9/1/97
TO: Dr. Onje' Erfan
FROM: Professor emeritus James R. Wilson
Subject: Report on the use of the NET-I for treatment of migraine.

This is a brief report on the effects of the Neuroelectric therapy instrument (NET-I) for treatment of migraine headache. Of the 100 patients initially recruited into this study, I randomly (and blindly, to you and to them) assigned 50 of them to receive a fully active NET-I while the other 50 received a placebo NET-I (the internal electrical circuit had been inactivated). Active and placebo NET-Is look and sound identical.

This note uses data collected at the 3-month follow-up, after subjects had been using the NET-I for three months. It does not compare their third-month response to earlier (two-month; one-month) response, although this could be done, as these data are available This note focuses on inclusion/exclusion of subjects from the analyses, and then on a particular, summary question asked of the subjects.

After discarding the data from the 8 people who never actually participated (i.e., signed up, but did not begin treatment), and the 3 patients whose physician's report showed that the patient had headaches other than migraine, we get 91 subjects for these analyses. 47 in the Active group and 44 in the Placebo group. Of these, six patients did not complete the 3-month follow-up questionnaire: 2 in the Placebo group and 4 in the Active group. This is not a significant group difference in quitting the study, and does not indicate that Placebo subjects were more prone to quit or avoid follow-up, as may have been expected.

A major indicator of whether a subject reported a benefit or effect from use of the NET seems to be question #7 on the Exit Questionnaire: "Please give us your rating about the overall effectiveness of the NET-I for treatment of Headache." Using the percent each reported for this question abbreviated as "Effect", the results are summarized below.

The 6 'no-shows' at 3-month follow-up were assigned a value of 0%, for "Effect". This seems to be conservative, in making no claim for efficacy of the NET-I for those who did not show up to report on its use.

There is an almost complete overlap in the distributions of "Effect" between the Placebo group and the Active group (from 0% "Effect" to over 90%), although the distribution of the Active group has higher scores on average, with a mean "Effect" of 55.7% for the Active group, compared to a mean "Effect" of 30.9% for the Placebo group. This is a statistically significant difference ($p<.001$), in favor of the Active NET-I.

Using 25% "Effect" as a cut-off point, those reporting less than 25% "Effect"were re-coded as 0 for Effect, and those reporting 25% or more "Effect" were coded as 1.0 -- in essence persons had to report at least 25% Effect, or were scored here as No Effect. This results in 43% (i.e., 19 of the 44 in the Placebo group) who report 25% or more "Effect" of the NET-I, and 72% (i.e., 34 of the 47 people in the Active group) who report 25% or more "effect". This is a statistically significant difference ($p<.005$), in favor of the active NET-I.

Discussion.

The data clearly indicate that the active NET-I was effective for treatment of migraine headache. Some subjects reported no help from NET use, but about 3/4 reported that they obtained significant relief from their headaches.

It is somewhat puzzling that the Placebo NET-I (audio signals only; electrical circuit inactivated) was also effective in alleviating headache for many subjects. This would seem to indicate either (1) the audio signals are helping to alleviate headache; or (2) the 'treatment atmosphere' (being in a study; discussions with a physician; expectations and hopes for help; etc.) has a substantial effect.

As is typical with extended human studies, several subjects dropped out, or failed to report results. In this study, interestingly, the drop-out rate was not different for subjects (blindly) assigned a placebo, compared to those (blindly) assigned an active device. As a conservative measure, these no-shows were assigned scores of 0 for effectiveness of the NET-I. However, since the groups were almost balanced with respect to no-shows, this makes little practical difference in the results. For example, leaving their data as 'missing' raises the percents for effectiveness somewhat for both groups, but the groups are still statistically different on this measure ("Effect").

You may wish to use the above analyses for your web-page, or for other publicity. I will continue with the analyses, next focussing on whether the NET-I helped to relieve PMS in those female patients who reported PMS, along with migraine.

The results of the Crossover phase of the study are as follow:

30 subjects participated, 4 had no measurable responses, 26 responded well, (40%—100%) or 87% response.