Institutional Review Board

FWA: 00007392 | IRB: 0004173

IRB Number: 001-21

Approved: 02/16/2021

Post-Approval Request(s):

Approval Expires: 02/16/2022

Office of Scholarship & Sponsored Projects
2043 College Way | UC Box A-133 | Forest Grove, OR 97116
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(W) www.pacificu.edu/about-us/offices/research-office

Proposal to Conduct Research

Research Review Boards

☑ **Institutional Review Board (IRB)**

Study Title

A Pilot Study of Cognitive Behavioral Therapy – Insomnia (CBT-I) among Professional Firefighters

IRB Proposal and Review Type

If you are not sure if your research is considered human subjects research, please use the *Request for Determination of IRB Jurisdiction* checklist available on the IRB website (www.pacificu.edu/irb) before continuing with this form. If needed, submit the *Request for Determination of IRB Jurisdiction* to the IRB at irb@pacificu.edu.

☐ **Request for Exemption**

☑ **Proposal to Conduct Human Subjects Research**

- ☑ Expedited Review
- ☐ Full Board Review

Research Personnel and Contact Information

Personnel #1	
Name **Kaylie Green, M.S.**	**Role** Principal Investigator
Institution Pacific University	**Program** School of Graduate Psychology
Email gree9218@pacificu.edu	**Telephone** 503-352-2498
Scope ☑ Recruitment ☑ Consent Process ☑ Data Collection ☑ Data Analysis (with personally identifiable information) ☑ Data Analysis (de-identified data) ☑ Other: Group co-facilitator	

Delete this Personnel entry

Personnel #2	
Name **Michael Christopher, Ph.D.**	**Role** Faculty Principal Investigator
Institution Pacific University	**Program** School of Graduate Psychology
Email mchristopher@pacificu.edu	**Telephone** 503-352-2498
Scope ■ Recruitment ■ Consent Process ■ Data Collection ■ Data Analysis (with personally identifiable information) ■ Data Analysis (de-identified data) ■ Other: Dissertation Supervisor / Faculty Investigator	

Delete this Personnel entry

Personnel #3	
Name **Nicole McCullough, Ed.S.**	**Role** Co-Investigator
Institution Pacific University	**Program** School of Graduate Psychology
Email nicole.r.mccullough@gmail.com	**Telephone** 503-352-2498
Scope ■ Recruitment ■ Consent Process ■ Data Collection ■ Data Analysis (with personally identifiable information) ■ Data Analysis (de-identified data) ■ Other: Group co-facilitator	

Delete this Personnel entry

Add Personnel

Funding and Sponsorship

Funding:

Funding for this study is:

☐ Internal (Pacific University) ☐ External ■ This study is not funded

☐ Other: _____

Be sure to maintain sponsorship records as related to this study. Should this proposal be selected for an internal or external audit, all grant and funding documents will need to be available for review during the audit.

Sponsor:

If this is a clinical investigation, list and describe who is sponsoring this study. Please provide addresses for all sponsors. If the sponsor and funding source are the same, please state as such. If you are conducting a clinical investigation, you are required to list and describe who is sponsoring this study. (If the study is not sponsored, then state Not Applicable.)

Conflict of Interest:

Describe any potential or apparent conflict(s) of interest that may exist. (If the study is neither funded nor sponsored, then state *Not Applicable.*)

None

Describe any other potential conflict(s) of interest that may exist.

None

Payment of Research Participants

Will you be paying your research participants? ☐ **YES** ■ **NO** ☐ **N/A**

Please refer to the Office of Research's website for current practices regarding payment of research participants. You may be required to submit additional documentation to the IRB depending on the source of funding."

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IRB Submission Guidance Document

Study Title

A Pilot Study of Cognitive Behavioral Therapy – Insomnia (CBT-I) among Professional Firefighters

Medical Device | Drug Study | Clinical Investigation

Medical Device Information

1. Are you using a medical device in your study that is not the subject of study? The device must be used in accordance with its approved indications, with no modifications (on-label use). ☒ **YES** ☐ **NO**

If you are using medical devices in your study, but they are not the object of your investigation, please refer to the devices in your procedures, along with any necessary clarifying information, and explain the role of the devices in your research. You may provide additional information below, as needed.

The Fitbit Inspire HR wrist worn device will be worn by eligible participants throughout the duration of the intervention and for two weeks following completion of the 6-week intervention to collect objective data on enduring sleep changes. This device is an FDA-registered medical device that is not the object of investigation and is being used "on label" only to gather data.
501(K) Number: K200948
Device Name: Fitbit ECG App
Regulation Number: 870.2345
Classification Product Code: QDA
Clinical Trials: NCT04176926

By signing and submitting this proposal, the researchers confirm that all devices used in this study are being used in accordance with its approved indications with no modifications (on-label use) following appropriate procedures. Researchers are responsible for ensuring appropriate use of the medical devices and will make available, upon request by the IRB, medical device numbers (PMA numbers, 510(k) numbers) or additional information, as needed.

2. Are you studying a medical device in your proposal? If the medical device is the object of study, is not being used in accordance with its approved indications, or has not been cleared for marketing, please select YES. (If other medical devices are also being used in the study, please select both options, but provide only the information regarding the medical devices being studied on the *Medical Device Study* form. ☐ **YES** ☒ **NO**

Drug Study Information

Are you conducting a drug study? ☐ **YES** ☒ **NO**

Biologic Information

Are you studying a biologic or other food product for human consumption? ☐ **YES** ☒ **NO**

- ☐ Biologic
- ☐ Other food product for human consumption

Clinical Investigation

Is this project considered a clinical investigation? ☐ **YES** ☒ **NO**

Consent Forms

☒ I will be collecting signed Informed Consent.

Complete the *Informed Consent*

☐ I will be submitting a Request to Alter or Waive Informed Consent.

Check all that apply:

- ☐ The documentation of signed informed consent will be waived.
- ☐ Alteration of informed consent documentation (modified consent documents, online *or* anonymous surveys, for instance).
- ☐ Request to waive Informed Consent.

Vulnerable and Non-Autonomous Populations

1. Will you be collecting data from (1) children/minors, people who (2) cannot provide their own consent or (3) have a disability or impairment?)

☐ **YES** ☒ **NO**

2. Will you be collecting data from pregnant women? ☐ **YES** ☒ **NO**

For non-autonomous individuals, researchers must first obtain permission from the parent or guardian, then informed assent from the potential participant. Please refer to Informed Consent information on the IRB website for additional information regarding the Consent Process, particularly as it applies to Permission and Assent. Based on the answers to these questions, the appropriate forms have been added to the proposal.

