**Online coping skills counseling for problem gambling**

**and trauma (randomized controlled trial)**

Final Report for the Manitoba Gambling Research Program

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**Table of Contents**

|  |  |
| --- | --- |
| **Section** | **Page** |
| Table of Contents | 2 |
| Abstract | 4 |
| Significance | 5 |
|  Key study questions | 5 |
|  Clinical, scientific, and public health impact | 5 |
|  The Seeking Safety model | 5 |
|  The CBT-PG Model | 6 |
|  The importance of Telehealth | 6 |
|  Specific aims and hypotheses | 6 |
| Terminology Box | 7 |
| Rationale and Literature Review | 8 |
|  Gambling and posttraumatic stress disorder (PTSD) | 8 |
|  Seeking Safety (SS) therapy | 8 |
|  SS session topics | 9 |
|  SS and problem gambling | 9 |
|  Pilot of Seeking Safety (SS) with PTSD and PG | 9 |
|  Adaptation of SS for problem gambling | 10 |
|  Telehealth treatments | 10 |
|  Treatment preferences in PTSD/GD samples | 10 |
|  Rationale for CBT-PG as the comparison condition | 11 |
| Methods | 11 |
|  Participants | 11 |
|  Study flow | 12 |
|  Study design | 12 |
|  Basis for sample size | 12 |
|  Conduct of treatments | 13 |
|  Randomization | 13 |
|  Other, non-study treatments (treatment as usual; TAU) | 13 |
|  Recruitment and engagement in the study | 13 |
|  Intent-to-treat design | 13 |
|  Measures | 13 |
|  Data Analysis | 14 |
| Results | 14 |
|  Sample | 14 |
| Attendance | 15 |
| Outcomes | 15 |
| Alliance and client satisfaction | 15 |
| Telehealth | 15 |
| External treatments | 15 |
| Fidelity | 16 |
| Discussion | 16 |
| References | 18 |
|  |  |
| **List of Tables** |  |
| Table 1. Intent-to-treat gambling outcomes for Seeking Safety (SS) versus Cognitive-Behavioral Therapy for PG (CBT-PG) | 24 |
| Table 2. Intent-to-treat trauma/PTSD outcomes for Seeking Safety (SS) versus Cognitive-Behavioral Therapy for PG (CBT-PG) | 27 |
| Table 3. Intent-to-treat other mental health outcomes for Seeking Safety (SS) versus Cognitive-Behavioral Therapy for PG (CBT-PG) | 30 |
| **List of Figures** |  |
| Figure 1. Consort Flow Diagram. | 33 |

**Abstract**

Studies show a compelling association between problem gambling and trauma, including high rates of childhood trauma and post-traumatic stress disorder (PTSD) among individuals with gambling disorder. However, there are currently no published controlled trials examining interventions for treating gambling disorder and trauma concurrently. The aims of the current study were to compare Seeking Safety (SS), an integrated treatment for PTSD and addiction to Cognitive-Behavioral Therapy for Pathological Gambling (CBT-PG), which addresses gambling alone. Sixty-five individuals with current comorbid gambling disorder and PTSD were randomly assigned to receive one of the two treatments. Primary outcome measures included assessment of net gambling losses and number of times gambling (Timeline follow-back), Clinician-Administered PTSD Scale, and PTSD Checklist. Secondary measures of gambling, trauma and functioning were also included. Primary assessments occurred at baseline, 6-weeks, post-treatment and 1-year follow-up. Participants improved across time on almost all study measures, including gambling, trauma/ PTSD, other psychiatric symptoms, functioning, and coping. Improvements were similar across CBT-PG and SS treatments. Participants receiving SS demonstrated significantly stronger session attendance. We also found strong therapeutic alliance and treatment satisfaction, and the telehealth format was rated as highly acceptable. Participants improved across time on almost all study measures, and the strong effect sizes on both gambling disorder and PTSD measures show that both treatments led to substantial symptom improvements, which is an important finding given how difficult it is to reach this population. These findings show that clinicians and patients have effective options when seeking treatment for concurrent gambling problems and trauma.

Trial registration: ClinicalTrials.gov NCT02800096; Registration date: June 14, 2016

**Full report**

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**Significance**

***Key study question.***We conducted a randomized controlled trial (RCT) to address co-occurring gambling disorder\* (GD) and posttraumatic stress disorder\* (PTSD). [*\**All terms with an asterisk are defined in the *Terminology box* below.] Our experimental treatment was Seeking Safety (SS), an evidence-based, widely adopted cognitive-behavioral therapy\* (CBT) coping skills model originally designed for co-occurring substance use disorder (SUD) and posttraumatic stress disorder (PTSD) ([1](#_ENREF_1)), which also has been successfully applied to co-occurring GD and PTSD in a pilot study ([2](#_ENREF_2)). Our comparison condition was CBT, one of the most studied, evidence-based methods for treating gambling problems ([3](#_ENREF_3), [4](#_ENREF_4)); specifically, we used CBT for Pathological Gambling (CBT-PG) developed by Dr. Robert Ladouceur in Canada ([5](#_ENREF_5), [6](#_ENREF_6)). Each treatment developer (Dr. Najavits for SS and Dr. Ladouceur for CBT-PG) provided training and guidance on fidelity. We conducted a *non-inferiority trial* to evaluate the impact of SS in relation to CBT-PG. This design is more useful from a public health standpoint than the classic *superiority trial* RCT (see explanation for these study designs in the *Terminology box*).\*

Our key study question was whether an integrated focus on GD *and* PTSD (the SS model) might offer a useful new option for clinical care compared to a purely gambling-focused approach (CBT-PG). This question—the impact of integrated versus non-integrated treatment for co-occurring disorders—is one of the key issues in the field currently ([1](#_ENREF_1), [7](#_ENREF_7), [8](#_ENREF_8)), and has never been studied in relation to GD and PTSD. This topic is particularly salient as trauma and PTSD precede GD onset in the majority of cases ([7](#_ENREF_7), [9](#_ENREF_9)), fitting what is often referred to as self-medication—people may be using gambling as a way to cope with the emotional pain of trauma. Quotations from patients illustrate this point ([7](#_ENREF_7)): “‘When I have ﬂashbacks, I usually go to the casino to calm down’’; ‘‘Gambling helps me to escape and not think about trauma.’’ Thus treating PTSD symptoms at the same time as GD, in integrated fashion, may help promote treatment engagement and recovery. Research shows that people with PTSD and GD want their PTSD to be addressed in the context of GD treatment ([10](#_ENREF_10), [11](#_ENREF_11)). This is a vulnerable population in need of care who may benefit from treating both disorders at the same time.

Both interventions (SS, CBT-PG) were provided via telehealth format\* in Manitoba and Ontario, to help promote access and engagement as people with gambling problems are known to have very low rates of treatment-seeking in formal therapeutic settings ([4](#_ENREF_4), [12](#_ENREF_12), [13](#_ENREF_13)). Both models have already been used successfully in telehealth format (see later in this report). We included individuals across the full range of severity of both disorders (GD could be mild, moderate or severe; PTSD could be full or subthreshold), to promote the broadest possible public health relevance.

***Clinical, scientific, and public health impact.***Our project was designed to advance the study of interventions to reduce problem gambling, focusing on a key comorbidity (PTSD). Our proposed method of providing both models in telehealth format was designed to further enhance our potential ability to reach a broader swath of problem gamblers, who typically do not show up to treatment programs. Overall, our project has strong public health significance. We hypothesized that addressing PTSD and GD at the same time in integrated fashion (SS) would do no worse than (or perhaps even better than) CBT-PG, thus providing another option to clinicians and patients. This is especially important in that people with both GD and PTSD want treatment of both rather than just their GD ([10](#_ENREF_10), [11](#_ENREF_11)). Addressing PTSD in addition to GD can also help better engage women and marginalized groups, such as First Nations populations, into treatment by addressing their traumatic past ([14](#_ENREF_14)). Moreover, our use of telehealth can help engage people who otherwise might not be able or motivated to access care. Our team has had a sustained focus on areas relevant to this report, including treatment-seeking and clinical characteristics of individuals with PTSD and GD ([9](#_ENREF_9), [10](#_ENREF_10), [13](#_ENREF_13), [15-17](#_ENREF_15)).

