

About LENS
(Low Energy Neurofeedback System)

**Information and Treatment Consent for
Adults**

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Informed Consent

You are seeking the LENS (the *Low Energy Neurofeedback System*, a form of biofeedback) treatment for a problem. Although various forms of LENS has been used since 1990, the current LENS configuration has been used since 1998 with enough success to warrant respect from former and current patients, as well as from some of the top scientific institutions in the U.S., although controlled studies are only now being performed.

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 us to provide successful treatment. As with any treatment, you must be comfortable 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 be treated on the basis of this information. Before you give your consent to be treated, we want you to read the following and ask as many questions as are necessary for you to understand this process.

1. LENS is not psychotherapy, although the results can sometimes evoke both negative and positive feelings. If you are engaged in counseling or psychotherapy, it will probably be necessary for you to stay in close contact with your therapist.
2. LENS is not a medical treatment and is no substitute for effective standard medical treatment. If you need medical treatment, 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 physician. It has been observed, so far, that the need for these medications often decreases. 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. The types of medication include:
 - medicine for sugar problems (diabetes)
 - medicine for thyroid problems
 - medicine for migraines and other headaches
 - medicine for seizure problems
 - medicine for emotional, thinking, or perceptual problems
 - medicine for movement problems and spasticity
 - medicine for low or high blood pressure
4. Anyone who is medically unstable should ask the therapist to consult your physician before you undertake this process.
5. You will be asked to report any odd or uncomfortable sensations or experiences to the therapist and to your physician.

WHAT IS LENS?

LENS involves measuring and recording electrical signals from the scalp, and using 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, more flexible in their functioning.

It has been used with more than 200,000 patients with a wide variety of symptoms, and at this time we are closely examining the short and long-term safety of this procedure.

THE LENS PROCEDURE:

The brainwave recording process may require the use of a mild abrasive gel or witch hazel to clean the skin. After that, some electrode gel or cream will be applied to ear clip sensor, and attached to both ears, to improve the quality of the recording. A third sensor will then be pressed to your 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 a client's brainwaves -- extremely faint electrical signals measured at discrete locations on the scalp. After a short assessment of the nature of these brainwaves by a clinician, the equipment itself then generates and disburses extremely faint, battery-generated 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. Your brain can detect the feedback, although you will not see anything. 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 are comfortable with the feedback in order to adjust it most effectively. This is a passive process. You will be asked to keep track of discomforts or side effects experienced during your treatment.

You will also be asked about your five most prominent symptoms before treatment, and asked to rank them.

In addition, you will be asked, both before treatment and every few sessions, to complete a questionnaire about your symptoms.

DURATION:

You will have as many sessions as you need, each session lasting between one second and several minutes duration. The rest of the time will be spent, as needed, talking about what effects, if any, the feedback has had on you. These sessions will occur on a weekly or biweekly basis.

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 occasionally a few 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 6 – 20 sessions. This is only an average range. However, treatment 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 over 40 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 can easily be in the hundreds of sessions to keep achieving increasing function.

RISKS:

LOW ENERGY NEUROFEEDBACK SYSTEM (LENS) AND SEIZURES:

The electromagnetic feedback is invisible – 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 has not been a primary reason to seek treatment with LENS. 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. LENS has never aggravated seizures.

One of the biggest sources of seizure is the hasty and medically uncontrolled decrease in anticonvulsants by the patient in attempts to decrease their side effects. We do not recommend such decreases, and urge patients to consult their physicians and our therapists about their desires to decrease their medications of any kind.

It is important that you realize that entering this treatment 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 treatment begins to take effect. Furthermore, they may be more intense for periods of two to three weeks before they decrease in severity and frequency. This can be a cause of concern to those in your life, personal and professional. You are advised to speak with them about this issue 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 a trillionth of a watt and is on for a few seconds during each session. A background signal 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. **No instances of problems with the emissions from the feedback have ever been recorded.**

Other Potential Concerns:

Brief Reactions:

There are some potential risks of discomfort involved in participating in this treatment. On the rare occasions when the feedback is too intense or the feedback periods are too long, you may feel uncomfortable, irritable, tense and/or anxious. When this happens, please tell the operator 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 irritability during the treatment. 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 patients that they can still function. At times, however, support from your own 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, it is almost certain that you will experience severe 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 your physician. If your LENS clinician has access to a photonic stimulator or laser, this type of pain is usually completely avoided. Ask about these devices.

You must report any and all medications you use while you participate in the treatment, and are not to change your medications without informing your therapist and your 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, such as 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 kinds of feelings you have while receiving LENS.

Here's a guide for thinking out what a feeling, benefit, or problem is due to: If you find yourself wondering or guessing more than three times about why you are feeling something, it is probably due to either LENS or another physical reason. If, on the other hand, you think you know why you are feeling the way you do, trust yourself.

