Official Title:

Efficacy of Soft Active Back Exosuit to Reduce the Risk of Occupational Low Back Pain and Injuries

NCT Number:

NCT05802914

Consent Approval Date:

03/14/2023

Permission to Take Part in a Human Research Study ***Participant Initials*** _____

Protocol Title: Efficacy of Soft Active Back Exosuit to Reduce the Risk of Occupational Low Back Pain and Injuries
Principal Investigator: D. Adam Quirk, PhD
Description of Study Population: Industrial Workers
Version Date: 02/15/2023 (v6)

Key Information

The following is a short summary of this study to help you decide whether or not to participate. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We have invited you to take part in a research study because you work at [redacted], our Industrial Partner.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You may discuss your decision with your family, your friends and/or your doctor.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to determine the effect of a wearable back exosuit ("exosuit") on the health and productivity of workers in an industrial setting. The exosuit is worn over the user's clothes. It has active parts that provide assistance to the user. The idea is that when the user moves, the suit can help complete that movement. We want to know if workers who wear a back exosuit during the workday will have lower rates of lower back pain or injury than those who are not wearing a back exosuit. We also want to know how well exosuit technology integrates into the workplace (for example, how this technology improves or hinders job performance).

How long will I take part in this research?

We expect that you would be in this study for about 4 months.

What will I be asked to do?

If you agree to participate, you will be asked to complete a Baseline Survey, which involves questions about your life, job, health, etc. This survey is required to participate. It should take about 45-60 minutes to complete.

After you complete the Baseline Survey, you will be assigned to a study group: exosuit or no exosuit. This is determined randomly. If you are put into the Exosuit Group, you will be trained on how to use the exosuit and be asked to perform your job while wearing the exosuit. If you are put into the No Exosuit Group, you will do your job as normal.

You will be asked to complete a survey every month to answer questions about your job, health, etc.

More detailed information about the study procedures can be found under the *"What can I expect if I take part in this research?"* section.

Is there any way being in this study could be bad for me?

The following risks are possible:

1. ***Breach in Confidentiality:*** It is possible that people who are not supposed to have access to your information could gain access.
2. ***Wearing the Exosuit:*** As with any assistive device, there is a length of time required to feel comfortable wearing it. You may experience risks due to the tightness of the suit (for example, redness, chafing, pinching, etc.) or rare risks due to the electrical components (e.g., burn).
3. ***Active Exosuit Assistance:*** Because the exosuit provides active assistance, you may find your balance is affected while wearing the suit. Any force the device provides is less than what a healthy adult can naturally generate to lessen the likelihood of the exosuit delivering too much force.

More detailed information about the risks of this study can be found under the *"What are the risks and possible discomforts?"* section.

Will being in this study help me in any way?

There are no direct benefits to you or others from participating in this research. The results of this research may lead to a new way to reduce workplace-related low back pain and injuries.

What happens if I do not want to be in this research?

Participation in research is voluntary. You can decide to participate, not to participate, or stop participation at any time without penalty or loss of benefits to which you are otherwise entitled. Your alternative to participating in this research study is not to participate.

Detailed Information

To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take your time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you decide to participate in this research, you will be asked to sign this form. A copy of the signed form will be provided to you for your record.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 617-432-1578 for the Director of Clinical Research, Dionna O. Williams, MPH, MS, CCRP; or 617-432-7704 for the Principal Investigator, Dr. D. Adam Quirk, Ph.D.

Permission to Take Part in a Human Research Study ***Participant Initials_____***

This research has been reviewed by the Harvard Longwood Campus Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the Office of Regulatory Affairs and Research Compliance (ORARC) at 617-432-2157 (or toll-free at 1-866-606-0573) or at irb@hsph.harvard.edu for any of the following:

- If your questions, concerns, or complaints are not being answered by the research team,
- If you cannot reach the research team,
- If you want to talk to someone besides the research team,
- If you have questions about your rights as a research participant, or
- If you want to get information or provide input about this research.

