Study Title: GamerFit: A Digital Intervention to Improve Physical Activity and Sleep Behaviors in Youth with Psychiatric Diagnoses

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GamerFit: A Digital Intervention to Improve Physical Activity and Sleep Behaviors in Youth with Psychiatric Diagnoses

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Project Summary

More than 1 in 4 children receive at least one psychiatric diagnosis (PD) before age 17. These youth face significantly elevated chronic disease risk including high prevalence of obesity, which is propelled by low physical activity (PA) levels, poor sleep, and social isolation. Unhealthy PA and sleep behaviors not only increase preventable chronic disease risks, they also worsen the cognitive and behavioral functioning challenges these youth experience. The goal of "GamerFit" is to test the delivery of a theory-based mHealth app that utilizes social support, exergaming, and telehealth coaching to improve PA levels, sleep, and psychiatric symptoms among youth participants (ages 13-17 y) with PD. In order to aid future intervention optimization, we will randomize up to 65 participants with at least one PD (in the RCT), with about half using the GamerFit app with weekly telehealth coaching sessions andabout half using only a commercial healthy habits app as a comparator group. The GamerFit app will provide access to a menu of exergames, progressive PA and sleep plan, integrated self-monitoring, pre-recorded videos addressing healthy PA and sleep habits, and motivational text messages to help users meet PA and sleep guidelines over 12 weeks. The project leverages our pilot data on exergaming and telehealth coaching to improve PA in youth with PD, and our interdisciplinary team has expertise in developmental psychology, PA and sleep intervention design, technology-based health promotion, and app development. The major research question is: Is a 12-week exergaming and telehealth coaching intervention, delivered via a smartphone app, an acceptable, feasible and effective method to improve PA and sleep behaviors in youth with PD?

The specific aims are as follows: Specific Aim 1: To examine feasibility and acceptability of the 12-week GamerFit intervention delivered through a mobile app to youth with PD and their parents. Specific Aim 2: To test the hypothesis that the 12-week GamerFit intervention delivered through a mobile app will improve PA levels and sleep quality and duration compared to a comparator group that uses an unstructured healthy habits tracking app. Exploratory Aims: To test the hypothesis that the 12-week GamerFit intervention delivered through a mobile app will improve mood, behavioral regulation, and perceived social isolation and support compared to the comparator group; and to test the hypothesis that behavioral effects will be sustained at week 16 (i.e. 4-weeks after the end of the intervention). We will also work with clinicians to explore approaches to incorporating the app, specifically PA prescriptions, into psychiatric treatment plans. This project impacts the field by testing the delivery of a theory- and evidence-based exergaming and telehealth coaching intervention targeting multiple health behaviors in youth with PD via a low-cost app.

Specific Aims

About 1 in 4 children receive at least one psychiatric diagnosis (PD) before age 17.[1] These youth face significantly elevated chronic disease risk[2-4] including high prevalence of obesity,[5-7] which is propelled by low physical activity (PA) levels[8,9] and poor sleep.[10,11] They are often excluded from organized sports and community exercise programming due to symptoms associated with their PD,[8,9,12] display unhealthy sleep behaviors such as falling asleep with screens and having irregular bedtimes,[11] and report experiencing extreme loneliness and social isolation that exacerbate physical inactivity and poor sleep.[13] Unhealthy PA and sleep behaviors not only increase preventable chronic disease risks, they also worsen the cognitive and behavioral functioning challenges these youth experience.[14] Increasing PA levels and sleep quality in youth with PD can effectively improve mood, behavioral regulation, and socialization.[15,17] Unfortunately, traditional in-person interventions have failed to engage youth with PD because of social stigma, inability to sustain adolescents' interest, and limited parental financial and time resources to support engagement.[18] Also, more than half of youth with PD have multiple diagnoses,[19] so existing behavioral interventions targeting PA or sleep in single diagnosis populations are of limited generalizability. Use of novel technologies in conjunction with disability science theoretical frameworks such as the Empowerment Model[72, 73] has shown promise in improving engagement in either PA *or* sleep interventions among youth with heterogeneous PD[20-22] by providing the tools and social support for sustained behavior change. Yet none have concurrently targeted *both* PA and sleep in youth with PD despite evidence of positive bidirectional relationships between sleep and PA that potentially amplify improvements to PD symptoms.[23]

Digital games are particularly attractive to youth given research on leisure time preferences,[74] including exergames (video games that integrate physically active play) and virtual rewards for positive reinforcement of behavioral changes.[24,25] However, these technology-centered interventions may still perpetuate social isolation, as adolescents play and engage with them in their homes, often alone. Integrating a live "coach" who interacts with the youth and parent over telehealth may be an effective approach to overcome the isolation of technology by increasing social support, remotely delivering tailored intervention content in a way that is acceptable to youth, and helping parents stretch limited resources to support their child's engagement. Further, an app-based coaching platform may provide a nexus for integrating health behavior promotion within clinical treatment plans that are aimed at alleviating PD symptom severity.[27] Therefore, mHealth/telehealth interventions to jointly improve long-term PA and sleep behaviors in youth with PD may be effective tools to both decrease chronic disease risk and improve mental health.

The goal of "GamerFit" is to test the delivery of a theory-based mHealth app utilizing telehealth coaching, exergaming, and on-demand exercise videos to increase PA levels and sleep hygiene, to ultimately improve chronic disease risk, behavioral regulation, mood, and perceived PA social support among participants (ages 13-17 y) with PD. The app will also allow clinical partners to explore approaches to incorporating PA and sleep prescriptions into patient treatment plans. We will randomize up to 65 participants with at least one PD; about half will use the GamerFit app with weekly telehealth coaching sessions and about half will only use a commercial healthy habits app (Fitbit app) as a comparator arm. Participants in the GamerFit condition will access a menu of exergames, progressive PA and sleep hygiene plan, integrated PA and sleep tracking and real-time automated feedback, pre-recorded videos using peer modeling to promote healthy PA and sleep habits, and motivational text messages to engage them in 60 minutes per day of moderate to vigorous PA plus 8-10 hours/day of sleep. Participants will also receive weekly live telehealth coaching sessions to help set PA and sleep goals and overcome PA and sleep barriers. Participants in the comparator arm will receive daily reminders to use the Fitbit app to track PA and sleep.

Specific Aim 1: To examine feasibility and acceptability (**primary aims**) of the 12-week GamerFit intervention delivered through a mobile app to youth with PD and their parents.

Specific Aim 2: To test the hypothesis that the 12-week GamerFit intervention delivered through a mobile app will improve PA levels and sleep hygiene, quality and duration (**secondary aims**) compared to a comparator group using an unstructured healthy habits tracking app.

Exploratory Aims: To test the hypothesis that the 12-week GamerFit intervention delivered through a mobile app will improve PA beliefs, mood, behavioral regulation, and perceived PA social support of participants compared to the comparator group, and to test the hypothesis that behavioral effects will be sustained at 4-weeks follow-up. We will also perform formative qualitative research with clinicians to explore approaches to incorporating the app, specifically PA and sleep prescriptions, into psychiatric treatment plans.

This project impacts the field by testing the delivery of a theory- and evidence-based exergaming and telehealth coaching intervention targeting both PA and sleep in youth with PD via a low-cost app. The findings of this R21 will be used to power a larger R01 trial to identify the potential of such an app as a cost-effective and scalable tool that can be seamlessly integrated into clinical and community-based treatment plans.

