HYPNOSIS FOR CHRONIC PAIN RELIEF IN CANCER SURVIVORS

STUDY PROTOCOL

Last Approved by Human Protections Review Committee: January 28, 2019, v. 3.0

RESEARCH PROTOCOL

Methods and Design

Design. The study design is a two-arm RCT. The study uses an expanded protocol from the pilot RCT. The primary outcome (pain intensity) and secondary outcomes (pain interference, anxiety, depression, fatigue, and sleep disturbance) will be assessed at baseline, mid-study, and end of study. In addition, pain intensity and anxiety will be assessed daily. Participants will be randomly assigned to the RHI or an attention control condition (relaxation recording). Furthermore, an extreme phenotype approach will be taken to study brain states as a mechanism for hypnosis-induced pain reduction. Five participants from each group who score low (score = 0 - 1)[50] on the hypnotic suggestibility scale and 5 participants from each group who score high (score = 4 - 5)[50] will be invited to undergo qEEG measurement.

Sample and Settings. A convenience sample of 100 cancer survivors with chronic pain will be recruited from the SCCA Survivorship Clinic. SCCA is a National Cancer Institute-designated comprehensive cancer center where more than 6,000 patients with cancer received treatment last year. In 2016, 194 patients were seen at the Survivorship Clinic (based on chronic pain prevalence estimate of 39%, 76 patients with pain).

Power Analysis. **Table 1** shows the minimal detectable change in the mean of the RHI group that can be detected given a total sample of 100 participants and 80% power, based on standard deviations observed in our prior research.

Table 1. Minimal Detectable Change in RHI Group

For N=100 (50/group), 80% power, alpha = 0.05, two-sided

Pain Score Standard Deviation		
Small SD (1.0)	**Expected SD (1.5)**	**Large SD (2.0)**
-0.57	-0.85	-1.13

Participant Inclusion and Exclusion Criteria. Participant inclusion criteria are: (1) self-reporting moderate or higher pain on average during the last week (> 3 on a 0-10 pain intensity numeric scale), (2) self-reporting chronic pain related to cancer or its treatment, (3) completed active cancer treatment other than maintenance therapy, (4) being ≥ 18 years of age, (5) functional fluency in English, and (6) mentally and physically able to participate and complete surveys. Participant exclusion criteria are: (1) a history of seizure disorder and (2) a significant brain injury or skull defect. Both exclusion criterion may impact qEEG measurement. We will not exclude potential participants based on use of pain medication, rather we will collect this information (drug, dose) and control for it in the data analysis.

Participant Recruitment. Staff at the SCCA Survivorship Clinic will screen Survivor Surveys completed by patients prior to their initial clinic visit from the past 2 years and during the study to identify patients who meet the pain intensity inclusion criteria. Names and contact information for patients will be given to the research team who will mail an information letter describing the study. The letter will include an opt-out postcard to be returned if the patient is not interested in being contacted by telephone about the study. Two weeks after the letters are mailed, patients will be contacted by telephone to further screen for eligibility and describe the study. If the patient is eligible and interested in participating, verbal and written consent to participate will be obtained. A study visit will be scheduled at the UW Health Sciences Center (HSC) for completion of the Stanford Hypnotic Clinical Scale and assignment of the intervention. The consent form and baseline questionnaires will be mailed to the participant to sign and complete respectively and return at the Week 0 (baseline) study visit.

Group Assignment. A SPSS randomization program will yield group assignments which will be placed in opaque, sequentially numbered sealed envelopes. Once the participant returns the completed baseline questionnaires and completes the in-person hypnotic clinical measure at the Week 0 study visit, the appropriate envelope will be opened and the participant will be notified of his/her group assignment. Based on their high or low hypnotic suggestibility score, eligible participants will be invited to participate in the qEEG study arm.

Intervention/Independent Variables. *Hypnosis Intervention*. The RHI consists of four 12- 18-minute digital recordings that I will make using standardized hypnosis scripts for pain reduction[25] and upload to a MP3 player. The scripts were developed for patients with chronic pain and tested by a psychologist who is an expert in hypnosis research (Jensen, co-mentor). Participants will listen to the recordings daily for 28 days in the prescribed order (4 recordings for 3 days each, and then any recording for the remaining 16 days). Selected recordings will be noted by the participant on the Daily Diary. The script includes an induction, suggestions for how to access inner resources and manage pain, and post-hypnotic suggestions for permanence of hypnosis benefits and self-hypnosis practice. *Attention Control.* The relaxation recordings will be uploaded to a MP3

player. Four different 12- 18-minute recordings of the selected genre will be listened to daily for 28 days (same prescribed order as the RHI).

Table 2a. Instruments.