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 us.

Please write notes about your feelings and questions, and bring them with you to your sessions.

A Perspective on Side Effects from LENS Treatment:

Although the unexpected is always a possibility, we have always found that any side effects that have occurred in LENS treatment were already familiar ones. In other words, the feelings and medical problems that arose have always been something that the patients have experienced and have had some trouble with in the past.

Those whose medical status is unstable are advised to consult with their physician about becoming more medically stable before undertaking this treatment. LENS tends to lower blood pressure, which can complicate some kinds of problems such as orthostatic hypotension.

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

And while none of these problems have been overwhelming to patients receiving LENS treatment, your comfort is of great importance to us: so sharing your feelings at any time will help make sure we can best cooperate with your therapist and/or physician.

If there is a medical emergency, call us with the particulars, including the location of the emergency room you will be going to, and when, and go there. If the clinician is informed, he or she may be able to meet you at the emergency room. An example of a problem which may need emergency care would be a severe asthma attack in someone with unstable asthma or blood sugar problems in a diabetic. These problems are usually unrelated to the reasons that a person is seeking LENS treatment, but may none-the-less be affected. It will be useful for the emergency room physician to know about the LENS treatment and decide for him or herself whether the treatment itself may present a problem needing clinician thought.

Between Sessions:

While many people feel energy, ease, clarity, and calmness after an 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 finish treatment. 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 LENS, the period during which the positive feelings occur becomes longer and the "wearing off" periods become shorter until they no longer occur. To date there have been no exceptions to this pattern.

Instead, people become clearer about the entire range of feelings they have, instead of staying numb and flat in their emotional responses.

Problem Cycles:

Research with the LENS has shown that especially long-lived anxiety symptoms correspond with certain complex patterns of signals recordable at the scalp. Although we do have some technology to identify and develop treatment plans with these patterns of brain activity, we do not yet have the technology to easily and efficiently identify them. Therefore relief from some kinds of life-long problems is often uneven, with rises and falls in the level of the problems. The symptoms can feel sharper, at times, than they were before; they then pass, and tend to rise less in subsequent cycles of rising and fallings. It has been our experience that during each cycle, both therapist and person receiving this treatment can become anxious and filled with doubt about the wisdom of this treatment. It is important to know that 97% of those treated have improved, while 3% have remained the same. No one has reported being worse. There is no guarantee that you will remain free from these problem cycles.

Considerations After Treatment:

It will be time to discontinue the LENS when you stabilize and achieve consistently better functioning. You may, however, become used to the stimulation that LENS provides you, and go into a slump after you discontinue it. The 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 into LENS treatment. 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 LENS has ended.

BENEFITS:

The LENS system has been shown in clinical use to bring about significant improvements in a relatively brief process of therapy in physical and emotional rehabilitation. Significantly shorter rehabilitation is of great importance in time, money, and patient 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, sleeping at night, a 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 treatment approaches to the LENS. Other forms of brainwave biofeedback, also known as EEG biofeedback, are also being used to treat 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 LENS for problems with mood.

PROBLEMS OR QUESTIONS:

You may ask questions at any time.

VOLUNTARY PARTICIPATION:

You are free to withdraw your consent and discontinue participation in the treatment at any time.

SPONSOR:

Your Name supervises this treatment. She can be reached by telephone at Your phone between the weekday hours of 9 a.m. and 5 p.m.

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 clinician or the clinician's staff

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

If you cannot sign, through physical disability or illiteracy, but are otherwise capable of being informed and giving verbal consent, a third party, not connected with the treatment, or next of kin or guardian may sign for you.

LIMITATIONS OF THIS CONSENT:

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

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

PERMISSION FOR TREATMENT:

I, a prospective patient, give my full permission to Therapist's Name, supervisor, or other staff of his/her office to use any data collected during the preparation and participation in the LENS sessions, and 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 this new treatment 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 this treatment.

Initial here: _____

My consent to participate in this treatment is given voluntarily and without coercion.

Initial here: _____

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

Initial here: _____

Your Name, or other staff of her office has my permission to contact my physician or health care provider to both inform him/her of the circumstances and outcomes of my treatment, and request pertinent medical information about me.

Initial here: _____

I hereby give my consent to Your Name, or the staff of his/her office, to record both benefits and unpleasant effects from LENS.

Initial here: _____

I have read and understood the contents of this Consent document, and consent to receive this treatment.

Initial here: _____

Signature of Clinician

Signature of Patient or Representative

Date

Date

Name: _____ Age: _____

Diagnosis: _____

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.)

| |
|----|
| 1. |
| 2. |
| 3. |
| 4. |
| 5. |

Initial here: _____

My five most prominent symptoms are:

| |
|----|
| 1. |
| 2. |
| 3. |
| 4. |
| 5. |

Initial here: _____