Preliminary Studies

Barriers to health behavior interventions among youth with PD. mPI Bowling conducted interviews with 23 parents of racially and ethnically diverse children with moderate to severe PD who were attending a therapeutic day school in Boston[38] to understand how PA, diet, sleep and screen-time interventions could be better tailored to this population. Parents reported preferences for home-based, remote interventions, their children's preferences for screen-based PA opportunities (e.g., exergaming, cybercycling), and a need for cost-effective approaches that did not additionally strain the family's financial and logistical resources.

Leisure-time preferences among youth with PD. A recent qualitative study explored leisure-time use among youth with PD.[74]Playing video games was reported as their most common activity; a major theme was that most youth perceived leisure activities as contributing to their mental health and wellbeing. Most activities were done alone; however, rather than describing these activities as isolating, participants said they helped with coping with stress. Leisure activities also gave them confidence in overcoming challenges they faced.

Exergaming and PA. mPI Staiano developed and tested the evidence- and theory-based GameSquad intervention,[50] which utilized an Xbox exergaming curriculum, telehealth coaching sessions delivered through the gaming console, and other theory-based components to produce significant improvements to MVPA and reductions in BMI, blood pressure, and blood lipids over a 6 month period, when tested among a racially and socio-economically diverse group of typically developing youth (n=46) with overweight and obesity.

Adaptation of exergaming and virtual health coaching for youth with PD. mPIs Bowling and Staiano created Adaptive GameSquad by modifying the original GameSquad intervention to meet the specific needs of youth with PD ages 11-17. We found that the approach was feasible and acceptable and that adolescents' participation in the intervention significantly increased both PA and sleep duration compared to a wait-list delay control condition.[82] However, feedback from parents, telehealth coaches and participants indicated that technological challenges with the Xbox-based exergaming, telehealth coaching connections and PA tracking could be greatly reduced or eliminated with the use of an mHealth app that integrated intervention components onto a mobile platform and expanded exergaming choices.

Exergaming and self-regulation in youth with PD. mPI Bowling conducted a study of the effects of cybercycling (an exergame played on a stationary bicycle) on self-regulation among n=103 youth with heterogenous moderate to severe PD, who were attending a therapeutic day school in Boston, MA.[20] Using a

14-week crossover design, participants were randomly assigned by classroom (k = 14) to receive the 7-week aerobic cybercycling PE curriculum during fall or spring. We found that participants experienced statistically and clinically significant reductions (-32% and -51%, respectively) in odds of poor self-regulation and learning-inhibiting disciplinary time out of class when participating in the intervention.

Methodology

Experimental design. We are proposing a rigorous scientific approach using a randomized comparative effectiveness trial with a robust comparator, gold standard measures of primary outcomes including PA and sleep, and blinded data collection and analyses. The prescribed PA builds each week from 10 daily minutes to 60 daily minutes, in keeping with current PA guidelines while ensuring feasibility and acceptability based on prior studies; the prescribed 8-10 hours/day sleep aligns with recommendations.[51]

Study participants. We will enroll up to 68 participants to the Beta Test and Clinical Trial, in total. For the Clinical Trial, we will enroll up to 65 youth with heterogeneous PD, including those with multiple diagnoses, in order to optimize generalizability. Eligibility criteria displayed below are as of the baseline visit for the randomized clinical trial (RCT).

Inclusion criteria (child):

1. 13-17 years of age
2. At least one PD diagnosis (excluding eating disorders) confirmed by parent report of physician diagnosis
3. IQ≥85/no intellectual disability that precludes participation confirmed by parent report
4. Can understand verbal English-language exergaming instructions
5. Physically capable of exercise confirmed by parent report
6. Has access to a smart phone or compatible tablet
7. Willing to download and use the app

Exclusion Criteria (child)

1. Families for whom the mPIs think the study and/or intervention is clinically/medically inappropriate (e.g. developmental delay, or emotional or cognitive difficulties, if the PI believes these factors will interfere with study/intervention participation)

Inclusion Criteria (parent)

1. Willing and able to be present during telehealth coaching sessions (teen < 18 years of age)
2. Can have a competent translator present during coaching sessions if not fluent in English

Inclusion Criteria (clinician)

1. Practicing clinical pediatric mental health provider
2. Willing and able to participate in an English-language focus group

We will use a quota sampling approach and work with clinical recruiting partners who serve diverse populations to achieve racial/ethnic minority representation lacking from many previous studies.

Recruitment. For the RCT, we will recruit and enroll up to 65 youth ages 13-17 with at least one psychiatric diagnosis from the greater Boston, Massachusetts area. Based on our history of successfully

recruiting over 200 youth with psychiatric diagnoses into previous studies including clinical trials, and our potential patient pool of 20,000 from our existing clinical partners, we are confident we will meet our enrollment target of 65 youth over 12 months, which equates to a rolling recruitment target of approximately 5 participants per month. Recruitment services for this clinical trial conducted at Merrimack College and supported by Pennington Biomedical Research Center (PBRC) are overseen by mPI Bowling, coordinated by Co-I Slavet, and supported by the Marketing Coordinator at PBRC. Below we describe in detail the recruitment and retention resources and strategies that we will provide for the proposed study.

Clinical Recruiting Sites. Recruiting at clinical sites will be overseen by Bowling and coordinated by Slavet. Clinicians at established sites that serve over 20,000 children and adolescents with psychiatric diagnosis will provide study information to parents and guardians of eligible participants during clinical visits and ask them to contact study personnel if they are interested in participating or learning more.

Study staff will attend parent and youth support groups to promote the study. If necessary, with written approval from clinical partners, electronic medical records will be searched for potentially eligible patients. We will work closely with each site to tailor recruiting efforts based on each site's policies and preferences. Trained research assistants will screen all incoming calls and emails and use a study checklist to determine study eligibility, assist Dr. Slavet in clinician follow-up, and schedule additional participant screening and consent as described in the research strategy.

Additional Recruiting Strategies. Support for additional recruiting efforts will be provided by the PBRC Marketing Coordinator, who specializes in paid and earned media including print and online marketing communications. She will design flyers and implement social media strategies (e.g., paid ads on Facebook, Instagram, and Twitter) and coordinate outreach on Massachusetts pediatric psychiatric advocacy websites with guidance by Bowling and Slavet. Trained research assistants and Slavet will also conduct local outreach via the Healthy Weight Research Network and through our community partners, and parent support group newsletters. We will also use traditional methods of face-to-face recruiting and flyer drops, targeting community venues for example branches of the local public library, commercial retail outlets, and community parks and recreational facilities, etc. In-person efforts may include, but are not limited to, making announcements about the study, distributing informational materials, and/or demonstrating procedures used in the study.

Procedures

Telephone screen. Research staff will perform a phone screen with parents to determine initial eligibility. At that time a virtual screening and consent visit will be scheduled if appropriate.

Virtual screening and consent visit. A virtual screening and consent visit will be conducted via a HIPAA-compliant video platform and REDCap software. Participants will receive a session link and consent form link via email to review prior to the virtual screen. During the live virtual screen, the trained staff member will review the consent form with the parent and the assent form with the adolescent, allowing time to answer questions. Because of the age of the adolescent, the adolescent will be expected to provide written assent unless the parent or adolescent prefers assent be documented verbally, such as due to a reading or writing deficit. After the parent and child provide written consent/assent, then the staff member will proceed to the data collection. Participants (with parental assistance as needed) will complete the 7-question Physical Activity Readiness Questionnaire for Everyone (PAR-Q+),[52,53] the Depression, Anxiety and Stress Scale-21 item (DASS-21),[83] and the Patient Health Questionnaire (PHQ-9).[91] Children who meet or exceed the threshold for severe depression symptoms will be referred to the participant's usual source of medical care and caregivers alerted. Those who indicate suicidal thoughts/ideation/plans/ actions during screening will be immediately connected to psychiatric care and caregivers alerted. If screened in, parents and participants will be formally oriented during this visit and will receive detailed information on the study purposes, goals, procedures, and timeline. This will include a brief demonstration video of the two intervention arms to enable the parent to confirm eligibility criteria, i.e. that the child is able to understand instructions and perform the recommended exercise. Parents and participants

will receive instructions on how to use the accelerometer, which will be mailed to them or dropped off with printed instructions and a log to collect data prior to the baseline assessment visit. The parent and participant will be scheduled for a Baseline Visit.

