Official Title:

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

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GENERAL INFORMATION	
Protocol/ESTR Record Number: IRB22-0308	
Version Number: 11	**Version Date:** 8/14/2026
Principal Investigator (PI): D. Adam Quirk, PhD	
Principal Investigator's Harvard Affiliation: Post-Doc	
Faculty Mentor: Conor Walsh, PhD	
Name of Person(s) Completing This Form: Adam Quirk, Sarah Sullivan	
Protocol Title: Efficacy of Soft Active Back Exosuit to Reduce the Risk of Occupational Low Back Pain and Injuries	

1. **Specific Aims**

PRIMARY AIM:
Evaluation of a soft wearable back exosuit to reduce occupational risk and impact of Low Back Injuries (LBI)

Objective 1-A: ***Determine whether individuals performing specific occupations with a back exosuit have reduced levels of work-interfering low back pain (LBP) or reduced rates of low back injury (LBI) compared to a non-exosuit group.***

a. **Background:** Physical jobs with higher peak and cumulative back extensor moments are more likely to result in employees developing a LBI (*1*, *2*).
b. **Hypothesis:** Given that our research (*3*) and others (*4*, *5*) demonstrate back exosuit technology can reduce peak and cumulative back extensor moments, we hypothesize exosuit users will be less likely to experience LBP or develop a LBI when compared to the control group.
c. **Outcome Measures:**
    i. Self-reported (collected monthly) measurements of:
        § LBP with perceived work-interference *[Cornell musculoskeletal discomfort questionnaire (CMDQ) (6)]*
    ii. Self-reported (collected at monthly) incidence of:
        § LBP leading to (*7*):
            a. Moderate work interference
            b. Three days of limited activity
            c. Seeking medical attention
            d. Taking time off work
    iii. Objective industrial-partner measures of:
        § A workplace occupational safety and health administration (OSHA) report claim

Objective 1-B: ***Determine whether individuals performing occupational tasks with a back exosuit will have reduced severity of LBI compared to a non-exosuit group.***

a. **Background**: A possible cause for some LBI includes loading spinal tissues above their tolerance leading to pain and disability (*8*). During a period of LBP, individuals avoid situations that increase loading spinal tissues (*7*).
b. **Hypothesis:** Given our back exosuit reduces measures of low back loads (3), we hypothesize:
    i. Back exosuit users will experience a smaller magnitude of spinal tissue overload, leading to less severe LBP when compared to the control group; evidenced by reduced LBP intensity, disability, and reduced medical cost (*9*).
    ii. Back exosuit users will find work demands tolerable earlier in their recovery and will be capable of returning to the workplace earlier when compared to the non-exosuit group.
c. **Outcome Measures:**
    i. Self-reported (collected monthly) incidence of:
        § LBP intensity *[Modified Numerical rating scale for pain (10)]*
        § Frequency of using over the counter medication and prescription medication for LBP
    ii. Self-reported measures (collected monthly):
        § LBP interference *[Modified brief pain index (BPI) (11)]*
        § Number of days off work following a LBI
        § Use of medical services for the treatment of LBI
    iii. Objective industrial partner measures (collected weekly):
        § Number of insurance claims for LBI
        § Number of days off work following a report of LBI
        § Number of days of reduced work productivity (participating in modified duties) following a report of LBI
        § The medical payouts incurred following a LBI claim

SECONDARY AIM:

Evaluation of whether soft wearable back exosuits impact job productivity

Job productivity is a multifactorial measure, including immediate job performance and measures that indirectly facilitate (i.e., reduced effort or fatigue) or hinder (i.e., discomfort) job productivity.

Objective 2-A: ***Determine whether exosuit users experience a hindrance in job performance compared to a non-exosuit group.***

a. **Background**: Back exosuits offer considerable potential to reduce the risk of back injuries. But previous exosuits can be uncomfortable, restricting or hindering task performance (*4*, *12*, *13*) particularly when individuals enter deep flexion (*14*).
b. **Hypothesis:** Our work demonstrates our lightweight soft-active back exosuit has been successful in minimizing discomfort and restriction during deep flexion when compared to other back exosuit designs (*3*). Thus, we hypothesize exosuit users will not differ from the control group for the below measures of job hindrance.
c. **Outcome Measures:**

i. Self-reported measures (measured monthly):
   § Discomfort leading to perceived work interference at non-assisted joints *[Cornell musculoskeletal discomfort questionnaire (CMDQ) (6)]*
   § Composite Total Body Pain Interference *[PEG-3 pain screening tool (15)]*

Objective 2-B: ***Determine whether the exosuit facilitates job performance compared to a non-exosuit group.***

a. **Background**: Back exosuits have been shown to decrease user effort during lifting tasks evidenced by decreased measures of muscle effort, fatigue and increased perceived ease of lifting (*16–19*).
b. **Hypothesis**: Given our back exosuit reduces measures of back extensor effort during a dynamic lifting task (3), we hypothesize back exosuit users will have improved job performance when compared to control participants evidenced by:
c. **Outcome Measures:**
   i. Self-reported measures (measured monthly):
      § Lower levels of perceived low back exertion *[Modified BORG CR-10 exertion scale (20)]*
      § Lower levels of perceived total body exertion *[BORG CR-10 (20)]*
      § Lower levels of perceived general workplace fatigue *[Modified BORG CR-10 fatigue scale (21)]*
   ii. Objective Industrial Partner measures (measured weekly):
      § Lower participant study withdrawal rates in the exosuit group compared to control group

TERTIARY AIM:

Identify barriers or facilitators of exosuit use

Objective 3-A: ***Determine factors that explain exosuit adherence or non-adherence in the intervention group.***

a. **Background**: Back exosuits are an external device and must have good usability to be adopted in a workplace long-term. Many domains represent usability, but actual use occurs when the user perceives the benefits of the device outweigh the cost of use (*22*).
b. **Hypothesis:** Our exosuit has been carefully designed to minimize known cost of previous back exosuits. It is comfortable, easy to don and adjust, and it acts automatically and intuitively to noticeably help a user without the barrier of perceived restriction. Thus, we hypothesize exosuit users will be more satisfied with the intervention, believing it reduces job effort and the risk of developing LBP. Despite our design to facilitate ease of use, we also hypothesize exosuit users will find usability of the exosuit improves over time evidenced by:
c. **Outcome Measures:**
   i. Self-reported (measured monthly):
      § Increased perceived: *satisfaction with group assignment, productivity, ability to lift safer, ease to complete work tasks, work satisfaction, support from company, thought of exosuit being a good idea, desire to*

use an exosuit, ease of using the device, ease of putting on the device, ability to adjust the device

- Decreased perceived: *likelihood of experiencing a back injury, levels of fatigue, low back discomfort, feeling the exosuit makes a job too complex, exosuit interference with job time*
- No change in perceived: *device comfort, number of times a user must take-off the exosuit during the workday, thermal discomfort, notice of skin issues, uncomfortable skin pressure, bumping or catching objects, experience of balance difficulties, experience of movement restriction*
- *Some of these questions are modified using the established system usability scale (23)*

ADDITIONAL ANALYSIS: ***Correct data for confounders and collect information to inform future studies.***

a. **Background:** The risk of developing LBP is multifactorial explained by individual, psychosocial and environmental (occupational or biomechanical) risk factors (*8*, *24*). Given the study cannot control all factors, and that the exosuit might interact with these risks to modify the effect size of the device, this study will account for baseline differences between the exosuit and control group measuring the following known risk factors:

b. **Outcome Measures:**

i. Self-reported measures (measured at baseline):

- History of LBP needing time off work or medical treatment (*24*)
- History of work interfering musculoskeletal injuries
- Age (*25*, *26*)
- Job Tenure (current job) (*26–28*)
- Heavy Work Tenure (# of years manual material handling) (*29*, *30*)
- Sex (*30*, *31*)
- Ethnicity (*31*)
- Education Level (*25*, *30*, *32*)
- Income Level (*27*)
- Substance Use (Smoking (*27*, *33*) and Alcohol (*34*)
- Comorbidities including inflammatory medical conditions (*35*, *36*)
- Levels of leisure time activity levels (*27*) [*Modified International Physical Activity Questionnaire (IPAQ) (37)*]
- Body mass index (*27*, *33*)
- Perceived job satisfaction (*28*)
- Perceived physical stressors (*25*, *31*)
- Perceived job demand, control and support (31, 34, *38-40*) [*Modified from the job content questionnaire*]
- Perceived physical job strain (*30*, *33*)
- Psychosocial distress (*41*, *42*) *[Brief symptom rating scale (BSRS)]*
- Perceived workplace safety climate (*43*)
- Job demands and/or exposure (physical exposure/loads) (*1*, *44–50*)

2. Background and Significance

2.1. Provide the scientific background and rationale for the research

LBP is a leading cause of disability worldwide (*51*). The cause of LBP is multifactorial, including individual (*24*), psychosocial (*38*), and biomechanical risks (*8*). Biomechanical risk factors have been identified as the second-best predictor of developing LBI (*25*), second only to an individual's history of previous LBP (*24*). Biomechanical risk factors often focus on physical job demands, which are higher in jobs which require: 1) manual material handling tasks, such as lifting, lowering, carrying, pushing and pulling, and 2) frequently adopting awkward postures, such as sustained (static holding) trunk flexion and asymmetric bending (*47*, *49*, *52*, *53*). These biomechanical risk factors increase the loads (peak forces and moments) to which spinal tissues are exposed (*54*), potentially leading to tissue overload (*53*, *55*). Frequent spinal loading throughout a working day has a cumulative effect. This cumulative loading is a unique risk factor to peak loading, as it captures the interaction between tissue overload and changes in tissue tolerance (fatigue) during repeated exposure to cumulative microtrauma (*1*, *2*, *45*, *56*).