Prisoners

Does your research involve prisoners? ☐ **YES** ☒ **NO**

HIPAA and FERPA

HIPAA

Will your research be using data covered by the HIPAA Privacy Rule? ☐ **YES** ☒ **NO** ☐ **N/A**

FERPA

Will your research be using student education record data protected by FERPA? ☐ **YES** ☒ **NO** ☐ **N/A**

Release Documentation

Participant Contact Information

Will you be collecting participant's contact information? ☒ **YES** ☐ **NO**

Print and use this form to gather your participants' contact information. Once all contact information is collected, enter the information into a master key and, if necessary, destroy all hardcopies of the *Participant Contact Information* form. Please describe this process in your proposal.

Recording Release

Will your research include an Audio Recording? ☑ **YES** ☐ **NO**

If an audio recording is part of your research, please state if the recording is for (1) transcription purposes or (2) will be maintained as research data. Please include an explanation of the audio recording on the consent documentation, as well as on the *Audio Recording Release* Form.

Photograph and Video Recording Release

Will your research use photographs or video to collect data? ☐ **YES** ☑ **NO**

International Research and Translations

International Research

Will you be conducting research internationally? ☐ **YES** ☑ **NO**

Translation

Will any verbal or written communication with participants be conducted in a language other than English? ☐ **YES** ☑ **NO**

Recruitment and Data Collection

Recruitment

Will you be recruiting participants for your research? ☑ **YES** ☐ **NO**

1) Please place all recruitment materials in one document, as possible, and upload separately on IRBNet.

2) List all recruitment materials that will be attached. Recruitment materials include but are not limited to emails, phone scripts, announcement scripts, posters, handouts, and flyers. You may also include text of emails, verbal scripts, etc. in the recruiting section of the proposal if more appropriate. Please do still indicate recruitment elements below, regardless of submission format.

- ☐ Phone-Call Script
- ☐ Announcement Script
- ☑ Email text
- ☐ Poster
- ☑ Handout
- ☑ Flyer
- ☐ Other (if other, please list all other forms of recruitment below)

Data Collection

1) Place all data collection materials in one document, when appropriate, and upload separately on IRBNet. PDFs of online surveys may be uploaded in a second document, as needed.

2) List all Data Collection materials. Data Collection materials include but are not limited to surveys, handouts, demographic forms, assessment tools, and interview questions.

- ☑ Assessment Tools
- ☑ Demographic Forms

☐ Interview Questions

☐ Handouts

☒ Online Survey:

Please provide the survey's URL:

For review please use mock participant ID # 998 and/or 999.

CBT-I Firefighter Remote Informed Consent - https://pacificu.co1.qualtrics.com/jfe/form/SV_bg6spQiNp5c7hFr
CBT-I Firefighter Documenting the Consent Process - https://pacificu.co1.qualtrics.com/jfe/form/SV_b7t1BYPwU0WPZFb
CBT-I Firefighter Baseline Survey - https://pacificu.co1.qualtrics.com/jfe/form/SV_73bFpmL6X77BhHv
CBT-I Firefighter Post-Intervention Survey - https://pacificu.co1.qualtrics.com/jfe/form/SV_1Y5dbW6A6Fh3DVP
CBT-I Firefighter 3mo Follow-Up Survey - https://pacificu.co1.qualtrics.com/jfe/form/SV_2uFCDpowJecMjVr

Please also provide a PDF of the survey as a separate upload.

☐ Surveys (paper) - Please upload as a separate document.

☒ Other (if other, please list all other forms of data collection below)

Participants will be instructed to wear the Fitbit Inspire HR wrist worn devices throughout the duration of the intervention and for two weeks following completion of the 6-week intervention to collect objective data on enduring sleep changes. Fitbit web accounts and associated gmail.com accounts will be set up for each participant using only participant ID number and non-identifying information. Only authorized study personnel will have access to these accounts for data collection purposes.

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Request for Exemption

Study Title

A Pilot Study of Cognitive Behavioral Therapy – Insomnia (CBT-I) among Professional Firefighters

Research Personnel

Investigator(s)

Faculty Investigator (required for student investigator research)

Clinical Investigation

Clinical Investigation ☒ **YES** ☐ **NO**

Please provide all Clinical Investigation Information on the *IRB Proposal Guidance Document*.

Study Overview

1. Purpose of the Study?
Briefly describe the hypothesis to be tested or the research question to be addressed.

2. What is the basis of this undertaking?
Briefly describe the nature of the project. Is this a program evaluation, action research, or a classroom activity, for example.

3. What do you plan to do with the results of this study?
Enter information here about how the results will be used, either by you or other parties. How will the results be shared or disseminated?

Describe if permission is required from a study location (i.e., to conduct your study at that location, etc.) and, if so, how that permission will be obtained. Provide documentation (letters of supports, etc.) of any authorizations as a separately uploaded document on IRBNet.

Authorizations

Data Collection

Answer the following questions to help determine the nature of the data that will be used in your study. If your study will include both types of data listed below, answer YES to both questions.

Will you be gathering new data for your study? ☑ **YES** ☐ **NO**

Will you be using data that already exists (archival data)? ☐ **YES** ☑ **NO**

How will the data and study materials be treated after the study is complete?
Provide a detailed explanation of data storage, location of data storage, data security, and length of time for which data will be kept, etc.

Request for Exemption - New Data

Does the study involve interaction with living people? ☑ **YES** ☐ **NO**

If yes, describe the nature of the interaction or intervention. If no (e.g., observation data), describe why it does not constitute interaction or intervention.

Recruitment

1. Describe the Sample Size and relevant demographics.

2. Describe and justify the inclusion of any non-autonomous subjects. ☐ N/A

3. Eligibility Criteria?
List and describe the key characteristics necessary for participants in the study.

4. Exclusionary Criteria
List and describe the criteria that would exclude subject participation in the study (e.g., pregnancy, specific medical condition, English language fluency, age, etc.).

5. Recruitment Plan

Study Methodology

1. Location of the Study

2. Study Materials, Measures, and/or Apparatus to be Applied

3. Procedures

4. Timeline for Recruitment, Data Collection, Analysis, and Dissemination

Risks

Explain how the minimal risk criterion is met.

Adverse Events

How will adverse events be handled and reported?

Benefit or Compensation

1. Describe the specific unique benefits subjects will realize via their participation in this study, if any.

2. Describe the payment or other reward participants will receive, if any.

Privacy

How will you protect the privacy of your participants?

