Statistical Analysis Plan

Cover Page

for the Clinical Study

"Comparing the Efficacy of a Dual-Frequency Laser-Emitting Device, the "invisared-RED Elite", With a Sham Device as Therapy for the Loss of Adipose Tissue (Body Fat) and Aesthetics in Overweight Individuals"

NCT03811093

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Statistical Analysis Plan

for

Invisa-RED Clinical Trial

Research Questions:

Research Question One (1): Is there a statistically significant difference in Percentage of Body Fat Lost when using an invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device when compared with a sham (placebo) device in an approved and standardized clinical protocol?

Null Hypothesis One (1): There is not a statistically significant difference in Percentage of Body Fat Lost when using an invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device when compared with a sham (placebo) device as a therapy in an approved and standardized clinical protocol.

Alternative Hypothesis One (1): There is a statistically significant difference in Percentage of Body Fat Lost when using an invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device when compared with a sham (placebo) device as a therapy in an approved and standardized clinical protocol.

Research Question Two (2): Is there a statistically significant difference in Inches Lost when using an invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device when compared with a sham (placebo) device in an approved and standardized clinical protocol?

Null Hypothesis Two (2): There is not a statistically significant difference in Inches Lost when using an invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device when compared with a sham (placebo) device in an approved and standardized clinical protocol.

Alternative Hypothesis Two (2): There is a statistically significant difference in Inches Lost when using an invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device when compared with a sham (placebo) device in an approved and standardized clinical protocol.

Research Question Three(3): Is there a statistically significant difference in Pounds of Body Fat Lost when using an invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device as a therapy when compared with a sham (placebo) device in an approved and standardized clinical protocol?

Null Hypothesis Three (3): There is not a statistically significant difference in Pounds of Body Fat Lost when using an invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device when compared with a sham (placebo) device as a therapy in an approved and standardized clinical protocol.

Alternative Hypothesis Three (3): There is a statistically significant difference in Pounds of Body Fat Lost when using an invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device when compared with a sham (placebo) device as a therapy in an approved and standardized clinical protocol.

Data Sets/Populations:

Criteria for Participants:
Participants will be taken from a random population of respondents to both email and social media recruitment. The number of participants is projected to be forty (40). There will be an equitable distribution of male and female participants. Women who are pregnant, trying to get pregnant, or nursing will be excluded from the study, as they should not receive Low-level Laser Therapy (LLLT). Note; there is no evidence of harm to an unborn baby however there have been no safety tests either, so for medical legal reasons we recommend never treating such individuals. The participants will be between the ages of 18-75 years. Inclusion criteria will be individuals that may benefit from a weight loss therapy.

Exclusion criteria will include the following:
• If you are pregnant, trying to get pregnant or nursing laser light therapy should be received only after the end of these conditions. There is no evidence of harm to an unborn baby however there have been no safety tests either, so for medical legal reasons we recommend never treating areas directly over a developing child.
• Individuals with hypertension, light sensitive epilepsy, cancer, heart disease, infectious skin disease, and severe varicose veins should not use this device.
• People suffering from infectious and acute disease such as a fever should not use this device.
• People who have hemorrhagic disease, vascular ruptures, skin inflammation, or any disease of the skin should not use this device.
• People who have immune system dysfunction such as Leukemia, Hemophilia, etc., and light sensitive persons should not use this device.
• Individuals with a history of melanoma, raised moles, suspicious lesions, keloid scar formation, or healing problems should not undergo laser light therapy.

• Individuals with active infections, open lesions, hives, herpetic lesions, cold sores, or tattoos and permanent make-up in the area of treatment should not undergo laser light therapy.
• People who have used isotretinoin (commonly known as Accutane), tetracycline, St. John's Wort, or any photo sensitizing drugs in the last year should not undergo laser light therapy.
• Individuals with autoimmune diseases such as Lupus, Scleroderma, or Vitiligo should not undergo laser light therapy.
• Individuals who have pacemakers or other electro-stimulation devices surgically implanted should not undergo laser light therapy.
• Any insulin dependent individual should consult their physician before undergoing laser light therapy.
• All individuals considered "vulnerable" such as children, pregnant women, nursing home residents or other institutionalized persons, students, employees, fetuses, prisoners, and persons with decisional incapacity.

From the population of prospective participants screened using the above criteria, each of the approximately 40 participants selected will be randomly assigned to one of two groups; the Care as Usual Group or the Sham (placebo) Group.

Analysis:

To examine the three (3) research questions, independent sample *t*-tests using the statistical analysis program SPSS will be conducted on the three comparative data sets. Each of the three data sets will be comprised of comparative results from the two trial groups, the Care as Usual Study Group and the Sham (placebo effect) Study Group.

Data set One (1) will be the comparative Percentage of Body Fat Lost results, Data Set Two (2) will be the comparative Inches Lost results, and Data Set Three (3) will be the comparative Weight of Body Fat Lost results.

An independent samples *t*-test is the appropriate statistical test when the purpose of research is to assess if differences exist on a continuous (interval/ratio) dependent variable by a dichotomous (2 groups) independent variable. The three continuous dependent variables to be tested are Percentage of Body Fat Lost or Gained, Weight of Body Fat Lost or Gained, and Total Inches Lost or Gained. The dichotomous independent variables for the three data sets are the invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device and the sham (placebo) device, each administered as therapy in a standardized clinical protocol. The assumptions of normality and homogeneity of variance will be assessed. Normality assumes that the scores are normally distributed (bell-shaped) and will be assessed using the One-Sample Kolmogorov-Smirnov test. Homogeneity of variance assumes that both groups have equal error variances and will be assessed using Levene's Test for the Equality of Error Variances.

Each t-test will be two- tailed with the probability of rejecting the null hypothesis when it is true set at $p < 0.05$. This ensures a 95% certainty that the differences did not occur by *The first t*-test using Data Set One (1) will assess if statistically significant differences exist on the dependent variable Percentage of Body Fat Lost. The second *t*-test conducted on Data Set Two (2) will assess if statistically significant differences exist on the dependent variable Inches Lost. The third *t*-test conducted on Data Set Three (3) will assess if statistically significant differences exist on the dependent variable Weight of Body Fat Lost. For each of the three data sets the independent variables are defined as an invisa-RED Technology Elite Low-level Laser Therapy (LLLT) device and as a comparator the sham (placebo) device. Data produced by both groups will be a result of a clinical trial governed and conducted by a randomized double-blind study using an approved clinical protocol.

Reference:

Statistics Solutions. (2013). Data analysis plan: Independent Sample t-Test [WWW Document]. Retrieved from http://www.statisticssolutions.com/academic-solutions/member-resources/member-profile/data-analysis-plan-templates/data-analysis-plan-independent-sample-t-test/