Given biomechanics can be a risk factor, they can act as a solution to prevent or relieve LBP. Many ergonomic interventions have been developed to reduce peak and cumulative spinal loads through individual education, administrative policy, and the incorporation of technological interventions (*57*). Technological interventions, including external lifting aids and workplace redesign, have demonstrated to be the most effective solution to reduce spinal loads and the likelihood of developing LBP (*57*, *58*). However, such interventions can be under-utilized, due to associated barriers to accessing external equipment, a time lag to train employees to incorporate external equipment into their routine, or that workplace redesign might not be possible for all occupational tasks (*50*, *59*).

Body worn assistive devices have been developed to provide the benefits of reduced spinal loading, in a highly usable package that can synergize with other technology interventions. The benefit of body worn assist devices is they pose no accessibility barrier and can accommodate an employee across a range of movements and environments. The most well-known body worn assistive device are back belts. Yet, back belts have questionable efficacy in modifying trunk biomechanics (*60*), including spinal loads and preventing first time or recurrent LBP (*61*).

Exoskeletons and exosuits are designed to augment human movement, generating assistive forces/moments to offload a joint of interest. Contrary to back belts, which are designed to restrict motion or increase intra-abdominal pressure (*60*), lower back exosuits (referring to suits or skeletons) generate assistive back and hip extensor moments, lowering these moments (loads) when individuals perform lifting and static flexion tasks (*5*). A variety of back exosuits have been shown to reduce surrogate measures of spinal load including peak biological hip and back extensor moments (*4*) and back and hip extensor muscle activity (*5*, *62*). In turn, these benefits have been estimated to reduce spinal shear and compressive forces (*63–65*). Over repeated lifts, back exosuit assistance has the additional benefit of slowing the rate of musculoskeletal and cardiovascular fatigue (*16*, *66*, *67*).

There is growing evidence that back exosuits have considerable potential to reduce the likelihood of developing LBI (*2*). *However,* their real-world efficacy remains unknown (*68*). External device back exosuits face usability challenges in that stakeholders of this technology must feel or expect the benefits of this device offset the cost of device use (*69*). Associated with the biomechanical benefits of back exosuits, users perceive reductions in task effort (*70, 71*), low back discomfort (*17, 72*), and total body fatigue (*73*). However, back exosuits can come at a cost of restricting the performance of tasks for which the exosuit was not designed to assist (*17, 72*), and minor body discomfort arising from heat, weight, anatomical malalignment, skin pressure, and movement restriction (*4, 12–14, 64, 74, 75*). Ultimately if the perceived cost of a device is too high or increases over time it can reduce an individual's intention to use exosuit technology (*22*).

Leveraging our experience in developing soft-textile exosuits designed to actively deliver forces consistent with an individuals intended biomechanics (*76–78*), we developed a soft, light weight (2.7kg), active back exosuit. Through the combination of design principles, including our autonomous active impedance controller, our back exosuit provides the biomechanical benefits of reduced spinal loads without the cost of discomfort and movement restriction (*3*). This device has been designed to be transferable to ecologically simulated occupational pallet building task common to the distribution center work task we seek to assist. Using this novel exosuit, we intend to fill the gap in the literature by establishing the real-world field efficacy of this back exosuit as a risk mitigation tool for employees participating in manual material handling. Thus, the overall purpose of this research is to determine whether four months of back exosuit use can reduce the severity and incidence of LBP. With a secondary purpose to fully describe the barriers, facilitators, and perceptions of usability when integrating exosuit technology into a workplace.

2.2. Describe the significance of the research, and how it will contribute to generalizability

The significance of this research is far reaching. To our knowledge this will be the first study designed to determine whether back exosuit or exoskeleton technology can reduce workplace LBP and injuries. Additionally, our study is designed to provide a holistic analysis of integration of exosuit technology into a workplace, to understand how this technology improves or hinders job performance, and how system usability might change over time. Through this analysis, our study will represent a method and keystone contribution towards analyzing exosuit technology in the workplace.

3. Research Locations and Collaborating Sites

Research Locations refer to the geographic location that the research will take place, not to the institutions or researchers you may be collaborating with. All Research Locations should be listed in ESTR as a Research Location. Collaborating Sites refer to institutions or researchers that are also taking part in the research study. All Collaborating Sites should be listed in ESTR as a Participating Site.

3.1. Where will the research activities take place? (check all that apply)

☒	**At Harvard;** *list any non-Harvard Longwood Medical Area (LMA) Schools here: A list of all Harvard Schools can be found here.* • Harvard John A. Paulson School of Engineering Applied Sciences, Harvard University-Area
☒	**At another location in Massachusetts;** *specify here:* • Verve Motion
☒	**In another state in the U.S.;** *specify here:* • Industrial Partner ([redacted])
☐	**Internationally;** *specify here:*
☐	**Remotely;** *specify here if any remote participant will be located in the European Economic Area (EEA), European Union (EU), and/or United Kingdom (UK) while participating:*

Note: The Industrial Partner in this study is [redacted].

3.2. Describe the sites or locations where the research will be conducted or overseen by the Harvard PI. (If conducting the study virtually or remotely, indicate the location of the researcher who is conducting the study.)

The research will occur at the following locations:

- ***Industrial Partner:***
  - Participant study procedures
  - Data collection
- ***Harvard SEAS:***
  - Participant enrollment
  - Data collection (via REDCap or paper, if applicable)
  - Adverse Event (AE) reporting
  - Data monitoring of all sites (as data is sent to Harvard)
  - Data analysis
- ***Verve Motion:***
  - Suit deployment and maintenance
  - Data collection (suit data transmitted to Verve Motion)
  - AE assessment

Dr. Walsh and Dr. Quirk will oversee all sites and research locations.

3.3. Describe plans for communication among sites regarding adverse events, interim results, protocol modifications, monitoring of data, etc. ☐ N/A.

ADVERSE EVENTS (AEs)

The primary method to collect AE data is via direct communication between the participant and Harvard using the Monthly Survey. Participants will be reminded to contact Harvard directly if an AE occurs.

Exosuit Group: Harvard will communicate exosuit-related AEs to Verve Motion. Harvard may work directly with Verve Motion to determine causality. If a participant reaches out to Verve directly or indirectly (via a supervisor), Verve Motion record those events in a log that's shared with Harvard weekly. In the event Verve Motion performs a fit adjustment, they will be asked to have the participant complete the Exosuit Survey. If the Industrial Partner encounters a workplace injury involving an exosuit user, they will be encouraged to contact Harvard. There may be times when the Industrial Partner and Verve Motion need to be consulted together to address exosuit issues regarding accessibility, employee usage, and exosuit discomfort.

PROGRESS REPORTS

Deidentified Reports: Deidentified group aggregate data may be reported to our collaborators (e.g., the Industrial Partner, Liberty Mutual) and our exosuit vendor, Verve Motion.

Identifiable Reports: Identifiable reports may be shared or discussed with our Industrial Partner (e.g., corporate, building managers, account managers, etc.) and Verve Motion. These reports could contain identifiable information (e.g., employee name) and compliance data (e.g., survey completion and exosuit use). The point of sharing and discussing identifiable data is twofold – 1) to tell our Industrial Partner and Verve Motion who is enrolled to facilitate data collection and participant scheduling and 2) to identify and resolve ongoing study barriers (e.g., workplace, exosuit, and other study barriers).

PROTOCOL MODIFICATIONS

Harvard will communicate to Verve Motion and the Industrial Partner directly if there are any protocol modifications that affect their roles.

DATA TRANSMISSION

Data from Verve Motion and the Industrial Partner will be shared with the study team via their secure processes. See Section 5.11.

DATA MONITORING

Harvard will be responsible for monitoring study data.

1. **Harvard Data:** Includes enrollment data and REDCap surveys. Quality Control (QC) frequency is described below.
    - ***Enrollment data:*** Performed after enrollment by a study team member who was not the person entering the data
    - ***REDCap survey data:*** Weekly
2. **Verve Motion Data:** Includes suit data, which will be shared with and reviewed by the study team (e.g., monitoring suit compliance and data outliers).

3. **Industrial Partner Data:** Includes outcomes data (e.g., health/injury rates, participant employment status), which will be shared with and reviewed by the study team.

3.4. Describe any local (international or state) laws, regulations, and/or customs affecting the research (e.g., age of majority, mandatory reporting requirements, etc.). ☒ N/A.