Informed Consent

1. How will informed consent be obtained and documented?
Describe the consent process for your study.

2. How will participant assent be obtained and documented?

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Proposal to Conduct Human Subjects Research

Study Title

A Pilot Study of Cognitive Behavioral Therapy – Insomnia (CBT-I) among Professional Firefighters

Research Personnel

Investigator(s)
Kaylie Green, M.S. (principal investigator), Nicole McCullough, EdS (co-investigator)

Faculty Investigator (required for student investigator research)
Michael Christopher, Ph.D.

Clinical Investigation

Clinical Investigation ☐ **YES** ☒ **NO**

Please provide all Clinical Investigation Information on the *IRB Proposal Guidance Document*.

Purpose

Provide enough relevant information to allow the IRB reviewers to understand the rationale and/or justification for the study and its merits (basic and/or applied), including any relevant study hypotheses and dissemination plans.

The purpose of this study is to investigate the feasibility, acceptability, and preliminary efficacy of an adapted Cognitive Behavioral Therapy - Insomnia (CBT-I) intervention in improving sleep in a firefighter population. The goals of this study include investigating whether a 6-week, virtually administered, culturally adapted, CBT-I intervention is feasible and acceptable for a firefighter population. Additional goals include investigating the impact of this intervention on parameters of sleep quality, depression, anxiety, stress, posttraumatic stress disorder, general health, vigilant attention, and family functioning within a firefighter population.

Recruitment

1. Describe the Sample Size and relevant demographics.

In order to obtain our minimum necessary sample size of 12 participants per arm (N=24) (based on a large anticipated effect size f= 0.41 an alpha of 0.05, and power of 0.80), at least 30 participants will be recruited to account for potential attrition. There are 347,570 full-time paid firefighters working in the United States and Canada with an average age of 38.8, 4.5% women, 9.2% Black, and 9% Latinx. We will be recruiting from a medium-sized fire department in the Pacific Northwest which may have slightly different demographics than the larger United States and Canada population, but it is expected that demographics will be similar.

2. Describe and justify the inclusion of any non-autonomous subjects. ☒ N/A

3. Eligibility Criteria?

List and describe the key characteristics necessary for participants in the study.

Requirements for inclusion in the study are: 1) English-speaking, 2) full-time professional firefighter, 3) at least 18 years of age, 4) a global Pittsburgh Sleep Quality Index score ≥ 5 (Grandner et al., 2006), 5) be willing and able to participate in all study activities including pre-, post-, and 3-month follow up assessments and 6-weeks of the CBT-I intervention, 6) agree to random assignment to one of two conditions (CBT-I or waitlist control group [WLC]), 7) have access to an email account, and 8) be willing to wear the Fitbit Inspire HR device throughout the duration of the intervention and for two weeks following completion of the 6-week intervention.

4. Exclusionary Criteria

List and describe the criteria that would exclude subject participation in the study (e.g., pregnancy, specific medical condition, English language fluency, age, etc.).

Participant exclusion criteria are: 1) endorsement of prior involvement in formal CBT-I interventions, and 2) unwillingness to give written informed consent. Research has cited that CBT-I may be beneficial for improving sleep in individuals with a wide range of conditions and variable demographics. Due to the wide range of potential benefit, a wide range of full-time firefighters will be recruited and should unforeseen disclosures of acute distress arise, the situation will be further evaluated by the principal investigator conducting the screening and assessments, who has several years of training as clinical psychology PhD student. If necessary, the faculty advisor, a licensed clinical psychologist will be contacted to further assess for participant safety.

5. Recruitment Plan

The chief of a moderate-sized, urban fire department within the Pacific Northwestern United States will be contacted via email to determine potential interest in the study and to gain approval on dissemination of study information within their department. Following approval from administration, information regarding the study will be disseminated through in-station fliers (mailed via USPS), email, and snowball recruitment. Potential participants will be encouraged to email the primary study investigator regarding interest and to arrange a screening appointment.

Study Methodology

1. Location of the Study

All study procedures will take place virtually via data-protected Zoom.

2. Study Materials, Measures, and/or Apparatus to be Applied

Self-report measures to be administered at three time points via Qualtrics Survey Software (pre-intervention, post-intervention, 3-month follow-up) include: a demographics questionnaire, The Pittsburgh Sleep Quality Index, Depression Anxiety Stress Scales -21, PTSD Checklist for DSM-5, Medical Outcomes Study 12-item Short-Form Survey, and McMaster Family Assessment Device - General Functioning Scale. The Consensus Sleep Diary will be completed by participants throughout the intervention and emailed weekly via participant's personal emails. Objective measures to be administered at three time points (pre-intervention, post-intervention, 3-month follow-up) include: The Psychomotor Vigilance Task (administered remotely via Inquisit Web software). Fitbit Inspire HR wrist worn devices will be worn by study participants throughout the intervention to assess objective sleep quality. Fitbit web accounts and associated gmail.com accounts will be set up for each participant using only participant ID number and non-identifying information. Only authorized study personnel will have access to these accounts for data collection purposes. Additional measures include participant weekly CBT-I attendance, which will be tracked and analyzed based upon average percentage of total number of sessions attended. Adherence to intervention components will be tracked via compliance with recommendations for the previous week. Acceptability will be assessed using four self-report questions derived from similar studies; the degree to which the participant liked the program, whether they found the home practice/requirements reasonable, whether they would recommend the program to a colleague, and whether they would take the program again in the future. Fidelity will be assessed to ensure therapist adherence to the intervention protocol in each session. A fidelity adherence measure of covered session topics, covered activities, and global instructor skill in presenting material will be used to for each weekly session. Sessions will be audio recorded and two research assistants will independently rate each item regarding covered session topics and covered activities on a 3-point Likert-type scale.

3. Procedures

All study procedures will be reviewed by the Pacific University IRB. Recruitment for this study will begin immediately following IRB approval. The chief of a moderate-sized, urban fire department within the Pacific Northwestern United States will be contacted to determine potential interest in the study and to gain approval on dissemination of study information within their department. Following approval from administration, information regarding the study will be disseminated through in-station fliers, handouts, email, and snowball recruitment. Potential participants will be encouraged to email or call the primary study investigator regarding interest and to arrange a screening appointment held virtually via data-protected Zoom. Prior to the screening appointment, participants will be emailed a PDF copy of the informed consent and a link to the Qualtrics CBT-I Firefighter Remote Informed Consent Survey (through which they will virtually sign the informed consent following review with the study coordinator).