Visit 1/Baseline visit (Week 0). Baseline assessments may be conducted following eligibility determination at screening but with the goal of conducting within approximately 2-3 weeks of the virtual screening and consent visit; they will occur remotely unless otherwise requested by the parent. Parents will return the accelerometer, and anthropometric, demographic and psychosocial measures will be completed.

Randomization. In advance of enrollment, Co-I and statistician Dr. Beyl will generate a gender- (male-identifying/female-identifying/non-binary) stratified randomization and adaptive randomization. After confirmation of eligibility, at the end of the baseline visit or on an alternative date, non-blinded study staff will inform the participant and parent of randomization group and will then guide participants to open and navigate the GamerFit app or Fitbit comparator app on the participant's device based on randomization. For the GamerFit arm, a unique code is assigned to each family such that the child and parent can both download and install the app on their phone, and parents can view the communication and content that their child sees. For participants in the GamerFit arm, the study staff member will schedule the first telehealth coaching session. All families will also be scheduled for their Visit 2 (W12).

End of treatment visit (Visit 2, W12) and follow-up (Visit 3, W16). Using the same participant/parent location choices, blinded study staff will conduct assessments at the end of intervention, including anthropometry and psychosocial measures. Parents will return the accelerometer at these visits, which will be mailed or dropped off to them 2-weeks earlier for the participant to wear for 7 days. If the accelerometry data do not meet wear-time criteria, the participant will be asked to re-wear the accelerometer unless deemed infeasible by the study team or mPIs. A window of +/- 2 month will be accepted for the W12 and W16 visits.

Study Schedule of Procedures

Study Procedures	Reporter	Pre-screen (W-3)	Screening Visit (W-2)	Baseline (W-1)	Readiness /Randomization Visit (W0)	Intervention (W1-12)	Visit 2 (W12)	Visit 3 (W16)
Phone/Web Pre-Screen	Parent	X						
Consent/Assent	Adolescent /Parent		X					
PAR-Q+	Parent		X					
DASS-21, PHQ9	Adolescent		X					
Accelerometer	Adolescent		X^D	X^R		X^D	X^R, X^D	X^R
Adolescent Height	Parent			X				
Adolescent Weight	Parent			X				
Demographics & Medical Hx	Parent		X					
Sleep hygiene/quality (ASHS)	Adolescent			X			X	X
Lifestyle Habits	Adolescent			X			X	X
Affect (PANAS)	Adolescent			X		X (Adapted/Daily)	X	X

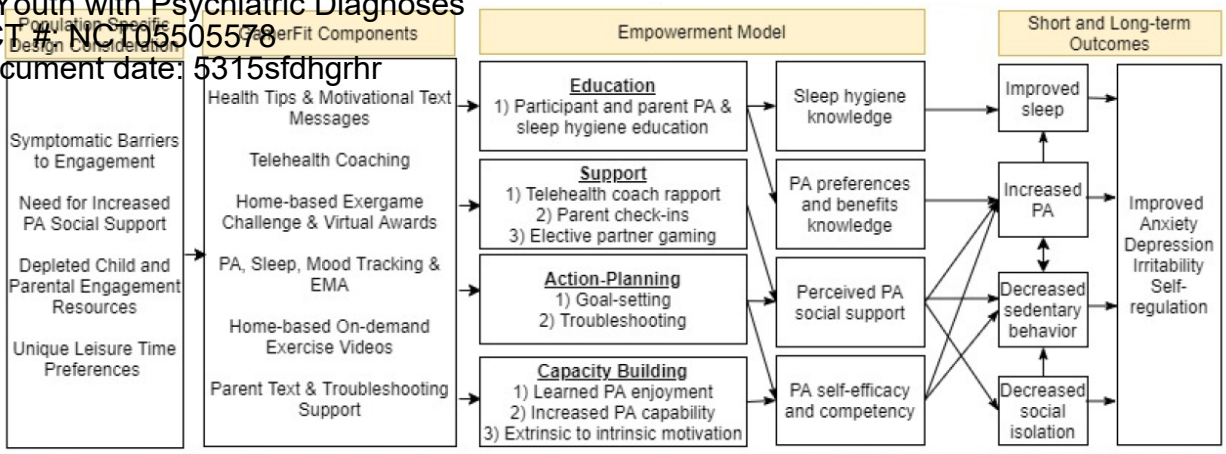
BRIEF-2	Adolescent /Parent			X			X	
Adolescent Exercise Benefits, Barriers, Preference, Regulatory/Self-Efficacy, Situational	Adolescent			X			X	X
Exercise Benefits and Barriers (EBBS)	Parent			X			X	X
Social Isolation and Support	Adolescent			X			X	X
Health-related Quality of Life	Adolescent			X			X	X
Readiness Interview	Adolescent /Parent				X			
Randomization					X*			
App Download & Set-up					X			
Fitbit Wear						X		
Acceptability Surveys	Adolescent /Parent					X (Weeks 4#, 8, 12)	End-of-intervention	
End-of-Intervention Surveys	Adolescent /Parent						X	

[D]Accelerometer distribution. [R]Accelerometer Return. SV and Visit 1 may be combined. Prior to Visit 2 and Visit 3, the accelerometer will be distributed approximately 2 weeks prior to the scheduled study visit. * Randomization will occur after all eligibility is confirmed at the end of Visit 1 or on an alternative date. #Week 4 acceptability surveys include an adapted exit survey for the teen to complete.

Description of the GamerFit App

The GamerFit app is an integrated e/mHealth delivery platform developed by the research team from the Adaptive GameSquad intervention and features multiple interfaces that coordinate key intervention components that are based on disability-informed empowerment theory[72-73] and tailored to meeting the particular needs of this population (see conceptual model in Figure 1). GamerFit is a app-based, mobile-friendly application, meaning that it can be accessed easily from a smartphone or tablet. The participant interface (Figure 2) will provide youth with: 1) their weekly exergaming challenge menu, 2) PA and sleep tracking via automated Fitbit sync, 3) push notifications to access the coaching video library, 4) EMA assessment of mood in relationship to PA and sleep, 5) EMI logging of sleep, 6) motivational text messaging, 7) the HIPAA-compliant telehealth portal, and 8) text reminders of upcoming intervention tasks (see Table 2 for detailed features by condition). The parents will receive: 1) reminder messages and 2) links to attend coach and participant check-ins

