, including the effects of treatment on feelings of shame and symptoms of the

disorder (alcohol abuse), will be recorded at baseline, mid-way through treatment, and end at an 8-week follow-up. This design allows for researchers to test not only if the treatment reduces feelings of shame and symptoms of alcohol abuse, but test the theory behind the treatment itself: will the effects of treatment on shame mediate its subsequent effects on symptoms? In other words, does the treatment reduce symptoms because it reduces shame?

At first glance, the relationship between substance use/misuse and shame seems apparent. On the surface, it appears that individuals with substance use disorders (SUDs) engage in behaviors that they feel ashamed of and therefore develop the aforementioned sense of shame. In clinical literature on addiction, shame is described as both a contributor to the development and maintenance of addiction problems and an effect of those same problems (Wiechelt, 2007). This reveals that the relationship between shame and addiction is not linear, as described above, but cyclical. As individuals discover that certain substances alleviate their negative feelings and pain, they form an addiction to those substances. As the addiction develops, they feel increasingly shameful and guilty about their loss of control. Feelings of overall shame have drastic life-impeding consequences, and because individuals who suffer from addiction have an increased sense of shame, those consequences are exacerbated. Wiechelt and Sales (2001) found that individuals with higher levels of shame were more likely to have difficulty with social adjustments than those with lower levels of shame. Difficulties with group-belonging and social compatibility have also been found to increase intrapersonal shame, further impeding the ability of addicts to stray from the addiction-shame cycle and maintain stability on the path to recovery. The pivotal moment in the path to recovery is breaking this cycle.

Individuals who struggle within this cycle often experience the consequences in all aspects of their life. Building relationships, both romantic and platonic, can be difficult when

overcome with feelings of shame. Individuals use their habits of hiding shame to protect their vulnerability (Ferguson, 2005), which they fear might be taken advantage of by others. Shame also plays a massive role in an individual's ability to succeed in the workplace. Counteracting shame-inducing events is not discussed in management or business literature and has yet to be thoroughly explored in the work setting. Research shows that interactions with peers, customers, and others in the work environment can trigger shame responses (Poulson, 2000) in individuals, which are physiological responses to a rejection of oneself by another (Thomas, 1995). In a more general sense, individuals who feel greater levels of shame about their SUD live in constant fear of being judged for everything from their substance use itself to their engagement with mental health treatment. Determining the most effective treatment methods for SUDs recovery among individuals with high levels of shame is imperative because treatment needs to address the core problems that underlie and cause symptoms, not just the symptoms themselves. Approaching treatment for people who feel shame about their substance use appropriately and respectfully is crucial to achieving optimal effectiveness. Research has found that individuals who attend treatment may feel shame about their own failed attempts to recover, as well as shame about being told to seek treatment by a figure of authority (Wiechelt, 2007). Shame about the treatment process hinders the growth and recovery of the individual and will have minimal effect if those feelings of shame associated with treatment are not first addressed, recognized, and mitigated during the beginning of the process.

Individuals with SUDs often need help and preparation before beginning treatment, and targeting the feelings of shame may be the best way to help them feel ready to undergo treatment. Slezakova (2018) explored the role of shame in guilt-proneness and self-forgiveness and their relation to motivation and readiness for treatment, as well as time in recovery.

Participants consisted of members of the community fitting diagnoses for substance abuse disorders. Participants completed an online survey consisting of a severity of substance use measure based on the DSM-V criteria, the Test of Self-Conscious Affect–3 (TOSCA-3) to measure feelings of guilt and shame, the Circumstances, Motivation, and Readiness scales (CMR) to determine motivation and readiness to seek treatment/attempt recovery, and the Heartland Forgiveness Scale (HFS) to measure the tendency to forgive oneself and others. Results supported the hypothesis that shame-proneness was high in individuals with low levels of self-forgiveness. Levels of shame- and guilt-proneness were found to have no relationship with motivation and readiness for treatment or time abstinent. It was also found that motivation for treatment was higher in individuals who had been abstinent and individuals who experienced more severe substance abuse. Readiness for treatment had no relationship with these variables. Motivation for treatment refers to an individual's desire to attend treatment and get help, and readiness for treatment refers to an individual's preparedness to attend said treatment. The results demonstrate the multifaceted and complicated nature of the relationship between shame, guilt, self-forgiveness, motivation and readiness for treatment, and time abstinent in a sample of substance abusers. This relationship emphasizes the importance of the ability for clinicians to build on their clients' strengths and skills acquired in, and in preparation for, recovery and cultivating self-forgiveness to support their motivation for recovery.

