

Optimized Brain

Information and Administration Consent Form

(Updated 07-26-2021)

Physical address is shared via email
Provider's Phone: 615.516.9985
E-mail: info@OptimizedBrain.co

Informed Consent

You are seeking LENS sessions (the *Low Energy Neurofeedback System*, a form of neurofeedback) to address symptom(s) you are experiencing.

Although no significant negative side effects have been observed so far, the non-significant ones that we have seen will be listed later. Your understanding of them will help you work with your LENS Provider to administer LENS sessions. As with any health/healing modality, please be aware that while the overall record of the use of LENS is quite successful, there can be no guarantee of success in your particular instance. You are therefore invited to consent to LENS sessions on the basis of this information. Before signing this document, please read the following and ask as many questions as are necessary for you to fully understand this process.

1. Although the results may sometimes evoke both positive and/or challenging feelings, LENS is not psychotherapy. Some clients may benefit from seeking support and clarity from a psychotherapist.
2. *LENS is not a medical treatment and is no substitute for standard medical care.* If you need standard medical care, you are encouraged to seek it.
3. If you are taking the following medicines, it will be necessary to stay in close contact with your prescribing healthcare provider. It has been observed, thus far, that the need for these medications often decreases with LENS sessions. They remain in your system unused, and people often start experiencing side effects from them because of the decreasing tendency of the body to rely on them. These types of medication include, but are not limited to, the following:
 - medication for blood sugar regulation (diabetes)
 - medication for thyroid problems
 - medication for migraines and/or other types of headaches
 - medication for seizures
 - medication for mood regulation or clarity issues
 - medication for movement disorders and/or spasticity
 - medication for blood pressure regulation
4. Any individual who is not medically stable should request that their LENS Provider consult their normal care / prescribing physician before undertaking LENS sessions.

5. You will be asked to report any unusual, odd, or uncomfortable sensations or experiences to your LENS Provider and to your normal care / prescribing physician.

WHAT IS LENS?

LENS involves measuring and recording electrical signals from the scalp, and uses the frequencies of those signals to guide the speed of a feedback signal from a feedback unit near you. The extremely weak electromagnetic pulses come from the EEG cables and will be neither visible nor will you be able to feel them. The recorded EEG signals influence the electromagnetic feedback. The feedback, in turn, changes the quantity and frequency of the recorded brainwave signals.

In contrast to other brainwave biofeedback procedures, the LENS does not maintain that faster brain waves are better for some problems, or that slower brain waves are better for other problems. Rather, LENS supports the brainwaves: at rest, becoming quieter, and at work, becoming more flexible in their functioning.

The LENS has been used with hundreds of thousands of clients with a wide variety of presenting symptoms.

THE LENS SESSION:

The brainwave recording process may require the use of a mild abrasive gel or witch hazel to clean the skin. After that, electrode gel/cream/paste will be applied to the earlobe clip sensors, and attached to both ears, to improve the quality of the recording. A third and fourth sensor will then be pressed to the forehead or other scalp sites, and held there with a wax paste.

No needles, shocks, skin penetrating, or other invasive procedures are used. The equipment assesses the client's brainwaves – extremely faint electrical signals measured at discrete locations on the scalp. After a short assessment of the nature of these brainwaves, the equipment itself then generates and disburses extremely faint electromagnetic feedback signals that the brain may respond to in beneficial ways.

During the sessions, your eyes will be closed and you will be asked to sit quietly, if possible. Although you will not see anything, your brain can detect the feedback. The speed of the feedback will be controlled by the signals picked up at the scalp.

Your only instructions will be to close your eyes and rest. You will not be asked to think of anything in particular, or to learn anything. You will be asked frequently if you note any changes resulting from the feedback in order to adjust it most effectively. This is a passive process. You will be asked to keep track of any improvements, discomforts, or side effects experienced during and after your LENS session.

In addition, you will be asked (both before administration and 48 hours after every session) to complete a short questionnaire to update your top 10 symptoms.

DURATION:

You will have as many sessions as you need, each session lasting between one second and several minutes in duration. The rest of the time will be spent, as needed, talking about what effects, if any, the feedback has had. These sessions will occur on a regular basis as agreed upon by yourself and your LENS Provider.

It is difficult to predict how many LENS sessions will be required. The following estimates are based on our experience. Some patients have needed fewer sessions, and some have needed more:

1. If your problem came on suddenly after a life of high functioning and you are comfortable with the longer periods of feedback, you can expect 4 – 10 sessions. This is only an average range. However, individuals may require more or less than the average figures.
2. If you have a lifelong history of multiple problems and are very sensitive to the feedback, you may need 20 or so sessions.
3. In a very few circumstances such as stroke, spinal cord injury, very severe head injury, or genetic physiological disturbances, the number of sessions may exceed 40.