3.5. Identify any approvals or permissions required of collaborating institutions, community leaders, or government officials, including approval from another IRB or local research ethics committee. *Upload copies to the "Study-Related Documents" page in ESTR.* **☐ N/A.**

- **Vendor Agreement**
  - Verve Motion to cover exosuit support
- **Collaboration Agreement (combined DUA)**
  - Boston University to cover collaboration and data use
- **Sponsor Agreement (combined Collaboration + DUA)**
  - Liberty Mutual to cover support, consultation, experimental design, manuscript preparation, manuscript publication
- **No-Cost Collaboration Agreement**
  - Industrial Partner to allow for workplace study activities and data use
- **Data Use Agreement**
  - University of Delaware to cover Ryan Pohlig, PhD, who is a biostatistician and may have access to deidentified study data
- **Reliance Agreement**
  - Boston University to cover collaborating study personnel
  - Harvard University-Area to cover collaborating study personnel, prime funding, research activities occurring at SEAS
- **IRB Authorization Agreement (IAA), as needed**
  - Industrial Partner to cover collaborating personnel as needed

3.6. Will you collaborate with any researchers not affiliated with Harvard to carry out this study?

☐ No ☒ Yes: *If yes, list which institutions they are affiliated with. If they are not affiliated with an institution, indicate that here. If yes, also indicate their responsibilities and scope of work in conducting this research.*

- **Boston University & Harvard University-Area:** Collaborating study team members
- **Liberty Mutual:** Collaborating study team members
- **Industrial Partner ([redacted]):** Collaborating study team members

3.7. Will your collaborators interact with human subjects, have access to identifiable data/specimens, and/or be responsible for the design, conduct, oversight, or reporting of the research?

☐ No ☒ Yes: *If yes, indicate if the collaborators will obtain their own IRB review.*

- **Boston University & Harvard University-Area:** Will be added to the study team via a Reliance Agreement
- **Liberty Mutual:** Will not be added to the study team
- **Industrial Partner:** Will not be added to the study team

3.8. Will any institution conducting research activities as part of this study, including collaborators, rely on Harvard LMA for IRB review?
☐ **No** ☒ **Yes:** *If yes, list each relying institutions, their site responsible Investigator, and describe what research activities will be conducted there.*

The following institutions will rely on Harvard LMA for IRB review:

- **Boston University:** SmartIRB #7006
- **Harvard University-Area:** SmartIRB #7006 (HUA IRB22-0357)
- **Industrial Partner (IAA), as needed:** We currently do not have personnel at our Industrial Partner who will act as researchers on this study. If this changes, we will submit a modification and an IAA to cover applicable personnel.

4. Study Team

4.1. Describe the scope of work of the Harvard PI and research team. Indicate who is responsible for the design, conduct, implementation, and/or reporting of the research. Indicate who is responsible for the creation, design, and/or implementation of the study documents/tools.

This is a collaborative study led by Dr. Conor Walsh and Dr. D. Adam Quirk.

Harvard is responsible for study design in collaboration with Boston University.

Harvard is responsible for study conduct, implementation, and reporting of the research in collaboration with Boston University, Liberty Mutual, the Industrial Partner, and Verve Motion.

For specific roles, see Section 3.5.

4.2. Describe the Principal Investigator's experience conducting research at the study site(s) and familiarity with the local research context.

Dr. D. Adam Quirk, the PI, has a decade of research experience in areas relevant to this project. In particular, he has been a consultant in investigating the barriers and facilitators of implementing ergonomics interventions to reduce musculoskeletal injuries and has overseen prospective studies designed to determine whether there are clinical and biomechanical risk factors that explain the recurrence of LBP. Dr. Quirk is a postdoctoral research associate mentored under Dr. Conor Walsh at Harvard School of Engineering and Applied Sciences.

Dr. Conor Walsh will serve as faculty mentor for this work. Dr. Walsh is the Paul A. Maeder Professor of Engineering and Applied Sciences at Harvard School of Engineering and Applied Sciences and an associate faculty member at the Wyss Institute. He is the founder of the Harvard Biodesign Lab, which brings together researchers from the engineering, industrial design, apparel, clinical and business communities to develop new disruptive robotic technologies for augmenting and restoring human performance.

This research aims to further the scientific understanding of how humans interact with wearable robots. The Harvard Biodesign Lab has published extensively in peer reviewed journals on the topic of wearable robots (http://biodesign.seas.harvard.edu).

Our team has biomechanics, engineering design, robotics, material science, and clinical expertise to achieve the aims described in Section 1. The investigators involved in this study are extremely familiar and comfortable with the cultures in which the research is taking place.

4.3. Describe how the Principal Investigator will ensure that sufficient time is devoted to conducting and completing the research.

Drs. Walsh and Quirk, in collaboration with the study team, will oversee recruitment and data collection to ensure all efforts are made to recruit the required number of participants within the recruitment period. Drs. Walsh and Quirk will hold periodic meetings with the study team to monitor the progress of the study and make sure tasks are completed appropriately and in a timely fashion.

4.4. Describe how all research staff members are trained to ensure that they are adequately informed about the protocol and study-related duties.

Study team members are required to take Human Subjects Research Training (i.e., CITI), Good Clinical Practice, and undergo a protocol-specific training presentation and pass a protocol quiz.

4.5. Describe the minimum qualifications for each research role (e.g., RN, social worker, phlebotomist, statistician), their experience in conducting research, and their knowledge of the local research context.

All research staff are required to complete CITI and Good Clinical Practice Trainings and are trained to conduct the assessments for which they are responsible. Our team has biomechanics, engineering design, robotics, and material science expertise to achieve the proposed aims.

The study will be conducted in compliance with the protocol, International Council for Harmonization/Good Clinical Practice requirements (ICH/GCP), and applicable state, local and federal regulatory requirements.

5. Study Design

5.1. Describe the study design type.

This is a randomized, single-blind*, controlled trial with individuals aged 18-65 who work as full-time (>35 hours/week) employees at our Industrial Partner and regularly bend, lift, or lower objects below hip height >50% of their working day for multiple periods lasting more than 1 hour without sitting. This study investigates the effect(s) of an experimental soft exosuit on occupational LBI. This is a study of up to 300 participants. Participants who work at our Industrial Partner will be randomly assigned to wear or not wear an exosuit while performing their normal job over a span of 4 months. Participants will complete survey data at baseline and monthly. Data will be collected from participants, the Industrial Partner, and Verve Motion.

*Note on single-blind: *While the participants will not be blinded, the statistician (Ryan Pohlig) will be. Dr. Quirk, the study PI and co-statistician but will not be blind. However, Dr. Quirk will not complete the primary intention-to-treat analysis defined in the statistical analysis plan of the study.*

5.2. Does the study involve more than one participant group?

☐ **No** ☒ **Yes:** *If yes, identify each group here and throughout all applicable sections.*

- **Group 1:** Exosuit (intervention)
- **Group 2:** No Exosuit (control)

5.3. Indicate the total duration of a participant's involvement.

Clinical Trial duration is 4 months following randomization and exosuit trainings.

5.4. Indicate the total number of participants to be screened (if applicable) and/or enrolled (i.e., signed consent form). If the proposed research involves secondary data analyses only, indicate the number of data, documents, records, and/or specimens that will be obtained.

The study aims to enroll (screen and consent) 300 participants to reach our target randomization of 150-180 participants. This enrollment number was selected as we anticipate some participants might withdraw before completing the Baseline Survey or at the time of randomization.

**Note: The Pilot Study aims to enroll 50 participants, not included in the enrollment total above.*

5.5. List inclusion and exclusion criteria and describe the screening process. Provide a rationale for any specific exclusion criteria.

ELIGIBILITY CRITERIA	
Inclusion Criteria	***Exclusion Criteria***
• 18-65 years old	• Temporary workers not directly employed by our Industrial Partner

- Works as a full-time (>35 hours/ week) employee for our Industrial Partner
- Regularly bends, lifts, or lowers objects below hip height >50% of their working day for multiple periods lasting more than 1 hour without sitting
- Can read and speak in English
- Has internet access
- Has completed an Exosuit Shift Demonstration
- Thigh circumference is > 19" and < 32"+
- Back length (Neck to Iliac Crest) is >18"+

- Diagnosed or self-reported sensory motor disorders (stroke, Parkinson's disease, ALS, multiple sclerosis, spinal cord injury, etc.)
- Use of a pacemaker or other powered, implanted medical devices
- Medical condition that would make the participant likely to break bones (i.e., osteoporosis or osteopenia)
- Spinal fracture in the past 2 years
- Spinal surgery at multiple vertebral levels in your lifetime, including vertebroplasty but excluding injections, such as steroids, nerve blockers, etc.
- Sought medical care for spinal surgery at a single vertebral level in the past 2 years, including vertebroplasty but excluding injections, such as steroids, nerve blockers, etc.
- Current malignant cancer
- Currently pregnant
- Skin issues / sensitivity that an exosuit could exacerbate (e.g., thin skin, sensitive skin, easy rashing, easy bruising or skinconditions, Epidermolysis Bullosa, etc.)
- A current episode of upper back or neck pain, requiring modified duties at work
- A recent episode of LBP resulting in pain (sharp, shooting, burning), radiating below one or both legs (past mid-thigh) in the last 3 months (e.g., sciatica)
- A recent episode of back pain resulting in time off work, modified duties, or seeking medical attention in the last 3 months

**Note: The study team member will rely on participant self-report during Screening
+Will be measured if and only if the participant does not appear to fit the exosuit during the Shift Demonstration

SCREENING PROCESS

- Interested participants will contact the study team. The study team can also contact interested participants.
- The study team will conduct screening via email, phone, or in-person using a screening tool to determine eligibility. The process is as follows:
  1. The study team member will give an overview of the study and answer any questions.
  2. If the participant is interested, the study team member will ask the screening questions.
  3. The study team member will determine if the participant is eligible.

a. If the participant is eligible, the study team member and participant will schedule time to go through the consent.
b. If the participant is ineligible, the study team member will tell the participant and thank him/her/them for their time.
c. If the study team member is unsure of the participant's eligibility status, the study team member will tell the participant and check with the rest of the study team. Following team discussion, the study team member will let the participant know the outcome.