Researchers have been studying the relationships between shame, guilt, and alcohol and drug problems for years. McGaffin, Lyons, and Deane (2013) tested the correlation and effects of guilt- and shame-proneness with self-forgiveness and substance abuse problems. They recruited 133 participants receiving residential treatment for substance abuse from five Salvation Army services in Australia. The participants completed a brief demographics questionnaire, as

well as the Test of Self-Conscious Affect-3 (TOSCA-3), the Heartland Forgiveness Scale (HFS), the Acceptance and Action Questionnaire – Substance Abuse (AAQ-SA), and the Empathic Concern and Personal Distress subscales of the Interpersonal Reactivity Index (IRI). Researchers measured shame and guilt, self-forgiveness, acceptance, empathy, and conciliatory behavior to examine correlations and relationships between them. Researchers hypothesized that shame and guilt would have a negative relationship with self-forgiveness. The results showed that the shame-proneness and guilt-proneness scales were positively correlated. Guilt had a positive association with self-forgiveness, and shame was negatively associated with self-forgiveness. Guilt was positively correlated with self-forgiveness because individuals experiencing feelings of guilt desire to change their behaviors and therefore are willing to forgive themselves to move forwards. Individuals experiencing shame had a negative correlation with self-forgiveness because although they feel negatively/shameful about their behavior, they do not yet think that it is at a point to which they need to change their behavior. Results showed that acceptance mediated the guilt and self-forgiveness relationship and indirectly affected the shame and self-forgiveness relationship. The results emphasize the importance of targeting acceptance when trying to reduce the effects of shame and guilt on self-forgiveness. This study should be repeated in clinical practice based on these same participants to develop treatments based on these implications.

Despite the abundance of available mental health care, treatment focusing on the relationship between shame and substance use on the path to recovery needs further investigation. Having said this, there are certain forms of intervention and treatment that have been found to have significant results among substance users also experiencing shame. Luoma, Kohlenberg, Hayes, and Fletcher (2012) found that patients struggling with feelings of shame

who participated in treatment revolving around mindfulness and commitment, essentially accepting the things that can't be changed and committing to taking actions to improve one's life, demonstrated improved treatment attendance and less substance use than those receiving their standard treatment as usual. Treatment as usual in this context refers to the routinely used treatment for addiction. The study investigated group-based intervention for shame based on principles of acceptance and commitment and found that it demonstrated efficacy as a treatment strategy for mitigating or decreasing that shame. These findings suggest that using a mindfulness and acceptance approach to treat feelings of shame related to substance use disorders (SUDs) produces more positive outcomes and improved patient health (Luoma et al., 2012). Emphasis on mindfulness and introspection during recovery is effective because it allows individuals to focus on specific aspects of themselves and their lives that they can actively improve upon and be proud, rather than shameful.

Recognizing and identifying the aspects and elements of various treatment options that are most effective is key to understanding and implementing interventions to mitigate the shame and substance use relationship and cycle effects. Research has shown that an individual's decision to seek or not to seek professional help is strongly associated with their comfort with self-disclosing information (Vogel & Wester, 2003). Thus, it is imperative to understand the patient's unique perspective and boundaries before beginning treatment. Ensuring that the patient is comfortable with the therapist and the personal information they disclose is crucial in beginning the treatment process. The therapist needs a complete understanding of and empathy for the patient's problems and concerns to establish the trust necessary for successful treatment. A crucial part of the therapist's empathy for the patient is having a sensitive and thoughtful ear for expressions of shame, often implicit expressions of shame shown in behavior rather than in

verbal self-report, so that this central experience can be brought out into the open and talked about.