During the screening appointment, participants will be verbally screened for eligibility given that screening will not entail questions regarding sensitive information. If eligible, participants will review informed consent with the study coordinator, following along with their own copy. The study coordinator will answer any questions that arise and ensure understanding and that all questions have been answered. Upon completion of review of the informed consent, participants will be instructed to open the link to the Qualtrics CBT-I Firefighter Remote Informed Consent Survey and will voluntarily attest to, sign, and date the informed consent. Upon completion, the study coordinator will ensure that the informed consent has been properly signed and dated. The study coordinator will then complete the Qualtrics CBT-I for Firefighters Documenting the Consent Process Survey which will record the time and date the consenting process took place and supporting information regarding the consenting process for the given participant. The study coordinator will sign and date the Qualtrics CBT-I for Firefighters Documenting the Consent Process Survey. Following the screening appointment, the study coordinator will mail the participant a copy of the signed and dated informed consent for the participant's record. Any hard copies of the informed consent forms will be stored in a locked filing cabinet in the research lab and will not be stored with any other study material.

The study coordinator will then send another email to the participant containing the link and instructions to complete the Qualtrics Baseline Survey, and instructions to download the Internet-based program called Inquisit for completing the PVT. Participants will be instructed to complete baseline assessments via computer (PSQI, DASS-21, PCL-5, SF12v2, FAD-GFS, and PVT). Following completion of these baseline assessments, participants will be randomly assigned (via 1.5:1 ratio (CBT-I:WLC) to one of two groups (CBT-I or WLC). The sample will be stratified by gender. Participants assigned to the WLC group will be provided the opportunity to participate in CBT-I following the study. The data collected from participants during this study will be identified only by a unique participant ID number that will be generated prior to the study. Participant contact information will be collected using the Participant Contact Information form in order to contact participants by phone or email for study assessment sessions, dissemination of study materials, and to provide data-protected Zoom links for the intervention sessions. Once all contact information is collected, the information will be entered into a master key and all hard copies of the Participant Contact Information form will be destroyed. Participant contact information will be permanently deleted following completion of the study. Electronic records will be stored on secure encrypted servers and available only to authorized personnel with a password. Survey questionnaires will be collected and stored using an internet-based program called Qualtrics that operates on a secure server. Vigilant attention task data will be collected and stored using an internet-based program called Inquisit and securely stored on Millisecond Software's server. Once downloaded, all data will be stored in HIPAA compliant Box files on Pacific University's secure encrypted servers.

Fitbit Inspire HR devices will be mailed to participants in both groups via tracked USPS mail, and the CSD (sleep diaries) will be distributed via email to participants randomized to the CBT-I group. Participants will be instructed to wear the Fitbit throughout the duration of the intervention and for two weeks following completion of the 6-week intervention to collect objective data on enduring sleep changes. Fitbit sleep data will be collected from participants via Fitbit web profiles that will be set up using non-identifying information. This will also require that we set up a non-identifying email for each participant profile that will include only participant ID number (Gmail. com email accounts will be set up for each participant using non-identifying information using only participant ID number). Only authorized study personnel will have access to the non-identifying email (Gmail.com email account) account and the Fitbit web profiles to collect and record data. Participants will not have direct access to this profile. Authorized study personnel will view the profiles weekly to sync the sleep quality data and record it within HIPPA compliant Box files, which only include participant ID numbers. Fitbit web profiles and Gmail.com accounts will be deactivated and deleted following study completion. Participants will mail Fitbit Inspire HR devices back to the study coordinator following the study using pre-paid, study provided envelopes.

Participants randomized to the CBT-I group will complete the CSD for the week prior to the first CBT-I session and continue to complete it throughout the intervention. CSD will be emailed back to the study coordinator weekly and data will be recorded into a HIPAA compliant Box file using only participant ID number. Sessions will be led by two graduate student therapists under the supervision of a

licensed clinical psychologist experienced in CBT-I interventions and studies involving first responders.

As part of the aim to increase the feasibility of this intervention for firefighters, two CBT-I groups will be offered concurrently. The two groups sessions will be provided each week on back-to-back days (i.e., Monday and Tuesday via data-protected Zoom and will be designed to cover the same material. Participants will be instructed to attend only one of the two sessions each week, but will be allowed the discretion to choose which they would attend. This addition to the study design was included due to the nature of firefighter shift schedules (i.e., 24-hour rotating shifts), that might otherwise limit ability to attend.

CBT-I group intervention sessions will be audio recorded to ensure that sessions are covering the appropriate and expected material. Participants will consent to audio recording during the informed consenting process and will be informed that all audio recordings will be destroyed upon completion of the study. Audio recordings will be immediately uploaded to secure HIPAA-protected files and the original audio recording will be deleted. Study staff who transcribe and code the audio recordings will not be involved in the trainings and therefore and will not be able to identify participants from the audio recordings. All audio recordings will be destroyed at the completion of the study.

Participants in both groups (CBT-I and WLC) will complete a similar battery of assessments (PSQI, DASS-21, PCL-5, SF12v2, FAD-GFS, and PVT) via Qualtrics CBT-I for Firefighters Post-Intervention Survey following the last CBT-I intervention session. Measures will be repeated again for both groups at 3-month follow-up via the Qualtrics CBT-I for Firefighters 3mo Follow-Up Survey, with the exception of Fitbit measurements.

Results of this study will only be presented as average responses that are grouped together with other study participants. We will not present individual responses or any personally identifiable information.

4. Timeline for Recruitment, Data Collection, Analysis, and Dissemination

Recruitment will begin as soon as IRB approval is obtained and will last for 60 days. Screening appointments and baseline assessments will occur on a rolling basis within those 60 days as participants express interest in the study. The first intervention session will occur 60 days after recruitment begins. Firefighters assigned to the CBT-I group will then participate in the 6-weeks of intervention, post-assessment, and a 3-month follow-up assessment. Data analysis will subsequently occur throughout the next 60 days and a write up and review will ensue. Then a formal dissertation defense will be scheduled and the data will be disseminated. Secondary dissemination in the form of publication will follow, if possible, in the next six months. Total project duration approximately one year.

Risks

1. Specifically identify and briefly describe the various risks to which participants may be exposed.

Participation in this study will pose minimal risk. Participants will engage in an 6-week Cognitive Behavioral Therapy – Insomnia (CBT-I) course, or in a no-intervention control group. The safety of the CBT-I course has been examined in numerous studies. Participants may experience minor physical or emotional discomfort during training related habit and behavior changes (i.e., exiting bed if not feeling sleepy may induce fatigue or frustration). It is possible that participants may experience distress when engaging in the vigilant attention task or answering questionnaire items related to sensitive information. There is minimal psychological risk associated with answering questions about how participants are feeling and functioning, and exposure to traumatic work and life events that could affect participants' mood. However, these risks are considered minimal to the extent that they are no greater than those ordinarily encountered in daily life. When providing information for study purposes, there is a risk that this information will not remain confidential. The investigators take this issue very seriously and every effort will be made to remove identifiers and keep information in a secure environment.