***The Seeking Safety model.***Seeking Safety (SS) is a present-focused, cognitive behavioral (CBT) approach that provides psychoeducation and coping skills to help patients attain greater safety in their lives. It was designed for flexible use: individual or group format (although in this study we used individual modality, which is the most feasible for telehealth sessions); males and females; any clinical setting; and all types of trauma and addiction. It offers topics to address cognitive, behavioral, interpersonal, and case management domains, e.g., *Safety, Honesty, Asking for Help, Healthy Relationships, Taking Good Care of Yourself, Coping with Triggers, Recovery Thinking, Creating Meaning, Compassion, Detaching From Emotional Pain (Grounding), Setting Boundaries in Relationships, Healing from Anger*. SS strives to build hope through emphasis on ideals; it uses simple, emotionally evocative language and quotations to engage patients. SS has been studied in over 35 treatment trials, including RCTs, with consistent positive outcomes, strong satisfaction, and a record of exceptional safety (lack of adverse events, even when conducted by peers and paraprofessionals). Research publications and summaries of the evidence are freely downloadable at www.seekingsafety.org (section Library). For reviews see ([18](#_ENREF_18)). Notably, a pilot study of SS in Canada showed positive outcomes for patients with current PTSD and PG ([2](#_ENREF_2)), which is described in detail in the Rationale and Background section below. Also, it has shown efficacy when delivered in 12 sessions ([7](#_ENREF_7), [19](#_ENREF_19)), thus allowing for a legitimate comparison to CBT-PG, which is 12 sessions in dosage ([5](#_ENREF_5), [20](#_ENREF_20)). SS is the most widely adopted model for PTSD/SUD in clinical settings, and has been translated into 14 languages, including a French translation funded by the Canadian government ([21](#_ENREF_21)). SS has also shown positive outcomes in several Canadian studies ([2](#_ENREF_2), [22-24](#_ENREF_22)), and strong outcomes, satisfaction and feasibility in a study with a First Nations Ontario sample ([25](#_ENREF_25), [26](#_ENREF_26)). SS can also be peer-led and has RCT evidence in that format ([27](#_ENREF_27)).

***The CBT-PG model.*** This evidence-based 12-session PG model by Ladouceur and Lachance ([5](#_ENREF_5), [6](#_ENREF_6)) has two primary components: *cognitive correction* and *relapse prevention*, plus a session of *motivational interviewing*. *Cognitive correction* helps to correct patients’ misconceptions about randomness, with four targets: (a) understanding the idea of randomness (e.g., each “throw of the dice” is independent); (b) understanding erroneous beliefs held by gamblers (e.g., how an illusion of control contributes to gambling habits); (c) erroneous perceptions that predominate during gambling, e.g., making links between independent events; and (d) correcting verbalizations and faulty beliefs using a recording of the patient’s verbalizations during a session of imaginal gambling (‘‘If I lose four times in a row, I will win for sure the next time’’). *Relapse prevention* is based on Marlatt’s (1985) model, including promoting awareness of high-risk situations and thoughts that might lead to gambling again. *Motivational enhancement* derives from Miller and Rollnick ([28](#_ENREF_28)) to build motivation to work on recovery from problem gambling. CBT-PG has shown positive outcomes in several RCTs ([20](#_ENREF_20), [29](#_ENREF_29), [30](#_ENREF_30)).

The two treatment approaches used in the present study are similar in terms of their focus on gambling symptoms. Only SS explicitly addresses trauma and PTSD. Although there has never been a head-to-head comparison of CBT and SS approaches, it is important to note that CBT for GD has demonstrated some beneficial effects on co-occurring psychiatric conditions, such as anxiety and depression (31).

***The importance of telehealth.*** Telehealth (see *Terminology box*) is increasingly used in medicine, including mental health services, which is sometimes called *telemental health*. Studies document consistent positive outcomes using telehealth for various mental health conditions including GD and PTSD (32-37). Telehealth provides important advantages over in-person sessions, such as access to care for rural and other remote populations; for people who cannot travel due to disability or other barriers; and for people with trust issues that make “arm’s length” distance more appealing. Studies comparing face-to-face versus telehealth counseling find no difference in outcomes or client satisfaction ([38-410](#_ENREF_37)). Telemental health has advanced such that there are now practice guidelines for it (42-43). Yet there are few studies of telehealth for problem gambling (34, 35,43). Given the very low use of mental health services by people with gambling problems ([12](#_ENREF_12), [13](#_ENREF_13)), telehealth may represent an important method to engage them. Moreover, among electronic methods for gambling treatment, having a therapist involved produces better outcomes compared to solely self-guided online treatment ([4](#_ENREF_4)).

 ***Specific aims and hypotheses.***Thus, our aims were as follows.

1. To conduct an RCT of SS versus CBT-PG in a sample of 70people with current GD and PTSD (i.e., full or subthreshold). The sample size was based on power analysis; allowing for 20% dropout, the target recruitment sample was 84, as detailed later in this report. Both interventions were provided by telehealth (remotely and electronically), given the known difficulty of engaging problem gamblers into care. In this study, both models were conducted by professional counselors, as that is the typical way they are conducted and on which their research evidence is based.

2. To evaluate outcomes from baseline to end of treatment and 12-month follow-up on gambling (money lost gambling and number of gambling sessions) and several secondary variables selected for their theoretical importance and/or their significant results in prior research. These included PTSD symptoms, coping skills acquisition, general psychiatric symptoms, global functioning, and cognitions.

 Our hypotheses were as follows: (a) SS will do no worse than CBT-PG on the primary gambling outcomes as both treatments are designed to address addiction; i.e., both will show improvement from baseline to end of treatment and maintenance of gains through the follow-up; (b) SS will show superior results on PTSD as SS is designed to address those, whereas CBT-PG is not.

 We emphasized the use of strong scientific methods based in part on the Alberta consensus statement for outcome trials on problem gambling (45). Our methods included clear inclusion/exclusion criteria, DSM-5 diagnoses based on structured clinical interviews, manualized treatments, certified therapists, fidelity monitoring, sample size based on power analysis, intent-to-treat analysis, psychometrically validated instruments, blind outcome assessment, and sophisticated data analysis using generalized estimating equations.

 \****Terminology***. Terms and abbreviations as follows. Studies have used different terms depending on when they were published and how broad a population they addressed.

 *Gambling-related disorders, substance use disorder, addiction****.*** We use *gambling disorder* (GD) when referring to the DSM-5 definition, which can be mild, moderate or severe (46); and *pathological gambling* (PG) for the DSM-IV definition (47). *Problem gambling* is not a diagnosis but is a widely used term to refer to gamblers who have any level of problem, such as the definition used in the Canadian Problem Gambling Index (48). *Gambling* refers to any engagement in gambling activity, regardless of pathology. *Substance use disorder* refers to the DSM-definition of such. *Addiction* is used to refer inclusively to any addictive disorder, such as gambling disorder, substance use disorder, etc. Our study used GD as an inclusion criterion.

 *Trauma/PTSD.* We use the term *trauma* to refer to a major stressful event as defined in the DSM (e.g., rape, severe car accident, hurricane, etc.) and *posttraumatic stress disorder (PTSD)* to refer to the mental health disorder that can arise from trauma (symptoms such as flashbacks, intrusive thoughts, etc.). The terms *trauma* and *PTSD* are used in both DSM-IV and DSM-5, and there was little change in their definitions between the two editions. *PTSD* refers to the full disorder in which all criteria are met. *Subthreshold PTSD* refers to clinically-important symptoms of PTSD but which do not fully meet DSM criteria. Our study used PTSD as an inclusion criterion, either full or subthreshold.

*Treatment / telehealth.**SS* refers to the Seeking Safety model. We use the term *cognitive-behavioral therapy (CBT)* in the broad sense to include any cognitive or cognitive-behavioral therapy; and the term *CBT-PG* for the Ladouceur model in this report. *Integrated treatment* refers to treating both addiction and mental illness at the same time, by the same clinician. *Online* refers to remote access of an intervention, which is also known by the term “telehealth.” *Telehealth* is defined as, “The use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration” (49). Note that the title for this report we used the term “online” but for greater clarity we refer to “telehealth” which is the broader term and more widely used for electronic provision of healthcare interventions. Specifically, we provided regular individual therapy sessions online using a secure site such that the therapist and client were able to see each other even though they were physically in different locations.

