

INFORMATION SHEET FOR PATIENT VOLUNTEERS**REDUCING RISK OF EXPOSURE TO COVID-19**

(To read in conjunction with BRIGH TMIND Patient Information Sheet)

BRIGH TMIND**BRAIN IMAGE GUIDED TRANSCRANIAL MAGNETIC in DEPRESSION**

During the COVID-19 Pandemic we have made changes to our normal BRIGH TMIND study procedures, to reduce the risk of exposure to the virus. This leaflet is to be read in conjunction with the BRIGH TMIND Patient Information Sheet. Share this and talk to others if you wish. Ask us if there is anything that is not clear.

What have we done to reduce the risk of exposure to COVID-19?

Where possible, we have reduced the need for you to travel to appointments by conducting assessments remotely. Where this cannot be avoided we have reduced the time of the assessment and ensured full social distancing and PPE measures can be followed, in full compliance with COVID-19 Government guidelines.

We have provided more detailed information below:

Baseline Assessment

This will now be split in to 2 sections; Part 1 - the main part of the assessment and Part 2- the THINC-it tasks. The THINC-it tasks are tasks to assess cognitive functioning such as reaction time.

The main part of the assessment will be completed by telephone or video call. We will post a consent form to you prior to the appointment which, if you are happy to take part, we will ask you to sign whilst on the call. This process will take approx 90mins. Please let the researcher know if you wish to take a break during the assessment.

The THINC-it cognitive tasks cannot be completed remotely as they need to be done on one of the research i-Pads. To avoid having to attend for a separate visit we will complete these tasks with you when you attend for your baseline MRI scan.

It is important that you bring your signed consent form (completed during the telephone assessment) with you when you attend for your MRI/THINC-it appointment.

We will telephone you the day before your MRI/THINC-it appointment to ensure you do not have symptoms of COVID-19, as per government guidelines. If you are required to follow government guidelines for self-isolation we will rearrange your appointment after this period ends.

The MRI and THINC-it visit will be completed following social distancing guidelines, using the required PPE and all equipment used will be cleaned before and after each use.

TMS Treatments-

We will telephone you the day before your first visit to ensure you do not have symptoms of COVID-19, as per government guidelines.

Access to the treatment area will be clearly signposted and the waiting area will allow social distancing measures. Staff will be wearing PPE and, on your arrival, your temperature will be taken and the COVID-19 symptom questions will be asked again. If you are required to follow

government guidelines for self-isolation we will rearrange your appointment to take place after this period ends.

The clinicians delivering the treatment will wear the required level of PPE. All equipment will be fully cleaned before and after each treatment use.

Face masks and hand sanitiser will be available for participants.

We ask that friends or relatives do not attend this appointment with you. We will pay their expenses if they drive you to the appointment but please ensure they do not enter the building where the treatment takes place.

To avoid spending excess time in the building where the TMS treatments are being given, please do not attend your appointment any more than 5 minutes prior to your appointment time.

Follow Up Assessments

These take place at 8, 16 and 26 weeks after the date of your first TMS treatment.

The 8 and 26 week assessments will no longer require you to complete any tasks on the i-Pad, so will now be completed entirely by telephone or video call.

The 16 week follow-up assessment will be split in to 2 parts – like the baseline assessment. There will be the main part of the assessment and the THINC-it tasks on an i-Pad.

The main part of the assessment will be completed by telephone or video call and the THINC-it tasks will be completed when you attend your 16 week MRI scan.

We will telephone you the day before your 16 week THINC-it / MRI scan appointment to ensure you do not have symptoms of COVID-19. If you are required to follow government guidelines for self-isolation we will rearrange your appointment after this period ends.

The THINC-it/MRI scan visit will be completed in full compliance with social distancing guidelines, and all equipment used will be cleaned before and after each use. PPE will be worn by staff and will be supplied to study participants.

If you have to travel by public transport, please make our research staff aware at your baseline assessment and they will provide by post free disposable face masks. If you are having issues with travel arrangements please speak with the research team, who will seek possible alternative travel arrangements.

If you have any concerns or questions please contact your local study team.

<<Enter localised contact details>>

Flowchart showing sequence of events with changes due to COVID-19