2. Describe the likelihood of these risks occurring, how they can and will be minimized, and how they will be handled should they occur.

Several safety measures will be put in place to ensure the safety, comfort, and confidentiality of participants. Care will be taken to inform potential participants fully, before they consent to participate, about all potential risks that may arise from their participation. If a participant endorses emotional distress as a result of completing an assessment, they will be further evaluated by the principal investigator conducting the assessments, who has several years of training as clinical psychology PhD student. If necessary, the faculty advisor, a licensed clinical psychologist will be contacted to further assess for participant safety. Regarding confidentiality, the data collected from participants during this study will be identified only by a unique participant ID number that will be generated prior to the study. Participant contact information will be collected using the Participant Contact Information form in order to contact participants by phone or email for

study assessment sessions, dissemination of study materials, and to provide data-protected Zoom links for the intervention sessions. Once all contact information is collected, the information will be entered into a master key and all hard copies of the Participant Contact Information form will be destroyed. Participant contact information will be permanently deleted following completion of the study. Electronic records will be stored on secure encrypted servers and available only to authorized personnel with a password. Survey questionnaires will be collected and stored using an internet-based program called Qualtrics that operates on a secure server. Vigilant attention task data will be collected and stored using an internet-based program called Inquisit and securely stored on Millisecond Software's server. Once downloaded, all data will be stored in HIPAA compliant Box files on Pacific University's secure encrypted servers.

Fitbit sleep data will be collected from participants via Fitbit web profiles that will be set up using non-identifying information, using a non-identifying email including only participant ID number (Gmail.com email accounts will be set up for each participant using non-identifying information using only participant ID number). Only authorized study personnel will have access to the non-identifying email (Gmail.com email account) account and the Fitbit web profiles to collect and record data. Authorized study personnel will view the profiles weekly to sync the sleep quality data and record it within HIPPA compliant Box files, which only include participant ID numbers. Fitbit web profiles and Gmail.com accounts will be deactivated and deleted following study completion.

Consensus Sleep Diaries will be emailed back to the study coordinator weekly and data will be recorded into a HIPPA compliant Box file using only participant ID number.

CBT-I group intervention sessions will be audio recorded to ensure that sessions are covering the appropriate and expected material. Participants will consent to audio recording during the informed consenting process and will be informed that all audio recordings will be destroyed upon completion of the study. Audio recordings will be immediately uploaded to secure HIPAA-protected files and the original audio recording will be deleted. Study staff who transcribe and code the audio recordings will not be involved in the trainings and therefore and will not be able to identify participants from the audio recordings. All audio recordings will be destroyed at the completion of the study.

Results of this study will only be presented as average responses that are grouped together with other study participants. We will not present individual responses or any personally identifiable information.

If the investigator(s) become aware of an adverse event, the IRB office will be notified by the next normal business day for minor events (e. g., emotional distress triggered by study questions about emotionally charged life events) and within 24 hours for major events (e.g., physical injury).

3. Describe any element(s) of deception of meaningful withholding of information associated with the study methodology.

N/A

4. Describe any treatment alternatives that may be advantageous to subjects, if clinical investigations are involved.

N/A

Adverse Events

How will adverse events be handled and reported?

In the event that participants become sick, injured, distressed, or otherwise uncomfortable as a result of their involvement in the research study, they may stop participation immediately. If such an event occurs, participants should promptly notify the principal investigator or the Pacific University Institutional Review Board. These contact numbers will be provided to participants.

If the investigator(s) become aware of an adverse event, the IRB office will be notified by the next normal business day for minor events (e. g., emotional distress triggered by study questions about emotionally charged life events) and within 24 hours for major events (e.g., physical injury, reported suicidal or homicidal ideation by a participant, report of a serious psychological reaction by a participant, accidental loss or disclosure of participant data, other violation of participant privacy).

If participants experience or are directly affected by an adverse event, they will be given the opportunity to withdraw any data collected from them during the study up to publication of the study results (after which point the data cannot be withdrawn).

Benefit or Compensation

1. Describe the specific unique benefits subjects will realize via their participation in this study, if any.

It is not known if there are any direct benefits to study participants. The information gained from this study may contribute to scientific knowledge about how the training program being studied affects well-being in firefighters. Participants may or may not experience psychological and/or physical improvement in any or all of the following areas: sleep quality, depression, anxiety, stress, post traumatic stress disorder, general health, vigilant attention, and family functioning.

2. Describe the payment or other reward participants will receive, if any.

Participants will not receive payment, reward, or compensation for participation in the study.

Privacy

How will you protect the privacy of your participants?

The data collected from participants during this study will be identified only by a unique participant ID number that will be generated prior to the study. Participant contact information will be collected using the Participant Contact Information form in order to contact participants by phone or email for study assessment sessions, dissemination of study materials, and to provide data-protected Zoom links for the intervention sessions. Once all contact information is collected, the information will be entered into a master key and all hard copies of the Participant Contact Information form will be destroyed. Participant contact information will be permanently deleted following completion of the study. Electronic records will be stored on secure encrypted servers and available only to authorized personnel with a password. Survey questionnaires will be collected and stored using an internet-based program called Qualtrics that operates on a secure server. Vigilant attention task data will be collected and stored using an internet-based program called Inquisit and securely stored on Millisecond Software's server. Once downloaded, all data will be stored in HIPAA compliant Box files on Pacific University's secure encrypted servers.

Fitbit sleep data will be collected from participants via Fitbit web profiles that will be set up using non-identifying information, using a non-identifying email including only participant ID number (Gmail.com email accounts will be set up for each participant using non-identifying information using only participant ID number). Only authorized study personnel will have access to the non-identifying email (Gmail.com email account) account and the Fitbit web profiles to collect and record data. Authorized study personnel will view the profiles weekly to sync the sleep quality data and record it within HIPPA compliant Box files, which only include participant ID numbers. Fitbit web profiles and Gmail.com accounts will be deactivated and deleted following study completion.

Consensus Sleep Diaries will be emailed back to the study coordinator weekly and data will be recorded into a HIPPA compliant Box file using only participant ID number.

CBT-I group intervention sessions will be audio recorded to ensure that sessions are covering the appropriate and expected material. Participants will consent to audio recording during the informed consenting process and will be informed that all audio recordings will be destroyed upon completion of the study. Audio recordings will be immediately uploaded to secure HIPAA-protected files and the original audio recording will be deleted. Study staff who transcribe and code the audio recordings will not be involved in the trainings and therefore and will not be able to identify participants from the audio recordings. All audio recordings will be destroyed at the completion of the study.