Figure 1. GamerFit Conceptual Model

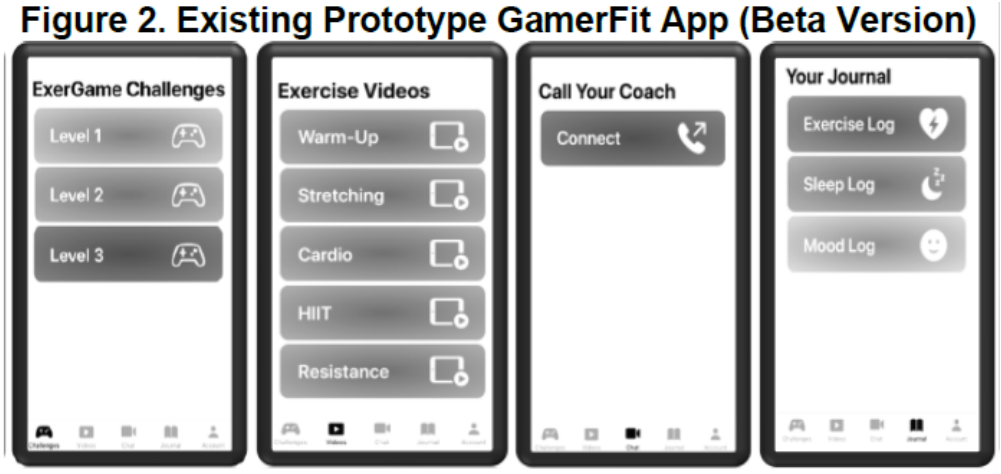


Telehealth coaches will review the weekly PA data and use previous sessions to send additional, tailored motivational messaging to participants. These messages will be tracked to form a messaging bank for future app development. Content developed as part of this study (e.g., motivational messaging algorithms and health tips texts) will be incorporated into the app in the first 6 months of the study. Usability testing will include up to 8 youth-parent dyads, not enrolled in the RCT, who will beta test the app.

Beta Test

We will recruit up to 8 youth ages 13-17 from the Merrimack/Boston area utilizing convenience sampling. The only requirements to participate in the Beta Testing includes age 13-17 and ability to understand/communicate in English, which will be confirmed prior to consenting. Consenting will be performed virtually via a telehealth platform (i.e. Zoom) using an oral consent and assent with both the participant and their parent/guardian. Participants can use their own device for testing or may utilize the study device that can be sent or delivered to their home. A trained staff member will guide the participant through a series of tasks within the GamerFit Beta app and acquire feedback on any usability concerns or constraints. Findings may inform the study team and app developer of potential improvements, bugs, and glitches within the app to correct prior to the RCT, or may indicate areas of focus for the telehealth coaching sessions to orient the users.

Figure 2. Existing Prototype GamerFit App (Beta Version)



GamerFit Condition

Participants in the GamerFit condition will receive a Fitbit device and the GamerFit app on their mobile device and/or computer, following the 12-week exergaming curriculum provided by the app. Each week they will have 3 exergaming sessions using RingFit Adventure and Just Dance for the Nintendo Switch, in order to complete

the required duration of PA. PA duration will build from approximately 10 minutes per session in Week 1 to approximately 60 minutes per session by Week 8 (sustained through Week 12). After each session is completed, a message from a virtual health coach will congratulate them and remind them of at least one positive self-reflection consistent with the education and capacity-building theoretical constructs (e.g., "exercise boosts your brain, so you might be thinking more clearly now" or "exercise is proven to improve our mood so you might be feeling better now that you finished your challenge"). On non-exergaming days, they will receive: a) text reminders for sleep (e.g. 8-10 hours/night, turn off screens 1 hour before bedtime, dim lights, use a consistent bedtime, etc.) and on-demand exercise videos to complete MVPA goals (i.e. 10-60 minutes [escalates throughout the intervention], preferably with a parent, sibling or friend); b) push notifications to watch a prescribed 5 minute video geared towards the health habit of the week; and c) motivational text messages (social support) tailored to their data (e.g. "You reached your goal!" or "You've almost reached your goal! Just get moving for 5 more minutes!"). They will also receive virtual badges and trophies in the app for completing activities and achieving goals. On all days they will receive EMI reminders to log their mood and sleep and sync their Fitbit. Parents will receive texts approximately three times a week reminding them to check that the Fitbit is charged and exergaming challenges are completed.

Participants will additionally receive weekly, live telehealth coaching sessions (approximately 15-20 minutes) with a trained coach to review their data, brainstorm solutions to barriers, learn tailored healthy habits, and receive positive reinforcement for progress. Parents will be required to be present and participate in live telehealth coaching sessions with their child unless the teen reaches age of majority (18) during the trial. In our Adaptive GameSquad study, telehealth coaches reported establishing strong rapport with all participants regardless of diagnosis, age or gender by week 3, allowing the later sessions 4-12 to efficiently deliver tailored support targeted at the health behaviors of greatest challenge to the participant. As in Adaptive GameSquad, coaches will utilize a scripted guide to lead sessions and introduce health tips but will adapt session content to specific participant needs.

Theoretical basis. Social cognitive theory (SCT) informed the development of the original GameSquad.[50] However, parents and youth with PD often have depleted psychosocial reserves due to the lived reality of PD and lack of support and inclusive programming. This presents an enormous barrier to participation and engagement in health behavior interventions. Therefore, GamerFit uses disability-oriented Empowerment Theory in recognition of these challenges.[72] GamerFit acts upon constructs of education, support, action-planning, and capacity-building to elicit sustained PA and sleep behavior change in populations with invisible disabilities.[73] Interacting with live telehealth coaching strengthens support[54] for both youth and parents and effectively delivers tailored education and action-planning, while eliminating burdensome travel logistics. The tailored exergaming curriculum and on-demand exercise videos leverage home-based leisure-time preferences and peer-modeling to build PA enjoyment, self-efficacy and capacity. Finally, integrated PA, sleep and mood tracking/EMI allows participants to connect PA and sleep behaviors to beliefs about symptomatic improvements and ongoing action-planning with coaches.

Comparator Condition

Youth assigned to the comparator condition will receive a Fitbit device (same as the intervention condition) and the Fitbit account activated on their device (e.g. phone/tablet/computer). They will receive instructions on using the PA and sleep tracking features, as well as a booklet of healthy habit tips. They will receive reminders to charge, sync and review their Fitbit data for the duration of the intervention.

Retention and Adherence Strategies

Parents will receive three text messages per week reminding them to check their child's engagement with their PA challenges, sleep goal, ensure Fitbit charging, and remind them of their live telehealth coaching appointment time. Participants will receive daily push reminders through the app, as well as additional weekly

texts and support from their telehealth coach. Our team has experience retaining youth with PD in PA studies and families in mobile-based studies. All 23 youth participants were retained with 90% adherence in the Adaptive GameSquad study,[82] and adherence was 82% in a 12-week PA study in adolescents involving 36 sessions (PI: Staiano).[65] We accommodate families by ensuring that: 1) coaching can be scheduled 6 days/week; 2) participants can access the app 24 hours/day, 7 days/week; and 3) parents can contact research staff with questions or for support.

Assessments

Assessments will be conducted remotely (unless parents request in-person data collection) at Weeks 0, 12 (end of intervention), and 16 (follow-up to test for preliminary evidence of sustained effects). Investigators (except clinical psychologist) and data collectors (except those informing the randomization/guiding the app installation) will be blinded to treatment assignment.

Primary Outcomes. *Feasibility* will be measured as participant accrual, retention, and adherence to the assigned app intervention. For the GamerFit condition, measures will include number of participants recruited and retained, number and minutes of exergame sessions completed per week, minutes of total PA and MVPA per week, number of coaching videos viewed per week, and percentage of live coaching sessions attended. *Acceptability* will be measured via satisfaction surveys delivered to participants and parents through the app/REDCap in Weeks 4, 8 and 12 and an end-of-intervention survey at Visit 2 (Week 12). Surveys will assess satisfaction in multiple domains (overall satisfaction, ease of use, helpfulness of coaching videos/live sessions, etc.) using a Likert scale.

