Abstract

Eye Movement Desensitization and Reprocessing (EMDR) therapy is a clinically proven and used therapeutic method for all ages of patients suffering from trauma related symptoms. By creating a clinically derived device that improves the EMDR therapy process for youth under the age of 18, these trauma related symptoms can hopefully be mitigated. By researching previous works done by clinicians and current patents an EMDR Therapy Mobile Application and Plushie System is developed involving two major systems: a phone application (app) and stuffed animal device. These two systems are completely customizable via the app and take proper ethical safety measures to ensure that comorbid conditions are not worsened by improper usage. The device uses an auditory, visual, and physical subsystem embedded within the stuffed animal to act as a means of delivering EMDR therapy by an approved therapist or clinician. This device will then be tested thoroughly to ensure that the device does not have adverse effects on patients and to confirm a non-negligible difference in patient improvement.

Purpose

Eye Movement Desensitization and Reprocessing (EMDR) has been proven to be effective in assisting the processing and desensitization of traumatic memories. This process involves having a patient hold a memory in their mind as they go through horizontal eye movement, tapping, buzzing, and other physical movements. This allows the patient to slowly process their traumatic event and replace negative and shocking emotions with calmer ones while focusing on an outside stimulus. This process involves 8 steps to properly work: client history, preparation, assessment, desensitization, reprocessing, body scan, closure, and

reevaluation. If not balanced properly with a patient's previous history of dysregulated emotions, comorbid conditions, and PTSD, this process can cause further harm the client as it can cause flashbacks, panic attacks, or other side effects.

With modern technology it is now possible to create new devices to help assist with EMDR therapy. Specially creating more user-friendly devices for EMDR therapy focused on traumatized youth. There are currently no major EMDR therapy devices that are specifically created to use with youth and by creating a new device that combines clinically sound techniques and user-friendly aspects. An EMDR Therapy Mobile Application and Plushie System (TMAPS) can be created to fill this hole in the market and by using research based techniques the device can be more clinically sound and avoid issues associated with EMDR therapy.

Proof of Concept

EMDR therapy is a clinically proven method to treating PTSD and trauma and has been strongly established in a clinical setting. Gainer et al summarizes EMDR therapy and illustrates examples of where it can be used and its applicable steps. EMDR therapy was created by Dr. Francine Shapiro and was proven by many other studies to be effective for treatment of PTSD symptoms. A comparison of CBT vs EMDR therapy found that EMDR therapy was equally effective for treatment of PTSD. Bossini et al found a strong correlation between EMDR therapy with neurobiological changes, some no longer meeting criteria for PTSD after treatment. Thus, EMDR therapy is an incredible way to help treat those suffering from PTSD and by creating a device that improves this process for both the patient and clinician the use of EMDR can be spread further. This summary also includes proof of long-term neurobiological changes that can

help permanently improve or reverse the symptoms of trauma. EMDR therapy seeks to treat trauma stemming from adverse life experiences. 24 randomized control trials support positive effects of EMDR treatment, 12 of which note rapid decreases in negative emotions and vivid images. From the summarization of Shapiro et Al.'s years of trials EMDR therapy has been clinically proven to be an effective treatment for trauma patients with limited negative side effects found through the many trials. This compilation of studies done by Shapiro et Al. highlights the continual efficacy of EMDR therapy and a long history of improvements. Because it is imbedded in clinical psychology TMAPS should be able to penetrate this market as an improvement of a process that is already well established.