Results of this study will only be presented as average responses that are grouped together with other study participants. We will not present individual responses or any personally identifiable information.

Informed Consent

1. How will informed consent be obtained and documented?

Describe the consent process for your study.

Prior to the screening appointment, participants will be emailed a PDF copy of the informed consent and a link to the Qualtrics Remote Informed Consent Survey (through which they will virtually sign the informed consent).

During the screening appointment, participants will be verbally screened for eligibility given that screening will not entail questions regarding sensitive information. If eligible, participants will review informed consent with the study coordinator, following along with their own copy. The study coordinator will answer any questions that arise and ensure understanding and that all questions have been answered. Upon completion of review of the informed consent, participants will be instructed to open the link to the Qualtrics Remote Informed Consent Survey and will voluntarily attest and sign and date the informed consent. Upon completion, the study coordinator will ensure that the informed consent has been properly signed and dated. The study coordinator will then complete the Qualtrics Documenting Consent Survey which will record the time and date the consenting process took place and supporting information regarding the consenting process for the given participant. The study coordinator will sign and date the Qualtrics Documenting Consent Survey. Following the screening appointment, the study coordinator will mail the participant a copy of the signed and dated informed consent for the participant's record. Any hard copies of the informed consent forms will be stored in a locked filing cabinet in the research lab and will not be stored with any other study material.

2. How will participant assent be obtained and documented?

N/A

Institutional Review Board
2043 College Way | UC Box A-133 | Forest Grove, OR 97116
(P) 503.352.1478 | (F) 503.352.1447 | (E) irb@pacificu.edu
(W) www.pacificu.edu/about-us/offices/institutional-review-board

Informed Consent

Study Title

A Pilot Study of Cognitive Behavioral Therapy – Insomnia (CBT-I) among Professional Firefighters

Research Personnel and Contact Information

Personnel #1	
Name **Kaylie Green, MS**	**Role** Principal Investigator
Institution Pacific University	**Program** School of Graduate Psychology
Email gree9218@pacificu.edu	**Telephone** 503-352-2498
Scope ☒ Recruitment ☒ Consent Process ☒ Data Collection ☒ Data Analysis (with personally identifiable information) ☒ Data Analysis (de-identified data) ☐ Other: Group co-facilitator	

Delete this Personnel entry

Personnel #2	
Name **Michael Christopher, PhD**	**Role** Faculty Principal Investigator
Institution Pacific University	**Program** School of Graduate Psychology
Email mchristopher@pacificu.edu	**Telephone** 503-352-2498
Scope ☒ Recruitment ☒ Consent Process ☒ Data Collection ☒ Data Analysis (with personally identifiable information) ☒ Data Analysis (de-identified data) ☒ Other: Dissertation Supervisor / Faculty Investigator	

Delete this Personnel entry

Personnel #3	
Name **Nicole McCullough, EdS**	**Role** Co-Investigator
Institution Pacific University	**Program** School of Graduate Psychology
Email nicole.r.mccullough@gmail.com	**Telephone** 503-352-2498
Scope ■ Recruitment ■ Consent Process ■ Data Collection ■ Data Analysis (with personally identifiable information) ■ Data Analysis (de-identified data) ■ Other: Group co-facilitator	

Delete this Personnel entry

Add Personnel

Study Invitation | Purpose | Location | Dates

You are invited to participate in a research study assessing the impact of an intervention intended to improve sleep quality. Cognitive Behavioral Therapy – Insomnia (CBT-I) will be compared to participation in a no-intervention control group. The purpose of this study is to investigate the feasibility, acceptability, and preliminary efficacy of an adapted Cognitive Behavioral Therapy - Insomnia (CBT-I) intervention in improving sleep in a firefighter population. The goals of this study include investigating whether a 6-week, virtually administered, culturally adapted, CBT-I intervention is feasible and acceptable for a firefighter population. Additional goals include investigating the impact of this intervention on parameters of sleep quality, depression, anxiety, stress, posttraumatic stress disorder, general health, vigilant attention, and family functioning within a firefighter population. This study aims to recruit 35 (maximum) eligible participants.

This study has been approved by the Pacific University Institutional Review Board. It will be conducted at Pacific University from Spring 2021 to Spring 2022. It is anticipated that the results of this study will be presented at relevant conferences and in research publications. These presentations and websites will not include information that can identify you. At most, the website will include a summary of the results.

Participant Characteristics and Exclusionary Criteria

Participants must meet the following requirements to participate in the study: 1) English-speaking, 2) full-time professional firefighter, 3) at least 18 years of age, 4) have a global Pittsburgh Sleep Quality Index score ≥ 5, 5) be willing and able to participate in all study activities including pre-, post-, and 3-month follow up assessments and 6-weeks of the CBT-I intervention, 6) agree to random assignment to one of two conditions, 7) have access to an email account, and 8) be willing to wear the Fitbit Inspire HR device throughout the duration of the intervention and for two weeks following completion of the 6-week intervention. Participants must not: 1) endorse prior involvement in formal Cognitive Behavioral Therapy – Insomnia (CBT-I) interventions, and 2) will be excluded if unwilling to give written informed consent.

Study Materials and Procedures

Study Screening
If you choose to participate in this study, you will be asked screening questions today to determine if you are eligible. This will include questions about basic demographics (age, employment status, etc.), prior involvement in formal CBT-I interventions, and sleep habits. The screening should last about 20 minutes, including time to review this Informed Consent form.

Participating in this study requires that you must have access to an email account. The virtual nature of this study requires the use of a phone, tablet, laptop, or desktop computer. If you do not have access to one of these devices, please let the study coordinator know during the consenting process and we will loan you one for the duration of the study. You also must be able to control the space from which you are communicating to ensure no other individuals are able to hear or read your responses or those of the investigators, as well as to maintain confidentiality of group members during the Cognitive Behavioral Therapy – Insomnia (CBT-I) intervention sessions.

Online Assessments
If you are eligible, you will complete 3 online assessment visits over the course of about 5 months. Each of the 3 study assessment visits will be completed remotely through data-protected Zoom and will last about one hour each. Your first Baseline study visit will be scheduled today and must be completed before the start of the intervention sessions. Once the intervention sessions are complete you will complete a post-training assessment visit. You will also complete assessment study visit 3 months after the intervention sessions have ended.

Online assessment visits will involve the following procedures:

Vigilant Attention Task and Questionnaires: We will ask you to complete a number of computer-administered questionnaires and an online basic attention task during the 3 assessment visits. We prefer you use a computer and be in a private place where you will not be distracted if possible. You will be asked to download a player app to be able to complete the online attention task, and can delete the player immediately after the task is complete.