Participation is voluntary
You are invited to take part in this research because you work at our Industrial Partner, [redacted] It is your choice whether or not to participate. If you choose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

How many people will take part in this research?
Up to 300 people will be enrolled into this research study.

What can I expect if I take part in this research?
If you agree to participate, will ask you to complete a Baseline Survey, which involves questions about your life, job, health, etc. This survey is required to participate.

After you complete the Baseline Survey, you will be assigned to a study group: Exosuit or No Exosuit. This is determined randomly. If you are put into the Exosuit Group, you will be trained on how to use the exosuit and be asked to perform your job while wearing the exosuit. If you are put into the No Exosuit Group, you will do your job as normal without wearing an exosuit.

You will be asked to complete a survey each month to answer questions about your job, health, etc. This will likely occur in person in a group setting. You would complete the survey on a tablet, using a unique link we send to you. We may work with you and your supervisor to schedule this survey.

Our study team will not determine or influence your workplace tasks. We want to monitor your productivity and workplace health that evolves naturally in the workplace. There are three ways we will obtain data for this study:

1. Data collected that you provide to us (e.g., survey data)
2. Data that the exosuit company, Verve Motion, provides us (e.g., exosuit data is automatically collected when you wear the suit)
3. Data from your employer (e.g., data your company already collects, such as workplace injury, back injury events, time off work or modified work duties due to back pain or injury, health insurance claims related to back pain, type of provider you accessed for your back pain)

During the study, our exosuit vendor, Verve Motion, may work with you to ensure the exosuit is comfortable and work with you set reasonable goals for exosuit use. They may tell you how often you wore it in the past and work with you to set goals for the future.

*Please note: If you are assigned to the exosuit group and use the high picker during your job, you will be specifically trained on how to use the exosuit with this equipment. You will also be assigned an exosuit without a carry handle to ensure the exosuit does not interfere with the fall harness. You cannot wear the exosuit on the high picker until you are trained to do so.

What are my responsibilities?
As a participant, you are responsible for:

1. Completing the Baseline Survey (45-60 minutes)
2. If you are assigned to the Exosuit Group, participating in the Exosuit Training
3. Performing your normal work duties with or without an exosuit
4. Completing the Monthly Survey (30-45 minutes)

What are the risks and possible discomforts?
There is always a risk of a breach in confidentiality, which means that people who are not supposed to have access to your research information could gain access. This risk is rare because of the steps we take to protect your privacy. For more information, see the *"If I take part in this research, how will my privacy be protected? What happens to the information you collect?"* section.

If you are assigned to the exosuit group, the following risks are also possible:

Possible Minor Risks:

- Skin risks (e.g., discomfort, redness, chafing, rash, pinching, numbness, tingling, swelling, itchiness, temporary skin indentation, blisters, discomfort)
- Movement and balance disruptions (e.g., which could lead to muscle cramps, pull, or soreness, joint discomfort, soreness or injury, general discomfort, including pain or exacerbation of existing discomfort/pain)

Fit and Comfort –
Minor redness, pinching, chafing, swelling, numbness, temporary skin indentation, or tingling is possible, due to the tightness of the suit. These are temporary effects and should disappear over time. To minimize these risks, we encourage you to seek help from Verve Motion or take a short break from the suit if these problems occur.

Exosuit Catching –
You may be startled, uncomfortable, or experience changes to your balance if the exosuit, straps, or cables get caught on something (e.g., shelf). To minimize this risk, the straps and cables are as short as possible, covered, and are close to your body.

Exosuit Bumping –
If you bump into objects (shelves), other equipment, or employees while wearing the back exosuit, this could be uncomfortable, startling, or alter to your movement and balance.

Exosuit Controls –
You will be allowed to control how much assistance the exosuit provides. It is possible that you could set parameters that are uncomfortable. However, to minimize this risk, the changes you can make are limited.

