Levels and Predictors of Activity in Users of Wearable Neurostimulators with Chronic Pain

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INTRODUCTION

About 100 million people in the U.S. have chronic pain. In addition to the direct experience of pain, people with chronic pain have significant physical and psychological morbidity through its interference with quality of life including sleep, activity and mood. Physical activity and exercise may reduce chronic pain severity and improve function.

Surface neurostimulation in the form of wearable devices is available as a non-pharmacological option for managing chronic pain. Ideally, these devices do not disrupt activity, thus enabling synergistic pain relief.

This cross-sectional study evaluates the users of a wearable neurostimulator to treat chronic pain. The study assesses their demographic and clinical characteristics, pain severity and interference, and independent predictors of activity levels as measured by daily step counts.

METHODS

Study Design and Subject Selection. De-identified data were collected from users of a wearable device to treat chronic pain (Quell®, NeuroMetrix, Waltham, MA) during a 9-month period (1/2017-9/2017). The device is worn on the upper calf and semi-continuously stimulates sensory nerves to provide widespread pain relief. The device monitors utilization and biometric parameters. One such biometric parameter is daily step count. An accelerometer embedded in the device allows automated and accurate measurement of steps taken when the device is worn. A companion smartphone app collects this data as well as demographics, painful health conditions, pain sites, pain intensity and interference with sleep, activity and mood on an 11-point NRS.

Inclusion criteria were users 1) providing demographic/clinical information, 2) having daily step count for at least 10 days, 3) reporting pain intensity and interference ratings for at least 5 days, and 4) consenting to use of anonymized data for research.

Data Analysis. Typical value for each covariate is defined as the median of all values logged for the covariate during the study period. Basic statistics of demographic, clinical, typical biometric, and typical pain rating values are reported. Independent predictors ($p<0.05$) of typical daily step count are determined using forward stepwise regression. Final linear regression model parameters using least square method is obtained.

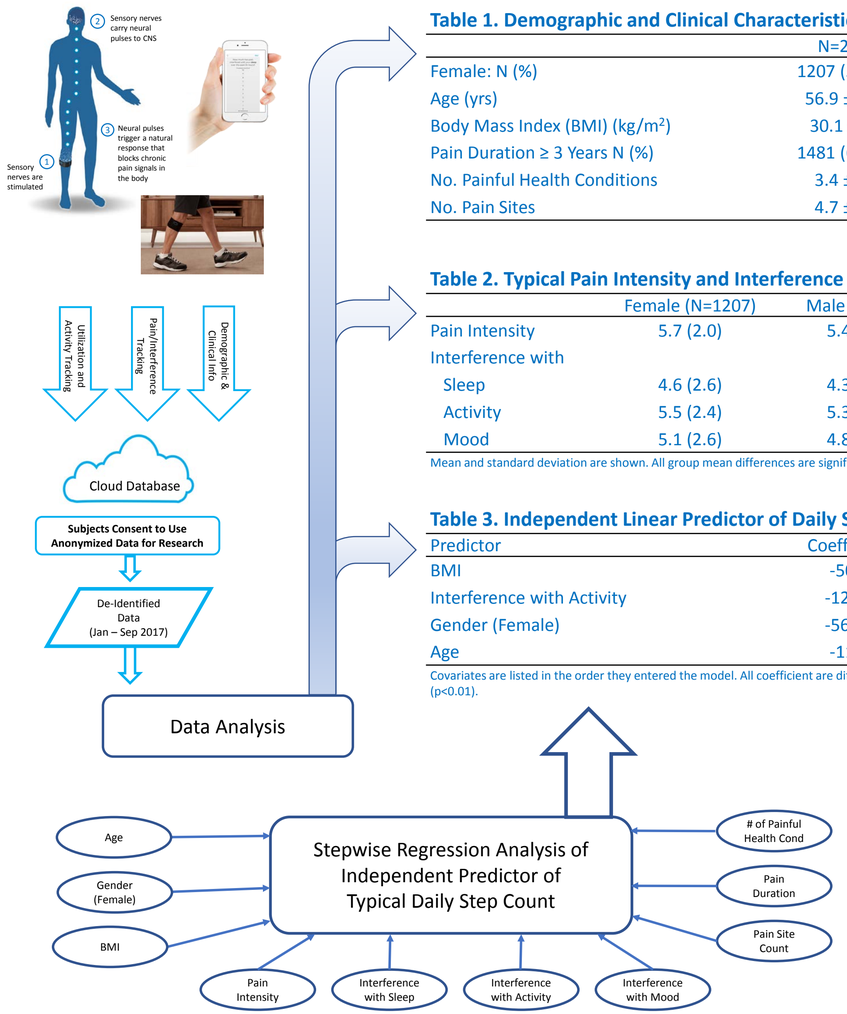

Table 1. Demographic and Clinical Characteristics

	N=2141
Female: N (%)	1207 (56.4%)
Age (yrs)	56.9 ± 14.1
Body Mass Index (BMI) (kg/m^2)	30.1 ± 6.7
Pain Duration ≥ 3 Years N (%)	1481 (69.2%)
No. Painful Health Conditions	3.4 ± 2.1
No. Pain Sites	4.7 ± 2.4

Table 2. Typical Pain Intensity and Interference (NRS 0-10)

	Female (N=1207)	Male (N=907)
Pain Intensity	5.7 (2.0)	5.4 (2.2)
Interference with		
Sleep	4.6 (2.6)	4.3 (2.7)
Activity	5.5 (2.4)	5.3 (2.5)
Mood	5.1 (2.6)	4.8 (2.7)

Mean and standard deviation are shown. All group mean differences are significant ($p<0.05$).

Table 3. Independent Linear Predictor of Daily Step Count

Predictor	Coefficient
BMI	-50.1
Interference with Activity	-129.5
Gender (Female)	-562.3
Age	-11.2

Covariates are listed in the order they entered the model. All coefficient are different from zero ($p<0.01$).

RESULTS

Demographic and Clinical Characteristics (Table 1). A total of 2141 users met the inclusion criteria. Users wore the device for a median 9.2 hours per day (interquartile range: 6.8–11.4 hours) and no statistically significant differences were found between genders.

Typical Pain Intensity and Pain Interference (Table 2). Female users had a slightly higher (0.2—0.3) pain intensity and interference scores than male users ($p<0.05$). Interquartile ranges for all users were 4.0—7.0 for pain intensity, 2.0—6.5 for interference with sleep, 4.0—7.0 for activity, and 3.0—7.0 for mood.

Independent Linear Predictor of Daily Step Count (Table 3). BMI, interference with activity, gender, and age were independent predictors of daily step count. Lower daily step count was associated with higher BMI, higher interference with activity, female gender, and older age. Least square linear regression model showed a decrease of 50 steps for each BMI unit increase, 129 steps for each activity interference point increase, 562 steps for female gender, and 11 steps for each year in age. Over half of subjects (54.6%) walked more than one mile (2000+ steps) daily while wearing the device.

CONCLUSIONS

Female subjects in this study cohort reported a slightly higher pain intensity and pain interference scores. In addition to female gender, higher BMI, and older age, a higher subjective score of pain interference with activity were associated with lower step count.

Nevertheless, more than half of chronic pain sufferers remained active during days when they worn the surface neurostimulator device to receive pain relieving therapy. This result suggests that the wearable neurostimulator does not impede activity.

Future studies are needed to evaluate synergies between neurostimulation therapies and activity levels and their impact on subjective pain intensity and interference scores.

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