“My Surgical Success”: Feasibility and Impact of a Single-Session Digital Behavioral Pain Medicine Intervention on Pain Intensity, Pain Catastrophizing, and Time to Opioid Cessation After Orthopedic Trauma Surgery—A Randomized Trial

Maisal S. Ziadni, PhD,* Dokyoung S. You, PhD,* Ryan Keane, BA,‡ Brett Salazar, BS,‡ Sam Jaros, BS,‡ Jesmin Ram, BA, Anuradha Roy, MSc, Natalie Tanner, BA,† Vafi Salmasi, MD,* Michael Gardner, MD,† and Beth D. Darnall, PhD* [Image 13x705 to 44x718]

BACKGROUND: Behavioral pain treatments may improve postsurgical analgesia and recovery; however, effective and scalable options are not widely available. This study tested a digital perioperative behavioral medicine intervention in orthopedic trauma surgery patients for feasibility and efficacy for reducing pain intensity, pain catastrophizing, and opioid cessation up to 3 months after surgery.

METHODS: A randomized controlled clinical trial was conducted at an orthopedic trauma surgery unit at a major academic hospital to compare a digital behavioral pain management intervention (“My Surgical Success” [MSS]) to a digital general health education (HE) intervention (HE; no pain management skills). The enrolled sample included 133 patients; 84 patients were randomized (MSS, n = 37; HE, n = 47) and completed study procedures. Most patients received their assigned intervention within 3 days of surgery (85%). The sample was predominantly male (61.5%), White (61.9%), and partnered (65.5%), with at least a bachelor’s degree (69.0%). Outcomes were collected at 1–3 months after intervention through self-report e-surveys and electronic medical record review; an intention-to-treat analytical framework was applied. Feasibility was dually determined by the proportion of patients engaging in their assigned treatment and an application of an 80% threshold for patient-reported acceptability. We hypothesized that MSS would result in greater reductions in pain intensity and pain catastrophizing after surgery and earlier opioid cessation compared to the digital HE control group.

RESULTS: The engagement rate with assigned interventions was 63% and exceeded commonly reported rates for fully automated Internet-based e-health interventions. Feasibility was demonstrated for the MSS engagers, with >80% reporting treatment acceptability. Overall, both groups improved in the postsurgical months across all study variables. A significant interaction effect was found for treatment group over time on pain intensity, such that the MSS group evidenced greater absolute reductions in pain intensity after surgery and up to 3 months later (treatment × time fixed effects; f(215) = 5.23; P = .024). No statistically significant between-group differences were observed for time to opioid cessation or for reductions in pain catastrophizing (f(215) = 0.20; P = .653), although the study sample notably had subclinical baseline pain catastrophizing scores (M = 14.10; 95% confidence interval, 11.70–16.49).

CONCLUSIONS: Study findings revealed that a fully automated behavioral pain management skills intervention (MSS) may be useful for motivated orthopedic trauma surgery patients and reduce postsurgical pain up to 3 months. MSS was not associated with reduced time to opioid cessation compared to the HE control intervention. (Anesth Analg 2022;135:394–405)
Question: Can a digital pain management skills intervention (My Surgical Success [MSS]) improve postsurgical outcomes?

Findings: MSS was associated with greater reductions in pain intensity up to 3 months after orthopedic trauma surgery compared to a digital health education control intervention (no pain management skills); no between-group differences in time to opioid cessation were found.

Meaning: A fully automated single-session behavioral pain medicine treatment may be feasible, as well as a useful analgesic adjunct to help motivated orthopedic trauma surgery patients recover from surgery with less pain.

GLOSSARY

CI = confidence interval; CONSORT = Consolidated Standards of Reporting Trials; EHR = electronic health record; HE = health education; I&D = irrigation and debridement; IRB = institutional review board; MCID = minimal clinical important change; MEDD = morphine equivalent daily dose; MSS = My Surgical Success; NIH = National Institutes of Health; NPRS = numeric pain rating scale; ORIF = open reduction and internal fixation; PCS = pain catastrophizing scale; PROMIS-SF = Patient-Reported Outcomes Measurement Information System short-form; RCT = randomized controlled trial; REDCap = Research Data Capture; SD = standard deviation; THA = total hip arthroplasty; USD = US dollars

US annual estimates suggest that 16.2% of the roughly 7 million orthopedic injuries result in an urgent surgical procedure. A fraction of patients will have poor surgical recovery and persistent pain. Up to 1 in 10 patients report moderate to severe pain 2 years after fracture surgery; and those taking prescription opioids 2 years later are 4 times more likely to report moderate to severe pain. Greater pain after surgery predicts the persistence of pain and prolonged opioid use. Thus, effective postsurgical analgesia appears to improve long-term outcomes.

Perioperative behavioral pain treatments offer an analgesic adjunct to medical care. Two recent reviews of perioperative behavioral treatments reported promising evidence for pain reduction after orthopedic surgery. A brief perioperative behavioral intervention was associated with reduced opioid use after breast cancer surgery. For chronic pain, 2 randomized controlled trials (RCTs) have shown that a single-session pain-relief skills intervention (“empowered relief”) significantly reduced pain catastrophizing, pain intensity, pain interference, and a range of secondary outcomes 3 months after treatment. Empowered relief was tailored to the surgical context and digitalized to create an on-demand treatment called “My Surgical Success” (MSS). MSS provides on-demand expert-led pain education and evidence-based cognition, emotion, and physiological self-regulatory skills. Our RCT of MSS versus digital health education (HE) in women undergoing breast cancer surgery revealed that women who engaged with MSS had 6.5 fewer days of postoperative opioid use without increased pain. We aimed to test MSS in orthopedic trauma surgery patients due to their substantial need for analgesia after surgery.

