Study Protocol

Study Title:

COMFORT: Community-engaged Options to Maximize and Facilitate Opioid Reduction through Treatment

CTN# 18111

Date 7/3/20

Washington State University Institutional Review Board (IRB)
Office of Research Assurances – Neill 427
P.O. Box 643143, Pullman, WA 99164-3143
Telephone: (509)335-7646 Email: irb@wsu.edu Web site: http://www.irb.wsu.edu/

Human Subject Application
Non-Exempt (Expedited and Full Board Review)

IRB USE ONLY

IRB application No: _____

Institutional Review Board: These assurances are acceptable and this project has adequate protections for participants. This project has been properly reviewed and filed and is in compliance with federal and state law, and University regulation.[1]

Review Status Assigned:

☐ Expedited ☐ Full Board
☐ No IRB Review Required ☐ Exempt ☐ Non-Regulatory Review

Approved at the Full Board Meeting on:_____

Approved as Expedited under ☐ 45 CFR 46.110... or ☐ 21 CFR 56.110....

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

Length of time:_____

Waiver(s) or Alteration(s) under :_____

Signature:_____ Print Name:_____ Date:_____

Instructions

- **Do not begin data collection prior to IRB approval.**
- **All materials must be typed; handwritten materials will be returned.**
- **If required, complete the addendums at www.irb.wsu.edu/forms-asp and submit them along with the application.**
- **Do not leave a question blank; write "n/a" if a question does not apply to the application.**
- **If any portion of your research is conducted at any Providence Health Care Ministry (including Providence Medical Groups) and/or St. Luke's Rehabilitation Institute, your project must receive review and approval by Providence IRB- Spokane and you should contact either Providence IRB-Spokane WSU HRPP at 335-7646 prior to filing this application.**
- **WSU researchers (faculty and staff) using DSHS records or facilities should contact WSU HRPP at 335-7646 prior to filing this application.**

[1] *https://policies.wsu.edu/prf/documents/2017/04/45-50-research-involving-human-subjects.pdf/* and *https://orso.wsu.edu/documents/2018/02/ogrd-memo-4.pdf/*

- **WSU researchers (faculty and staff) participating in research with Pacific Northwest University of Health Sciences (PNWU) investigators should contact WSU HRPP at 335-7646 prior to filing this application.**

1. Principal Investigator (PI) Contact Information: (*PI must be WSU faculty or staff, and will be the study supervisor at WSU. Students, post-doctoral researchers, and visiting faculty may not serve as PI, but may be listed as co-investigators in Section 1. All correspondence will be directed to the PI listed below.*)

   Last Name: Wilson First Name: Marian

   Department: Nursing Area: Position: Assistant Professor Campus: Spokane

   Address/Mail Code: 412 E Spokane Falls Blvd Phone: 508-324-7443 E-mail: marian.wilson@wsu.edu

2. Study Title: COMFORT: Community-engaged Options to Maximize and Facilitate Opioid Reduction through Treatment

3. ☐ Yes ☒ No Is this a student's project in which you are serving as a mentor?

SECTION 1. General Information

1. Level of Review: ☒ Expedited (**Complete Addendum 1 and submit with the application**)

   *Expedited Research must meet this definition: The probability and magnitude of harm or discomfort anticipated in the research **are not** greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. 45 CFR 46.102(i).*

   ☐ Full Board

   *Full Board Research meets this definition: The probability and magnitude of harm or discomfort anticipated in the research **are** greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests, or are not in a category allowed for Expedited Research – 45 CFR 46.110.*

The application will not be processed until the PI, Co-PI, and Key Personnel have completed CITI training.

- The PI, Co-PI and Key Personnel must have completed the appropriate CITI training within the last 5 years.
- **Biomedical Health Sciences Researchers** must complete CITI – Good Clinical Practice **and** CITI - Biomedical Research.
- **Social Behavioral Researchers** must complete CITI – Social/Behavioral Research.
- For **Non-WSU Personnel**, provide equivalent certificates or contact the IRB to access WSU CITI training. For non-English speaking personnel, contact the IRB at irb@wsu.edu.
- For CITI training options, visit the CITI website at http://www.citiprogram.org
- If you have any further questions, contact the IRB Program Assistant at 335-7646 or see the webpage http://www.irb.wsu.edu/CITI.asp or email irb@wsu.edu.

2. Human Participant Training Record (CITI –WSU) of **Principal Investigator**:
   Date of Training: 9/26/15 Ref #: 4503372

3. Estimated Study Start Date: 6/20/20

4. [x] Yes [ ] No Is this research supported in whole or in part by a grant or contract?
If yes, complete below:

Funding Agency(s), Foundation, or Business: Institute of Translational Health Sciences and Rayce Rudeen Foundation

PI on Grant/Contract: Marian Wilson ORSO #:

Grant Title/Contract: Academic/Community Partnership Award.

Check if funding is from: National Institute of Health: [x]
If required, has registration been completed with clinicaltrials.gov? [ ] Yes [ ] No
(Include Addendum 8.)
Provide either the registration number, or a reason this has not been completed: not required

5. [ ] Yes [x] No Does the research require another IRB's review? If yes, complete below.

Name of the IRB: FWA number or equivalent number:
NOTE: PI is responsible for securing approval and keeping a copy of the documentation.

6. [ ] Yes [x] No Does the PI, Co-PI, or any other person responsible for the design, conduct, or reporting of this research have an economic interest in or act as an officer or director of any outside entity whose financial interest would reasonably appear to be affected by the results of the study? **If yes**, complete below:

Name of the person with potential financial conflict of interest (FCOI):

Explain the FCOI:

Explain how the potential FCOI will be managed below. (*If the economic interest is a "significant economic interest" as defined in WSU's Executive Policy #27, submit the management plan established with the Conflict of Interest Committee.*)[2]

7. [ ] Yes [x] No Has any PI, Co-PI, or any other person responsible for the design, conduct, or reporting of the research received or will receive any financial assistance (other than a WSU grant or WSU award) including, but not limited to: equipment, staff, data transfers, proprietary information, or financial help? **If yes**, complete below:

Name of the recipient(s):

Explain the assistance:

[2] See also: *https://research.wsu.edu/resources-researchers/operations-support/coi/*

Explain how the potential conflict of interest will be managed below. (*If the economic interest is a "significant economic interest" as defined in WSU's Executive Policy #27, submit the management plan established with the Conflict of Interest Committee.*)[3]

☐

8. ☒ Yes ☐ No Is the proposed research study conducted at an outside (non-WSU) facility or entity (such as a hospital, clinic, school, school district, factory, office, etc..,)?

If yes, provide the name(s) of the facility or entity: none

The researcher has an obligation to ensure that the outside entity is aware of the proposed research study and has no objections (i.e. agrees to participate). In order to respect the rights of entities, research to be conducted at these locations may require a letter from an authorized representative to the WSU IRB or researcher acknowledging the research study and their willingness to allow the proposed research.

9. Provide the location(s) or address(es) at which research will be conducted:
10.
11. ☐ Yes ☒ No Is the proposed research study specifically targeting Alaska Natives/Native Americans as a subject population?

In order to respect the sovereign governments, research to be conducted on Native American tribal lands will require a letter from the Tribal Council (or equivalent authorized signatory) to the WSU IRB acknowledging the research study and their willingness to allow the proposed research.

12. ☐ Yes ☒ No Does the research require approval from other WSU compliance committees? *Radiation Safety Committee (RSC), Institutional Animal Care and Use Committee (IACUC), or Institutional Biosafety Committee (IBC).*

If yes, PI has responsibility to seek approval from the other committees required for this research. Work cannot start until final approval is received from **all** appropriate committees.

SECTION 2. Study Description

Provide a brief summary of the proposed research. Use lay language and avoid technical terms. IRB members not familiar with the area of research must understand the nature of the research. The application will be returned without further review if summary is too technical.

