

About LENS

(Low Energy Neurofeedback Systems)

Information and Treatment Consent for Adults

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Informed Consent

You are seeking LENS (the Low Energy Neurofeedback System, a form of biofeedback) treatment for a problem. Although various forms of LENS have 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 ones that we have seen will be listed later, and 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 treatment on the basis of this information. Before you give your consent for treatment, we want you to read the following and ask as many questions as are necessary for you to understand the process.

- 1) LENS is not psychotherapy, although the results can sometimes evoke both negative and positive feelings. If you are engaged with 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 having side effects from them because of the decreasing tendency of the body to rely on them. The types of medication are:
 - medicine for sugar problems (diabetes)
 - medicine for thyroid problems
 - medicine for migraines and other head aches
 - 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 your 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 assembly near you. The extremely weak electromagnetic pulses come from the EEG cables and will be neither visible nor felt. 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, LENS does not maintain that faster brainwaves are better for some problems, or that slower brainwaves are better for other problems. Rather, LENS supports the brainwaves, at rest, becoming quieter, and at work, more flexible in their functioning.

The preliminary observations made with LENS have been encouraging enough for us to begin the serious study of potential adverse and beneficial effects. You are being asked for your written consent to participate in this new treatment, and need to consider both the benefits and risks of doing so.

WHAT WE ARE LOOKING FOR

The purpose of this consent is to better describe long- and short-term side effects of LENS, which has been used since 1990. In clinical use, the LENS device has been observed to significantly help people with symptoms from the following:

- depression
- post-traumatic stress disorder symptoms of:
 - ~ anxiety
 - ~ hyper vigilance (or vigilant alertness)
 - ~ fears
 - ~ anger/rage
 - ~ deep sadness
 - ~ irritability and restlessness
 - ~ feelings of helplessness
 - ~ sleeping problems
- obsession/compulsions
- closed-head injury symptoms of:
 - ~ irritability and explosiveness
 - ~ loss of energy, motivation, and sense of humor
 - ~ problems of clarity, thinking, and estimating clearly
 - ~ memory difficulties
 - ~ sleeping problems
 - ~ being unable to do more than one thing at a time
 - ~ problems following conversations and reading material
 - ~ problems absorbing and taking to heart what people say
- spasticity, movement, and balance problems caused by stroke and in some cases spinal cord injury
- chronic fatigue syndrome
- fibromyalgia pain
- multiple personality and other dissociative disorders
- attention-deficit and hyperactivity problems
- autism in children and young adults

It has been used with approximately 100,000 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. A small amount of electrode gel will be applied to ear-clip sensors, and are attached to both ears to improve the quality of the recording. A third sensor will then be pressed to your forehead and other scalp sites, held in place by the electrode gel.

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. In fact, you will be asked to not think of any imagery or constructive thoughts which might help you. This kind of helpfulness has often slowed the progress of this treatment.

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 order, from most to least prominent.

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

DURATION

You will have as many sessions as you need, with each session lasting between one second to several minutes in 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, while others may need 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 13-20 sessions. This is only an average range; however, treatment may require more or less than average figures.
- 2) If your problem came on suddenly after a life of high functioning, and if you are so sensitive to the feedback that the feedback needs to be severely limited, you can expect approximately 30-40 sessions.
- 3) If you have a lifelong history of multiple problems and are very sensitive to the feedback, you may need over 100 sessions.
- 4) 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 session 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.

With very few exceptions, seizure activity has not been a primary reason to seek treatment with LENS, even though seizures are a reasonably common background occurrence. There have been reported seizures in those who have had prior seizures. These seizures may have initially been brought about by allergies and inhalant hypersensitivities, asthma, orthostatic hypotension, blood sugar changes, fatigue and overwork, and changes in medication. When used properly, this LENS appears to have acted as an anticonvulsant and has led to medically supervised decreases in anticonvulsants.

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 patient to consult their physicians and 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 personal and/or professional life. 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 a million times 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 anxious. This rarely happens for more than a second at a time. When this happens, please tell the operator so the settings on the equipment can be adjusted to make the feedback less intense and shorter in duration for your comfort.

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 muscles to keep these fibers from spasms. 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 be comfortable during this painful period. Those who can take medication are advised to do so with the advise and supervision of your physician. If your equipment operator has access to a photonic stimulator or laser, this type of pain is usually avoided, so ask about these devices.