Our primary aim was to test the feasibility of MSS in orthopedic trauma surgery inpatients after fracture surgery. Our secondary aims were to evaluate the impact of MSS on postsurgical pain intensity, pain catastrophizing, and opioid cessation up to 3 months after surgery. While others have examined digital behavioral treatments for acute postoperative pain during hospitalization or in the early weeks after surgery, to the best of our knowledge, no study has examined their impacts on outcomes 3 months after surgery.

METHODS

Study Design and Oversight

This clinical trial was performed at an academic hospital setting in the San Francisco Bay area. The trial tested for acceptability and feasibility of MSS in orthopedic trauma surgery patients, as well as preliminary efficacy for pain catastrophizing, pain intensity, and time to opioid cessation after surgery. The study protocol was approved by the Stanford University institutional review board (IRB 42569), and written consent was obtained from all patients participating in the trial. The trial was registered before patient enrollment with clinicaltrials.gov (NCT03764839; https://clinicaltrials.gov/ct2/show/NCT03764839?cond=orthopedic+trauma+surgery&draw=2&rank=1; principal investigator: Beth Darnall, PhD; date of registration: May 12, 2018). The study followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines on clinical trials.

Patient Participants

Patients were recruited from the Stanford Orthopedic Trauma Clinic and hospital surgical recovery unit with electronic and print advertisements in waiting areas and patient rooms, describing a no-cost, non-drug study involving 2 treatments to help with postsurgical recovery. A total of $80 compensation was possible for completing the study surveys.
Inclusion criteria for participants were: (1) orthopedic trauma surgery was either scheduled within the next 7 days or had occurred within the past 7 days, (2) 18 to 80 years of age, (3) English fluency, and (4) ability and willingness to complete electronic study procedures, including questionnaires and receipt of treatment via a study handheld computer (ie, iPad) or their personal computer device. Exclusion criteria were: (1) inability to complete study procedures (eg, cognitive ability, mental status, or medical status) or lack of access to Internet and phone that would prevent participation in study procedures, (2) long-term opioid use (>3 months) before surgery, (3) known pregnancy, (4) ongoing legal action related to pain or disability claim, (5) multiple surgeries and/or infections, (6) injury not related to fracture or trauma, and (7) current substance use disorder documented in the patient’s electronic medical record.

Eligible hospital patients were enrolled in the study after informed consent, and they were provided an iPad to complete the study procedures. Participants completed their baseline survey and immediately were e-randomized and assigned to 1 of 2 digital treatment groups. Only 2 patients participated in the study from home after hospital discharge.

**Randomization Procedures and Participant Blinding**
Participants were randomly assigned to a study treatment group through the Research Data Capture (REDCap) system with a 1:1 ratio to ensure an equal number of patients in each group. Data were deidentified for analyses, and outcome assessors were blinded to study group assignment. Participants in both intervention groups received their treatment online, and all participant-reported data were collected online. There was no in-person or live online contact with a study therapist. In-person research staff contact was limited to enrollment. After hospital discharge, study staff contact with participants was limited to telephone and online communications regarding data collection and participant payment.

**Data Protection and Investigator Blinding**
Participant identification was protected with a unique study identification number. All data were received electronically, instantly locked in the database, and stored with double password protection. Research staff were unblinded to individual group assignment; the statisticians and nonstaff investigators remained blinded to treatment assignment group until the database was locked.

**Assessment Time Points**
All measures were administered after study enrollment. A pretreatment baseline assessment included demographic variables (age, sex, race, ethnicity, relationship status, education, occupation, and annual household income) and the outcome measures listed below. Clinical variables (surgery status and duration of surgery) and prescribed opioid medications were extracted from electronic health records (EHRs) by medically trained study staff. For MSS participants, a brief treatment satisfaction and acceptability e-survey was administered immediately after treatment was received. Brief surveys were deployed every 3 days to assess postsurgical opioid use until opioid cessation was achieved or until the study period was complete at the 3-month time point. Posttreatment monthly assessments (months 1–3) mirrored the pretreatment baseline survey (minus demographics).

**Outcome Measures**

**Primary Outcome.** Feasibility was assessed in 2 ways. First, feasibility and acceptability of the MSS digital intervention replicated published methods and were determined by participant ratings for treatment acceptability, satisfaction, usefulness of information presented, ease of understanding, and likelihood to use the pain management skills learned. The rating scale ranged from 0 to 6; thus, a score of 4.8 or greater on each item would indicate exceeding the 80% threshold of acceptability. The second feasibility index was the percentage of patients who agreed to participate after being approached and invited to enroll in the study.

**Secondary Outcomes.**

**Pain Intensity.** Respondents rated their average pain intensity over the previous 7 days on a Numerical Pain Rating Scale (NPRS) of 0 (no pain) to 10 (worst pain imaginable). Assessment of pain intensity using an NPRS has been supported in previous studies.

**Pain Catastrophizing Scale.** The 13-item pain catastrophizing scale (PCS) measures patterns of negative cognition and emotion in the context of actual or anticipated pain. The response scale ranges from 0 (not at all) to 4 (all the time); total sum scores range from 0 to 52. The PCS has good internal and psychometric consistency and a high coefficient alpha (0.87). Higher presurgical scores have been shown to predict poorer postsurgical outcomes, including greater and persistent pain and opioid use.

**Opioid Use.** Prescribed opioid type and dose at baseline were extracted from medical charts by medically trained study staff. Brief surveys were deployed every 3 days after surgery to collect patient-reported opioid use (type of opioid medication, dose, and frequency of use over the past 72 hours). All opioid doses were converted to morphine equivalent daily.
dose (MEDD) by a pain physician blinded to individual treatment group assignment who applied the Centers for Disease Control and Prevention conversion protocol, similar to other research. Study staff confirmed prescribed opioid doses at baseline via medical chart review.

Time to opioid cessation was defined as 3 consecutive surveys reporting no opioid use over the past 3 days equivalent to >9 days of no opioid use.

