ORIGINAL CLINICAL RESEARCH REPORT

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"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

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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 analytic 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)

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Accepted for publication April 13, 2022.

DOI: 10.1213/ANE.0000000000006088

Funding: Primary funding from the National Institute on Drug Abuse: K23DA047473 (M.S.Z.), K23DA048972 (D.S.Y.), and K24DA053564 (B.D.D.).

Conflicts of Interest: See Disclosures at the end of the article.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's website (www.anesthesia-analgesia.org).

Study registration: Clinicaltrials.gov (NCT03764839).

Reprints will not be available from the authors.

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KEY POINTS

- **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.[1] 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,[2] and those taking prescription opioids 2 years later are 4 times more likely to report moderate to severe pain.[2] Greater pain after surgery predicts the persistence of pain and prolonged opioid use.[3–6] 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.[7,8] A brief perioperative behavioral intervention was associated with reduced opioid use after breast cancer surgery.[9] 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.[9–11] 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.[9,10,12] 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.[9] 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[13] or in the early weeks after surgery,[9] 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[14] (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, nondrug 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[9] 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).[15] Assessment of pain intensity using an NPRS has been supported in previous studies.[16]

Pain Catastrophizing Scale. The 13-item pain catastrophizing scale (PCS)[17] 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).[18] Higher presurgical scores have been shown to predict poorer postsurgical outcomes, including greater and persistent pain and opioid use.[3–6]

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,[19] similar to other research.[20,21] 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 Information System short-form (PROMIS-SF) measures for pain interference, physical function, sleep disturbance, depression, anxiety, social isolation, and fatigue.[22,23] Table 1 displays the demographic and clinical characteristics for the study sample.

Study Group Interventions

My Surgical Success. The MSS intervention, housed within REDCap,[24] 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.[9] 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[25] 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 TTEST) 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 χ^2 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)	.322[a]
Sex, No. (%)				
Female	32 (38.10)	15 (40.54)	17 (36.17)	.635[b]
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)	.877[c]
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 (0.000)	
Other	15 (17.86)	5 (13.51)	10 (21.28)	
Missing	2 (2.38)	1 (2.70)	1 (2.13)	
Ethnicity, No. (%)				
Hispanic	10 (11.90)	3 (8.11)	7 (14.89)	.411[b]
Non-Hispanic	73 (86.90)	34 (91.89)	39 (82.98)	
Relationship status, No. (%)				
Married/cohabitating	47 (55.95)	20 (54.05)	27 (57.45)	.815[c]
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 (0.0)	
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)	.122[c]
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)	.616[c]
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)	.999[a]
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)	.226[d]
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)	.214[d]
Duration of surgery, min (SD)	140.39 (70.79)	136.30 (66.22)	143.70 (74.83)	.640[a]
Baseline opioid dose, MEDD mg (SD)	56.58 (64.44)	53.43 (82.35)	59.05 (46.60)	.059[d]
Surgery type, No. (%)				
I&D	4 (4.76)	2 (5.41)	2 (4.26)	.246[c]
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 (4.76)	
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 (1.13)	
Revision THA	1 (1.19)	1 (2.70)	0 (0.00)	
Surgery location, No. (%)				
Upper extremity	19 (22.6)	12 (63.2)	7 (36.8)	.069[c]
Lower extremity	65 (77.4)	25 (38.5)	40 (61.5)	

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.

[a]Two-sample *t* test with pooled variance.

[b]Wald $\chi 2$ test.

[c]Fisher exact test.

[d]Wilcoxon 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[26] from baseline to 3-month follow-up. We applied a minimal clinical important change (MCID) threshold of 1.5 for pain intensity.[27] 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 with no baseline assessment (n = 49) were censored at the time of randomization. As noted previously, n = 13 who participated in the study procedures were omitted from the primary analysis because they were enrolled before finalization of the trial registration. We report here a final sample of 84 participants who were randomized (MSS, n = 37; HE, n = 47). Two participants completed the baseline assessment and did not engage with their allocated intervention. Survey completion across both groups was relatively high; with completion rates at 1 month (MSS = 92%; HE = 94%), 2 months (MSS = 89%; HE = 87%), and 3 months (MSS = 97%; HE = 87%).

