A Psychotherapy Development Study for Internet Gaming

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Protocol & Statistical Analysis Plan

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Protocol: A psychotherapy development study for internet gaming
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Abstract

The fifth edition of the Diagnostic and Statistical Manual for Mental Disorders (DSM-5) introduces Internet gaming disorder (IGD) as a Substance-Related and Addictive Disorder in Section 3, Conditions for Further Study. Although research is in the nascent stages, existing studies demonstrate that IGD is associated with psychosocial distress including suicidality, and adverse vocational and educational outcomes in youth. Internet gaming disorder also shares substantial overlap with substance use, and it primarily affects adolescents, who rarely seek treatment on their own. Parents more often express concerns about their child's game playing behaviors, and data suggest that parents can have strong influences on it. This psychotherapy development study will evaluate feasibility, acceptability, and effect sizes of a behavioral intervention designed to help parents reduce gaming problems in their children. Sixty concerned parents and their children will complete parental and self-report inventories and structured diagnostic interviews regarding the child's gaming behaviors, substance use and psychosocial functioning. Participants will be randomized to either a control condition consisting of referral for mental health issues and family support services or to the same plus a 6-week family-based behavioral intervention designed to assist with better monitoring and regulating the child's game playing behaviors and encouraging and rewarding alternatives to game playing. Gaming and other problems will be assessed pre-treatment, mid-treatment, at the end of treatment, and at a 4-month follow-up. This study is unique in evaluating initial psychometric properties of a parental version of a measure that uses the DSM-5 criteria for IGD in a clinical sample, and it will also assess associations of IGD with substance use, psychological symptoms, and family functioning over time. Most importantly, this study will be the first randomized trial of an intervention designed to reduce gaming problems, and results are likely to guide future research and treatment efforts related to this condition.

Specific aims

Internet gaming disorder (IGD) affects about 1%-2% of the population, and primarily adolescent males. This grant application represents the first randomized study of treatments for IGD.

There are four important and timely reasons why a study of interventions for youth with gaming problems is necessary. First, this condition is gaining international attention with its recent inclusion in the DSM-5. Second, IGD shares extensive overlap with substance use disorders with respect to comorbidity, risk factors and presenting features. Third, IGD is associated with adverse consequences that parallel many of those related to substance use disorders, such as poor school performance and serious physical and mental health outcomes including suicidality. Finally, efficacious treatments for this condition may reverse or minimize its adverse effects, and youth who are still living with their families can benefit from parental support in reducing gaming problems. Although clinicians are already treating this condition primarily in specialized residential programs, there are no systematic evaluations of interventions designed to reduce gaming problems and no empirically based guidelines for clinicians treating this condition on an outpatient basis.

We adapted principles and theories of behavioral and family-based interventions for substance use disorders for IGD. In this pilot study, 60 parents and their children with IGD will be randomly assigned to one of two conditions: referral to services for related conditions, or the same plus a 6-week behavioral family intervention in which parents and children will meet weekly with a therapist to learn to monitor game playing, restructure the environment to be less conducive toward playing, set realistic goals related to frequency of game playing, and encourage and reward behaviors incompatible with game playing. Sessions will also focus on improving parent-child communication. Parents and children will complete evaluations assessing gaming, substance use, attention problems, and psychosocial functioning pre-, mid-, and post-treatment and 4 months later.

Specific aims are:

1. **To evaluate the feasibility and acceptability of this intervention**. The proportion of participants who complete 6 sessions will be determined, along with parent and child satisfaction ratings of the treatment. We will consider the treatment feasible and acceptable if we are able to recruit the full sample and 70% or more of the families complete treatment and express moderate to high levels of satisfaction overall and with the majority of the session topics.

2. **To examine the effect size of the intervention in reducing gaming**. Parent and child reports of frequencies and durations of game playing will be compared over time between conditions to derive effect size estimates. We hypothesize that the behavioral family intervention will reduce the frequency and duration of game playing episodes relative to the control condition. We also expect that a lower proportion of youth in the intervention condition will meet current DSM-5 criteria for IGD following treatment.

Exploratory aims are to examine putative mechanisms of change including structural changes in the home environment, frequencies of monitoring gaming, participation in alternate activities, and family communication and functioning. If we can identify potential mechanisms of change for gaming behavior, we can focus subsequent psychotherapy development efforts on addressing those processes more directly.

We will also assess the effect size of the intervention on secondary outcomes including indices of substance use, attention problems, depression, sleep, psychosocial functioning and quality of life. We expect that the intervention will result in improvements along some or most of these domains if it yields benefits in reducing gaming.

In addition, we will evaluate concordance between parent and child reports on measures of gaming and gaming problems. These data will help inform development of diagnostic and assessment tools for IGD.

If the intervention is feasible and acceptable and medium or larger effect sizes are noted for decreasing gaming, we will propose a larger scale, longer-term study after modifying the intervention based on experiences with this pilot study. Even in the absence of treatment-specific effects, these results will provide valuable information about how gaming and psychosocial functioning change over time and about the relationship between gaming and other addictive behaviors (i.e., substance abuse) in a clinical population. Further, the study has the potential to shed light on important mechanisms of change for youth behaviors in the context of a family-based addiction treatment, an area understudied in substance abuse treatment as well. Given increasing scientific interest in IGD, this novel study is timely and critical for addressing concerns related to this emerging public health issue.

Background and significance

The vast majority of children play video or electronic games. A nationally representative study of US youth ages 8-18 years found that 88% played games electronically, 68% played at least weekly, and 23% daily (Gentile, 2009). On the 2013 Youth Risk Behavior Surveillance System, 41% reported using computers for non-school work and gaming an average of >3 hours per day (Kann et al., 2014). Although most video game playing is harmless, excessive play can lead to psychosocial and even medical problems such as game-induced seizures and deaths (BBC, 2005; Chuang, 2006; Reuters, 2007). Although very few cases rise to these extremes, governments of some Asian countries have declared problem game playing to reach epidemic proportions. Providers have established specialized treatment clinics around the world, including in the US.

The American Medical Association (2007) called for consideration of a condition related to excessive gaming as a mental disorder, and the 5th edition of the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM-5;* APA, 2013) includes Internet gaming disorder (IGD) as a Substance-Related and Addictive Disorder in Section 3, "Conditions for Further Study." This designation recognizes the personal and public health significance of the condition, and it encourages further research of its diagnosis, comorbidities, and biological underpinnings, as well as its natural progression and treatment. This study will address many of these issues.

Diagnosis. The DSM-5 lists 9 criteria for IGD, and an international group (Petry et al., 2014) suggests their operationalization. Ko et al. (2014) administered clinical interviews based on the DSM-5 criteria to young adults in Taiwan: those with current gaming problems; those with past problems; and those who never had problems. Meeting ≥5 criteria best distinguished those with "normal" levels of play from those with problems, and the specific criteria had adequate to good diagnostic accuracy, providing support for the DSM-5 classification system. We (Rehbein et al., 2015) developed a screening instrument, Video Game Dependency Scale (VGDS), based on DSM-5 criteria and administered it to 11,003 students; it had excellent reliability and discriminant validity. This study will be the first to evaluate the psychometrics of a parental version of the VGDS, and it will assess concordance between parent and child reports of symptoms and diagnosis.

Risk factors. Although an understanding of IGD is in early stages, male gender is clearly a risk factor. Regardless of how gaming problems are classified, studies ubiquitously find higher rates of game playing and problems in males than females (Choo et al., 2010; Desai et al., 2010; Mentzoni et al., 2011). In our DSM-5 evaluation of IGD (Rehbein et al., 2015), 2.0% of males had IGD versus 0.3% of females. Younger age is consistently associated with gaming as well. Using less stringent classification systems than the DSM-5, Festl et al. (2013) found a 7.6% prevalence rate of gaming problems for youth under 19 years and a 3.7% rate for those 20 and older. Mentzoni et al. (2011) noted that 15.4% of males aged 16-21 years, and 9.7% of males aged 22-27, had gaming problems; rates in other age groups, and for females of all ages, were under 3%.