CONSENT PROCESS

- Conducted by the study team
- Electronic and in-person consent processes
- See Section 7 for more information

5.6. Check each age range applicable to participants or data/specimens.

☐ Ages 0-7
☐ Ages 8-17
☒ Ages 18+
☐ Other; specify:

5.7. Describe study procedures.

DEVICE SHIFT DEMOSTRATION

To be eligible for the Pilot Study or the Clinical Trial, all participants must first complete a Shift Demonstration with the exosuit. This shift includes the following:

- ***Shift Demonstration Eligibility:*** Full-time Industrial Partner employees who bend, lift, or lower objects below hip height >50% of their working day for multiple periods lasting more than 1 hour without sitting. Employees will have a chance to confirm eligibility at the beginning of the Risk and Release Form.
- ***Risk and Release:*** Exosuit Trainers or a study team member will ensure all employees sign a Risk and Release Form before trying on an exosuit.
- ***Shift Demonstration:*** Employees who sign the Risk and Release Form will be able to sign-up for a work shift demonstration.
  - ***Suit Fit and Brief Training:*** Exosuit Trainers will ensure the exosuit fits and provide brief training on how to control the suit. If the exosuit cannot be fitted to the employee, the trainer will ask if the employee is comfortable with the trainer taking measurements of thigh circumference and hip length to verify eligibility. If the participant refuses measurements or has thigh or hip measurements not compatible with the exosuit, they will not be able to complete the demonstration. They will be asked to complete the Shift Demonstration Return Survey (REDCap or paper form).
  - ***Shift Demonstration:*** If the suit fits, employees will wear the exosuit during their regular workplace activities (e.g., 3-4 hours).

- ***Device Return:*** At the end of the Shift Demonstration, employees will return the exosuit to Verve Motion. They will be asked to complete the Shift Demonstration Return Survey, which seeks to determine if an employee is interested in the Pilot Study or Clinical Trial and if the employee would like to leave contact information.

- ***Anonymous Survey:*** Following the Shift Demonstration, employees will be asked if they wish to complete an Anonymous Survey about their exosuit experience (REDCap).

PILOT STUDY 1

To test research infrastructure, Verve Motion will provide the industrial sites (e.g., 2230 and 1920) exosuits (e.g., 10 & 20 respectively). Interested employees will be screened, consented, survey trained, and complete the Baseline Survey, as described in the *Clinical Trial Section*. These participants will undergo Exosuit Training and wear the exosuit during their normal workday for a few weeks. Participants will complete the Weekly Survey each week and the Comprehensive Survey at the end of the pilot. We may receive data from the Industrial Partner and Verve, as outlined in *Section 5.7-Clinical Trial Data Collection*.

Participating in the Pilot Study does not exclude participants from participating in the Clinical Trial. Participants will be reminded that while they will be allowed to wear the exosuit during the Pilot Study, they may or may not be randomized into the Exosuit Group during the Clinical Trial.

Participants who complete the Pilot Study and wish to participate in the Clinical Trial will be randomly assigned to Group 1 or 2 with a unique stratification bracket for Pilot participants.

PILOT STUDY 2

To implement the findings from Pilot Study 1, we will conduct Pilot Study 2. Pilot Study 2 will follow the same processes as Pilot Study 1 (see *Pilot Study 1* above for details). However, returning participants (those who participated in Pilot 1) will not be asked to complete the full Baseline Survey (instead, they would indicate in the survey they have already completed it).

CLINICAL TRIAL

SCREENING & CONSENT

- More information on the screening process can be found in Section 5.5.
- More information on the consent process can be found in Section 7.
- Following consent, the team will register a unique login for participants to access surveys. The study team will login to a secure, https-protected domain during in-person survey sessions, so participants can access their REDCap survey links.

BASELINE SURVEY

- ***Frequency:*** Once informed consent is received, study participants will be asked to complete the Baseline Survey. The survey is completed on REDCap and will likely be scheduled in-person in a group setting but could also be completed virtually. Refreshments may be provided. Completion of this survey is a requirement to proceed in the study.
    - If REDCap is down, a study team member will go through the survey with the participant, recording their answers on the printed paper survey. Responses will be manually entered into REDCap. We will keep all paper surveys.
- ***Duration:*** This REDCap survey should take approximately 40-60 minutes to complete.

RANDOMIZATION

Following completion of the Baseline Survey, a research team member will randomly assign participants to the Exosuit or Control Group, using a 2:1 randomization ratio. Using a blocked (N=3) seeded randomization approach, participants will be stratified by their building, LBP history (yes or no), and job tenure (greater or less than 90 days). Within specific strata, participants will be randomized using a series of predetermined seeded randomization lists (i.e., Randomization Workbooks). This method will ensure for every 3 participants who enter a stratum, 2 will be placed in the exosuit group. Using relevant data, these strata can correct for confounders known to lead to participant dropout or the risk of LBP. Following randomization, participants will be recruited for this study over a 4-month period. The 4-month study duration will begin once participants complete the Baseline Survey and the Exosuit Training (if in the Exosuit Group).

- ***Exosuit Group:*** *Defined as individuals performing their everyday job while wearing a back exosuit*
- ***Control Group (No exosuit):*** *Defined as individuals performing their everyday job without using a back exosuit*

DURATION OF INVOLVEMENT

Participants will be involved in the study for about 4 months, starting from the time that they are randomized and complete appropriate training (e.g., Exosuit Training, as applicable). During this time, control participants will perform work as usual. The Exosuit Group will be asked to wear the exosuit when performing aspects of their job that involve bending, lifting, or lowering objects below hip height. Both groups will be asked to complete the following:

1. **Monthly REDCap Survey:** Data collected monthly for 4 months following randomization. The survey is expected to take 30-45 minutes to complete.

STUDY PREPARATION

Fitting Participants to a Suit + Suit Training

- ***Participants:*** *Exosuit Group only*
- ***Location:*** *Onsite, in-person to ensure fit and suit competency*
- ***Point of Contact (POC):*** *Exosuit Trainers*
- ***Procedures:*** *All participants in the Exosuit Group will undergo formal training under the supervision of an Exosuit Trainer (Harvard or Verve employee). This could occur*

individually or in a group setting, depending on the number of participants who need to be trained. Training will ensure the exosuit fits the participant properly. Training will cover how to properly fit the exosuit (don, doff and adjust the exosuit) use of the controller handle, as well as minor troubleshooting and maintenance (replacing batteries, ensuring device is charged, connecting the exosuit to a USB at shift end, etc.). At this training, participants will be assigned a suit and suit ID. Following training, the Exosuit Trainer will record the assignment in a document shared with Harvard.

- ***Participants who have a Powered Industrial Truck Operator (PITO) License:*** All employees who operate a high picker have a PITO License (29 CFR 1910.178(l)), which ensures they know how to safely operate this equipment. Because participants may acquire a PITO License during the protocol, all participants will be trained on how to use the exosuit safely with the high picker. The carry handle will be removed from all exosuits to ensure participant safety (see Section 12.1). All exosuit users will be reconsented to this change and retrained on how to use the exosuit while on the high picker.

WEARING THE SUIT

Suit Use

Participants in the Exosuit Group are enccuraged to wear the exosuit throughout their working day while bending, lifting, or lowering objects below hip height. Upon Exosuit Training, participants will be provided with a unique suit and suit ID. They will be requested to use their unique suit properly fitted for them.

Suit Controls

Exosuit assistance is delivered using an active motor informed by a validated and tested generic sensor-based controller. This controller considers the current position (upright or bending) and the desired direction of the participant to modify how it applies assistance. The exosuit is designed to respond to how the individual bends, delivering higher assistance when an individual extends (lifts) but immediately reducing assistance if the participant seeks to flex (lower). Using this sensor-based controller, the suit will automatically enter slack mode during activities when the back is upright (e.g., walking, carrying, pushing, pulling, running), so there is no interference during many tasks and activities commonly encountered in the workplace. When the suit provides assistance during bending (e.g., lifting and lowering), it provides less assistive forces than what the body generates naturally.

Participant Control over the Exosuit

The participant will have limited control over the exosuit via a shoulder-mounted handle. During Exosuit Training, the participant will learn to control the exosuit using the following modes:

- **On / Off Mode**: This switch determines whether the device is on or off. Users will be instructed to transition between these modes when they don or doff the exosuit, including if they make any major adjustments to exosuit fit.
  - ***Off:*** The suit is fully inactive, it does not track sensor data, and is not capable of applying forces.

- ***On:*** The suit undergoes a 1-2 second calibration after which it is capable of tracking sensor data and applying forces as directed by the exosuit's mode (active or slack).

- **There are two modes in the "on" phase:** active and slack.
  - ***Active Mode:*** This is the default mode when the exosuit is turned on. In active mode, the exosuit responds to the user's motion to deliver assistive forces via a generic sensor-based controller profile. The participant will have access to three handle buttons designed to modify exosuit assistance. These buttons do not change the way the exosuit delivers force, they change the overall assistance provided by the suit defined by the following two assistance gains:
    - Bottom button = High assistance, designed to deliver a maximum assistance of 250N when lifting
    - Middle button = Medium assistance, delivering approximately 75% of the high profile

    Users will be instructed to select between these modes based on their comfort, and as they move between more or less demanding lifts.

  - ***Slack Mode:*** This mode is engaged when the participant presses the top button. In slack mode the exosuit remains on, is capable of tracking sensor data, and keeps the exosuit ribbon cable tight on the user's body by applying a constant 5-10N of assistance to the user. Unlike active mode, assistance provided by the exosuit does not change as the user moves. Users will be instructed to select this mode when exosuit assistance can be bothersome and not helpful (e.g., while sitting).