With our target demographic being children 18 and under it is essential that EMDR therapy and our methods be proven effective for those in this demographic. Karadag et al set out to investigate if EMDR therapy was an effective treatment for children and adolescents. Using self-administered questionnaires were filled out pre and post the 6-week treatment. The PTSD symptom scale decreased from 60 to 24 for the PTSD symptom scale and from 59 to 41 for the STAI-T scale. This was a significant enough decrease to show that EMDR treatment is effective for children. TMAPS is designed for a target demographic of children and as EMDR is an effective method of treating youth with trauma TMAPS should be able to be applicable for treatment. Additionally, this study gives a baseline of how effective EMDR therapy should be for children thus if our device is tested both our control and non-control groups can compare the results with this previous study to highlight any discrepancies in the testing process. Montalbo et al. aimed to find the effectiveness of stuffed animals for group psychotherapy and its utilization. 84 students were selected from a class and split into groups of 4-6 people, 60 answered post therapy questions to evaluate the effectiveness of the stuffed animals on the session. A fisher test

was then used on the results and a p value of 0.0305 was found, finding a strong correlation between the stuffed animal and its effectiveness. Despite the demographic used in the study being college-aged students stuffed animals Montalbo et al. show a clear correlation of the improving effects of stuffed animals in therapy sessions. Integrating this medium in TMAPS should help increase the usage rate in youth EMDR therapy as a noticeable improvement in therapy should occur beyond the apps functions.

By analyzing previous studies, parameters to test the devices effectiveness on patients can begin to take form. In a study by Carlson et Al. 35 male veterans participated in the study and went through a pretreatment and posttreatment analyzation receiving EMDR therapy in between for 3 months. The study found on the self-administered and clinician-administered CAPS test patients steadily found a decrease in their intensity and frequency of PTSD related symptoms. The study also found a decrease in heart rate and EMG values for patients post treatment. Our design can be modeled off a similar method of testing to determine if our device has a significant increase in EMDR treatment efficacy and decrease in patient symptoms.

Despite TMAPS being a nouveau invention, by looking at previous devices and patents various shortcomings and similarities can be devised. *REMOTE EMDR THERAPY DEVICE* (US 2022/0215933 A1) outlines a design for a remote EMDR therapy device that can be used with the patient's mobile device. The system involves the users iPhone or android device to connect to a desktop assembly that then sends a signal to two handheld assembly that vibrate accordingly. The device uses both Bluetooth and Wi-Fi to connect from the phone to the desktop assembly. This patent is still under review of the time of writing but if it is approved this device poses a potential threat to our invention as a new method of phone to device connection may have to be clarified or established. This device however clarifies its intent for a purely physical stimulation

system and TMAPS uses multiple stimulation methods without a desktop assembly, thus maintaining a strong difference in our devices should be essential in our prototyping process. *INTERACTIVE PLUSH TOY* (US 7,566,258 B2) defines a design for an interactive plush toy with LED eyes or features that can be used to interact with the user. This device uses LEDs attached to a central circuit board and the LEDs are then cycled on or off or otherwise effected by the circuit board and user input. The devices primary use is for children to play and interact with the plush as a fun toy with no clinical application mentioned. As an integrated circuit board and attached system of LEDs is used in TMAPS another clear differentiation must be made to ensure that our system remains outside the constraints of this patents by clarifying multiple connections to the circuit board and a unique circuit board therein. Goga et al. outline a design for an actuator based EMDR therapy system to be used by PTSD and trauma patients. The device consists of a chatbot connected to a tactile, video, and audio module that are customizable to the patient's needs. The chatbot acts as a questioner while the other modules act as stimulation to the patient while they go through the therapy. The device found a significant effect of the system on reducing the stress and anxiety of a traumatic event. The device was also shown to improve the negative cognition and emotions of the traumatic event. This device was clinically proven to be extremely effective in assisting in EMDR therapy but lacked the finesse and detail that a therapist can provide that a robot cannot. This device is extremely similar to TMAPS device outline minus the chatbot however by clarifying that this is a tool designed to assist clinicians rather than replace them will diversify our device. Additionally, our device being positioned to address specifically youth struggling with trauma will help TMAPS define its own new market.

