Occupational Therapy's Role in Promoting Community Wellness Utilizing Sit-Stand Workstations

NCT03052426

IRB Approval Date: 2/2/2017

Protocol Questionnaire

Human Subject Research

Does the protocol meet the federal definition of research? For help determining the type of research you are conducting, see the DHHR Human Subject Regulations Decision Charts at http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html.
Yes

Does the research involve living person(s)?

Yes

Will information from individual person(s) be collected as part of this research?

Yes

Funding Source

Is there a secured funding source?

No

Locations of Research

Will the research take place at an off campus location?

No

Select the location(s) where the research will be conducted. At least one location must be selected.

WVU Campus

Will this study require an Inter-Institutional Authorization Agreement (IAA)?

No

Design

Does the research involve surveys/interviews/questionnaires? If so, attach a copy of the interview/survey questions on the Notes & Attachments page.
Yes

Will you be asking any questions that are likely to distress your subjects (e.g., questions about abuse, trauma, or suicide ideation)? If so, attach counseling services referral list on the Notes & Attachments page.
No

Please provide a lay summary (written at 6th grade level) that includes a statement about the purpose and the general aims of the research.
The aim of this study is to combat the growing global health issue of sedentary behavior and the associated health consequences of prolonged sitting in the workplace. The population of desk-based workers makes up a relatively large population and are an important target for this health promoting initiative with a focus on improving posture, encouraging movement, and fostering a more active and healthy business community. It's important to recognize that occupational therapy practitioners can contribute to community health promotion/disease prevention programs by the skill-set of practitioners to understand habits and routines that influence the adoption and maintenance of healthy behaviors.

Fully describe all procedures to be performed, from start to finish, numbering your procedures 1,2,3 or A, B, C (e.g., 1. Recruiting, 2. Consent, 3. Collecting data, 4. How findings will be shared, etc.).
1. Obtain IRB approval 2. Distribute fliers around the HSC building and send an email through the wellness office to all faculty and staff in the HSC building. 3. Make an Excel file of all interested participants. 4. Contact participants to ensure eligibility. 5. Randomly assign participants to one
of three groups: (1) Sit-Stand station with 4-6 educational sessions and instructions to alternate standing and sitting every 90 minutes, (2) Sit-stand station with 4-6 educational sessions and instructions to stand for 20-30 minutes every hour, (3) Sit-stand station with 4-6 educational sessions with instructions to alternate sitting and standing every hour. *all groups will attend same educational sessions. 5. Schedule meeting to review and collect informed consent documents and distribute and collect the Stages of Change Questionnaire, the Cornell Musculoskeletal Discomfort Questionnaire, and the Movement at Work Questionnaire. 6.Install sit-stand work stations in each participants office space. 7. Provide educational sessions on use of sit-stand workstations and the behavioral monitoring self-report form. 8. Within 2 weeks of installation of sit-stand workstation complete observation with each participant to ensure safe and efficient use. 9. Collect behavioral

monitoring self-report forms weekly from all participants. 10. Send reminder email or text prompts to participants for designated time intervals for the group which they are enrolled. 11. After 3 months re-distribute the Stages of Change Questionnaire, Cornell, and Movement at Work Questionnaires. 12. After 6 months re-distribute the Stages of Change Questionnaire, Cornell, and Movement at Work Questionnaires and collect all sit-stand workstations. 13. Clean and analyze data. 14. Write up report and prepare for presentation or publication.

Please describe the investigational procedures that will be performed throughout the duration of the study.
Observation of participants in natural working environment, questionnaires/surveys.

Please describe the standard of care procedures that will be performed throughout the duration of the study.
All participants will be given the same questionnaires/surveys and behavioral tracking forms. All participants will also receive the same education on the use of the sit-stand workstation and other helpful office ergonomic tips.

Will you be assigning or randomizing participants to groups or conditions (e.g., control, placebo)?

Yes

Describe the group assignment.

All the groups will receive the same educational sessions and complete the same questionnaires. The only difference in groups is in the instructions for alternating sit-stand time. One group will alternate every 20-30minutes, one every 60 minutes, and one every 90 minutes.

Describe what is known about this topic and why this study is needed. Please include at least two reference citations to support your rationale.
Prolonged sedentary activity and a reduction in human energy expenditure are detrimental to many domains of health. In recent years, "populations have become increasingly sedentary, with many adults spending a minimum of 70% of their waking hours sitting" with little neuromuscular stimulation (Owen, Sparling, Healy, Dunstan and Matthews, 2010). Desk-based workers make up a relatively large proportion of this population making them an important target for health promotion initiatives focusing on solutions to implement healthy workspaces and foster a more active business community. Although there is rich literature on the many benefits of reducing sedentary behavior, there is a call for further research on the feasibility and long-term effects of sit-stand desks on achieving this reduction in office settings (Grunseit, et al., 2012). Occupational therapy practitioners have the capacity to address this health issue with their background in community disease prevention and health promotion to improve an individual's wellness and quality of life. More research is also needed to establish the specific role of occupational therapy in workplace wellness interventions and apply

occupation in its natural settings such as the workplace by maximizing performance, function, and wellness. By implementing sit-stand work stations with educational sessions into offices of desk-based employees long-term, we will better be able to analyze how effective this strategy is at decreasing sitting time and measure health and behavioral outcomes associated with using this intervention. Grunseit, A. C., Chau, J. Y.-Y., van der Ploeg,