 *Non-inferiority trial.* Such trials compare a new model to an existing evidence-based treatment (EBT) to evaluate whether the new model does no worse than the EBT (in our case, SS versus CBT-PG). If the new model does no worse, both treatments may be legitimately recommended to clinicians and patients, thus providing more choice. A non-superiority trial can show a new treatment to be as effective as an established treatment, while possibly highlighting other benefits of the new treatment including safety, tolerability, cost or convenience(50) Further, a non-inferiority trial has all the benefits of a superiority trial, i.e., it can also show one treatment to be superior to the other) without having to add additional sample size (51). The classic, older method of conducting just a superiority trial has been problematic in psychotherapy research as active treatments almost never outperform other active treatments; this has been found also specifically in the PTSD and addiction fields ([4](#_ENREF_4), [8](#_ENREF_8), [52](#_ENREF_52), 53); in such cases, no positive assertion can be made as the null hypothesis has not been rejected. Only a finding of one arm being superior to the other results in a positive assertion (i.e., one treatment has outperformed the other and thus can be recommended over the other).

 *Intent-to-treat (ITT) analysis*. ITT analysis is a method for analyzing data from a clinical trial where data from all individuals randomized to a treatment condition are included in the outcome analyses, regardless of whether they completed treatment, or how many treatment sessions they completed.

**Rationale and Literature Review**

***Gambling and posttraumatic stress disorder (PTSD).*** Gambling problems and GD are highly associated with other psychiatric disorders, including substance use disorder (SUD), mood disorders, and personality disorders (54). Existing literature also indicates some evidence for a compelling association between trauma and/or PTSD and problem gambling. Studies show that individuals with problem gambling experience significantly higher levels of childhood trauma and adverse childhood events than individuals with no such history ([55-56](#_ENREF_54)). Estimates of PTSD among those with problem gambling range from 12.5% to 56% 57). A recent review by Moore and Grubbs found rates of PTSD among individuals with GD as high as 56%, but the highest rates among individuals from treatment-seeking and vulnerable populations. With regard to the PG diagnosis, lifetime comorbidity between PTSD and PG is 14.8%; and PG is a significant predictor of PTSD ([12](#_ENREF_12)). Among treatment-seeking individuals with PG, 34% had a high level of PTSD symptoms with the latter assessed by self-report checklist ([15](#_ENREF_15)). In another study of treatment-seeking problem gamblers, similar associations were found and a significant gender difference was discovered, with women reporting more childhood abuse than men (54). Among military veterans entering treatment for PTSD ((59), 17% met DSM-IV criteria for PG. In a study by Kausch (60)) of 111 veterans entering a gambling treatment program, 64% reported a history of emotional trauma; 40.5%, physical trauma; and 24.3%, sexual trauma; most trauma had occurred in childhood. Studying a similar group of veterans seeking residential treatment, Grubbs et al. (61) found PTSD rates of 42.5%, and PTSD was associated with positive expectancies and coping motives for gambling. Grubbs et al. (62) also found PTSD among veterans seeking treatment for GD to be associated with gambling-related cognitive distortions. Similarly, Scherrer (63) used a twin cohort design to determine that childhood and lifetime traumatic events are significantly associated with PG. Peltzer (64)) also found an association between trauma history and gambling severity in a sample of South African horse-race gamblers. In one of the earliest studies on this topic, Taber (65) found a 23% prevalence of major traumatic events in a sample of pathological gamblers seeking treatment. In a study of 843 elderly adults, 11% were identified as "at risk" gamblers, with current PTSD symptoms one of the strongest predictors (66). In a Canadian study, we found that 19% of community-recruited problem and pathological gamblers met lifetime criteria for PTSD ([9](#_ENREF_9)). These studies have also been able to identify basic characteristics of individuals with PG and PTSD (or trauma history). The common pattern appears to be greater pathology and worse functioning among people pathological gamblers with PTSD (or trauma history) than those without (15, 54, 60, 65). Experience of childhood trauma is also associated with greater dropout from gambling treatment (67).

***Seeking Safety* (SS)therapy.** SS is described in detail here as it is the experimental treatment proposed in this trial and is not familiar to most experts in the gambling field, in contrast to CBT-PG. SS is based on five principles ([1](#_ENREF_1)): (a) Safety as the priority of this first-stage treatment. Safety encompasses various elements: discontinuing or at least decreasing addictive behavior such as problem gambling and/or SUD, reducing suicidality, letting go of dangerous relationships (such as domestic abuse and addicted friends), gaining control over extreme symptoms such as dissociation, self-harm such as cutting, and aggression toward others. The concept of first-stage treatment as stabilization and safety has been consistently recommended separately in both the trauma and addiction literatures (68-70). (b) Integrated treatment*.* SS is designed to treat PTSD and addiction at the same time. An integrated model is consistently recommended as more sensitive to client needs. A survey of patients with this comorbidity found that they also prefer simultaneous treatment of both disorders (71); this was also replicated with people with PTSD and problem gambling ([10](#_ENREF_10)). (c) A focus on ideals. Each disorder individually, and especially in combination, lead to loss of ideals. SS seeks to instill countervailing humanistic themes to restore patients' feeling of potential for a better future. The title of each topic is framed as a positive ideal, one that is the opposite of some pathological characteristic of trauma and addiction. For example, the topic *Honesty* combats denial, lying, and the “false self”. (d) Three content area: cognitive, behavioral, and interpersonal. Each domain is key for recovery and aims to thus address the “whole person”—mind, actions, and relationships.(e) Attention to clinician processes. Clinician processes are explicitly addressed in SS, including building an alliance, compassion for patients’ experience; using the coping skills in one’s own life.

Because SS is present-focused, it does not require participants to describe past trauma, thus promoting stabilization and functioning. It has no known adverse events in over 20 years of implementation across thousands of programs and as documented in a major multisite trial (72). SS is widely reported as easy to follow and written in clear language; it has been used with highly diverse patients in age, ethnicity, reading level, cognitive ability, and level of symptoms and chronicity. Its high level of flexibility represents an important public health goal: to provide effective treatment within the realistic context of diverse settings, clinicians, and patients. It has also been successfully conducted by peers (73).

***SS session topics****.* The SS manual provides a clinician guide and client handouts. Each SS session focuses on a topic that represents a *safe coping skill* relevant to both trauma and addiction. There are 25 SS topics, but the model was designed for a high level of flexibility and any number of topics can be done in the time available (74). Indeed, several major RCTs have used 12 sessions of SS and all have shown positive outcomes ([18](#_ENREF_18), [19](#_ENREF_19)). Each SS topic offers: (a) A brief summary; (b) A clinician orientation that provides background about the topic, clinical strategies for conducting the session, discussion of counter-transference issues, and "tough cases" of typical difficulties patients may raise; (c) A quotation that is read aloud at the start of each session to emotionally engage patients; (d) A client handout that summarizes the main points in the session and ideas for “commitments” (i.e., homework). The session structure has: (a) Check-in: patients report, since the last session, addictive behavior frequency and quantity (and any other unsafe behaviors), positive coping, emotional state, and completion of the homework (about 5 minutes per client); (b) Quotation: the quotation is read aloud and discussed (about 3 minutes); (c) Relate the topic to patients' lives: the topic (a safe coping skill) is taught and rehearsed (30-40 minutes); (d)Check-out: patients name one thing they got out of the session and select a "commitment" (homework) to complete.

***SS and problem gambling.***SS is also the only integrated PTSD/addiction model that has been studied in any problem gambling population. Indeed, other than a small early pilot on Eye Movement Desensitization and Reprocessing Therapy (75), it is the only PTSD model at all that has been studied. The SS pilot on co-occurring PTSD and PG ([2](#_ENREF_2)) used the model as is (no modifications other than asking patients to apply the coping skills in the model to gambling, as well as any other current problems). Outside of research, SS has also been implemented clinically for problem gambling in the context of PTSD for many years. Clinicians are trained to always apply SS to any current problems in patients' lives, and thus the coping skills can be applied to any addiction and any trauma, as well as other problem areas of a person’s life. SS has been successfully implemented with diverse populations including patients with homelessness, domestic violence, adolescents, military veterans, criminal justice involvement, people living with HIV, people living with serious and persistent mental illness, as well as people of diverseethnicities and cultures.13,17,18,59 SS was, from the beginning, designed for a high level of flexibility as patients with trauma and addictions come through many different pathways into treatment. There has been one formal pilot study of SS for PG,2 which is described in the next paragraph, and which was conducted by a Canadian treatment program that specializes in treating women with trauma and problem gambling.