Active Mode Malfunction –
It is possible that an unanticipated problem could occur and the exosuit could apply more or less force than expected. This could be uncomfortable, startling, change your balance, and cause you to modify your movement to correct for this. However, the exosuit delivers less force than what a healthy adult can naturally generate, so you should be able make up for too much or too little exosuit assistance. The company that makes the exosuits will perform regular maintenance on the exosuits to ensure they continue to be in good shape for use. We can help reach out to them at any time.

Rare Risks:

- Skin risks (e.g., burn/heat production, electric shock)
- Serious injury or death from a fall (High Picker Users)

Electrical Safety –
As with any electrical device, there is a very minimal risk of electrical shock, burn, or heat production. To reduce this risk all electrical components are sealed in non-conducting plastic boxes and all wires are coated. The components with the ability to generate heat will be located away from your body (i.e., they will not touch the skin). The components also have cooling fans inside them to allow ventilation and minimize the heat production if it occurs. Electronics will be periodically checked throughout the study.

High Picker Safety –
If you use the high picker while wearing the exosuit, you could accidentally anchor the arrest tether to the exosuit. Doing so could result in serious injury or death if you were to fall. To reduce this risk, we have modified the design of the exosuit for use on the high picker. Specifically, we have removed the exosuit carry handle, so it is less likely that the fall harness is incorrectly attached to the exosuit.

It is also possible that you could experience the same balance disruptions described above (catching, bumping, malfunctions, actuator failure), while on the high picker.

To lessen these risks, you: 1) can only operate the high picker with the exosuit if you have a PITO License, 2) will be trained to use the exosuit with the high picker, and 3) will be assigned an exosuit without a carry handle.

Are there any benefits from being in this research study?
There are no direct benefits to you or others from participating in this research. The results of this research may help us understand if exosuit technology could be used in the workplace to reduce workplace-related low back pain and injuries.

What happens if I say yes, but I change my mind later?
You can leave the research at any time, it will not be held against you.

> ***If you stop participating (e.g., completing surveys or wearing the exosuit, if you are in the exosuit group) without telling us,*** we may continue to use data we have already collected from you. We may continue to collect data from your employer.
>
> ***If you no longer want to be part of the study,*** please let us know. We will no longer collect new data from you or your employer, but we may continue to use data we have already collected from you.

Will I be compensated for participating in this research?
You could receive up to $100 in gift cards for participating in this study. This includes:

- ***Baseline Survey:*** $20 Amazon Gift card and branded apparel
- ***1st Monthly Survey completed on-time:*** $20 Amazon Gift card
- ***2nd Monthly Survey completed on-time:*** $20 Amazon Gift card and branded apparel
- ***3rd Monthly Survey completed on-time:*** $20 Amazon Gift card
- ***4th Monthly Survey completed on-time:*** $20 Amazon Gift card and branded apparel

You must complete the Monthly Surveys within the month of receiving the survey links to be eligible for the gift cards and apparel. We will work with you and your supervisor to schedule these surveys.

If you are in the exosuit group, you will also have to wear the exosuit for more than 64 hours every two months to be eligible for the branded apparel. This is approximately 2 hours a day, with 1 week off for a break.

What will I have to pay for if I participate in this research?
It will not cost you anything to participate in this research.

What happens if I am injured as a result of participating in this research study?
If physical injury resulting from participation in this research should occur, although Harvard's policy is not to provide compensation, medical treatment will be available including first aid, emergency treatment and follow-up care as needed, and your insurance carrier may be billed for the cost of such treatment. In making such medical treatment available, or providing it, the persons conducting this research project are not admitting that your injury was their fault.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?
Efforts will be made to limit the use and disclosure of your personal information to people who have a need to review this information. We cannot promise complete secrecy.

Your Privacy
Your employer will know that you are in the study. We will work with them to schedule study activities. Your supervisor will give you time to complete these study activities during your workday. We may communicate with your supervisor if you are not completing surveys or wearing the exosuit, so they can meet with you to determine if the reason is work-related. If it is not work-related, they can connect you to our team or Verve Motion. They should never pressure you to continue in the study.

Due to the location of the study and potential that you are wearing an exosuit, we cannot guarantee your complete privacy.

