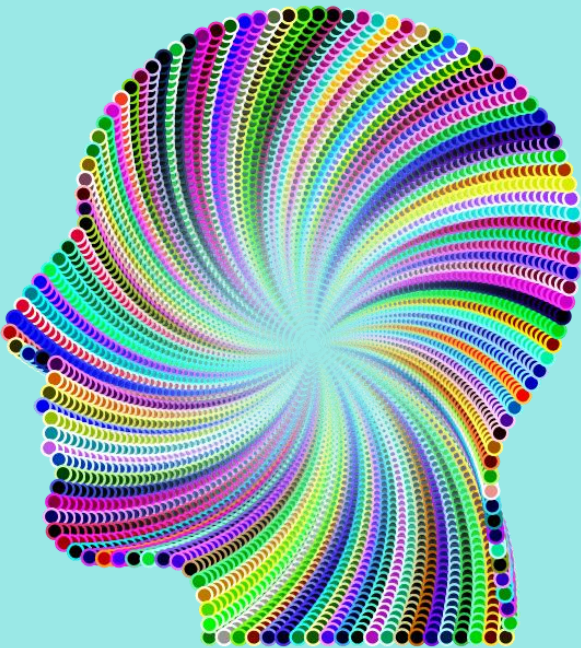


The “HIGH” Road To Success

Background

In recent years psychedelics (MDMA/Ecstasy) in treating mental health illness is undergoing a renaissance. Trials on this subject in the UK have been fairly limited. At C&VUHB we are helping to deliver the MP18/MAPS study evaluating the safety & effectiveness of MDMA-assisted psychotherapy for treatment of PTSD. It is the 1st study of its kind that we have facilitated in the CRF.

PTSD is a chronic debilitating mental health disorder that occurs following a traumatic event.



- MDMA** is capable of inducing unique psychopharmacological effects, such as:
- ❖ Decreased feelings of fear and defensiveness
 - ❖ Increased feelings of wellbeing
 - ❖ Increased sociability and extroversion
 - ❖ Increased interpersonal trust

MAPS/MP18

- For each participant, the study will consist of the following periods:
- ❖ Screening Period: phone screen, informed consent, eligibility assessment, and enrolment of eligible participants
 - ❖ Preparatory Period with Enrolment Confirmation: medication tapering, Preparatory Sessions and Baseline assessments leading to Enrolment Confirmation
 - ❖ Treatment Period: 2 monthly Experimental Sessions and associated Integrative Sessions over ~8 weeks plus one CAPS-5 assessment from two trained therapists to attempt to process their trauma
 - ❖ Follow-up Period and Study Termination: ~4 weeks with no study visits, followed by Primary Outcome CAPS-5 and Study Termination visit

Challenges:	Successes:
Multi-professional working across multiple sites PI fairly new to research Therapists new to research	Effective communication between Research Team, PI, Therapists, Cardiologist, Night Attendant, IR’s, junior doctor, CRF facility. Established WhatsApp group
Long set-up time, difficulty with funding, institutional anxieties Study Team based around the world	Communication – weekly Zoom meetings and always available at the end of emails/phone for advice
Tight restrictions in handling IMP- needing CRF to be approved by Home Office	Home Office approvals for IMP given Oct 2022 PI licensed to handle drug CCTV installed Safe installed
MDMA expiration end 03/2023- tight deadline to recruit patients to undergo experimental sessions x 2 2 participants undergoing screening but require long tapering & washout periods	New batch of MDMA approved, due 04/2023
IT issues- recording sessions, ePRO’s, IR sessions Wi-Fi stability and confidentiality. Unfamiliar databases	Stability of Wi-Fi for recording sessions Use of Cardiff University Wi-Fi for uploading, quiet room identified for recordings, Familiarity with digital platforms & recording equipment

Outcome

To date we have screened 3 participants, 1 failed screening, 1 undergoing screening, 1 beginning enrolment & preparatory stage

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