ONGOING STUDY ACTIVITIES: OVERVIEW

The participants will perform their normal workplace tasks with or without wearing the exosuit (intervention and control group, respectively). Workplace tasks will not be influenced or determined by the study team. Participating in this study will not affect the employees' relationship with their employer. The Industrial Partner will not have access to participants' identifiable survey responses.

Supervisors and account managers will be trained to support their employees in the study. This support is necessary to ensure employees can participate in the study during working hours without workplace barriers. This support includes: working with their employees to schedule study activities, allocating time for employees to complete study activities during working hours, identifying and addressing workplace barriers, and facilitating communication between participants, the study team, and Verve Motion.

Industrial Partner leadership may disseminate study messages (e.g., updates on recruitment events, re-recruitment efforts, and study progress) to employees during Pre-Work Communication Meetings (PCMs). See the PCM document for more information.

Intervention Group (Exosuit Users)

Participants will be encouraged to wear the exosuit for the entire working day, while completing aspects of their job that involve repetitive lifting. The participant may doff the exosuit when not bending, lifting, or lowering objects below hip height (e.g., breaks, extended sitting). Exosuit compliance will be measured by data the suit automatically collects.

Verve Motion will check in with participants for device troubleshooting. For suit refittings, Verve Motion may complete or have the participant complete the Exosuit Survey, which captures refittings due to discomfort. Verve Motion may work with the participant to set goals for comfortable exosuit use. This may involve providing the participant data on their previous exosuit use to inform goals for future use (e.g., time used, weight offloaded, etc.). See also Section 18.1.

Control Group
Participants will perform their normal work activities without an exosuit.

Monthly Surveys (All Groups)

- ***Frequency:*** Participants will perform a monthly survey in REDCap, starting 1 month after the intervention begins – for the Exosuit Group, this would be 1 month following Exosuit Training; for the Control Group, this would be 1 month following randomization. These will be sent by email, through REDCap, or completed by phone. Survey completion could occur individually or in a group setting. Refreshments may be provided.
    - If REDCap is down, a study team member will go through the survey with the participant, recording their answers on the printed paper survey. Responses will be manually entered into REDCap. We will keep all paper surveys.
- ***Duration:*** REDCap surveys should take approximately 30-45 minutes to complete.

Study Support Reports (All Groups)
Relevant Industrial Partner staff (e.g., account and building managers) may receive an Identifiable Study Report regarding their employees' study compliance (e.g., exosuit use and survey completion), so they can identify and address workplace barriers and communicate to the study team as needed. See Section 3.3 *on Identifiable Reports*.

DATA COLLECTION

Data Collected by the Study Team

- Risk & Release and Shift Scheduling Form
- Shift Demonstration Return Survey
- Anonymous Survey (Optional)
- Screening Data
- Baseline Survey data to collect self-reported demographic, anthropometric, and LBP risk factors
- Monthly Survey data to collect self-reported LBP/LBI events, severity, intervention satisfaction, perceived effort, productivity, discomfort, fatigue, and system usability

- Exosuit Survey data to collect reason for exosuit refit or reason the participant no longer chooses to wear the exosuit

Data Collected by Verve Motion

- Suit sensor data
- Suit compliance data (time active, time slack, time at each level of gain)

Data Collected by the Industrial Collaborator

- OSHA reports of back injuries
- Participant time off work due to back injuries
- Participant employment status
- Participant time in modified duties (duration of lost time) due to back injuries
- Participant insurance cost for services related to back injuries

5.8. Does the study involve the use of deception and/or incomplete disclosure?
☒ **No** ☐ **Yes:** *If yes, explain the use of deception/incomplete disclosure and describe why it is necessary to achieve the goals of the study.*

5.9. When all research-related study procedures are complete, are there plans for long-term follow-up?
☒ **No** ☐ **Yes:** *If yes, indicate what data will be collected during this period.*

5.10. Does the study involve the collection of specimens (e.g. blood, cells, tissues, fluids, secretions, recombinant or synthetic nucleic acids, biological toxins, bacteria, virus, fungi, etc.)
☒ **No** ☐ **Yes:** *If yes, indicate the COMS Registration Number or plans to obtain COMS approval.*

5.11. Does the study involve the use of existing data, documents, records, and/or specimens for secondary analysis?
☐ **No** ☒ **Yes:** *If yes, indicate how, when, where, and from whom data, documents, records, and/or specimens will be obtained.*

Our Industrial Partner and Verve Motion will send us data that they have collected on the participants for use in this study (e.g., data they already collect, such as workplace injury, back injury events, time off work or modified work duties due to back injury, health insurance claims related to back pain or injury, type of health care provider accessed due to back injury). For a complete description of the data from our Industrial Partner and Verve Motion, see Section 5.7.

5.12. Are there provisions for medical and/or psychological support resources available to participants (e.g., in the event of incidental findings, research-related stress)?
☒ **No** ☐ **Yes:** *If yes, describe the provisions and their availability.*

5.13. Describe the data and safety monitoring plan for the study. This plan should outline how study progress will be monitored throughout the lifecycle of the research to ensure the safety of subjects, as well as the integrity and confidentiality of data.

Monitoring Plan: Dr. Walsh and Dr. Quirk will have ultimate responsibility for data safety and monitoring. Data and safety monitoring will occur on a regular basis.

- **Data Monitoring:** Incoming data will be regularly monitored. See Section 3.3.
- **Device Accountability:** See Section 24.5 for the Device Monitoring Plan.

Confidentiality: All data will be stored in a confidential manner. See Section 15.3 for data confidentiality requirements.

Adverse Events: AEs will be tracked regularly using the Monthly Survey and Exosuit Survey.

- **Time Period:** Participants will complete the Monthly Survey approximately every month (with the first survey at Month 1 and last survey at the end of Month 4). Participants will be asked to complete the Exosuit Survey whenever they are refitted to the exosuit. These surveys include a section about AEs.
- **Frequency:** The study team will review these surveys weekly.
- **Follow-up:** The study team can follow-up with participants directly (e.g., email or phone call) for more information.
- **Communication with Verve Motion:** Harvard will communicate exosuit-related AEs to Verve Motion and may work directly with Verve Motion to determine causality.

We recognize that some participants may reach out to the Industrial Partner or Verve Motion to report an AE. If this occurs, the Industrial Partner or Verve Motion will share details of this event with Harvard.

If the Industrial Partner encounters a workplace injury involving an exosuit user, they will be encouraged to contact Harvard. There may be times when the Industrial Partner and Verve Motion need to be consulted together to address exosuit issues regarding accessibility, employee usage, and exosuit discomfort.

5.14. Are there any anticipated circumstances under which participants will be withdrawn from the research without their consent?
☐ **No** ☒ **Yes:** *If yes, describe the circumstances for withdrawal as well any associated procedures to ensure orderly termination, appropriate referrals, and/or follow-up care.*

A participant may be withdrawn from the study if he/she is:

- Found ineligible to participate
- Unable to complete study-related tasks (e.g., misses two consecutive surveys without explanation)
- Unable to follow instructions to ensure their safety and integrity of the study

In any case of withdrawal, study staff will complete the Drop/Withdrawal Form to document and explain the participant's removal. Voluntary withdrawals will also be tracked.

6. **Recruitment Methods** ☐ **N/A.** *Skip to next section.*
Upload recruitment materials to the "Local-Site Documents" page in ESTR.

6.1. Indicate how, when, where, and by whom participants will be recruited. Provide a list of materials used to recruit participants, e.g., emails, posters, and/or scripts here.

Recruitment may occur via IRB-approved flyers, emails with IRB-approved text, exosuit demonstrations, information sessions, or word of mouth at the Industrial Partner. Industrial Partners may be given our eligibility criteria in advance and identify participants who may be interested in the study. Promotional materials (e.g., pens, stickers, mugs, etc.) with our study logo may accompany any of the active recruitment strategies described above.

7. **Consent Process**
Upload consent form(s) and debriefing materials, if applicable, to the "Local-Site Documents" page in ESTR.

7.1. Describe how the research team will invite participants to take part in the research and obtain consent to participate. If the research team will not obtain informed consent, provide justification for requesting a waiver or alteration of consent (and/or parental permission).

CONSENT OVERVIEW

Risk & Release Form: All participants who complete an Exosuit Shift Demonstration will be asked to sign a Risk & Release form. They will not sign a consent form, as this is not research. It is merely an exosuit demonstration to help employees determine whether they would like to participate in the Pilot Study and/or the Clinical Trial.

Informed Participation: Participants who complete the Anonymous Survey will not sign a consent form. Instead, the first page of the survey will include a consent form. Individuals completing the survey will need to acknowledge it (check a box) before moving on to the survey questions. The survey itself will not collect names.

Informed Consent: Participants in the Pilot Study and Clinical Trial will go through the informed consent process described below.

IN-PERSON CONSENT

If all eligibility criteria are met, the participant will be given a copy of the study consent form for review. A designated individual who is authorized to obtain consent will go through the

consent form with the potential participant and answer any questions. If the participant is interested, he/she will be asked to sign two copies of the consent form (i.e., one for our record and one for them to keep). Consent will only need to be obtained once before the first study visit.