In addition to aspects of mindfulness and acceptance and self-forgiveness interventions, cognitive behavioral therapy (CBT) targeted towards feelings of shame in individuals with substance use disorders has demonstrated efficacy both as a monotherapy and in conjunction with other treatment methods (McHugh et al., 2010). Although CBT for substance use is characterized by certain treatment elements such as operant learning strategies and skills-building interventions, several core tenets focus specifically on overcoming the powerfully reinforcing effects of psychoactive substances (McHugh et al., 2010). However, few interventions address shame specifically, outside of the context of particular disorders. To change this, Self-Acceptance Group Therapy (SAGT) was developed as a treatment explicitly focused on shame, applicable to all diagnoses, and based on a cognitive-behavioral framework of treatment (Gratz & Schoenleber, 2018). SAGT involves psychoeducation about the nature of a psychological disorder, training clients in the use of cognitive and behavioral shame regulation skills, and social support-building to promote self-acceptance. Gratz and Schoenleber (2018) found that this 8-week SAGT treatment program yielded significant improvements in shame and self-acceptance, and these improvements were maintained at post-treatment follow-up one month later.

Peterson (2007) conducted a study to compare the efficacy of Acceptance and Commitment Therapy (ACT) to TAU. She recruited 24 participants committed to the Mississippi State Hospital with diagnoses of comorbid depressive and alcohol use disorders, representing populations of people diagnosed with depression and substance abuse. Participants were randomly assigned to either receive ACT intervention or TAU. Participants' severity of

depression and alcohol use were measured pre-treatment, during treatment, and before discharge. Peterson found that participants who received ACT required smaller doses of treatment until they met the criteria for discharge and were significantly less depressed than their counterparts in TAU. These results imply ACT is an effective treatment method for individuals with depressive and substance use disorders. This study should be repeated with a larger sample size to establish the validity of these results.

These outcomes warranted further exploration. Luomo, Kohlenberg, Hayes, Bunting, and Rye (2009) explored the assessment and treatment effectiveness of self-stigma in substance-abusing populations. Self-stigma refers to how a person becomes aware of public stigma about their diagnosis, agrees with them, and then internalizes and applies those beliefs to themselves. Participants were 88 individuals diagnosed with substance use disorders (SUD), recruited from a residential treatment program for substance use. Researchers developed an acceptance-based treatment known as Acceptance and Commitment Therapy (ACT) for self-stigma. Participant treatment consisted of 6 total hours of group workshop focused on mindfulness, acceptance, and values work concerning self-stigma, completed over the course of two sessions. The primary outcome variables of interest were measures of internalized shame and internalized stigma. Baselines were measured using the internalized shame scale both at pre-treatment and measured again at a post-treatment follow-up. Data revealed that reported levels of shame and internalized stigma had drastically decreased at post-treatment. This study indicates that ACT for self-stigma and internalized shame has promise as an effective treatment for substance abuse- alcohol. However, a limitation was the lack of a control group, making this study strictly correlational. Thus, it cannot be concluded that ACT caused the observed improvement, only that it was associated with these outcomes. This limitation could be addressed by a randomized controlled

trial comparing participants with a SUD undergoing ACT to those participating in TAU. The proposed study will do precisely that, in addition to determining whether directly targeting feelings of shame subsequently reduces symptoms of the SUD.

In addition to researchers testing ACT as a potential treatment, the effectiveness of self-forgiveness as an intervention was studied by Scherer, Worthington, Hook, and Campana (2011), in comparison to a treatment-as-usual (TAU) group. Participants included 79 adults (18 y/o +) living in Michigan, the U.S., diagnosed with alcohol abuse or dependence enrolled in outpatient psychotherapy. Participants were randomly assigned to either a self-forgiveness-focused intervention condition or TAU. Participants completed questionnaires at three points throughout the study (pretest, posttest, and a 3-week follow-up). The intervention condition was explicitly designed to promote self-forgiveness. Researchers measured self-forgiveness using the Self-Forgiveness Feeling and Action (SFFA), drinking refusal efficacy using the Drinking Refusal Self-Efficacy Questionnaire-Revised (DRSEQ-R), and guilt and shame using the Personal Feelings Questionnaire-2 (PFQ-2). Results showed that participants who received the intervention reported a greater increase in self-forgiveness after treatment than those who received TAU, or their routine alcohol abuse treatment. For drinking refusal self-efficacy, participants who received the intervention reported greater drinking refusal self-efficacy after treatment than those in the TAU condition. Participants who received the intervention also reported greater decreases in guilt over time than those who received TAU. Participants who received the intervention also reported feeling lower levels of shame over time than participants who received TAU. This study was one of the first to put previous theory based on the correlation between shame, guilt, and alcohol abuse into practice by creating an intervention focused on self-forgiveness for alcohol-related transgressions.