Gaming problems are also linked to drug use, and particularly illicit drug use. In a study of over 4500 students, boys who used marijuana, nicotine, and alcohol were substantially more likely to report problems with gaming than non-users (Van Rooij et al., 2014). In a survey of nearly 2000 video game players, Porter et al. (2010) found no differences between those with and without gaming problems in terms of alcohol use, but those with gaming problems were more likely to use illicit drugs. Walther et al. (2012) evaluated over 2500 students and found no association between alcohol and nicotine use and gaming but a positive relationship with marijuana use. In CT, where the proposed study will be conducted, Desai et al. (2010) surveyed over 4000 high school students, and 4.7% of the video game players reported problems with their playing; although drinking did not differ based on gaming problems, problem gamers more often used nicotine and illicit drugs. Substance use and gaming may also share a neurobiological basis, with fMRI studies finding some similar deficits in pre-frontal cortex functioning (e.g., Chen et al. 2014; Han et al. 2010; Kim et al. 2015; Ko et al. 2013, 2105).

Attention deficit hyperactivity disorder (ADHD), social anxiety, depression and suicidality are related to IGD as well. In cross sectional studies, persons with gaming problems have greater ADHD symptoms (Choo et al., 2010; Gentile, 2009; Rehbein et al., 2010) and depression (Desai et al., 2010; Mentzoni et al., 2011; van Rooij et al., 2010) and lower sociability and social competence than those without (Festl et al., 2013; Lemmens et al., 2009; Lo et al., 2005; Rehbein et al., 2010). In a prospective study of over 1,300 youth, Swing et al. (2010) found game playing correlated with more attention problems initially, and this relationship persisted throughout a 13-month period. Among over 700 youth, heavy game playing was associated with an increase in depression over the one-year study period, and greater depression predicted more game playing as well as withdrawal from sports and other activities (Romer et al., 2013). Gentile et al. (2011) followed over 3000 students for 2 years and found that as gaming became more pronounced, depression, anxiety, and social phobia symptoms increased while school performance suffered. Excessive gaming is also related to suicidality (e.g., Messias et al., 2011; Rehbein et al., 2010), further underscoring its public health significance.

Thus, drug use and psychological symptoms are correlated with and likely involved in the development of IGD and/or arise from it. However, the few available longitudinal studies reported upon natural changes over time. They did not address how treatment impacts changes in gaming and related problems.

Treatments. Reviews of treatment for IGD (King et al., 2011; Petry et al., 2015; Winkler et al., 2013) find few randomized trials exist. Most interventions involve intensive multi-modal therapy provided in residential care (Cash et al., 2012; Koo et al., 2011; Rumpf et al., 2014; Shek et al., 2009). Few patients, and typically the most severe, seek residential care. This level of care is also expensive, and it is likely more cost-effective to provide effective outpatient services to individuals before problems become severe enough to warrant residential care.

Young (2007) describes cognitive-behavioral therapy (CBT) to treat outpatients with Internet problems more generally, i.e., not limited to gaming. In a non-randomized evaluation, most of 114 adults who received this treatment reduced symptoms by the 8th session, and improvements were maintained through a 6-month follow-up. In one of the only randomized trials, Du et al. (2010) assigned 56 youth in Shanghai to 8 sessions of CBT or a no treatment control. Internet use decreased similarly in both groups, but those assigned to CBT had improvements in time management skills and reductions in psychological symptoms relative to controls. Jager et al. (2012) describe an ongoing study in Germany comparing CBT to a wait-list control. That study will be the first large scale randomized study of treatment for “Internet addiction,” but it is not limited to persons with gaming problems, who differ substantially from those with general “Internet addiction” in terms of demographics, comorbidities, severity and course (Kiraly et al., 2014; Ko et al., 2007; Li et al., 2014; van Rooij et al., 2010).

This study focuses on developing an intervention specifically for gaming, the Internet-based activity most likely to lead to clinically significant problems (Kiraly et al., 2014; Ko et al., 2007; Li et al., 2014; van Rooij et al., 2010). IGD is conceptualized similarly to other common problems in adolescence, including substance use disorders, and these disorders are strongly influenced by family systems and respond well to approaches that target family interactions and improve both monitoring and contingencies around the problem behaviors (Hogue & Little, 2009; NIDA, 2014). Further, few youth or young adults seek mental health treatment generally or addictions treatment specifically (Alegria et al., 2011; SAMHSHA 2009ab). More often, parents express concerns, and decades of research on adolescent substance abuse treatment demonstrate the strongest evidence base for family-based interventions (Tanner-Smith et al., 2013; Waldron & Turner, 2008). Therefore, this study will focus on treating parents along with their children.

Similar to the substance abuse field, parental involvement, particularly monitoring and supervision, can have strong influences on children's game playing (e.g., Lin et al., 2009; Young, 2009). Allowing video game systems in a child's bedroom relates to more frequent playing (Roberts & Foehr, 2008) and greater use of violent and mature-rated games (Olson et al., 2007). Parental guidelines related to playing time are inversely associated with excessive playing as well. Carlson et al. (2010) surveyed 7,415 youth and found those who reported their parents had well-defined rules regarding playing were less likely to play excessively than those whose parents did not. In addition, frequent monitoring of behaviors is associated with improved outcomes along many dimensions (e.g., Michie et al., 2012; Steinberg et al., 2013). In a longitudinal study of parental monitoring of children's media usage including game playing, greater monitoring had benefits on academic performance, social functioning and sleep (Gentile et al., 2014). The intervention we developed teaches parents, as well as children, to monitor game playing and to establish and maintain clear expectations. It provides communication skills training and also assists parents in restructuring home environments to be less conducive toward game playing and to encourage other recreational activities. Borrowing from effective behavioral family interventions for substance use disorders (Meyers et al., 1998; Miller et al., 1999; Stanger et al., 2009; Waldron et al., 2007), the treatment also encourages use of positive contingencies for non-game playing behaviors. In an uncontrolled study of brief family therapy for IGD, Han et al. (2012) found improvements in family cohesion were related to decreases in gaming along with increases in caudate nucleus activity in response to affection stimuli, suggesting a role for family therapy and a possible biological mechanism underlying response to it.

This stage 1 pilot study is designed to assess feasibility, acceptability and effect sizes of a family based behavioral intervention for reducing gaming in youth. Consistent with guidelines for psychotherapy development (Carroll & Onken, 2005; Onken et al., 2014; Rounsaville et al., 2000), it incorporates all components of Stage 1 research such as identifying a target population and outcomes, outlining therapeutic procedures based on theoretical models, and specifying and measuring potential change mechanisms. As such, this study will provide a strong foundation for informing future research and clinical treatment with this population.

This study is **innovative** on several levels: 1) it is the first randomized trial of an intervention specifically directed toward IGD; 2) it examines potential mechanisms of change, including environmental changes (removal or relocation of devices in the home) and monitoring gaming, participation in alternate activities, and family functioning and communication; 3) it assesses comorbidities of gaming, substance use, and related conditions and evaluates changes in these symptoms over time; and 4) it is the first to evaluate psychometric properties of a parental assessment tool based on the DSM-5 IGD criteria, a critical aspect for diagnoses of youth. Results will provide valuable information on the nature, course, and treatment of this new "addictive disorder."

Preliminary studies. This team has extensive experience in areas of direct relevance to this proposal. First, Dr. Petry has received nearly 20 years of continuous NIDA funding to develop and evaluate behavioral therapies for drug use disorders. She was also awarded the first NIH grant for treatment of another non-substance addictive disorder-- gambling disorder. Her work on gambling is internationally renowned (see biosketch).

Second, Dr. Petry has adapted behavioral therapies for use with adolescents and youth (e.g., DP3-DK097705; Godley et al., 2014; Petry et al., 2009,2015bc) and is joined by adolescent clinical psychologists: Drs. Zajac and Chang. Dr. Chang has 15 years' experience treating adolescents in family therapy, and Dr.

Zajac has a NIDA-funded K23 to evaluate behavioral therapy for transition age youth with drug use disorders. She also served as the director of an adolescent substance abuse clinic at the Medical University of SC.

Dr. Cash and Ms. Rae are leading authorities on treating IGD. They founded the first residential program dedicated to treating this condition and recognize the need for earlier, family-based interventions. As consultants, they will provide invaluable input to the therapy manual and advice on clinical issues.