**Surgery Characteristics.** Surgery date was extracted from the orthopedic trauma surgery unit daily surgery list. Type of surgery and duration of surgical procedure were extracted from the electronic medical records and validated by medically trained study staff.

Exploratory outcomes included the National Institutes of Health (NIH) Patient-Reported Outcomes Measurement System short-form (PROMIS-SF) measures for pain interference, physical function, sleep disturbance, depression, anxiety, social isolation, and fatigue. Table 1 displays the demographic and clinical characteristics for the study sample.

**Study Group Interventions**

**My Surgical Success.** The MSS intervention, housed within REDCap, contained 3 brief pain psychoeducational videos (45 minutes total) and a welcome message from the orthopedic trauma surgeon. A personalized plan for surgical success was automatically emailed to participants, and they were provided a 20-minute binaural relaxation response app for daily use. Video content included information and skills to regulate cognition, emotion, and physiological hyperarousal related to pain and stress; learners were guided to self-tailor the information by completing their personalized plan for surgical success.

**Health Education.** Patients randomized to HE intervention received digital text education about health and nutrition framed in terms of its importance in enhancing recovery after surgery (this group did not receive any video). See Supplemental Digital Content 1, Supplemental Appendix A, http://links.lww.com/AA/D964 for detailed information on study interventions.

**Power Calculation**

To detect a feasibility of 80% assuming a null feasibility of 50%, power of 0.8, and alpha of 0.05, 14 participants were needed in the treatment group to assess the primary study aim. While our preregistered primary aim was feasibility, the study was powered to test for opioid cessation as a more conservative estimate of sample size needed to test the secondary aims. The study was designed to detect a hazard ratio of 1.89 and a mean cessation time of 13 days in controls, as observed in opioid cessation for MSS in our previous study of breast cancer patients. We set a power threshold of 0.8 and a 2-tailed alpha of 0.05. We used the PS Power and Sample Size Program to calculate our needed sample size of 41 events in the treatment group and 41 events in the control group. Our target enrollment was 50 for each treatment group. Our final sample consisted of 37 in MSS and 47 in HE. Note that an additional 13 patients were enrolled in the study (for a total sample size of N = 97) the month before CT.gov approval, and thus, these 13 participants were omitted from the primary analysis to remain in strict compliance with reporting data only for participants enrolled after trial registration is approved. These additional 13 participants followed all study procedures.

**Statistical Analysis**

All analyses were conducted using SAS Studio 3.8 enterprise edition and a modified intent-to-treat analysis. All randomized participants were included in the analysis as long as they participated in at least 1 follow-up measure. All confidence intervals (CIs) reported are 95% CIs as reported by SAS. We used an alpha of 0.05 for statistical significance.

Acceptability and feasibility were verified by calculating proportions. Group differences for continuous variables were determined through the appropriate t test (PROC TTTEST) or Wilcoxon-rank sum (PROC NPAR1WAY) if the data were skewed. Assumptions of normality and homoscedasticity were examined by plotting the residuals from the mixed-effects linear models, which were then visually inspected and found to be acceptably distributed. Group differences for categorical variables were evaluated using χ² analysis (PROC FREQ).

Secondary outcomes were evaluated at the 0-, 30-, 60-, and 90-day time points, for which day 0 was defined as surgery day. Monthly pain intensity, pain catastrophizing, and opioid use were assessed using mixed linear modeling. As this method is robust against missing data, there was no need for imputation. To ensure no bias related to missing data, analyses were run using the last value varied forward. Mixed linear modeling (PROC MIXED) fits fixed and random effects to the data. Random effects are the adjustments for within-person variations across time. Fixed effects, reported in this article, are the parameters that apply across individuals in the cohort, including the treatment-time interaction effect. We excluded a baseline interaction effect, as these measures were collected before treatment. A significant negative difference between the MSS and HE groups suggests.
### Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