Studies have shown that shame plays an integral role in the treatment of alcohol abuse. Ianni, Hart, Hibbard, and Carroll (2010) examined whether symptoms of alcohol abuse are positively correlated with the experience of shame and negatively related to self-forgiveness. Additionally, they tested the hypothesis that the association of alcohol misuse and self-forgiveness would be especially pronounced among individuals reporting higher levels of shame. They recruited 567 college students dealing with varying levels of shame and alcohol abuse. This was a correlational study where participants self-reported data on shame, alcohol use, and self-forgiveness. Participants completed the Heartland Forgiveness Scale- Self-forgiveness Subscale (HFS), the State Shame and Guilt Scale- Shame Subscale (SSGS), and the Alcohol Use Disorders Identification Test (AUDIT). The results showed that shame moderated the association between alcohol and self-forgiveness. Within the high-shame subgroup, high levels of self-forgiveness were related to low levels of alcohol misuse. This study suggests that the ability to forgive oneself may reduce the likelihood of alcohol abuse in people who experience high levels of shame. Further research should test this hypothesis by comparing an intervention focused on self-forgiveness among alcohol abusers experiencing shame to a control group undergoing treatment as usual.

Since studies that focus on self-forgiveness and self-acceptance are effective, it may be due to their effects on shame, especially as forgiving oneself and accepting oneself often involve forgiving and accepting shame. Thus, psychotherapy that focuses specifically on the shameful experiences of the patient may be more effective, considering that shame is a seminal emotional experience of people who abuse alcohol. As previously stated, shame is both a cause and an effect of alcohol abuse, contributing to the development and maintenance of substance abuse and the effect of those same problems. Breaking this vicious cycle is a necessary step to recovery.

The purpose of the proposed study is to determine whether shame-focused psychotherapy reduces symptoms of alcohol abuse more than TAU by targeting underlying feelings of shame, building on the results of the research reviewed above. Researchers will conduct quantitative analyses to determine if: (1) the treatment reduces feelings of shame relative to TAU, (2) the treatment reduces symptoms of alcohol abuse, and (3) the effects of the treatment on shame mediate its subsequent effects on reducing symptoms. If results confirm all three hypotheses, it will show that the treatment is effective because it alleviates feelings of shame. In addition to determining its efficacy for reducing symptoms, the principal contribution of this study is that it tests the psychotherapeutic rationale, or theory, upon which the psychotherapy is based.

Proposed Methods

Recruitment and Screening

Participants will be members of the local community recruited through posted advertisements, asking if the person would like treatment for a substance use problem. The advertisement will specify alcohol as the abused substance to obtain a participant pool with alcohol abuse specifically. Under that question on the post will be a statement explaining that researchers are offering treatment to people in the community free of charge, as a part of a study about the treatment of substance use (alcohol use) at a local academic medical center. Under this will be directions to an online questionnaire. The person will be asked to fill out and answer questions about their demographic information, indicate substance use or not, how often they use the substance, a checklist of substance abuse symptoms, and their contact information.

Once a person completes the online questionnaire, a brief phone screening will be scheduled between a member of the research team and the potential participant. After obtaining informed consent during this initial screening, the person will be asked questions to acquire more

in-depth information about whether the person meets the exclusion criteria listed below. The phone screener will also tell the potential participant that if they are accepted to participate in the study, they will be randomly assigned to either a new type of psychotherapy for people who have problems with alcohol or a traditional form of psychotherapy. This will ensure that participants are blind to the treatment they may receive. Barring the revelation of any exclusion criteria, the participant will be scheduled for an in-person diagnostic interview.

Diagnostic Assessment and Participants

At the baseline session, the participant will be given a semi-structured clinical interview organized according to the DSM-V, the Structured Clinical Interview for DSM-V (SCID-V, described below). To measure their baseline level of shame, the person will also complete a detailed questionnaire assessing experiences of shame in relation to drug use, the Experience of Shame Scale (Andrews et al., 2002). Participants will also complete a brief questionnaire called the Alcohol Use Disorders Identification Test (World Health Organization, 1989) to measure their baseline severity of abuse.

