22/10/2020

Cover Letter

Dear reviewers,

It is a pleasure to connect. Hope you are safe and well.

This is regarding the submission **Protocol ID:** 3/1/333011/HRD

Indian Council of Medical Research Registration id: 3/1/333011/HRD

Study Title: Development of Intelligent Virtual Reality Therapy System (IVRTS) and Testing Its Clinical Efficacy: Revolutionizing Evidence-Based Psychotherapy

This is to request registration of clinical trials. This novel development is extremely relevant in today's world. When the world is sitting on the verge of a Mental Health Crisis. We need to revolutionize the Psychotherapy modality for two reasons, first being the shortage of Mental Health Professionals compared the huge number of cases that would need help and secondly accessibility. When social isolation has become the new norm, one needs innovative tools to be able to effectively handle the situation sitting at home, and yet be equally effective, if not more. This project has huge potential as well has huge social impact for the treatment of Anxiety Disorders which currently effects 80% of the world population according to the World Health Organization. Science and Technology is the only way this situation can be tackled. The development of this novel technology would reduce the cost of treatment of Anxiety disorders, PTSD and Phobias considerably. Also, it would make the accessibility of treatment widely available and more comfortable for the masses. This is a much needed technological development in the field of Psychiatry.

The Documents attached are:

1. **Research article (Protocol + Statistical plan) Dated 01/08/2020**

Thank you.

Warm regards,

Dr. Akshay Kumar

01/08/2020

Development of Intelligent Virtual Reality Therapy System and Testing Its Clinical Efficacy: Revolutionizing Evidence-Based Psychotherapy

01/08/2020

Development of Intelligent Virtual Reality Therapy System and Testing Its Clinical Efficacy: Revolutionizing Evidence-Based Psychotherapy

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ABSTRACT

Background: To take the existing VR technology to the next level, we developed a novel Intelligent Virtual Reality Therapy System (IVRTS). ***Aim:*** The objective of this project had three aspects: Namely, development of the novel IVRTS technology involving the development of a hardware device, development of Artificially Intelligent Psychotherapeutic software-interface and testing it's clinical efficacy. ***Methods***: It used a two-phased methodology; Development of the novel technology and testing its Clinical Efficacy. After development of Novel IVRTS. A 7-week intervention was designed for each subject.
The sample of 500 patients, meeting the criteria of Acrophobia and Anxiety, underwent the interventions at The GTB hospital (The University of Delhi), for a total 3500 sessions, ranging 5250 hours for over 2 years. The subjects were randomly divided into 4 groups: IVRTS Group, Mindfulness group, CBT group and Control Group. ***Registration:*** The ethics committee and clinical trial registration number is 3/1/333011/HRD. ***Results:*** The IVRTS group reported significant reduction in Acrophobic and Anxiety symptoms. The Pre and Post intervention, mean and SD reduced from 28.60±8.45 to 11.10±4.03 on HAMA; from 8.10±1.56 to 3.73±1.23 on SUDS and increased from 72.87±6.21 to 87.07±3.79 on WHO-QOL-BREF. It was also seen the mean comparison of reduction was significantly higher compared to the CBT and Mindfulness Groups. It also indicated enhanced Quality of Life ($p < .001$) compared to The Mindfulness Group and CBT Group. ***Conclusion:*** IVRTS decreased symptoms of Acrophobia and Anxiety, enhanced Quality of Life significantly than other treatment groups. Development of this technology is a land-mark innovation.

Key Words: Anxiety; Virtual Reality; Phobias; Treatment Intervention.

01/08/2020

INTRODUCTION

There is no shortage of literature on Anxiety Disorders and how it disrupts lives of many across the world. There are also ample of researches around the world on various psychotherapeutic modalities that have proven to be effective interventions for the treatment of Anxiety. Hiller[1] concluded the positive effects of Cognitive Behavior Therapy on symptoms of Anxiety. Mindfulness is another modality proven to be useful as an intervention for Anxiety[2]. However, despite plethora of research in the field of Anxiety Disorders and its treatment, according to recent report by The Anxiety and Depression Association of American released in 2020, the prevalence of Anxiety is ever increasing[3]. There is an urgent need of newer and novel modalities for three reasons; Firstly, the shortage of clinicians in comparison to the number of cases affected by technology and secondly, lack of accessibility of therapists by millions of people and finally to improve the efficacy and results of the treatment. Keeping these three in mind we have developed a technology that will take care of all of the three mentioned points. Also, with the current changing trends when people are now preferring or are even forced to avail services sitting at home, new technological innovations are imperative. The Institute of Medicine[4] candidly cites the critical shortage of therapists trained in empirically based psychological treatments and how this remains a major public health concern. Another study argues that how is shortage is a major barrier to accessing these treatments by people across the world[5]. Taking this into consideration, A prominent study cites that the Use of new technologies is the only way overcome these issues and to improve widespread accessibility and quality of treatments [6-8].