1. Brief (500 words or less) summary of research study:

Purpose:

The purpose of the COMFORT pilot study is to examine the feasability, effectiveness, and acceptability of a project that aims to removes barriers to receiving chronic non-cancer pain treatment by increasing the usage of non-pharmacological pain management therapies in the

[3] See also: *https://research.wsu.edu/resources-researchers/operations-support/coi/*

Spokane, WA area. Innovations in the field of chronic non-cancer pain management are needed to ensure that compassionate conversations occur when opioid dose tapering is being considered and that adults being managed in primary care settings have access to safe and effective pain management options. The research team aims to collect evidence about the receptivity and effects of non-drug interventions that are known to be helpful for pain when offered to patients with pain who are considering or attemptng tapering of opioid dosages. With U.S. opioid overdose deaths on the rise, more patients with chronic non-cancer pain are being asked to reduce their opioid use while insurance plans do not cover many non-drug therapies that have shown to be effective. This project will build evidence about how free access to non-drug options may be received by patients and whether this approach can aid in reducing reliance on opioids for pain management. We will provide all options and study activities using telephone or internet to protect against contagious disease during the COVID-19 pandemic. We will also investigate participants' satisfaction and receptivity to online options in times of pandemic.

Design:

The COMFORT project will utilize a non-randomized one group pre-postest design to investigate feasibility, acceptability, and preliminary effects of a pilot program to invite chronic non-cancer pain patients by their primary care providers to accept free consultations and short-term treatment with diverse healthcare practitioners (e.g. chiropractors, physical and massage therapists, and yoga therapists). Invitations will be extended by healthcare providers to patients who from an urban health clinic that serves low income adults and who have an opioid dose reduction under consideration. Measures of pain, mood, quality of life will be examined for preliminary effects as well as measures of the pilot project feasibility (percent participants approached and recruited, percent consented) and acceptability measures (satisfaction, percent of sessions attended). Measurements will be taken before and after 30 participants are invited to try one of four non-drug pain management options at no charge. All therapies and study activities will be delivered using zoom technology for telehealth and/or phone to protect patients and research staff during times of pandemic.

Procedures: **(Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), drug dosing information (if any), use of records, and subject time required. For projects involving receipt of data or "big data", include a list of fields and/or overlapping source layers (i.e., combining newspaper accident reports, police reports, and medical charts) that will be received; also include a process for who will strip unnecessary data and how this will be completed. For projects involving multiple phases or complex designs, attach flow chart(s) describing the sequence of study procedures.)**

Project investigators will begin by working with community-based primary care providers to develop a process to identify and invite adults diagnosed with chronic non-cancer pain and prescribed opioids to try a non-opioid treatment option plan using the COMFORT project's recruitment script (Appendix). Interested participants will receive study information and be contacted via telephone by study staff and screened for eligibility; those individuals deemed

eligible will be invited to an informed consent meeting. Post-consent a baseline survey will be sent electronically and once completed, a pain assessment will be conducted by a registered nurse (the PI, a certified pain management RN) via telehealth. Each participant will be asked to choose two treatment modalities for a consultation and brief trial and schedule a weekly 45-minute appointment for six weeks; individuals will receive three rounds of the two different modalities they choose using a shared-decision making process that allows guidance by research staff who are knowledgeable about the therapy selection. Data will be collected in multiple ways including via healthcare practitioners (e.g. McCaffery Initial Pain Assessment Tool, Functional Rating Index, etc.), participants (e.g. surveys for demographic information, health history, pain level, satisfaction, and medication usage), study staff (e.g. attendance records) and from clinical records (medication dose prescribed) using IRB-approved protocols. An exit interview will be audio-taped to capture more specific information about patient experiences. See Data Collection Plan table below. Data will be analyzed using descriptive summary statistics, paired t tests for pre and post-test effect size calculations, and content analysis for qualitative data. Sample size of 30 was chosen based on the number needed to generate sufficient pilot data to calculate effect sizes for future trials (Jacobsen & Melnyk, 2012).

All study activities including the informed consent meeting will be completed using telehealth principles using Zoom technology and/or telephone. Participant will review consent document and be informed that consent is implied by completion of the initial baseline survey. No signatures will be collected but the participant will receive a mailed or emailed copy of the consent. We will use WSU-licensed Zoom accounts.

Data collection plan

Measure	T1 Week 0	T2 - Week 3	T3 Week 6
Baseline Measures			
Demographics & Medical History	√		
Modality Selection Questionnaire	√		
McCaffery Pain Assessment (by RN)	√		√
Functional Index (by RN)	√		
Medication goal	√	√	√
Primary Self-reported Outcomes			
Pain Intensity and Pain Interference (PROMIS)	√	√	√
Self-efficacy of Symptoms/Emotions (PROMIS)	√	√	√
Current Opioid Misuse Measure (COMM)_	√	√	√
Depressive Symptoms (PHQ-8)	√	√	√
Anxiety (GAD)	√	√	√
Spiritual Well-being Scale	√		√
Interpersonal Needs Questionnaire	√	√	√
Additional Data			
Program Satisfaction Questionnaire		√	√
Post Program Interview			√
Program Engagement (program attendance records)	√	√	√
Medication Dose (clinical record)	√		√

Data collection will be taken at baseline, Week 3 and Week 6.

Cultural Competency: (**For projects involving select populations, provide the researchers' qualifications for working with the subjects.**)

The PI has conducted 10 studies on chronic pain populations and has received specialized training and certification in pain management nursing.

2. What will each participant be asked to do in their role as a participant?

Interested participants will agree to be screened for project eligibilty via telephone after receiving study information; if deemed eligible, participants will be asked to attend an informed consent meeting with study staff held over phone or Zoom videoconferencing that will last about 1 hour. After consent a registered nurse will conduct a thorough pain assessment on each participant guided by the McCaffery Initial Pain Assessment Tool and the Functional Rating Index (20 min). The participants will be asked to choose one non-opioid treatment modality (selcting from yoga, physical therapy, massage or chiropractic therapy). After selection of the treatments, participants will be asked to schedule and attend six treatment appointments (three sessions of 2 different modalities) over the course of six weeks. Prior to the first assessment by the nurse, participants will be asked to complete a baseline survey via Qualtrics electronic survey that includes baseline demographic and health history information as well as create one goal related to their prescribed opioid use (e.g. reduce their dose or avoid a dose increase). Participants must be willing to attend treatment sessions that last for 45 minutes weekly and take place primarily using Zoom vidoeconferencing and phone back-up. Attendence at each scheduled appointment will be logged and participants will be asked to complete surveys after

each modality trial focused on satisfaction, pain level, symptoms, and medication usage (see Appendix for survey items). At the end of the six week study period an exit interview via phone of 60 minutes or less will be conducted with each participant which will include questions related to identifying their preferences and the challenges they experienced with each treatment modality, goal setting/achievement, and the COMFORT process as well as their desire and likelihood of continuing each treatment option they trialed during the project. Because we are using telehealth, all "treatments" will be guided by the practitioner, representing a consultation and educational experience versus a "hands-on" treatment approach that would normally be used in person. Eg. Chiropractor may assist in teaching posture awareness by watching the person walk and giving advice, and massage therapist may have participants use tennis balls to roll on painful areas to simulate massage – these are activities within the practitioners' usual scope and range of patient educational activities.

SECTION 3. Data Collection Methods

Check all method(s) to be used. If participants will be shown media (such as a video), provide a copy of the media, or a link to its location, or a thorough description of the material contents to the IRB.

1. [x] Survey/Questionnaire
   [ ] Phone [ ] In person [x] Internet [x] E-mail [ ] Postal mail

   If checked, submit copies (if applicable, translated versions) of all the data collection methods and questions mentioned under survey/questionnaire. Use a secure system for digital methods, such as Qualtrics, which is WSU approved.