Table 1 displays the baseline characteristics by treatment group. Review of the electronic medical records revealed that the study sample was prescribed an average of 56.58 MEDD after surgery. The demographic 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, 4.42–5.12). 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,

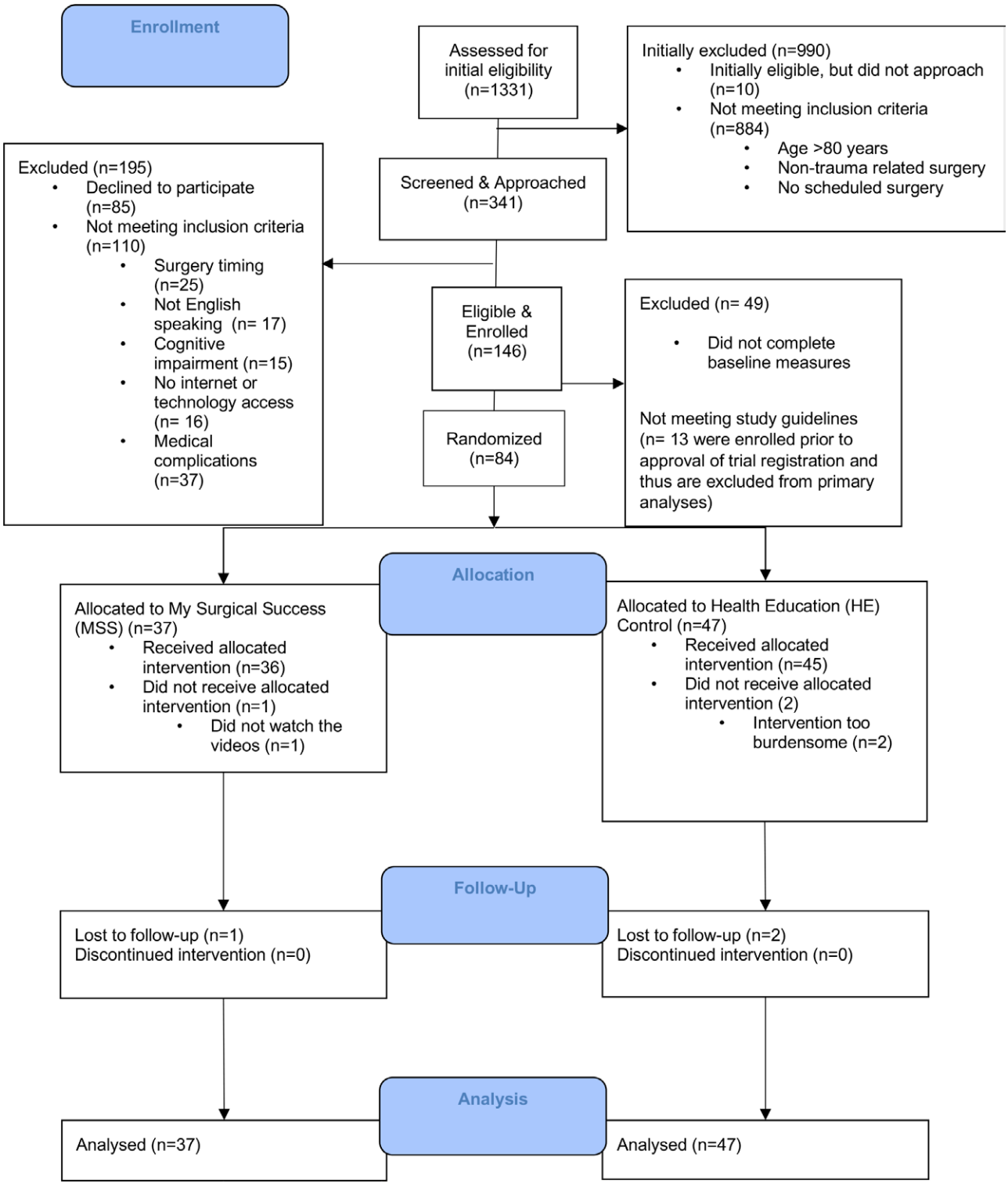

Figure 1. CONSORT diagram and participant flow. CONSORT indicates Consolidated Standards of Reporting Trials; HE, health education; MSS, My Surgical Success.

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

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 (8.81)	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.