Virtual Reality Technology: Rationale

Many researchers have proved the usefulness of Virtual Reality Technology in the treatment of Psychological Disorders, and many studies have quoted efficacy of the treatment as well[9]. The research in the VR field is progressing but still is at a very nascent stage[10]. However, despite some VR projects being worked upon in the current times, the technology is not being used widely, due to its limited proven efficacy. The current VR technology that exists is only limited to placing a patient in his or her phobic situation virtually and not beyond that. In this current project we attempted to fill this gap by using 2 important novel technological developments. Firstly, we moved beyond just the visual imaging and added haptic touch sensors as well as motion sensors to the device. Secondly, we developed an automated intelligent interactive Psychotherapy software to compliment the virtual reality as a part of the device and finally we tested its clinical efficacy to make sure the novel technology is effective. When the world is sitting on the verge of a Mental Health Crisis due to the global pandemic. We need to revolutionize the Psychotherapy modality for two reasons, first being, the shortage of Mental Health Professionals compared the anticipated cases that would need help due to this unique global condition and secondly accessibility. When social isolation has become the norm for prevention, one needs innovative tools to be able to effectively handle the situation sitting at home, and yet be equally effective, if not more. This is the dire need of the society today and the project has immense potential as well has huge social impact for the treatment of Anxiety Disorders which currently effects 80% of the world population according to the World Health Organization[11], which is predicted to grow further due to the current global pandemic. The development of this novel technology would reduce the cost of treatment of Anxiety disorders, PTSD and Phobias considerably, which would make interventions

viable for people across the world currently not being able to afford long term Psychological sessions. It would also reduce the treatment time by approximately half. It would make the accessibility of treatment widely available and more comfortable for the masses.

The current Virtual Reality technology to treat Anxiety phobias and general stress was at a very nascent stage, where a subject was immersed into phobic situation and is expected to get stage-wise comfortable with it. The current existing Virtual Reality technology to treat phobia is still relatively new and lacks both theoretical and clinical research. VR applications need to go beyond only immersing the person into a phobic situation. Our proposed research & development project aimed to integrate complex and proven effective psychotherapies (visual, auditory, interactive, kinesthetic, motion sensing and tactile), automated, intelligent and integrated with the Virtual Reality Technology, which the subject or patient will be able to control and undergo themselves, then it's initial clinical efficacy was examined. Keller and Bunnel[12] explain, Virtual Reality being a technological system helps subjects to experience computer and machine generated situations in lab settings. The technology is being widely utilized in Psychological treatment and research. Rizzo[13], mentions that people totally experience Virtual reality when it mimics real life at the highest possible level and the users start believing that the situation simulates the real actual world experience that it is recreating. This project developed new technology, devices, and intelligent psychotherapeutic software programs in VR for curing phobias, anxiety, stress and even stress management. The current technology in this field that existed is only at a level of immersing a subject in a realistic VR image/scene and is not beyond that. Currently, this technology was not useful in the treatment, and that is the reason had not entered widely in clinical settings yet.

To take this technology to the next level, one needed to develop a novel VR technology/device, which is intelligent, as well as which would interact and stimulate "Whole brain activation" and help the subject overcome phobia/stress/anxiety effectively. This required developing a device which had motion sensors, interactive sensors which allowed the subject to feel and interact with the image, scenario, program real- time and other psychotherapeutic intelligent technological hardware components and intelligent interactive psychotherapeutic software programs fostering this process, all built in one integrated compact device.

Furthermore, the main components of this project included –Hardware, software, system interfaces and data. The data being collected by the wireless sensor contains information about the health status of the user is stored in a database. Health status data included information about blood pressure, heart rate and other physiological parameters as well.

This project is aimed to develop both hardware and software technology and finally test its clinical efficacy to treat Phobias, General Anxiety, Stress and PTSD. According to the DSM 5 published by the American Psychiatry Association[14], specific phobias are associated with fear or Anxiety attached to a specific situation or Object Like water, animals, animals, public speaking, needles, heights, blood etc. DSM Also defines Generalized anxiety disorder (GAD) as a condition in which a person Feels intrusive, excessive, and persistent worrying to the extent that daily functioning becomes difficult.

Anxiety and Stress is becoming a global epidemic, The World Health Organization[15], estimates that 1 in 3 from Clinical Anxiety and 1 in 5 individuals are suffering from Clinical Depression. About 80% of the world is suffering from general stress.

It is said that situation improves with pumping in of resources and putting in efforts; but in this situation despite putting in huge funds, highest quality of resources, the best human minds and fierce efforts, the problem is only increasing. The development of this novel technology will be a landmark step towards the intervention of these conditions the world is battling in present times.

Existing Work in VR

According to Garcia Et al[16], Virtual Reality has gained widespread acceptance in the field of psychiatry. Mainly pertaining to phobias within anxiety disorders, VR has been found to be useful in the treatment of phobia of spiders[17], heights[18], flying[19] and claustrophobia[20], to name a few. As VR allows for the creation of images and scenarios, the subject can be taken back to the fearful or anxiety-provoking situation. The therapist can then guide and monitor the subjects' responses and thereby treat anxiety. Walshe and Lewis et al[21] mentions in their research that VR has thus also been successfully utilized to treat phobia of driving in patients who have Post-Traumatic Stress Disorder (PTSD) after an accident. Also, Horváthová and Siládi [22] proved in their research how Virtual environments created by virtual reality (VR) tools can help to make the treatment of certain types of phobias more efficient. Further Keller and Bunnel eta al[23], using systematic literature search analyzed VR based treatments and emphasized on their benefits viz-a-viz psychiatric and Psychological research and intervention to overcome anxiety.

