The Effect of Theraworx/[pH]uel on night-time cramps and spasm symptoms including quality of life, depression and sleep quality

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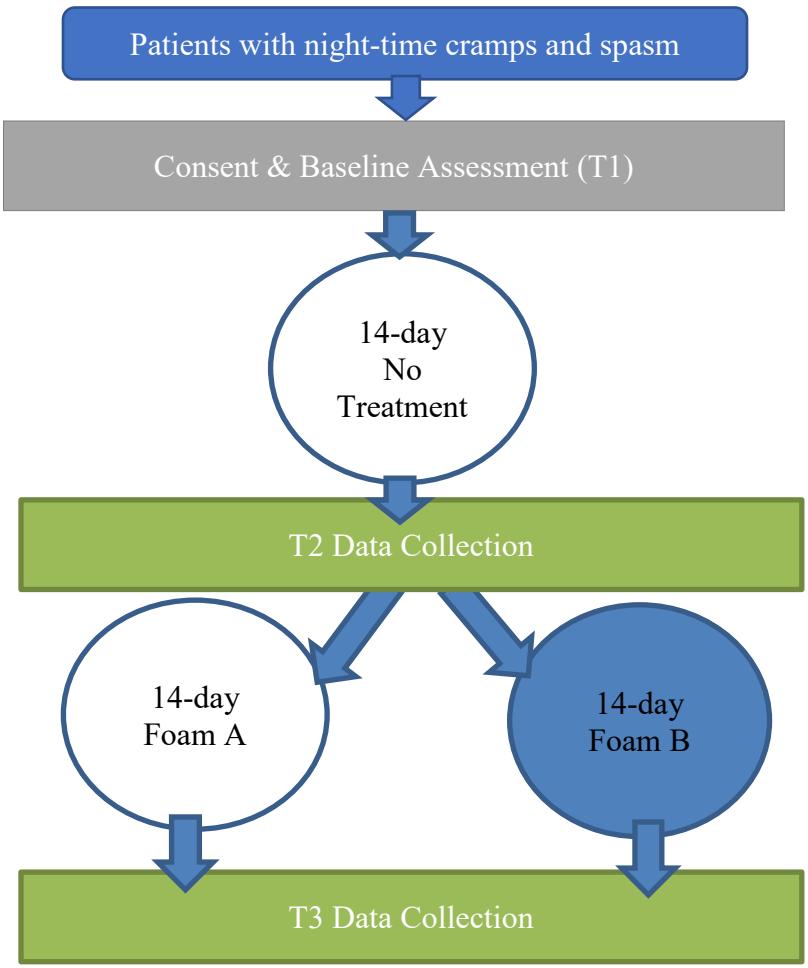
Protocol

Potential subjects were recruited through various targeted methods including newspaper ads, fliers in pharmacies and physician offices, social media, sleep disorder support groups and word of mouth. Individuals were excluded from the study if they were pregnant, have been previously diagnosed with a Restless Leg Syndrome (RLS), previously diagnosed with schizophrenia or any other neurological disorder. Individuals were included in the study if they reported experiencing night-time leg cramps on average at least three times per week. Eligible individuals were scheduled to attend an initial assessment (Baseline) at a community-based physical therapy clinic. During this visit the study was described by a member of the research team and the individual was asked to provide written consent to participate in the protocol (RB#: SSR.2016.3). Following providing informed consent, the subjects were asked to complete a series of questionnaires about their demographic characteristics, symptoms associated with NLC including sleep quality, quality of life and depression. Once these questionnaires were completed all subjects engaged in a 14-day no treatment period in which they were told not to change their usual activities and treatments. Each morning during the 14 day no treatment period subjects were asked to complete a Symptom Log on which they documented the frequency and severity of night-time cramps they experienced the previous night.

Subjects returned to clinic following this 14-day no treatment period (Post Control) and completed the same questionnaires excluding the demographic questions, since these demographic characteristics were not expected to change during the trial. Variables that were collected at the Post Control data collection point included the same measures of sleep quality, quality of life and depression as were collected at Baseline. Subjects were asked to refer their responses on these instruments to the previous 2 weeks following completion of the Baseline assessment. Once the subjects completed these instruments they were randomly assigned to one of two study groups by selecting 1 of 50 shuffled envelopes. Within 25 of these envelopes a card indicated “Foam A” and the remaining 25 envelopes contained a card indicating “Foam B.” Subjects received two 3 ounce foam dispensers corresponding to their group assignment (Foam A or Foam B) and a 2-week Compliance and Symptom Log. The contents of these two foams remained blind to the subjects and the data collectors throughout the duration of the study until analysis. One of the foams contained Theraworx Relief™ (treatment) and the other contained a physiologically inert substance (placebo). Subjects were instructed to apply the foam they had been assigned to their entire upper and lower legs and feet using 8 pumps from the product dispenser per leg (upper thigh to foot) before retiring each evening for the next 14 days. If a subject experienced leg cramps after applying their assigned foam, they were instructed to reapply 2 pumps of the foam to the affected area in response to each event. Each morning during the 14 days in which subjects applied the foam they were asked to complete the Compliance and Symptom Log that documented the frequency and severity of night-time cramps and their use of the assigned foam they used to treat their night-time cramps the previous evening. Following 14 consecutive evenings of applying their assigned foam, subjects returned to the community clinic (Post Treatment), and return their completed Compliance and Symptom Log to the research staff. During this final visit subjects again completed the same measures of sleep quality, quality of life and depression that they completed during their Baseline and Post Control visits, referring their responses to the previous 2 weeks when they were applying the assigned foam to their legs. Subjects were compensated for completing the Baseline and Post Control and Post Treatment data collection visits.



Analysis:
Once all of the data were collected the contents of the foams were disclosed as Foam A containing the Placebo and Foam B containing the Treatment. The analysis was conducted in two phases. During phase 1 descriptive statistics were calculated to describe the demographic characteristics of the sample in order to assess the external validity of the results and the application of the findings to the larger population of patients suffering with NLC. Further descriptive analysis determined if the outcome variables met the assumptions of parametric statistics. The second phase of the analysis involved addressing the study hypotheses. Repeated measures analysis of variance (R-ANOVA) were calculated to determine if any of the outcome variables significantly ($p<.05$) differed between or within the two study groups over the duration of the study. Main or interaction effects detected by the R-ANOVA were explored further through calculating Tukey's post hoc comparisons. Finally, univariate comparisons (e.g. t-tests) determined if compliance rates or reported benefits differed between the study groups.