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Authors

Baumgartner, Jennifer N
Quintana, Desiree
Leija, Linda
et al.

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Widespread pressure delivered by a weighted blanket reduces chronic pain: A randomized controlled trial

Running title: An RCT of weighted blankets for chronic pain

Jennifer N. Baumgartner[a], Desiree Quintana[b], Linda Leija[c], Nathaniel M. Schuster[d], Kelly A. Bruno[e], Joel P. Castellanos[f], and Laura K. Case (corresponding author)[g]

[a]UC San Diego Health, Department of Anesthesiology
9500 Gilman Drive MC 0719
La Jolla, CA 92093
858-822-4460
jebaumgartner@health.ucsd.edu

[b]UC San Diego Health, Department of Anesthesiology
9500 Gilman Drive MC 0719
La Jolla, CA 92093
dquintana@health.ucsd.edu

[c]UC San Diego Health, Department of Anesthesiology
9500 Gilman Drive MC 0719
La Jolla, CA 92093
lleija@health.ucsd.edu

[d]UC San Diego Health, Department of Anesthesiology
9400 Campus Point Drive
La Jolla, CA 92037
858-657-7072
nmshuster@health.ucsd.edu

[e]UC San Diego Health, Department of Anesthesiology
9400 Campus Point Drive
La Jolla, CA 92037
kbruno@health.ucsd.edu

[f]UC San Diego Health, Department of Anesthesiology
9400 Campus Point Drive
La Jolla, CA 92037
jcastellanos@health.ucsd.edu

[g]UC San Diego Health, Department of Anesthesiology
9500 Gilman Drive MC 0719
La Jolla, CA 92093
858-246-4968
lcase@health.ucsd.edu

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ABSTRACT

Pleasant sensation is an underexplored avenue for modulation of chronic pain. Deeper pressure is perceived as pleasant and calming, and can improve sleep. Although pressure can reduce acute pain, its effect on chronic pain is poorly characterized. The current remote, double-blind, randomized controlled trial tested the hypothesis that wearing a heavy weighted blanket – providing widespread pressure to the body – relative to a light weighted blanket would reduce ratings of chronic pain, mediated by improvements in anxiety and sleep. Ninety-four adults with chronic pain were randomized to wear a 15-lb. (heavy) or 5-lb. (light) weighted blanket during a brief trial and overnight for one week. Measures of anxiety and chronic pain were collected pre- and post-intervention, and ratings of pain intensity, anxiety, and sleep were collected daily. After controlling for expectations and trait anxiety, the heavy weighted blanket produced significantly greater reductions in broad perceptions of chronic pain than the light weighted blanket (Cohen's $f = .19$, *CI* [-1.97, -.91]). This effect was stronger in individuals with high trait anxiety ($p = .02$). However, weighted blankets did not alter pain intensity ratings. Pain reductions were not mediated by anxiety or sleep. Given that the heavy weighted blanket was associated with greater modulation of affective versus sensory aspects of chronic pain, we propose that the observed reductions are due to interoceptive and social/affective effects of deeper pressure. Overall, we demonstrate that widespread pressure from a weighted blanket can reduce the severity of chronic pain, offering an accessible, home-based tool for chronic.

The study purpose, targeted condition, study design, and primary and secondary outcomes were pre-registered in ClinicalTrials.gov (NCT04447885: "Weighted Blankets and Chronic Pain").

Perspective: This randomized-controlled trial showed that a 15-lb weighted blanket produced significantly greater reductions in broad perceptions of chronic pain relative to a 5-lb weighted blanket, particularly in highly anxious individuals. These findings are relevant to patients and providers seeking home-based, nondrug therapies for chronic pain relief.

Keywords: chronic pain; pressure; anxiety; weighted blanket; pleasant touch; massage

Introduction

Chronic pain is the leading cause of disability worldwide [73]. Efforts at treatment have spawned an ongoing opioid crisis, exposing the need for nondrug treatment options [113]. Chronic pain is amenable to modulation by cognitive interventions such as cognitive behavioral therapy and mindfulness meditation [107, 112, 146, 162]. However, such therapies require resources and training, highlighting a need for more accessible complementary approaches.

Chronic pain has a strong affective component [17 10, 11, 32, 138, 148, 158] and is frequently accompanied by deficits in emotional regulation [141]. One underexplored therapeutic avenue for modulating chronic pain is pleasant sensation, which shares overlapping affective neural circuitry with pain [129]. By attending to pleasant sensations, individuals may break habitual loops of catastrophizing and negative bias towards incoming sensation that contribute to pain chronification [60].

The “Social Touch Hypothesis” [108, 116], more recently referred to as the “Affective Touch Hypothesis” [98], proposes that the C-tactile (CT) afferent pathway is a specific sensory pathway that conveys the positively valenced social/affective components of touch. CT sensory afferents are unmyelinated, low-threshold mechanosensory afferents present predominantly in hairy skin [108, 150, 161] that respond maximally to gentle stroking at slow velocities (i.e., strongest firing for 1-10 cm/s). CT-optimal touch induces positive affect, decreases anxiety [20, 91, 92, 116, 119, 120], and activates affective and interoceptive brain regions [20, 63, 82, 97, 117] critically involved in descending pain modulation [137] and pain relief by complementary therapies [153, 167, 168].

We recently called for the expansion of the Social/Affective Touch Hypothesis to include deep pressure [20] – embedded in hugs, cuddling, and massage – as another bottom-up pathway for social/affective touch. Deep pressure is employed in therapeutic settings to induce calm [23, 64, 143] and may be especially beneficial in anxious individuals [39, 64]. We recently demonstrated in healthy adults that deep pressure from a compression sleeve is perceived as pleasant and calming, and activates the mid-insula [20].

Several studies demonstrate that pleasant social/affective touch can modulate pain. CT-optimal touch reduces experimental pain in healthy adults [45, 67, 89] [111] [94] beyond cognitive effects [89], and can reduce ratings of chronic pain [34]. Pressure delivered through massage improves mood and pain [46, 49-53, 71], with deeper pressure eliciting greater improvements and greater pleasantness [36, 47, 58]. Widespread mechanical compression also reduces experimental pain in healthy adults [72], potentially via sensory gating effects [99, 149, 160]. However, the affective and sensory effects of deep pressure have not been tested in chronic pain.