NOVELTY OF THE PROJECT

The approach of the Novel Intelligent Software interface approaches follows the basic premise that human beings think in terms of images rather than words. While the existing modes of treatment for phobias rely mainly on talk therapies and counseling; This novel intelligent software treatment methodology

deals with the development of VR programs integrated with hardware for simulating various phobia-inducing situations, followed by novel automated integrated most effective psychotherapy; altering these images to reduce the anxiety experienced. Our treatment package includes a VR device integrated with easily comprehensible voice commands, along with a user manual and easy user interface, thereby reducing the effort of training required for operating the device. The framework is a combination of the therapy methodologies with VR, motion sensors, biofeedback and fNIRS. This would eliminate the need for a therapist by making the patient self-sufficient in handling the overall treatment themselves. In the long run, this would prove to be more cost-effective and socially accessible.

METHODOLOGY

Objective, Approaches, hypotheses and choice of method

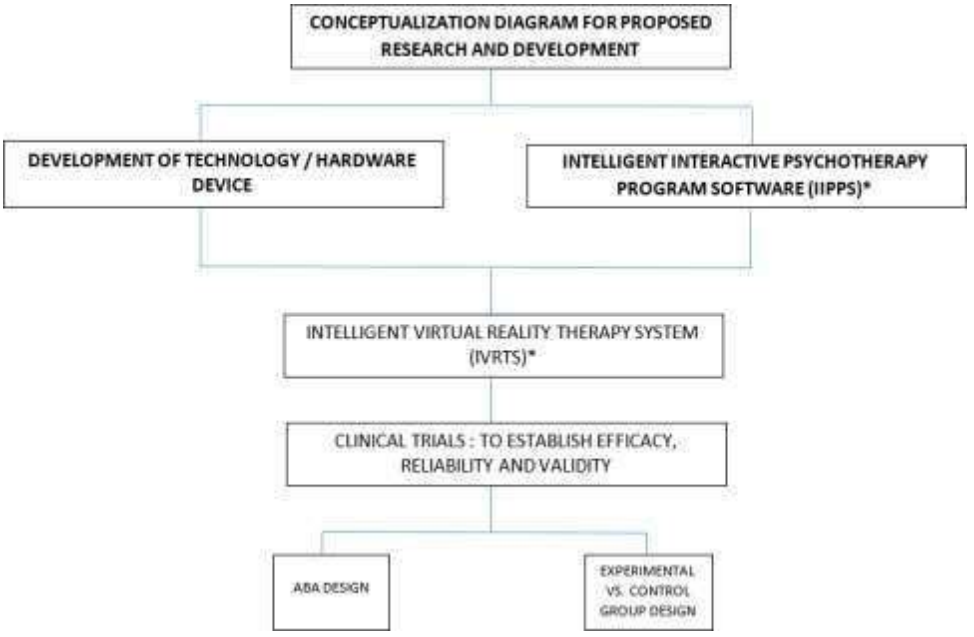

Figure 1: Conceptualization of research and development of project

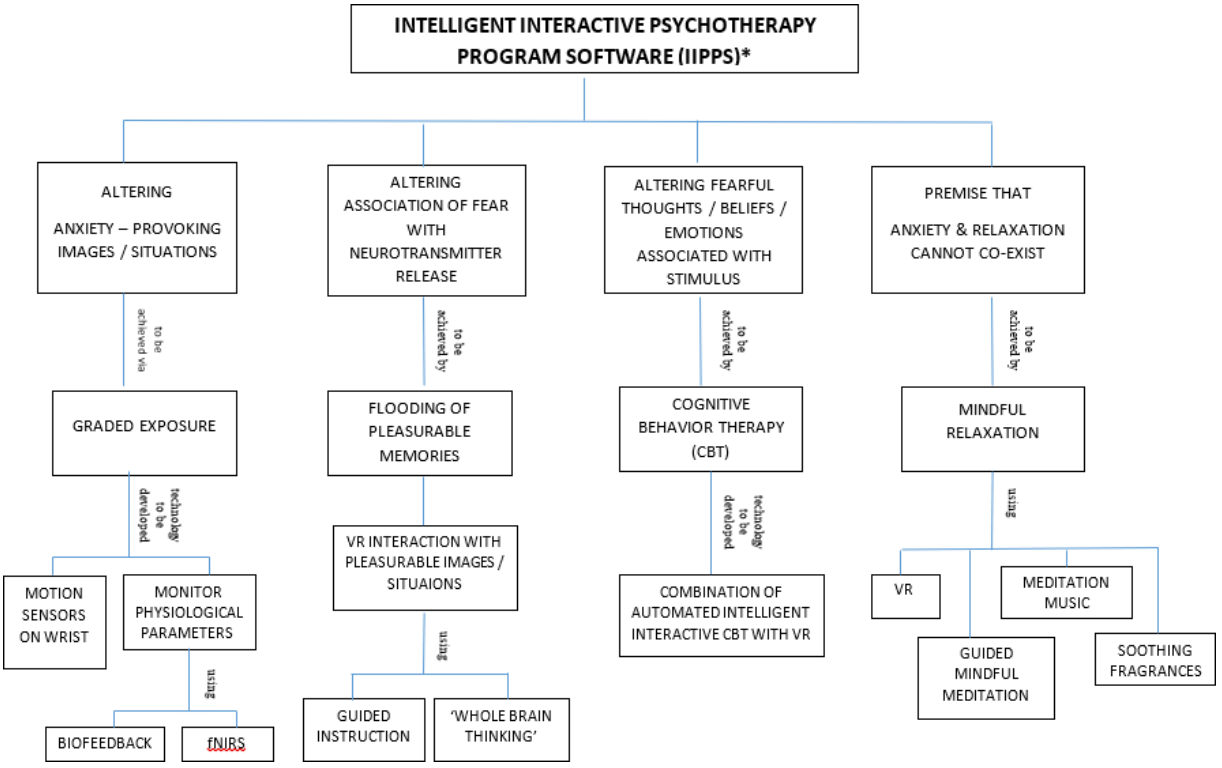

Figure 2: Intelligent Interactive Psychotherapy Program Software (IIPPS)

Objective

To develop Novel Technology, Intelligent Virtual Reality Therapy System (IVRTS) and test its Clinical Efficacy to treat phobias and anxiety, compared to Mindfulness Meditation and Cognitive Behavior Therapy (Talk Therapy).