You must report any and all medications you use while participating in treatment, and are not to change your medications without informing your therapist and your physician.

When is Something a Side Effect or Benefit?

While LENS and its antecedents have been used since 1990, it is sometimes difficult to know when a feeling is a benefit or is a problem due to LENS, or due to something else happening, like an oncoming cold, allergy, life stress, or some other kind of physical change in you, completely unrelated to LENS. Additionally, your background can play a large part in the kinds of feelings you have while receiving treatment.

Here is a guide for determining the nature of a feeling, benefit, or problem: 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. Telling us your feelings at any time will help reduce the side effects and make sure we can best cooperate with your therapist and/or physician.

Should you have a medical emergency, such as a severe asthma attack 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 is useful for the emergency room physician to know about the LENS treatment and decide for her- or himself whether the treatment itself may present a problem needing the clinician's thought.

Between Sessions

While many people feel energy, ease, clarity, and happiness after a LENS session, these positive feelings may precede feelings of fatigue, depression, and anxiety between sessions. Those "rebounding" from good feelings often feel discouraged and doubtful about their ability to finish treatment. The rebound appears to be the brain's way of struggling to remain in the old, familiar, and dysfunctional state.

As people continue with LENS, both the intensity of the good feelings and the unpleasant rebound periods tend to become shorter and less intense until the exaggerated feelings no longer occur. To date, there have been no exceptions to this pattern.

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

Problem Cycles

Research with 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, at times, feel sharper than they were before. They then pass and tend to rise less in subsequent cycles of risings and fallings. It has been our experience that during each cycle, both therapist and patient can become anxious and filled with doubt about the wisdom of this treatment. It is important to know that no one has remained worse, and all but 3% have remained the same. The rest have improved. There is no guarantee that you will remain free from these problem cycles.

Considerations After Treatment

It will be time to discontinue LENS when you stabilize and achieve consistently better functioning. You may, however, become used to the stimulation that LENS provides you. You may go into a slump after you discontinue. The slumps that have occurred have lasted between a few days to a month. They 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 treated with 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 our ability to function in your work and personal life.
- The return of clarity and 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

None of the alternative treatments to LENS treatment appear to act as rapidly as LENS. Other forms of brainwave biofeedback, also known as EEG biofeedback, are also being used to treat the effects of head

injuries. EEG biofeedback, however, 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

D. Scott Stanley, PhD, LMFT, LPC, supervises this treatment. He can be reached by telephone at 281.960.3991 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 case of unlawful behavior such as suspected child abuse
- In 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 this protocol will be conducted by individuals legally and responsibly entitled to do so.

PERMISSION FOR TREATMENT

I hereby give my permission for D. Scott Stanley, PhD, LMFT, LPC, 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 above).

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)

D. Scott Stanley, PhD, LMFT, LPC, has my permission to contact my physician or health care provider to both inform her/him of the circumstances and outcomes of my treatment, and request pertinent medical information about me. _____ (initial here)

I hereby give my permission to D. Scott Stanley, PhD, LMFT, LPC, 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)

Clinician Signature

Patient or Representative Signature

Date

Date

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

1.
2.
3.
4.
5.

My five most prominent symptoms are:

1.
2.
3.
4.
5.

Sensitivity Questionnaire

People are so amazingly different. Below is a list of statements that other clients have made about themselves. For each statement that is true, please indicate on a scale from 1-10, where "1" indicates the statement is rarely so, and "10" indicates the statement is always so. Do not mark the statements that are not true for you.

SENSITIVITY

I feel when the weather is about to change.	
I can easily tell whether a medication is going to work or not.	
I can sense unhealthy environments and then take care of myself.	
I can sense my need for food before I even feel hungry.	
I can sense smells and scents that others seem not to notice.	
I feel beforehand when I'm about to come down with a cold or flu.	
I have a wide appreciation for tastes in different foods.	
I can feel the difference between quietness and stillness.	
I can feel the difference between relaxation and comfort.	
I select my friends by how I feel when I'm with them rather than by appearances.	
I sense mood, energy shifts, and attention changes in people around me.	
I need to do things at my own pace.	
I am very creative.	
I know quickly when something is going to work out—such as a job or relationship.	
I have some abilities that some people consider psychic.	