One potential therapeutic tool to administer deep pressure is a weighted blanket – a blanket sewn with weighted materials that provide widespread pressure to the body. Weighted blankets elicit similar affective effects as deep pressure including feelings of calm [24, 41, 65] and reductions in anxiety [110] [22]. In addition, weighted blankets improve insomnia in healthy adults [2] and psychiatric patients [41]. In addition to sensory gating and modulation of affect [4, 76, 122, 127, 151], weighted blankets could plausibly reduce pain by decreasing anxiety [4, 76, 122, 127, 151] or improving sleep [140, 156]. The present study tested the hypothesis that a heavy versus light weighted blanket would reduce perceptions of chronic pain, mediated by improvements in anxiety and sleep. Further, we explored whether trait anxiety would alter these effects.

Method

The current study was a double-blind, between-subjects randomized controlled trial conducted remotely during the COVID-19 pandemic (June-November 2020). A heterogeneous sample of adults with chronic pain were randomly assigned to wear a heavy or light (placebo control) weighted blanket during a brief and weeklong trial, respectively, with self-report and ecological momentary assessment data collected pre-post blanket wearing.

Participants

The UC San Diego IRB approved procedures in the current study in accordance with the Declaration of the World Medical Association. All participants provided informed consent digitally via Research Electronic Data Capture (REDCap) software. In compensation for their time and effort, participants were offered to keep the weighted blanket and fitness tracker (total value ~$130.00). In addition, participants who completed all study sessions were mailed a $20.00 gift card.

Participants with chronic pain were recruited using ResearchMatch, a secure national registry that connects research volunteers with studies. A message with the headline “Do you have a chronic pain diagnosis and are you interested in trying a weighted blanket?” was sent to a random sample of potential volunteers who listed a chronic pain diagnosis in their profile (the study ad was not visible to anyone who had not previously registered with a diagnosis of chronic pain). The study team contacted interested individuals by email with additional information about the study and a link to complete an online screening survey in REDCap to determine eligibility.

Individuals were eligible if they were at least 18 years of age, fluent in English, diagnosed with chronic pain, willing to sleep with a weighted blanket and a fitness watch for one week, able to safely lift at least 15 lbs (6.8 kg), and willing to use their personal smartphone and data plan to complete study assessments. Individuals were excluded if they were pregnant, had a major medical condition, were current or previous users of a weighted blanket, or were claustrophobic.

Sample Size Determination

Sample size determination was based on previous studies of weighted blankets for anxiety [24] and sleep [2] and was calculated using G*power version 3.1.9.7. Based on the effect size estimated from data for changes in sleep quality of Cohen's $d = 0.75$ [2], two independent groups, $\alpha = 0.05$, and power = 0.80, we determined the current study would require 48 participants in each group. This value was rounded up to $n = 50$ in each group for a total of $N = 100$. However, $N = 135$ was approved by the IRB to account for study dropout. The trial was stopped once we reached our targeted sample size of 100 completed participants. We were approved to analyze data from all completed participants.

Randomization and Blinding

Participants were randomized with replacement, stratified by sex, to two weighted blanket groups of equal size using an Excel-based random number generator programmed by the investigators. Allocation was concealed as the research coordinator accessed this random number generator at the moment of each random assignment, to assign participants to either intervention. Only the research coordinator accessed the LifeData® System (see Ecological Momentary Assessment) and the enrollment logs. Further, all assessments were conducted remotely and digitally; there was no interaction between participants and investigators (other than the research coordinator). Study investigators (aside from the coordinator) were thus considered blinded. However, final data analysis was not conducted in a blinded manner. In order to blind participants to the blanket weight manipulation, all participants were told that they would be receiving a "weighted blanket" in the mail. Participants were informed that various blanket weights would be used in the study, but were not informed about the specific blanket weights used, or whether their blanket was heavier or lighter than others in the study.

Weighted Blankets

Participants were randomly assigned to receive a 15-pound [lb.; 6.8 kilograms (kg)] “heavy” weighted blanket or a 5-lb (2.3 kg) “light” weighted blanket – similar to weights employed by Ekholm et al [41]. The light weighted blanket served as an active control condition to control for widespread body contact and blanket-related positive outcome expectancies. All blankets were commercially available (SensaCalm, Chattanooga, TN), grey, twin-sized (38” x 72”), and made from a cotton/polyester blend. Blankets were weighted with hypoallergenic, non-toxic glass beads evenly distributed across the blanket, thus providing consistent, widely distributed pressure stimulation across the body. Weighted blankets are considered wellness devices and are not regulated by the U.S. Food and Drug Administration.

Ecological Momentary Assessment (EMA)

The present study employed smartphone-based EMA [33, 79, 105] methods to remotely guide participants through the study and capture momentary daily changes in study ratings (see Measures). After enrollment, participants received a study manual that supplied detailed instructions on how to download and complete assessments within the LifeData® System (www.lifedatacorp.com), a HIPAA compliant web-based system designed for human subjects research that is compatible with all smartphones. Daily automated prompts to complete study procedures and ratings were sent each morning to participants’ personal smartphones using the LifeData® System. Participants were instructed to delay their responses if it would be inappropriate to respond when a prompt was received (e.g., when driving).

Measures

EMA items

EMA items assessed **1)** chronic pain intensity (“Please rate your current level of pain”) [125], **2)** state anxiety (“Please rate your current level of anxiety”) [1], **3)** sleep quality (“Please rate your quality of sleep last night”), **4)** blanket-related pain expectations (“Please rate how you expect the weighted blanket will affect your pain, if at all”), **5)** blanket pleasantness (“Please rate pleasantness of the weighted

blanket"), and **6)** blanket use ("Please rate how much of the night you wore the weighted blanket"). Items were displayed on a 100-point visual analog scale (VAS) ranging from 1 = "no pain / extremely anxious / extremely poor / increase pain a lot / extremely unpleasant / not at all" to 100 = "worst pain ever / extremely calm / extremely good / decrease pain a lot / extremely pleasant / all of the night," respectively. For ease of interpretation, pleasantness ratings were rescaled from 1 = "extremely unpleasant", 100 = "extremely pleasant" to -100 = "extremely unpleasant," 0 = "neutral," 100 = "extremely pleasant." VASs appeared on participants' smartphone devices and moved horizontally via tapping from left to right. Numerical values were not visible to participants. A free entry prompt was provided to report medication use ("Please list any regular, daily medications [prescribed or not] you have taken this week for pain [if possible, list dosage as well"]).