Concept

Virtual Reality has a vast potential in healthcare. One such area where VR is becoming a promising technique is the treatment of Phobias and Anxiety Disorders. There are various types of phobias, and amongst them, some occur more commonly in individuals, in general. In the treatment of phobia using VR, the patient re-enters a computer-generated environment that is the imitation of the situation or an object the patient possesses the fear of. It helps people to encounter situations or objects they fear while being in a completely safe and controlled environment. The environment is

controlled in a manner that the level of fear gradually rises for the patient as he/ she can overcome a prior level of that fear. Generally, a VR set-up is built to treat a specific kind of phobia. Furthermore, using such a set-up for the treatment of patients requires training to integrate VR into therapy. This project aimed to design and model a system with a simple user interface to treat all kinds of common phobias, Post Traumatic Stress, and General Anxiety. This system primarily aims to have the patient treated at the end of therapy unlike the short-term effectiveness of talk therapies, and could be an alternative to drug therapy. This system will lead to cost reduction for the patient and time saving for the therapist as taking outpatient in the actual stimulus environment would be eliminated. This system achieved its goal by combining intelligent software with various hardware which will excite all the four senses, namely, sense of sight, hearing, feelings, touch, and enable hand movements to control a certain part of the therapy, enabling whole brain activation for the process. Such an integrated system creates a more immersive environment to produce better stimulus and overcome the unwanted response to a feared object or situation. This project aimed to build a Virtual Reality Therapy System, which is beyond the currently existing Virtual reality phobic situation immersive systems. This project aimed to build a Novel 'Intelligent Virtual Reality Therapy System' (IVRTS), that has inbuilt automated and integrated complex and most effective intelligent psychotherapies and body Bio-feedback, with various therapy options and settings that a person or patient can select and operate themselves. Furthermore, the research project also aimed to test the clinical efficacy of the Intelligent Virtual Reality Therapy System (IVRTS) on Phobic Patients in actual clinical settings.

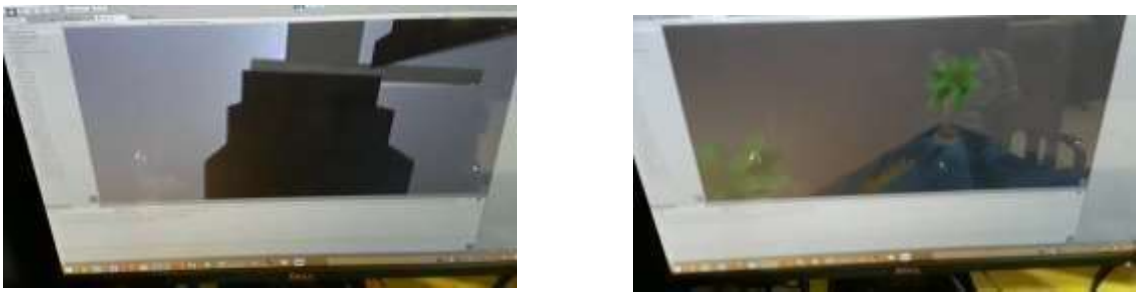

Figure 3: Image of the computer on which Developed Virtual vfx is being developed

Technology Components and Clinical Trials

The researchers specified VR scenarios for the simulation and treatment of these categories. The VR equipment that is being used is with the research partner, Innlandet hospital trust are (20 oculus go, 5 Lenovo mirage and 10 Samsung gear (7 and 8), and 1 oculus rift) in their premises which has been used in cooperation with Gjøvik Hospital, Norway for various purposes.

In this health-related research, the researchers first applied to health research ethics committees for permissions and once the permissions are taken, then the researchers identified the sample or user groups, through seminars at the Gjøvik hospital, using social media, etc. The researchers made sure that the user consent is received, the participation in our studies are voluntary and their participation can be ended any time by the user without any penalties for the user. Also, the Clinical Trials took place at The Psychiatry OPD of the Guru Tegh Bahadur Hospital of The University of Delhi.

Figure 4: The software detects the pupil, after detection it determines the focus point of gaze to control the virtual interaction

Hypothesis:

(i) The new novel developed technology Intelligent Virtual Reality Therapy System (IVRTS) is more effective in reducing symptoms of Phobia and Anxiety as compared to Mindfulness Meditation and Cognitive Behavior Therapy Groups.

(ii) The novel IVRTS Group scores significantly lower on both Hamilton Anxiety Inventory (HAM-A) and Subjective Units of Dysfunction Scale (SUDS) compared to all three, The Control Group, The Mindfulness Group Cognitive Behavior Therapy (CBT) Group.

(iii) The Novel IVRTS Group scores significantly higher on WHO Quality of Life Scale (WHO QOL BREF) compared to all three, The Control Group, The Mindfulness Meditation Group and The CBT Group.