Aim	Study Measures	Variable Measured	Week 0	Daily	Week 2	Week 4
1	***PROMIS 29 v. 1.0** *29-item questionnaire, Cronbach's α 0.92-0.97.*[52]	Pain interference, anxiety, depression, fatigue, sleep	X		X	X
1	***PROMIS v.1.0-Pain Intensity 3a** *3-item questionnaire, Cronbach's α 0.92-0.97.*[52]	Pain intensity	X		X	X
2	***PROMIS Self-Efficacy for Managaging Symptoms**	Self-Efficacy	X			X
3	**qEEG**	Brain activity/state	X		X	X

* National Institute of Nursing Research (NINR) Common Data Elements

Table 2b. Instruments. *(See appendix for the following instruments*)**:**

Aim	Study Measures	Variable Measured	Week 0	Daily	Week 2	Week 4
1	**Daily Diary** *9-item questionnaire completed at bedtime, feasibility of participants completing it on a daily basis was established in pilot study.*	Pain intensity, anxiety, and use of RHI or relaxation recording (including which recording used)		X		
2	**Fear of Progression Questionnaire** *12-item questionnaire,*[53] *Test-retest reliability 0.94; Cronbach's α .87.*[54,55]	Fear of cancer recurrence	X			X
2	**Connor-Davidson Resilience Scale 10** (CD-RISC-10)	Resilience	X			
2	**Stanford Hypnotic Clinical Scale for Adults** *5-item scale, 20 minutes to administer, product-moment correlation between total score and Stanford Hypnotic Scale C total score 0.72.*[56]	Hypnotic suggestibility	X			
2	**Tellegen Absorption Scale** *34-item multi-dimensional scale,*[57] *test-retest reliability 0.85.*[58]	Absorption (Imaginative involvement, tendency to become mentally absorbed)	X			
2	**Credibility/Expectancy Questionnaire** *4-item questionnaire, test–retest 0.62-0.78, Cronbach's α 0.84-0.85.*[59]	Treatment outcome expectancy	X			
1	**Demographic Questionnaire** *15-item questionnaire.*	Socio-demographics; cancer & treatment, and pain history; co-morbidities; pain interventions	X			
3	**Structured Interviews** *Each interview is anticipated to last 20 minutes and will be audio-recorded*.	Barriers and facilitators associated with undergoing qEEG measurement; how intervention works				X

Data Collection Schedule and Procedures. *Study Enrollment.* The research assistant (RA) will contact potential study participants by telephone to screen, obtain verbal consent, and schedule the Week 0 study visit at the UW HSC. Baseline questionnaires and consent form will be mailed to the participant with instructions to complete 1-2 days before the Week 0 study visit.

Week 0 Study Visit. The RA will meet with the participant to (1) collect completed questionnaires and signed consent form; (2) administer the Stanford Hypnotic Clinical Scale; (3) share group assignment; (4) provide teaching about the RHI or relaxation recording, and participant study responsibilities; (5) administer the Credibility/Expectancy Questionnaire; and (6) inform participant if they are eligible for the qEEG measurement. Participants who are ineligible for the qEEG measurement (or eligible but not interested in participating) will begin using the assigned intervention at home on the same day as the Week 0 visit. The RA will schedule telephone calls with ALL participants to complete study measures at Week 2 (within 5 days of using the assigned intervention for 14 days), and Week 4 (within 5 days of using the assigned intervention for 28 days). Structured interviews with the RA also will be conducted by telephone. Participants will be reminded to return

the Daily Diary in the provided pre-posted return envelope. Participants in the qEEG study arm will undergo the first qEEG at the Week 0 visit and begin using the assigned intervention at this time. All qEEG measurements will take place at the UW Integrative Brain Imaging Center (IBIC). Week 2 and Week 4 qEEGs will be scheduled at the Week 0 visit and will take place within one day of completing study measures.

qEEG Protocol: The participant will complete a 0-10 pain intensity numeric scale pre- and post-qEEG. During the qEEG, the intervention group participant will listen to the RHI and the attention control group participant will listen to the relaxation recording via the MP3 player (Table 3). The EEG technologist will fit an electrode cap with premeasured sites using the international 10/20 system[60] to the participant's head and the participant's scalp and will prep the earlobes with Nuprep (Weaver and Company, Aurora, CO, USA). The electrode sites will be filled with Electro-Gel (Electro-Cap International, Eaton, OH, USA) and prepped to ensure impedance values between 3 and 5 Kohms between each electrode site and each ear individually. The signals will be amplified using a bandpass of 0.53-70 Hz and sampled at the rate of 250 Hz. for 10 minutes (eyes closed) with an EGI Geodesic EEG System 300 using 128-channel HydroCel Nets. Participants will be monitored throughout the recording to ensure that they remain awake.