Data Confidentiality
Your employer and Verve Motion will share data with us that has your name on it. Surveys you complete will be linked to your initials and email address. Some identifiable data may be shared with Verve Motion, as it relates to the exosuit.

Organizations that may inspect and copy your information include the IRB and other representatives of this organizations involved in this research, such as the Food and Drug Administration (FDA), National

Institutes of Health (NIH), the Department of Health and Human Services, and Navitas Life Sciences (NIH's contract research organization).

Protecting your Data
Your data will be stored on a secure server with access limited to those discussed above under *Data Confidentiality*. If we share your data with anyone else, it will be labeled with a unique participant number and no other identifying information. Only the study team will have access to the key linking your identity to your unique participant number. Your name will not appear in any report of the study results.

Employment Status
Participating in this study will have no effect on your employment status. Neither your supervisor nor your employer will have access to your individual survey responses.

Data Sharing
It is possible that we may use the de-identified data we collect (which cannot be used to identify you) with our collaborators, or in publications, presentations, or for teaching and training purposes. It could also be used for future research studies or distributed to another investigator for future research studies without your additional informed consent (e.g., NIH Heal Initiative).

Promotional Materials
You may be approached and asked to appear in promotional materials for Harvard University or affiliated sponsors. A separate media release form will be utilized in these circumstances. In these cases, videographers and photographers may record your study visits. If you do not give permission to use photos or videos on your consent form, researchers will refrain from contacting you for appearance in promotional materials.

NIH Heal Initiative
This study is part of the NIH HEAL Initiative focused on understanding and developing new treatments for addiction and pain. Research gives us the best information and progresses more quickly when data is available from many studies and many individuals, and when many researchers can work with the data and samples and analyze them in different ways. Therefore, your data could be used for this and other NIH HEAL Initiative studies. Your stored data could also be made widely available to other researchers. The shared data may be used indefinitely for research not related to this study or the HEAL Initiative, without asking you for additional consent.

Your study data will be stored securely at Harvard or at sites NIH selects for this study. Your data will be stored indefinitely. We will do our best to protect your personal information. Your name and other personal identifying information will not be kept with the data. Your data will either be stored without a code linking them to you or they will have a code that links to your identifying information. If your data has a code, the key to the code will be kept at Harvard in a separate, secure area and will not be shared outside of the Harvard study team.
If you withdraw from this research study before it is done, we will keep and continue to use data that have already been collected.

Potential benefits of sharing of data
There is no direct benefit to you from the storage and sharing of your data, but sharing may help researchers learn more about lower back pain and other diseases, which may help you or others in the future.

Risks of sharing data
Even though we will protect your privacy as much as possible, there is a very small chance that the data could be identified as yours. The risk of this happening is very small but may increase in the future as technology changes.

Products developed from research using your data
Research using data from this study may lead to new tests, drugs, or devices with commercial value. You will not receive any payment for any product developed from research using your data. If you do not want your data used for other research, you should not participate in this study.

Clinical Trial Requirements
The sponsor, monitors, auditors, the IRB, and FDA will be granted direct access to our data to conduct and oversee the research. By signing this document, you are authorizing this access.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Certificate of Confidentiality
This research is covered by a Certificate of Confidentiality from the NIH. This means that the researchers cannot release or use information or documents that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal FDA. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers, or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Can I be removed from the research without my OK?
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons include:

- If you are found ineligible or unable to complete the tasks

- If more circumstantial issues arise, such as persistent scheduling conflicts, suit size unavailable, or the research is not compatible in other ways
- If you are unable to follow verbal instructions to ensure your safety and the integrity of the study

What else do I need to know?
This research is being funded by the NIH and Liberty Mutual.

Your information may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family.

The device technology being studied has been licensed to Verve Motion. Dr. Walsh is a board member, paid consultant, and holds equity in Verve Motion. This disclosure is made so that you may determine whether these potential financial interests affect your willingness to participate in this study. If you have questions or would like a list of all study team members who are named inventors on the technology, please see the above section of this document, *"Who can I talk to?"*, for study personnel contact information.