VIRTUAL CONSENT

Informed Consent Conversation (Zoom or phone)

If all eligibility criteria are met, participants will be sent the IRB-approved consent form (either electronic or paper). A study team member trained to obtain consent will schedule a time to go over the consent with the participant over Zoom or phone. For this meeting, we may request participants be in a private room, if possible and as always, they will be allowed to have a family member or caregiver present. For participants who are new to the study team, identity verification is required during remote consent discussion (e.g., participant displays driver's license/ID on screen during Zoom call). A designated individual who is authorized to obtain consent will go through the consent form with the potential participant and answer any questions.

Electronic Consent Signatures

If participants were emailed a PDF version of the consent, they will be asked to electronically sign the electronic consent form using Adobe with Part 11 features enabled. Adobe Sign will automatically send the consenter and participant a signed copy of the fully signed consent form with an associated audit trail. This correspondence should be saved and uploaded into the participants study binder. When Adobe Sign is not a feasible option, the participant may be sent the consent as a fillable PDF and asked to type their name, signature, date and time of signage; or print the consent form, sign, date, time stamp, and scan/email the consent form back to the study team member in charge of consent. The consenter will also sign and time stamp the consent and email the completed form back to the participant via secure file transfer (via https://filetransfer.harvard.edu/) or via Harvard's Outlook Encryption option for their records. The completed form and email correspondence will be saved in the participant study file.

Paper Consent Signatures

If participants were mailed a paper copy of the consent, they will be asked to sign two copies (filling in the appropriate dates, selecting all relevant check boxes). Participants will be provided with a pre-paid envelope to mail the forms back to the research team. Once obtained, the team member in charge of obtaining consent will sign both forms, keeping one for our records and mailing the other back to the participant for their records.

RECONSENT

Participants will be reconsented if there have been significant IRB-approved changes to the consent form. A designated individual who is authorized to obtain consent will go through the changes with the participant and answer any questions. Participant signatures will be obtained via one of the following ways described above.

If the study requires additional consent or forms (e.g., HIPAA Authorization Form, re-consent, etc.), the above procedures will be used.

7.2. For participants under the local age of majority (e.g., 18 years old in Massachusetts), who may reach this milestone during the course of their participation in the study, describe plans to obtain informed consent as parental permission and/or child assent would no longer be valid for such participants. ☒ N/A

7.3. Describe how the research team will document the consent process (e.g., participant/researcher will both sign and date the consent document; participants will thumbprint the consent document; electronic consent will be obtained and associated with the participant's research record). If the research team will not obtain signature and date, provide justification for requesting a waiver or alteration of documentation of consent (and/or parental permission).

See Section 7.1.

7.4. If the research involves remote or electronic consent, describe how the research team will collect and maintain consent documentation (e.g., all pages of the signed consent form will be returned digitally and associated with the participant's research record; if the requirement for written documentation (signature) is waived, the consent process will be documented in a log; FDA-regulated research will include an identity verification process). ☐ N/A

See Section 7.1.

7.5. Will participants be offered a copy of the consent information?
☒ Yes ☐ No: *If no, explain why not.*

7.6. If consent will be obtained in a language other than English, identify the language(s) that consent information will be provided, who will be responsible for translation, and the provisions for communicating this information to participants. ☒ N/A

7.7. If the research involves deception and/or incomplete disclosure, describe the debriefing process. Explain when participants will be debriefed, who will debrief them, and how they will be debriefed. ☒ N/A

7.8. If the research involves secondary use of existing data, documents, records, and/or specimens, and the research team will not obtain consent, describe how consent was originally obtained. Additionally, either upload the original consent form to the ESTR record or confirm that the original consent process obtained participants' permission to share or use their data/specimens for future research projects. ☒ N/A

8. HIPAA Privacy Protections ☐ N/A. *Skip to next section.*
HIPAA applies to US-based research involving the collection or use of protected health information (PHI) from a hospital, health center (including the Harvard Dental Center), health

plan, or health insurance plan (i.e. a covered entity). The Privacy Rule will not directly regulate researchers who are engaged in research within organizations that are not covered entities even though they may gather, generate, access, and share personal health information (PHI). The Privacy Rule applies only to individually identifiable health information held or maintained by a covered entity. Individually identifiable health information that is held by anyone other than a covered entity, including an independent researcher who is not a covered entity, is not protected by the Privacy Rule and may be used or disclosed without regard to the Privacy Rule.

8.1. Explain how the Privacy Rule applies to this specific research project.
The Industrial Partner will share OSHA data (e.g., workplace injury) and insurance claims data (including medical costs and types of providers accessed to treat back pain or injuries) with the study team. Once the study team receives this data, it will be stored in accordance with the provisions described in Section 15.3.

8.2. Describe the covered entity involved in this research that holds or maintains the PHI that will be used by the researchers.
The Industrial Partner will share participant employee OSHA data with the study team.

8.3. Describe plans for obtaining authorization to access protected health information or provide the rationale for a waiver of authorization.
The Industrial Partner will share OSHA data of employees who have consented to this study.

9. Research Subject to the European Union (EU) General Data Protection Regulation (GDPR) ☒ **N/A.** *Skip to next section.*
GDPR applies to research involving the collection of "personal data" from research subjects who are located in the EU/EEA/UK. This includes biospecimens. The EU/EEA includes the 27 states of the European Union (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, & Sweden) and five additional countries: Iceland, Liechtenstein, Norway, Switzerland, & United Kingdom.

9.1. Describe plans to collect and/or obtain "pseudonymized data" (e.g., coded data) and/or identifiable data and/or biospecimens from participants in the EEA/UK.

9.2. Describe plans to destroy "pseudonymized data" (e.g., coded data) and/or identifiable data and/or biospecimens at the conclusion of the study.

9.3. Will data collected from individuals located in the EEA/UK include any of the following? (check all that apply)

- ☐ Health Information
- ☐ Racial or Ethnic Origin
- ☐ Political Opinions
- ☐ Religious or Philosophical Beliefs
- ☐ Trade Union Membership
- ☐ Sexual Orientation/Sex Life
- ☐ Biometric Data
- ☐ Genetic Data

☐ Criminal Activity ☐ None of the above

10. Research Subject to the Family Educational Rights and Privacy Act (FERPA)

☒ **N/A.** *Skip to next section.*

FERPA applies to research involving the collection of individually identifiable information from student records or personal education information from an education program (defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education).

10.1. Describe plans to collect and/or obtain individually identifiable information from student records or personal education information from an education program.

11. Vulnerable Populations ☐ **N/A.** *Skip to next section.*

11.1. Identify all vulnerable populations (e.g., children; pregnant women, human fetuses, neonates; prisoners; elderly; economically disadvantaged; employees or students of the investigator or sponsor; undocumented individuals; refugees; racial and/or ethnic minorities; illiterate or low literacy; military personnel; terminally ill; cognitively impaired or mentally ill; persons with a stigmatizing disease or condition, e.g., AIDS/HIV, etc.) and describe safeguards to protect their rights and welfare.

The Industrial Partner's employees may enroll in this research only if ALL the following conditions are met:

- The employee:
  - Is aware that participation in the study is completely voluntary and will not be used to sway benefits or employment status
  - Is aware their employer knows they are in the study
  - Is aware their supervisors will not have access to their individual responses but will know they are enrolled in this study and may help them address workplace barriers regarding their participation
  - Has had ample time to read over the consent form
- The consenter:
  - Is not in a senior or supervisory role to the employee

12. Risks

Risks may be physical, psychological, social, legal, reputational, and/or financial.

12.1. Describe the reasonably foreseeable risks, discomforts, and/or inconveniences to participants and/or the group/community to which they may belong. Indicate the probability, magnitude, and duration of each risk.

RISKS FOR BOTH GROUPS

Rare risks to both the control and exosuit could include breach of confidentiality. See Section 15.3 for provisions to maintain confidentiality.

CONTROL GROUP RISKS

Participation in the study should present no additional risk to the participants. The control group will perform their regular work activities and inclusion in the study will not modify work demands. The objectives of this study are to monitor pain, fatigue, exertion, and discomfort that develop naturally in the workplace.

INTERVENTION GROUP RISKS

The exosuit leverages a similar design and force delivery strategy to other soft-active exosuits, delivering assistive forces to the participant to reduce loads experienced by biological tissue (*76–78*). This device (*3*) and many others (*76–78*) using this soft-active approach have been tested in over 300 individuals, including individuals with neurological dysfunction (e.g., IRB22086, IRB13-2794, IRB15-1816, IRB16-1845).

Possible Minor Risks:

- Skin discomfort, redness, chafing, rash, pinching, numbness, tingling, swelling, itchiness, temporary skin indentation, and blisters
- Movement and balance disruptions
- Muscle cramps, pulls, or soreness
- Joint discomfort, soreness, injury, and 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, participants will be trained to seek help from Verve Motion or take a short break from the suit if these problems occur.

High Picker Note: Using the exosuit while on the high picker may be uncomfortable. To mitigate the risk of discomfort, participants will be trained to position the exosuit above the harness in a way to prevent the exosuit from compressing rigid metal components. Since the exosuit is worn over the harness, participants can easily adjust the exosuit if they experience discomfort.

Exosuit Catching

Should the device, straps, or cables get caught on something (e.g., shelf), it can be startling, uncomfortable, or disrupt natural movement and balance. To minimize this risk, the straps and cables are as short as possible and are routed close to the body through covered surfaces where possible to reduce the likelihood of catching.

Exosuit Bumping

The exosuit will project from the back and has the risk of bumping into objects (shelves), other equipment, or employees. Bumps can be uncomfortable, startling, or could disrupt your natural movement and balance. To minimize this risk our exosuit has a low-profile design so participants quickly adapt to the device.