Finally, Dr. Petry was at the forefront of efforts for including IGD in the DSM-5. As the primary representative to the APA Substance-Related Disorders Workgroup with expertise in behavioral addictions, she led the subcommittee on non-substance addictions and wrote the text for this condition that the Board of Directors approved and included in the DSM-5 (APA, 2013; Petry & O'Brien, 2013). Dr. Petry also collaborates internationally with experts in IGD (Petry et al., 2014, 2015a; Rumpf et al., 2015) and has edited a book (Petry, 2015).

Approach

Subjects will be recruited by ads directed at parents, e.g., "Has your child developed problems from playing video games too much?" Staff will inform callers that the study involves both parent and child participation.

Inclusion criteria are: (1) parent/guardian of a 10-19 year old residing in the same household ≥8 months/year; and (2) child meets DSM-5 IGD criteria by self-report or by parent report (see below and Human Subjects).

Exclusion criteria are parent or child has a significant other mental health condition that may impact response to treatment (active suicidality, psychosis), and parent or child is unable to attend 6 sessions over 8 weeks.

Child age range spans early to late adolescence, and residential criteria ensure the child lives primarily with the target parent (allowing for visitation of divorced parents, but not boarding students). The child must meet DSM-5 IGD criteria via the self-reported or parent-reported VGDS or semi-structured interview. The self-report version of the VGDS has established psychometric properties (Rehbein et al., 2015) and we have found evidence of validity of the parent-version of the VGDS in our current pilot study, as evidence by concordance between the parent VGDS and a clinical interview administered by doctoral level clinicians.

Informed consent. Persons who call and appear eligible will be invited to an in-person assessment, at which we will obtain written informed consent from parents and children aged 18 years; those <18 will provide assent.

Assessments. Staff will administer instruments with established psychometric properties (when available) to assess study entry criteria, hypothesized mechanisms of action, and outcomes. Most measures will be collected at baseline (BL), week 4, post-treatment, and a week 24 follow-up. There are some exceptions. The demographic interview will be administered at BL only. The AUDIT, DUDIT, BRIEF, BIS-11 (parent and child versions), SRS, and the DERS will be administered at BL and post-treatment only. The SCID, TLFB, and the T-ASI will be administered at BL, post-treatment, and week 24 only. Abbreviated versions of some measures will be administered at the follow-ups. Some variability in the scheduling of the follow-ups will be allowed to account for variability between families in how quickly they complete the 6 sessions of therapy.

Both parents may participate and will complete the parental assessments (est. 2 hours), and both (when available) can participate in the therapy, consistent with how family therapy is typically provided. Both parents and children will complete a therapy satisfaction form post treatment. Children and parents will receive $30 in gift cards for completing the baseline assessment and the 4 week follow-up and $50 in gift cards for the post-treatment and 24 week follow-up interviews (up to $160/family member).

Family members may complete their follow-up measures through the survey function of REDCap in advance of their in-person meetings. When the research assistant calls to schedule the follow-ups, participants will be given the option of receiving the survey link through e-mail, receiving a paper copy of the assessments by mail, or completing the measures when they arrive for their in-person meeting. The week 4 assessment can be completed in its entirety by the participant at home through REDCap or the mail, unless the participant prefers an in-person meeting. Study visits may be completed over the phone if needed.

Parents will provide:

- basic demographics, including age, SES, gender, and education of parents and child, and indices of the child's school functioning: grades, tardiness, absences and disciplinary issues

- modified Treatment Service Review (TSR; McLellan et al., 1992) questionnaires about histories and current treatments received (of the child). Additional questions specific to treatment for video game addiction treatment will be administered at all time points.
- Parents will provide data about their own psychological symptoms (Brief Symptom Inventory [BSI]; Derogatis, 1992)
- emotional regulation (Difficulties in Emotion Regulation Scale [DERS]; Gratz & Roemer, 2004).
- Parents' perceptions of their child's gaming will be evaluated by a revised VGDS (Rehbein et al., 2015), which includes items about types and locations of all gaming devices in the home and frequencies with which they monitor their child's gaming behaviors.
- a semi-structured clinical interview using DSM-5 criteria (SCID; Petry et al., 2014), assessed over past year and past 2 months at BL and past 2 months at other time points.
- Parents will complete a TimeLine Follow-Back (TLFB; Sobell & Sobell, 1990) of the child's gaming, time spent watching others play online (e.g., YouTube, Twitch), and sleep
- Child's participation in extracurricular activities will be assessed via a checklist from the Michigan Study of Adolescent Life Transitions study (MSALT; Eccles & Barber, 1999)
- A modified version of the Parenting Style Index (Steinberg, Lamborn, Dornbusch, & Darling, 1992), which includes a checklist of types and frequencies with which they use tangible rewards (money, goods) and verbally praise their child
- the Brief Family Assessment Measure (BFAM; Skinner et al., 1995, 2000)
- Perceived Social Support Scale (PSSS; Procidano & Heller, 1983).
- Child Behavior Checklist (CBCL; Achenbach, 2001), an index of child competencies and internalizing and externalizing symptoms
- Conners' Parent Rating Scale—Revised (CPRS-R; Conners, 2008), a measure of emotional and behavioral problems, including ADHD.
- Parents will assess their own quality of life via the Quality of Life Inventory (QoL: Frisch et al., 1992)
- quality of life of their child using the caregiver version of the Questionnaire for Measuring Health-related Quality of Life in Adolescents (KINDL-R; Ravens-Sieberer, 2000).
- AUDIT (Saunders et al., 1993) a brief questionnaire about their own alcohol use
- DUDIT (Hildebrant, 2105) a brief questionnaire about their own substance use
- parent version of the Behavior Rating Inventory of Executive Functioning (BRIEF; Guy et al., 2004) will evaluate executive function of their child
- the Social Responsiveness Scale, a brief autism spectrum screen (Constantino et al., 2003)
- the Barrett Impulsiveness Scale (BIS-11), a measure of their own impulsivity (Patton, Stanford, & Barratt, 1995)

Children will complete parallel instruments:

- VGDS (Rehbein et al., 2015), including items about types and locations of gaming devices in the home,
- DSM-5 based clinical interview for IGD (SCID; Petry et al., 2014);
- TLFB of days and durations of play, time spent watching others play online (e.g., YouTube, Twitch), and sleep
- participation in extracurricular activities via the MSALT assessment (Eccles & Barber, 1999) and school functioning.
- A modified version of the Parenting Style Index (Steinberg, Lamborn, Dornbusch, & Darling, 1992), which includes a checklist of types and frequencies of tangible rewards (money, goods) and verbal praise provided by parents will be administered
- indices of social support and family communication including the PSSS
- BFAM
- Teen Addiction Severity Index (Kaminer et al., 1999);
- Social Phobia and Anxiety Inventory for Children (Beidel et al., 1995);
- Center for Epidemiological Studies-Depressed Mood scale (Radloff, 1977);
- Pittsburgh Sleep Quality Index (Buysse et al., 1989).
- the Youth Self-Report (Achenbach, 1991) of emotional and behavioral problems,

- DERS (Gratz & Roemer, 2004),
- quality of life KINDL-adolescent version (Ravens-Sieberer, 2000)
- the adolescent version of the Barrett Impulsiveness Scale (BIS-11), a measure of their own impulsivity (Patton, Stanford, & Barratt, 1995)

Randomization. After baseline, families will be randomized via a computerized algorithm (Stout et al., 1994) to groups below. Groups will be stratified by child age (≤15 or over), sex, and parents participating (one vs. both).

A. Referral for care. Therapists will explain that gaming problems often co-occur with other mental health problems, and effective treatment for the latter may reduce gaming as well. Therapists will refer parents to local support groups such as Department of Mental Health and Addiction Services and National Association for Mental Illness support groups. Adolescents will be referred for appropriate services as well, e.g., depression, social anxiety, ADHD, or substance use depending on co-occurring problems.

B. Referral plus Behavioral therapy will consist of referral for other services plus 6 family sessions (adapted from Petry, unpublished; Appendix). In Session 1, therapists will review baseline information, refer for other services, and orient participants to treatment. They will remind parents that although they cannot prevent playing entirely, they can better understand why and when their child is playing and alter their reactions toward it, which may decrease the extent of play and problems. Therapists will describe methods to re-arrange the home to better monitor and be less conducive toward playing; this may include altering locations of or removing some (or all) gaming devices from the home. Therapists will review a tracking form and instruct parents how to and benefits of closely monitoring their child's playing. Children will be asked to keep their own log as well.