Training Courses and Random Assignment:
After the Baseline study visit you will be randomly assigned to one of two conditions:

The Cognitive Behavioral Therapy – Insomnia (CBT-I) course focuses on mitigating poor sleep quality and promoting the adoption of behaviors conducive to quality sleep. This course includes modules on developing habits conducive to better sleep, adapting variable bedroom environments, and establishing techniques to reduce worry and frustration around falling asleep.

Non-Intervention Control Group (NIC) will not receive training during the course of the study, but will be offered the opportunity to receive training after the study ends.

Random assignment is similar to a coin toss and allows research studies to better assess the impacts of their training programs being studied. The study coordinator will let you know what group you are randomly assigned to and the exact dates and times the training courses will take place.

As part of the aim to increase the feasibility of this intervention for firefighters, two CBT-I groups will be offered concurrently. The two groups sessions will be provided each week on back-to-back days (i.e., Monday and Tuesday and will be designed to cover the same material. You should attend only one of the two sessions each week, but will be allowed the discretion to choose which best fits with your work schedule. You should only join the study if you can be available to attend the training courses during the dates and times offered (i.e., one class per week).

If you are randomly assigned to the CBT-I group, you will meet on data-protected Zoom once a week for 6 weeks as a group with other full-time firefighters who are eligible and have agreed to participate in the study. These intervention sessions will be 1-1 ½ hours long. The group intervention sessions include education, discussion, problem solving components, and weekly home practices to help integrate course material into daily life. The intervention sessions will be audio recorded to assure instructors are providing the sessions in a consistent way and to allow supervision and feedback to the instructors. You may be asked to watch videos or look at various handouts outside of the training sessions. This material will be emailed to you via the email you provided during the informed consent/screening process.

As part of the study, Fitbit Inspire HR devices will be mailed to participants in both groups via tracked USPS mail, You will be instructed to wear the Fitbit throughout the duration of the intervention and for two weeks following completion of the 6-week intervention to collect objective data on enduring sleep changes. Fitbit sleep data will be collected from you via Fitbit web profiles that study coordinators will set up using non-identifying information. This will also require that we set up a non-identifying email for your profile that will include only your participant ID number (Gmail.com email accounts will be set up for each participant using non-identifying information using only participant ID number). Only authorized study personnel will have access to the non-identifying email (Gmail.com email account) account and the Fitbit web profiles to collect and record data. You will not have direct access to this profile. Authorized study personnel will view the profiles weekly to sync the sleep quality data and record it within HIPPA compliant Box files, which only include participant ID numbers. Fitbit web profiles and Gmail.com accounts will be deactivated and deleted following study completion.

If you are randomly assigned to the NIC group, you will not attend the intervention sessions during the course of the study. At the end of your participation in the study, you will have the opportunity to attend the CBT-I training course.

Time Requirements:
If you agree to take part in this study, you will be asked to complete three 60-minute study assessment visits over about 5 months. These will all be via data-protected Zoom. If you are randomly assigned to the CBT-I group, you will also attend 6 days of training for a total of 6-9 training hours, and asked complete home practices that may vary in time requirements. The total time for these study activities are about 12 hours for participants of the CBT-I group and 3 hours for participants of the NIC group.

Risks | Risk Reduction Steps | Clinical Alternatives

1. Anticipated Risks and Strategies to Minimize or Avoid Risk

1. Anticipated Risks and Strategies to Minimize or Avoid Risk
Participation in this study will pose minimal risk. You will engage in a 6-week Cognitive Behavioral Therapy – Insomnia (CBT-I) course, or in a no-intervention control group. The safety of the CBT-I course has been examined in numerous studies. You may experience minor physical or emotional discomfort during training related habit and behavior changes (i.e., exiting bed if not feeling sleepy may induce fatigue or frustration). It is possible you may experience distress when engaging in the vigilant attention task or answering questionnaire items related to sensitive information. There is minimal psychological risk associated with answering questions about how you are feeling and functioning, and exposure to traumatic work and life events that could affect your mood. However, these risks are considered minimal to the extent that they are no greater than those ordinarily encountered in daily life. When providing information for study purposes, there is a risk that this information will not remain confidential. The investigators take this issue very seriously and every effort will be made to remove identifiers and keep your information in a secure environment.

2. Unknown Risks

2. Unknown Risks
It is possible that participation in this study may expose you (or an embryo or fetus, if you are or become pregnant) to currently unforeseeable risks.

3. Advantageous Clinical Alternatives

3. Advantageous Clinical Alternatives
The alternative to participating in this research study is to not participate and to seek treatment or a similar training in the community.

Adverse Event Handling and Reporting Plan

In the event that you become sick, injured, distressed, or otherwise uncomfortable as a result of your involvement in the research study, you may stop your participation immediately. If such an event occurs, promptly notify the principal investigator or the Pacific University Institutional Review Board.

In the event that you become sick, injured, distressed, or otherwise uncomfortable as a result of your involvement in the research study, you may stop your participation immediately. If such an event occurs, promptly notify the principal investigator or the Pacific University Institutional Review Board.

If the investigator(s) become aware of an adverse event, the IRB office will be notified by the next normal business day for minor events (e.g., emotional distress triggered by study questions about emotionally charged life events) and within 24 hours for major events (e.g., physical injury, reported suicidal or homicidal ideation by a participant, report of a serious psychological reaction by a participant, accidental loss or disclosure of participant data, other violation of participant privacy).

If you experience or are directly affected by an adverse event, you will be given the opportunity to withdraw any data collected from you during the study up to publication of the study results (after which point the data cannot be withdrawn).

Direct Benefits and/or Payment to Participants

a. Benefit(s)

a. Benefit(s) —It is not known if there are any direct benefits to you as a study participant. The information gained from this study may contribute to scientific knowledge about how the training program being studied affects well-being in firefighters. Participants may or may not experience psychological and/or physical improvement in any or all of the following areas: sleep quality, depression, anxiety, stress, post traumatic stress disorder, general health, vigilant attention, and family functioning.

b. Payment(s) or Reward(s)

N/A

Promise of Privacy

We will take several steps to ensure your privacy. Data will be kept in a confidential manner. Electronic records will be stored on secure encrypted servers and available only to authorized personnel with a password. The Informed Consent form will be signed prior to data collection and will be collected and stored using an internet-based program called Qualtrics that operates on a secure server. Questionnaire data will also be collected and stored using Qualtrics and securely stored on the company's server. Vigilant attention task data will be collected and stored using an internet-based program called Inquisit and securely stored on Millisecond Software's server. Once downloaded all data will be stored in HIPAA compliant Box files on Pacific University's secure encrypted servers.