Secondary Outcomes. *Sleep hygiene and quality* will be measured using the validated Adolescent Sleep Hygiene Scale (ASHS), a 32-item self-report measure used to assess adolescent sleep hygiene.[56] The ASHS includes 4 qualitative items to ascertain usual bedtime and wake time on weekdays and weekends and 28 quantitative items that are used to calculate 9 subscale scores: physiological (5 items), cognitive (6 items), emotional (3 items), sleep environment (4 items), daytime sleep (1 item), substances (2 items), sleep stability (4 items), bedtime routine (1 item) and bed sharing (2 items). *Sleep duration and physical activity levels* in Weeks 0, 12 and 16 will be assessed using Actigraph GT3X-BT accelerometer for 7-days, 24 hours/day around the participant's waist. The validity and reliability of accelerometers have been well established. Accelerometers will be initialized to record data in 1-second epochs, and established cut-points will be used to estimate PA intensity levels of light, moderate, and vigorous.[57] A previously published algorithm will be used to differentiate sleep.[58] Activity counts will be used to estimate minutes and percentage of total time spent in light, moderate and vigorous activity using validated equations.[57] SMS messaging will be used to improve wear adherence.[60] We will also include self-reported PA and sleep questions (including the Godin-Shepherd Leisure-Time questionnaire and items adapted from NHANES) in the Lifestyle Habits questionnaire delivered in Weeks 0, 12 and 16, in case PD symptoms (e.g., sensory dysregulation) preclude accelerometer minimum wear time. To assess adherence in the treatment group, weekly minutes of PA will be tracked via the GamerFit app.

Exploratory Outcomes. *Affect* will be assessed using the Positive and Negative Affect Scale Short Form (PANAS-SF) in Weeks 0, 12 and 16, which is validated in this population.[61] Additional ecological momentary assessment (EMA) of affect will be made via the app at randomized algorithmic intervals for assessment in relation to PA bouts. Participants will be prompted to identify their current mood given approximately four choices (fatigued, energetic, depressed, good mood) validated for EMA.[62] *Self-regulation* will be assessed at Week 0 and 12 through parent- and participant-report using the Behavior Rating Inventory of Executive Function, 2nd edition (BRIEF2) which is well-established, commonly used, and validated for use in this population.[63] *PA knowledge and beliefs* will be measured using scales from the Adolescent Physical Activity Perceived Benefits and Barriers Scale (youth) and the Exercise Benefits and Barriers Scale[85] (parents). *Perceived social isolation and social support* will be measured via the NIH Patient-Reported Outcomes

Measurement Information System (PROMIS) scales (social isolation, 4-item, emotional, instrumental and informational support, 12-items total). *Health-related Quality of* Life will be measured using the CDC Healthy Days measure (4-item core module and 5-item symptoms module). Clinical *PA prescription:* Virtual focus groups will be held with clinicians at recruiting sites to gather perceptions of the app as a clinical tool, including review of app features, identification of methods to best aggregate mood and PA data for clinician review, and identification of approaches for incorporation into psychiatric treatment plans. Methodological and analysis details are provided in the "Statistical Design and Power" section. Additional details can be found in Appendix A.

Potential Covariates. *Anthropometry*: BMI is not an outcome; however, due to remote data collection height and weight will be parent-reported at baseline for use as a covariate. *Screen-time/video game use* will be measured via the Lifestyle Habits questionnaire. *Sociodemographic information* will be provided by parents on participant (age, sex, race/ethnicity, grade, PD diagnoses, medication status), parent education, marital status and income.[90]

Statistical Analysis

For the power analysis, we used a two-sample t-test (α=.05, 1-β=.8), assuming up to 20% of participants could drop-out during the study. While the primary aims of this study are the feasibility and acceptability needed for larger future studies, this study is powered on PA, a secondary outcome. Estimates obtained from the Adaptive Game Squad study, which uses a similar intervention, showed a between group difference of 60 +/-72 minutes/day of PA between the intervention and control groups. Based on these estimates, 60 total participants need to complete the study to provide 80% power to test the PA hypothesis. We allow for a slightly higher enrollment (n=65) to ensure participants who have started screening can have the opportunity to enroll once the initial goal of n=60 is reached. Intent-to-treat analysis will be used so all randomized subjects will be retained. General linear models and mixed effect linear model will be used to estimate group effects. Distribution of the responses will be checked based on the Shapiro–Wilk test. Sensitivity analysis will be conducted to determine how the missing data affect the results, using both completers and Markov Chain Monte Carlo algorithm methods.

Study Title: GamerFit: A Digital Intervention to Improve Physical Activity and Sleep Behaviors in Youth with Psychiatric Diagnoses
NCT #: NCT05505578
Document date: 5315sfdhgrhf

Study Timeline

	Year 1 (2022-23)												Year 2 (2023)									
	Month 1 start date	2	3	4	5 jul	6 aug	7 sep	8 oct	9 nov	10 dec	11 jan	12 feb	1 mar	2 apr	3 may	4 jun	5 jul	6 aug	7 sep	8 oct	9 nov	10 dec
App Development and Usability Testing																						
Finalization of Protocol, Surveys and Consents																						
IRB Modification																						
Training of Study Staff																						
Recruitment							10	10	6	6	6	6	6	6	4							
Screening Visits																						
Week 0 Baseline Assessments and Randomization																						
Intervention																						
50% Enrollment Complete																						
100% Enrollment Complete																						
Week 12 End of Intervention Assessments																						
Week 16 Follow-Up Assessments																						
Focus Groups with Clinicians on app utilization in treatment plans																						
Data Collection Complete																						
Data Analysis																						
Paper Submission																						
R01 Submission																						

Data Management

Each participant will be issued an ID number that will be utilized throughout the study. A secure master file linking names, addresses and ID numbers will be maintained in a confidential computer file accessible only to the investigators. Access to data files can be made only with permission of the Principal Investigator. Privacy in the context of this study includes confidentiality of data and personal information. During interviews, measurements, and the study staff will ensure full privacy of participants and will ensure that the data are stored in a secured area. Hard copies of study data will be kept in a secure, locked cabinet at PBRC and electronic copies of study data will be kept in the secure PBRC and REDCap databases. All study staff must be HIPAA certified. Only de-identified data will be used for analysis.

PBRC's Pediatric Obesity and Health Behavior Laboratory, with guidance from Co-I Dr. Beyl, will be responsible for database design, database implementation, and manual data entry of clinic visit data. The research staff will be responsible for managing intervention data using the REDCap secure, web-based

database/survey application. PBRC's Biostatistics Core will cooperate with the data manager who will manage the data entry to ensure data quality.

Protection of Human Subjects

Sources of Materials: Participants will undergo a series of assessments that will provide study data. Research staff will perform a phone screen with caregivers to determine initial eligibility. At that time a virtual screening and consent visit will be scheduled if appropriate. The virtual screening and consent visit will be conducted via HIPAA-compliant video platform and REDCap software. Participants will receive a Zoom session link and consent form link via a REDCap email, allowing them to participate and provide guardian consent/youth assent via a mobile phone, tablet or computer. Caregivers and participants will be formally oriented during this visit and will receive detailed information on the purposes, goals, procedures, and timeline. Caregivers and participants will receive instructions on how to use an accelerometer, which will be mailed to them or dropped off with printed instructions to collect data prior to the baseline assessment visit. Participants will complete the 7-question Physical Activity Readiness Questionnaire for Everyone (PAR-Q+)52,53 and the Depression, Anxiety and Stress Scale-21 item (DASS-21)[83] and the Patient Health Questionnaire (PHQ-9)[91] to determine eligibility, and a baseline assessment visit will be scheduled if appropriate. The PAR-Q+ is a seven-question pre-participation screening tools for physical activity. It is designed to determine whether or not, and to what degree, individuals are able to become more physically active. The DASS-21 is a validated tool for screening depression symptoms in adolescents, with cutpoints for severe and very severe depression.[83] Children who meet or exceed the threshold for severe depression symptoms will also be asked a direct suicidality question from the PHQ9. If a risk of suicidality is indicated, risk management protocols will be immediately activated including staff notifying Dr. Slavet so that the participant can be referred to their usual source of medical care and caregivers alerted.

