# Clinical and Treatment Variables Associated with Effectiveness of Wearable Transcutaneous Electrical Nerve Stimulation in Individuals with Chronic Knee Pain

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## PURPOSE

**Background**

- One-quarter of adults suffer from frequent knee pain, which limits function, decreases mobility and impacts quality of life.
- Chronic knee pain is usually managed pharmacologically. These medications may cause adverse events and can create addiction risk (opioids).
- Transcutaneous electrical nerve stimulation (TENS) is a non-invasive, low risk, pain relief option for people with chronic pain.

**Wearable TENS**

TENS device designed for a predetermined location (see Figure 1).


Figure 1

**Study Objective**

Determine clinical and treatment variables associated with the effectiveness of wearable TENS on the upper calf in individuals with chronic knee pain in a real-world setting.

## METHODS

**Design**

- Retrospective, observational study of a real-world wearable TENS database.
- Wearable TENS (Quell®, NeuroMetrix, Waltham, MA), see Figure 1.
- TENS device automatically collects usage data, and objective activity and sleep measures from an accelerometer within the device. Companion smartphone app collect demographics, pain characteristics and pain ratings. All data stored in cloud database.
- Pain ratings provided at the user's discretion and include pain intensity and pain interference with activity, sleep and mood on an 11-point numerical rating scale (NRS).

## METHODS (continued)

**Inclusion Criteria**

Device users with the following data recorded in the database were included: 1) age, gender, height, and weight; 2) pain duration >3 months, 3) pain frequency ≥ several times a week, 4) baseline and follow-up pain ratings, 5) baseline pain intensity ≥4, 6) self-reported knee pain and 7) ≥10 weeks of wearable TENS use.

- A valid baseline pain rating occurred on the first day of device use or within the prior 6 days (latest one used).
- A valid follow-up pain rating occurred between weeks 9 and 15 following start of device use (median of all ratings within time window were used).

**Outcome Measures**

The study outcomes were the baseline to follow-up change in pain intensity and pain interference with function (defined as average of the three pain interference values).

**Statistical Analyses**

The relationships between predictor variables and the outcomes were determined by multivariable linear regression. Variables with $p<0.05$ were retained as statistically significant outcome predictors.

**Table 1. Baseline demographic and pain characteristics.**

| | |
|---|---|
| Age (years) | 58 (14) |
| Female | 62.7% |
| BMI (kg/m2) | 31.8 (7.3) |
| No. pain sites | 5.8 (2.5) |
| No. pain conditions | 3.5 (2.0)* |
| Pain duration ≥4 years | 79% |
| Baseline pain intensity (0-10 NRS) | 6.8 (1.6) |
| Baseline pin interference (0-10 NRS) | |
| Sleep | 6.2 (2.8) |
| Activity | 7.3 (2.2) |
| Mood | 6.7 (2.5) |

*Most common: arthritis (77%, 46% osteoarthritis), prior leg injury (50%), prior back injury (50%)

## RESULTS

A total of 367 wearable TENS users met the inclusion criteria. See Table 1 for baseline demographic and pain characteristics. TENS usage:

- Daily utilization 76% (SD 27); %days ≥ 30 minutes stimulation
- Overnight utilization 34% (SD 33); %nights ≥ 30 minutes stimulation
- Weekly therapy 41 (SD 25) hrs/week

The mean follow-up period was 88 (SD 15) days and the mean number of pain ratings forming the follow-up rating was 11 (SD 13).

Change in pain intensity from baseline to follow-up was -0.93 (SD 2.3); $p<0.001$). Change in pain interference with function was -1.2 (SD 2.5); $p<0.001$). The multivariable regression model is shown in Table 3.

**Table 3. Multivariable regression models.**

| Variable | Pain Intensity | Pain Interference |
|---|---|---|
| Age (years) | -0.19 | |
| Female | 0.29 | |
| Self reported herniated disc | 0.95 | 1.0 |
| Constant pain throughout day* | 0.58 | 0.57 |
| Pain intensity | -0.64 | 0.21 |
| Pain interference with sleep | | --0.16 |
| Pain interference with activity | | -0.26 |
| Pain interference with mood | | -0.18 |
| Daily utilization (%) † | -0.016 | -0.024 |
| Overnight utilization (%)‡ | -0.012 | -0.015 |
| | R2=0.28, F(20, 346)=6.87, p<0.001 | R2=0.30, F(20, 342)=7.40, p<0.001 |

*Participant reported that pain was constant throughout day rather than worse at particular times, during rest or with activity (i.e., intermittingly).
† Each percentage increase in daily utilization reduces pain intensity by 0.016 points and pain interference by 0.024 points.
‡ Each percentage increase in overnight utilization reduces pain intensity by 0.012 points and pain interference by 0.015 points.

## CONCLUSIONS

- Pain intensity and pain interference with function improved following 10-weeks of wearable TENS use.
- Utilization may be a modifiable factor for wearable TENS effectiveness. Use during sleep may confer distinct pain relief benefits.
- Wearable TENS may be more effective for pain that occurs intermittently during the day.
- Participants with self-reported disc herniation reported less pain relief from wearable TENS. This association should be explored further.

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