2. [x] Interview
   [x] One-on-one [ ] Focus group [ ] Oral history [ ] Other: [ ]

   If checked, submit copies (if applicable, translated versions) of all the data collection methods and questions mentioned under Interview.

3. [ ] Observation of Public Behavior
   [ ] Classroom [ ] Public meetings [ ] Other: [ ]

4. [x] Examination of Archived Data/Secondary or Records that contain any of the direct or indirect identifiers listed under HIPAA or FERPA.
   See also: *https://policies.wsu.edu/prf/documents/2017/04/90-78-use-ssn-forms.pdf/*

   Briefly describe who will provide the record and what it will contain: Clinic partners will provide a record of medication dose ordered at baseline and at 6 weeks

   List all fields that the researchers will receive: name (needed for communication of data) and medication dose, date prescribed, any additional information in chart records regarding medication dose changes

If data is being de-identified state who will do this and when: de-identification will occur by PI after receiving the information from the clinic by creating a spreadsheet with de-identified codes

If the research has a Memorandum of Understanding (MOU) or Data Sharing Agreement (DSA) with the entity providing the data or records, a copy of this Memorandum or Agreement must be provided to the IRB.

5. ☐ Taste Evaluation
   ☐ Wine/alcohol ☐ Non-wholesome food
   (Wholesome foods can be reviewed under Exemption Determination.)

6. ☐ Examination of Human Pathological or Diagnostic Tissue Specimens (e.g. blood, bodily fluids…)

7. ☐ Experimental (Unproven or Untested Procedures)
   ☐ Biomedical ☐ Psychological ☐ Other:

8. ☒ Recordings
   ☒ Voice ☐ Video ☐ Digital ☐ Image ☐ Other

   If Other is checked (e.g., GPS or accelerometer recordings), describe:

   Check the purpose of the recordings: ☒ For transcription ☐ Other

If Other is checked, explain below: (e.g., for speech pattern analysis, archiving purposes, presentation at the meetings etc.) Include this information in Section 2, under "Procedures".

Note: A confidentiality agreement is required for transcription and translation of the recordings if the job is done by project personnel such as graduate student, teaching assistant, and undergraduate student and also for professionals hired for the work. **Have the transcriber sign Addendum 10. The researcher must keep this on file until the research data is destroyed.**

9. ☐ Other:

SECTION 4. Confidentiality and Protection of Data

Review the following guidance before answering the questions and completing the table:

1. Identify all the types of data you will be analyzing for your research (example: online survey, questionnaires, one-one-interview, focus group interviews, audio, video and digital images).

2. Determine the level of confidentiality you will have at each stage of the data (collection, analysis, storage and dissemination). When this is completed, then fill in the table.
   For example, if a researcher was conducting a survey and collecting an email address to conduct follow-up focus groups and individual interviews, then transcribing the interviews without identifiers for analysis, and later deleting the recordings, the data would move through different stages of confidentiality. The

researcher would have five types of data: 1. Survey, 2. Focus Group Recording, 3. Interview Recording, 4. Focus Group Transcription, and 5. Interview Transcription.

A. Survey – collected with an email address so this is Intentionally Identified. However, after receipt, the researcher assigns a Confidential Unlinked code to the survey. Later, after conducting interviews and focus group interviews, the researcher transcribes the interviews and links them which creates a Confidential Unlinked code to connect the three data points from the subject.

B. Interviews and Focus Group Interviews – these are being audio-recorded so they are considered Intentionally Identified. Then the researcher transcribes the interviews and assigns the transcriptions a Confidential Unlinked code to connect them to the other three data points. The original recordings are stored, but are not analyzed or disseminated.

C. The researcher then analyzes all data together with the Confidential Unlinked code. The researcher distributes it with a pseudonym rendering it either Anonymous or Confidential Unlinked, depending on whether the information disseminated could lead back to a potential subject, or whether the researcher used a small or large subject pool (i.e. all WSU college students versus only female WSU college students taking one course, from one professor, during one semester, etc.)

3. Table Completion- See example of surveys, interviews, focus groups, recordings, and transcriptions completed in the table.

A. Level of Confidentiality

Delete the highlighted examples in the table below and complete the methods of data for your research to match with the level of confidentiality at each stage of the data. If you have questions, please contact the IRB at 335-7646. *Guidelines are provided at: https://orso.wsu.edu/documents/2018/02/guideline-10.pdf/*

Stages of Data	**Level of Confidentiality**			
	Anonymous *(No identifiers that link the data to a specific subject)*	**Confidential Unlinked** *(Collected with identifier, but all identifiers & codes are removed)*	**Confidential Coded** *(Linked to a specific subject by a code, not by a direct identifier)*	**Intentionally Identified:** *(Linked to a specific subject by personal identifiers)*
Collection				Surveys, medication and clinical record data, interview

				recordings
Analysis			Surveys, medication and clinical record data, interview recordings	
Storage			Surveys, medication and clinical record data, interview recordings	
Dissemination	Surveys, medication and clinical record data, interview recordings			

If HIPAA data is being used, increased data protections are required for all systems and IT services that store, process, and/or transmit the data, to include researcher computer endpoints and data collection devices. A signed Business Associates Agreement is required with all third party vendors that store, process, and/or transmit HIPAA protected data.

B. Data Protection: (Check all that apply.)

[x] Coded to a Master List – for Confidential Coded or Confidential Unlinked
If checked, will the master list be kept separate from the data? [x] Yes [ ] No [ ] N/A

[x] Locked Office (not private) [ ] Locked Private Office [x] Locked Cabinet

[ ] Restricted Computer [x] Password Protected Computer [x] Fire Wall System

[x] Cloud Storage. *See guidelines at: https://security.wsu.edu/policies-and-guidelines/* .

[x] Encrypted Data. *See guidelines at https://policies.wsu.edu/prf/index/manuals/executive-policy-manual-contents/ Executive Policy #8.* **All data must be encrypted at all stages of storage and transfer. Usage of WSU OneDrive complies with this policy.**

[ ] Other: [ ]

C. Data Location:

1. Indicate what countries data may be collected from:

[x] United States only.

[ ] European Union countries that have adopted the GDPR.

[ ] Other Countries: list here (or state "worldwide" if appropriate): [ ]

Note that countries that have adopted the General Data Protection Regulation *https://ec.europa.eu/info/law/law-topic/data-protection_en* of the European Union have additional data security requirements.

2. Describe the location of data storage at each stage in the research process. If relevant, include WSU campus locations (with building and room numbers), off-campus sites, international sites, and cloud storage locations. *For example, "Surveys will be conducted in the field on a WSU-owned tablet. Each night, data will be uploaded to the cloud and deleted from the tablet. Upon return to WSU, data will be stored on WSU-owned computer. Printed copies of data will be stored on the Pullman WSU campus in Neill Hall room 427."* Data copies on paper will be stored for permanent storage in locked file cabinet at the College of Nursing Room 426B and on the PIs password protected work computer after being downloaded from the Qualtrics survey site and OneDrive shared folders.

D. Data Administration

Complete the following as per the guidelines in WSU's Executive Policy #8. *https://policies.wsu.edu/prf/documents/2017/06/ep8-university-data-policies.pdf/* . Include responsible parties name, title, WSU affiliation, and contact information:

Data Custodian: Marian Wilson PI will assume responsibilities If your college or department does not have anyone identified as Data Custodian, the Primary Investigator (PI) can act as the Data Custodian for the systems and data they are responsible for. However, the PI should consult with their Area Technology Officer or their IT department on how to comply with applicable information security and privacy requirements. Data Custodian responsibilities are listed in WSU's Executive Policy #8. *https://policies.wsu.edu/prf/documents/2017/06/ep8-university-data-policies.pdf/*

Data Users (if different from the personnel list on this application):

[x] Yes [ ] No Will any service be storing, processing, or transmitting WSU Confidential or Regulated data at a 3rd party facility (e.g., Microsoft Azure, AWS, Dropbox, Box or other vendor or 3rd party site)?