The data collected from you during this study will be identified only by a unique ID number that will be generated prior to the study. Your name and other directly identifiable information will be stored separately from your study data. Only authorized study team members will be able to link your identifiable information with your ID number.

Once all contact information is collected, authorized study team members will enter the information into a master key stored in HIPAA compliant Box files on Pacific University's secure encrypted servers and, if necessary, destroy all hardcopies of the Participant Contact Information form. Participant contact information will be permanently deleted following completion of the study.

Fitbit sleep data will be collected from you via Fitbit web profiles that study coordinators will set up using non-identifying information. This will also require that we set up a non-identifying email for your profile that will include only your participant ID number (Gmail.com email accounts will be set up for each participant using non-identifying information using only participant ID number). Only authorized study personnel will have access to the non-identifying email (Gmail.com email account) account and the Fitbit web profiles to collect and record data. You will not have direct access to this profile. Authorized study personnel will view the profiles weekly to sync the sleep quality data and record it within HIPPA compliant Box files, which only include participant ID numbers. Fitbit web profiles and Gmail. com accounts will be deactivated and deleted following study completion.

The university uses a Protected Zoom account that provides extra security. You will have the option to change your screen name in Zoom if you choose. Your study assessment visits held on Zoom will not be recorded. The CBT-I sessions will be audio recorded. Audio recordings will be immediately uploaded to secure HIPAA-protected files and the original audio recording will be deleted. Study staff who transcribe and code the audio recordings will not be involved in the trainings and therefore and will not be able to identify participants from the audio recordings. All audio recordings will be destroyed at the completion of the study.

CBT-I sessions will be held in a group format, meaning that other firefighters will be participating in the sessions at the same time. There is an inherent risk to confidentiality by participating in a group intervention. Study coordinators will emphasize that participants in the study keep participant identity and discussions confidential. Participants will be asked to ensure they are in a private space during interventions sessions.

Results of this study will only be presented as average responses that are grouped together with other study participants. We will not present individual responses or any personally identifiable information. None of your responses to any of the study materials will be shared with anyone at your fire department.

Medical Care and Compensation in the Event of Accidental Injury

☐ **N/A**

During your participation in this project it is important to understand that you are not a Pacific University clinic patient or client, nor will you be receiving complete [state the appropriate kind of care (e.g., medical care, eye care, mental health care, physical therapy, etc.)] as a result of your participation in this study. If you are injured during your participation in this study and it is not due to negligence by Pacific University, the investigator(s), or any organization associated with the research, you should not expect to receive compensation or medical care from Pacific University, the investigator(s), or any organization associated with the study. If you are injured and it directly is related to your participation in this study as a research subject, please contact the Pacific University Institutional Review Board at 503-352-1478.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate will not affect your relationship with the university or your fire department. You may choose to skip any question you would prefer not to answer or withdraw from the study at any time without negative consequences. If you choose to withdraw after beginning the study, the data you have already provided will be destroyed up to the date that the data is published (after which the data cannot be withdrawn). If significant new findings are discovered during the course of this research that could impact your decision to continue participation, such findings will be shared with you and you will be given the opportunity to withdraw from the study.

Contacts and Questions

The investigator(s) will be happy to answer any questions you may have at any time during the course of the study. If you are not satisfied with the answers you receive, please call the Pacific University Institutional Review Board at 503-352-1478 to discuss your questions or concerns further. If you have questions about your rights as a research subject, or if you experience a research-related injury of any kind, please contact the investigator(s) and/or the IRB office. All concerns and questions will be kept in confidence.

Statement of Consent

	YES	NO	
	____		I am 18 years of age or over.
	____		All my questions have been answered.
	____		I have read and understand the description of my participation duties.
	____		I have been offered a copy of this form to keep for my records.
	____	____	I voluntarily agree to participate in this study and understand that I may withdraw at any time without consequence.
x	____	____	I am a full-time professional firefighter.
x	____	____	I agree to randomization.
x	____	____	I agree to participate in all study activities including pre-, post-, and 3-month follow up assessments and 6-weeks of the CBT-I intervention if randomized to receive the intervention to the best of my ability.
x	____	____	I voluntarily consent to audio recording of the CBT-I group sessions.
x	____	____	I have access to an email account that I am willing to use for this study.
x	____	____	I am willing to wear the Fitbit Inspire HR device throughout the duration of the intervention and for two weeks following completion of the 6-week intervention

Add Row

Signature	Date
Printed Full Name	Participant Study Role
Signature	Date
Printed Full Name	Study Role*

*This individual must be trained in obtaining informed consent and have authorization from the principal investigator and/or faculty advisor to do so.

Institutional Review Board
2043 College Way | UC Box A-133 | Forest Grove, OR 97116
(P) 503.352.1478 | (F) 503.352.1447 | (E) irb@pacificu.edu
(W) www.pacificu.edu/about-us/offices/institutional-review-board

Participant Contact Information

Study Title

A Pilot Study of Cognitive Behavioral Therapy – Insomnia (CBT-I) among Professional Firefighters

This contact information is required in case any issues arise with the study and you need to be notified and/or to provide you with the results of the study, if you wish.

Would you like to have a summary of the results after the study is completed? ☐ **YES** ☐ **NO**

Participant's Name (Please Print): _____ **Date of Birth:** _____

Parent/Guardian's Name (Please Print): _____

Address: _____

_____

_____

Telephone: _____ **Email Address:** _____

As part of ongoing compliance efforts, the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) may inspect any and all records pertaining to this study. OHRP and FDA auditors maintain strict confidentiality of all records reviewed.

Institutional Review Board
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(W) www.pacificu.edu/about-us/offices/institutional-review-board

Audio Recording Release

Study Title

A Pilot Study of Cognitive Behavioral Therapy – Insomnia (CBT-I) among Professional Firefighters

Audio Recording Release

I give permission to Pacific University to audio record me for research purposes. Such audio recordings may be used in association with articles, presentations, or displays in which the results of various research projects are reported. No commercial use may be made of my audio recordings. I understand that I may be identifiable in these audio recordings. I am 18 years of age or older, or this form has been signed by my parent/guardian. Please refer to the consent documentation for additional details regarding the use and storage of audio files.

Printed Name: _____

Signature: _____ **Date:** _____

Parent/Guardian's Name (Please Print): _____

Signature: _____ **Date:** _____

Address: _____

_____

_____

As part of ongoing compliance efforts, the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) may inspect any and all records pertaining to this study. OHRP and FDA auditors maintain strict confidentiality of all records reviewed.