

The Play Game Trial



An information leaflet
for adolescents
who continue to have symptoms
following a mild traumatic brain injury

You have been given this information because you are over 13 years old and you may be able to take part in a clinical research study. This booklet will explain what a clinical research study is and will tell you about the Play Game study.

WHAT ARE CLINICAL RESEARCH STUDIES?

Most people take some kind of medicine from time to time. Before a medicine can be used, it must be tested carefully to make sure that it works well and is safe. Clinical research studies are used to test medicines.

The decision to take part in a clinical research study is up to you and your parent/guardian. Nobody is forced to enter a research study.

WHY IS THIS STUDY BEING DONE?

Although most kids recover quickly following a concussion, some continue to have symptoms for months. These symptoms are called **post-concussion symptoms** and can include headaches, dizziness, problems thinking and mood changes.

This study will help us learn more about Melatonin. Melatonin is produced naturally in the brain. Melatonin is very safe and commonly sold in pharmacies to help people sleep. Recently, researchers have found that Melatonin can also protect the brain after injury and can reduce headaches, and improve mood.



We are exploring whether Melatonin can speed up the recovery after a concussion when compared to a placebo (sugar tablet). It will also use some new technologies to monitor your response to treatment and help doctors understand how brain circuits adapt in kids who do and do not recover quickly.

WHAT WOULD I HAVE TO DO IF I TAKE PART IN THIS STUDY?

TREATMENT WITH MELATONIN OR PLACEBO

You will receive a treatment for 28 days, this will be either:

- Low dose Melatonin
- Higher dose Melatonin
- or a placebo (a safe substance that is not a medication).

They will all look the same and taste like sweet peppermint. It is taken by mouth (dissolves under the tongue), 1-2 hours before bedtime.

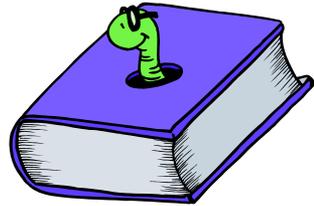
The treatment you receive is randomized i.e. selections are made in a manner similar to drawing numbers from a hat.

Neither you, nor the study coordinator nor the physician, will know whether you received Melatonin or placebo.

BEFORE AND AFTER THE STUDY YOU WILL HAVE

Health Check (1 hour):

- You will be seen by a brain injury doctor
- You will be asked to complete some questionnaires about your symptoms

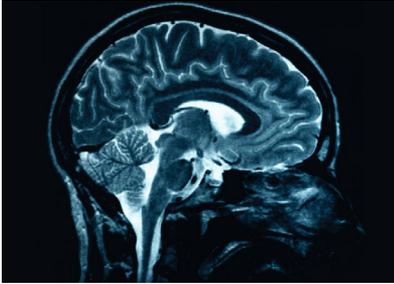


Cognitive Testing (30 mins)

- In order to examine your thinking abilities (i.e., attention and memory) brief assessments will be done using a series of games and mini-tests on a laptop computer. Most kids find this fun.



BEFORE AND AFTER THE STUDY YOU WILL HAVE:



Magnetic Resonance Imaging (MRI) (1 hour)

- MRI is a safe procedure
- For most of this scan you will simply have to lay still.
- During the scan, you will be asked to respond to pictures by pressing appropriate buttons (fMRI).

fMRI helps us understand how the brain works in children who have had a concussion and how it differs from children without these problems.

Transcranial Magnetic Stimulation (TMS) (1 hour):

TMS uses magnets to stimulate specific areas of the brain. It helps us to understand how the brain is working. It is painless and very safe.

Small stickers are placed over muscles in the hands to

fMRI uses a large magnet and **does not use any radiation.**

You will lie on a table that will move into the scanner for about one hour and you will be asked to lie still during the scan. The scanner makes loud, banging sounds but you will be wearing protective ear-plugs. You will be able to talk to and hear.

Because you must lie with your head and neck inside the scanner tube, you may become anxious in the enclosed space.

Should you feel like you cannot tolerate remaining in the scanner for any reason, you can interrupt the study and rest outside the scanner. You are always free to terminate the procedure if you choose.

measure a response to these stimulations.

We will arrange this on the same day of your MRI. You sit in a comfortable chair and watch movies or simply rest during the test.

Actigraphy and Sleep Diary

The Actiwatch® is worn and looks like a wristwatch and helps monitor how you are moving and how you sleep.



- You will be asked to wear this for the duration of the study, a few days before treatment starts and until a few days after the treatment ends.
- We also ask you to write down when you go to bed in a diary.

We also will ask for sample of urine on three separate days.

IS IT SAFE TO TAKE PART IN THIS CLINICAL RESEARCH STUDY?

Before a clinical research study can start, it is carefully thought about by a team of scientists, non-scientists and members of the public. The study is only allowed to go ahead if this team is happy that everyone taking part in the study will be looked after properly and safely.

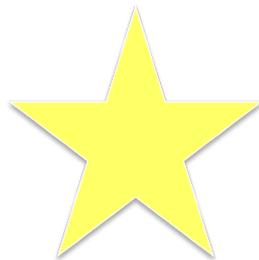
Melatonin is safe. Don't drive after taking it in the evening. Don't take if you could be pregnant.

The placebo contains lactose (a type of sugar). It is safe and has no side effects unless you are lactose intolerant.

There are no known risks to the brain imaging scans.

If you have metallic objects in your body or if you are pregnant, you cannot take part in the study.

TMS is safe and well tolerated in children and young people. Occasionally, some children experience headache.



IS THERE ANYTHING ELSE THAT I SHOULD KNOW?

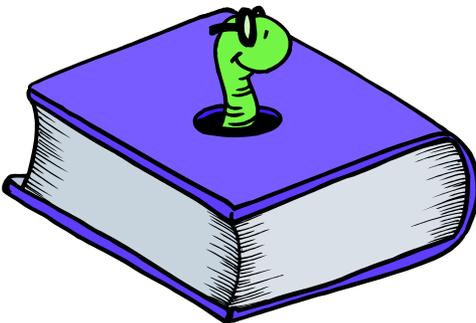
If you do decide that you want to take part in the study you can ask the study team any questions you may have at any part in the research study.

You would have to come to the Alberta Children's Hospital at the times that you have agreed. This is very important to make sure the study is a success.

We will provide you with a \$50 gift certificate at the end of the study as a small token of our appreciation.

Even though we can't promise that you would feel better when taking the research study medication, by being involved in this study you may help us understand concussion and post-concussion syndrome better than we do now.

The information we get from this study may help us provide better treatments for kids in the future.



I'M INTERESTED IN TAKING PART! WHAT HAPPENS NEXT?

If you think you would like to take part in this clinical research study, you should first talk to your parents or guardians. If everybody agrees, and you want to take part, your parent or guardian will need to make an appointment with the study doctor.

Two important things must be done:

A parent or guardian must sign an informed consent document to show that they understand what you will need to do as part of the study and that they agree you may join.



You will be asked to sign an assent form to show that you also agree to take part in the study and that you understand what you will need to do.



THANK YOU

Thank you for thinking about taking part in
the Play Game Study



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or

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