Session 2 will focus on goal setting for gaming, ranging from 0 to ≤12 hrs/week (Council on Communications and Media, 2013). It will begin with a review of past weeks' logs. Therapists will troubleshoot difficulties with monitoring and concordance of child and parent logs. They will review patterns of play to identify high-risk times and days, and circumstances that may have impacted playing. Therapists will outline norms related to game playing and media use in general to guide selection and maintenance of reasonable goals.

In session 3, therapists will review logs and how actual gaming aligned or not with goals. Therapists will also introduce the concept of replacing high-risk game playing times with alternate activities. The parent, and child, will review a list of recreational activities the child does or may enjoy. At least 2-3 activities will be identified to occur at high risk gaming times in the upcoming week. Over the next week, participants will continue recording gaming and times in which parents encouraged alternate activities and the child's responses.

Session 4 will review goals in light of increasing alternate activities, and therapists will introduce the concept of rewarding non-game playing behaviors this session. They will outline possible rewards, and parents will develop a concrete plan to reward their child for not playing during high-risk times in the next week.

Session 5 will continue discussions of rewards for non-gaming playing behaviors. Therapists will review rewards provided and encourage continued rewarding of non-game playing and other positive behaviors in the future. The session will focus on communication styles, and the parent and child will role play assertive communication skills, especially as they relate to game playing.

Session 6 will review progress and discuss long-term goals. Therapists will remind parents to continue to monitor play, offer alternatives to play, and reward non-gaming behaviors to prevent relapse. The therapist will help parents to problem solve any barriers to successful implementation of the behavior plan.

Six sessions will be scheduled about once per week over 8 weeks, allowing for missed or re-scheduled sessions. The goal will be to complete 6 sessions over 8 weeks; no reschedules will occur after week 12. Sessions may be completed over the phone if needed.

Study visits and follow-up assessments will be scheduled as described above and we have many procedures in place to schedule and complete visits as planned (e.g., collection of contact information, reminder calls and cards, etc.). However, some flexibility is required to protect participants from unnecessarily limiting study procedures to a specific calendar day. If a participant misses an appointment, research staff will attempt to contact and reschedule, but we anticipate late and missed appointments.

Training and therapists: Treatment will be conducted by Drs. Zajac, Chang, and a post-doctoral fellow. Training and supervision will consist of didactics, role plays and review of audiofiles of role-plays and actual sessions. Tapes will be rated for general skills and intended content by a modified Yale Adherence Competence Scale (YACS; Carroll et al., 2000). Therapists will begin treating patients once they score good or better on YACS items on role plays. Once recruitment begins, we will ask participants to consent for audiotaping, although they may participate in the study without taping (see Human subjects). If YACS item ratings on tapes fall below a mean of "good," additional training and supervision will occur. Drs. Chang and Zajac have already met these adherence levels as part of a previous study using the same intervention. Any additional therapists will be trained and supervised by either Dr. Zajac or Chang.

Design considerations:

Why this control condition? We considered other control conditions but elected this one because it allows for evaluation of follow-up effects (unlike waitlist conditions), controls for some expectancy effects (unlike no treatment controls), and increases ability to ascertain benefits of the behavioral family therapy if they exist. A therapist attention control condition is premature in Stage 1 research (Rounsaville et al., 2000), but represents an important next step if we note benefits in this pilot trial.

Why not focus on abstinence? Abstinence from gaming will be encouraged for youth who are willing to consider a short- or long-term (or indefinite) goal of no game playing. Although we expect that many parents will desire that their child refrain entirely from playing, most children probably will not share this goal. To avoid alienating youth in these situations, therapists will review "normal" play (Gentile, 2009) and negotiate reasonable limits between parents and youth using recommended guidelines (Council on Communication Media, 2013), which may include an initial period of no gaming. Therapists will also encourage parents and youth to re-arrange the home environment to be less conducive toward gaming (e.g., removing gaming equipment from bedrooms) and to better identify and monitor play (e.g., by setting timers or parental controls) especially for devices that can be used for purposes beyond gaming (i.e., computers, smartphones).

Why this duration? A 6-week intervention allows for coverage of topics thought important for altering gaming behavior (Council on Communication Media, 2013). It is long enough to demonstrate change if it is efficacious and but not so long that topics will become redundant. It is also within the range of other brief family-based therapies (e.g., Coatsworth et al., 2001), and an even shorter 3-week (5 session) family intervention has shown promise in decreasing gaming (Han et al., 2012). Given the treatment's emphasis on developing parenting skills, the 6-week protocol allows time between sessions for parents to practice new skills at home and problem solve barriers to implementation. If this IGD treatment is efficacious in reducing gaming problems, it is likely that best practices will be to integrate it alongside other evidence-based treatments to address co-occurring substance use and mental health disorders. However, the purpose of the current study is to evaluate the feasibility, acceptability, and preliminary effect size for this IGD approach. If parents or children recommend more or fewer sessions in the therapy satisfaction questionnaire, subsequent studies can alter the duration.

Data analysis

Enhancing reproducibility. Instruments chosen are reliable and valid, although some gaming specific instruments are new, and this study will assess their psychometric properties (see below). Careful training of evaluators will precede study initiation, and assessment interviews will be audiotaped and rated for reliability when participants agree to taping (see Human Subjects; >90% of participants agree to taping in our trials). Evaluators blind to treatment conditions will conduct assessments, and obtaining information from multiple sources (parent and child) will allow for assessment of concordance between reports (see below).

Primary aims. We will examine baseline (BL) indices and other services received during treatment using the Treatment Service Review, and any differences between groups that relate to outcome can be used as covariates in subsequent analyses. Analysis will be conducted on an intent-to-treat basis, using all randomly assigned subjects. We will evaluate during treatment (BL to post-treatment) and longer-term (follow-up) effects.

Aim 1: To evaluate the feasibility and acceptability of this intervention, the proportion assigned to the intervention who complete all 6 sessions will be examined, as will parent and child ratings of satisfaction.

Aim 2: To examine the effect size of the intervention on reducing game playing days and durations of play, we will analyze TLFB data collected at each assessment period, with the greater report of parent or child

used for each day. Hierarchial linear models (HLM; Gibbons et al., 1993; Raudenbush & Bryk, 2002) will compare differences between groups over time. HLM is specifically designed for repeated measures designs with missing data, allowing for intra-subject serial correlation and unequal variance and covariance structures over time by incorporating available trend data for each individual with information on the group from which the subject is drawn. Maximum likelihood estimation enables analyses to be performed for the full trial without having to drop subjects with incomplete data, and both continuous and dichotomous variables can be analyzed. The model will include factors representing group, time, and their interaction, along with any important covariates.

We will also compare proportions of subjects by group who are no longer gaming problematically, i.e., child reports no current DSM-5 IGD criteria and/or <5 criteria, and parent confirms no more problems for the most conservative approach. Logistic regressions will include important demographics and baseline indices of distress and severity of problems in Step 1. Step 2 will add treatment to determine if it adds unique variance in predicting outcomes after controlling for baseline indices.

Power analyses. This pilot is designed to assess feasibility, acceptability, and effect sizes. Thirty subjects per group are sufficient to address the former, to estimate effect sizes, and to detect moderately large differences of Cohen's (1988) *d* = 0.65 with Type I error rate α=.05, Type II error rate β=.20, and power [1-β] = .80. If medium or larger effect sizes are noted, a larger randomized trial will be proposed to assess long-term efficacy.