The development of an ethically and clinically sound phone application (app) is an essential part of our TMAPS creation. Marotta-Walters et al. review 12 available EMDR therapy

phone apps available on the market. 9 criteria were evaluated by clinicians trained in EMDR, professional counselors, and doctoral students. Of the 12 apps available 6 were deemed beneficial for use by clinicians and none were approved for use by just the client for risk of making comorbid conditions worse. Future apps should include clear disclaimers, customization options, and should be only used with a trained clinician. By following Marotta-Walters et al.'s outline of a superior EMDR phone application the TMAPS app will be developed with high standards from the beginning and set a new precedent for future EMDR apps. By combining this method with TMAPS's nouveau stuffed animal device our whole system will be able to redefine two separate markets. Thus, if one market is more successful than the other our devices focus can be shifted to ensure that that vacancy is filled. Furthermore, by having high ethical standards our app will be more effective in ensuring top quality care for patients and avoiding possible triggering of comorbid conditions that can arise and worsen already traumatic symptoms. Finally, by emphasizing customization with the TMAPS app not only will the patient have a more enjoyable and customizable experience, but the therapist will have more control over the EMDR therapy and therefore allow better results from sessions.

Design Specifications

App System:

A large portion of inspiration for the apps various features can be outlined by Marotta-Walters et al.'s review of current EMDR phone applications. By defining certain app capabilities, functions, and subsystems our device's application will be clinically sound and ethically superior to current market apps.

Initial Bootup: It is essential that our device and app only be used by approved clinicians as the risk of comorbid conditions occurring due to non-professional error is high and dangerous. By our device first checking user ID with a login or simple user confirmation this mitigates the risk of unauthorized users using our device. After checking user ID a disclaimer will appear of the potential risks of EMDR therapy and specific risks that may occur with use of our device. This yet again decreases the risk of uneducated usage leading to misuse of TMAPS. Finally, our device opens to a home screen with 4 general options available for the user to choose from: Visual, Auditory, Physical, and Settings.

Visual Subsystem: This subsystem connects to the LED integrated into the approximate belly button of the stuffed animal device. Once connected the app displays multiple options arranged for the clinician to choose from and possible customization options. This includes a slider for LED intensity, a button to manually turn on the LED, a rhyme pattern chooser for the LED to flicker to, and a RGB slider to choose the color of the LED to the user's preference. The intensity and color of the LED allow the clinician and patient to have control over the aesthetic of the light and further customize their experience to ensure maximum comfort and attention. The manual button and pattern chooser allow the interval of the LED to be chosen by the clinician manually for their preference or automatically flicker in a designated pattern of their preference.

Physical Subsystem: This system connects to the ERM vibration motor connected to the circuit system in the device. Then opens to a selection of customizations of a slider for the motor's intensity, selection of vibration patterns, or manual switch for vibration. Similarly to the visual subsystem the intensity is for patient comfort and sensitivity and the vibration patterns are for the clinician to choose the best method of stimulation, wether that be automatic or manual.

Auditory Subsystem: After connecting to the circuit board, the auditory subsystem accesses the database of sounds stored onboard the device. The customization options include a slider for volume, a pause/play button, and a drop-down menu of available sounds downloaded. The slider acts to customize the user experience and pause, and play activate the designated audio file at the therapist's command. To ensure limited data is stored and used auditory files can be accessed in the settings menu, allowing a choice of pre-made sounds to download or an option to download a MP4 file of the therapists choosing to further allow complete customization of the auditory stimulation.

Settings and User Care: This program is completely done within the app an opens a menu of options a user can choose from including privacy, disclaimers, auditory files, account information, and customer support. As patient anonymity is hugely important due to HIPAA regulations our device allows complete customization of one's information by checking the privacy tab for options about data sharing and account information to ensure only essential information is being shared. The disclaimers and auditory file tabs act as continuations of the auditory and boot up subsystems. Finally, the customer support tab opens an option of FAQ's and direct contact with our affiliates to help answer any questions, concerns or issues that may arise from TMAPS.