Authorization to Use and/or Share Your Protected Health Information (PHI)
Federal law requires Harvard to protect the privacy of health information that identifies you. This information is called Protected Health Information. In the rest of this section, we refer to this simply as "health information." If you decide to take part in this research study, your health information may be used within Harvard and may be shared with others outside of Harvard.

Below is more information about how we plan to use and share your health information.

Health information about you that might be used or shared during this research
[redacted] already collects health information about you. If you decide to enroll in this study, we will ask to share some of your health information with us. This includes:

- Workplace injury, back injury events, time off work or modified work duties due to back pain or injury
- Health insurance claims related to back pain
- Type of health care providers you accessed for your back pain

Reasons we need this health information about you
We will use or share your health information to help understand whether exosuit technology reduces workplace-related low back pain and injuries.

People and groups that may use or share your health information

1. **People or groups within Harvard**
   - ✓ Researchers and the staff involved in this research study
   - ✓ Harvard review board that oversees the research
   - ✓ Staff within this institution who need the information to do their jobs

2. **People or groups outside of Harvard**
   - ✓ People or groups that we hire to do certain work for us (e.g., data storage companies, our insurers, or our lawyers)

- ✓ Federal and state agencies such as the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protection, and other U.S. or foreign government bodies, if required by law or involved in overseeing the research
- ✓ Our study funders and people or groups it hires to help perform this research study
- ✓ Other researchers and collaborators who are part of this research study
- ✓ Our Safety Officer who oversees the data (study information) and safety of this study

How long your health information might be used or shared with others
Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

Applicability
If we remove identifiers (e.g., your name) from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Your Privacy Rights
You have the right not to sign this form permitting us to use and share your private information for research. If you do not sign this form, you cannot take part in this research study because we need the private information of everyone who takes part.

You have the right to withdraw your permission for us to use or share your private information for this research study. If you would like to withdraw your permission, you must notify Dionna O. Williams at dionna.williams@wyss.harvard.edu.

If you withdraw your permission, we will not be able to take back any information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality.

If you withdraw your permission, you cannot continue to take part in this research study.

Checkboxes for PHI Authorization

Your employer is required by law to protect your health information. By signing this consent form, you authorize your employer to release your health information to us for this research.

☐ I give permission to the research team to receive, use, and share health information that identifies me for this research study.

Checkboxes for Participation in Future Studies

The results of this research may lead to additional research studies in the future. Please check the appropriate box below to let us know if you would like to be contacted about possible participation in any future research studies of a similar nature.

☐ I would like to be contacted for possible participation in future research studies.

☐ I would not like to be contacted for possible participation in future studies.

Permission to Take Part in a Human Research Study ***Participant Initials_____***

Study Requirements

The following boxes are required. If you do not agree to the conditions below, you will not be allowed to participate in this study.

☐ I acknowledge that I will be randomly assigned to the exosuit or no exosuit group.

☐ I acknowledge that I will not use the high picker while wearing the exosuit unless I: 1) have a PITO License, 2) have been trained to use the exosuit with the high picker, and 3) have been assigned an exosuit without a carry handle.

☐ I acknowledge that my supervisor will know I am enrolled in this study and help me address workplace barriers regarding my participation but will not have access to my individual survey responses.

☐ I acknowledge that my colleagues may see that I am participating in this study.

☐ I acknowledge that my employer will send you data for use in this study.

☐ I acknowledge that I will complete the surveys required in this study.

☐ I acknowledge I will communicate to the study team if I have any questions or concerns.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled. I understand that if I am returning this form electronically or remotely that all pages must be sent back to the researchers.

I consent to participate in the study.

SIGNATURE

Your signature below indicates your permission to take part in this research.

_____	
Name of participant	
_____	_____
Signature of participant	Date and Time
_____	_____
Signature of person obtaining consent	Date and Time
_____	
Printed name of person obtaining consent	