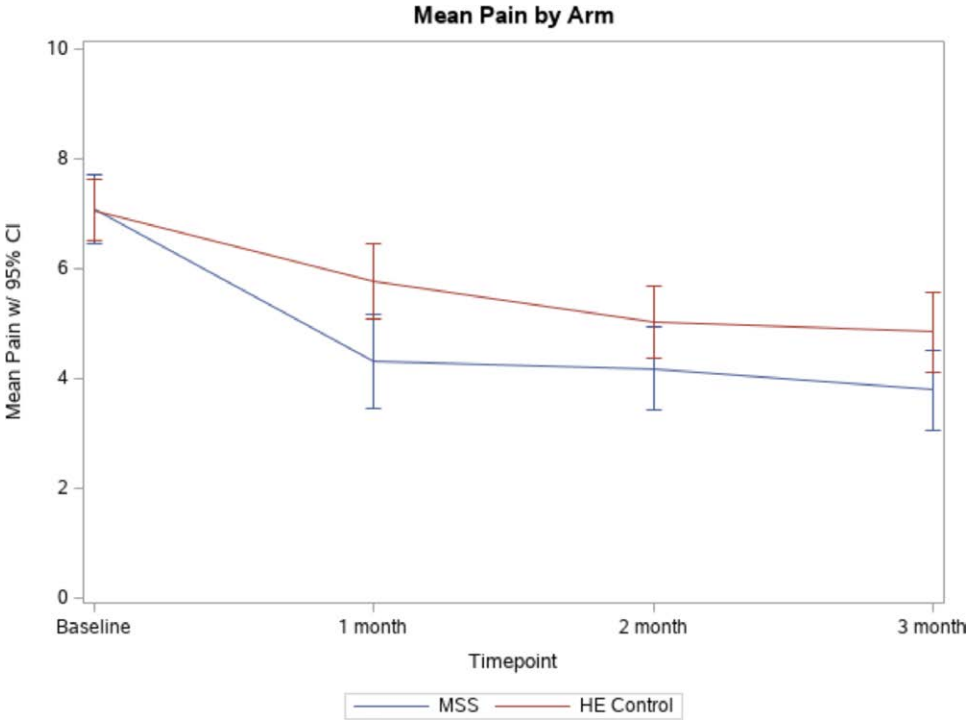

Figure 2. Reductions in pain intensity between the study groups from baseline to 3 months after treatment. CI indicates confidence interval; HE, health education; MSS, My Surgical Success.

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.

DISCUSSION

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 nonsurgical 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.

Table 3. Treatment Group Differences

	Fixed effect absolute difference		
Measures	**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 to3.75)
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.

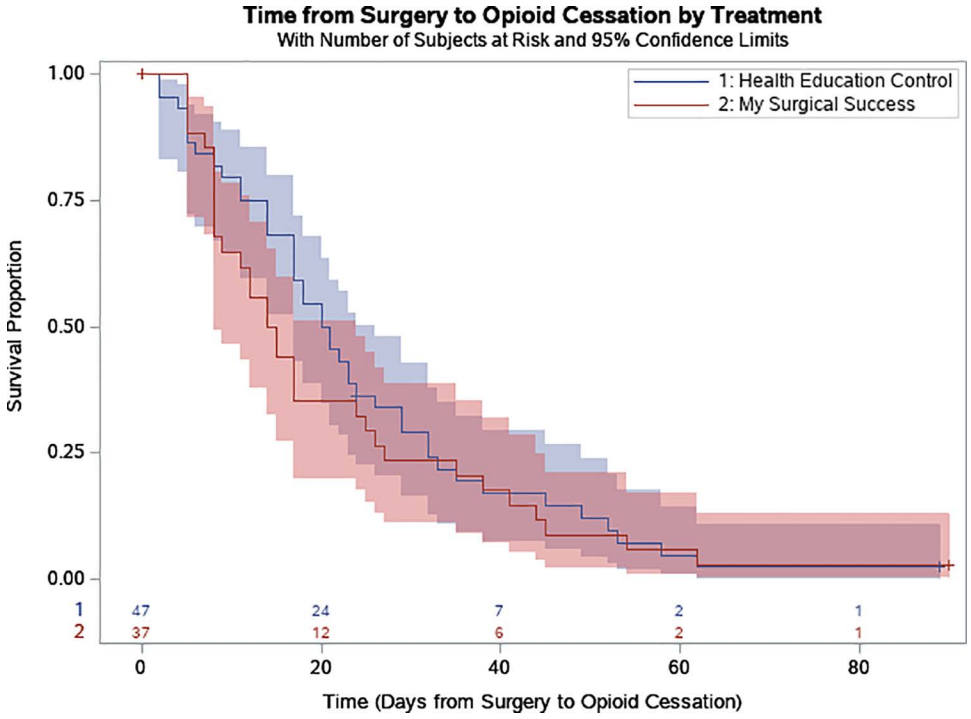

Figure 3. Kaplan-Meier survival curve for opioid cessation under "My Surgical Success" versus health education control.

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,[30] 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.[3,31–33] 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

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.[15] 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),[34,35] 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.[36]

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.[9] 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,[9] 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.[17,37]

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

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Conflicts of Interest: None.
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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.
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Conflicts of Interest: None.
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Conflicts of Interest: None.
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Conflicts of Interest: None.
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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.

Contribution: This author helped with study design and implementation and manuscript preparation and revisions.
Conflicts of Interest: None.
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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.

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