(iv) The new technology proves to be effective and a steppingstone towards a newer era in the treatment of Mental Health issues using Mental healthcare engineering.

Sample

The Clinical Trials were carried out on 500 adults with Acrophobia which is fear of heights co-morbid with Generalized Anxiety. The sample for the study was recruited from the patients/subjects attending the adult psychiatric OPD of the department of Psychiatry GTB Hospital of The University of Delhi and fulfilling the

ICD-10 diagnostic criteria for assessment of Acrophobia and generalized anxiety. The study was conducted on an initial 500 subjects attending the psychiatric OPD of the department of Psychiatry GTB Hospital of the University of Delhi. The subjects were equally and randomly assigned to three groups namely; Novel Intelligent Virtual Reality System (IVRTS) Group (n=125), Mindfulness Meditation Group (n=125), Cognitive Behavior Therapy (CBT) Group (n=125) and The Control Group (n=125).

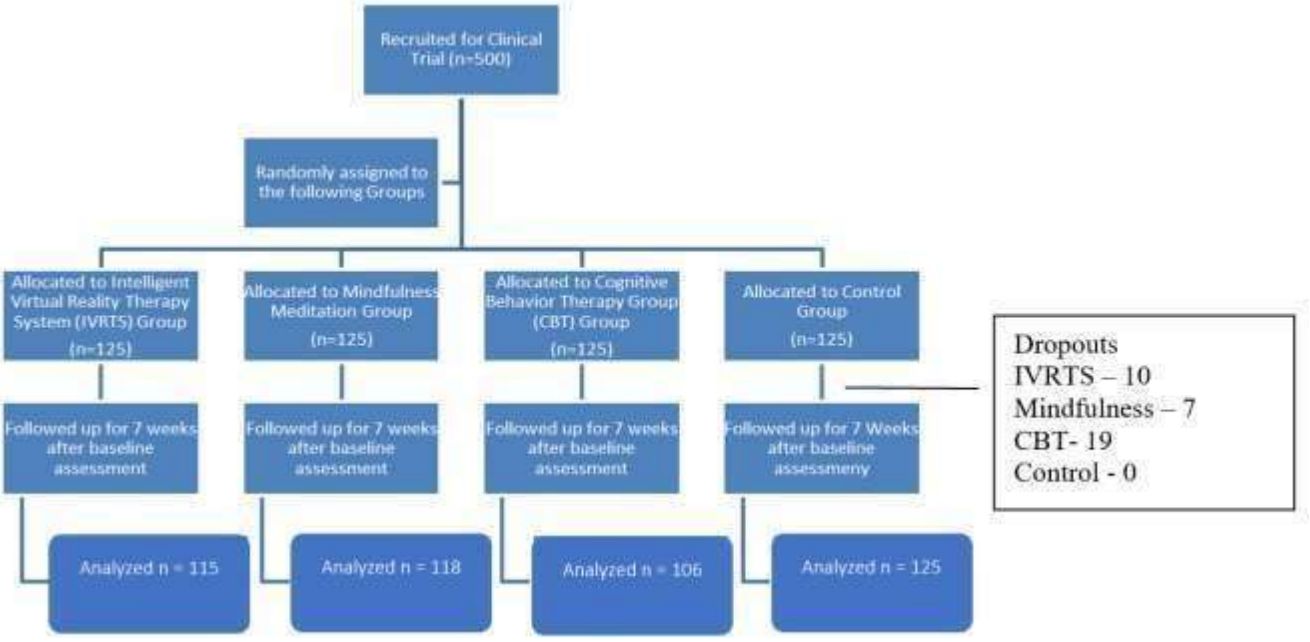

Figure 5: Consort Diagram

Inclusion Criteria

The Inclusion criteria included patients visiting the Psychiatry OPD of University College of Medical Sciences of the University of Delhi and the attached GTB Hospital. Furthermore, those patients were selected who reported fear of heights and scored mild, moderate and Severe anxiety as assessed on Hamilton Anxiety Inventory. The patients were in the age group between 18 to 60 years of age.

Exclusion Criteria

Patients who had any Psychotic disorder or symptoms co-morbid were not selected for the study. Furthermore, patients below 18 years of age and aver 60 years of age were also not selected for the program

Registration

All procedures involving human subjects/patients were jointly approved by The University College of Medical Sciences (University of Delhi) and Delhi Psychiatry Society Ethics Committee registration. Registration number 3/1/333011/HRD. The patients were first recruited on 5th February 2018 for the project.

Procedure and Approaches

To achieve the stated objective, a two-fold approach comprising of qualitative and quantitative analysis was undertaken. A 7-week intervention course was designed for each subject to reduce symptoms and enhance quality of life as well as to establish clinical efficacy. The intervention was conducted on a sample of 500 patients diagnosed with Acrophobia co-morbid with generalized anxiety who underwent the intervention at The GTB hospital of The University of Delhi, for a total of 3500 sessions, ranging up to 5250 Hours over a period of 2 years. Written informed consent was obtained from all participants. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All procedures involving human subjects/patients were jointly approved by The University College of Medical Sciences (University of Delhi) and Delhi Psychiatry Society Ethics Committee registration. Registration number 3/1/333011/HRD. Further study carried out A-B-A research design which mainly involved establishing a baseline condition, introducing an experimental treatment and then returning to the baseline. The subjects

completed standardized self-report measures of Hamilton Anxiety Inventory (HAM-A), Subjective Units of Dysfunction (SUDS) and WHO Quality of Life - BREF Questionnaire (QOL-BREF) at baseline, after seven intervention sessions post assessments on the same scales were repeated to assess the efficacy.

