King's College London

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PG Cert/PG Dip/MSc Examination

7PADRERC Research Skills: From Reviewing and Critical Analysis to Research Ethics
Coursework 2 Paper

Final word count: 1589
(word limit: 1500 words +10%)

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Student ID Number 19071714 Date 21 October 2021

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INFORMATION SHEET FOR PARTICIPANTS

TITLE (2.5%)

(This should not be the same as the title of the published article, please provide an appropriate title.)

What are the effects of brain stimulations on impulsivity on individuals diagnosed with a mental illness such as alcohol use disorder?

Invitation Paragraph (5%)

You are invited to take part in a research study.

The decision to take part to the study is entirely up to you. If you don't want to take part, you don't have to.

Before deciding if you want to take part, it is important for us that you understand what your participation involves.

This sheet contains information that will be useful for you to understand why this research is being done, what it involves for the participants and to decide if you want to take part in the study. Please take time to read it carefully.

Please feel free to ask any question if there is something unclear or you don't understand.

We also encourage you to discuss about participating in this study with your family, friend or doctor.

Please also note that even if you choose to take part, you have the right to change your mind at a later stage and withdraw your participation from the study at any time and without any reason.
The withdrawal will absolutely not affect your clinical care in any case.

What is the purpose of the study? (30%)

Individuals suffering with neurobiological disorders such as alcohol use disorder experience impulsivity and loss of control leading to taking alcohol despite knowing the adverse consequences of their act.

We are interested in testing a new possible approach to see if it could have an effect on impulsivity. This new approach uses a procedure called High Frequency Repetitive Transcranial Magnetic Stimulation (HF-rTMS).

This TMS procedure involves a non painful way of stimulating a specific part of the brain.

This stimulation results from a brief magnetic field generated by a small coil placed over the head. This magnetic field passing through the scalp and the skull will create a slight changes in the neural activity of the part of the brain that is under the coil. This stimulation is repeated at a regular interval to increase local brain activity.

This procedure has been developed as an effective treatment for depression and previous studies found some effects applying this procedure to alcohol dependent patients.

We hope this research will deepen our understanding of the effects of the TMS procedure on the ability to control impulsivity in the specific case of the psychiatric illness of unhealthy alcohol use.

In this study, we wish to compare the results of participants who will receive a real form of the procedure to participants who will receive a sham procedure or a placebo. If you participate to the study, you will not know whether you receive the real form of the procedure or the placebo.

This study has been approved by the Medical Ethical Committee of the Academic Medical Centre Amsterdam (2015_064) and is registered is The Netherlands Trial Register (with the number 5291).

Why have I been invited to take part? (5%)

You have been invited because it seems that you have been recently diagnosed with the medical condition of alcohol disorder. The Jellinek Centre in Amsterdam put your name on our list as a potential participant for this research study as it focuses on individuals who met the criteria of a diagnosis of alcohol use disorder.

What happens to me if I take part? (35%)

If you decide to take part to the study, we will ask you to sign the consent form. Upon signing the consent form, we will go through a screening process with you to make sure that the criteria for our study are met and there is no risk for you to participate in the study.

If all the criteria are met and if you agree to continue, you will be enrolled in the study. Please note that you can change your mind at any moment and decide to not carry on with the study.

This study involves stimulating your brain in a particular region called dorsolateral prefrontal cortex, located in the front top of your head (see figure 1 below).

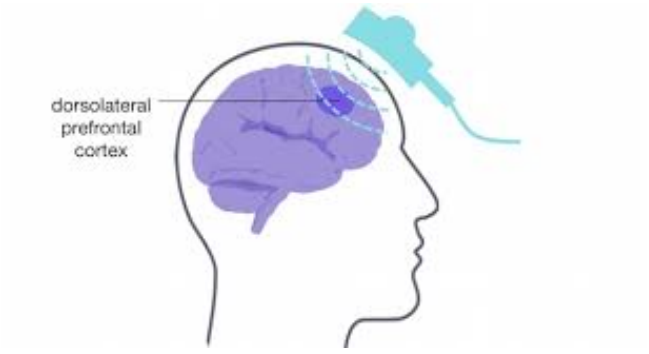

Figure 1. TMS procedure on the dorsolateral prefrontal cortex

The stimulation is made by generating a small magnetic field using a stimulator in a form of coil connected with a machine that will produce a current.
A cap will be placed over you head to make sure that the stimulation is done on the area of interest.