Quantitative Sleep Measurement

Participants received a consumer-based, wristwatch fitness tracker (LETSCOM ID115 U HR Fitness Tracker) to wear around the wrist of their nondominant hand during the weeklong trial. The fitness tracker provided an exploratory, quantitative measurement of the amount of time spent in deep and light sleep, as well as heart rate (not reported here due to poor data quality). The device estimates sleep stages using a combination of movement and heart rate patterns. Sleep is determined after detecting inactivity for one hour. During sleep, the device tracks changes in heart rate variability to determine stages of light and deep sleep. After enrollment, participants received a study manual that supplied detailed instructions on how to setup the fitness tracker, download the corresponding smartphone-based application, and upload nightly sleep data to the LifeData® System. A ratio of deep to light sleep was calculated for statistical analyses; values greater than 1 indicated more time spent in deep relative to light sleep.

Psychological Assessments

The Pain, Enjoyment of Life, and General Activity Scale (PEG). The PEG [86] is a three-item questionnaire derived from the Brief Pain Inventory [28] that

measures global chronic pain intensity (“What number best describes your pain on average in the past week”), and pain interference with enjoyment of life (“What number best describes how, during the past week, pain has interfered with your enjoyment of life”) and general activities (“What number best describes how, during the past week, pain has interfered with your general activity”). Items were measured on an 11-point scale ranging from 0 = “no pain / does not interfere” to 10 = “pain as bad as you can imagine / completely interferes,” respectively. Items were averaged into a total score with higher values indicating greater pain intensity and interference (session 1 α = .89, session 3 α = .90).

The State Trait Anxiety Inventory (STAI). The current study employed the STAI [142] Trait version (STAI-T), which is a widely used 20-item scale that measures generalized, long-standing feelings of anxiety [the STAI State version was not measured]. Participants rated items, such as “I feel strained” and “I am relaxed (reversed scored)” on a four-point scale ranging from 1 = “not at all” to 4 = “very much so.” Items were summed into a composite score with higher values indicating greater trait anxiety (α = .94).

Debriefing Questionnaire. At the end of the study, participants completed a debriefing questionnaire to assess the degree to which they had insight into the weighted blanket they received. Participants reported whether they believed their blanket was “much lighter than expected, weighed as expected, or was much heavier than expected” on a 100-point VAS. Participants also reported which weighted blanket they believed they had received.

Additional social and psychological measures were collected that were not included in the present analyses.

Procedure

Session 1 (Pre-intervention)

After providing informed consent, participants were contacted via email with instructions for downloading the LifeData® smartphone application. During session

1, participants completed EMA items on medication use and blanket-related pain expectations. After providing EMA ratings, participants were directed to REDCap to report demographical information (age, sex, race, height, weight, medical and pain diagnoses) and complete the PEG and STAI. Upon completing session 1, participants were randomized by the research coordinator to receive a heavy weighted blanket or a light weighted blanket and a fitness tracker by mail.

Pre-Blanket Wearing Nights

Participants were instructed to sleep while wearing the fitness tracker (no weighted blanket) around the wrist of their nondominant hand for three nights and complete EMA ratings assessing chronic pain intensity, anxiety, and sleep quality each morning. EMA prompts also requested participants to upload their sleep tracker data from the previous night.

Session 2 (Brief Trial)

Session 2 was an initial brief trial of the weighted blanket and was initiated in the LifeData® application when participants indicated they had received their weighted blanket and were ready to complete assessments. During session 2, participants provided EMA ratings of pain intensity, anxiety, and expectations. Participants were then instructed to lie down for 15-minutes while wearing the fitness tracker, without the weighted blanket. Next, participants were instructed to lie down again and wear the fitness tracker and weighted blanket for an additional 15-minutes. Participants then provided EMA ratings of pain intensity, anxiety, and blanket pleasantness.

Blanket-Wearing Nights (Weeklong Trial)

After completing session 2, participants were instructed to sleep while wearing the fitness tracker and weighted blanket for seven nights and complete EMA ratings of pain intensity, anxiety, sleep quality, and blanket use each morning. Daily EMA prompts also requested participants to upload their sleep tracker data from the previous night.

Session 3 (Post-intervention)

Immediately after completing the seventh day of blanket EMA ratings, participants were asked to complete session 3 assessments. For participants who did not complete the session immediately, frequent reminders were sent allowing study completion for up to two weeks. During session 3, participants completed EMA items on medication use. After providing EMA ratings, participants were directed to REDCap to complete the PEG. At the end of the session, participants completed the debriefing questionnaire.

Debriefing

One week after the last participant completed the study, the study coordinator emailed participants to debrief them on their participation. The email stated **1)** the study purpose, **2)** that two weighted blankets, 5 and 15-lbs, were used in the study, **3)** a brief summary of study findings, and **4)** the blanket weight they received.

Statistical Analyses

All analyses were conducted in SPSS Version 26 (IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp). The study purpose, targeted condition, study design, and primary and secondary outcomes were pre-registered in ClinicalTrials.gov (NCT04447885: “Weighted Blankets and Chronic Pain”). The *preregistered* primary outcome was change in chronic pain ratings from before to after wearing a weighted blanket during the brief and weeklong blanket trials, respectively. For the weeklong trial, we compared pre-blanket wearing VAS ratings (average pain VAS rating from the 3 pre-blanket wearing nights) to the final night of weighted blanket use (pain VAS rating from the morning after night 7 of blanket wearing). Pre- and post-blanket wearing pain ratings were compared in a 2 (time: pre, post) × 2 (group: light blanket, heavy blanket) repeated measures (RM) analysis of covariance (ANCOVA), after adjusting for trait anxiety and expectations.