| Characteristics                              | Total sample (N = 84) | MSS (n = 37) | HE control (n = 47) | P value |
|----------------------------------------------|-----------------------|--------------|---------------------|---------|
| Age, mean years (SD)                         | 49.53 (17.14)         | 51.62 (18.84) | 47.84 (15.64)       | .322a   |
| Sex, No. (%)                                 |                       |              |                     |         |
| Female                                       | 32 (38.10)            | 15 (40.54)   | 17 (36.17)          | .635b   |
| Male                                         | 51 (60.71)            | 22 (59.46)   | 31 (61.70)          |         |
| Other                                        | 0 (0.00)              | 0 (0.00)     | 0 (0.00)            |         |
| Race, No. (%)                                |                       |              |                     |         |
| White                                        | 52 (61.90)            | 25 (67.57)   | 27 (57.45)          | .877c   |
| Asian/Pacific Islander                       | 13 (15.48)            | 5 (13.51)    | 8 (17.02)           |         |
| Black                                        | 2 (2.38)              | 1 (2.70)     | 1 (2.13)            |         |
| American Indian/Alaska Native                | 0 (0.00)              | 0 (0.00)     | 0 (0.00)            |         |
| Other                                        | 15 (17.86)            | 5 (13.51)    | 10 (21.28)          |         |
| Missing                                      | 2 (2.38)              | 1 (2.70)     | 1 (2.13)            |         |
| Ethnicity, No. (%)                           | 10 (11.90)            | 3 (8.11)     | 7 (14.89)           | .411b   |
| Hispanic                                     | 73 (86.90)            | 34 (91.89)   | 39 (82.98)          |         |
| Relationship status, No. (%)                 |                       |              |                     |         |
| Married/cohabitating                         | 47 (55.95)            | 20 (54.05)   | 27 (57.45)          | .815c   |
| Never married                                | 18 (21.43)            | 8 (21.62)    | 10 (21.28)          |         |
| Divorced                                     | 8 (9.52)              | 3 (8.11)     | 5 (10.64)           |         |
| Separated                                    | 1 (1.19)              | 0 (0.00)     | 1 (2.13)            |         |
| Widowed                                      | 1 (1.19)              | 1 (2.70)     | 0 (0.00)            |         |
| In a relationship but not cohabitating       | 8 (9.52)              | 5 (13.51)    | 3 (6.38)            |         |
| Education, No. (%)                           |                       |              |                     |         |
| Up to high school                            | 8 (9.52)              | 3 (8.11)     | 5 (10.64)           | .122c   |
| Some college/associate's                    | 17 (20.24)            | 7 (18.92)    | 10 (21.28)          |         |
| Bachelor’s degree                            | 29 (34.52)            | 16 (43.24)   | 13 (27.66)          |         |
| Master’s degree                              | 16 (19.05)            | 3 (8.11)     | 13 (27.66)          |         |
| Professional/doctoral degree                 | 13 (15.48)            | 8 (21.62)    | 5 (10.64)           |         |
| Employment, No. (%)                          |                       |              |                     |         |
| Full time                                    | 44 (52.38)            | 17 (45.95)   | 27 (57.45)          | .616d   |
| Part time                                    | 4 (4.76)              | 1 (2.70)     | 3 (6.38)            |         |
| Retired                                      | 18 (21.43)            | 11 (29.73)   | 7 (14.89)           |         |
| Student                                      | 6 (7.14)              | 4 (10.81)    | 2 (4.26)            |         |
| Unemployed                                   | 5 (5.95)              | 2 (5.41)     | 3 (6.38)            |         |
| Disabled                                     | 3 (3.57)              | 1 (2.70)     | 2 (4.26)            |         |
| Household income (USD), No. (%)              |                       |              |                     |         |
| <25,000                                      | 9 (10.71)             | 4 (10.81)    | 5 (10.64)           | .999a   |
| 25,000–45,000                                | 6 (7.14)              | 3 (8.11)     | 3 (6.38)            |         |
| 45,000–65,000                                | 5 (5.93)              | 2 (5.41)     | 3 (6.38)            |         |
| >65,000                                      | 53 (63.10)            | 23 (62.16)   | 30 (63.83)          |         |
| Prefer not to say                            | 11 (13.10)            | 5 (13.51)    | 6 (12.77)           |         |
| Surgery status (%)                           |                       |              |                     |         |
| Yes, had surgery before recruitment          | 71 (84.52)            | 34 (91.89)   | 37 (78.72)          | .226d   |
| No, had surgery after recruitment            | 12 (14.29)            | 3 (8.11)     | 9 (19.15)           |         |
| Days after surgery, mean (SD)                | 1.86 (1.56)           | 2.03 (1.78)  | 1.70 (1.33)         | .214c   |
| Duration of surgery, min (SD)                | 140.39 (70.79)        | 136.30 (66.22)| 143.70 (74.83)     | .640c   |
| Baseline opioid dose, MEDD mg (SD)           | 56.58 (64.44)         | 53.43 (82.35)| 59.05 (46.60)       | .059d   |
| Surgery type, No. (%)                        |                       |              |                     |         |
| I&D                                          | 4 (4.76)              | 2 (5.41)     | 2 (4.26)            | .246c   |
| ORIF                                         | 61 (72.62)            | 26 (70.27)   | 35 (74.47)          |         |
| ORIF, I&D                                    | 9 (10.71)             | 5 (13.51)    | 4 (8.51)            |         |
| THA                                          | 5 (4.76)              | 0 (0.00)     | 4 (7.66)            |         |
| Repair bone defect                           | 1 (1.19)              | 1 (2.70)     | 0 (0.00)            |         |
| Repair malunion                              | 1 (1.19)              | 1 (2.70)     | 0 (0.00)            |         |
| Repair nonunion                              | 1 (1.19)              | 0 (0.00)     | 1 (1.33)            |         |
| Revision THA                                 | 1 (1.19)              | 1 (2.70)     | 0 (0.00)            |         |
| Surgery location, No. (%)                    |                       |              |                     |         |
| Upper extremity                              | 19 (22.6)             | 12 (36.3)    | 7 (14.89)           | .069e   |
| Lower extremity                              | 65 (77.4)             | 25 (86.7)    | 40 (85.1)           |         |

Data are mean (standard deviation [SD]) unless indicated as No. (%). P values are all nonsignificant between groups.

Abbreviations: HE, health education; I&D, irrigation and debridement; MEDD, morphine equivalent daily dose; MSS, My Surgical Success; ORIF, open reduction and internal fixation; SD, standard deviation; THA, total hip arthroplasty; USD, US dollars.

aTwo-sample t test with pooled variance.

bWald χ² test.

cFisher exact test.

dWilcoxon rank sum test.
that the MSS treatment is effective for decreasing that outcome at that time point. Exploratory analyses on pain-related outcomes (pain interference, anxiety, depression, sleep disturbance, and physical function) were also conducted using the above methods.

Opioid cessation was assessed by survival analysis using the brief surveys that were completed every 3 days. If a patient did not have 3 opioid-free surveys by the most recent follow-up, they were considered censored in regard to opioid cessation. Meier survival estimates and a log-rank test were performed comparing the MSS and HE groups (PROC LIFETEST). A Cox proportional hazards model was also fit to the data (PROC PHREG). The proportional hazards assumption was verified using a log-log plot and by finding a nonsignificant time-group interaction effect in the Cox model. Both methods are robust to missing data and have no need for imputation.

Finally, as an index of clinical meaningfulness, responder analyses were conducted by calculating the proportion of participants with 15% (minimal), 30% (moderate), and 50% (substantial) improvement from baseline to 3-month follow-up. We applied a minimal clinical important change (MCID) threshold of 1.5 for pain intensity. For these analyses, we first excluded patients with missing 3-month values. We then performed sensitivity analyses using the last value carried forward and multiple imputations.