If yes, please provide the following:

The name of all vendors or 3rd party services that will be used to store and process WSU data: OneDrive, Qualtrics

A list of data elements that will be stored, processed, or transmitted by the service(s): Survey and interview data as outlined in Appendix 1. Interview data will be audio recorded and transcribed onto paper format that will be stored in PIs OneDrive file on password protected computer; after transcription has been completed, audio recordings will be destroyed.

[ ] Yes [x] No Whether the data elements will contain any information that contains identifiers and could be used to link Confidential or Regulated information to an individual.

E. Types of Data

Select the category (or categories) that describe your data, per the guidelines in WSU's Executive

Policy #8. See: *https://policies.wsu.edu/prf/documents/2017/06/ep8-university-data-policies.pdf*

☐ Public ☐ Internal ☒ Confidential ☐ Regulated

F. Data Retention and Disposition

WSU's Business Policy & Procedures Manual requires that all research materials (consent forms, surveys, voice / video / digital / images, etc.) to be kept for a minimum of three years after completion of the study. See: WSU BPPM 90.01 - *https://policies.wsu.edu/prf/index/manuals/90-00-records/90-01-research-sponsored-project-records/*

Check one of the options:

☐ The data will be retained securely for 3 years after the completion of the research and then destroyed/deleted.

☒ The data will be retained indefinitely.

☐ The data retention schedule is different than those at: WSU BPPM 90.01 - *https://policies.wsu.edu/prf/index/manuals/90-00-records/90-01-research-sponsored-project-records/*

How long will it be retained? ☐

What will the final disposition of the data be? ☐

G. Data Destruction

1.) Describe how the data will be destroyed: Paper copies will be stored indefinitely in a locked cabinet under supervision of the PI after transcribing into spreadsheets for analysis, electronic versions of surveys will also be stored indefinitely. Audio recordings will be permanently erased after analysis completed

It is recommended that paper records be shredded, physical tapes be erased and physically destroyed, and electronic media be scrubbed after the files are deleted. (Entirely de-identified data where all links to individual identity including any information that could identify participants may be retained.) See: WSU BPPM 90.01 - *https://policies.wsu.edu/prf/index/manuals/90-00-records/90-01-research-sponsored-project-records/*

SECTION 5. Human Subject Population

1. Approximate number of subjects to be enrolled (**answer for each subject group.** For example: minors' #s, elderly #s.) 30
   Note: Your allowed actual enrollment can vary by +/-10% - if your enrollment will vary outside of this range, you must submit an amendment request.

2. Please identify subjects that will be recruited by **checking all that apply in 2A and 2B**. Submit additional materials as required.

   A. Children or Adult:

Age	**Consent/Permission /Assent forms Required and Translations to be submitted with Application, unless Addendum 6 is submitted.**
☐ Birth to 3 years	Parental Permission Form
☐ 4-7 years	Parental Permission Form and Child's Assent
☐ 8-17 years	Parental Permission Form and Child's Written Assent
☒ 18 & over	Written Consent

B. Target Population for Recruitment

☐	Neonates/Fetuses *(Include Addendum 2)*
☐	Children *(Include Addendum 2)*
☐	Prisoners *(Include Addendum 3 or 3A)*
☐	Pregnant women *(Include Pregnancy Addendum)*
☐	Decisionally impaired
☐	HIV/AIDS patients
☐	Native American Tribes with whom WSU has agreement
☐	Crime victims
☐	Substance abusers
☐	Persons living outside the U.S.
☐	Non-English speaking
☐	Terminally ill
☐	Institutionalized individuals
☐	College students
☒	Men
☒	Women
☒	Other: patients with chronic, non-cancer pain prescribed opioids who have access to computer or smartphone and internet access

3. Are there groups of people you are purposefully excluding? ☒ Yes ☐ No

If yes,

A. Check all that apply:

☐ Ethnic groups

☐ Adults 65 or older

☒ Children (under 18)

☒ Pregnant women

☐ Males

☐ Females

☒ Non-English speaking

☐ Sexual orientation

☐ Marital status

☐ Race

☐ Religion

Other: Individuals with chronic pain caused by cancer.

B. Explain the reasons or justifications for the exclusion criteria:

C. The surveys are in English only and intended for adult respondents. Pregnant women may have unstable physical or hormonal states that could create too much variability in measurements and may have contraindications for some of the non-drug treatment modalities. Due to COVID-19 precautions, and need to minimize risks of unnecessary exposure, we only offer telehealth so participants must have access to computer or smartphone and internet access

SECTION 6. Human Subject Recruitment

1. Recruitment/advertising methods:

Check all that apply. Submit a copy of all the materials that will be used.

☒ Person to person solicitation

☐ Snowball sampling

☒ Phone

☐ Postal mail

☒ E-mail

☒ Poster

☒ Media (TV, newspaper, radio, web site, social media) Specify: Facebook, Twitter, CHAS clinic website or reader boards

☐ IRB Approved Listserv:

☐ Subject Pool or Recruitment Pool: ☐

☐ Other: ☐

☐ None (e.g., for studies using existing specimens or secondary data)

2. How will potential subjects be identified? How will potential subjects be approached? Answer for each subject group.

Explain in detail: We will recruit up to 30 participants from the CHAS clinics in the Spokane region who are prescribed any opioid for any chronic, non-cancer-based painful medical condition (greater than 3 months) and report at least moderate (5) pain symptoms on the Numeric 0-10 Pain Scale.

Clinic staff will provide potential participants a study flyer either in person if they are in clinic or electronically if seen in telehealth visit and ask if they would like to be contacted with further information (Appendix 1). Potential participants will have the option of contacting research team members directly using a private voice mail. A standardized script will be used to guide the invitation and limit coercion that states: (Appendix 1). If potential participants agree, they will receive a copy of the informed consent and will be asked if they wish to be screened for eligibility. Research assistants who have received training in screening will proceed with the screening process. If determined to be eligible and they agree, participants will be contacted by a member of the research team for the informed consent process. Their preferred contact information will be collected on a HIPAA-compliant form that will remain secure at their facility's office until the information is relayed to the researchers by phone or in person. Potential participants may choose to contact researchers on their own using the contact information on the informed consent.

Flyers will be made available for distribution to the clinic staff for internal communications or to be posted in public view at the discretion of each facility's administration team (Appendix).

Eligibility criteria are: 1) enrollment in treatment at the CHAS Perry St or partnering clinic; 2) age greater than 18 years; 3) ability to read, speak, and write English; 4) diagnosed with a chronic, non-cancer-based painful medical condition; and 5) ability to provide informed consent. Exclusion criteria were chosen to limit confounding treatment effects and include: 1) pregnancy; 2) diagnosis of a cancer-based painful medical condition; and 3) any other medical or psychiatric condition that the PI or Co-PI (Dr. Lutz, physician of record) determine might compromise safe study participation (including but not limited to active psychosis, history of frequent psychiatric hospitalizations, severe anxiety with claustrophobia, aggression). Eligibility status will be determined based on 1) patient self-report at the screening interview and 2) each participant's screening interview and pain assessment screening to be performed by Dr. Wilson prior to entering the study. No absolute known contraindications to any of the 4 offered treatment modalities exist, however, each of the providers will use their clinical skills and judgement to provide patient care appropriate to each person's specific condition and have the experience and licenses to perform such treatments in WA state. All treatments will be given based on the informed decision of each participant per standard patient care procedures for each modality. Participants will be ineligible if they do not have access to a computer or smartphone with internet connectivity for telehealth sessions.

3. Who will obtain consent/assent/permission and when will that be done? Answer for each subject group, please note these persons must be listed as having completed CITI training or equivalent in Section 1.