Stuffed Animal Device:

Electronic Components: An RGB LED, ERM vibrator motor, and speaker are attached to a Wi-Fi and Bluetooth capable connecting microcontroller that communicated with the phone app. The microcontroller is encased in an insulated plastic cover to ensure connectivity to the phone and safety of the components due to user error. All electronic components are connected using insulating wire to ensure no shorting between wires or user. The microcontroller is encoded

to emit signals as well as receive feedback from all attached devices as well as connecting to a designated phone that runs the application.

Stuffed Animal: The genus of the stuffed animal has yet to be determined due to the personal preference of many and the lack of studies of the optimal animal genus to choose from. For the TMAPS prototype a stuffed brown bear is used as the basis of our design due to its common social connotation of the common stuffed animal. The LED is implanted in the stuffed animal's belly button region or other clearly visible region designated by the stuffed animal species. The speaker is implanted close to the plushie skin to ensure a clear sound can resonate without muffling. The motor is implanted in the deepest part of the stuffed animal to ensure even vibrations throughout.

Methods

To test the efficacy of the device and test any possible negative or positive side effects of the device a research study can be proposed. Although final production of the device and any issues/changes that come to the device post-prototype can lead to changes in the fundamental usage of the device; this research study outline can still be proposed to test the general characteristics of the TMPAS.

Persons: The study would include volunteer psychologists and their patients ages less than 18 who have a previous history of PTSD or other related trauma incidents. 50% of psychologists with approximately 50% of the patient population would use regular EMDR therapy techniques with a current device. The remaining psychologist and patient groups would

use the new device and adapt it to regular EMDR therapy techniques with simply the device and its customizations changing.

Device Usage: Both the control group and the device group would follow basic EMDR therapy guidelines set by the American Psychological Association. EMDR will be applied 3 times for each mode of stimulation: physical, visual, and auditory by the psychologist. The exact minor customizations of EMDR therapy for each person should be noted by the psychologist for both the control group and the device group, once identified major outliers in customization deemed extraordinary will be excluded from the data set.

Efficacy Analysis: Each group will start off taking the Post Traumatic Stress Diagnostic Scale (PDS), the PTSD Checklist (PCL) and Davidson Trauma Scale (DTS) to set a baseline of the patient's current trauma. Each of these scores will be scored accordingly to try and scale the trauma level of the patients. Then each patient will undergo weekly EMDR therapy in their designated group for 3-6 months depending on the budget/availability of patient groups. After the designated period the patients will be rescored, and the results of both tests can be used as a comparison of the efficacy of the device. If a patient at any time needs to stop the therapy in either group, the psychologist should immediately stop EMDR and note the reason for the halt.

Discussion

It is important to note in this device outline that prototyping and testing will greatly affect the final design and multiple aspects of TMAPS may have to be changed to ensure that actual implementation can be achieved with current technology. However, the fundamental ideas and ideals of an ethically and clinically derived EMDR therapy device should remain constant and I

the forefront of its creation to not only create a device capable of improving patient life but differentiating TMAPS from other devices on the relatively unregulated market.

TMAPS also uses a small number of assumptions and estimations about the target users and device characteristics. Frontmost is the shape and size of the stuffed animal, clinical research does not cover the effects of stuffed animals frequently enough to confirm a definite size or genus of animal to choose from, therefore an assumption of a moderately sized teddy bear is used as a basis due to its western societal norm of a common stuffed animal to own and enjoy. Additionally, the need for new EMDR therapy is used as it is hard to gauge the need for more EMDR therapy devices needed for younger patients without further research or a customer survey. Devices currently in development and not released to the public are also not considered as it is impossible to try and determine these devices without firsthand knowledge.

Conclusions

As TMAPS is not yet prototyped nor tested, its viability is incredibly difficult to predict without further steps. Future steps could include the creation of a mock-up or prototype as well as initial tests and surveys to determine missing features and interest for usage in therapy. Despite its unpredictable future, the motivation behind a more clinically sound device for younger patients should stand as an inspiration for the continuation of technology improving therapy. By ensuring that ethics are in the forefront of its creation TMAPS will strive to improve patients lives while continuing to be competitive and innovative in the EMDR therapy device market.

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