The Therapeutic Software of IVRTS

The researchers developed four different technological approaches to develop the Psychotherapeutic Software. (1) Since phobias are known to stem from mental images of situations or objects which an individual has learned to be fearful of. Thus, the most effective way to treat them, then, would be to alter these anxiety-provoking images with the help of graded exposure of an image of a situation or object which induces maximum pleasure and positive emotions within the individual. This was achieved with the help of development of motion sensors to detect the wrist movements of the subjects, which aided in achieving the desired goal of stimulating the pleasure-inducing stimulus to reduce anxiety. This was accompanied by monitoring the subject's physiological parameters through body biofeedback and fNIRS depicting the changes brought about by VR therapy and keeping the record of the same. (2) When an individual encountered a fearful stimulus, certain kind of neurotransmitters are released in the brain and over time, the body and mind of the individual learn to associate the release of these neurotransmitters with fear. This association was altered by flooding the individual's mind with pleasurable memories in the form of positive images using Virtual Reality Technology and thereby replacing unpleasant memories attached to the neurotransmitter release with pleasant memories. It was followed by guided instruction from the IVRTS device along the concept of 'Whole Brain Thinking' wherein all the five sense organs are used to exercise all the parts of the brain to take advantage of a wide spectrum of thinking. (3) As described in Figure 1, Cognitive Behavioral Therapy

(CBT) states that it is not the situation itself but the thought associated with the situation (stimulus) which makes an individual fearful. Altering this thought and the emotions related to it is hence helpful in treating phobias. This was achieved by integrating an automated intelligent Cognitive Behavior Therapy software program with the VR device. 4) Finally, the researchers used Mindfulness Relaxation as a treatment for phobia. This was implemented by making the subject face the anxiety-provoking situation with the help of VR equipment and simultaneously working on reducing the anxiety emotions with the help of guided mindfulness meditation accompanied by meditation music, along with the developed automated intelligent therapy software interface. This methodology was intended to put the subject in a peaceful state of mind, detaching them from negative thoughts and fears, working on the principle that anxiety and relaxation cannot coexist.

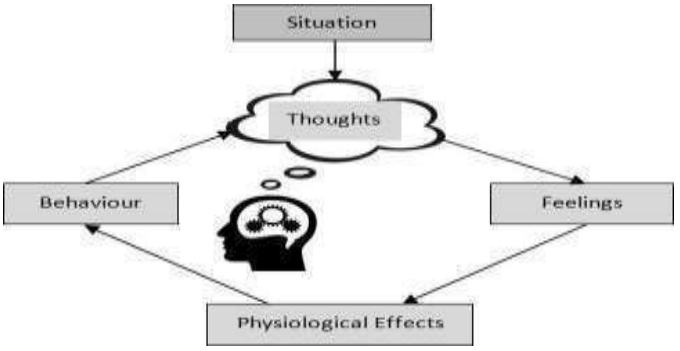

Figure 6: Understanding CBT Software

Project Plan

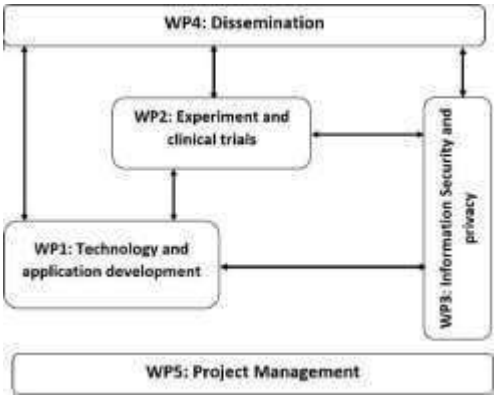

Figure 7: Project plan

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OUTCOMES AND RESULTS

The quantitative and qualitative results were analyzed with the appropriate statistical and analytical tools. Various statistical modalities were used to establish efficacy, efficiency and the frequencies evaluated. Paired sample t- test were conducted in this study to assess the statistical significance of the interventions. Independent sample t-test and ANOVA were tested in the data. Correlation analysis was also performed, The association between two categorical variables is enumerated by Chi-square test.

Scale	Mindfulness (n=118)		Control (n=125)		t-value	F-value	p-value
	Pre	Post	Pre	Post			
	Mean±SD		Mean±SD				
HAMA	32.86±5.76	19.62±4.24	33.70±6.08	28.00±6.49	8.350	2.327	0.000
SUDS	8.24±0.95	5.69±1.04	8.27±1.11	6.03±1.29	1.228	0.178	0.225
QOL	73.86±7.73	84.10±5.19	75.47±5.44	82.53±4.85	-2.229	6.242	0.030

Table 1: Mean comparison between Mindfulness Meditation group (n=118) and control group (n=125)