Explain who will obtain consent/assent/permission: Willing participants will be contacted by a research team member or designated assistant to obtain consent

Explain how and when consent/assent/permission will be obtained: After initial contact and screening for eligibility, as soon as possible participants will be asked to set up a phone or video conference meeting to review the informed consent materials.

4. Describe any screening tools/procedures. Answer for each subject group.:

Explain in detail: The complete eligibility script is in Appendix 1. It will be done by research assistants in person at the clinics or by phone if the person prefers and gives contact information

5. Will subjects be compensated (including extra credit*)?
☐ Yes ☒ No

A. What is the compensation, how much will the subject be offered, and how will they receive it? (i.e. extra credit, money, cash, gift card – specify type, etc.) If amount is over $50 in any single increment, the department may be required to collect identifying information.[4] If this interferes with subject confidentiality, explain how this will be resolved.
Explain in detail: No direct compensation is offered, however, the treatment sessions will all be free and valued at approximately $75-$150/session.

B. When will the participants be compensated?
☐ Before the study ☐ Installments during the study ☐ Withdraw/complete the study

C. If extra credit is being offered, how much will the subject be offered, and how will they receive it? If students will be receiving extra credit for participation, they must be able to complete an alternative assignment for the same amount of credit should they choose not to participate. This assignment must be comparable, with respect to time and effort, as participation in the research.
Explain in detail:

SECTION 7. Informed Consent/Parental Permission/Assent Process

Choose all that apply and **attach appropriate forms to this application.** (Templates available at http://www.irb.wsu.edu/) **Note:** For a list of required elements of informed consent see the definitions at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116.)

[4] See WSU BPPM Section 70.44 and *https://policies.wsu.edu/prf/documents/2017/04/70-44-gift-cards-cash-equivalents-purchase-use.pdf/* , *https://policies.wsu.edu/prf/documents/2017/04/45-53-incentive-payments-research-participants.pdf/* , *http://policies.wsu.edu/prf/documents/2017/10/45-53-distribution-log-for-payments-of-cash-gift-cards-and-other-cash-equivalents-and-tangible-property.pdf* , and *http://policies.wsu.edu/prf/documents/2017/10/45-53-record-of-distribution-and-request-for-taxpayer-number-and-certification.pdf*

1. [x] Adult(s) [ ] Parent(s) [ ] Guardian(s)

[x] Written	A consent or permission form that contains all of the required elements of informed consent.
[ ] Alteration of Informed Consent process	Requesting IRB approval for waiver of some or all of the elements of informed consent or permission (i.e. medical record review, deception research, or collection of biological specimens). **If checked,** complete ***Addendum 4*** and submit with the application.
[x] Waiver of Documentation of Informed Consent	Requesting IRB approval for waiver of the requirement for documentation of informed consent or permission (i.e. telephone survey or mailed survey, internet research, or certain international research). **If checked,** complete ***Addendum 5*** and submit with the application.
[ ] Waiver of Informed Consent Process	Requesting IRB approval for waiver of the requirement for the informed consent or permission process (i.e. medical record review, deception research, or collection of biological specimens). **If checked,** complete ***Addendum 6*** and submit with the application.

2. [ ] Children [ ] Vulnerable Population

[ ] Written	An assent or consent form that contains all of the required elements of informed consent.
[ ] Alteration of Informed Consent process	Requesting IRB approval for waiver of some or all of the elements of informed consent (i.e. medical record review, deception research, or collection of biological specimens). **If checked,** complete ***Addendum 4*** and submit with the application.
[ ] Waiver of Documentation of Informed Consent	Requesting IRB approval for waiver of the requirement for documentation of informed consent (i.e. telephone survey or mailed survey, internet research, or certain international research). **If checked,** complete ***Addendum 5*** and submit with the application.
[ ] Waiver of Informed Consent Process	Requesting IRB approval for waiver of the requirement for the informed consent process (i.e. medical record review, deception research, or collection of biological specimens). **If checked,** complete ***Addendum 6*** and submit with the application.

3. What steps have you taken to prevent potential coercion or undue influence in recruiting subjects and obtaining consent or assent?

Explain in detail: All personnel involved in recruitment will be briefed to understand consent process, voluntary nature of study, and participant rights to refuse. This is stated in the consent and will be reiterated verbally. Scripted messages will be used to standardize interactions between facility collaborators and participants to protect and preserve rights. Participant identities will be disclosed to clinic medical staff only as needed for mental health safety and evaluation purposes. All other communications regarding recruitment and study activities will be directed towards clinic staff who do not have any investment in the study outcomes.

SECTION 8. Risk and Benefit Assessment

1. Potential risks to participants: **(Check all that apply).** *These risks must also match the Risks listed in the Consent/Assent/Permission documents as well as mitigation strategies in Section 8.4 and 8.5.*

   [x] Invasion of privacy to the subject or family

   [x] Breach of confidentiality

   [x] Physical harm or discomfort

   [x] Psychological/emotional discomfort or distress

   [ ] Psychological effect that is more than discomfort or distress

   [ ] Social stigmatization

   [ ] Economic (e.g., employment, insurability)

   [ ] Legal

   [ ] Any study related activity which subjects might consider sensitive, offensive, threatening, or degrading?

   [ ] Withholding standard care and procedures

   [x] Significant time or inconvenience

   [ ] Other:

2. Does the study pose risk to individuals other than the participants? no

   Explain in detail:

3. Indicate which of the category listed below accurately describes the specific potential risk level based on all items in Section 8, question 1 on the application:

   [x] No more than minimal risk[5] to participants

   [ ] More than minimal risk to participants.

[5] "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests. 45 CFR 46.102(i).

☐ Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects (usually emergency research).

4. How will you minimize these potential risks in order to protect subjects' rights and welfare?

Explain in detail:

Privacy/confidentiality:
Participants will be told that there are potential risks from taking part in this study, such as the loss of confidentiality that comes from giving out personal information. They will be told the research team is minimizing this risk by using a secure web site and not attaching any identifying information like names or social security numbers that will be connected to survey information. Data will be coded and secured. Email communicatons will be deleted to decrease breaches of privacy and an approved survey program. Qualtrics and OneDrive will be used to maximize security. Zoom technology will be used for videoconferencing due to its enhanced protection features and no participant sessions will be recorded.

Psychological/ emotional discomfort/distress:
Participants will be told on informed consent about potential psychological risk with these statements: "It is possible you will feel stress or psychological discomfort when you are answering personal questions or engaging in any of the non-drug treatment options. You are encouraged to contact any member of the study team if you feel you need additional counseling or other support, and we will refer you to the appropriate services."

Physical harm/discomfort/:
Occasionally, participants may have adverse effects from any one of the chosen non-drug treatment options such as pain, muscle strain, or increased fatigue. These risks will be reduced through the screening histories, physical exam by each treatment provider, and your own communications with providers about your body and preferences. You will not be forced to do anything you are not comfortable doing or believe may cause you harm.
We have chosen experienced providers to provide treatments who have many years of evauating patients are who will take every precaution to preserve your safety and well-being.

Significant time: Recognizing that this study entails significant time, we will provide each participant with a written schedule and be sure they understand the time commitment prior to consenting. We will allow flexibility in certain aspects of the study when feasible, such as the appointment days and times and provide reminder calls..

5. In the event that any of these potential risks occur, how will it be handled (e.g. compensation, counseling, etc.)? Include supporting materials.

Explain in detail:

Privacy/confidentiality: Known breaches of confidentiality will be reported to participants and researchers will make every attempt to assure future data protections. Conversations will occur in private areas as much as possible. Medical and eligibility screenings will take place in private.