**RESULTS**

**Patient Characteristics and Preliminary Analyses**

Figure 1 shows the CONSORT diagram and participants’ flow, which occurred from December 2018 to January 2020. A total of 341 patients were identified as initially eligible, and were approached and screened by research staff. A total of 133 patient participants were identified as eligible and enrolled, and those who agreed to participate (63%; 84 of 133 patients approached).

Table 1 displays the baseline characteristics by graphic and surgery variables (Table 1) and baseline characteristics (Table 2) did not differ significantly between the 2 treatment groups except for sleep disturbance, suggesting that randomization created equivalent study groups.

**Feasibility and Acceptability (Primary Aim)**

Feasibility and acceptability metrics revealed that for MSS, mean scores met or exceeded an 80% (4.8) threshold for items related to “easy to understand” (M = 5.70; 95% CI, 5.54–5.86), “usefulness” (M = 4.82; 95% CI, 4.48–5.16), “satisfied” (M = 4.86; 95% CI, 4.51–5.22), “likelihood of use” (M = 5.00; 95% CI, 4.68–5.32), and “relevant” (M = 4.77; 95% CI, 4.4.2–5.12). Overall, more than half the participants rated the video length as “just right.” About 98% reported the information was at least somewhat relevant to them, every participant identified at least 1 skill they could use, and 88% reported positive satisfaction ratings. Additional feasibility was assessed by the percentage of patients who agreed to participate (63%; 84 of 133 patients approached).

**Preliminary Efficacy (Secondary Aim)**

Using intention-to-treat analyses, we found that MSS was superior to HE for pain intensity reductions across all time points after treatment (treatment × time fixed effects interaction, F[215] = 5.23; P = .024) (Figure 2). Table 3 displays the between-group pain intensity differences from an additional mixed linear model treating the monthly surveys as categorical allowing for the elucidation of expected additional benefit of MSS at each time point. Our analysis found group differences of –1.37 (95% CI, –2.30 to –0.44), –0.97 (95% CI, –1.84 to –0.09), and –1.14 (95% CI, –2.02 to –0.27) at 1 month, 2 months, and 3 months, respectively, which were statistically significant. Clinically meaningful reductions in pain intensity were found for both groups (MSS = –3.28, 46.3%; HE = –2.21, 31.3%). As much as 69% (25/36) of MSS and 49% (22/45) of HE participants achieved a 30% or more reduction in pain intensity, considered a moderately clinically important reduction in pain. For MSS, 47% (17/36) achieved the substantially clinically important reduction in pain of 50%, while for HE, 27% (12/45) reached that threshold. Supplemental Digital Content 2, Table S1, http://links.lww.com/AA/D965, displays the means and mean-group comparisons for all variables at all time points.

The full sample was noted to have slightly subclinical levels of presurgical PCS scores at baseline (<15). MSS was not superior to HE for pain catastrophizing reductions at 1–3 months after treatment (Table 3). At 3 months after treatment, clinically meaningful reductions in PCS scores were found for both treatment groups (MSS = –6.92, 49.7%; HE = –7.74, 54.4%), and MSS was not superior to HE. As much as 75% (27/36) of MSS and 62% (28/45) of HE participants achieved a >30% reduction in pain catastrophizing. For MSS,
67% (24/36) achieved a >50% reduction in pain catastrophizing, while for HE, 53% (24/45) reached that threshold. No statistically significant between-group treatment effects were observed for anxiety, depression, fatigue, social isolation, pain interference, or sleep disturbance.

**Time to Opioid Cessation After Surgery**
Six patients were censored in the adjusted models (MSS, n = 3; HE, n = 3), either because they were not prescribed opioids (n = 5) or did not take opioids beyond their procedure day (n = 1). The Kaplan-Meier product-limit survival estimates are presented.
The primary aim of our RCT was to test the feasibility and acceptability of a single-session behavioral pain intervention (MSS) in patients undergoing orthopedic trauma surgery. Indeed, the MSS engagement rate was 63%, which exceeds 20% to 60% Internet-based behavioral health engagement rates for the non-surgical extant literature.28,29 MSS ratings exceeded thresholds for being acceptable, perceived as useful, and having high treatment satisfaction ratings, thus suggesting feasibility for future research and clinical care. Nonengagers (37%) did not complete baseline surveys; therefore, we are unable to characterize this subgroup. Lack of engagement and attrition may be due to specific sample characteristics, perceived intervention burden, or other factors.

**DISCUSSION**

Table 2. Baseline Measures Between Treatment Groups

| Variables                  | MSS (n = 37)       | HE control (n = 47) | SD  |
|---------------------------|--------------------|---------------------|-----|
| Pain intensity            | 7.08 (1.91)        | 7.06 (1.89)         | 0.01|
| Pain catastrophizing      | 13.92 (13.92)      | 14.23 (11.24)       | –0.03|
| PROMIS pain interference  | 65.92 (10.96)      | 70.00 (7.24)        | –0.44|
| PROMIS anxiety            | 56.25 (8.86)       | 56.54 (9.41)        | –0.03|
| PROMIS depression         | 52.84 (8.18)       | 50.73 (9.38)        | 0.23 |
| PROMIS fatigue            | 56.33 (8.14)       | 55.69 (10.15)       | 0.07 |
| PROMIS sleep disturbance  | 51.93 (6.87)       | 56.59 (7.94)        | –0.62|
| PROMIS social isolation   | 44.33 (8.58)       | 44.59 (8.17)        | –0.03|

PROMIS assessments are standardized to a nonclinical reference with a mean of 50 and an SD of 10.

