

CONSENT FORM - Clinical, Research and Financial

Transcranial Magnetic Stimulation Consent Form (V1.4) Pioneer Health TMS Service for Smoking Cessation

Patient Name: _____

Patient DOB: _____

Patient Address: _____

Patient Phone No: _____

Indication for TMS:

- **Smoking Cessation**

Magnetic stimulation refers to stimulation of nerve cells (neurons) in the brain and this is referred to as Transcranial Magnetic Stimulation or TMS. TMS works by generating powerful magnetic pulses that reach through the bone of the skull to stimulate parts of the brain. By targeting different parts of the brain TMS can treat a variety of psychiatric and neurological conditions. Depending on the frequency of the magnetic pulse TMS can either stimulate or inhibit nerve cells and neural circuits. There is strong evidence that TMS is effective in treatment of depression and other psychiatric conditions, and emerging evidence that TMS is effective for neurological conditions such as chronic pain conditions and addiction.

There is a growing body of evidence that TMS is effective in the treatment of nicotine addiction and **smoking cessation**. In 2020 the US FDA approved the BrainsWay TMS device as an aid for short-term smoking cessation in adults. Published data has demonstrated that TMS reduces cigarette craving and increases the likelihood of smoking cessation.

What can you expect from magnetic stimulation treatment:

The magnetic pulse emitted by the TMS machine coil is experienced as a rapid tapping sensation on the scalp of the patient. On the forehead and the front of the scalp this pulsation can be experienced as painful, so we usually reduce the intensity of the magnetic pulse to comfortable levels. After the first 3-4 sessions of magnetic stimulation, most patients tolerate the treatment well. As the magnetic coil emits a tapping sound, we offer hearing protective ear plugs for each treatment. The length of your smoking cessation TMS treatment session is usually 15 minutes with a cue provocation procedure before each TMS session and a brief motivational video after each session. You will have a total of 13 TMS sessions spaced over 5 weeks. (For the first two weeks you will have 5 sessions per week, followed by weekly sessions for 3 weeks.)

Adverse effects of magnetic stimulation:

Transcranial Magnetic Stimulation (TMS) and Peripheral Magnetic Stimulation (PMS) are safe and have few side effects.

Common adverse effects of TMS treatment are as follows:

- Headache
- Scalp discomfort
- Tingling, facial muscle twitching
- Noise related discomfort (patients are offered ear plugs during neuromodulation therapy)

Rare adverse effects of TMS are as follows:

- Seizure (the chance of seizure is one in 30 thousand, which is lower than the seizure rate for patients treated with antidepressants.)
Please note that in the unlikely event that you do experience a seizure during treatment, this will affect your fitness to drive.
- Syncope (fainting)
- Mood elevation (elevated mood tends to settle on cessation of treatment)

Unlike electroconvulsive therapy (ECT) TMS causes NO adverse cognitive effects such as memory loss.

Cost of magnetic stimulation:

In Australia, TMS is only covered by Medicare for treatment resistant depression. Unfortunately, there is currently no Medicare support for the use of magnetic stimulation for the treatment of conditions other than depression. This means that patients wishing to access this treatment will need to pay privately for magnetic stimulation treatment with no Medicare rebate being available. At the time of writing there are no private health insurers that will cover the cost of magnetic stimulation for smoking cessation, though we encourage you to petition your private health insurers to change this.

Please be aware that the magnetic stimulation fee is not refundable. If you require future maintenance magnetic stimulation therapy or a further treatment cycle, a separate fee will apply.

Your magnetic stimulation treatment cycle quote:

Your number of magnetic stimulation treatments covered by this quote:

Patient Consent

I consent to be involved in the Pioneer Health TMS research project. (Your data would be used for the purposes of research, publications and case reports in a de-identified manner):

Yes

No

I verify that I have read and understood the above information and that I have had sufficient opportunity to discuss my magnetic stimulation therapy with the doctor.

I verify that I have understood the cost of my magnetic stimulation treatment cycle, and that I have agreed to pay the full quoted treatment cycle fee. I understand that non-payment of the quoted fee will result in cessation of the magnetic stimulation therapy. I also understand that the treatment cycle fee is non-refundable.

Patient's Name: _____

Patient Signature: _____

Date: _____

Doctor's Name: _____

Doctor's Signature: _____

Date: _____