Psychological/ emotional discomfort/distress: As informed in the consent process, if the study staff learns that depression screening or other study data suggests the possibility of severe or

higher depressive symptoms (as defined by the PHQ-9 guidelines) or participants indicate any suicidal, homicidal, or self-harm plan, that information will be reported to the study medical director and primary provider of record. Participants will be encouraged to seek a professional evaluation and be given a number for the suicide hotline. Research personnel and treatment providers will be trained to notify the PI or study physician if any psychological or emotional distress is noted. The primary investigator or licensed co-investigator will be available at all times to provide advice and intervene as necessary. The participating treatment providers will be given directions on how to handle unexpected medical or mental health events.

Physical harm/discomfort: Participant comfort will be assessed after each study treatment session and opportunity will be available to minimize any immediate adverse events. All treatment sessions will be delivered by trained and experienced licensed providers and any problems dealt with using usual procedures that are standard for their professions (see letters of commitment in Appendix), such as stopping treatment when necessary and initiating emergent care (calling 911). Providers will be trained to alert PI for adverse events such as physical symptoms of agitation, increased pain, nausea, tremors, etc. A physician and/or licensed healthcare provider with relevant experience with pain populations (RN, MD) will be available at all times via phone during the treatment sessions to trouble-shoot any adverse events or unexpected responses. If deemed necessary, participants will be seen by a licensed healthcare provider for evaluation. Participants are informed during consent process that they or their health insurance will be responsible for costs if any additional medical or psychological services are needed. The study team will assist in connecting them with resources if needed using state sponsored services.

Significant time: If unexpected time delays occur due to scheduling conflicts or other unanticipated delays, the PI will express appreciation and offer apologies with an additional $10 gift card as a thank you for additional time spent.

6. Is it possible that you will discover a subject's previously unknown physical or psychological condition (e.g. disease, depression, suicidal ideation, genetic predisposition, etc.) as a result of your procedures?

   [X] YES

   [ ] NO

   If yes, what would they be and how will you handle these situations?

   Explain in detail: [ ]

   [ ] It is possible health information will be provided on the surveys that suggests some underlying physical or psychological conditions. These will be reviewed by the PI and followed up with to be sure participants have the resources they need if any concerns arise

   [ ]

7. Describe the expected benefits of this project *(NOTE: compensation is not considered a benefit)*:

   A. To the individual subjects:

   Explain in detail: Participants may benefit directly from participation due to the consultation and treatment provided by non-opioid treatments and also receive the satisfaction of contributing to science. It is possible they will receive some relief of pain or emotional distress via the treatment sessions.

B. To society:

Explain in detail: The knowledge gained from this study will increase the understanding of whether non-drug pain treatments can assist with opioid dose reduction and symptom management.

8. Explain how, in your assessment, benefits of this study outweigh the risks. (e.g. risk/benefit ratio)

The risks associated with participation in this study are no greater than those ordinarily encountered by adults who seek medical treatment and pain relief of any kind. Because the benefits could be life-changing if they improve outcomes for pain and opioid use, it is our belief that the knowledge gained from this study will outweigh any potential risks.

SECTION 9. Research Involving Potential Reportable Activity

1. Will the project involve the potential discovery of child abuse?
☐ Yes ☒ No

If yes, there are legal obligations to disclose to the proper authorities certain information about reportable activities obtained during research. **This obligation and intended course of action must be communicated to the participants in the consent form.**

SECTION 10. Research Involving Deception

1. ☐ Yes ☒ No Will any information be purposely withheld from the participants or will they be given any misinformation?
If yes, this will require alteration of informed consent process. **Complete Addendum 4** and submit along with the application.

2. Why is the deception necessary?

Explain in detail: ☐

3. How and when will the subjects be debriefed after the project? **Attach debriefing script.**

Explain in detail: ☐

SECTION 11. Research Involving Health Insurance Portability and Accountability Act (HIPAA)

Address the following questions regarding the use of protected health information:

1. [x] Yes [ ] No Will health information be obtained from a covered entity[6] (a health care provider who bills health insurers e.g., WSU Cougar Health Services)?

2. [ ] Yes [x] No Does the research involve the provision of healthcare in a covered entity, such as WSU Cougar Health Services?

3. [ ] Yes [x] No If the study involves the provision of healthcare, will a health insurer or billing agency be contacted for billing or eligibility?

4. [x] Yes [ ] No Does the research involve use or creation of protected health information[7]?

If no, to all the questions above you are **not** subject to HIPAA.
If yes, to any of the questions above **complete Addendum 7** and submit with the application. Please be advised that HIPAA protected data cannot be stored in the cloud per WSU policy. https://security.wsu.edu/policies-and-guidelines/.

SECTION 12. Research Involving Investigational Drugs, Devices, Alcohol, Blood, Tissue, Bodily Fluids or other Biological Specimens

1. [ ] Yes [x] No Will any investigational new drug (IND) be used?
If yes, complete **Addendum 8** and attach it to the application.

2. [ ] Yes [x] No Will any other drugs be used?[8]
If yes, complete **Addendum 8** and attach it to the application.

3. [ ] Yes [x] No Will any investigational device (IDE) be used?
If yes, complete **Addendum 8** and attach it to the application.

4. [ ] Yes [x] No Will alcohol be ingested by the subjects?
If yes, describe what type and how it will be administered[9]:

---

[6] The Administrative Simplification standards adopted by Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) apply to any entity that is

- a health care provider that conducts certain transactions in electronic form (called here a "covered health care provider").
- a health care clearinghouse.
- a health plan.

An entity that is one or more of these types of entities is referred to as a "covered entity" in the Administrative Simplification regulations.

[7] Protected health information is individually identifiable health information used by HIPAA-covered entities and their business associates in the relation to the provision of healthcare.

[8] "Drug" definition: *https://www.fda.gov/drugs/informationondrugs/ucm079436.htm*. WSU Cannabis Research Policy: *https://orso.wsu.edu/documents/2018/02/guideline-15.pdf/*

[9] Refer to the guidelines for administration of ethyl alcohol in human experimentation (OGRD Memo No. 18 *http://www.orso.wsu.edu/documents/2018/02/guideline-18.pdf'*) and NIAAA.

5. ☐ Yes ☒ No Will blood, tissue, bodily fluids, or other biological specimens be collected? **If yes,** complete **Addendum 9** and submit with the application.

Note: if you are using blood, tissue, bodily fluids or other biological specimens, you may also need to seek Institutional Biosafety Approval before you begin the research. Contact the WSU Biosafety Coordinator at 509-335-7195 or ibc@wsu.edu.

A. ☐ Yes ☒ No Will any of the blood, tissue, bodily fluids, or other biological specimens be used for genetic testing?

B. Do your studies involve the analysis of genes known to be implicated in the disorder(s), syndrome(s) or condition(s) you are studying? If so, what genes will you be studying?
no

C. Alternatively, do your studies involve finding the gene(s) that may cause the condition or genetic markers that co-segregate with this condition?

no

D. Please confirm that the samples will not be used for any purpose other than to study genes related to the diseases discussed in the application and the consent form.

SECTION 13. Investigator's Responsibilities and Assurances

Indicate that you have read and will comply with each statement by checking the boxes.

1. x I certify that the information provided in this application, and in all attachments, is complete and correct.

2. x I understand that I have ultimate responsibility for the protection of the rights and welfare of human participants, the conduct of this study, and the ethical performance of this research.

3. x I agree to comply with all WSU policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding eh protection of human participants in research.

4. x I agree that legally effective informed consent, permission and/or assent will be obtained from human subjects as required and documented using the IRB approved forms, unless waived by the IRB.

5. x I understand that my research is subject to post-approval review by HRPP staff on behalf of the IRB.

6. x I certify and agree that:
   - The project will be performed by qualified personnel according to the WSU IRB-approved application.