Based on the diagnostic criteria of the DSM-V, if the person meets the criteria for Substance Abuse – Alcohol, they will be asked to participate. If the participant meets diagnostic exclusion criteria, they will be excluded from the study and referred to an appropriate setting for treatment. The exclusion criteria will include a diagnosis of any of the following: psychotic disorders, Autistic Spectrum Disorder, Substance Dependence, Bipolar Disorder, Obsessive-Compulsive Disorder, Post-traumatic Stress Disorder, Eating Disorder, chronic medical conditions (neurological problems, cancer, HIV, Lupus). Individuals diagnosed with these disorders are being excluded because they can have brain-based differences in functioning and other differences in psychological functioning, which can confound the effect of the treatment.

Two hundred fifty participants ages 18-30 with a DSM-V diagnosis of Substance Abuse - Alcohol, ideally 125 males and 125 females, will be identified. This sample size is determined by a power analysis, as described below. This age range strikes a balance between a targeted population of young adults with a prevalent substance disorder and the need to meet the large sample size of a randomized control trial. All participants will provide written informed consent and will be compensated for their participation with free treatment.

Overview and Study Design

This study will follow a randomized, controlled trial design. If the potential participant accepts the study invitation, they will be randomly assigned to either a shame-based treatment group or the TAU control group by a research assistant blind to the corresponding treatments for each group. Thus, neither the participant nor the research assistant who randomly assigns them will know which group the participants are placed in at first. A computer will create the pre-determined randomization sequence for participant placement. These procedures will allow for a randomized, double-blind intervention.

Treatment will be done in 12, 50-minute individual sessions in either the shame-based treatment group or the treatment as usual group, scheduled once per week. All therapists will be PhD-level clinical psychologists, administering manualized treatment. There will be a treatment manual for each group, following the basic principles and rules for administering that psychotherapy. Participants will be responsible for attending sessions, each one week apart. In this study, TAU refers to supportive-expressive psychotherapy, where the therapist(s) will be specifically instructed not to focus on feelings of shame. Following the manual, the shame-based intervention will consist of treatment focused solely on targeting underlying feelings of shame in participants, where therapists will address practices proven to decrease levels of shame over the

course of treatment. Therapists conducting TAU will keep the conversation consistent with addressing substance abuse without discussing the levels or feelings of shame in participants.

In this study, a potential problem is making sure that therapists adhere to the treatments. Therapists in both TAU and the shame-focused intervention will be rigorously trained by clinical psychologists who have expertise in the respective treatments. Every fourth session will be audio or visually recorded for each therapist, and participants will be made aware of this and provide consent. Independent raters will assess the degree to which the therapists are following the respective treatment manuals. If any therapist gets lower than at least an 80% adherence rating, that patient's data will be excluded from the study.

Researchers will measure the impact of treatment on participants' symptoms, levels of shame, and severity of alcohol abuse from pre-treatment to post-treatment and at follow-up 8 weeks after treatment to determine if participants have maintained their gains.

Measures of Treatment Outcomes

Treatment attendance. This measure includes the number of participants who rejected the invitation to attend treatment and participate in the study, those who attended all sessions, some sessions, no sessions, or scattered sessions.

Structured Clinical Interview for DSM-V Diagnosis (SCID-V). The SCID-V is a semi-structured interview for making major DMS-V diagnoses, administered by a clinician, trained mental health professional, or supervised graduate student with expertise in DSM-V classifications. The person is asked a series of questions about their possible experiences with mental illness aligned with following the flow of the diagnostic decision tree of the DSM-V to determine a diagnosis.

Experience of Shame Scale (ESS; Andrews et al., 2002). By answering honestly, individuals indicate the degree to which they feel each statement applies to their life and experiences with feelings of shame. Questions are answered on a four-point scale, ranging from 'not at all' to 'very much'. Examples of questions include "have you felt ashamed about your personal habits?" and "have you felt ashamed about the type of person you are?".

Alcohol Use Disorders Identification Test (*AUDIT*; World Health Organization, 1989). A simple and effective method of screening for unhealthy alcohol use, defined as risky or hazardous consumption or any alcohol use disorder. Participants respond to 10 questions regarding the frequency and severity of their alcohol consumption and any interference it may have in their lives. Examples of questions include "how often do you have six or more drinks on one occasion?" and "have you or someone else been injured due to your drinking?".

Power Analysis to Determine Sample Size

The indicated sample size of N=250 is based on the goal of achieving a moderate to large effect of the treatment (Cohen's d=.80-1.0) with a power level of .80, statistical significance threshold p=.05, and assuming 20% attrition of participants. In randomly controlled trials, attrition of participants is inevitable, similar to ordinary psychotherapy when the goals are purely clinical. Thus, the final sample size will be about 200, meaning each treatment group will have about 100 participants.