***Pilot of Seeking Safety (SS) with PTSD and PG****.*As mentioned, evidence-based therapy for PG thus far has not addressed PTSD and likewise, PTSD treatment studies have not addressed PG, nor even assessed for gambling problems. The SS pilot study on PTSD and PG evaluated seven outpatients with current comorbid PG and PTSD, and included both genders and 29% minorities ([2](#_ENREF_2)). Statistically significant improvements were found in *PTSD/trauma* (the PTSD Checklist (76) criterion B symptoms; the Trauma Symptom Inventory (77) overall mean and subscales anxiety, dissociation, sexual abuse trauma index, sex problems; and the World Assumptions Scale (78) benevolence subscale); *gambling* (the Gamblers Beliefs Questionnaire (79) overall mean and subscales illusion of control); *functioning* (the Basis-32 (80) overall mean and depression/anxiety subscale); *psychopathology* (the Brief Symptom Inventory (81) overall mean and subscales anxiety and depression; and the Addiction Severity Index (82), ASI, psychiatric composite score); *self-compassion* (the Self-Compassion Scale (83) overall mean and subscales isolation, overidentified, and self-judgment); and *helping alliance* (the Helping Alliance Questionnaire (84) overall mean). One variable indicated worsening (employment composite subscale on the ASI), possibly reflecting measurement issues. SS attendance was excellent (average of 18.86 sessions). PTSD onset occurred prior to PG onset for most of the sample (n=6; 86%), and most (n=6; 86%) believed the two disorders were related. Overall, we found that SS can be effectively conducted for comorbid PTSD and PG, with improvements in numerous domains and high acceptability. However, this was clearly a small-sample pilot, with all of the methodology limitations that accrue to such studies. Thus, we had the goal of an RCT as an important next scientific step. The RCT results are summarized in this report.

***Adaptation of SS for problem gambling.***SS was not formally adapted for gambling on the current project. SS already addresses addiction and has shown positive outcomes in a sample with current PTSD and PG in a prior study (per above). Further, SS is highly flexible and thus inherently allows for adaptation while still achieving fidelity to the model. In SS, clinicians are trained to use “adaptations within the model” (providing examples, language, and information relevant to their population), but not “adaptations outside the model” (e.g., changing the format or content). SS has been used without formal adaptation in a wide variety of co-occurring populations with success.

***Telehealth treatments.*** During COVID, SS has been used extensively in telehealth format and the book publisher released a PDF version for the handouts for that purpose. SS also had a pilot study, with positive findings when delivered remotely via telehealth. Dr. Justin Enggasser (personal communication, 6/1/15) conducted a small study to assess the feasibility of telehealth SS in the Veterans Affairs system in the U.S. with a sample of 6 military veterans with SUD and trauma symptoms. All three feasibility measures indicated extremely positive views of SS in telehealth format: the Client Satisfaction Questionnaire (85) (M=30.67 out of a possible 32; SD=1.53); the Helping Alliance Questionnaire-II ([82](#_ENREF_82)) (M=5.16 out of a possible 6; SD=.79); the Telepresence in Videoconference Scale composite (M=89.17 out of a possible 100; SD=9.46) (86-87). SS is long established as a very safe treatment due to its present-focused, coping skills focus, and thus was selected by Dr. Enggasser as a strong choice for telehealth delivery. CBT-PG has been the basis of two outcome studies using telehealth delivery for people with problem gambling (34,36), both with positive outcomes. One study was a Finnish, 8-session model that was adapted in part from Dr. Ladouceur’s CBT-PG ([33](#_ENREF_33)); in an uncontrolled but large study of 471 patients, they found positive results on various gambling variables and other outcomes. The other study (36) was a Swedish 8-module self-guided model via the internet with telephone support, also adapted in part from Dr. Ladouceur’s CBT-PG, finding significant improvements in PG as well as other domains compared to a wait-list control, with results sustained up to 36 months follow-up.

***Treatment preferences in PTSD/GD samples.*** Our team has also conducted other research on PTSD/GD comorbidity, including topics such as treatment preferences, treatment utilization, and a comparison of a sample with current PTSD and PG versus those with either disorder alone ([11](#_ENREF_11), [13](#_ENREF_13)). Among the various results from that body of work, a key finding was that individuals with PTSD/PG rated PTSD treatment more appealing than gambling treatment. This is consistent with prior research in PTSD/SUD comorbidity, in which PTSD treatment was found more appealing than SUD treatment ([69](#_ENREF_69)). Clinically this makes sense: patients may experience more internal suffering from the PTSD (e.g., flashbacks, nightmares) whereas the addiction is typically more externalized (causing social, legal, and medical problems). Addiction is also known to be subject to much greater denial and minimization than is PTSD. Thus, we believe that PTSD treatment may be especially appealing to PTSD/PG patients and ultimately may be a more appealing “hook” to engage them in treatment.

Dr. Ledgerwood has also conducted research on co-occurring GD and PTSD finding rates of lifetime PTSD to be about 34% among treatment seeking pathological gamblers ([15](#_ENREF_15)) and about 19% among community-recruited gamblers ([9](#_ENREF_9)). In one study of treatment-seeking gamblers, over 83% of pathological gamblers who had low frequency of PTSD symptoms had experienced a significant trauma in their lifetime ([15](#_ENREF_15)). In another study, Ledgerwood and colleagues found that the presence of PTSD was associated with poorer substance abuse treatment response among patients receiving contingency management (88). Additionally, Dr. Ledgerwood’s work has revealed greater exposure to childhood trauma among individuals with GD who are identified as fitting the antisocial-impulsivist and emotionally vulnerable subtypes of the etiological Pathways Model, suggesting that trauma is an important precipitating factor for specific individuals with GD (89).

***Rationale for CBT-PG as the comparison condition.*** CBT-PG was selected as the comparison for several reasons. First, there is a strong evidence-base for CBT-PG. As detailed earlier, CBT in general is the most evidence-based type of behavioral therapy for PG ([3](#_ENREF_3)), and within different CBTs, the CBT-PG developed by Dr. Ladouceur in Canada is one of the earliest and strongest in its evidence-base. Three RCTs show that it produced significant improvements. Both Sylvain et al. ([30](#_ENREF_30)) and Ladouceur et al. ([29](#_ENREF_29)) compared it to a wait-list control in samples with PG; and both studies found that CBT-PG showed greater improvement on numerous gambling outcomes and maintenance of gains through one year. Smith et al. ([20](#_ENREF_20)) compared the cognitive modules to a behavioral exposure model in a sample with problem gambling and found that both study arms showed significant improvement in gambling which was maintained through 6-month follow-up. As mentioned earlier, CBT-PG served as the basis for telehealth delivery in two Scandinavian studies as detailed above in *Telehealth treatments*. Second, CBT-PG focuses only on gambling and not on trauma. Thus, it allows us to compare a model that addresses addiction only (CBT-PG) to an integrated model designed to address both addiction and trauma (SS). This question—the impact of integrated versus non-integrated treatment for co-occurring disorders (COD)—is one of the key issues in the COD field currently (90) ([7](#_ENREF_7)), and has never been studied in relation to problem gambling. Third, it is a 12-session model, thus allowing for equivalent-dosage comparison as SS also is evidence-based in 12-session delivery ([18](#_ENREF_18), [19](#_ENREF_19)).

**Methods**

***Participants.***Participants were recruited from Manitoba and Ontario (the latter province was added midway through the study, with approval from the funder, due to low recruitment numbers for Manitoba). We recruited via using online listservs, Craigslist, and Canadian gambling and mental health programs. We randomized 65 individuals with current comorbid GD and PTSD. We included individuals across the full range of severity of both disorders (GD could be mild, moderate or severe; PTSD could be full or subthreshold), for the broadest possible public health relevance (47,91). Our definition of GD was per the Diagnostic Interview for Gambling Severity for DSM-5, and allowed in anyone with mild or higher level of symptom endorsement. Our definition of PTSD was per the PTSD criteria for DSM-5 using the Clinician-Administered PTSD Scale (CAPS-5) (92), which is widely viewed as the gold-standard PTSD assessment (93). Our scoring of the CAPS-5 for study inclusionary purposes (including both PTSD and subthreshold PTSD) will be per the criteria of the National Center for PTSD, which developed the CAPS-5 (a total score of 0-19=asymptomatic/few symptoms, 20-39=mild PTSD/subthreshold, 40-59=moderate PTSD/threshold, 60-79=severe PTSD symptomatology, >80=extreme PTSD symptomatology). Exclusion criteria were: current psychotic or bipolar I disorder; suicidal or homicidal ideation with intent and/or plan; and currently engaging in or planning to engage in any manualized, formal, evidence-based PTSD therapy (e.g., Eye Movement Desensitization or Reprocessing Therapy; Prolonged Exposure; Cognitive Processing Therapy) as those would confound our attempt to evaluate the impact of trauma/PTSD therapy in this trial. We kept our exclusionary criteria minimal because this promotes generalizability of our results. Also, prior studies of both SS and CBT-PG have routinely used such criteria without adverse events.