Baseline assessments will be conducted within approximately 2-3 weeks of the virtual screening and consent visit; they will be conducted remotely. Parents will return the accelerometer via mail or pick-up, and anthropometric, demographic and psychosocial measures will be completed via REDCap. In advance of enrollment, Co-I and statistician Dr. Beyl will generate a gender- (male identifying/ female-identifying/non-binary and racial/ethnic- (white non- Hispanic/non-white or Hispanic) stratified adaptive randomization (see "Statistical Design and Power" for more information). Non-blinded study staff will help download/open the correct version of the app (GamerFit or commercially-available Fitbit app) onto the participant's device based on randomization. Study staff will conduct remote assessments at the end of the intervention (Week 12) and at a follow-up assessment (Week 16). These assessments include self-reported anthropometry and psychosocial measures. Caregivers will return the accelerometer at these visits, which will have been mailed or dropped off to them 2- weeks earlier for the participant to wear for 7 days.

Data are confidentially collected from study participants and are only used for research purposes. All nonelectronic data (e.g., signed consent forms) will be stored in a secure, locked filing cabinet at mPI Bowling's office. The PBRC Computing servers will be used as a central location for data processing and management of electronic data, which will be entered via REDCap and stored in REDCap. REDCap is software that was developed by Vanderbilt University, with collaboration from a consortium of institutional partners and the NIH National Center for Research Resources, for secure, HIPAA-compliant electronic collection and management of research and clinical trial data from multiple sites on a single study. For the purpose of publication and presentation, data are used only in aggregate, and no identifying characteristics of individuals are shared publicly.

Potential Risks: This study does not involve major risks to participants. It is recognized that there are some risks involved in the assessment visits. The risks for physical, psychological, social, or legal harm are minimal for the testing procedures planned for this study. Our research staff members have performed all testing procedures in many studies with no serious adverse events. Adolescents will be asked to engage in physical activity that aligns with public health recommendations and is similar to physical activity they would experience

in daily life, such as in physical education class at school. Risks to individuals who increase physical activity are rare, but could include: temporary shortness of breath similar to moderate exercise, muscle soreness the following day, dizziness, fainting, blood pressure elevation, irregular heartbeat or heart attack, mild irritation of the skin from the wearable accelerometer used to measure physical activity. In addition to the risks listed above for the intervention, participants may experience a previously unknown risk or side effect. Risks associated with study procedures will be continually assessed and monitored throughout the study by the mPIs and the Data Safety Monitoring Board. Pennington Biomedical and Merrimack College has well-defined emergency procedures already in place should any adverse events be encountered.

Adequacy of Protection against Risks

Recruitment and Informed Consent: The participants are child volunteers who will be recruited through referrals and advertisements by healthcare providers with JRI and Triumph Center, among others. Research staff will perform a phone screen with caregivers to determine the child's initial eligibility. At that time a virtual screening and consent visit will be scheduled if appropriate. As stated previously, the virtual screening and consent visit will be conducted via secure, HIPAA-compliant video conference platform and REDCap software. Participants will receive a Zoom session link and consent form link via a REDCap email, allowing them to participate and provide guardian consent/youth assent via a mobile phone, tablet or computer. All questions and concerns will be clarified before consent and assent are obtained. Caregivers and participants will be formally oriented during this visit and will receive detailed information on the purposes, goals, procedures, and timeline. The Health Insurance Portability and Accountability Act Authorization will be provided to parents. Given that the participants in this research include children, all aspects of the study will be explained to the adolescent in understandable terms, and the adolescent's written assent is sought only after the investigator is satisfied that all the adolescent's questions have been fully answered. Adolescents who do not freely give an assent will be excluded regardless of parental permission. Parent(s) will receive an electronic copy of the consent and assent for themselves and for their child.

Protections against Risk: Risks will be minimized by the remote nature of the study, as well as having highly qualified staff members administer all study procedures and evaluations. This is a remote intervention that automatically adheres to ongoing COVID- 19 sanitation and social-distances protocols based on local COVID-19 guidelines. The study staff will not provide ongoing medical care that might become necessary during the course of the study but will be available for study-related emergencies and will refer and help participants obtain appropriate medical care for study related events. Parents of study participants will provide the study team with contact information for their child's medical care during the screening portion of study enrollment, and the Risk Management Manual of Procedures will outline for the study team to forward relevant medical information to the child's healthcare professional for crises or other medical or psychiatric concerns.

Efforts to minimize the potential risk of the assessment methods include frequent monitoring by the investigators to assure that no volunteer suffers any adverse effects from participating in the research. Pennington Biomedical and Merrimack College have well-defined emergency procedures already in place should any adverse events be encountered. Any participant or staff member exposed to blood or bodily fluids will immediately report to the nearest urgent care clinic for assessment and referral to an external occupational medicine provider for prophylactic treatment, if necessary. Proper cleaning and sanitation will be used to prevent irritation from measurement devices like the accelerometer. If irritation persists, devices may be adjusted or removed. Risks associated with study procedures will be continually assessed and monitored throughout the intervention by the Pennington Biomedical Intervention Resource Unit and with consultation of the institution's pediatric medical officer Dr. Sarabeth Broder-Fingert (a developmental pediatrician) and the mPIs Dr. Bowling and Dr. Staiano. Participants with known serious disease will be excluded from the study for their own safety.

All data collected in this project will be subject to the same confidentiality requirements that are in place for our other studies. All volunteers are assured of their confidentiality both verbally and in the informed consent

form. The clinical facilities that house participant records are strictly limited to the staff of the research institution and to research volunteers. This is accomplished by a variety of stringent security measures. Nearly all data are collected via REDCap. Any paper records are locked in the mPI Bowling's secure office. Volunteers' paper records are filed according to ID numbers. All forms in the chart, with the exception of the consent form, display only the ID number. Electronic data storage is similarly restricted with only the principal investigators and authorized persons having access to the databases containing confidential clinical records, i.e. those containing names or other identifying information.

Potential Benefits
Benefits of participating in this study should outweigh the risks. In particular, participants may experience improved physical activity levels and sleep quality. This study promises to provide important information about physical activity promotion for adolescents with psychiatric diagnoses, which will ultimately benefit the population as a whole.

Importance of Knowledge to be Gained
This project impacts the field by testing the delivery of a theory and evidence-based exergaming and telehealth coaching intervention targeting multiple health behaviors in youth with psychiatric diagnoses via a low-cost app (free to the adolescents). The findings can identify the potential of such an app as a cost-effective and scalable intervention tool, while utilizing technology to reduce barriers to recruiting and engagement in healthy behaviors during bouts of remote learning and disruption in psychiatric treatment.

Data and Safety Monitoring Plan
The proposed study involves minimal risks to the participants, but participants are adolescents with at least one diagnosed psychiatric disorder who will be asked to change their physical activity habits, nutrition, sleep, and screen-time over a 12-week period using a smartphone app-based intervention. Therefore, a Data and Safety Monitoring Board (DSMB) will review the protocol and monitor conduct of this study. We will establish a DSMB that will meet once each year (virtually), and we will provide reports to the DSMB prior to each meeting. Data on adverse events and recruitment will be presented. Any significant health problems coming to our attention during the study will be referred to the participant's usual source of medical care, with his/her permission. We will cooperate fully with his/her physician by providing relevant records. The DSMB will be comprised of the Safety Officer, a member with expertise and background in biostatistics for clinical trials, and at least 1 parent of a child with a disability. Dr. Broder-Fingert will serve as the Safety Officer. She will also act as the Independent Monitor, as she is not in either mPI's chain of command and is not directly involved with the study.