H. P., & Bauman, A. (2013). "Thinking on your feet": A qualitative evaluation of sit-stand desks in an Australian workplace. BMC Public Health, 13, 365. Owen, N., Sparling, P. B., Healy, G. N.,

Dunstan, D. W., & Matthews, C. E. (2010). Sedentary Behavior: Emerging Evidence for a New Health Risk. Mayo Clinic Proceedings, 85(12), 1138-1141. doi:10.4065/mcp.2010.0444

What method are you going to use to analyze the data?

Data will be coded and analyzed using a statistical software program. Any qualitative data that is collected will be member checked.

Expedited Review

Is this study only minimal risk?

Yes

Does the research qualify for Expedited Review Category 1 - use of FDA-approved medical device?
No

Does the research qualify for Expedited Review Category 2 - blood sample collection?

No

Does the research qualify for Expedited Review Category 3 - noninvasive collection of biological specimens?
No

Does the research qualify for Expedited Review Category 4 - noninvasive standard care procedures?
No

Does the research qualify for Expedited Review Category 5 - evaluation of data (e.g., medical records review)?"
No

Does the research qualify for Expedited Review Category 6 - voice, video, digital, or image recordings?
No

Does the research qualify for Expedited Review Category 7 - behavior, surveys, interviews, etc.?
Yes

Briefly describe how the research meets the requirements of the expedited category(ies) selected.

Participants will be required to complete multiple questionnaires as they participate in the intervention. The questionnaires will be assessing changes in behavior, movement at work, and discomfort at work.

Will subjects intentionally be deceived as to the purpose of the study?

No

Does the study involve intervention and/or manipulation of the subjects or the subjects' environment (e.g., educational intervention or training, experimental or quasi-experimental design)?
Yes

Describe how and where researchers will interact with participants, explaining how these interactions will be kept private.
Researchers will interact with participants on an individual basis in the participants private office space. In the event that the participant does not have a private office a private space will be reserved at the participants request.

Describe and assess any potential possibilities for risk or harm to the subjects as a result of their participation in the research, including discomforts, hazards, or inconveniences to the subjects. The primary inconvenience for the participants will be the need for them to clear a space to install the sit-stand work station at their desks. Depending on what group the participant is in, they will be asked to track how often they stand throughout the day which could be an inconvenience or potential discomfort. The sit-stand desk does have mechanical parts that could potentially pinch or injure a participant if not used correctly.

Is the research categorized as interventional medical research? No

HIPAA

Does the research involve protected health information (PHI)?

Yes

Will the HIPAA and consent forms be combined? If not, attach a separate HIPAA Authorization to the Notes & Attachments page.
Yes

Are you requesting a HIPAA waiver? If yes, attach a HIPAA Waiver Form on the Notes & Attachments page.
No

Will the research being conducted at a covered entity require authorization from the subject? If yes, attach a HIPAA Form on the Notes & Attachments page - only if a combined consent with HIPAA is not used.
No

Are you transferring identifiable data to or from another institution? If yes, attach a signed and WVU Legal Counsel approved HIPAA Data Use Agreement Form on the Notes & Attachments page.
No

Will the research being conducted at a covered entity involve data that is de-identified? If yes, attach a HIPAA De-Identification Certification Form on the Notes & Attachments page. You can find the form here (this is only for NHSR studies).
No

Will the study include deceased individuals? If yes, attach a HIPAA Decedents Form on the Notes & Attachments page.
No

Will data/samples with identifiers be received from another entity? If yes, attach a signed, Legal Counsel approved HIPAA Data Use Agreement Form on the Notes & Attachments page.
No

Subjects

Will any of the subjects be less than 18 years old?

No

Indicate the maximum number of subjects to be enrolled or medical records to be reviewed at all sites by the WVU or VAMC research team.
20

Provide a rationale for choosing your sample size.

This study will consist of 3 groups of 6 individuals receiving the sit-stand workstation. The workstations are being donated to us to complete the research. And 18-20 workstations is the max that we can receive.

State the requirement(s) to become a participant in the study (e.g., age range, sex, language spoken, class enrollment/ranking).
Participants must spend > 50% of their work day seated at the computer. Participants can be male or female and must be ages 18 years or older. Participants must be primarily English speaking. Participants must work within the Health Sciences Center building at West Virginia University.

Explain why selection of participants will be equitable addressing gender, ethnicity, and/or race of subjects.
Attempts will be made to choose 50% males and 50% females for the study. However, given
the nature of the work it is probable that we will have a higher percentage of females than males enrolled. No one will be ineligible based on race or ethnicity.