We covaried session 2 expectations because they were measured immediately after participants saw and felt their blankets for the first time, thus providing a better assessment of their perceived effectiveness of the blanket rather than an appraisal of the effectiveness of weighted blankets in general for pain relief. The *preregistered* secondary outcomes included changes in anxiety and sleep from before to after wearing a weighted blanket during the brief (anxiety only) and weeklong blanket trials, and were entered into 2 × 2 RM ANCOVAs, controlling for trait anxiety. For all ANCOVAS, post hoc tests were conducted using the Bonferroni correction to determine the nature of significant time × group interactions. For the brief trial, we compared pre- (15-mins before wearing weighted blanket) to post-intervention (after wearing the weighted blanket for 15-mins) VAS ratings. PEG scores were also compared pre- (session 1) to post-intervention (session 3). Normality assumption for ANOVA was examined using the skewness and kurtosis indices on repeated measures within each group. All key study variables were within normal ranges, justifying the use of parametric tests. A significance criterion of $p < .05$ was employed.

Mediation and moderation hypotheses were not preregistered. Mediation models tested for an indirect effect of weighted blanket group on pain reductions via blanket-related changes in anxiety and sleep, respectively. Models were estimated with an ordinary least squares (OLS) path analytic framework implemented in the SPSS PROCESS Macro Version 3.4 (Model 4) [69, 124]. Significance of indirect effects was predicated on bias-corrected bootstrapped approximations with 5,000 iterations and 95% bias-corrected confidence intervals. Trait anxiety and session 2 expectations were entered as covariates in all mediation models. Lastly, moderation analysis was also implemented in PROCESS (Model 1) to explore the boundary conditions by which blanket pressure influenced pain reductions as a function of trait anxiety, adjusting for expectations. Pain, anxiety, and sleep difference scores (i.e., post - pre), respectively, were computed and entered in mediation and moderation models as appropriate. Assumptions for OLS (normality; linearity; absence of multicollinearity; homoscedasticity) were met before estimating models. A significance criterion of $p < .05$ was employed.

Results

Participant flow through the study

211 individuals were assessed for eligibility, 118 were randomized to the intervention (53 to heavy blanket and 65 to light blanket), 16 were lost to follow-up (2 heavy blanket and 14 light blanket), and 8 were excluded after randomization but prior to analysis based on two criteria: **1)** baseline PEG scores were less than 4 (n = 7), indicating a "mild" level of pain – a criterion employed in previous research [100], and **2)** weighted blanket was reported to be worn less than 30% of each night on average, over the weeklong trial (n = 1), leaving 94 in the final sample (47 in each group; see CONSORT diagram).

Sample characteristics

The total sample consisted of 94 participants [age M = 43.8, SD = 12.8 years, range = 19-69; n = 75 (80%) female; n = 81 (86%) White, n = 8 (9%) Black, n = 4 (4%) Hispanic / Latino, n = 1 (1%) other] from 33 states and territories in the US. Participants' average body mass index (BMI) was 31.6 (SD = 10.3; range = 17.6-75.1). See Table 1 for study demographics and baseline ratings. Overall, participants reported "moderate" levels of pain at baseline across all levels of analysis. After initial use, both the light (M = 26.7, SD = 35.5) and heavy (M = 35.2, SD = 43.4) weighted blankets were rated as mildly to moderately pleasant [t (92) = -1.0, p = .30], at levels similar to our previous research on pleasant gentle stroking and deep pressure [20]. At the end of the study, when asked which blanket participants believed they had received, 68% of participants in the light weighted blanket group accurately guessed they had received a light blanket (15% had "no idea"), and 62% of participants in the heavy weighted blanket group accurately guessed they had received a heavy blanket (25% had "no idea") [χ^2 (2, N = 94) = 42.9, $p < 0.001$)].

Two pain physicians at UC San Diego (NMS and KAB) independently categorized participant-reported diagnoses of chronic pain based on published standards [34, 144, 145], with a third pain physician serving as tie-breaker (JPC). The

majority of the sample consisted of participants with chronic primary pain (n = 57, 61%) and secondary musculoskeletal pain (n = 57, 61%), followed by neuropathic pain (n = 18, 19%). A relatively smaller proportion of participants had secondary visceral pain (n = 7, 7%), cancer-related pain (n = 2, 2%), posttraumatic / post-surgical pain (n = 1, 1%), and secondary headache / orofacial pain (n = 1, 1%). Many participants (N = 38, 40%) had chronic pain diagnoses that met the criteria for more than one diagnostic category.

Basic relationships and covariate selection

Descriptive statistics and bivariate correlations among pain, anxiety, and sleep constructs are summarized in Table 2. Higher trait anxiety was correlated (medium to large effect sizes) with several outcome measures, two of which survived a more conservative Bonferroni corrected p-value for multiple comparisons (employed to reduce the risk of type 1 error), computed as α = .05 divided by k number of comparisons (k = 18; Bonferroni adjusted p-value = .0003) [31]. Therefore, trait anxiety was selected as a covariate in subsequent analyses. In addition, session 2 expectations were controlled for to isolate effects of blanket pressure independent from placebo expectancy effects. Although not displayed in Table 2, age and BMI were not significantly correlated with any outcome measures (ps > .05), and therefore were not entered as covariates.

No significant difference between heavy and light weighted blanket in pain intensity VAS rating reductions (preregistered primary outcome)

Brief weighted blanket trial (session 2): A 2 × 2 RM ANCOVA controlling for trait anxiety and session 2 expectations revealed a non-significant main effect of time (F(1, 90) = .9, p = .36), group (F(1, 90) = 1.4, p = .23), and time × group interaction (F(1, 90) = 1.4, p = .24, Cohen's f = .07) on chronic pain intensity VAS ratings from before to after 15-minutes of blanket wearing (covariates, p's > .05; Table 3, Figure 1A).

