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. Participant Consent Form (includes – Participant Information Sheet + Participant consent form – dated 05/02/2018)
2. Letter of Research Clinical and Ethical Registration (Dated 05/02/2018)

Thank you.

Warm regards,

Dr. Akshay Kumar

05/02/2018

PARTICIPANT INFORMATION SHEET

(PARTICIPANT NAME AND RELATIVE/ATTENDANT NAME)

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

Purpose of study: Research

Duration of the study: 7 weeks

Tools: Hamilton Anxiety Inventory, (Hamilton, 1959), Quality of Life scale-BREF (WHO, 1996), Subjective Units of Dysfunction, (Wolpe, 1969).

Procedure: A 7-week intervention course will be designed for each participant to reduce symptoms of phobia and enhance quality of life as well as to establish clinical efficacy.

The participants will be assigned to three groups using circumstantial sampling methodology. Group 1: IVRTS, Group 2: Mindfulness, Group 3: Cognitive Behaviour Therapy, Group 4: Control Group.

Participants assigned to IVRTS group will be taken through a Novel Virtual Reality Intervention with automated Artificially Intelligent Psychotherapy system. Participant in the CBT group will be taken through talk cognitive behaviour therapy and participants in the mindfulness group will be taken through mindfulness meditation. The interventions will be also be verbally explained to the participant by the researcher in detail before the session starts.

Further study will be carried out using A-B-A research design (Pre and Post intervention) 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 will be repeated to assess the efficacy.

Benefits expected as an outcome of the research: The study hypothesizes reduction in symptoms of Anxiety and Phobia.

Foreseeable risks: Minimal

Confidentiality: Would be highly maintained

Freedom: To participate and to withdraw from research anytime without penalty or loss of benefits.

Research team contact: Dr. Akshay Kumar

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05/02/2018

DATA COLLECTION AT UNIVERSITY COLLEGE OF MEDICAL SCIENCES (UCMS) AND GTB HOSPITAL
(Department of Psychiatry)

STUDY PARTICIPANT'S CONSENT FORM

S. No. Date:

Patient's Name:

1. I have been explained the details of the study entitled "**Intelligent Virtual Reality Therapy System (IVRTS) and Testing Its Clinical Efficacy: Revolutionizing Evidence-Based Psychotherapy.**" and my questions regarding the study have been answered to my satisfaction in a language understood by me.

2. I understand that I have the right to withdraw from the study at any time and to decline to answer any particular question.

3. I understand that my participation in this study is confidential and that no material that could identify me will be used in the analysis and in any reports based on this.

I hereby provide informed consent to take part in the study entitled "**Intelligent Virtual Reality Therapy System (IVRTS) and Testing Its Clinical Efficacy: Revolutionizing Evidence-Based Psychotherapy.**"

Signature /Thumb impression of participants

(Right if male/Left if female)

Signature if witness/signature of guardian

Name and address of witness/guardian

Signature of Investigator

Form Approved/Ethical Clearance

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Letter of Research

05/02/2018

This is to acknowledge and certify that Dr. Akshay Kumar is conducting the research project IVRTS – An intelligent intervention to overcome Anxiety at The University College of Medical Sciences (University of Delhi) and GTB Hospital in the Psychiatry OPD.

The research project is funded and registered by The Indian Council of Medical Research (ICMR) - 3/1/333011/HRD (Registration id as given by the Indian Council of Medical Research).

The research is being conducted with proper ethical code of research as well as permissions of Clinical Trials.

The research is being conducted with the due consent of The University of Delhi (DU) and The Indian Council of Medical Research (ICMR).

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