Statistical Analyses

Researchers will analyze the data for all measures using a 2x2, Treatment Group (between-subjects) by Measurement Time (within-subjects), ANOVA tests, assessing change in symptoms and shame from baseline to post-treatment. The same ANOVA will be used to test if

participants maintain possible treatment gains from post-treatment to follow-up. Since there are only two groups in this RCT, post-hoc statistical tests are not necessary. Clinical significance, or effect size, of changes in each measure, will be assessed as Cohen's d, determining the magnitude of the standardized mean difference between the treatment groups. If a treatment has a large effect size, it has a significant impact on reducing symptoms. If treatment is found to be clinically significant for all hypotheses, it will mean that the treatment has had a meaningful impact on how much it reduced symptoms of alcohol abuse.

A mediation analysis will be conducted to test the hypothesis that effects of shame-based intervention versus TAU on levels of shame (the mediator, M) will mediate the effects of these interventions (the independent variable, IV) on changes in symptoms of substance abuse (the dependent variable, DV). Mediation is demonstrated by testing the significance of: (1) the effect of the IV (intervention) on changes in the DV (symptoms of substance abuse); (2) the effect of the IV on the M (levels of shame); and (3) the effect of the M on the DV (the beta weight of the mediator, using a t-test in the linear regression). Figure 1 illustrates these three pathways. Step 1 will be assessed by the ANOVA described above. Step 2 will be tested by a 2x2 Treatment (Shame-focused therapy vs. TAU) x Measurement time (Pre- and post-treatment), ANOVA of effects on feelings of shame (M), to determine if the shame-focused psychotherapy reduced feelings of shame significantly more than TAU. Step 3 is tested by a multiple regression: are changes in shame caused by the treatment (relative to TAU) significantly more associated with changes in symptoms? The predictors are changes in shame caused by the active treatment (Shame-focused) and changes in shame caused by TAU. The DV (outcome variable) is changes in symptoms. The multiple regression will determine whether treatment-induced changes in shame more strongly predict – are more strongly correlated/associated with – changes in

symptoms. There will be a correlation between these variables for both the treatment group and the TAU group. This analysis will determine if the association/correlation between these variables is significantly higher for the treatment than for TAU. To demonstrate that levels of shame mediate the effects of the treatment on symptoms, the mediation analysis must show that all three paths are significant. If the treatment relative to TAU has a significant effect in all three paths, it reveals that levels of shame partially mediate the effect of treatment on symptoms of substance abuse.

Discussion

The purpose of this study is to determine whether a shame-based psychotherapy intervention reduces symptoms of alcohol abuse more than treatment as usual (TAU), and whether or not the effects of the treatment on shame mediate its ensuing effects on symptoms. Researchers predict that: (1) the treatment will reduce symptoms of alcohol abuse relative to TAU; (2) the treatment will reduce feelings of shame relative to TAU; and (3) the effects of treatment on shame will mediate its effects on reducing symptoms, and that these effects will be maintained at an 8-week follow-up. These hypotheses will be tested by a randomized controlled trial comparing a 12-week shame-focused psychotherapy intervention with TAU. Measures will include treatment attendance, severity of symptoms, and levels of shame, the hypothesized mediating variable.

If hypothesis 1 is confirmed, the interaction effect for Treatment and Time on symptoms will show that the treatment reduced symptoms significantly more than TAU. If hypothesis 2 is confirmed because the interaction effect is significant for feelings of shame, it will show that the treatment reduced shame significantly more than TAU. Hypothesis 3 is tested by all three paths of the mediation analysis. If all three are significant, it will show not only that treatment reduced

feelings of shame and reduced symptoms, but that the treatment reduced symptoms because it reduced feelings of shame. The effect on reducing feelings of shame partially mediated, or explained, why the treatment reduced symptoms. The mediation analysis is particularly important because it tests the rationale, or the clinical theory, behind the treatment. Finally, if the treatment is found to be clinically significant with respect to all hypotheses in terms of effect sizes, it will show not merely that the treatment was effective, but that it had a meaningful impact on how much the symptoms were reduced, how much the treatment reduced shame, and how much the treatment affected attendance. The treatment has a meaningful clinical impact to the extent that it reduced shame, enhanced attendance, and reduced symptoms.