Abbreviations: HE, health education; MSS, My Surgical Success; PROMIS, Patient-Reported Outcomes Measurement Information Systems; SD, standard deviation.

in Figure 3. The difference in curves shows directionality, but it is not statistically significant (Wilcoxon \( P = .239 \)). The mean time to cessation for the MSS group was 20.91 vs 24.21 days for the HE control group.

Importantly, as noted earlier, the first 13 participants were enrolled in the month before final trial registration approval, and thus were excluded from current analyses. All study procedures were followed by all 13 participants; as such, we have replicated and attached all analyses, including data from the 13 participants, as they provide additional information and context that is relevant for future research, in addition to improved study power (Supplemental Digital Content 3, Table S2, http://links.lww.com/AA/D966). Results showed a robust and consistent statistically significant interaction effect on pain intensity, whereby patients in the MSS group evidenced greater reductions in pain intensity up to 3 months after surgery. Similarly, we did not observe statistically significant between-group differences in time to opioid cessation.

Figure 2. Reductions in pain intensity between the study groups from baseline to 3 months after treatment. CI indicates confidence interval; HE, health education; MSS, My Surgical Success.
Digital health interventions are promising and increasing in demand, despite often having lower engagement rates than control or in-person interventions. Increased uptake has been partly driven by recent coronavirus disease-related restrictions that prevented receipt of in-person care, and is supported by on-demand treatment availability. The current study included several enhancements to optimize patient engagement in MSS. First, MSS involved a modular and brief format (three 15-minute video segments) that is well-suited to an inpatient population. Second, the medical rationale and pain treatment philosophy were enhanced with a video welcome message from the chief of orthopedic trauma surgery. Third, the orthopedic trauma surgery team supported patient enrollment and understanding of behavioral pain treatment.

The secondary aims of this study were to test the between-group differences for pain intensity, pain catastrophizing, and time to opioid cessation after surgery. The MSS group reported reduced pain intensity after surgery compared to the HE control group, with enduring effects demonstrated at 3 months after surgery. Enhanced longitudinal analgesia for MSS recipients is a crucial finding in light of evidence showing that poorly managed acute postsurgical pain predicts pain persistence and prolonged need for opioids after surgery. Viewed through this lens, postoperative pain management is crucial for optimized surgical recovery.

Patients in both treatment groups reported pain reduction over time after surgery, and this aligns with the natural history of surgical recovery. However, 3 months after surgery, the full study sample was still reporting moderate pain intensity. This finding underscores the importance of long-term pain management after orthopedic trauma surgery, and integration of adjunctive analgesic options such as MSS may play a role. Specifically, 3 months after orthopedic trauma surgery, pain intensity was improved by

### Table 3. Treatment Group Differences

| Measures       | Fixed effect absolute difference | 1 month | 2 months | 3 months |
|----------------|----------------------------------|---------|----------|----------|
| Pain intensity | –1.37 (–2.30 to –0.44)           | –0.97 (–1.84 to –0.09) | –1.14 (–2.02 to –0.27) |
| Pain catastrophizing scale | –2.64 (–6.62 to 1.33)           | 1.51 (–2.42 to 5.45) | –0.47 (–4.24 to 3.30) |
| PROMIS pain interference | –2.59 (–6.16 to 0.98)           | –0.93 (–4.72 to 2.85) | –2.91 (–7.22 to 1.41) |
| PROMIS anxiety | –1.48 (–4.69 to 1.74)            | 1.45 (–2.20 to 5.09) | –0.01 (–3.78 to 3.75) |
| PROMIS depression | –1.28 (–4.29 to 1.73)           | –2.05 (–5.15 to 1.04) | –0.94 (–4.21 to 2.33) |
| PROMIS fatigue | –1.70 (–5.54 to 2.13)            | 0.00 (–3.46 to 3.46) | –1.29 (–5.35 to 2.77) |
| PROMIS sleep disturbance | –1.50 (–4.98 to 1.98)           | –0.79 (–4.18 to 2.61) | –0.70 (–4.31 to 2.91) |
| PROMIS social isolation | –0.48 (–3.67 to 2.71)           | –2.35 (–5.36 to 0.66) | –0.45 (–3.84 to 2.94) |

A negative value indicates the treated group (MSS) reported less of that variable than the control group (HE).

Abbreviation: PROMIS, Patient-Reported Outcomes Measurement Information Systems.
an additional 1.14 points for MSS patients compared to HE patients. In terms of clinical meaningfulness, this difference falls below the 2-point threshold for an MCID established by Farrar et al. However, other studies have established that the MCID is closer to a 13% change from baseline (approximately 1.4 points on a 0–10 scale), which approximates the difference observed in the current study. Surgical duration and surgery type did not vary at baseline and were not included as covariates in further analyses. Results provide preliminary evidence for MSS benefits in orthopedic trauma surgery patients and stand in contrast to other research reporting negative findings for different behavioral perioperative interventions applied in disparate surgical populations.

In regard to our secondary aim for time to opioid cessation, we did not observe a between-group difference despite showing reduced pain intensity for the MSS group. This finding contrasts our previous study in breast cancer surgery patients, in which MSS was associated with significantly reduced time to opioid cessation. Orthopedic trauma surgery is associated with greater pain intensity over a longer period of time, and postsurgical pain and the need for analgesic medication may be further amplified as patients engage in physical rehabilitation and daily exercise regimens. We studied patient-reported use of opioids as a more granular and precise index than prescriptions.

For our final secondary aim, we examined group changes for pain catastrophizing scores, as pain catastrophizing improved substantially after surgery for both treatment groups, again supporting the natural history of improvement after surgery. However, similar to findings from our previous MSS trial, we cannot rule out a potential floor effect as baseline levels of pain catastrophizing were below the published ranges for clinically moderate or high levels in surgical populations.

Strengths of the study include a longitudinal design to 3 months after surgery, randomization with an active control group, inclusion of a range of surgery types, frequent sampling of opioid use to minimize recall bias, intention-to-treat analysis, and largely inpatient receipt of treatment to quantify the impact of early receipt of perioperative behavioral pain treatment.