RISKS:

LENS and Seizures:

The electromagnetic feedback is not visible to the naked eye – although the feedback signal's influence on the signals measured at the scalp (EEG) is clearly present on the screen of the video monitor.

Seizure activity may be a primary reason to seek LENS sessions. There have been reported seizures in those who have had prior seizures. These seizures may have initially been brought about by allergies and/or inhalant hypersensitivities, asthma, orthostatic hypotension, blood sugar changes, fatigue, overwork, and/or changes in medication.

One of the biggest sources of seizure activity is the hasty and medically uncontrolled decrease in anticonvulsants by the client in attempts to decrease their side effects. We do not recommend such decreases, and urge clients to consult their prescribing healthcare provider about their desires to decrease medications of any kind.

It is important that you realize that LENS sessions alone will not abruptly stop your seizures if you have a history of them. In other words, you will continue to have seizures as you have had them in the past until neurofeedback begins to take effect. Furthermore, the client may experience an increase in the frequency of the CORE 8 events (seizures, tics, migraines, headaches, cluster headaches, stuttering, Tourette, and sometimes explosiveness) after which they begin to decrease in frequency and duration. This can be a cause of concern to those in your life, both personal and professional. You are advised to speak with those in your life about this item and be aware of and comfortable with their potential reactions before you start.

Electromagnetic Field Side Effects:

The long-term effects of using electrical field feedback as we use it is unknown. The intensity of our field is less than one trillionth of a watt and, on average, is on for only a few seconds during each session. A background signal that is approximately a thousand times less than the feedback signal is also present as soon as the EEG begins to read the brainwaves. For reference, a cellular telephone generates a signal at least millions of times greater than the power of the LENS feedback signal.

OTHER POTENTIAL CONCERNS:

Brief Reactions:

There are some potential risks of *temporary* discomfort after receiving LENS sessions. On the rare occasions when the feedback is too intense or the feedback periods are too long, you may temporarily feel wired, tired, irritable, and/or anxious. If this occurs, inform your LENS Provider and the settings on the equipment can and will be changed to make the feedback less intense and shorter in duration, to the extent that you are once more comfortable.

Longer Lasting Reactions:

You may experience one- or two-week periods of anger, fear, and/or irritability. You may feel as if you have tremendous energy to do things, or feel very tired. These longer-lasting reactions have especially tended to occur with particular feelings that people have been struggling to control for a long time. While these feelings can be intrusive and bothersome, it has been the experience of previous clients that they can still function. At times, however, support from a therapist or physician may be useful and should be relied upon.

If you have some degree of spastic paralysis after a stroke or other brain injury, there is a good possibility that you may experience significant pain in paralyzed parts of your body, typically for a period of a week. This pain occurs as the muscles soften around the spastic fibers, and these fibers no longer have stiff muscle fibers to keep these fibers from spasming. As the muscles continue to soften, the spasms stop, sensation starts to return, and muscle control starts the long process of improving. Those who have problems taking pain medication, perhaps because of

adverse side effects, are advised to consider what they need to do to comfort themselves during this painful period. Those who can take medication are advised to do so and consult their physician. If your LENS Provider has access to a photonic stimulator or laser, this type of pain is usually completely avoided. Inquire about these devices.

You must report any and all medications you use while you participate in LENS sessions, and are not to change your medications without consulting your prescribing physician.

When is Something a Side Effect or a Benefit?

While we have had experience since 1990 with the LENS and its antecedents, and are familiar with many of its benefits and side effects, it is sometimes difficult to know when a feeling, benefit, or other problem is due to LENS, or due to something else happening in a person's life. This could be due to anything from an on-coming cold, allergy, a stress in your life, or some other kind of physical change in you, completely unrelated to LENS. In addition, your own background can play a very big part in the kind of experience you have while receiving LENS sessions.

You do not have to know whether something may be due to LENS, or whether it may be due to something else. If you notice something and wonder about why you are experiencing it, make note of it for later discussion with your Provider.

We recommend that you write notes about your feelings and experiences and make note of any questions that might come up. Bring these notes with you to your sessions to discuss with your Provider.

A Perspective on Side Effects from LENS Sessions:

Although the unexpected is always a possibility, we have always found that any side effects that have occurred in LENS sessions were already familiar ones. In other words, the feelings and medical problems that arose have always been ones that the clients have experienced and are familiar with.

Those whose medical status is unstable are advised to consult with their physician about attaining more medical stability before beginning LENS sessions. For example, the LENS may cause a relaxation effect and for some, a subsequent decrease in blood pressure, which may impact orthostatic hypotension.