Exploratory aims are to evaluate potential mechanisms of actions of the intervention including: changes in number and location of gaming devices in the home, frequency of monitoring child's game playing (via self reports in both groups, and confirmed by completed logs in Group B), child's participation in alternate activities (ACC), and parental rewarding of child behaviors and family communications (PSSS, BFAM scores). Following recommendations of Morgenstern and Longabaugh (2000) for assessing mediation, Model 1 examines whether the treatments engender differential outcomes on gaming indices (i.e., Aim 2 above). Model 2 will test if potential mediators change differentially over time by condition. For these analyses, a composite indicator for each construct will be utilized (e.g., summary scores of number/location of gaming devices, monitoring frequencies, ACC, PSS and BFAM scores). Model 3 will examine partial correlations between post-treatment scores on these indices and gaming outcomes, after controlling for baseline scores. If these three models show significant effects, the final model will assess associations between these variables and gaming outcomes. Step 1 of this model will include baseline scores of the potential mediator(s). In step 2, treatment group will be entered, and in step 3, post-treatment scores of the mediator(s) will be included, and resulting predictive power of treatment condition examined. If treatment is no longer significant and the post-treatment mediation term is significant, criteria for full mediation are met. Although we do not expect to find full mediation with this sample size, potential mediators with medium or higher effect sizes in Models 2-3 will be considered for future evaluation and inclusion in this intervention, if main effects of treatment are noted (Aim 2).

We will also assess effect sizes on secondary outcomes, e.g., substance use, psychosocial functioning and symptoms, sleep, and quality of life. HLM, outlined above, will compare groups over time on these indices.

Finally, we will evaluate the psychometric properties of a semi-structured diagnostic interview based on the DSM-5 IGD criteria as well as the parent version of the VGDS. Briefly, internal reliabilities of symptoms and diagnostic criteria will be calculated using Cronbach's alpha. Parent and child reports on self-report and interviews will be compared using Shrout and Fleiss intraclass correlations for continuous variables and Kappa's for diagnostic assessments, with respect to endorsement of specific criteria and diagnosis. For both parent and child versions, we will also examine correlations with TLFB gaming behavior and other indices as we did previously (Rehbein et al., 2015) to determine convergent validity. Thus, this project allows for initial psychometric evaluation of a parent report measure and a structured clinical interview for IGD in youth.

Future directions. This study will inform future research and treatment for IGD. In terms of assessment and diagnosis, psychometrically robust assessment tools are critically needed for research in epidemiological and clinical samples, and this study is a step toward developing and validating such tools.

In terms of treatment, if the intervention is feasible and acceptable and leads to changes in gaming beyond that of the control condition, we will propose a larger scale, longer-term study. We can modify the intervention based on experiences by removing unhelpful sessions, and adding to those that appear to lead to clinically important changes and that show promise for mediating changes in gaming. Even in the absence of

treatment-specific effects, these results will provide valuable information about how gaming and psychosocial functioning change over time. Given increasing scientific, clinical, and public interest in this condition, this study is timely and critical for addressing diagnostic and clinical concerns related to this new "addictive disorder."

Human Subjects

1. RISKS TO THE SUBJECTS
   a. Human Subjects Involvement and Characteristics.

i.Inclusion Criteria.

Subjects will be 60 parents/guardians and their children. The inclusion criteria for the families are: the parent is the legal guardian of a 10-19 year old residing in the same household ≥8 months/year with the child, and the child meets DSM-5 IGD (APA, 2013) criteria by parent or child report.

This age range for children spans early to late adolescence. Although we considered including younger or older children, interventions may differ substantially for children at more extreme ends of the age spectrum. In particular, younger children may benefit more from complete removal of gaming devices as they may not need them for school work assignments, and older children will be less likely to be living with parents and thereby may not benefit from an intervention aimed at both parents and children. The proposed age range spans that which will be most likely to benefit from a family intervention.

The residential criterion ensures that the child lives primarily with the participating parent so that changes in the parent's behaviors are more likely to impact the child's gaming behaviors. This criterion allows for regular and frequent visitation of children to homes of divorced parents. However, if custody is equally split between parents and only one participates in the intervention, then changes in one parent's behaviors are going to be less likely to impact changes in gaming behaviors than if the child resides the majority of the time with the participating parent. This living requirement also ensures that the child resides with the parent most of the year, because children boarding away at schools, for example, will be less likely to benefit from this intervention than those who reside primarily with their participating parent(s). When two parents/guardians are available, both will be encouraged to participate in the treatment, but to enhance generalization of the interventions we felt it impractical to mandate participation of both parents/guardians.

Gaming will be defined by playing video games on any electronic device including computers, smartphones, televisions, tablets, and gaming consoles or handheld devices (Xbox, Nintendo, Wii, etc). Consistent with the DSM-5 description of IGD (APA, 2103), the gaming need not be over the Internet, but the vast majority of individuals with IGD play primarily Internet-based games (e.g., Rehbein et al., 2010). Responses from the child or parent that indicate the child meets DSM-5 criteria for IGD via the VGDS or semi-structured interview of DSM-5 criteria will qualify the family for study *participation* because best methods for diagnosis are not yet well established. The DSM-5 criteria (APA, 2103; Ko et al., 2014; Petry et al., 2014) and the VGDS (Rehbein et al., 2015) have some established psychometric properties. These criteria allow for a broad range of participation and mirror issues present when families present for treatment, while still ensuring sufficient homogeneity in the sample that clinically significant harms have arisen from gaming.

ii. Exclusion Criteria.

Participants will be excluded if parent or child has a significant *major* other mental health condition that may impact response to treatment (including but not limited to active suicidality, psychosis, bipolar disorder), or parent or child is unable to attend 6 weekly sessions over 8 weeks.

Individuals with major acute psychiatric illnesses that may impact ability to participate in the study may not participate. Anyone with active suicidal intentions, psychosis, or bipolar symptoms, for example, will be referred for appropriate psychiatric care. If symptoms subside and patients are receiving appropriate psychiatric care, they may be reconsidered for participation in this study when stable. Parents or children with other mental disorders (substance use disorders, depression, anxiety, attention deficit hyperactivity disorder) may participate, as these other conditions are common among those with IGD. Participants will be referred for treatment of these conditions as indicated. Receipt of

other mental health treatment before and during the study period will be documented in the Treatment Services Review, and any differences in mental health services that occur between groups and relate to outcomes can be controlled in analyses.

If either parent or child is unable to attend sessions regularly over the next two months, they cannot participate, or will be reassessed for eligibility after returning from extended vacations or while away.

iii. Ineligible Patients.

Some patients will choose not to enroll or will not qualify for this study. They will be referred to other facilities (e.g., other substance abuse treatment clinics or detoxification services, mental health treatment facilities) as appropriate.

iv. Treatment Clinics, Services, and Patient Population.

Patients will be recruited primarily from advertisements and word of mouth referrals directed at parents in the greater Hartford, CT, area, e.g., ""Worried about how much your child plays video games?" We have successfully recruited hundreds of persons with gambling disorder, a disorder with a lower base rate than IGD, into clinical trials using similar techniques (e.g., Petry et al., 2006). The study team will ensure that the opportunity to participate in this project is made maximally available to populations at-risk for Internet gaming disorder. To do this, we will systematically distribute flyers and place ads widely to ensure that we are not over-sampling from a single population. For example, we will share our flyers with school counselors in both affluent and disadvantaged areas and run ads in local papers and on radio stations that have wide distribution areas. Past research indicates that males will likely be overrepresented in our sample, and less is known about the prevalence of IGD in different racial/ethnic and socioeconomic groups. However, we will regularly (i.e., after every 10 participants recruited) evaluate the distribution of gender, race/ethnicity, and socioeconomic status of our sample and make adjustments to our recruitment efforts based on these results.

We will also advertise the study at health fairs and at local programs that provide adolescent substance abuse prevention and intervention and at schools.

Treatment will be provided at the University of Connecticut School of Medicine, located just outside of Hartford, CT, with easy access by highway and bus lines to local communities. Given the lack of any specific treatment for IGD in this densely populated region, we anticipate no difficulties recruiting 60 families into this study.

b. Sources of Materials. Research material includes parent and child self reports from interviews, questionnaires, and observation of patients by study staff. None of these materials will be available to legal, educational, or employer representatives. Data obtained for research purposes will be at no cost to patients.

c. Potential Risks. Risks associated with participation in this research study include:

i. Disappointment if not assigned to one's preferred treatment group;
ii. Discomfort from being asked questions about gaming, alcohol and drug use, and psychosocial problems;
iii. For those assigned to the brief family behavioral intervention, standard discomforts associated with participating in family therapy, including disagreement or discord.
iv. Potential breach of confidentiality.
v. For those assigned to the brief family behavioral intervention, potential discovery of illegal behaviors on the part of the youth due to increased parental monitoring of Internet activity.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a. Recruitment and Informed Consent.