Weeklong weighted blanket trial: Chronic pain intensity VAS ratings were compared between blanket groups from before to after the weeklong trial of blanket wearing, controlling for trait anxiety and expectations. As with brief pain ratings, neither the main effect of time ($F(1, 83) = .0$, $p = .85$), group ($F(1, 83) = .8$, $p = .37$), nor the time × group interaction was significant ($F(1, 83) = 2.3$, $p = .14$, $f = .12$; covariates, p's > .05; Table 3, Figure 1B).

In a series of exploratory (not preregistered) one-way ANCOVAs, we compared blanket-related chronic pain intensity reductions (i.e., difference scores) within the three most frequent pain diagnostic categories – primary, musculoskeletal, and neuropathic pain – controlling for trait anxiety and expectations. One-way ANCOVAs were employed due to patient overlap in diagnostic categories. Pain intensity reductions were largest in the heavy weighted blanket group ($M_{diff} = -15.9$, $SD_{diff} = 23.8$) relative to the light weighted blanket group ($M_{diff} = -3.9$, $SD_{diff} = 26.8$) in participants with musculoskeletal pain ($F(1, 51) = 4.8$, $p = .03$, Cohen's $d = .47$; $M_{diff} = -15.9$, $SEM = 7.3$), whereas there were no significant differences between groups for participants with primary or neuropathic pain (p's > .05; Figure 1C; covariates, p's > .05).

Across all pain intensity analyses, patterns of results were unchanged after statistically accounting for opioid medication use and study completion date.

Heavy weighted blanket reduces PEG pain ratings significantly more than the light weighted blanket

To test effects of pressure on broader pain perceptions, we also examined changes in chronic pain intensity and interference as measured by the PEG after the weeklong trial. A RM ANCOVA controlling for trait anxiety and expectations revealed non-significant effects of time ($F(1, 90) = .8$, $p = .38$) and group ($F(1, 90) = .6$, $p = .46$) on PEG ratings. However, there was a significant time × group interaction ($F(1, 90) = 4.5$, $p = .04$, $f = .19$), which was associated with significantly reduced PEG pain ratings in the heavy weighted blanket group ($M_{diff} = -1.4$, $SEM = .2$, $p < .001$, 95% CI [-2.0, -.9]) and, to a lesser degree, in the light weighted blanket

group (M_{diff} = -.7, *SEM* = .2, $p < .01$, 95% *CI* [-1.1, -.3]) [Table 3, Figure 2A; covariates, *p*'s > .05, time × STAI, $F(1,90) = 3.4$, $p = .07$, $f = .16$)].

Exploratory one-way ANCOVAs controlling for trait anxiety and expectations were conducted to compare blanket-related PEG reductions within primary, musculoskeletal, and neuropathic pain categories. PEG reductions were largest in the heavy weighted blanket group (M_{diff} = -1.64, SD_{diff} = 1.62) relative to the light weighted blanket group (M_{diff} = -.9, SD_{diff} = 1.3) in participants with primary pain ($F(1, 57) = 4.3$, $p = .04$, $d = .49$; M_{diff} = -.8, *SEM* = .4), whereas there were no significant differences between groups for participants with musculoskeletal or neuropathic pain (*p*'s > .05; Figure 2B; covariates, *p*'s > .05).

Patterns of results were unchanged after statistically accounting for opioid medication use and study completion time. The mean number of days elapsed between the end of the weeklong trial to session 3 completion was low, $M = 1.7$, $SD = 2.32$, and did not differ between groups $t(92) = 1.5$, $p = .13$. In addition, including these data as a nuisance variable did not alter results. Due to the non-significant effect of blanket pressure on pain intensity VAS ratings, we performed supplementary analyses on the 3-item PEG scale to evaluate the degree to which the overall PEG effect was driven by its two subcomponents, pain intensity or pain interference, respectively. PEG interference items (2-3) were averaged into a single score for session 1 and session 3, respectively, and entered into a RM ANCOVA, excluding the pain intensity item (item 1), controlling for trait anxiety and expectations. The main effect of time ($F(1, 89) = .3$, $p = .57$), group ($F(1, 89) = .4$, $p = .53$), and interaction ($F(1, 89) = 2.5$, $p = .14$) were non-significant (covariates, $p > .05$), suggesting that pain intensity played a role in the overall PEG effect. We also conducted this analysis in the subgroup of patients with chronic primary pain. Here, we found that the overall PEG effect was largely maintained for the average PEG interference items ($F(1, 57) = 3.9$, $p = .05$, $d = .49$).

Deep pressure elicits greater pain relief in participants with high trait anxiety

The overall model assessing the moderating effect of trait anxiety in the association between blanket group and PEG reductions, controlling for expectations, was significant ($F(4, 89) = 3.3$, $p = .01$, $R^2 = .13$). Importantly, the interaction between blanket group and trait anxiety on PEG reductions was also significant (b = -.1, $SEM = .0$, $p = .02$, 95% CI [-.12, -.01]), providing evidence for a conditional effect. As depicted in Figure 3, the heavy weighted blanket produced greater PEG reductions in participants who reported “medium” ($M = 50.7$, b = -.7, SEM = .3, p = .03, 95% CI [-1.3, -.1]) or “high” (+1SD = 62.1, b = -1.4, $SEM = .4$, $p < .01$, 95% CI [-2.3, -.5]) levels of trait anxiety [“low” (-1SD) trait anxiety, $p = .85$)]. In contrast, chronic pain reductions were relatively unaffected by the light weighted blanket across all levels of trait anxiety. The Johnson-Neyman technique [70] revealed that the value of trait anxiety where the conditional effect became statistically significant was 49.9 (b = -.61, $SEM = .31$, $p = .05$). In the current sample, 56% of participants had trait anxiety sums above this value.

These results were unchanged after accounting for other potential contributing factors, including opioid medication use, study completion date, session 3 completion, and baseline PEG levels.

