Approved 10-4-16

Pediatric Anxiety Intervention with an Entertaining Video Game: Feasibility study

Background:

With a lifetime prevalence of nearly one-in-three adults, anxiety disorders, including social anxiety disorder (SAD), are the most prevalent mental health problem [14]. Childhood is a critical age for intervention as problematic anxiety begins early in life with a median onset age of 11 years, compared to 20 and 30 for substance use and mood disorders [14]. Untreated clinical anxiety tends to persist throughout childhood leading to additional psychopathology such as an eightfold increase in depression and threefold increase in suicidal ideation [16,21–25]. Although a wealth of data supports the efficacy of Cognitive Behavioral Therapy (CBT) for childhood anxiety disorders [10–13], as many as 70% of youth receive little or no treatment [15,18,29]. Compared to other disorders in primary care settings, fewer children in need receive treatment for anxiety (31%) than do for depression (40%) or ADHD (79%) [15]. When patients do receive treatment it is rarely evidence-based CBT, with less than 25% of psychotherapy in primary care settings consists of CBT and as little as 7% of community therapist reporting using CBT [30,31]. Moreover, when CBT is delivered in the community it rarely involves exposure (approximately 33%) compared to cognitive restructuring (97%) and relaxation (80%) [32,33]. This is unfortunate because repeated exposure to fear provoking situations is frequently described as the active ingredient in CBT [34–42]. Unfortunately, even with proper training the current brick and mortar mental health establishment does not have an adequate number of providers to address the populations' psychiatric needs [48].

To address the implementation gap, technologies will need to not only improve the quality of care provided in traditional settings, but also allow patients to receive interventions that require less contact with health professionals [48]. One potential use of technology is the development of immersive video games. The current pilot study is part of a collaboration between the current investigators, Advanced Medical Electronics (AME), and Pine Technical College to develop development of an immersive video game for children with social anxiety disorder (SAD). The game will be developed by AME with clinical content developed by the current investigators, and graphics developed by Pine Technical College. The current proposal is for a feasibility study of the phase I prototype version of the immersive videogame.

The pilot study has the following Aims:

1) Demonstrate that children enjoy the game and find it easy to use
2) Examine whether playing the game motivates children to complete real world exposures
3) Examine whether the tasks in the game increase children's confidence to do real world exposures
4) Examine whether parents believe the game would facilitate engagement in exposure therapy.

Methodology

Participants. Twenty children with SAD who have received fewer than 3 treatment sessions and a parent will be recruited to pilot the video game. Participants will be identified by Drs. Whiteside and Biggs through the PADC using purposive sampling methods [64]. Families will be remunerated $50 for their time.

Procedures. Each child will participate in a single (up to) 3-hour visit, allowing for breaks as needed. Staff from Mayo Clinic HealthCare Policy & Research experienced in qualitative data analysis and not involved with the patients' medical care or development of the video game will conduct the study visits. During the first 15 minutes the child and parent will be introduced to the

game and the rationale for feasibility study. Next, the child will interact with the game for up to 30 minutes. During this time the interviewer will observe, code and record the child's interaction with the game. The child will then have the opportunity to perform a real life exposure of giving a short speech about one of their favorite games. If the child completes the speech s/he will earn additional time with the video game. For the remaining time the researcher will interview the child about his or her experience with the game and then will ask for observations and opinions from the parent. The measures, topics for the semi-structured interview, and a guide for the participant interaction are detailed in the document *Script and Measures*.. The guide has been developed and reviewed by Drs. Whiteside, Biggs, and Vickers Douglas to ensure that questions and follow-up probes are easily comprehended and delivered in a sensitive manner. The semi-structured guide will follow guidelines for minimizing bias and increasing the reliability and validity of interview data [65,66]. All interviews will be audio-recorded.

Analyses. For qualitative data analyses, themes regarding usability and treatment satisfaction will be identified and a coding strategy will be developed. Analysts with experience in qualitative data analysis will code interviews using methods of content analysis, i.e., systematic process of sorting and coding information based on themes. [64,67]. QSR's NVivo 9 (QSR International, Doncaster, Victoria, Australia; NVivo 2010) qualitative data software analysis program will be used to facilitate data coding and sorting. Based on the observational and interview data, the study investigators will refine the beta-version of the videogame and develop a detailed proposal for the final product.

Quantitative analyses will include descriptive statistics examining the degree to which children find the video game engaging, changes in anxiety and willingness to complete a real life exposure, and parents ratings of utility. Success criteria are as follows:

1. 80% of the children describe the game as engaging and easy to use based on quantitative interviews.
2. Anxiety ratings regarding giving a speech will decrease by 30% from before to after the video game play.
3. 75% of the children will be willing to give the speech following game play.
4. Child and parent ratings of game value will average 7 out of 10 or higher.

Protection Human Subjects

Appropriate steps will be taken to insure the confidentiality of data form survey respondents, study therapists, patients, and parents. To begin with, participants will be assigned study codes that are not based on the individual's information. All written, electronic, and audio recording material and data will be identified only by code. The key linking participants to study codes will be kept in a locked cabinet separate from the data. All paper-generated data will be stored in locked files in the office of Dr. Whiteside. All computer-generated data will be maintained in password-limited, secure network drive files. To protect patient confidentiality, only authorized persons at Mayo Clinic, the sponsor (NIMH), and the Institutional Review Board will have the right to review research records. Confidentiality of those records will be protected to the extent permitted by law. Research records will be kept separate from identifying information in a locked cabinet and will not be released without the participant's consent unless required by law. Identifying information will be removed prior to publication and presentation of the study results.

The original NIMH proposal for the full study has been included as attachment. The NIMH proposal document does not reflect the changes to the procedures outlined here.