Per the UW IBC, raw recordings will be band-pass filtered between 0.5-100 Hz, and exported to Matlab (MathWorks, Natick, MA, USA) and then remontaged to the average reference montage. Plotted data will be inspected for potential artifacts (e.g., evidence of eye blinks, eye movements, body movements) and entire epochs will be removed if one or more channels exhibit presence of artifact. qEEG spectrum will be calculated from the first 2 minutes of artifact-free data with fast Fourier transform using 4-second epochs with 1/32 seconds of overlapping window advancement factor. The relative EEG power will be computed for each of five bandwidths (delta, 1.5-4 Hz; theta, 4-8 Hz; alpha, 8-13 Hz; beta, 13-30 Hz; gamma, 30-55 Hz), and *the power estimates will be used for all subsequent analyses by our research team*. Relative power measures show a closer correspondence to underlying cortical activity than does absolute power.[61]

Table 3. qEEG Measurement Timeline

	Pre-Session	During Session	Post-Session
Week 0	10 minutes eyes closed	13 minutes RHI or relaxation	10 minutes eyes closed
Week 2	10 minutes eyes closed	13 minutes RHI or relaxation	10 minutes eyes closed
Week 4	10 minutes eyes closed	13 minutes RHI or relaxation	10 minutes eyes closed

All participants will receive $50 for their participation, which will be distributed as follows: after return of the baseline questionnaires ($25) and diary ($25). Participants also will be given $25 to pay for parking and gas, or for public transportation for the visit to the UW HSC. The 20 participants undergoing qEEG will receive an additional $50 after completing each qEEG for a total of $150. They also will be given $25 to pay for parking and gas, or for public transportation to the UW IBIC for two visits ($50). Data will be managed using REDCap (Research Electronic Data Capture).[62] The RA will be responsible for data entry and I will verify its accuracy.

Data Analysis. *Aim 1*: **Does the RHI work?** *Evaluate the efficacy of RHI in reducing self-reported pain intensity (primary outcome) and pain interference, anxiety , depression, fatigue, and sleep disturbance (secondary outcomes) at 4 weeks compared to the attention control condition (relaxation recording).* We will use ANCOVA controlling for baseline scores and co-variates including pharmacologic treatments to test whether *mean pain intensity* at week 4 differs between the RHI and relaxation groups. The same analysis will be done for the secondary outcomes. In addition, we will graphically describe trajectories of daily pain and anxiety at Weeks 0, 2, and 4, based on the Daily Diary for pain intensity and anxiety in the RHI and relaxation groups. This approach will allow us to understand whether an increased dose of the intervention (i.e., 4 weeks vs. 2) is necessary to achieved significant reduction in pain intensity.

Aim 2: **For whom does the RHI work?** *Examine if psychological factors (hypnotic suggestibility, mental absorption, treatment outcome expectancy, and fear of cancer recurrence) moderate the relationship between RHI and pain intensity at weeks 0, 2, and 4.* The following multiple regression model will be estimated: $PAIN_{week2} = Pain_{week0} + PSY_{week0} + RHI + PSY_{week0}xRHI$, where moderator effects will be indicated by the interaction term $PSY_{week0}xRHI$. We will measure Cohen's d for each of the levels of the moderator and compare them to determine the moderator effect. The resulting effect size will be used to estimate the sample size in a larger follow-up study (e.g., R01).

Aim 3: **How does the RHI work?** *Compare brain states as measured by qEEG in cancer survivors with chronic pain receiving the RHI relative to the attention control condition (relaxation recording) at weeks 0, 2, and 4.* We will use multiple regression models controlling for baseline scores and co-variates (e.g., medication use) to compare the change in theta activity from *pre-session* to *during session* between RHI and relaxation

groups. We will also compare the change in theta activity from *pre-session* to *post-session* between groups. This will be replicated for all 3 time points: Weeks 0, 2, and 4. Replication allows us to assess if theta activity changes during the study period. We will also explore other bandwidths (e.g., alpha, beta, delta, gamma) in our analysis. Medium or larger effect sizes for changes in bandwidth activity will be used to indicate that more formal testing in future research is warranted. *Explore the mediation effects of brain states (theta activity) on pain intensity at weeks 0, 2, and 4*. Cross-sectional analyses will examine mediation at weeks 0, 2, and 4 for how RHI and theta activity jointly affect pain intensity. The mediating effects model implicit in **Figure 1** will be tested using multiple regression models. Effect sizes (Cohen's d) will be computed for looking at the biological mechanism in a larger, more definitive study. *Structured interviews.* Transcribed interview data will be organized in ATLAS.ti7 (Scientific Software Development, Berlin, Germany). Content analysis[63,64] will be used to understand the barriers and facilitators associated with undergoing qEEG measurement and perceptions on how the intervention works to reduce pain.

In summary, this study is extremely important because it will provide scientific evidence on the efficacy of a symptom self-management intervention that cancer survivors can easily use to manage a distressing symptom. Furthermore, this study is innovative in that it will increase our understanding of how this intervention works and who will most likely experience pain reduction when using this low-cost, accessible, and convenient intervention.

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