Exosuit Controls
Because participants can adjust exosuit assistance, it is possible that they could set parameters that cause some discomfort. However, the controller changes they can make are limited to minimize this risk. The maximum assistive force delivered by this device and controller is less than what a healthy adult can naturally generate, reducing the risk of selecting an option that generates too much force.

Active Mode Malfunction
The exosuit provides active assistance based on a sensor and computer. For this reason, a sensor malfunction or unanticipated problem could result in the device applying a different force than expected. This experience could be uncomfortable, startling, result in movement or balance disruptions, and cause the participant to modify movement to correct for this malfunction. Because the assistive force delivered by the device is less than what a healthy adult can naturally generate, their body should make up for unexpected exosuit assistance. When participants experience this issue, they will be trained to turn-off and remove the suit. They will be instructed to ask Verve Motion for help if the problem persists.

Actuator Failure
The exosuit applies assistance using a motor (actuator) and a nylon ribbon cable. There is a rare risk of actuator failure or ribbon catching resulting in the device applying more or less force than expected at an unexpected time. If the sensors malfunction there is a risk participants will be startled and modify movement to correct for this malfunction, this experience could be uncomfortable, startling, or could result in disruptions in movement and balance. Risk of actuator failure will be minimized by regular maintenance performed throughout the study.

<u>Rare Risks:</u>

- Burn/Heat production
- Serious injury or death from a fall (High Picker Users)
- Electrical shock

Electrical Safety
As with any electrical device, there is a very minimal risk of electrical shock. To reduce this risk all electrical components will be sealed in non-conducting plastic boxes and all wires will be coated. All electronics will be periodically checked through the study.

During operation, there is a risk of uncomfortable heat production. The components with the ability to generate heat will be located away from the body (i.e., they will not touch the skin). The components also have cooling fans inside them to allow ventilation and minimize heat production if it occurs. All suit components will be periodically checked throughout the study.

High Picker Note: The exosuit is designed to be worn over clothing and is coated with durable cables. However, wearing the exosuit over a harness could increase exosuit wear and tear. Verve Motion will inspect the suit for wear and tear when they conduct their regular electronics checks.

Serious Injury or Death (High Picker Users)

While wearing the exosuit on the high picker does not increase the likelihood of balance disruptions, the seriousness of falling is elevated. Participants who use the high picker while wearing the exosuit could anchor the arrest tether to the exosuit. Doing so could result in serious injury or death in the case of a fall. To minimize the possibility of this occurrence, the team has modified the exosuit design for this participant group to remove the carry handle. Removing the handle removes the opportunity that the arrest/fall harness is erroneously attached to the handle, rather than the proper anchor point. Participants will be informed of these risks and the need to wear their fall harness consistent with their training. To mitigate this risk, participants can only operate the high picker with the exosuit if they have a PITO License, will be trained to use the exosuit with the high picker, and will be assigned an exosuit without a carry handle.



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

12.2. Identify whether any of the information collected, if disclosed outside of the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, or reputation.

While this study does collect sensitive data, we believe the information collected, should it be disclosed outside of the research, would only pose minimal risk to the participants. The sensitive data collected as part of this study is data provided by the participants' employer and the research activities are comparable to what research participants would ordinarily encounter during their daily lives.

This study will have no effect on participants' employment status. While supervisors may know their employee is enrolled in this study and may them address workplace barriers regarding their participation, they will not have access to participants' individual responses.

12.3. Outline provisions in place to minimize each risk identified above.

See Section 12.1.

13. Benefits

13.1. Describe the potential benefits to individual participants, if any, and/or society. If there are no direct benefits, state that here. Note: payment/compensation is not a benefit.

There are no direct benefits to participating. However, the results of this research may lead to a new method to reduce workplace related low back pain and injuries.

14. Participant Privacy

14.1. Describe provisions to protect participants' privacy (their ability to control and limit the extent, timing, and circumstances of sharing information about themselves with others, e.g., the use of a private interview room) and to minimize any sense of intrusiveness that may be caused by study questions or procedures.

Testing Location: Due to the location of testing and nature of intervention, we cannot guarantee privacy during the study.

Data Confidentiality: See Section 15.

Promotional Materials – Separate Media Release Form: Participants 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 participant study activities.

15. Data Confidentiality

15.1. Indicate the identifiability of the data/specimens: (check all that apply)

☒	Data will not contain any direct or indirect identifiers (anonymous data), e.g., underlying data did not collect identifiers and/or the data provider will remove the identifiers before sharing with Harvard agents.
☒	Data will contain direct or indirect identifiers, but the research team will remove them upon receipt (de-identified data).
☒	Data will contain direct and indirect identifiers (i.e., number, letter, symbol, or combination thereof) and the research team will maintain a key that links identifiers to individual participants (coded data).
☒	Data will contain direct identifiers (identifiable data).
☐	None of the above; describe:

15.2. Have any identifiable data/specimens been de-identified for use in this research study?
☒ **No** ☐ **Yes:** *If yes, describe how you will prevent any re-identification.*

15.3. Identify where data/specimens will be stored (e.g., on campus at Harvard or remotely, in a specimen laboratory) and describe the provisions to maintain confidentiality (e.g., password protection, encryption, locked filing cabinets, etc.). Refer to the Investigator Manual and the Harvard Research Data Security Policy for additional information.

Identifiable Data: Identifiable data will be collected and shared with the following essential individuals –

- **Survey data:** Includes participant initials and email address. These data will be stored on REDCap, accessible only to study team members. The study team may share identifiable responses with Verve, as they relate to exosuit fit/comfort.
- **Verve suit data:** Includes participant names, as this is the method Verve Motion uses to track data. This data will be shared with the study team via Harvard Google Drive. Only Verve Motion and the study team will have access to these identifiable data.
- **Industrial Partner HR data:** Includes participant names, as this is the method they use to track data. This data will be shared with the study team via Harvard Teams. Only our Industrial Partner and the study team will have access to these identifiable data. *Note: OSHA data will be de-identified.*
- **Identifiable Reports:** Includes participant names. These reports will be stored in Harvard Teams. Only our Industrial Partner, Verve Motion, and the study team will have access to these identifiable reports, either shared in Teams or via encrypted email.

Participant Code: Data when shared with non-essential individuals (i.e., those not identified above in *Identifiable Data*) will be labeled using a participant ID number.

Participant ID Code List: A code list linking the participant's name and consent form to the participant number will be kept electronically on the Wyss Institute/Harvard secure server space. Access is limited to Dr. Quirk and select study team members. This list will be archived upon closure of the research project with the IRB separately from other study forms on firewall-protected, clinical research team digital storage.

Research Data: All data will be shared within the research team and will be stored on the Wyss Institute/Harvard firewall- and password-protected server with access limited to the research team (i.e., SharePoint, REDCap, Isilon) or in the locations described above in *Identifiable Data.* Harvard Google Drive may be used to transfer identifiable data between Verve Motion and the study team. Harvard Teams may be used to transfer identifiable data between the Industrial Partner and the study team.

Institutional Dropbox, Teams, or Google Drive accounts may also be used to store de-identified/coded information or presentations, but personal Dropbox, Teams, and Google Drive accounts will not be permitted. Data may be transferred as a local copy on encrypted password

protected personal computers for processing or to prepare media material for publications, presentations, or training purposes.

Paper Documents: Any paper documents will be stored in a locked file cabinet, accessible to the research team. This locked file cabinet is kept at Harvard, which requires an ID Badge to enter and has security guard monitoring. Paper files may also be scanned and stored electronically as described above under *Research Data*.

15.4. Indicate whether any data/specimens will be transferred/transmitted and describe the plan to share the data/specimens (e.g., outside of Harvard, to other researchers, to collaborators). Indicate who may request access and how. If data/specimens will be transferred/transmitted/shared, describe how, when, and to whom.

Collaborators, Publications, Presentations, or Teaching/Training
We may use data, images, and recordings we collect with our collaborators or in publications, presentations, or for teaching/training purposes. We have included this information in the consent form. Participant name and other personally identifying information will not be kept with the data when shared outside the study team.

NIH Heal Initiative
Note: The NIH Heal Initiative applies to data collected prior to May 2025 (i.e., when NIH/NIAMS funding was active).
This study is part of the NIH HEAL Initiative focused on understanding and developing new treatments for addiction and pain. Participant data could be used for this and other NIH HEAL Initiative studies insofar as it provides evidence of whether an intervention (exosuit) can reduce the development of LBP. 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 for additional consent.

Data will be stored securely at Harvard or at sites NIH selects for this study. Participant name and other personally identifying information will not be kept with the data. Data will be stored with or without a code that links to identifying information. If the 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.

Withdraw
If participants withdraw from this research study before it is done, we will keep and continue to use data that have already been collected.

15.5. Indicate whether participants' permission will be obtained to share their data/specimens and/or use their data/specimens in other future research projects.

Additional permission will not be obtained. The consent form includes data sharing language.

15.6. Will recordings be obtained in this research study?

☒ No ☐ Yes: *If yes, select the kind(s) of recording and describe the transcription and destruction plan.*

☐ Audio recording	☐ Video recording
Transcription plan: Destruction plan:	

15.7. Indicate who is responsible for data/specimen management and how the research team and/or other collaborators are permitted access to information.

Drs. Walsh and Quirk, in collaboration with the study team, will be responsible for monitoring the overall progress and integrity of all aspects of the research. The research will be monitored by the Principal Investigators and Research Manager on a periodic basis.