Table 1 represents the mean comparison between Mindfulness group and the Control Group of respondents while before and after intervention. On The Hamilton Anxiety scale, most of the respondents in The Mindfulness Group had very severe condition while before intervention with mean score (M=32.86), but it reduced to mean score (M=19.62). While in the control group, most of the respondents had very severe condition while before intervention with mean score (M=33.70) and moderate to severe condition while after intervention with mean score (M=28.00). The obtained t-value and p-value for Hamilton scale are 8.350 and 0.000 respectively. Here, p-value is less than 0.01; it indicates that there is a statistically significant difference between mindfulness and control group of respondents based on Hamilton scale. Similarly when considered the Subjective Unites of Dysfunction Scale (SUDS), most of the respondents of The Mindfulness Group, felt ‘Freaking out’ while before intervention with mean score (M=8.24) and ‘Moderately upset’ while after

intervention with mean score (M=5.69). But in the control group, most of the respondents felt 'Freaking out' while before intervention with mean score (M=8.27) and 'bad' while after intervention with mean score (M=6.03). The obtained t-value and p-value for SUDS are 1.228 and 0.225 respectively. Here, p-value is greater than 0.05, and indicated that there is no significant difference between mindfulness and control group of respondents based on SUDS. Similarly, obtained t-value and p-value for Quality of life are -2.229 and 0.030. Here p-value is less than 0.05; and shows a statistically significant difference between Mindfulness and Control group in relation to WHO Quality of life (QOL - BREF) scale of respondents.

Scale	CBT (n=106)		Control (n=125)		t-value	F-value	p-value
	Pre	Post	Pre	Post			
	Mean±SD		Mean±SD				
HAMA	32.52±5.24	21.03±4.29	33.70±6.08	28.00±6.49	6.905	2.312	0.000
SUDS	8.24±0.98	5.34±1.14	8.27±1.11	6.03±1.29	2.366	0.344	0.021
QOL	73.62±5.23	83.28±5.06	75.47±5.44	82.53±4.85	-2.714	0.002	0.009

Table 1: Mean comparison between CBT group (n=106) and Control group (n=125)

Table 2 presents the mean comparison between CBT group and control group of respondents before and after intervention. On the Hamilton Anxiety scale, most of the respondents of the CBT Group had very severe condition while before intervention with mean score (M=32.52), which reduced to mild to moderate severe after the intervention witj mean score (M=21.03). In control group, most of the respondents were in very severe condition while before intervention with mean score (M=33.70) and improved to moderate to severe condition after the intervention with mean (M=28.00). The obtained t-value and p-value for Hamilton scale are 6.905 and 0.000 respectively. Here, p-value is less than 0.01, it indicates a statistically significant difference between CBT and control group of respondents based on Hamilton Anxiety scale. Similarly, on the SUDS of respondents, most of the respondents felt 'Freaking out' while before intervention with mean (M=8.24) and

'Moderately upset' after the intervention with mean (M=5.34). But in the control group, most of the respondents felt 'Freaking out' before the intervention with mean (M=8.27) and felt 'bad' after intervention with mean (M=6.03). The obtained t-value and p-value for SUDS is 2.366 and 0.021 respectively. Here, p-value is less than 0.05, indicating a statistically significant difference between CBT and control group of respondents based on SUDS. Similarly obtained t-value and p-value for Quality of life are -2.714 and 0.009. Here p-value is less than 0.01; indicating a statistically significant difference between CBT and Control group in relation to The WHO Quality of life (QOL- BREF) scale of respondents.

Scale	Novel IVRTS (n=115)		Control (n=125)		t-value	F-value	p-value
	Pre	Post	Pre	Post			
	Mean±SD		Mean±SD				
HAMA	28.60±8.45	11.10±4.03	33.70±6.08	28.00±6.49	8.088	23.503	0.000
SUDS	8.10±1.56	3.73±1.23	8.27±1.11	6.03±1.29	7.503	2.315	0.000
QOL	72.87±6.21	87.07±3.79	75.47±5.44	82.53±4.85	-6.313	4.519	0.000

Table 3: Mean comparison between IVRTS (n=115) and Control group (n=125)

Table 3 presents the mean comparison between The Novel Intelligent Virtual Reality Therapy System (IVRTS) and control group of respondents. On the Hamilton Anxiety scale of, most of the respondents of the Novel IVRTS Group had a score representing moderate to severe condition before the intervention with mean (M=28.60), and reduced to mild condition after the intervention with mean (M=11.10). In the control group, most of the respondents were in very severe condition before intervention with mean (M=33.70) and moved to moderate to severe condition after intervention with mean (M=28.00). The obtained t-value and p-value for Hamilton Anxiety scale is 8.088 and 0.000 respectively. Here, p-value is less than 0.01, it indicates that there is a statistically significant difference between The Novel IVRTS Group and The Control Group on Hamilton scale. Similarly, on the SUDS of respondents, most of the respondents of The IVRTS Group felt 'Freaking out' before the intervention (M=8.10) and 'No Significant Distress' after the intervention with mean

(M=3.73). In the control group, most of the respondents felt 'Freaking out' before the intervention with mean (M=8.27) and moved to feeling 'bad' after the intervention with mean with mean (M=6.03). The obtained t-value and p-value for SUDS are 7.503 and 0.000 respectively. Here, p-value is less than 0.01, it indicates that there is a statistically significant difference between The Novel IVRTS Group and The Control group based on SUDS. Similarly, the obtained t-value and p-value for The WHO Quality of life Scale were -6.313 and 0.009. Here p-value is less than 0.01, and indicates a statistically significant difference between The Novel IVRTS and Control group on The WHO Quality of life (QOL-BRF) scale of respondents.