 Our sample criteria were designed to represent typical treatment-seeking people with GD and PTSD by having minimal exclusionary criteria so as to keep our sample as broad as possible.

 **Study flow.** Our CONSORT diagram demonstrating flow through the study is presented in Figure 1. One hundred and sixteen individuals were recruited of which 65 were randomized, 32 to SS and 33 to CBT-PG. By site, 34 were in Manitoba (18 SS, 16 CBT-PG) and 31 in Ontario (14 SS, 17 CBT-PG). Of those not randomized, the most common reasons for exclusion were lacking either GD or PTSD, although other reasons included not being in the province of Manitoba or Ontario or having bipolar disorder not under control via medication. The 116 people filled out the informed consent form. Of the 65 randomized, assessments were completed by 57 at 6 weeks (88%); 50 at end of treatment (77%); and 34 at 1 year (52%); these counts are from the Timeline Follow-back, which comprised our two primary outcomes. Other measures are highly comparable but may have slightly different numbers; for example, the PCL-5, which was an online self-report measure differs slightly from the TLFB, which was done via phone interview. The PCL-5 had 55 at 6 weeks (85%), 50 at end of treatment (77%), and 36 at 1 year (55%). Overall, considering the difficulty of a clinical trial in general and a hard-to-reach population such as those with GD, these assessment completion rates are strong.

***Study design****.* This RCT compared SS to referral to CBT-PG, both in telehealth format. Both models were conducted identically in terms of study design and dosage; only their content differed, per their respective manuals. They were conducted in weekly individual sessions of 1 hour, with end of treatment at 3 months. We also had a 1-year follow-up. All participants were allowed to receive any other services they naturalistically were receiving or sought out ("treatment as usual"; TAU), for ethical reasons as well as to obtain a typical outpatient sample and thus promote generalizability. The only exception was current formal PTSD treatment as described in our exclusionary criteria above. By comparing the two treatments in telehealth modality (SS versus CBT-PG), we sought to control for modality (telehealth) and gambling treatment (both treatments address it), while varying trauma focus (only SS provided it).

 ***Basis for sample size****.* Power calculations were performed on the basis of a test for non-inferiority by our statistician, as follows. (See *Terminology box* for definition and rationale for a non-inferiority design.) “This study would be the first randomized non-inferiority trial comparing SS to CBT-PG for a gambling population. Interpretation of non-inferiority results is based on the two-sided 95% confidence intervals (CI) of the group difference. If the lower two-sided 95% confidence limit of the group difference lies above the predefined non-inferiority limit (Δ), which marks the limit for clinically not relevant group differences, non-inferiority of the SS to CBT-PG will be concluded. The non-inferiority test results would indicate that the SS is no worse than CBT-PG. For determining the non-inferiority limit, we relied on Ladouceur et al. ([29](#_ENREF_29)) which is the most relevant RCT as it evaluated CBT-PG and used two variables that are considered key outcomes for gambling treatment trials, per the Alberta consensus statement (45): total amount of money spent on gambling and frequency of gambling (called “number of gambling sessions” in Ladouceur et al.) ([29](#_ENREF_29)). We used posttest data on those two variables. The non-inferiority limit (Δ) was predefined as < 0.5 of the CBT effect. Alpha level was set at .05 for the power calculations. The null hypothesis to reject states SS is worse than CBT-PG in decreasing gambling problems. For the proposed study, a sample of 70 participants (n=35 per arm) would, for “total amount of money spent on gambling,” assuming mss = 44, mCBT = 39, and SD = 173, result in a power of 85% to reject the null hypothesis. Likewise, for “number of gambling sessions” with mss =0.7, mCBT = 0.5, and SD = 1.4, we would have a power of 88% to reject the null hypothesis. We are adding 20% (n=14) in case of dropout, thus resulting in our final target of n=84 (42 per study arm). As we are using the recommended intent to treat analytic framework (45), dropout will mean, for our study, those who don’t complete at least 2 of the 3 major assessments (see *Measures* for details).

 We considered that, because very few studies have used tele-health approaches for testing treatments, our power analyses may have been affected by several unknown factors. For example, it was possible that if in-person treatment is more impactful than remote treatment, the effect size may have been overestimated, and the required sample size may have been underestimated. Conversely, because in-person treatment requires participants to be more pro-active and invest more time, this form of treatment may not have achieved the same rate of retention or compliance as tele-health. This may have had to effect of reducing our dropout rate relative to in-person treatment (thus increasing our power). We balanced each of these factors when developing our sample size, but it is important to note that these factors where unknowns at the study inception.

***Conduct of treatments****.* Both treatments were conducted in individual format as: (a) both CBT-PG and SS are evidence-based in this modality; and (b) it is most feasible for scheduling telehealth sessions. Sessions were weekly for 12 weeks. Clinician training and fidelity monitoring were done in identical “dosage” for each condition, with the developer of each model conducting an initial 1-day training (Dr. Najavits for SS and Dr. Ladouceur for CBT-PG), using webinar in keeping with the electronic nature of this study. Fidelity checks were done by raters selected by the relevant developer as being an expert for the model). Clinicians were paid for their participation on a fee-for-service basis. We recruited four Manitoba clinicians, two clinicians per study arm with no cross-over between arms so as to avoid contamination. The clinicians went through training for the study treatment they were assigned to per the developers’ standards, which was, for both, a 1-day training in the model. When we added the Ontario location to the study, the Manitoba clinicians served that location as well, as all of it was still telehealth.

***Randomization.*** For randomization we used a web-based research randomizer for clinical trials. To keep the study manager blind (as s/he did interview-based measures throughout), a different staff person kept the randomization log and did the assignments to study conditions.

 ***Other, non-study treatments (treatment as usual; TAU).***All participants were allowed to be in treatment-as-usual (TAU) during the study (e.g., medication, Gamblers Anonymous, other therapies) as long as such treatments were not evidence-based models designed to treat PTSD as those could have confounded our attempt to evaluate the impact of PTSD/trauma treatment on our sample (see *Key Study Question*). We allowed other types of treatments for several reasons. First, given the telehealth nature of our study, we were not going to be providing any face-to-face clinical contact, which patients may understandably have chosen to seek out, and ethically it would have been inappropriate to prohibit face-to-face care. Asking patients not to engage in other treatments could have compromised their clinical state. Second, in the real-world patients who attend a telehealth intervention would not be restricted from attending other treatments. If we constrained participants solely to our telehealth interventions, our results would not be generalizable and could bias the study toward healthier participants (i.e., those who don’t feel they need additional treatment). Third, if a client had a clinical emergency, s/he would be referred to any necessary care.

 ***Recruitment and engagement in the study.*** As the study goal was to engage a broader population of people with GD (such as those who do not want to attend or cannot attend in-person sessions), we focused our recruitment online. We did so via: (a) online community forums such as Craigslist; (b) email blasts to Manitoba- and Ontario-based gambling and mental health programs; (c) posting on listservs to professional groups such as the Addictions Foundation of Manitoba, the Canadian Psychological Association, the Canadian Association of Social Workers, etc. All potential participants underwent a brief web-based screen and if the potential participant appeared interested and eligible, they could access the Informed Consent Form as the starting point for their participation in the study.

 ***Intent-to-treat design.***We used intent-to-treat analysis and followed all patients for all assessment points regardless of intervention attendance, which is the most rigorous method (45). ***Measures.*** All measures were selected for their relevance to the goals of this project, their theory-based relevance to the study, the need for rigorous assessment of the target diagnoses (PTSD, GD), their widespread use in other research, and their psychometric reliability and validity. Although we had many measures, the burden to patients was reasonable as many are brief measures. We had three major assessments at which all measures were collected: baseline, end of treatment (EOT), and 12-month follow-up (except for the SCID exclusionary criteria modules for mania and psychosis). We also had one minor assessment at 6 weeks (treatment midpoint) comprised of a smaller battery as identified below.