REACTIVITY

I have unpleasant reactions to certain weather changes.	
I have unpleasant reactions to certain foods.	
I have unpleasant reactions to certain medications.	
I have unpleasant reactions to certain smells.	
I can have unpleasant reactions to certain sounds and lights.	
I have unpleasant reactions to not eating when I need to.	
I can be shocked by my reactions.	
My friends/family have a hard time being around me.	

HARDINESS

I have no problems with the weather.	
I have a lot of physical energy/stamina.	
I can do a lot of thinking/planning without getting tired.	
I have no problems with foods.	
I have no problems with medications.	
I don't get upset easily.	
I can work in spite of pain.	
When life hits me hard, I get back on my feet nevertheless.	

BEHAVIORAL SUPPRESSION

Certain unpredictable things used to have a big effect on me, but no longer do.	
I have almost forgotten how embarrassing things used to be for me.	
My friends/family used to have a hard time being around me.	
I'm not troubled by any emotions/feelings.	
In the past I had problems like migraine/tics/seizures/explosive episodes that I no longer have.	

CNS Functioning Assessment

Name: _____ Date of Birth: _____ Age: _____

Today's Date: _____ Time: _____ Diagnosis: _____

Are you able to drive a motor vehicle? Yes Partially No

Are you able to work or study? Yes Partially No

Are you able to sustain a close relationship with someone? Yes Partially No

How frequently, *in the past 24 hours*, have you had problems in the following areas?
Please pick a number from 0 to 10. "0" means *Not at all*, and "10" means *All the time*.

If one or both of your parents had this, place a *P* in the column headed by "Parents?"

If the problem came on suddenly, put an *S* in the column head by "Suddenly?"

Sensory	Frequency (0-10)	Parents?	Suddenly?
Light, in general, or lights, bother you	_____	_____	_____
Problems with the sense of smell	_____	_____	_____
Problems with vision	_____	_____	_____
Problems with hearing	_____	_____	_____
Problems with the sense of touch	_____	_____	_____
Emotions			
Problems of sudden, unexplained changes in mood	_____	_____	_____
Problems of sudden, unexplained fearfulness	_____	_____	_____
Problems of unexplained spells of depression	_____	_____	_____
Problems of unexplained spells of elation	_____	_____	_____
Problems with explosiveness	_____	_____	_____
Problems with suicidal thoughts or actions	_____	_____	_____
Clarity			
Feel "foggy" and have problems with clarity	_____	_____	_____
Problems following conversations (with good hearing)	_____	_____	_____
Problems with confusion	_____	_____	_____
Problems following what you are reading	_____	_____	_____

	Frequency (0-10)	Parents?	Suddenly?
Realize you have no idea what you have been reading	_____	_____	_____
Problems with concentration	_____	_____	_____
Problems with attention	_____	_____	_____
Problems with sequencing	_____	_____	_____
Problems with prioritizing	_____	_____	_____
Problems not finishing what you start	_____	_____	_____
Problems organizing your room, office, paperwork	_____	_____	_____
Problems with getting lost in daydreaming	_____	_____	_____
You cover up that you don't know what was said or asked of you	_____	_____	_____
Energy			
Problems with stamina	_____	_____	_____
Fatigue during the day	_____	_____	_____
Trouble sleeping at night	_____	_____	_____
Problems awakening at night	_____	_____	_____
Problems falling asleep again	_____	_____	_____
Activation or Anxiety			
Restlessness	_____	_____	_____
Problems with irritability	_____	_____	_____
Daydreaming	_____	_____	_____
Worrying	_____	_____	_____
Always moving	_____	_____	_____
Cold hands or feet	_____	_____	_____
Palpitations	_____	_____	_____
Memory			
Forgot what you have just heard	_____	_____	_____
Forgot what you are doing, what you need to do	_____	_____	_____

	Frequency (0-10)	Parents?	Suddenly?
Problems with procrastination and lack of initiative	_____	_____	_____
Problems not learning from experience	_____	_____	_____
Movement			
Problems with paralysis of one or more limbs	_____	_____	_____
Problems focusing or converging the eyes	_____	_____	_____
Pain			
Head pain that is steady	_____	_____	_____
Head pain that is throbbing	_____	_____	_____
Shoulder and neck pain	_____	_____	_____
Wrist pain	_____	_____	_____
Tender areas of muscles	_____	_____	_____
All-over pain	_____	_____	_____
Joint pain	_____	_____	_____
Other pain _____ (specify)	_____	_____	_____