LIMITATIONS
Findings should be qualified within several study limitations. First, no satisfaction data were collected for the HE group. However, we found a low attrition rate for HE participants after receipt of the intervention and study engagement that was comparable to the MSS group. Second, results may not generalize to: (1) populations with greater baseline pain-related distress, (2) different surgical types or populations, or (3) lower socioeconomic populations. Third, a large number of screened patients were ineligible to participate due to study criteria. Finally, regular logging of opioid use may serve as an intervention or possibly lead to observer bias, both of which move our observations toward the null.

CONCLUSIONS
Results suggest that a low-cost, efficient, fully automated behavioral pain medicine treatment may be a useful pain management adjunct for motivated orthopedic trauma surgery patients and may reduce postsurgical pain up to 3 months after surgery. MSS offers significant advantages for increasing access to behavioral pain medicine with low/no risks and low/no implementation costs, and may support enhanced recovery after orthopedic trauma surgery.

ACKNOWLEDGMENTS
We wish to acknowledge the nurses and medical staff at the Stanford Orthopedic Trauma Surgery Unit for their help in facilitating the data collection for the study.

DISCLOSURES
Name: Maisa S. Ziadni, PhD.
Contribution: This author led study development, implementation, and coordination; data collection and management; and manuscript preparation, revisions, and submission.
Conflicts of Interest: None.
Name: Dokyoung S. You, PhD.
Contribution: This author helped with data collection and preparation and manuscript preparation.
Conflicts of Interest: None.
Name: Ryan Keane, BA.
Contribution: This author helped with data collection and preparation and manuscript preparation.
Conflicts of Interest: None.
Name: Brett Salazar, BS.
Contribution: This author helped with data collection, chart reviews, and manuscript revisions.
Conflicts of Interest: None.
Name: Sam Jaros, BS.
Contribution: This author helped with statistical analyses and manuscript preparation.
Conflicts of Interest: None.
Name: Jesmin Ram, BA.
Contribution: This author helped with study management, data collection, and manuscript revisions.
Conflicts of Interest: None.
Name: Anuradha Roy, MSc.
Contribution: This author helped with data collection and management and manuscript revisions.
Conflicts of Interest: None.
Name: Natalie Tanner, BA.
Contribution: This author helped with data collection and manuscript revisions.
Conflicts of Interest: None.
Name: Vafi Salmasi, MD.
Contribution: This author helped with data analysis and preparation and manuscript revisions.
Conflicts of Interest: None.
Name: Michael Gardner, MD.
My Surgical Success for Orthopedic Trauma Surgery

Contribution: This author helped with study design and implementation and manuscript preparation and revisions.

Conflicts of Interest: None.

Name: Beth D. Darnall, PhD.

Contribution: This senior author led the study design and contributed to study implementation, manuscript preparation, and manuscript revisions.

Conflicts of Interest: B. D. Darnall receives royalties for 4 pain treatment books she has authored. She is the principal investigator for pain treatment research grants and awards from the National Institutes of Health (NIH) and the Patient-Centered Outcomes Research Institute. She is a chief science advisor at Applied VR, and serves on the boards of directors of the American Academy of Pain Medicine and the Institute for Brain Potential. She is a current scientific member of the NIH Interagency Pain Research Coordinating Committee and the Pain Advisory Group of the American Psychological Association. She was an appointed member of the Centers for Disease Control and Prevention Opioid Workgroup (2020–2021).

This manuscript was handled by: Michael J. Barrington, MB BS, FANZCA, PhD.