 (1) Screening. Basic eligibility screen. We used a GD/PTSD screening used by Dr. Najavits in her prior pilot SS study on GD/PTSD, which also includes demographics (age, gender, ethnicity, etc.). (2) Psychopathology. For current DSM-5 trauma/PTSD symptoms we used the Clinician-Administered PTSD Scale (CAPS-5) (92), with an inclusion criterion of 20 or higher on its severity scale, as specified earlier to identify subthreshold or higher PTSD (see Participants section). For current DSM-5 problem gambling, the Diagnostic Interview of Gambling Severity (DIGS) (94), which per personal communication with Dr. Winters was valid for DSM-5 by omitting the legal criterion and using the cut-off of 4 or more symptoms endorsed. For our inclusion criterion of current GD, we also ensured that participants reported gambling in the prior month on the Timeline Follow-back. For the study exclusion diagnoses (see *Participants*), we used the MINI Neuropsychiatric Interview. Our primary outcomes, money spent gambling and number of gambling sessions, were assessed per the Alberta consensus guidelines. Money spent gambling was net loss in the prior month using the Timeline Follow-back, which has been validated for that purpose (45,95). Gambling sessions was assessed as number of days in the past month in which gambling occurred, again in keeping with the Alberta guidelines, and using the Timeline Follow-back. These primary outcomes were assessed by a blind rater at all timepoints. Our secondary outcomes included the PTSD Checklist (PCL-5) for DSM-5 (96), as the PCL-5 has been found highly convergent with the CAPS-5, and the Trauma Symptom Checklist 40 (97), which assesses a broader range of trauma symptoms than the PCL-5. Note that these are not primary outcomes because our primary outcomes had to be based on measures already studied for CBT-PG (see *power analysis* earlier). Finally, for psychopathology we also included the Brief Symptom Inventory 18 (98) for overall psychiatric symptoms and the Brief Addiction Monitor (99), as SUD is often comorbid with gambling problems.

 (3) Coping / Functioning / Cognition. The Gamblers’ Beliefs Questionnaire (79); Gambling Self-Efficacy Questionnaire (100); PTSD World Assumptions Scale; Basis-32 (101); the Coping Self-Efficacy Scale (102).

 (4) Treatment Measures. Helping Alliance Questionnaire (HAQ); Treatment Services Review (103) to assess TAU treatments; Client Satisfaction Questionnaire (CSQ) (85); and the Telepresence in Videoconference Scale (TVS) (87); the latter evaluates acceptability of the telehealth format.

 (5) Fidelity. Fidelity for SS was per the SS Adherence Scale (104) and for CBT-PG per the fidelity check measure for that model (105)rotating across sessions and patients (to sample across treatment content), based on the full recording per session (telehealth sessions were recorded). Fidelity was rated by a colleague Dr. Najavits chose for SS and by a colleague Dr. Ladouceur chose for CBT-PG.

 Measures were collected at baseline, midpoint (6 weeks), and end of treatment (EOT), as well as 12 month follow-up, except the MINI, the CAPS-5 and DIGS (done at all points except mid-point), the CSQ, and the TVS (done at mid-point and end of treatment only). At 6 weeks a smaller battery was collected, consisting of the two primary outcomes (net loss of money spent gambling and number of days gambling in past month), the two trauma measures (PCL-5, TSC-40), the BSI-18, and the BASIS-32. Data collection was electronic for self-report measures and phone for interview-based measures. ***Ethical issues.***The study was approved by the University of Windsor (the primary REB), the University of Manitoba REB and the New England IRB.

 ***Data Analysis***. We used descriptive statistics to characterize the sample and two-tailed independent samples *t*-tests or chi square tests to compare by study condition at baseline. To minimize Type 1 error we analyzed one summary score per variable rather than including subscales except for the BAM, which has three summary scores (risk, use and protective factors). We used multiple imputation procedures in SPSS to address missing data so as to include the full intent-to-treat sample; we used the pooled result of 100 imputations. For continuous variables, imputed outcome data were analyzed with two-way mixed analysis of variance (ANOVA). Mauchley’s test of sphericity was conducted and if significant, Greenhouse–Geisser estimates were used. Effect sizes are reported as partial eta-squared and interpreted as 0.01 (small), 0.09 (medium), and 0.25 (large) (Watson,2016). All results are reported on the intent-to-treat sample.

 **Results**

***Sample***

There were no differences between treatment conditions on any characteristic as baseline, so the full sample is described here. The mean age of the sample was 44.93 (sd=11.99). In terms of gender, 58.7% was female, 39.7% male, and 1.7% nonbinary. Race/ethnicity was 68.8% White, 31.3% minority. In the sample, minority representation was 12.5% Indigenous, 9.4% Asian, 6.3% Black and 3.2% Hispanic.

 The most common gambling types were: slots (76.1% of the sample), internet gambling (48.5%), lottery (48.5%) and blackjack (34.3%). The two treatment conditions did not differ at baseline on any of the twelve gambling types surveyed.

***Attendance***

The only significant difference between treatment conditions (across all study results) was that SS had higher session attendance than CBT-PG: x=8.34 (sd=4.77) vs. 5.67 (sd=4.58), t=2.31, p=.02.

***Outcomes***

Outcome results are summarized in Tables 1-3. We conducted a two way mixed ANOVA, which means that the data were analyzed across the full range of timepoints [i.e., ‘time’ in the columns in the table]. Overall, the findings were highly consistent. On almost every measure the sample improved significantly over time but there was no difference between treatment conditions. This held true on our primary outcomes (gambling net losses and number of gambling sessions) as well as secondary outcomes that included psychopathology, beliefs about gambling, gambling self-efficacy, functioning, PTSD symptoms on both interview and self-report measures, coping. The only non-significant measures were the Columbia Suicide Scale (though that did reach trend level) and the World Assumptions Scale.

 The degree of change, known as *effect size* showed large effect sizes for gambling (number of times gambled, DIGS number of symptoms, and gambling self-efficacy) and PTSD (the PTSD Checklist and the CAPS-5), as well as coping (the Coping Self-Efficacy Scale). There were medium effect sizes on all other measures (net loss gambling, Gamblers Beliefs, Trauma Symptom Checklist and the Brief Symptom Inventory) except the BASIS-32, which had a small effect size. We are not interpreting the effect size for the Columbia Suicide Scale or World Assumptions Scale as the main effects for these were not significant.

 As for which timepoints showed change, the predominant pattern of significant improvement was from baseline to later timepoints (6 weeks, end of treatment, and sometimes to one-year follow-up)

as noted by the significant “a”, “b” and “c” entries in the last column of the table. On one measure there was continued improvement from end of treatment to one-year follow-up (“f” in the last column)-- the Gambling Self-Efficacy Questionnaire. However, three measures showed significant worsening from end of treatment to 1 year follow-up (the DIGS, Gamblers Beliefs Questionnaire and the Coping Self-Efficacy Scale). Yet on all three of these people were still significantly better than at baseline (“c” in the last column). These end of treatment to 1 year results would suggest the need for continued therapy to help people sustain the gains achieved during treatment.

***Alliance and client satisfaction***

Therapeutic alliance was scaled 1-6 with higher representing better alliance. It was strong in both treatment conditions at 5.19 for SS (sd=.54) and 4.57 for CBT-PG (sd=.22) at 6 weeks, with no difference below conditions. The client satisfaction scale, scaled 0-3, also had the same pattern: very strong in SS (x=2.26, sd=.41) and CBT-PG (x=2.39, sd=.28) with no difference between them.

***Telehealth***

The telepresence scale, scaled 0-10 (higher is better) assessed acceptability of the telehealth format. It showed high acceptability (SS x=7.84, sd=1.54, CBT-PG x=7.84, sd=1.54) with no difference between conditions.

***External treatments***

 On the Treatment Services Review patients were asked about their past-month use of behavioral treatments or support (such as 12-step groups) aside from the study treatment they were receiving. Patients in SS showed an increase in total number of sessions across all types from 2.12 (sd=4.10) at baseline to 7.89 at 6 weeks (sd=7.11) to 6.65 (sd=6.24) at end of treatment. Patients in CBT-PG had 6.41 (sd=9.11) to 5.95 (sd=9.37) to 5.38 (sd=6.09) respectively. There is no interpretation of these findings per se (increasing use of treatment could be considered positive or negative, depending on the individual patient). However, it is part of the SS model to encourage people to use outside supports; and given their low rate on that at baseline it makes sense that SS patients would increase their use of supports over time.

***Fidelity***

Fidelity spot checks for both treatments indicated that all therapists met the fidelity standards for their treatment, with no concerns.

**Discussion**

The area of GD/PTSD treatment is novel territory and this study provides a first-ever RCT to address integrated treatment for this population. We compared two evidence-based models, one focused solely on GD (CBT-PG) and the other on both GD and PTSD (Seeking Safety). Both were delivered in telehealth format, which allowed for greater accessibility, given the very low rate of treatment-seeking among people with GD.

 Our findings were highly consistent. Patients improved across time on almost all study measures, including gambling, trauma/PTSD, other psychiatric symptoms, functioning, and coping. Effect sizes (the degree of change) was large on many measures and medium on others, indicating that our sample was able to strongly benefit from the treatments. Only two measures did not show this pattern: the World Assumptions Scale and the Columbia Suicide Scale (the latter likely because base rates are low).