During this TMS procedure, you will receive short trains of pulses that last less than a second.

There will be a sound produced by the machine which although normal might produce some incomfort. That's why we will offer you to wear ear plugs during the procedure.

Each TMS procedure usually last about 30 to 40 minutes.

This study will take place over 10 consecutive workdays.

Some sessions contains only the TMS procedure and for some sessions, you will be asked to perform three simple tasks before or after the TMS procedure. These tasks will require you to sit in front of a computer screen.
You will be presented with words, numbers or arrows that will appear on the screen and you will be asked to respond using a keyboard and following certain rules that will be explained to you beforehand.
These tasks are not meant to be difficult.

The 10 sessions schedule looks like as follows:

- Session 1 – You will be asked to fill in some questionnaires. These questionnaires are necessary to confirm your eligibility to the study and needed to assess your level of control and impulsivity prior to any intervention. Then you will be performing three computer-based taks. After that, you will receive the first TMS procedure.

- Session 2 to session 4 – You will be returning to the research centre every workday and will receive a TMS procedure. There will be no computer-based task on these sessions.

- Session 5 – During the same session you will receive the TMS procedure and will be asked to do three computer-based tasks afterwards.

- Session 6 to session 9 – There will be only the TMS procedure performed on these sessions.

- Session 10 – This is the last day of the study. You will be receiving the last TMS procedure and will be asked to complete the final computer-based tasks.

Following each session, you will be asked to report possible side effects of the TMS procedure.

Please note that you will be participating in a randomised controlled research study: some of the participants will not receive the TMS treatment but a placebo which means that you will be placed under the same conditions of a person that will receive the brain stimulation – you will have a coil placed over your head – but there will actually be no stimulation. The repartition of the participants in either of the two groups is made randomly by a computer software.
On the final session, you will have the opportunity to tell if you think you have received the treatment or the placebo and will receive a full debrief about the study.

Am I eligible to participate in this study? (10%)

(This section should include any inclusion and exclusion criteria)

You have been invited to this study because you have been diagnosed with alcohol use disorder.
However, due to the constraints of the study and the procedure, there will be some supplementary criteria that we need to verify before you can participate to the study.

We will go through a screening process with you.

We will first look at the age range that we are particularly interested to look at and ask you some questions to confirm the diagnosis.

The screening will involve making sure that there is no contraindications for you to undergo the TMS procedure such as history of epilepsy seizures or if are under certain medications or using some recreational drugs. This is

because these conditions can put you at risk if you procede with the procedure.

Some psychiatric disorders may influence the results that we want to look at so we will be asking you some questions regarding your psychological condition. Please note that your answers will remain confidential.

Due to the presence of some words-based tasks, we will also verify the fluency of the language and assess basic memory.

What are the possible benefits and risks of taking part? (10%)

This is a research study and not a treatment program. Therefore, there might not be any direct effect benefit to you from your participation to the study. However, your involvement will help research in psychiatric disorder and in particular the effect of the TMS procedure on individuals diagnosed with alcohol use disorder.

The vast majority of research suggest that the TMS procedure is safe. However, some people may experience some side effects. This include headache, pain, discomfort coming from the sound that the machine produces, tapping sensation or brief muscle cramp.
Some people might also experience tiredness and discomfort from sitting still and doing the tasks.

If experienced, these effects usually disappear within few hours after the procedure.

There might be other side effects and should you experience any, you will be able to report them to the researcher at the end of each session.

Although considered safe, there are rare cases in the past where the TMS procedure have caused seizure.

Due to the risk of seizure, there are some conditions for which taking TMS is not possible. This can include having metal implants, history of epilepsy or brain illness such as a stroke.
It is also not recommended to undergo the TMS procedure if you are pregnant.
If you experience any of these conditions, it is very important that you mention it to us before the study during the screening process.

How is the project being funded? (2.5%)

This study is funded by a grant (VIDI Grant) awarded to researchers who have already spent several years doing postdoctoral research to develop an innovative research.

*[**PLEASE NOTE:** Participant information sheets normally also provide information on data protection/confidentiality, dissemination of results and contact information. You are **not** required to include these sections in your coursework. You are also **not** required to include the consent form].*