Informed Consent: A trained research staff member (Bachelors level or above), under supervision of the PI, will obtain informed consent. All potential subjects will receive an explanation of this study protocol, its potential risks and benefits, and alternative treatment available. Following resolution of any questions, parents/guardians and adult children (i.e., age 18) who agree to participate will be asked to sign the study

consent form and HIPAA document. A signed copy of the consent and HIPAA forms will be given to each participant. Assent will be obtained from children under the age of 18, and both child and parent must agree to participate prior to collection of study data or randomization to a condition. As noted above, individuals who choose not to participate or who are deemed ineligible will be referred for other services as indicated.

An audiotaping section within the consent form will be utilized for recording of interactions between research staff and study patients, including baseline and follow-up interviews and therapy sessions. These audiofiles are utilized only for quality control procedures, to rate staff according to set standards in interview and treatment administration. Patients may participate in the study even if they do not choose to allow audiotaping (in our prior and ongoing studies, less than 5% of patients refuse audiotaping, and in this case both child and parent must agree or taping will not occur). The audiotaping consent section will explain that the purpose is to rate the staff member's interviewing and treatment administration skills.

b. Protection Against Risks. The following will protect against potential risks:

i. Random group assignment is used, and about half of families will be assigned to the referral alone condition and half to the referral plus brief family behavioral therapy condition. These proportions will be outlined in the informed consent form, and patients will be made aware that they have about a 50% chance of being assigned to the family behavioral therapy condition. Patients may voluntarily end study participation if they are dissatisfied with their assignment.

ii. The interviews and sample collections are brief, patients may skip questions or take a break if uncomfortable, and the particular instruments chosen are intended to minimize discomfort.

iii. A trained and supervised doctoral level therapist will deliver the intervention. Discord or disagreements between children and parents will be addressed in therapy, and one full session of the treatment is devoted toward improving communication skills.

iv. All data will be coded by number, not name, and a "key" form will be kept in a separate locked file cabinet. No information will be provided about the patients enrolled in this study to anyone outside of the clinical and research teams, except in emergency situations (e.g., patient deemed a threat to him/herself or others) or as required by law (e.g., child abuse/neglect). The study therapists are all doctoral level with substantial experience handling crises. If a therapist learns of potential abuse/neglect, they will notify the Connecticut Department of Children and Families (DCF) as required by law. If a therapist has concerns about potential suicidal or homicidal ideation, the therapist will conduct a comprehensive risk assessment and, if deemed necessary, the participant will be transported immediately to the emergency room for acute evaluation and treatment. Within the research context, research assistants may also hear indications of risk of harm to self or others or abuse/neglect. RAs will be well-trained on how to handle these situations. Specifically, the RA will immediately contact the PI, study coordinator, or study therapist who will assess safety and manage the crisis directly or instruct the RA on how to address risk, including (if necessary) arranging for transportation to an emergency room or reporting concerns about abuse or neglect to DCF.

Audio data will be collected digitally, will be stored on a password protected secure server, and destroyed at the end of the study; only research personnel will review the audio files for training, supervision, and adherence monitoring purposes. As noted earlier, an audiotaping section within the consent form will be used in the study, and patients may participate in the study without allowing audiotaping. All audio files will be labeled by number, not name, and the "key" form will be kept separate in a locked file cabinet.

v. It is possible that the increased monitoring of Internet activity that is part of the behavioral treatment may lead to uncovering illegal Internet activity on the part of the youth. During the informed consent procedure, youth and parents will be informed of this risk. It will also be made clear to the parents and youth that any information disclosed to the research team that indicates that the patient is a threat to him/herself or others will be reported as required by law to the Connecticut Department of Children and

Families (DCF). See 2biv above for details. It is possible that other behaviors (e.g., buying/selling drugs, gambling) that are illegal but do not require mandated reporting may be uncovered by increased parental monitoring. Although these situations do not represent a threat to confidentiality, they may lead to loss of the patient's privacy and could cause increased conflict in the parent-child relationship. This risk is similar to that in adolescent substance abuse treatment, when parents are encouraged to increase monitoring through random urine drug screens and room searches. This risk will be mitigated by 1) as noted above, informing both parent and youth about this potential risk as part of the informed consent procedure; 2) closely following mandated reporting laws in handling this information; 3) teaching skills in treatment (e.g., communication) that can help parents and youth negotiate conflict situations; and 4) provision of individualized referrals to help address any conflict or symptoms that persist. Of note, these risks are similar to those that would occur in outpatient family-based treatment in the community, which commonly focuses on increased parental monitoring and supervision of children's behaviors.

c. Potential Benefits of the Proposed Research to the Subjects and Others.

The anticipated benefits to participants in the study include careful evaluation of the child's game playing, substance use and psychosocial and family functioning, and a potential for reducing their game playing. Parents and children will each receive $30 in gift cards for the intake and 4 week follow-up and $50 for the post-treatment and 4-month follow-ups. Total compensation is up to $160 per family member.

Benefits to society include a potential improvement in the effectiveness of treatment for Internet gaming disorder.

d. Importance of the Knowledge to be Gained. The potential risks of these treatments are minor compared to the risk incurred by Internet gaming disorder. The risk/benefit ratio appears favorable.

Detailed Data and Safety Monitoring Plan

1. Brief description of the protocol: This study will be one of the first clinical trials examining the efficacy of a brief family-based intervention for Internet gaming disorder (IGD), which has been introduced as a Substance-Related and Addictive Disorder in Section 3, Conditions for Further Study, in the fifth edition of the Diagnostic and Statistical Manual for Mental Disorders (DSM-5). This psychotherapy development study will evaluate feasibility, acceptability, and effect sizes of a behavioral intervention designed to help parents reduce gaming problems in their children. Sixty concerned parents and their children will complete parental and self-report inventories and structured diagnostic interviews regarding the child's gaming behaviors, substance use and psychosocial functioning. Participants will be randomized to either a control condition consisting of referral for mental health issues and family support services or to the same plus a 6-week family-based behavioral intervention designed to assist with better monitoring and regulating the child's game playing behaviors and encouraging and rewarding alternatives to game playing. Gaming and other problems will be assessed pre-treatment, mid-treatment, at the end of treatment, and at a 4-month follow-up. This study is unique in evaluating initial psychometric properties of a parental version of a measure that uses the DSM-5 criteria for IGD in a clinical sample, and it will also assess associations of IGD with substance use, psychological symptoms, and family functioning over time. Most importantly, this study will be the first randomized trial of an intervention designed to reduce gaming problems, and results are likely to guide future research and treatment efforts related to this condition.

2. Primary and secondary outcome measures: Primary dependent variables are: a) feasibility of the intervention as evidenced by the proportion of patients assigned to the intervention who complete all 6 sessions as well as parent and child ratings of satisfaction and b) number of game playing days and durations of play. Secondary analyses will examine proportions of subjects by group who no longer meet diagnostic criteria for IGD, substance use, psychosocial functioning and symptoms, sleep, and quality of life.

3. Inclusion/exclusion criteria. Study inclusion criteria are: (1) parent/guardian of a 10-19 year old residing in the same household >8 months/year; and (2) child meets DSM-5 IGD criteria by self-report or parent report.

Exclusion criteria are: (1) parent or child has a significant other mental health condition that may impact response to treatment (active suicidality, psychosis), and (2) parent or child is unable to attend 6 sessions over 8 weeks. Only minimal exclusion criteria will be used to ensure that the sample is as representative of adolescents with IGD as possible. Because autism spectrum disorders, attention deficit/hyperactivity disorder, and other learning or developmental disorder conditions are common among adolescents with IGD, individuals with these conditions will
not be excluded unless their disorder is so severe that it is likely to impact their ability to participate in the treatment.

4. Sample size. Participants will be sixty parents and their children. This pilot is designed to assess feasibility, acceptability, and effect sizes. Thirty subjects per group are sufficient to address the former, to estimate effect sizes, and to detect moderately large differences of Cohen's (1988) *d* = 0.65 with Type I error rate α =.05, Type II error rate β =.20, and power [1- ß] = .80. If medium or larger effect sizes are noted, a larger randomized trial will be proposed to assess long-term efficacy.