I. Study Identification Information
A. NIH Study Number – 1R21HD106465
B. Study Title – GamerFit: A Digital Intervention to Improve Physical Activity, Diet and Sleep Behaviors in Youth with Psychiatric Diagnoses
C. Name of Principal Investigators (PI) – April Bowling, ScD and Amanda E. Staiano, PhD

II. Study Overview
A. Brief Description of the Purpose of the Study – The goal of "GamerFit" is to test the delivery of a theory-based mHealth app that utilizes telehealth coaching and exergaming (i.e. video games that require physical activity), with the goal of acting through the multi-process action control framework to move participants from intention to action to improve physical activity (PA) and sleep among youth participants (ages 13-17 y) with PD. In order to aid future intervention optimization, we will randomize up to 65 participants with at least one psychiatric diagnosis, with about half using the GamerFit app with weekly
telehealth coaching sessions (GamerFit) and about half using only a commercial healthy habits app (Fitbit) as a comparator group. Participants in the GamerFit condition will access a menu of exergames, progressive PA and sleep plan, integrated PA and sleep tracking and real-time automated feedback

through ecological momentary intervention, pre-recorded videos addressing healthy diet and sleep habits, and motivational text messages to engage them in at least 8 hours of sleep and 60 minutes per day of moderate to vigorous PA by week 9 and sustained through week 12. Participants will additionally receive weekly live telehealth coaching sessions to help set PA and sleep goals, overcome barriers, and provide personalized tips. Participants in the comparator arm will receive twice weekly reminders to use an unstructured healthy habits app provided on their mobile device (i.e. the Fitbit app). The remote intervention delivery will reduce barriers to engagement and disruptions to treatment due to COVID-19. Primary study outcomes include feasibility and acceptability of the GamerFit intervention as well as changes in physical activity and sleep levels. Exploratory outcomes include changes in perceived social support and psychiatric symptoms, as well as preliminary evidence of sustained changes in behavioral outcomes at 16-week follow-up. This study does not involve administration of an investigational agent and poses minimal risk to participants. Serious adverse events will be reported to the NIH and to the Pennington Biomedical Research Center (PBRC) IRB.

B. Adherence Statement – The Data Safety Monitoring Plan (DSMP) outlined below for R21HD106465 will adhere to the protocol approved by the Pennington Biomedical Research Center IRB.

III. Confidentiality

A. Protection of Subject Privacy – All study participants are assured of their confidentiality both verbally and in the informed assent and consent forms. All data are identified with a randomly generated identification code unique to the participant. All forms in the participant's chart, with the exception of the consent form, display only the identification code so that names and other personal health information are not linked to study data. All medical records are stored in locked areas. Access to these areas is limited to the clinical support staff and the mPIs of the study.

B. Database Protection – All non-electronic data (e.g., signed consent forms in the rare event REDCap e-consent is not possible to obtain for a study visit) will be stored in a secure, locked filing cabinet at the mPI Bowlings' office. The data computing servers will be used as a central location for data processing and management of electronic data. Electronic data will be stored in REDCap. REDCap is a secure, HIPAA-compliant software that was developed by Vanderbilt University, with collaboration from a consortium of institutional partners and the NIH National Center for Research Resources, for electronic collection and management of research and clinical trial data. REDCap data collection projects rely on a thorough study-specific data dictionary defined in an iterative self-documenting process by all members of the research team. As part of the data dictionary development process, individual fields can be denoted as "identifiers." When exporting a de-identified dataset, these variables are omitted. Additionally, the data export tool also allows for the shifting of dates for a limited data set export. REDCap provides a secure, web-based application that is flexible enough to be used for a variety of types of research, provides an intuitive interface for users to enter data, and has real time validation rules (with automated data type and range checks) at the time of entry. It offers easy data manipulation with audit trails and ad hoc reporting functionality for reporting, monitoring and querying participant records, and an automated export mechanism to common statistical packages (SPSS, SAS, Stata, R/S-Plus). Currently, REDCap installations support electronic signatures by positively identifying the user through a unique username and password combination. Data being analyzed will be exported in de-identified format. Identities of participants will not be revealed in the presentation or publication of any result from this project. All individuals working on this project will undergo IRB and HIPAA training and will be educated about the importance of strictly protecting participants' rights to confidentiality. Participants will be informed of law-mandated instances in which confidentiality could be breached. A strict data management plan will be implemented to ensure overall study integrity and confidentiality.

C. Confidentiality during AE Reporting – Adverse events will be reported to the study mPIs, Project Manager, Data and Safety Monitoring Board, Independent Monitor, and to the PBRC IRB throughout the trial. Adverse event data will be analyzed semi-annually, but serious or life-threatening

adverse events require immediate reporting and follow-up (see Section IV, E). AE reports and annual summaries will not include subject-identifiable material. Each will include the identification code only.

IV. Adverse Event Information
A. Definition - An adverse event (AE) is any untoward medical occurrence in a participant temporally associated with participation in the clinical study. An adverse finding can include a sign, symptom, abnormal assessment (vital signs, etc.) or any combination of these.

A Serious Adverse Event (SAE) is any adverse event that results in one or more of the following outcomes:

- Death
- A life-threatening event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly or birth defect
- Important medical event based upon appropriate medical judgment

B. Classification of AE Severity – AEs will be labeled according to severity which is based on their impact on the participant. An AE will be termed 'mild' if it does not have a major impact on the participant, 'moderate' if it causes the participant some minor inconvenience and 'severe' if it causes a substantial disruption to the participant's well-being. The mPIs will consult with the Clinical Services Director to determine the severity of AEs. We anticipate most adverse events will be "mild" and the participant will be able to resume daily activities within a day or two of reporting the event.

C. AE Attribution Scale – AEs will be categorized according to the likelihood that they are related to the study intervention. Specifically, they will be labeled either related or unrelated to the study intervention, and this relationship will be confirmed by the Safety Officer and/or the study mPIs.

D. Expected Risks – This study does not involve major risks to the participants. All expected risks are minimal and are addressed in the protocol and consent form. Risks will be minimized by having highly qualified staff members administer all study procedures and evaluations, by using standard laboratory techniques and precautions, and through frequent monitoring of study participants to prevent and identify any adverse effects from participating in the research.

All study procedures with expected risks and procedure-specific plans to minimize these risks are listed below:

1. Self-report Instruments – Each parent and adolescent is asked to complete periodic acceptability surveys. Parents/caregivers will complete surveys on the adolescent's sociodemographics and the adolescent's self-regulation abilities, and each adolescent will complete a battery of psychological and behavioral surveys. The parent and adolescent will not be required to answer items if the items make them feel uncomfortable. The adolescent and parent will be provided with a private area to complete these surveys to reduce discomfort or will complete them online.

2. Accelerometry – The adolescent may find the activity monitor uncomfortable to wear; however, the device is small, lightweight, and the belt/wrist-strap can be adjusted to make it as comfortable and easy to wear as possible. For participants with sensory issues that prohibit them from wearing the accelerometer, we will use the self-report measures to estimate baseline and follow-up physical activity.