REFERENCES

1. Jarman MP, Weaver MJ, Haider AH, Salim A, Harris MB. The national burden of orthopedic injury: cross-sectional estimates for trauma system planning and optimization. J Surg Res. 2020;249:197–204.
2. Noori A, Sprague S, Bzovsky S, et al; HEALTH Investigators. Predictors of long-term pain after hip arthroplasty in patients with femoral neck fractures: a cohort study. J Orthop Trauma. 2020;34(suppl 3):S55–S63.
3. Hah JM, Cramer E, Hilmoe H, et al. Factors associated with acute pain estimation, postoperative pain resolution, opioid cessation, and recovery: secondary analysis of a randomized clinical trial. JAMA Netw Open. 2019;2:e190168.
4. Veal FC, Bereznicki LR, Thompson AJ, Peterson GM, Orlikowski C. Subacute pain as a predictor of long-term pain following orthopedic surgery: an Australian prospective 12-month observational cohort study. Medicine. 2015;94:1.
5. Katz J, Jackson M, Kavanagh BP, Sandler AN. Acute pain after thoracic surgery predicts long-term post-thoracotomy pain. Clin J Pain. 1996;12:50–55.
6. Hanley MA, Jensen MP, Smith DG, Ehde DM, Edwards WT, Robinson LR. Preamputation pain and acute pain predict chronic pain after lower extremity amputation. J Pain. 2007;8:102–109.
7. Szeverenyi C, Kekecz Z, Johnson A, Elkins G, Csernatory Z, Varga K. The use of adjunct psychosocial interventions can decrease postoperative pain and improve the quality of clinical care in orthopedic surgery: a systematic review and meta-analysis of randomized controlled trials. J Pain. 2018;19:1231–1252.
8. Tong F, Dannaway J, Enke O, Eslick G. Effect of preoperative psychological interventions on elective orthopaedic surgery outcomes: a systematic review and meta-analysis. ANZ J Surg. 2020;90:230–236.
9. Darnall BD, Ziadni MS, Krishnamurthy P, et al. “My surgical success”: effect of a digital behavioral pain medicine intervention on time to opioid cessation after breast cancer surgery—a pilot randomized controlled clinical trial. Pain Med. 2019;20:2228–2237.
10. Darnall BD, Roy A, Chen AL, et al. Comparison of a single-session pain management skills intervention with a single-session health education intervention and 8 sessions of cognitive behavioral therapy in adults with chronic low back pain: a randomized clinical trial. JAMA Netw Open. 2021;4:e2113401.
11. Ziadni MS, Gonzalez-Castro L, Anderson S, Krishnamurthy P, Darnall BD. Efficacy of a single-session “empowered relief” zoom-delivered group intervention for chronic pain: randomized controlled trial conducted during the COVID-19 pandemic. J Med Internet Res. 2021;23:e29672.
12. Darnall BD, Sturgeon JA, Kao MC, Hah JM, Mackey SC. From catastrophizing to recovery: a pilot study of a single-session treatment for pain catastrophizing. J Pain Res. 2014;7:219–226.
13. Spiegel B, Fuller G, Lopez M, et al. Virtual reality for management of pain in hospitalized patients: a randomized comparative effectiveness trial. PLoS One. 2019;14:e0219115.
14. George SZ, Wittmer VT, Fillingim RB, Robinson ME. Sex and pain-related psychological variables are associated with thermal pain sensitivity for patients with chronic low back pain. J Pain. 2007;8:2–10.
15. Farrar JT, Young JP Jr, LaMereaux L, Werth JL, Poole MR. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain. 2001;94:149–158.
16. Cook KE, Dunn W, Griffith JW, et al. Pain assessment using the NIH Toolbox. Neurology. 2013;80:S49–S53.
17. Sullivan MJ, Bishop SR, Pivik J. The pain catastrophizing scale: development and validation. Psychol Assess. 1995;7:524–532.
18. Picavet HS, Vlaeyen JW, Schouten JS. Pain catastrophizing and kinesiophobia: predictors of chronic low back pain. Am J Epidemiol. 2002;156:1028–1034.
19. Ramachandruni S, Fillingim RB, McGorry RP, et al. Mental stress provokes ischemia in coronary artery disease subjects without exercise- or adenosine-induced ischemia. J Am Coll Cardiol. 2006;47:987–991.
20. Carroll IR, Hah JM, Barelka PL, et al. Pain duration and resolution following surgery: an inception cohort study. Pain Med. 2015;16:2386–2396.
21. Hah J, Mackey SC, Schmidt P, et al. Effect of perioperative gabapentin on postoperative pain resolution and opioid cessation in a mixed surgical cohort: a randomized clinical trial. JAMA Surg. 2018;153:303–311.
22. Lai JS, Cella D, Choi S, et al. How item banks and their application can influence measurement practice in rehabilitation medicine: a PROMIS fatigue item bank example. Arch Phys Med Rehabil. 2011;92:S20–S27.
23. Revicki DA, Cook KE, Amtmann D, Harnam N, Chen WH, Keefe FJ. Exploratory and confirmatory factor analysis of the PROMIS pain quality item bank. Qual Life Res. 2014;23:245–255.
24. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42:377–381.
25. Dupont WD, Plummer WD Jr. Power and sample size calculations. A review and computer program. Control Clin Trials. 1990;11:116–128.
26. Farrar JT, Dworkin RH, Max MB. Use of the cumulative proportion of responders analysis graph to present pain data over a range of cut-off points: making clinical trial data more understandable. J Pain Symptom Manage. 2006;31:369–377.
27. Kovacs FM, Abraira V, Royuela A, et al. Minimal clinically important change for pain intensity and disability in patients with nonspecific low back pain. Spine (Phila Pa 1976). 2007;32:2915–2920.
28. Geraghty AW, Torres LD, Leykin Y, Pérez-Stable EJ, Muñoz RF. Understanding attrition from international Internet health interventions: a step towards global eHealth. *Health Promot Int.* 2013;28:442–452.
29. Hauser-Ulrich S, Künzli H, Meier-Peterhans D, Kowatsch T. A smartphone-based health care chatbot to promote self-management of chronic pain (SELMA): pilot randomized controlled trial. *JMIR Mhealth Uhealth.* 2020;8:e15806.
30. Eccleston C, Blyth FM, Dear BF, et al. Managing patients with chronic pain during the COVID-19 outbreak: considerations for the rapid introduction of remotely supported (eHealth) pain management services. *Pain.* 2020;161:889–893.
31. Hah JM, Nwaneshiudu CA, Cramer EM, Carroll IR, Curtin CM. Acute pain predictors of remote postoperative pain resolution after hand surgery. *Pain Ther.* 2021;10:1105–1119.
32. Singh JA, Lemay CA, Nobel L, et al. Association of early postoperative pain trajectories with longer-term pain outcome after primary total knee arthroplasty. *JAMA Netw Open.* 2019;2:e1915105.
33. Vasilopoulos T, Wardhan R, Rashidi P, et al; Temporal Postoperative Pain Signatures (TEMPOS) Group. Patient and procedural determinants of postoperative pain trajectories. *Anesthesiology.* 2021;134:421–434.
34. Salaffi F, Stancati A, Silvestri CA, Ciapetti A, Grassi W. Minimal clinically important changes in chronic musculoskeletal pain intensity measured on a numerical rating scale. *Eur J Pain.* 2004;8:283–291.
35. Bird SB, Dickson EW. Clinically significant changes in pain along the visual analog scale. *Ann Emerg Med.* 2001;38:639–643.
36. Ziehm S, Rosendahl J, Barth J, Strauss BM, Mehnert A, Koranyi S. Psychological interventions for acute pain after open heart surgery. *Cochrane Database Syst Rev.* 2017;7:CD009984.
37. Roh YH, Lee BK, Noh JH, Oh JH, Gong HS, Baek GH. Effect of anxiety and catastrophic pain ideation on early recovery after surgery for distal radius fractures. *J Hand Surg Am.* 2014;39:2258–64.e2.