Official Title: Effect of Wearable Health Technology on Patients Treated for Chronic Pain at Geisinger Health System

NCT#: NCT03299556

Date of Document: September 12, 2017

Protocol Synopsis

Protocol Number:	2017-0196
Title:	Effect of Wearable Health Technology on Patients Treated for Chronic Pain at Geisinger Health System
Sponsor:	Purdue Pharma L.P. One Stamford Forum 201 Tresser Boulevard Stamford, CT 06901-3431
Study Phase:	Phase 4
Study Sites:	The study will be conducted in the United States at 1 site, the Multidisciplinary Pain Program at Geisinger Health System
Indication:	Chronic Pain
Background:	Care for the chronic pain patients can be challenging. Providers are dependent on patients' recall of their symptoms between visits to gauge disease severity and treatment progress. Providers often lack timely access to patients' data on symptom severity, thereby limiting the providers' ability to effectively manage and optimize long-term treatment regimens for their patients. Recent use of wearable health technology (WHT) has been effective in improving patient outcomes. Many wearable biosensors and their applications have been introduced in different stand-alone or interactive formats. WHT apps may have interactive capabilities involving active health or behavior change information that collects data from the user. WHT can detect abnormal and unforeseen situations and monitor physiological parameters and symptoms through these trackers. This technology has transformed healthcare by allowing continuous monitoring of patients without hospitalization. Medical monitoring of patients' body temperature, heart rate, brain activity, muscle motion and other critical data can be delivered through these trackers. When integrated with an expert-directed chronic pain intervention program like Geisinger's Multidisciplinary Pain Program (MPP), WHT (eg iPhone, Apple Watch) may improve comprehensive patient management and outcomes for patients living with chronic disease. WHT can also provide real-time data, allowing a healthcare provider to engage in more proactive patient care.
Objectives	To assess whether the addition of WHT to the Geisinger MPP leads to improvements in clinically meaningful patient outcomes, reductions in healthcare utilization and costs.

Patient Population: The study population will be adult (≥18 to <76 years) chronic pain patients being treated at pain clinics in the Geisinger healthcare system.

There will 3 study groups, a WHT treatment group, a concurrent Medical Pain Management (MPM) control, and an historic MPP control:

1. WHT treatment group: patients admitted to the MPP during a predefined 12-month period who consented to participate in the study.
2. MPM control group: patients from MPM clinics within Geisinger during the same 12-month period.
3. Historic MPP control group: patients who completed the MPP 12 months before the start of this study (ie, before WHT was introduced to the MPP in August 2017).

Study Design: This is a prospective, non-randomized, non-blinded trial with historic and concurrent controls to assess the effect of the addition of WHT (Apple Watch, iPhone, Pain App, and physician and patient dashboards) on patient and health system outcomes. The WHT intervention group will include patients enrolled in the Geisinger's MPP Program over 1 year, with 1 year of follow up. Patients in the WHT group will be compared to patients in 2 control groups: patients enrolled in the MPP in the preceding year (historic control group), and patients enrolled on the MPM over the same period (concurrent control group).

The WHT intervention will consist of the following:

- Patient and HCP tracking of patient-reported pain, pain management, disability, depression and medication usage over time
- Patient and HCP tracking of quality of sleep and activity over time
- Prompts to patients to engage in self-care, including non-pharmaceutical pain management therapies consistent with their MPP training
- HCP alerts if patients exceed pre-specified thresholds in pain or functioning

Patients will use the WHT 20 hours per day, every day for a period of 12 months. Patients will attend study visits at baseline and months 2, 4, 6, 8, 10 and 12. Patients consented into the WHT group will participate in the study for 12 months from the day of enrollment.

Outcome data for control patients will be collected retrospectively from the electronic health record (EHR). Assessments will have occurred as part of their standard of care.

Estimated Study Duration: Twelve months of enrollment, with 12 months of follow-up, for a total of 24 months.

Outcome Measures:

Study Aim 1 (Between- Group Differences)

- Primary Clinical Endpoints
  - A difference in the change in pain scores over time from baseline to month 12 (M12) as measured by the Numerical Pain Score (NPS)
  - A difference in the change in depression scores over time from baseline to M12 as measured by the Patient Health Questionnaire (PHQ-9)
  - A difference in the change in pain medication use over time from baseline to M12, calculated as mean daily morphine equivalents (MEQs)
- Secondary Clinical Endpoints
  - A difference in the change in physical function/disability over time from baseline to M12 as measured by the Oswestry Disability Index (ODI)
- Endpoints Related to Resource Utilization
  - A difference in the change in healthcare resource utilization over time (quarterly) from baseline to M12: number of hospitalizations, emergency department (ED) visits, inpatient, outpatient visits, rehabilitation visits, and pharmacy/medication orders
  - A difference in the change in healthcare costs over time (quarterly) from baseline to M12: total, inpatient, outpatient, rehabilitation, and pharmacy

Study Aim 2 Comparisons within WHT Group

- Sleep: change in number of hours and number of restful hours per night over time from month 1 (M1) to M12
- Activity level: change in number of steps and minutes of exercise per day over time from M1 to M12
- Daily pain scores: change in worst pain of the day (mean value for the month), number of episodes of breakthrough pain (episodes per 7 days), and mean level of breakthrough pain (mean value for month) over time from M1 to M12

Sample Size:

Sample size estimated to be at least 240 WHT patients, 1000 MPM patients, and 150 historic MPP patients. Based on these sample sizes, and assuming a 10% drop-out rate, detectable effect sizes at 80% power for the primary clinical outcomes as analyzed by repeated measures analysis of variance (ANOVA) model and using an omnibus F test (difference in changes between the groups at any time) are:

- NPS: 0.35 versus MPM; 0.42 versus historic MPP
- PHQ-8: 1.40 versus MPM; 1.81 versus historic MPP
- MEQs: 11.51 versus MPM; 17.58 versus historic MPP

Statistical Methods:	For clinical outcomes (primary, secondary, and exploratory), the effects of WHT will be quantified by calculating the change from baseline in clinical outcome variables in the WHT group over 12 months. For primary and secondary outcomes that are measured in the WHT group plus at least 1 control group, generalized linear modeling or nonparametric methods (depending on the score distributions) will be used to compare outcomes across the cohorts. Patient demographic and clinical characteristics that differ between groups at baseline will be included in multivariate adjusted models. Repeated measures models will be used to generate point estimates and 95% confidence intervals (CIs) for least square mean (LSM) differences, odds ratios (ORs), or risk ratios (RRs). Where appropriate an overall F statistic will be generated to compare the change in groups across the study period (interaction of group*time). For the analysis of healthcare utilization, a log-link function with a Poisson or negative binomial distribution will be used. For cost outcomes, a log-link function with a gamma distribution will be used. Otherwise, the same techniques described above (eg, GLM methods to account for matched groups, estimates, and CIs) will be used. For analysis related to clinical outcomes collected only in the WHT group, the effects of WHT will be quantified by calculating the change from baseline over 12 months and using repeated measures ANCOVA models to compare to the null hypothesis (0 change).
Date of Protocol:	12 September 2017