Importantly, our focus was on changes in symptom reduction (rather than abstinence or symptom remission, per se). We conceptualized treatment success in terms of symptom reduction, which might involve abstinence/remission, or may also be consistent with a harm reduction perspective. Larger trials would be needed to more fully examine differential abstinence and remission. But the results of the present trial clearly show the benefits of both treatments for reducing both gambling and trauma symptoms.

 The main findings related to gambling and trauma were also clinically significant. Our gambling data show substantial reductions in dollars gambled and number of gambling episodes. Scores on the DIGS declined from scores reflecting moderate levels of gambling disorder (i.e., scores over 7), to average scores reflecting sub-threshold gambling disorder (ranging from 2.8 to 3.8). Trauma measures similarly demonstrated clinically significant improvement. The CAPS-5 scores declined from an average score reflecting moderate/threshold level symptoms of PTSD, to average scores reflecting mild/subthreshold PTSD symptoms. Similar improvements were demonstrated on the PCL-5. Thus, overall the study treatments resulted in substantial clinical improvements on both gambling and PTSD.

 However there was no difference between treatment conditions (SS and CBT-PG) except for SS achieving significantly stronger treatment attendance. It may be that by addressing PTSD, not just GD, patients were more engaged in treatment. This is consistent with research showing that patients with both PTSD and problem gambling are more interested in trauma treatment than gambling treatment ([10](#_ENREF_10)).

 Our finding of both treatments doing equally well fits with the literature on evidence-based practices, which consistently finds no difference among well-constructed treatments (8). Notably, although CBT for GD does not explicitly address co-occurring psychopathology, there is evidence that this approach can improve depression and anxiety symptoms among individuals receiving treatment (31). The good news is that there are multiple options that work, allowing clinicians and patients to choose what they prefer. Although it may be a surprise that the gambling-only treatment, CBT-PG, did just as well on PTSD as the integrated treatment (SS), this too is consistent with the existing literature on integrated treatments for PTSD/SUD ([8](#_ENREF_8)).

 We also found strong client satisfaction and obtained strong minority participation in this study, which was heartening to see. Our telehealth scale, moreover, indicated that the telehealth format was highly acceptable. Other study strengths included interview-based diagnoses of both problem gambling and PTSD, blind evaluation of our primary outcomes, and the use of validated study measures.

We were able to recruit most of our desired sample but fell slightly short, which is a known issue in the gambling field as GD has a low base rate relative to other psychiatric disorders and, moreover, people with GD are known to be very low on treatment-seeking ([12](#_ENREF_12), [13](#_ENREF_13)). We had designed the study for telehealth format due to this well-known challenge. The use of statistical multiple imputation helped us obtain the strongest analysis possible. We had a sample of 65 patients rather than the proposed 70, and it is highly unlikely that the additional five patients would have changed the study conclusions. Nevertheless, it is important to consider the essential role of clinical trial recruitment strategies, as these strategies are often the ultimate predictor of a study’s success or failure. We used several different traditional and web-based strategies, including social media advertising, enlisting of recruitment experts, peer-recruitment and other strategies. We placed advertisements on several social media sites including Kijiji, Craigslist, Facebook and others. We also conducted more conventional recruitment strategies including posting flyers, and reaching out to colleagues in the field who might be able to refer participants. We recommend that future studies similarly enlist as many different recruitment sources as possible to maximize recruitment reach. Further, the use of treatment approaches that also maximize reach, such as web-based interventions, may make it easier to recruit large numbers of participants.

 Our study findings should be considered within the context of its limitations. Our sample size, although adequate for assessing the study aims, is small (N = 65). Larger trials may have greater power to detect smaller effect sizes between treatment conditions. Our study assessments were all self-report measures, which may increase the chances of socially desirable responding. This issue is consistent across all studies of GD and PTSD, as there are no biochemical measures to detect the presence of gambling behavior or PTSD symptom counts. Nevertheless, we used thoroughly validated assessments, and incorporated rater blinding procedures to minimize any issues related to assessment validity. SS participants reported slightly more external treatment than those in the CBT-PG condition, and it is possible that this difference may have interfered with a pure comparison of SS and CBT-PG. Finally, we did not include a non-treatment control or waitlist condition, which would have allowed us to determine the efficacy of SS compared to no treatment. We decided against a no-treatment control condition for several reasons. First, it would be unethical to withhold treatment from those seeking care. Second, studies have already demonstrated that our comparison treatment is efficacious in treating GD compared to minimal-care approaches (4). Finally, our interest in the present investigation was whether SS, which addresses both GD and trauma, was comparable to an established evidence-based intervention that focuses only on GD. This goal was successfully addressed in the current study.

Additionally, several issues (lessons learned) should be considered in future trials examining the efficacy of SS or other forms of treatment. We experienced differential treatment dropout in the trial; thus, on average, participants in the two conditions may have received different doses of treatment. Future trials should be powered to account for differential treatment dropout, and investigators of future studies may consider strategies that may reduce dropout (e.g., compensation for participant attendance, condensing treatment into a shorter period of time). The frequency of assessment in the present study may have also made it difficult to detect frequent fluctuations in gambling or trauma symptoms, particularly early in the treatment period. Unfortunately, it was beyond the scope of this study to conduct ecological momentary assessment or daily diary approaches that might capture these instances, and such assessment methods might be helpful in larger trials.

 Despite the limitations and lessons learned in this study, it is important to acknowledge the importance of our findings. We were successful in demonstrating our aims, that SS and CBT-PG are equally effective at treating GD and trauma. It is hoped that future research will continue to study the interplay between GD and PTSD. In the words of one of our study patients, “PTSD is the only real and useful understanding of how it…derail[ed] my soul… thank you for the opportunity to save my existence from being dead and disturbed, tormented inside-- a way back to a life of value, productive and hopefully joyful.”

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Table 1: Intent-to-treat gambling outcomes for Seeking Safety (SS) versus Cognitive-Behavioral Therapy for PG (CBT-PG)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Baseline mean (SD)  | 6 weeks mean (SD)  | End oftreatmentmean (SD) | 1-year follow-upmean (SD) | ***Treatment******x Time*** F (df)p*ηp²* effect size1 | ***Treatment***F (df) p*ηp²* effectsize | ***Time***F (df) p*ηp²* effectsize | ***Comparisons for significant effects*2** |
| ***Primary Gambling Outcomes3*** | SS | CBT-PG | SS | CBT-PG | SS | CBT-PG | SS | CBT-PG |  |  |  |  |
| Net gambling loss in Canadian dollars(Timeline Followback) | 1851.58(3244.97) | 3278.45(8389.17) | 805.09(1531.31) | 447.72(876.84) | 368.90(891.62) | 432.90(690.30) | 569.50(1335.07) | 523.34(1048.51) | 1.063(3)p = .366*ηp² =* .017 | .320(1)p = .573*ηp² =* .005 | 7.144(3)**p < .001***ηp² =* .102 | **a=.01****b=.006****c=.01**d= .07e=.62f=.21 |
| Number of times gambled(Timeline Followback) | 9.82(6.01) | 10.63(6.28) | 5.23(5.3) | 4.43(6.27) | 3.30(3.33) | 3.73(3.87) | 4.51(4.5) | 4.24(3.66) | .402(3)p=.752*ηp² =* .006 | .003(1)p=.957*ηp² =*.000 | 28.835(3)**p<.001***ηp² =* .314 | **a<.001****b<.001****c<.001****d=.03**e=.59f=.11 |
| ***Secondary gambling measures*** |  |  |  |  |  |  |  |  |  |  |  |  |
| Diagnostic Interview for Gambling Severity | 7.19(1.45) | 7.48(1.31) | -- | -- | 2.81(2.30) | 3.40 (2.78) | 3.77 (2.29) | 3.84 (2.55) | 0.33 (2,126)p=.72*ηp²* =.01 | 0.66 (1,63)p=.42*ηp²* =.01 | 97.41 (2,126)**p<.001***ηp²* =.61 | a= --**b<.001****c<.001**d= --e= --**f=.03** |
| Gambling Self-Efficacy Questionnaire  | 2.64(1.01) | 2.67(0.92) | -- | -- | 3.61 (1.37) | 3.29 (1.12) | 3.99 (1.19) | 3.76 (.99) | 0.99 (2,126)p=.37*ηp²* =.02 | 0.57 (1,63)p=.45*ηp²* =.01 | 48.29 (2,126)**p<.001***ηp²* =.43 | a= --**b<.001****c<.001**d= --e= --**f<.001** |
| Gamblers Beliefs Questionnaire  | 3.86(1.25) | 3.75(1.37) | -- | -- | 4.73 (1.23) | 4.31 (1.37) | 4.33 (1.24) | 4.03 (1.27) | 0.48 (2,126)p=.62*ηp²* =.01 | 1.13 (1,63)p=.29*ηp²* =.02 | 10.42 (2,126)**p<.001***ηp²* =.14 | a = --**b<.001****c=.03**d= --e= --**f=.03** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

1Effect size (partial eta squared, *ηp²*) are interpreted as 0.01 (small), 0.09 (medium) and 0.25 (large) per Watson40; they are reported to three decimal places to avoid misinterpretation due to rounding.