5. List of participating enrolling clinics. Patients will be recruited from the greater Hartford, CT area. Treatment will be provided at the University of Connecticut School of Medicine and other community sites if transportation becomes a barrier.

6. Projected timetable. Project start-up, including programming the interviews in the REDCap system and training of a research assistant and study therapists, will occur during the first month following receipt of the award. In addition, initial review of the therapy manual by the consultants will occur during month 1. Recruitment efforts will begin in month 2 and continue through month 18 of the award. The final participants will be recruited in month 18 to allow for the 4 month follow-up and for data analysis and manuscript preparation.

7. Target population distribution (e.g., women, minorities, etc). IGD primarily affects adolescent males. Thus, we expect that males will be overrepresented among the children participating in the study. We expect to recruit both mothers and fathers, but we expect that mothers will participate in the study more often than fathers will. Less is known about the prevalence of IGD in different racial/ethnic and socioeconomic groups. The study team will ensure that the opportunity to participate in this project is made maximally available to populations at-risk for IGD. To do this, we will systematically distribute flyers and place ads widely to ensure that we are not over-sampling from a single population. For example, we will share our flyers with school counselors in both affluent and disadvantaged areas and run ads on the Internet, in local papers and on radio stations that have wide distribution areas.

8. Data acquisition and transmission. Instruments chosen are reliable and valid, although some gaming specific instruments are new, and this study will assess their psychometric properties. Careful training of evaluators will precede study initiation, and assessment interviews will be audiotaped and rated for reliability when participants agree to taping (see Human Subjects; >90% of participants agree to taping in our trials). Evaluators blind to treatment conditions will conduct assessments, and obtaining information from multiple sources (parent and child) will allow for assessment of concordance between reports (see below).

9. Data entry methods. Procedures for data processing, management, and analysis are developed and refined. Interviews will be administered by a trained research assistant, who will enter data via a laptop computer using REDCap, a secure online data entry platform. The interview is programmed to check data at the time of entry to ensure that entered values are within the specified range and that items are not inappropriately skipped.

10. Data analysis plan. We will examine baseline (BL) indices and other services received during treatment using the Treatment Service Review, and any differences between groups that relate to outcome can be used as covariates in subsequent analyses. Analysis will be conducted on an intent-to-treat basis, using all randomly assigned subjects. We will evaluate during treatment (BL to post-treatment) and longer-term (follow-up) effects.

Aim 1: To evaluate the feasibility and acceptability of this intervention, the proportion assigned to the intervention who complete all 6 sessions will be examined, as will parent and child ratings of satisfaction.

Aim 2: To examine the effect size of the intervention on reducing game playing days and durations of play, we will analyze TLFB data collected at each assessment period, with the greater report of parent or child used for each day. Hierarchial linear models (HLM; Gibbons et al., 1993; Raudenbush & Byrk, 2002) will compare differences between groups over time. HLM is specifically designed for repeated measures designs with missing data, allowing for intra-subject serial correlation and unequal variance and covariance structures over time by incorporating available trend data for each individual with information on the group from which the subject is drawn. Maximum likelihood estimation enables analyses to be performed for the full trial without having to drop subjects with incomplete data, and both continuous and dichotomous variables can be analyzed. The model will include factors representing group, time, and their interaction, along with any important covariates.

We will also compare proportions of subjects by group who are no longer gaming problematically, i.e., child reports no current DSM-5 IGD criteria and/or <5 criteria, and parent confirms no more problems for the most conservative approach. Logistic regressions will include important demographics and baseline indices of distress and severity of problems in Step 1. Step 2 will add treatment to determine if it adds unique variance in predicting outcomes after controlling for baseline indices. See section 4 above for power analysis.

Exploratory aims are to evaluate potential mechanisms of actions of the intervention including: changes in number and location of gaming devices in the home, frequency of monitoring child's game playing (via self reports in both groups, and confirmed by completed logs in Group B), child's participation in alternate activities (ACC), and parental rewarding of child behaviors and family communications (PSSS, BFAM scores). Following recommendations of Morgenstern and Longabaugh (2000) for assessing mediation, Model 1 examines whether the treatments engender differential outcomes on gaming indices (i.e., Aim 2 above). Model 2 will test if potential mediators change differentially over time by condition. For these analyses, a composite indicator for each construct will be utilized (e.g., summary scores of number/location of gaming devices, monitoring frequencies, ACC, PSS and BFAM scores). Model 3 will examine partial correlations between post-treatment scores on these indices and gaming outcomes, after controlling for baseline scores. If these three models show significant effects, the final model will assess associations between these variables and gaming outcomes. Step 1 of this model will include baseline scores of the potential mediator(s). In step 2, treatment group will be entered, and in step 3, post-treatment scores of the mediator(s) will be included, and resulting predictive power of treatment condition examined. If treatment is no longer significant and the post-treatment mediation term is significant, criteria for full mediation are met. Although we do not expect to find full mediation with this sample size, potential mediators with medium or higher effect sizes in Models 2-3 will be considered for future evaluation and inclusion in this intervention, if main effects of treatment are noted (Aim 2).

We will also assess effect sizes on secondary outcomes, e.g., substance use, psychosocial functioning and symptoms, sleep, and quality of life. HLM, outlined above, will compare groups over time on these indices.

Finally, we will evaluate the psychometric properties of a semi-structured diagnostic interview based on the DSM-5 IGD criteria as well as the parent version of the VGDS. Briefly, internal reliabilities of symptoms and diagnostic criteria will be calculated using Cronbach's alpha. Parent and child reports on self-report and interviews will be compared using Shrout and Fleiss intraclass correlations for continuous variables and Kappa's for diagnostic assessments, with respect to endorsement of specific criteria and diagnosis. For both parent and child versions, we will also examine correlations with TLFB gaming behavior and other indices as we did previously (Rehbein et al., 2015) to determine convergent validity. Thus, this project allows for initial psychometric evaluation of a parent report measure and a structured clinical interview for IGD in youth.

11. <u>Quality assurance plan</u>: All research staff will be thoroughly trained and supervised regarding administration of interviews and completion of all necessary forms. Some measures will be entered directly into REDcap, an online data entry system that allows for direct input of data. REDCap allows for restriction of response values to insure that responses entered are valid and fall within the specified range. REDCap also prompts interviewers if responses are missing, thus greatly improving the accuracy of data collection. Finally, REDCap allows for direct download of complete data into a variety of software programs, including Excel and SPSS.

In addition, the project coordinator reviews at least 5% of the entered data for accuracy. Research assistants regularly audio-record their research interviews, and the project coordinator or other study staff listens to these recordings to insure accuracy of administration of interviews and recording of data in REDcap. If any specific variables are found to be consistently problematic, the project manager and research assistant will implement a specific training action plan to resolve the problem. The project manager is responsible for study documentation, including data correction and electronic data files. Prior to the conduct of the final analyses, the raw data will undergo extensive examination by the PI or project coordinator.

12. Reporting mechanisms of AEs/SAEs to the IRB, FDA, and NIDA. Types of SAEs in this population are as follows: (a) onset of clinically significant suicidal ideation, intent or action; (b) onset of clinically significant homicidal ideation, intent or action; (c) deterioration of mental status to an extent that requires inpatient hospitalization or overnight stay at an acute treatment facility. All SAEs will result in the completion of an SAE Form within 48 hours to the Project Coordinator. Deaths and possibly study related SAEs will be reported immediately to the PI and within 72 business hours to the NIH project officer. We will follow our IRB's standard policy on reporting of SAEs, which is to report all serious, unexpected related to possibly related AEs to the IRB within 5 working days.

An Adverse Events Monitoring Form will be adapted from one being used in our ongoing trials. This form collects detailed information about all adverse events, how they were handled, and their potential relationship to study participation. The procedures for SAE reporting also include written documentation using the clinical notes related to the adverse event and specific forms detailing the event with a sign-off by appropriate supervisory personnel.

Other adverse events, such as suicidal ideation that does not require hospitalization, will also be recorded on an Adverse Events Monitoring Form. Clinically significant increases in gaming or other problems detected at follow-ups will result in referrals for further treatment.