Weighted blankets do not significantly improve anxiety or sleep (preregistered secondary outcomes)

Anxiety

A 2 × 2 RM ANCOVA controlling for trait anxiety revealed a non-significant effect of time ($F(1, 91) = .5$, $p = .50$) on anxiety VAS ratings from before to after 15-minutes of blanket wearing. There was a significant main effect of group ($F(1, 91)$ = 4.44, $p = .04$, $f = .19$), with anxiety VAS ratings being significantly lower in the heavy weighted blanket group on average than the light weighted blanket group (M_{diff} = -6.3, $SEM = 2.98$, $p = .04$, 95% CI [-12.2, -.4]). However, the time × group interaction was non-significant ($F(1, 91) = .2$, $p = .68$; covariate, $p > .05$; Table 3, Figure 4A). Likewise, there was no significant effect of time ($F(1, 84) = .5$, $p = .49$), group ($F(1, 84) = .1$, $p = .78$), or time × group interaction ($F(1, 84) = .84$, $p = .36$) on anxiety ratings after the weeklong trial (covariate, $p > .05$; Table 3, Figure 4B).

One outlier was detected in this analysis using a *z* score +/- 3 criterion (not preregistered); removal of this outlier did not significantly alter results.

Sleep

Sleep quality VAS ratings after the weeklong trial did not differ as a function of time ($F(1, 84) = .0$, $p = .97$). There was a significant effect of group ($F(1, 84) = 4.1$, $p = .046$, $f = .19$), with sleep quality ratings being significantly lower on average in the heavy weighted blanket group when compared to the light weighted blanket group ($M_{diff} = -6.4$, $SEM = 3.2$, $p = .046$, 95% *CI* [-12.70, -.11]). However, the interaction of time with group was non-significant ($F(1, 84) = .03$, $p = .86$; Table 3, Figure 5A; covariate, $p > .05$). The main effect of time in the ratio of deep to light sleep after accounting for trait anxiety was non-significant ($F(1, 63) = 2.9$, $p = .09$, $f = .17$). The main effect of group was significant ($F(1, 63) = 7.4$, $p = .01$, $f = .31$), such that participants wearing the light weighted blanket spent more time in deep relative to light sleep on average than the heavy weighted blanket group ($M_{diff} = .25$, $SEM = .1$, $p = .01$, 95% *CI* [-.43, -.07]). However, the time × group interaction was non-significant *(*$F(1, 63) = .6$, $p = .45$; Table 3, Figure 5B; covariate, $p > .05$). Two outliers were detected in this analysis using a *z* score +/- 3 criterion; removal of these outliers did not significantly alter results.

Anxiety and sleep did not significantly mediate blanket-induced pain reductions

Mediation analyses tested the hypothesized indirect effects of weighted blanket-related changes in pain via changes in anxiety and sleep, respectively, after controlling for trait anxiety and expectations. However, none of the indirect effects were significant (*p*'s > .05). Opioid medication use, study completion date, session 3 completion (when PEG was entered as the outcome variable), and removal of the aforementioned outliers did not alter these results. Table 4 displays a summary of all paths in each model.

Discussion

The current study demonstrated a greater effect of a heavy versus light weighted blanket in reducing chronic pain intensity and interference ratings as measured by our secondary pain outcome (PEG [86]). The effect of weighted blanket pressure on PEG ratings was significant after controlling for trait anxiety and for expectations of pain relief. In contrast, there was no overall effect of weighted blankets on purely sensory aspects of chronic pain as measured by our primary pain outcome (VAS pain intensity ratings), or any differential effect of greater pressure. This is consistent with studies showing that complementary approaches tend to alleviate the burden of chronic pain without reducing pain intensity [8, 162]. These results suggest that deeper pressure from a heavy weighted blanket can reduce social/affective components of the chronic pain experience, above and beyond cognitive and placebo effects.

In contrast to our hypotheses, weighted blankets did not significantly alter anxiety or sleep, and changes in these variables were not significant mediators of blanket-related pain reductions. However, it is possible that differences would emerge under different or longer duration conditions. The non-significant effect of weighted blankets on anxiety and sleep is surprising because previous studies have shown that weighted blankets reduce anxiety [22, 24, 41, 65, 110, 155] and insomnia [2, 41], and suggests other mechanisms for the pain-relieving effect. The classic neurophysiological explanation for touch-induced analgesia is gate control theory, which posits that activation of large myelinated fibers by cutaneous stimulation inhibits ascending nociception at the level of the spinal cord [43, 77, 99, 160]. Recently, A-beta stimulation was found to inhibit laser pain in the same dermatome at the level of the spinal cord, providing evidence for this theory [149]. We recently demonstrated that deep pressure sensation is conveyed by A-beta afferents [19], suggesting that deep pressure might reduce pain through this mechanism. Peripheral effects of deep pressure, including increases in blood flow [104] and local tissue oxygenation [6, 101] could also contribute to the antinociceptive effects of weighted blankets.

In the current study, however, deeper pressure reduced broader, more social/affective perceptions of chronic pain (i.e., PEG ratings). The overall effect size we

observed is similar to that seen with other commonly used non-drug interventions for chronic pain such as spinal manipulation and exercise [80]. This is intriguing because our study was conducted during a period of elevated social isolation and psychological distress (COVID-19 pandemic) [9, 83]. Various mammalian species engage in deep body-to-body pressure for thermal regulation [62] and take comfort in firm pressure in the absence of others [68]. In humans, moderate pressure massage provided by mothers to their preterm infants is effective at alleviating depression and anxiety in both members of the dyad [44, 48]. We speculate that deeper pressure sensations may be wired, in part, to communicate close bodily contact with conspecifics, imparting a sense of physical and psychological safety that could inhibit pain-related fear responses. Fear of pain is thought to develop when pain sensations are appraised as threatening, triggering hypervigilance and avoidance behaviors [157], and ultimately, increasing chronic pain intensity and disability [95]. Similarly, individuals exhibiting hyperarousal from posttraumatic stress disorder demonstrate hyperalgesia and increased temporal summation of pain [103]. The pleasant and calming effects of deep pressure may thus reduce hyperarousal [5, 20, 90, 159], reducing affective aspects of chronic pain.