In outline format and chronological order, describe what will be done to identify and recruit participants (e.g., A, B, C or 1, 2, 3).
1. Fliers will be distributed throughout the HSC building and an email will be sent from the wellness program to all HSC faculty and staff. 2. Interested participants will contact a member of the research team who will verify their eligibility to participate. 3. If eligible, participants will placed on
a list in Excel with an email address or phone number to be contacted. 4. Participants will then be randomly drawn from the list and contacted to participate in the study. The team will draw 9-10 males and 9-10 females to participate. 5. In the event that there are 20 or fewer participants who are eligible all will be contacted to participate regardless of gender.

Will your study target any of the following vulnerable groups: cognitively impaired, pregnant women and fetuses, or prisoners?

No

Does this research involve participants who could be coerced or unduly influenced, such as current students/employees of research team members?
No

Does the protocol deal with cancer prevention, treatment, or diagnosis (including surveys)?

No

Has this protocol been reviewed by Clinical Trials Working Group (CTWG)? If yes, please attach the CTWG's correspondence on the Notes & Attachments page.
No

Consent Procedures

Will SIGNED informed consent be obtained from subjects (all or in part)?

Yes

Will the informed consent form be translated into any other language(s)?

No

Is a waiver of informed consent being requested (i.e., there will be no consent process at all)?

No

Describe the consent process (using 1, 2, 3 or A, B, C), addressing when, where, and how participants will be informed.
1. Once a participant is determined to be eligible he/she will be contacted by a member of the research team to set up a time to meet in a private space to go over the informed consent form. 2. Eligible participants will review the consent form and will be given the opportunity to ask any questions. 3. The member of the research team will answer any questions or clarify any areas on the form that need to be clarified. 4. Once there aren't any more questions and the participant is comfortable with the details of the study, the participant and research team member will sign the form. 5. Once the form has been signed the participant will place their master code (explained in the confidentiality section) on the consent form and remit it to one of the research team members.

Are you requesting an alteration of consent (e.g., short form, braille consent or witnessed verbal consent)?
No

Indicate who will be consenting subjects and describe the process of training all personnel who will be obtaining consent.
The PI or any of the Co-I's will be responsible for consenting subjects for the study. All of them have completed the required CITI trainings.

Is a waiver of the requirement to obtain written documentation of the consent process being requested (if yes, attach the information to be provided to the participants)?
No

Potential Benefits

Is there any known benefit to the individual subject as a result of participating in the research? Payments to subjects should not be included in this section, but addressed in the Payments/Reimbursements section.
Subjects will get to trial a sit-stand workstation free of cost during the timeframe in which they participate in the study. Potential benefits that can occur from the use of the sit-stand work station include but are not limited to: decreased discomfort with work tasks, increased productivity, decreased muscle strain, improved circulation, and increased energy.

Describe the potential benefit(s) to society and/or scientific / medical knowledge of the planned work.
Most studies that have examined the use of sit-stand work stations have not looked at the dose of sitting versus standing to determine if there is a difference. By examining this relationship we may be better able to provide guidelines for the use of this type of equipment.

Confidentiality

Does this study have a Federal Certificate of Confidentiality? If yes, attach the certificate on the Notes & Attachments page.
No

At any point during this study, will identifiable data be viewed or recorded?

Yes

Data must be kept for a minimum of three (3) years after study completion. In addition to the required 3 years, how much longer will the data be kept?
Data will only be kept for the minimum of 3 years.

Where will data be securely located?

The data will be securely located in a locked filing cabinet in the PI's office.

How will data be destroyed?

Data will be shredded upon reaching the 3 year timeframe.

Will anyone other than the PI, research team members, or IRB have access to the identifiable data (e.g., sponsor/funding source, other collaborators)?
No

Describe the steps that will be taken to maintain the privacy of subjects (e.g., where interaction takes place) and the confidentiality of data (e.g., master code).
Subjects will be provided with directions to create a master code from a member of the research team that will be used when they complete and return any questionnaires or

forms, including the consent form, related to the study. The master code will consist of the first two letters of the first name, last two digits of birth year, and first two letters of last name. The consent forms containing the master codes will be kept and stored separately from the data.

Financial Considerations

Will the subject be paid (money, gift certificates, coupons, etc.) to participate in this research project?
No

Will the subjects incur any costs to participate in this project (e.g., travel, physician fees, study procedures, study drugs)?
No

Will WVU students receive extra credit for participating in this research project?

No

Advertisements

Will there be advertisements for this study?

Yes

Select all the types of advertisement methods that will be utilized. For assistance with creating protocol advertisements, utilize the Advertisement Checklist on the ORIC website http://oric.research.wvu.edu/r/download/6466.
Flyer, Recruitment Letter

Describe where the ad(s) will be placed and attach a copy of the advertisement(s) on the Notes & Attachments page.
The flyer will be posted around the Health Sciences Center building. The recruitment letter will be sent through the employee wellness office to staff and faculty at the HSC building.

Sample Collection

Will sample(s) be used?

No

Biological Safety

Does the study involve the handling of any infectious and/or non-infectious agents or recombinant DNA?
No

Data Protection for IRB

Does the project have data protection requirements?

No