- The equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
- All data collected for this research is the property of Washington State University (WSU)[10], which retains rights of access and ownership both during my association with and after my separation[11] from WSU.
- Unless otherwise prohibited by a data sharing agreement or other contract signed by WSU, I will retain an appropriately secured back up copy of all data in a manner compliant with WSU policies, with two WSU personnel having access to it.
- WSU-owned data held on non-WSU devices and WSU devices will be destroyed in accordance with Executive Policy 8. *Note: Refer to the "data retention and disposition" section in the policy, page 8.*
- Unanticipated problems, adverse events, and new information that may affect the risk– benefit assessment for this research will be reported to the WSU IRB Office (509-335-3668; irb@wsu.edu) and to my Department Chair/Director/Dean.
- I am familiar with the latest edition of the WSU IRB Policies and Procedures Manual[12], and I will adhere to the policies and procedures explained therein.
- Student and co-investigators on this project have received adequate training and are knowledgeable about the regulations and policies governing this research.
- No change will be made to the human subjects protocol or consent form(s) until approved by the WSU IRB.
- I will ensure adequate supervision of all research project personnel and to meet with the investigator(s), if different from myself, on a regular basis to monitor study progress.

7. x I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until IRB approval has been obtained.

PI Name: Marian Wilson Signature*: _____ Date: 6/13/20

***Only required if not submitted from the PI's WSU email account. Please scan the application with signature and e-mail the application.**

Submission Checklist:

- ☐ Completed application
- ☐ Required addenda – see list at: http://www.irb.wsu.edu/forms.asp
- ☐ Consent/Assent/Permission or Addendum 6, and translated copies
- ☐ Data collection materials or links
- ☐ Recruitment materials
- ☐ All personnel have completed CITI training or equivalent

[10] *https://policies.wsu.edu/prf/index/manuals/45-00-contents/45-35-managing-research-records/ - "Ownership" Section.*
[11] *https://policies.wsu.edu/prf/index/manuals/60-00-personnel/60-74-employee-departure-procedures/ - "Facilities/Property" Section.*
[12] *http://www.irb.wsu.edu/resources.asp*

How to Submit:

1. **All submissions (application and the supporting materials) should be emailed to irb@wsu.edu. Subject line: "Human Subject Application, for expedited or full board review submission".**
2. **Ideally submissions should be sent by the PI. If someone other than the PI (example: graduate student, post doc, co-PI or staff) is submitting the application on behalf of PI, the submission must be copied to PI. The e-mail should come from a WSU e-mail address.**

WASHINGTON STATE UNIVERSITY
WSU College of Nursing

Research Study Consent Form

Study Title: COMFORT: Community-engaged Options to Maximize and Facilitate Opioid Reduction through Treatment

Researchers:

Principal investigator:
Marian Wilson PhD, MPH, RN-BC | Assistant Professor
Washington State University College of Nursing, Spokane, WA
509-324-7443 marian.wilson@wsu.edu

Co-investigator:
Robert Lutz MD, MPH | Adjunct Professor
Washington State University Department of Nutrition, Exercise & Physiology,
Health Officer Spokane Regional Health District
Spokane, WA
509-324-1469 blutz@srhd.org

Sponsor: Institute of Translation Health Sciences and Rayce Rudeen Foundation

KEY INFORMATION ABOUT THIS STUDY

- Your consent is being sought for research. Participation is voluntary.
- This research study is being done to examine whether patients with non-cancer chronic pain will benefit from non-opioid pain management strategies.
- Participants will complete weekly surveys, receive a 1-hour orientation and pain assessment, and be invited to try 2 different non-opioid pain treatment options over 6 weeks' time.
- All activities will be conducted via internet or phone.
- Participants will be scheduled for six 45-minute treatment sessions of their choice: 3 sessions of either yoga therapy or physical therapy and 3 sessions of either massage therapy or chiropractic therapy. All consultation and therapy sessions will be conducted via internet or phone.
- Participants will need to have access to a computer or smartphone with internet access for the treatment sessions and initial pain assessment.
- Participants will be asked to complete an audiotaped 1-hour interview via phone at the end of the 6 weeks to talk about their experience.

- Participants will be asked to wear a small finger probe to measure sleep, heart rate, and oxygen level for 5 days and 5 nights, and complete a daily sleep diary (this part of the study is optional and adds approximately 15 extra minutes per day to complete the diary).
- Payment – $75 for completing all the surveys and interview. An additional $25 may be earned for returning the sleep diary. Participants may choose to receive a gift card from Fred Meyer or Amazon by mail or email.
- The potential risks from taking part in this study include experiencing possible feelings of stress, embarrassment, or loss of privacy when you are answering personal questions. Trying new non-opioid treatment risks include potential increased pain, muscle strain, stress, and fatigue.
- The potential benefits to you for taking part in this study are not guaranteed. The treatments chosen for this experiment are known to be beneficial for some people with pain, but we cannot know whether it will help you personally. It is possible that in the future the information learned from this study will benefit other people with your condition. This is a study and should not be considered part of your medical treatment.
- We plan to enroll 30 adults in the study.
- This project is being funded by grants from two sources: The Institute of Translational Health Sciences and the Rayce Rudeen Foundation

What you should know:

You are being asked to take part in a research study carried out by Dr. Marian Wilson and the research team. This form explains the research study and your part in it if you decide to join. Please read the form carefully, taking as much time as you need. Ask the researcher to explain anything that you do not understand. Your participation in the study is voluntary. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. You may refuse any question, test, or procedure. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later. This study has been approved for human subject participation by the Washington State University Institutional Review Board.

What is the purpose of this study?

This research study is being done to study how adults prescribed opioids for chronic noncancer pain respond to invitations to try non-opioid options. The options available in this study are massage therapy, yoga therapy, chiropractic and physical therapies. This is a clinical trial, not a treatment. Due to the COVID-19 pandemic, these options will be available via telehealth visits using a computer or smartphone with internet connection to protect you and our research staff from any contagious disease.

If you do not have a smart phone or access to a computer with internet, then you will not be eligible to participate in the study.

You are being asked to take part because you are a patient at one of our partnering clinics who is prescribed opioids; are experiencing a level 5 or above pain level symptom burden on a 0-10 scale; has been identified as someone who might benefit from a reduced opioid dose; are 18 years of age or older; can speak and read English; and can provide consent.

You cannot take part in this study if you: are pregnant; and/or have a medical or psychiatric condition that the investigators determine would compromise safe study participation (including unstable medical conditions that might require frequent medication changes or hospitalizations).

What will I be asked to do if I am in this study?

If you take part in the study, you will be asked to meet with a member of the research team via phone or computer conferencing using the internet for a complete review of this informed consent form. This meeting will last 30-60 min. If you agree after this information session to join, you will be asked to complete an online survey that will be sent to you via an email link to a secure website. A secure website is one that protects or disguises your private information while you are using the Internet. You will need a computer with Internet connection or a smartphone to complete surveys throughout this study. The online survey will contain information that can be used to identify you including your email address and a unique code number that can be linked to your name by the main researcher. You will also be asked your age, education level, race, health history, and marital status. We will not ask for your name, phone number, or other identifying information on the survey website. It should take no more than 10 minutes to complete this initial survey. Once this is completed, a registered nurse will perform a complete pain assessment using videoconferencing. You will also be asked to list the medicines you are currently taking, both prescription and over-the-counter, as well as supplements. You will be given information about each of 4 non-opioid options available to study participants. You will be asked to choose two to try – between yoga therapy, physical therapy, guided massage therapy or chiropractic consultation. You will be assisted in scheduling a total of 6 appointment one per week of your choice: 3 sessions of 2 different therapies.