In line with a fear of pain account, we found that deeper pressure was more effective for individuals high in trait anxiety. Previous research has revealed benefits of deep body compression [85] and interoceptive exposure [55] in highly anxious individuals, potentially related to greater negative appraisals of pain and bodily sensations in such individuals [93]. “Interoceptive exposures” that expose patients to bodily sensations in order to decondition the associated fear reduce anxiety sensitivity [16] and pain-related distress [56], as well as increase pain acceptance [56]. Learned safety – whereby a conditioned stimulus is unpaired from an aversive unconditioned stimulus, becoming a predictor of safety – reduces conditioned fear responses [38, 84, 128, 133] and facilitates anxiolytic, exploratory behaviors [128]. Similarly, positive emotions are associated with approach-orientated behaviors, resilient stress responses [12, 61, 134], and analgesia [54, 118, 152, 154]. It is possible that deep pressure sensation may constitute an interoceptive exposure that deconditions fear of pain and promotes approach behaviors that reduce the burden of chronic pain over time.

The role of the insula in affective processes offers insight into the neural mechanisms that might underpin the hypothesized safety signaling of deep pressure. We recently showed that deep pressure activates the mid-insula, slight anterior to representations of CT touch [20]. In rodents, the insula underlies the buffering effects of safety on stress and anxiety behaviors [26, 27]. The insula is strongly interconnected with the amygdala [96, 102, 109], a limbic hub critically involved in fear and threat processing, as well as heightened pain perception [7, 74, 121, 126, 163]. The insula [102, 109] and amygdala [96] are also well connected with the striatum (putamen; caudate), a neural substrate involved in positive mood [15, 66, 88, 114, 136, 139] and the top-down regulation of pain [154, 164]. In humans, safety conditioning reduces activity in the amygdala and increases activity in the left caudate and prefrontal cortex [123], indicative of executive-level control of fear and stress responses. Thus, activation of the insula by deep pressure is well situated to modulate limbic activity to downregulate threat, generating calm and safety. However, future psychological and neuroimaging research is required to test the effects of deep pressure on the proposed associations with fear of pain, anxiety sensitivity, and interoception.

The insula is also widely accepted to support interoception [29, 30, 81], raising the possibility that amplification of interoceptive input in the insula may be a mechanism by which deep pressure alleviates, or deconditions, chronic pain. Massage therapy, which incorporates pressure, has been described as facilitating body awareness [90]. Further, osteopathic manipulation [40] and gentle touch therapies improve interoceptive accuracy [21]. Individuals with chronic pain exhibit a reduced capacity to accurately detect their internal bodily sensations [14, 34, 35, 37, 57 132], and interoceptive awareness is inversely associated with chronic pain [34, 37, 135]. Interoceptive interventions have successfully reduced symptom severity in patients with somatoform disorders [131], a population similarly susceptive to interoceptive deficits [35]. Whether such an interoceptive mechanism would require conscious attention to interoceptive sensations – or the conscious noticing and savoring of pleasant sensations in particular [60] – remains an open question.

Finally, the affective – and putatively social – effects of deep pressure may also operate in an ascending manner through the broad central release of oxytocin, a neuropeptide with pro-social, anxiolytic, and analgesic effects [115]. Oxytocin

reduces chronic pain perception [165] and is released from tactile stimulation in rats [3], and from moderate pressure massage in humans [106]. The behavioral effects of oxytocin are thought to stem from centrally projecting neurons in the paraventricular nuclei (PVN) and supraoptic nuclei of the hypothalamus [13]. In rats, gentle stroking stimulates hypothalamic oxytocin neurons [115], and light pressure and touch induce oxytocin release that acts directly in the amygdala and hypothalamus, with indirect effects on the hypothalamic-pituitary-adrenal axis [147], mediating fear and stress responses [130]. A spinohypothalamic projection pathway was recently identified in rodents and primates that may play a role in autonomic and emotional responses to nociceptive stimuli [78, 169]. Given that projections for affective touch have been identified in the spinoparabrachial pathway [25], it is plausible that similar spinohypothalamic projections might convey affective components of deep pressure sensation to the hypothalamus, stimulating release of oxytocin. From the PVN, oxytocinergic neurons project to the rostral agranular (anterior) insula. Indeed, oxytocin enhances social approach behaviors in rodents by suppressing activity in the anterior insula [166], a region extensively interconnected with affective brain regions and brainstem areas involved in descending pain inhibitory control [75 59]. However, the hypothesized role of oxytocin in supporting the social/affective effects of deeper pressure requires further investigation.

Our exploratory analyses revealed that PEG reductions produced by the heavy weighted blanket relative to the light weighted blanket were largest in patients with chronic primary pain, which included fibromyalgia, back pain, and migraine. In contrast, pain intensity reductions were largest in the heavy weighted blanket group in patients with musculoskeletal pain, including arthritis, Ehlers Danlos Syndrome, and degenerative disc disease. This is surprising given that pressure pain thresholds are significantly lower in musculoskeletal patients [18, 87], which may be attributed to greater sleep disturbance in this population [87]. It would be interesting to determine whether this effect would increase or decrease with an even heavier weighted blanket. Although these differences comprise promising avenues for future research, they should be regarded as highly tentative because numerous participants had chronic pain diagnoses that were classified into multiple categories.

Study limitations

Findings from the current study should be interpreted in light of several limitations. First, the control condition in the current study was a 5-lb (2.3 kg) blanket, which distributed some pressure to the body. It is possible that our inability to detect a significant overall effect of weighted blankets on several of our outcome measurements could be because of active effects of this light blanket. Second, debriefing revealed incomplete masking of participants due to the physical nature of the weighted blanket. Future research employing a no-treatment or waitlist control group is needed to confirm the relative effects of deeper and light pressure on pain, anxiety, and sleep in various chronic pain conditions. Third, assessment of sleep quality by a single-item VAS has not been validated, which may have limited our ability to detect an effect of the weighted blanket on sleep. Fourth, due to the brief nature of the PEG, it is difficult to fully understand the relative contributions of blanket pressure on pain intensity and interference, which both appear to contribute to the overall PEG effect. PEG results are additionally limited because we did not measure whether participants continued to wear their blankets until the completion of session 3 assessments. However, the mean number of days from the end of the weeklong trial to session 3 completion was very low ($M < 2$) and did not significantly influence the results. Fifth, we employed two exclusion criteria based on reported levels of chronic pain at baseline and blanket adherence. Yet, intention-to-treat analyses are generally recommended in randomized controlled trials [42] and should be employed in future research. Finally, participants' chronic pain diagnoses were based on self-report, and were not confirmed by medical providers. However, participants had registered their diagnosis before being contacted about the study, and we excluded participants with PEG scores below a clinical cutoff value.