An ongoing database of adverse events will be maintained by the study coordinator. About once per month, in research team meetings, all events that occurred in the previous month will be reviewed. In addition and according to university policy, the local IRB maintains records of adverse events, and records are sent to NIH per policy. Aggregate data on reports of adverse events are reviewed on at least an annual basis by the IRB for study continuation according to their established policies. Any temporary or permanent suspension of patient accrual will also be reported to NIH. We anticipate that unexpected and possibly study-related SAE's will be rare, because patients will be receiving a psychosocial intervention.

13. Reporting mechanism of IRB actions to NIDA. The PI will be responsible for informing NIDA of any actions taken by the Institutional Review Board as a result of its regular or special reviews of the project.

14. Report of changes or amendments to the protocol. The PI will receive approval from the NIDA project officer prior to making any major changes to the study protocol (unless there is an immediate safety concern) and also provide timely reporting to the NIDA Project Officer of any changes in the IRB approval status, and other major problems or issues that could have a significant impact on participants.

15. Trial stopping rules. A decision to discontinue the study will be based primarily on serious adverse events (SAEs). The study will be stopped if unexpected and possibly study-related SAEs occur in 15% or more of the study sample or the trial appears futile to continue (e.g., unacceptably high rates of study refusal or withdrawals).

16. Conflict of interest. The PI and the research team do not have any conflicts of interest to report.

17. Potential risks and benefits for participants. The risks associated with participation in this research study are minimal but include: (1) disappointment if not assigned to one's preferred treatment group; (2) discomfort from being asked questions about gaming, alcohol and drug use, and psychosocial problems; (3) for those assigned to the brief family behavioral intervention, standard discomforts associated with participating in family therapy, including disagreement or discord. (4) potential breach of confidentiality; and (5) for those

assigned to the brief family behavioral intervention, potential discovery of illegal behaviors on the part of the youth due to increased parental monitoring of Internet activity.

The following will protect against potential risks:
(A) Random group assignment is used, and about half of families will be assigned to the referral alone condition and half to the referral plus brief family behavioral therapy condition. These proportions will be outlined in the informed consent form, and patients will be made aware that they have about a 50% chance of being assigned to the family behavioral therapy condition. Patients may voluntarily end study participation if they are dissatisfied with their assignment.

(B) The interviews and sample collections are brief, patients may skip questions or take a break if uncomfortable, and the particular instruments chosen are intended to minimize discomfort.

(C) A trained and supervised doctoral level therapist will deliver the intervention. Discord or disagreements between children and parents will be addressed in therapy, and one full session of the treatment is devoted to improving communication skills.

(D) All data will be coded by number, not name, and a "key" form will be kept in a separate locked file cabinet. No information will be provided about the patients enrolled in this study to anyone outside of the clinical and research teams, except in emergency situations (e.g., patient deemed a threat to him/herself or others) or as required by law (e.g., child abuse/neglect). The study therapists are all doctoral level with substantial experience handling crises. If a therapist learns of potential abuse/neglect, they will notify the Connecticut Department of Children and Families (DCF) as required by law. If a therapist has concerns about potential suicidal or homicidal ideation, the therapist will conduct a comprehensive risk assessment and, if deemed necessary, the participant will be transported immediately to the emergency room for acute evaluation and treatment. Within the research context, research assistants may also hear indications of risk of harm to self or others or abuse/neglect. RAs will be well-trained on how to handle these situations. Specifically, the RA will immediately contact the PI, study coordinator, or study therapist who will assess safety and manage the crisis directly or instruct the RA on how to address risk, including (if necessary) arranging for transportation to an emergency room or reporting concerns about abuse or neglect to DCF.

All audiorecordings will be stored digitally on a password protected secure server and destroyed at the end of the study; only research personnel will review the recordings for training, supervision, and adherence monitoring purposes. An audiorecording section within the consent form will be used in the study, and patients may participate in the study without allowing audiorecording. All audio files will be labeled by number, not name, and the “key” form will be kept separate in a locked file cabinet.

(E) It is possible that the increased monitoring of Internet activity that is part of the behavioral treatment may lead to uncovering illegal Internet activity on the part of the youth. During the informed consent procedure, youth and parents will be informed of this risk. It will also be made clear to the parents and youth that any information disclosed to the research team that indicates that the patient is a threat to him/herself or others will be reported as required by law to the Connecticut Department of Children and Families (DCF). See 17D above for details. It is possible that other behaviors (e.g., buying/selling drugs, gambling) that are illegal but do not require mandated reporting may be uncovered by increased parental monitoring. Although these situations do not represent a threat to confidentiality, they may lead to loss of the patient’s privacy and could cause increased conflict in the parent-child relationship. This risk is similar to that in adolescent substance abuse treatment, when parents are encouraged to increase monitoring through random urine drug screens and room searches. This risk will be mitigated by 1) as noted above, informing both parent and youth about this potential risk as part of the informed consent procedure; 2) closely following mandated reporting laws in handling this information; 3) teaching skills in treatment (e.g., communication) that can help parents and youth negotiate conflict situations; and 4) provision of individualized referrals to help address any conflict or symptoms that persist. Of note, these risks are similar to those that would occur in outpatient family-based treatment in the community, which commonly focuses on increased parental monitoring and supervision of children’s behaviors.

18. Collection and reporting of SAEs. See Section 12.

19. Management of SAEs or other study risks. As noted above, SAEs will be documented and reported on a regular basis to the project director, the PI, the IRB, and NIDA as indicated. Discussions of SAEs will occur during monthly meetings between the study staff and the PI will be available to have more frequent meetings about SAE reporting as needed. During the monthly meetings, the PI and research staff will examine and discuss any SAEs and AEs over the past month as well as patterns of AEs and SAEs that have occurred over the course of the study. Other information related to study risks, including retention data and any participant complaints, will also be reviewed and discussed during these meetings. This information will guide decision making about whether recruitment should continue unchanged, whether a protocol amendment is needed to mitigate risks, or whether recruitment needs to be stopped pending further investigation. If the study needs to be stopped due to safety concerns, the IRB and NIDA will be promptly informed within 72 hours.

20. Plans for interim analysis of efficacy data. Because sample size is relatively modest (i.e., effect sizes are unlikely to be large enough to detect differences during interim analyses) and safety risk is quite low, we are not planning to conduct a preliminary analysis of accumulating efficacy and safety data by treatment assignment.

21. Responsibility for data and safety monitoring. The Principal Investigator, Co-Investigators, other study personnel, and the Institutional Review Board (IRB) will provide safety oversight for the project. The PI, Co-Is, and study personnel will review safety data about monthly and make any decisions about modifications or stoppage of the trial as noted in section 19. The PI will also be responsible for conducting a literature search on treatments for IGD annually to identify any findings that might influence study procedures or conduct. The PI will report any information related to unanticipated risks or new information that might change the risk-benefit ratio to the IRB and NIDA Project Officer. This information may come from the current study or new findings from other studies. Any changes in the protocol or consent as a result of this information will be promptly reported to the NIDA Project Officer.

22. Frequency of DSM reviews: The PI meets about monthly will research staff to monitor study progress. The informed consent process, fidelity to inclusion and exclusion criteria, and the integrity of the overall data and safety monitoring plan are also reviewed in these meetings. Problems identified during monitoring will lead to an immediate corrective plan and possible reporting to the IRB and NIDA Project Officer, depending on the problem.

23. Content of DSM Report. Reports will include data that inform progress of the study, including baseline demographics, adverse events data, and accrual status. In addition, a database of AEs and SAEs will be maintained by the study coordinator. About once per month, in the research team meetings, all adverse events will be reviewed that occurred over the prior month, as well as over the course of the trial. In addition, the local IRB maintains records of AEs and SAEs. All SAEs are reviewed and records sent to NIDA and the IRB per their standard policies.

A DSM report will be sent to NIDA on an annual basis, at the same time as the Annual Non-Competing renewal. The categories include: 1) description of any non-administrative changes in the study protocol; 2) baseline sociodemographic characteristics of new enrollees; 3) any new quality assurance problems or changes; 4) any new regulatory issues; 5) summary of all AEs/SAEs and any related changes to the consent form or study protocol; 6) any significant protocol violations and deviations, and any corrective actions undertaken to eliminate future occurrences; and 7) summary of the literature review conducted in the prior year to assess for any newly reported risks associated with IGD interventions.

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