If all the hypotheses are confirmed, my results will be consistent with prior research. Prior studies have shown that treatments that enhance self-acceptance and self-forgiveness in people who abuse drugs are effective (McGaffin et al., 2013). The findings would be consistent because accepting oneself and forgiving oneself are actions related to the feeling of shame; shame is one of the emotions that underlies self-acceptance and self-forgiveness (Wiechelt, 2007). The treatment is designed to target the source of the cyclical nature of the relationship between shame and substance abuse, as described in prior research, rendering it an effective treatment for reducing symptoms of substance use because it reduces levels of shame. According to this rationale, this treatment should generate change that lasts because it not only improves symptoms but targets the feelings of shame that underlie those symptoms. If the mediation analysis is significant, it will show that the treatment effectively targeted and addressed underlying feelings of shame, which is precisely what it is designed to do.

Shame is both a cause and effect of abuse and addiction. Thus, by addressing shame, the prompting force of substance use is alleviated as well as the feelings caused by that same

substance use. Shame is the centerpiece of this cycle of shame and substance use. If effects are maintained at the follow-up, it will be further evidence that treatment is working because it addresses an underlying emotional issue faced by people who abuse alcohol. These results will be achieved and maintained specifically because this treatment is designed to target a deep feeling and root cause of substance abuse and addiction. The mediation analysis will confirm the effectiveness of this treatment, even measuring at the 8-week follow-up, as the participants should have a new relationship with their feelings of shame. This new relationship will be based on reducing feels of shame, allowing the person to accept their flaws and recognize that their problems do not define who they are.

Although this will be a professionally conducted trial, there is always an opportunity for potential problems to arise. The first potential problem, and the biggest problem, is recruitment and maintaining enough participants to achieve clinical significance. Participants will be recruited from Alcoholic Anonymous meetings, and targeted advertisements will be posted on social media sites related to alcohol abuse and addiction to address this problem. This direct advertising will help minimize attrition and the possibility of not having enough participants.

Another potential problem is ensuring therapists' adherence to the treatment manuals. Therapists in both TAU and the shame-focused intervention will be thoroughly trained in the respective treatments. Every fourth session will be audio or visually recorded, and participants will provide consent. Independent raters will assess how closely the therapists are following the respective treatment manuals. If any therapist gets lower than at least an 80% adherence rating, that patient's data will be excluded from the study.

During the diagnostic process, participants may experience some distress when describing events of their psychiatric history, such as traumatic events. If the participant no

longer wishes to continue the interview, they may stop at any time. If a participant describes suicidal feelings or other intense psychological problems, they will be immediately referred to appropriate treatment and be excluded from participation. Another problem that may arise is the potential increase in severity of one's illness, meaning the person might need additional or different treatment. In this case, if patients report any change in psychiatric status to which they meet exclusion criteria, treatment will be stopped, and they will be referred to appropriate alternative treatment and excluded from the study.

An additional and likely inevitable problem is the attrition of participants. If a participant fails to attendant treatment, their therapist will reach out to them (for example, a personal phone call) to bring them back in. The therapist will do so once more if the participant fails to attend treatment after the first attempt, for a total of two attempts to have them return to their respective treatment.

If the hypotheses are confirmed, the implications for future research are considerable. First, future research should use the same treatment but target people who recently started abusing alcohol. Using this treatment to prophylactically target shame in individuals experiencing high levels of it even before they begin using substances, such as in adolescents, may stop the onset of the vicious cycle of shame and alcohol abuse, circumventing it altogether. In addition, future research should test the effects of this treatment on other forms of substance abuse. People abuse various substances to dissociate from shame, self-medicating with all drugs, not only alcohol.

Additionally, future research should compare the efficacy of this shame-focused psychotherapy to CBT, the currently prevailing treatment for alcohol abuse. The driving assumption of CBT is that cognition drives emotion. Therefore, the focus of the therapy is on

maladaptive cognition, or the unrealistic/irrational thinking processes that are assumed to cause negative emotions like shame. However, CBT is not designed to target directly the underlying emotions of substance abuse in the same way that the proposed treatment does. If the theory behind this proposed treatment is correct – if targeting underlying emotions is necessary to/for effectively reducing symptoms of alcohol abuse - it will be more effective than CBT and will maintain its effects on reducing symptoms will be for longer.

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Figure 1