2 “a” refers to baseline compared to 6 weeks. “b” is baseline to end of treatment. “c” is baseline to 1 year followup. "d" is 6 weeks compared to end of treatment. "e" is 6 weeks compared to 1-year followup. "f" is end of treatment compared to 1-year followup. Significant timepoints are bolded.

3Higher scores indicate worse pathology on all measures except the Gambling Self-Efficacy Scale, Gamblers Beliefs Questionnaire on which higher scores indicate stronger mental health.

Table 2: Intent-to-treat PTSD/Trauma outcomes for Seeking Safety (SS) versus Cognitive-Behavioral Therapy for PG (CBT-PG)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Baseline mean (SD)  | 6 weeks mean (SD)  | End oftreatmentmean (SD) | 1-year follow-upmean (SD) | ***Treatment******x Time*** F (df)p*ηp²* effect size1 | ***Treatment***F (df) p*ηp²* effectsize | ***Time***F (df) p*ηp²* effectsize | ***Comparisons for significant effects*2** |
| ***Primary Trauma/PTSD Outcomes3*** | SS | CBT-PG | SS | CBT-PG | SS | CBT-PG | SS | CBT-PG |  |  |  |  |
| Clinician-Administered PTSD Scale | 2.01(.75) | 2.08(.62) | -- | -- | 1.25(.46) | 1.22(.51) | 1.25(.34) | 1.20(.55) | .30(1.68, 104.20)p=.70*ηp²* = .01 | .003(1,62)p=.96*ηp²* = .00 | 57.44(1.68, 104.20)**p<.001***ηp²* = .48 | a= --**b<.001****c<.001**d= --e= --f=.84 |
| PTSD Checklist -Total Score | 2.05(.86) | 2.17(.77) | 1.47(.68) | 1.58(.60) | 1.34(.89) | 1.30(.58) | 1.27(.62) | 1.35(.61) | .323(3)p=.809*ηp²* =..005 | .229(1).634*ηp² =*.004 | 33.84 (3)**p<.001***ηp²* =.349 | **a=<.001****b=<.001****c=<.001****d=.007**e=.24f = .36 |
| Trauma Symptom Checklist 40 | 1.25(.51) | 1.25(.41) | .94(.43) | 1.16(.44) | .95(.51) | 1.00(.41) | .93(.50) | 1.08(.49) | 2.077(3)p=.105*ηp²* *= .032* | 1.158(1)p=.286*ηp²**=.018* | 12.827(3)**p<.001***ηp²**=.169* | **a<.001****b<.001****c<.001**d=.06e=.27f=.56 |
| World Assumptions Scale | 3.55(.58) | 3.47(.60) | -- | -- | 3.60 (.60) | 3.51 (.58) | 3.58 (.51) | 3.56 (.60) | 0.41(1.83,117.37)p=.66*ηp²* =.01 | 0.22 (1,64)p=.64*ηp²* =.003 | 1.30(1.83,117.37)p=.28*ηp²* =.02 | a= --b=.28c=.16d= --e= --f=.66 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

1Effect size (partial eta squared, *ηp²*) are interpreted as 0.01 (small), 0.09 (medium) and 0.25 (large) per Watson40; they are reported to three decimal places to avoid misinterpretation due to rounding.

2 “a” refers to baseline compared to 6 weeks. “b” is baseline to end of treatment. “c” is baseline to 1 year followup. "d" is 6 weeks compared to end of treatment. "e" is 6 weeks compared to 1-year followup. "f" is end of treatment compared to 1-year followup. Significant timepoints are bolded.

3Higher scores indicate worse pathology on all measures except the World Assumptions on which higher scores indicate stronger mental health.

Table 3: Intent-to-treat secondary function and mental health outcomes for Seeking Safety (SS) versus Cognitive-Behavioral Therapy for PG (CBT-PG)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Baseline mean (SD)  | 6 weeks mean (SD)  | End oftreatmentmean (SD) | 1-year follow-upmean (SD) | ***Treatment******x Time*** F (df)p*ηp²* effect size1 | ***Treatment***F (df) p*ηp²* effectsize | ***Time***F (df) p*ηp²* effectsize | ***Comparisons for significant effects*2** |
| ***Other Outcomes3*** | SS | CBT-PG | SS | CBT-PG | SS | CBT-PG | SS | CBT-PG |  |  |  |  |
| *Brief Symptom Inventory-18 item version* | 1.63(.95) | 1.53(.76) | 1.16(.71) | 1.36(.83) | 1.15(.72) | 1.12(.46) | 1.24(.67) | 1.28(.55) | 1.02(2.68, 168.82)p=0.381*ηp²=.016* | 0.035(1, 63)p=0.851*ηp²=0.001* | 8.89(2.68, 168.82)**p<.001***ηp²=.124* | **a=.002****b<.001****c<.001**d=.09e=.98f=.12 |
| *BASIS-32* | 1.59(.80) | 1.48(.59) | 1.10(.57) | 1.22(.62) | 1.23(.71) | 1.20(.48) | 1.28(.74) | 1.33(.64) | .824 (2.62, 156.93)p=0.47*ηp²* =.01 | 5.48(1,60)p=.02*ηp²* =.08 | 9.55 (2.62, 156.93)**p<.001***ηp²=.014* | **a<.001****b<.001****c<.006**d=.41e=.10f=.15 |
| Columbia Suicide Scale | 1.88(2.08) | 1.84(2.05) | -- | -- | 1.83 (1.84) | 1.83 (1.74) | 2.29 (1.45) | 2.37 (1.78) | 0.03 (1.80,111.81)p=.96*ηp²* =.00 | 0.002 (1,62)p=.97*ηp²* =.000 | 2.88 (1.80,111.81)p=.06*ηp²* =.04 | a = --b=.88c=.08d= --e= --**f=.04** |
| Coping Self-Efficacy Scale | 3.93(2.02) | 4.33(1.73) | -- | -- | 5.26 (1.57) | 5.30 (1.64) | 4.89 (1.90) | 4.95 (1.48) | 0.66(1.80,111.55)p=.50*ηp²* =.01 | 0.185 (1,62)p=.67*ηp²* =.003 | 21.21(1.80,111.55)**p=<.001***ηp²* =.26 | a= --**b<.001****c<.001**d= --e= --**f= .02** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

1Effect size (partial eta squared, *ηp²*) are interpreted as 0.01 (small), 0.09 (medium) and 0.25 (large) per Watson40; they are reported to three decimal places to avoid misinterpretation due to rounding.

2 “a” refers to baseline compared to 6 weeks. “b” is baseline to end of treatment. “c” is baseline to 1 year followup. "d" is 6 weeks compared to end of treatment. "e" is 6 weeks compared to 1-year followup. "f" is end of treatment compared to 1-year followup. Significant timepoints are bolded.

3Higher scores indicate worse pathology on all measures except the Coping Self Efficacy Scale on which higher scores indicate stronger mental health.

**Figure 1. CONSORT Flow Diagram**

Analysed (n=32)
 Excluded from analysis (n=0)

## Enrollment

## Follow-Up

## Analysis

Analysed (n=33)
 Excluded from analysis (give reasons) (n=0)

Lost to follow-up (n=5 at 6 weeks; 10 at end of treatment; 18 at 1-year). Discontinued intervention (n=3)

Lost to follow-up (n=6 at 6 weeks; 9 at end of treatment; 14 at 1-year) Discontinued intervention (n=3)

Allocated to Seeking Safety (n=32)

 Received allocated intervention (n=29)

 Did not receive allocated intervention (n=3)

## Allocation

Allocated to CBT-PG (n=33)

 Received allocated intervention (n=26)

 Did not receive allocated intervention (n=7)

Randomized (n=65)

Excluded (n=51)

  Not meeting inclusion criteria (n=39)

  Declined to participate (n=6)

  Other reasons (n=6)

Assessed for eligibility (n=116)