In sum, we demonstrate that a deeper pressure weighted blanket reduces aspects of chronic pain and pain interference, relative to a light pressure weighted blanket. We also provide evidence for an individual difference factor – trait anxiety – in elucidating who might benefit the most from deeper pressure. These findings are promising given the low-cost and accessibility of this intervention, as well as its excellent safety profile [22, 110]. Further research is required to determine whether effects of the weighted blanket extend beyond the period of use. In addition,

research is required to determine whether conscious attention or positive reappraisal of bodily sensations are operational mechanisms supporting the benefits of deep pressure, and for which chronic pain conditions the blanket may be most effective. Overall, we show that deeper pressure sensations can be leveraged to reduce the burden of chronic pain, offering a low-cost and easy-to-use tool for individuals with chronic pain, especially those high in trait anxiety.

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Figure legends

Figure 1. Changes in ratings of chronic pain intensity before and after use of a light or heavy weighted blanket. (A) Mean visual analog scale (VAS) ratings of chronic pain intensity provided during the brief trial (grey bars = pre-blanket wearing, green bars = post-blanket wearing) of the heavy weighted blanket or light weighted blanket are displayed. However, the time × group interaction was non-significant. (B) Mean VAS ratings of chronic pain intensity provided during the weeklong trial (grey bars = pre-blanket wearing, green bars = post-blanket wearing) of the heavy or light weighted blanket are displayed. However, the time × group interaction was non-significant. (C) Mean changes in VAS pain intensity ratings from baseline to night 7 of weighted blanket use within diagnostic categories of primary pain, musculoskeletal pain, and neuropathic pain are displayed. Pain intensity reductions were greatest in the heavy weighted blanket group relative to the light weighted blanket group in participants with musculoskeletal pain, whereas there were no significant differences between groups for participants with primary or neuropathic diagnoses. All pain intensity ratings were collected on a 0 (no pain) to 100 (worst pain ever) VAS scale. All values displayed are adjusted for session 2 expectations and trait anxiety. Asterisks indicate significance differences at the *$p < .05$ level.

Figure 2. Changes in chronic pain PEG scores before and after use of a light or heavy weighted blanket. (A) Mean Pain, Enjoyment of Life, and General Activity Scale (PEG) [86] scores collected during baseline and after one week of use for the heavy weighted blanket and light weighted blanket are displayed. Both blanket groups significantly reduced PEG scores from baseline (session 1; grey bars) to one week (session 3; green bars). However, PEG reductions were significantly greater in the heavy weighted blanket group than in the light weighted blanket group. (B) Mean changes in PEG scores from baseline to after one week of use within diagnostic categories of primary pain, musculoskeletal pain, and neuropathic pain are displayed. PEG reductions were greatest in the heavy weighted blanket group relative to the light weighted blanket group in participants with primary pain, whereas there were no significant differences between groups for participants with

musculoskeletal or neuropathic pain. The PEG measured pain intensity and interference on a 0 (no pain / does not interfere) to 10 (pain as bad as you can imagine / completely interferes) scale. PEG scores are displayed after adjusting for session 2 expectations and trait anxiety. Asterisks indicate significance differences at the *$p < .05$, **$p < .01$, and ****$p < .0001$ levels.

Figure 3. Moderating effect of trait anxiety in the association between blanket weight and chronic pain PEG reductions. There was a significant interaction between weighed blanket group and trait anxiety in predicting Pain, Enjoyment of Life, and General Activity Scale (PEG) [86] reductions. Post hoc probing of this interaction revealed that PEG reductions were significantly greater in the heavy weighted blanket group (dark green line) for chronic pain patients who reported “medium” (mean) and “high” (+1 standard deviation) values of trait anxiety. PEG reductions were unchanged in the light weighted blanket group (light green line). The dotted grey line represents the exact value of trait anxiety where the conditional effect became significant (49.87). The PEG measured pain intensity and interference on a 0 (no pain / does not interfere) to 10 (pain as bad as you can imagine / completely interferes) scale. PEG reductions are displayed after adjusting for session 2 expectations. Asterisks indicate significance differences at the *$p < .05$ and **$p < .01$ levels.

Figure 4. **Changes in ratings of state anxiety before and after use of a light or heavy weighted blanket.** (A) Mean visual analog scale (VAS) ratings of state anxiety collected during the brief trial (grey bars = pre-blanket wearing, green bars = post-blanket wearing) are displayed for the heavy weighted blanket and light weighted blanket groups. However, the time × group interaction was non-significant. (B) Mean VAS ratings of state anxiety collected during the weeklong trial in the heavy weighted blanket and light weighted blanket groups are displayed. There were no significant differences in anxiety ratings from the 3-night baseline period (grey bars) to night 7 of weighted blanket use (green bars). Anxiety values are after adjusting for trait anxiety. State anxiety ratings were collected on a 0 (extremely calm) to 100 (extremely anxious) VAS scale.

Figure 5. Sleep quality ratings and deep to light sleep ratio values before and after use of a light or heavy weighted blanket. (A) Mean visual analog scale (VAS) ratings of sleep quality collected during the weeklong trial for the heavy weighted blanket and light weighted blanket groups are displayed. There were no significant changes in sleep quality ratings from the 3-night baseline period (grey bars) to night 7 of weighted blanket use (green bars). Sleep quality ratings were collected on a 0 (extremely poor) to 100 (extremely good) VAS scale. (B) Deep to light sleep ratio values during the weeklong trial are displayed. Ratio values were calculated as the ratio between the average amount of time spent in deep versus light sleep, as measured by a fitness tracker, with values greater than 1 indicating more time spent in deep relative to light sleep. There were no significant differences in deep to light sleep ratio values from the 3-night baseline period (grey bars) to night 7 of weighted blanket use (green bars). Sleep values are after adjusting for trait anxiety.

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