It is also important to know that when the problems have occurred during LENS sessions, many have been a fraction of their former intensity, which means that often they have been more manageable than in the past.

While these problems have only rarely been overwhelming to clients receiving LENS sessions, your comfort is of great importance to your LENS Provider: so, sharing your feelings at any time will help make sure we can best cooperate with your therapist and/or physician.

Between Sessions:

While many people feel energy, ease, clarity, and calmness after a LENS session, these positive feelings may initially wear off between sessions. This "wearing off" of the good feelings may cause clients to become discouraged and doubtful about their ability to reach their goals. The wearing off appears to be the brain's way of struggling to remain in the old, familiar, and dysfunctional state. As people continue with the LENS, the period during which the positive feelings occur becomes longer and the "wearing off" periods become shorter until they no longer occur.

And for others, some become clearer about their entire range of emotions, rather than staying numb and flat in their emotional responses.

Considerations After Treatment:

It will be time to discontinue the LENS when you stabilize and achieve consistently better functioning. A few people, however, become used to the stimulation that LENS provides, and go into a slump after discontinuing sessions. The session slumps that have occurred have lasted between a few days and a month, and have been less of a problem than those that brought people in for LENS sessions. During this period your body will become accustomed to being open to its own internal useful stimulation. Most of those who have received LENS have continued to improve long after regular LENS sessions have ended.

BENEFITS:

The LENS system has been shown in clinical use to bring about significant improvements in a relatively brief process in physical and emotional rehabilitation. Significantly shorter rehabilitation is of great importance in time, money, and client hopes.

*You may experience an end to the problems affecting you since your head injury and/or psychological trauma, and to the problems that have interfered with your ability to function in your work and personal life.

*The return of clarity, energy during the day, restful sleep, sense of humor, motivation to get things done, ease of getting things done, memory, ability to read and listen with little or no distraction, and the absence of depression, irritability, impatience, and explosiveness have been observed repeatedly.

ALTERNATIVES:

There are other approaches to that of the LENS. Other forms of brainwave biofeedback, also known as EEG biofeedback, are also being used to address the effects of head injuries. However, EEG biofeedback, which has also not been subject to controlled studies, appears to take longer, and appears considerably less effective than the LENS for problems with mood and functioning.

PROBLEMS OR QUESTIONS:

You are encouraged to ask questions at any time.

VOLUNTARY PARTICIPATION:

You are free to withdraw your consent and discontinue participation in LENS sessions at any time.

CONFIDENTIALITY:

Your identity will not be disclosed without your separate consent, except as specifically required by law. Examples of legal requirements for breaking confidentiality are:

- * under court order
- * in the case of unlawful behavior such as suspected child abuse
- * in the case you bring legal action against the Provider or the Provider's staff

With these exceptions, any data released or published will not identify you by name.

LIMITATIONS OF THIS CONSENT:

This signed form may not be used as consent for any other modality. Participation in any other modality requires a separate form.

All procedures performed under the protocol will be conducted by individuals legally and responsibly entitled to do so.

PERMISSION FOR UNDERGOING LENS SESSIONS:

I, a prospective client, give my full permission to Bryan Maynard, or other staff of their office, to use any data collected during the preparation and participation in LENS sessions. I give up all

implied and actual ownership of any data collected. I understand that when data is used, my confidentiality will be protected, and that my identity will not be revealed unless required by law (as outlined previously).

I acknowledge that I have been given an opportunity to ask questions regarding the LENS and that these questions have been answered to my satisfaction.

Initial here: _____

I acknowledge that I have read and understand the above information, and agree to participate in LENS sessions.

Initial here: _____

My consent to participate in LENS sessions is given voluntarily and without coercion.

Initial here: _____

I understand that I may discontinue LENS sessions at any time, and that I may refuse to consent without penalty.

Initial here: _____

Provider's name, or other staff of their office has my permission to contact my physician or health care provider to both inform them of the circumstances and outcomes my LENS sessions, and request pertinent medical information about me.

Initial here: _____

I hereby give my consent to Provider's name, or the staff of their office, to record all effects of the LENS.

Initial here: _____

I have read and understand the contents of this "Information and Administration Consent Form," and consent to receive LENS sessions.

Initial here: _____

Signature of Provider

Signature of Client or Parent/Guardian

Date

Date

Client's Printed Full Name: _____ Age: _____

Diagnosis (If Applicable): _____

MEDICATION:

I am currently taking the following medications and doses, and have noted what the medications are for and what effects they have on me (If I am taking no medication, I will write "none" across all five lines below.)

MEDICATION	DOSE
1.	
2.	
3.	
4.	
5.	

Initial here: _____

My five most prominent symptoms are:

1.
2.
3.
4.
5.

Initial here: _____