E. SAE Reporting – SAEs that are unanticipated, serious, and/or possibly related to the study intervention will be reported to the study mPIs and the institution's safety officer, as well as to the Independent Monitor, the PBRC IRB, and the NIH in accordance with requirements. Anticipated SAEs or those unrelated to the study

intervention will be reported to the same individuals/entities in accordance with requirements. Serious adverse events will be reported within 48 hours. Other adverse events that are not serious but are unexpected and are associated with the study procedures will be reported within 10 days.

V. Data Quality and Safety Review Plan and Monitoring

A. Data Quality and Management
1) Description of Plan for Data Quality and Management – The mPIs and project manager will review all data collection forms on an ongoing basis for data completeness and accuracy as well as protocol compliance. A statement reflecting the results of the review will be sent to the NIH in the annual report (non-competing continuation). Any protocol deviations will be reported to the PBRC IRB. Although there are additional reports to be produced by the study coordinator as a result of this DSMP, there are no substantive changes to the study protocol that might require review by the NIH.

2) Frequency of Review– The types of data reviewed and the frequency of review are detailed in the following table (see next page):

Data type	Frequency of review	Reviewer
Subject accrual and protocol adherence	Quarterly	Principal Investigators, Independent Monitor, DSMB Chair
Adverse event rates*	Quarterly	Principal Investigators, Independent Monitor, DSMB Chair
Rates of study completion	Quarterly	Principal Investigators, Independent Monitor, DSMB Chair
Stopping rules report regarding statistical power implications of dropouts and missing data	Yearly	Principal Investigators, Independent Monitor, Biostatistician, DSMB

B. Subject Accrual and Compliance
1) Measurement and reporting of subject accrual, adherence to inclusion/exclusion criteria, protocol adherence, and rates of study completion – Review of subject accrual, adherence to inclusion/exclusion criteria and study procedures as listed in the protocol, and rates of study completion will occur quarterly. These data will be reviewed by the study mPIs and Independent Monitor.
2) Stopping rules – Data on subject accrual and completion rates will be synthesized and evaluated yearly to determine if the study should be terminated. One of the most likely reasons for early termination is the failure to recruit or retain participants; therefore, these data will be evaluated yearly to determine if failure to recruit or attrition is jeopardizing the ability to empirically test the study aims. These data will be reviewed by the study mPIs and Independent Monitor, with consultation from the statistician, and by the DSMB.
3) AE rates and out of range data – AE rates will be evaluated quarterly and out of range data will be evaluated yearly by the study mPIs, Independent Monitor, and DSMB including the Safety Officer, to ensure proper AE reporting and to regulate procedures to protect participant safety.

C. Stopping Rules – This study may be stopped prior to its completion if: (1) adverse effects that significantly impact the risk-benefit ratio have been observed; (2) study recruitment or retention becomes futile; (3) any new information becomes available during the trial that necessitates stopping the trial; and (4) other situations occur that might warrant stopping the trial. The mPIs will include assessments of AEs and recruitment futility in the annual progress report to NIH to monitor these variables. The mPIs will consult with the statistician if

necessary to assess the impact of significant data loss due to problems in recruitment, retention, or data collection.

D. Designation of an Independent Monitor – The Safety Officer, Dr. Broder-Ringert, has been designated as the independent monitor for this study. This individual is not in either mPI's chain of command and is not directly involved with the study.

E. Safety Review Plan – Study progress and safety will be reviewed monthly (and more frequently if needed). Progress reports, including patient recruitment, retention/attrition, and AEs will be provided to the Independent Monitor and reviewed quarterly, as outlined above. An annual report will be compiled and will include a list and summarization of adverse events. In addition, the annual report will address (1) whether adverse event rates are consistent with pre-study assumptions; (2) reason for dropouts from the study; (3) whether all participants met entry criteria; (4) whether continuation of the study is justified on the basis that additional data are needed to accomplish the stated aims of the study; and (5) conditions whereby the study might be terminated prematurely. The annual report will be signed by the study mPIs and Independent Monitor and will be forwarded to the DSMB, PBRC IRB and NIH to review the progress of this study on an annual basis.

VI. Informed Consent

The participants are volunteers that will be originally recruited through Justice Resources Institute (JRI), Triumph Center, and others to both advertise and clinically recruit participants.
Research staff will perform a phone screen with caregivers to determine initial eligibility. At that time a virtual screening and consent visit will be scheduled if appropriate. The virtual screening and consent visit will be conducted via HIPAA-compliant video platform and REDCap software. Participants will receive a session link and consent form link via email, allowing them to participate and provide guardian consent/youth assent via a mobile phone, tablet or computer.

Parents will agree to the Health Insurance Portability and Accountability Act Authorization. All questions and concerns will be clarified before signing the consent form. Given that the participants in this research are children, all aspects of the study will be explained to the child in understandable terms, and the child's written assent will be sought only after the investigator is satisfied that all the child's questions have been fully answered. Children who do not freely give an assent will be excluded regardless of parental permission. Parent(s) will receive an electronic copy of the signed assent and consent forms

VII. Compensation

All participants will receive a Fitbit device (approximate value: $80), and GamerFit intervention participants will also receive a suite of exergames for their gaming system (approximate value: $100) as compensation for enrolling in the study. Intervention participants will also be offered a new or reconditioned Nintendo Switch (approximate value: $260) for use during the study. They will be allowed to keep the system at study end. Participants will not receive incentives until after baseline data collection, and adolescents will be informed they can keep the devices/games permanently if follow-up data collection is completed. This is a similar compensation structure that we successfully used with 100% participant retention in our Adaptive GameSquad pilot study. The intervention participants receive additional compensation compared to the Fitbit comparator group due to the additional burden and time commitment involved in that arm of the study. In order to better balance the compensation between groups, the Fitbit comparator group can receive up to an additional $30 for completing follow-up assessments.

Appendix A – Clinician Focus Groups

Aim: Virtual focus groups will be held with clinicians at recruiting sites to gather perceptions of the app as a clinical tool, including review of app features, identification of methods to best aggregate mood and PA data for clinician review, and identification of approaches for incorporation into psychiatric treatment plans.

Participants: To achieve this aim, up to 4focus groups will be held with approximately 2-3 practicing mental health clinicians from (k=4) recruiting sites (JRI, Triumph, Manville, Somers Trust) for a total of 6-10 participants. The number of participants included per focus group will be limited to 6. Additional participants from additional recruiting sites may be added as time and budget allow, if preliminary results indicate that more diversity is needed to achieve theme saturation. Participants will receive $50 for participation.

Methods: Focus groups will be held remotely via zoom, facilitated by trained study team members, and will be recorded. Focus group participants will first be asked for verbal consent to participate in and record the session. Any participants not granting consent will be excused. Participants will then be presented with an overview of the intervention, and then preview the app. They will then be allowed to ask questions about the app, its features, and the intervention as a whole. Then participants will be administered a semi-structured instrument with questions regarding: 1) perceptions of using PA and sleep prescriptions in pediatric psychiatric treatment plans, 2) perceptions of implementation considerations (feasibility, acceptability, accessibility, implementation fidelity) and 3) approaches for delivering those prescriptions via the GamerFit application.

Qualitative Data Analysis: Focus group discussions will be audiotaped, transcribed, and coded by study staff. Research assistants will be trained and certified to code all transcripts. We will use standard qualitative methods (data immersion, clustering of preliminary categories, editing, exploring new categories and subcategories, and identifying major themes). Qualitative analysis will include: 1) individual quotes will be isolated in transcripts, 2) a hierarchical coding system will be developed to organize the quotes to capture the full range and depth of participant response, and 3) the structure, frequency, and interrelationships of the coded quotes will be used to inform interpretation of results. The process includes both inductive analysis (fact to theory) and deductive analysis (theory to fact). At least two independent reviewers will review each transcript line-by-line for patterns and themes.

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