Scale	**Mindfulness**		**CBT**		**Novel IVRTS**	
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**
	Mean±SD		**Mean±SD**		**Mean±SD**	
HAMA	32.86±5.76	19.62±4.24	32.52±5.24	21.03±4.29	28.60±8.45	11.10±4.03
SUDS	8.24±0.95	5.69±1.04	8.24±0.98	5.34±1.14	8.10±1.56	3.73±1.23
QOL	73.86±7.73	84.10±5.19	73.62±5.23	83.28±5.06	72.87±6.21	87.07±3.79

Table 4: Efficacy of Interventions based on the HAMA, SUDS and WHO QOL scale

Finally Table 4, shows the comparison analysis between the various interventions to show which intervention proved to be the most effective and efficient for the patients. Interventions namely, Mindfulness Meditation, CBT and Novel Intelligent Virtual Reality Therapy System (IVRTS). The mean scores after intervention on both The Hamilton Anxiety Scale and The Subjective Units of Dysfunction Scale for the Novel IVRTS Group is significantly less than the mean scores (HAMA=11.10, SUDS=3.73) of The Mindfulness Group (HAMA=19.62, SUDS=5.69) and the CBT Group (HAMA=21.03, SUDS=5.34). In addition, The Novel IVRTS Group has a higher mean score on The WHO Quality of Life Scale (QOL=87.07) compared to the Mindfulness Group (QOL=84.10) and the CBT Group (QOL=83.28). The p-value is less than 0.01 respectively indicating a significant difference between Novel IVRTS compared to other interventions including CBT, Mindfulness and

Control groups. Considering the all the above comparisons of statistical significance modalities namely, The Mean Scores, Standard Deviations, t-scores and p-scores. The study concludes that, The Novel Intelligent Virtual Reality Therapy System (IVRTS) intervention is the most effective and efficient intervention compared to Mindfulness and even CBT.

Through the various approaches explained henceforth, the researchers aspired to create a more effective, image-based treatment system for phobias, based on the combination of principles of Psychology and Virtual Reality. The treatment methodologies thus aimed to automate the process oftherapy thereby making the process faster and more practical. Moreover, the new technology is for the first time used to develop human, AI interaction for treatment, using interactive sensors, intelligent automated psychotherapy interface, and VR imagery scenarios.

DISCUSSION AND CONCLUSION

Through the various approaches explained henceforth, the researchers aspired to create a more effective, image-based treatment system for phobias, based on the combination of principles of Psychology and Virtual Reality. The paper is a good step towards incorporating technology in Psychiatry. In today's age when the rest of the medical fraternity (Radiology, cardiology, neurology etc.) has moved towards Artificial Intelligence and robotics for diagnosis and interventions. Psychiatry is still at a nascent stage in using technology for its advantage. Not to forget, the subjectivity in the field of Psychiatry is also its biggest strength, which cannot do without the subjective empathetic human touch, this technology is not to replace but to complement the subjective human intervention. The treatment methodologies thus aimed to automate the process of therapy thereby making the process faster and more practical. Moreover, the new technology is for the first time used to develop human, AI interaction for treatment, using interactive sensors, intelligent automated psychotherapy interface, and VR imagery scenarios. The strengths of this technology are successful

development of novel new technology which uses Virtual Reality Imaging in combination with Artificially Intelligent Psychotherapy and Incorporated with tactile interactive sensors. a person will be able to touch the feel of water (In case of Hydrophobia) or experience the feel of air (in case of acrophobia) and so on through the tactile sensors. The Novel Technology proved be to highly effected, so much so that our clinical trials concluded the Novel Intelligent Virtual Reality Therapy System (IVRTS), to be significantly more effective than Cognitive Behavior Therapy, as well as Mindfulness Meditation. The Novel IVRTS, reduced Anxiety levels of patients and improved their Quality of Life, significantly more compared to CBT and Mindfulness. There is a need of new technology for treatment, keeping in view the acute shortage of manpower of trained mental health professionals, which can never keep pace with increasing population and psychiatric morbidity, especially challenges arising from COVID-19 pandemic.

Relevance to society

When the world is sitting on the verge of a Mental Health Crisis. We need to revolutionize the Psychotherapy modality for two reasons, first being; the shortage of Mental Health Professionals compared the huge number of cases that would need help and secondly accessibility. When social isolation has become the new norm, one needs innovative tools to be able to effectively handle the situation sitting at home, and yet be equally effective, if not more. According to Freeman[24], there are large benefits of Psychological therapies using automated Virtual reality systems. This project has huge potential as well has huge social impact for the treatment of Anxiety Disorders which currently effects 80% of the world population according to the World Health Organization[25]. Science and Technology is the only way this situation can be tackled. The development of this novel technology would reduce the cost of treatment of Anxiety disorders, PTSD and Phobias considerably. It would also reduce the treatment time by approximately half. Also, it would make the accessibility of treatment

widely available and more comfortable for the masses.

Limitations, Challenges and Future Scope

The challenges the project could face both Nationally and Internationally a few, namely, Cross-Cultural reliability. The efficacy of the developed technology would need to be established cross-culturally, for which it would require subjects from Norway, India and also it could be extended to other regions and cultures to establish its validity for practical usage. Finding such a variety of subjects could prove to be a challenge but can be achieved**.** This project has immense advantages and enormous scope in un the coming future. This technology will be a landmark step in the way Psychotherapy is conducted across the world. The IVRTS, will increase the widespread availability of Psychotherapy to millions of individuals who are currently deprived of it, due to social taboo or shortage of Mental Health Consultants or just non-availability of resources. This novel technology would also reduce the cost of Psychotherapeutic interventions, and most importantly will be a major steppingstone towards a healthier world, because of its capability to touch masses in exponentially large numbers

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