Your pain treatment sessions each last around 45 minutes. You will be allowed to choose from a selection of times available to schedule your sessions. You and your therapy provider will decide times that work best for you both. No matter when the appointment is scheduled, you will be expected to attend on time. If you find that you

cannot keep a scheduled appointment, we ask that you let the investigators know as soon as possible using the phone number provided to you. The session will not be rescheduled. If you miss two scheduled sessions without notifying the treatment providers, the rest of your sessions will be cancelled out of courtesy to the treatment providers. After each session you will be asked to complete a brief 10-minute survey that reports on your pain and how the treatment session went for you. At the conclusion of the 6 weeks of treatment, you will be asked to schedule a one hour interview to explain more fully your experiences receiving the pain treatments. This interview will be audio-recorded and completed over the phone. You will have the option of participating in a collection of additional sleep data by wearing tracking equipment at home. This portion of the study is intended to help understand how to measure sleep that may be affected by pain in our participants. If you choose this option, you will select a 5-day period when you will wear a small disposable probe on a finger at bedtime to measure your sleep hours, heart rate and oxygen levels while you sleep. It is called the NightOwl and you can read about it if you wish via the following link: www.nightowl.care. You will be asked to spend about 15 minutes on a videoconference call to receive instructions on the sleep and oxygen monitoring equipment that will be sent to you in the mail. While you wear the NightOwl device, you will be asked to complete a brief daily diary logging your hours of time to bed, the medicine you take, exercise, and any naps you take. We will ask you to return the diary in a pre-stamped envelope after the 5 days of measurement.

You will have the right to refuse to answer any questions you choose and to drop out from the study if you choose at any time. Participants may request results of the study from members of the research team once the study is completed.

All participants will have the option of additional meeting time with researchers via phone if they need more information on participation.

Are there any benefits to me if I am in this study?

The potential benefits to you for taking part in this study are not guaranteed. If you agree to take part in this research study, there may or may not be direct medical benefit to you. It is possible that your condition may remain unchanged or even get worse. Although the chosen treatment options are known to help people with pain, they are generally provided in person and each person responds differently. Because you will only receive three sessions of any one treatment option, and it will only be available as a telehealth visit using the computer or smartphone, we do not know if the dose will be enough to help you, which is part of the reason why we are doing this study.

It is possible that in the future the information learned from this study will benefit other people with your condition and help advocate for health plans that will include these treatments. We will also learn more about how well we can help people using telehealth and how sleep may be measured for people with pain.

Are there any risks to me if I am in this study?

The potential risks from taking part in this study include possible feelings of stress, embarrassment, or loss of privacy when you are answering personal questions. You are encouraged to contact a member of the study team if you feel you need counseling, or other support and we will refer you to the appropriate services. If you reveal that you have plans to harm yourself or others, the research team will follow state laws regarding reporting of such information.

Each of the treatments provided have risks that will be explained to you by your provider including potential increased pain, muscle strain, stress due to trying something new, or fatigue. These risks will be reduced through the screening histories, each providers' assessment that they will conduct during your initial consultation visit, and your own communication to the providers about your body, health, and preferences. You will not be forced to do anything you are not comfortable doing or believe may cause you harm. We have chosen experienced providers to provide treatments who have many years of evauating patients and who will take every precaution to preserve your safety and well-being. Although we are using Zoom technology for the study activities that has privacy protections built in, there is always some risk of computer "hacking" or interference with private online activities that may be distressing to you if they should occur.

If you choose to participate in the optional sleep data collection, the NightOwl finger probe collects data about your sleep, heart rate and oxygen level that is uploaded to a cloud-based system and requires you to download an app on your phone. We will show you how to use the app in the videoconference training so that no identifying information will need to be shared with this company about your name, your health information, or any other information you share with the research team. It is possible we will see some abnormalities on our sleep screening that could be important for your health. While we cannot diagnose or treat your health problems, we can share with you if we see something outside of normal sleep variations so you can discuss this with your health provider if you choose. Such information may cause you additional stress and worry. We will provide additional resources that may be accessed to investigate your sleep problems if you request this. If you decide wearing the finger probe is too much trouble, you may choose to skip this part of the data collection and just fill out the sleep diary and you will still be paid the additional $25 for returning the diary. The finger probe is disposable and does not need to be returned.

There can be no guarantee, however, that no harm will come from trying a new pain treatment approach. You or your health insurance will be responsible for costs if any additional services are needed. No commitment to pay your bills for additional healthcare needs or for any adverse results from participating in this study is made by investigators, your primary care provider or clinic, or the participating colleges at Washington State University.

Will my information be kept private?

A potential risk from taking part in this study is the loss of privacy that comes from giving out personal information and using web-based survey systems. The potential risk of loss of privacy related to reporting thoughts of harm are mentioned above. The research team is reducing additional risks by using a secure website and computer to store all study information and limiting access to your information. We will not store any identifying information like names or social security numbers with our data file. The data for this study will be kept confidential to the extent allowed by federal and state law. No published results will identify you, and your name will not be associated with the findings. A key will be kept that allows the researchers to connect your survey information with your study identification number. Under certain circumstances, information that identifies you may be released for internal and external reviews of this project by the Institutional Review Board that oversees this research. The results of this study may be published or presented at professional meetings, or used to support future research grant applications, but the identities of all research participants will remain anonymous.

The survey data for this study will be kept indefinitely and stored using electronic files using password-protected computers accessible only by the Washington State University study team. Identifiers will be removed from the identifiable private information. The only information we will ask your healthcare provider to give us from your medical records will be to confirm any changes in your pain medicine prescriptions throughout the study timeframe. If you do not agree to this, you may choose to not join the study. Your audio recordings will be destroyed after the interview analysis is completed. A code will be created by the primary investigator to match surveys with identities; however, all study data will be stored in a file without names attached to protect privacy. Conversations about your participation will be limited to those necessary for study team members or health care providers to conduct the recruitment, study procedures, and share your survey results if you choose.

Are there any costs or payments for being in this study?

There will be no cost to you for taking part in this study. Your insurance will not be billed.

The treatment sessions are valued at approximately $75 to $150 per session and will be free to you. If you miss a scheduled session, you will not be charged, but you will lose the opportunity for that free session. It will not be rescheduled. You will receive a $75 gift card from one of the two available vendors at the time that we complete your final interview. You will receive another $25 gift card if you have opted to provide sleep data and we receive the returned sleep diary. These payments are meant to thank you for your time spent participating in the study.

Who can I talk to if I have questions?

If you have questions about this study or the information in this form, please contact the researcher Marian Wilson, PhD, MPH, RN-BC, Associate Professor, Washington State University College of Nursing, Spokane, WA, 509-324-7443, marian.wilson@wsu.edu
If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the Washington State University Institutional Review Board at (509) 335-7646, or e-mail irb@wsu.edu, or regular mail at: Neill 427, PO Box 643143, Pullman, WA 99164-3143.

What if I have a study-related injury or want to withdraw?

If you have a study related injury, illness, distress and want to report this to the researchers, contact Marian Wilson, PhD, MPH, RN-BC, Associate Professor, Washington State University College of Nursing, Spokane, WA, 509-324-7443, marian.wilson@wsu.edu. In order to withdraw your previously collected data from the study, you must let Dr. Wilson know via phone, text, or email.

What are my rights as a research study volunteer?

Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part. You may choose not to answer specific questions or to stop participating at any time. You will be given a copy of the consent form for your records.

What does my consent mean?

By clicking “I agree” and completing the initial baseline survey, that has health-related and demographic questions, you are giving your consent to take part in this research.

Your consent means that:

- You understand the information given to you in this form
- You have been able to ask the researcher questions and state any concerns
- The researcher has responded to your questions and concerns
- You believe you understand the research study and the potential benefits and risks that are involved.
- You are giving your voluntary consent to take part in the study.

Statement of Consent

- You are giving your voluntary consent to take part in the study.
- You agree that the researcher may audio record you to aid with data analysis for the final interview. The researcher will not share these recordings with anyone outside of the immediate study team.
- You agree to be contacted with reminder calls the day before each of your scheduled treatment sessions.

You will be provided a copy of this document.

☐ I agree (click box to note your agreement to join the study and proceed to the baseline survey)