A study regulatory binder will be maintained by the study team. Access to study databases will only be granted to those who are on the IRB-approved study team.

15.8. Indicate how long data/specimens will be stored and describe the plans at the end of the storage period (e.g., are data/specimens destroyed, returned to data/specimen provider, etc.).

Seven Year Storage: The protocol will be officially closed with the IRB once identified data analysis is complete. At this point, the code list linking the participant to their study data and all other identifiable information stored on SharePoint will be moved to a server only accessible to the clinical research staff and stored for long term data retention. The signed consent forms will be stored with participant files. This data will be stored for seven years at the Wyss Institute, per Harvard document retention suggestions and guidelines.

End of Storage Period: Upon completion of university/sponsor long term storage guidelines, all identifying information will be destroyed (shredded or permanently deleted electronically). Coded data will be stored indefinitely.

16. Data/Statistical Analyses Plan

16.1. Describe plans for analysis (including the statistical method, if applicable).

This study is a randomized, single-blind, controlled trial. While the participants will not be blinded, one statistician (Ryan Pohlig) will be.

Primary Objective 1-A: Determine whether back exosuits reduce LBP with work interference
LBP with work interference will be monitored monthly using the CMDQ Scale (6). This scale involves the calculation of a composite score at multiple body locations, when considering an individual's self-report of pain frequency, intensity, and disability (work interference). As this scale captures pain frequency and intensity, it will function as this study's key outcome

measure. The parametric composite score at the low back location will be calculated at five time points: Baseline (month 0), and with each monthly survey (1, 2, 3 and 4).

A Linear Mixed Model (LMM) will be used to test the hypothesis whether the exosuit group experiences reduced work interfering LBP when compared to the no-exosuit group and determines whether the effect of the exosuit improves or diminishes over the time of the experiment using the uncorrected LMM that contains at least 2 factors (group (2) and time (5)).

Larger models will be developed to correct significant confounding variables. A LMM was selected as it allows for the inclusion of time-varying covariates and estimates in the presence of missing data without listwise deletion. Significance for this co-primary outcome measure will be set with an exploratory alpha of 0.05. Significant interaction and main effects will be post-hoc tested by examining simple main effects or simple effects, respectively, using Fisher's LSD procedure for pairwise comparisons. These models assume linearity and normality, which will be evaluated using Box-Cox and Shapiro-Wilk tests, respectively. Outliers and influential cases will be screened for and removed. Violations of the assumptions will be remedied using a robust standard error or recommended Johnson transformation using Minitab 19.

Primary Objective 1-A: Determine whether back exosuits reduce LBI rates

To determine whether the exosuit reduces the likelihood of developing LBP, the definition of a LBP incidence will be characterized by 4 operational definitions. 1) CMDSQ score at the low back greater than 6.0 (a score corresponding to: discomfort 1-2 times per week with severe discomfort and severe interference, or discomfort 3-4 times a week with moderate discomfort and interference), 2) self-report of activity limiting LBP > 3 days, 3) self-reported LBP resulting in time off work, and 4) self-reported LBP resulting in seeking medical attention. Using each definition, a participant's injury status will be categorized as yes or no at baseline and every month. If the participant is categorized in the affirmative at any follow-up time point (Month 1-4) without LBP at baseline, they will be defined as developing LBP.

Definitions with an incidence rate above 10% will be entered into a General Estimating Equation (GEE) will be used to test the hypothesis whether the exosuit group experiences a lower proportion of LBP than the control group. Larger models will be developed to correct significant confounding variables. A GEE was selected as it allows for the inclusion of time-varying covariates and estimates in the presence of missing data without listwise deletion. The distribution and fit function for the GEE will be selected based on minimizing the information criteria (Akaike Information Criteria and Bayesian Information Criteria). As the outcome measures of incidence could be below threshold (10%) for all definitions of LBP, significance for this co-primary outcome measure will be set with an exploratory alpha of 0.05.

Secondary and Tertiary Objectives

Parametric data listed in the secondary and tertiary objectives will be tested using a linear mixed model (LMM) that contains at least 2 factors (group (2) and time (5)). Larger models will be developed to correct significant confounding variables. The significance for these outcome measures will be corrected using the most conservative Bonferonni adjusted alpha to prevent inflation of type-I error.

Inclusion of Confounding Baseline Data

Baseline confounders between the exosuit and non-exosuit group will be compared using t-test, Wilcoxon, or Chi-square test for parametric, rank order, and categorical data respectively. Factors which obtain an alpha of 0.05 will be entered as co-variates into larger LMM and GEE models described above to correct for group differences.

Missing Data

Mixed models and estimating equations use all available information for each participant which enables estimates and tests for significance in the presence of missing data.

Loss to Follow-Up Analysis

Enrolled participants' data will be defined as complete or lost to follow up at 4 months. Baseline characteristics between participants who were and were not lost to follow up will be compared using t-test, Wilcoxon, or Chi-square test for parametric, rank order, and categorical data respectively.

Adverse Event Analysis

Many AEs will be analyzed as part of our Secondary and Tertiary Objectives. However, key AEs (thermal discomfort, skin issues, body discomfort, bumping, and movement disruptions) will be analyzed similar to objective 1-A. For Months 1-4, monthly survey data will be used to calculate an AE score for each category by multiplying the frequency score used in the CMDQ by perceived severity (Mild=1, Moderate=4, and Severe=9). These data will be compared in an LMM for group (2) and time (4).

The Likelihood of AEs will be compared similar to objective 1-A. Over the duration of the study, the presence or absence of the AEs gathered in the Monthly survey noted above will be considered for each event with a score greater than 13.5. These AEs will be compared using a GEE. The likelihood of Severe or Unexpected AEs (Cancer, hospitalization, Cardiac, etc.) will be considered present or absent and will be compared using a Chi-Square analysis.

Note on Suit Compliance

Primary analysis will be conducted using an "intention to treat" approach (exosuit vs. control). A secondary analysis will be included correcting data to a participant's average exosuit usage (compliance) and the amount of time worked (occupational exposure). Verve Motion suit data will confirm the amount of time the device was active (i.e., hours per week, days per week). Industrial Partner data will indicate the amount of time the participant worked (i.e., hours per week, days per week). The study team will cross-reference suit use with employee time worked to determine suit compliance. Exosuit compliance thresholds will be accounted for as a covariant in our statistical analyses. Similar to all co-variates, percentage of exosuit use and an employee's time worked will be included as a parametric co-variate, or as a non-parametric ordinal category as determined by our biostatistician, to understand the dosage effect of the exosuit.

16.2. Is there a sample size/power calculation?

☐ No ☒ Yes: *If yes, describe the calculation and the scientific rationale, and, if applicable, by site and key characteristics such as participant demographics.*

A sample size and power calculation were conducted for each of our co-primary outcome measures.

Primary Objective 1-A: Determine whether back exosuits reduce LBP with work interference
Considering the Cornell Musculoskeletal Discomfort Questionnaire (CMDQ) there exists a singular study which demonstrates using a shoulder exosuit can reduce workplace discomfort in a small longitudinal pilot study (80). Despite data from Kim et al., suggesting the effect size of an exosuit is quite profound leading to a 20-point reduction in shoulder discomfort, our group anticipates a modest reduction the low back CMDQ of 7. Considering occupational scores of LBP specific CMDQ scores have a standard deviation of 10 (80, 81), our anticipated modest reduction in workplace discomfort would have a medium effect size (d=0.7). Thus, the study would require a sample of 66 participants (33 exosuit users and 33 controls) to determine an uncorrected difference between the exosuit and non-exosuit group, to achieve 80% power with a probability of 5%.

Primary Objective 1-A: Determine whether back exosuits reduce LBI rates
There exists no study which demonstrates the in-field efficacy of an exosuit or exoskeleton to reduce the odds of developing a LBI. Studies do exist to characterize the impact of back extensor moments on developing occupational LBP (46). In a prospective study, Coenen et al. demonstrates individuals who developed LBP were exposed to higher (0.33±0.17MNms) cumulative back extensor moments than those who did not (0.30±0.10 MNms). Using the short-term biomechanical reduction in back extensor moments as measured in our experimental work (3), we calculated our exosuit would reduce cumulative back extensor moments by 0.06MNms if an individual were to lift at a rate of 5 lifts per minute for 7 hours. Considering this estimated cumulative back extensor moment reduction, our exosuit would have a medium effect size (d=0.3-0.6) when using the minimum (0.10) and pooled (0.135) standard deviation of cumulative occupational loads. Thus, we would require a sample size of 90 (45 suits and 45 controls) or 160 participants (80 suits and 80 controls) when using the minimum or pooled standard deviation respectively in order to have 80% power to detect a difference between the exosuit and non-exosuit group with a probability of 5%.

Our randomization goal of 150-180 was selected to ensure the study could determine whether the exosuit can reduce the odds of developing LBP when assuming a 35% participant dropout rate and using our most conservative effect size predicted with a pooled variation in cumulative spinal moments. However, Objective 1-B will likely be this studies most dependable primary outcome measure.

17. Costs and Compensation ☐ **N/A.** *Skip to next section.*

17.1. Identify any costs that participants may incur during the study, including transportation costs, childcare, or other out-of-pocket expenses.

Harvard will not be responsible for any costs that result from any incidental finding seen during the study procedures or physical injury related to the research.

17.2. Identify remuneration that participants may receive during the study. Specify the amount, timing of disbursement, and method (e.g., money, gift cards, in-kind, incentives, raffles, and transportation). Describe how compensation will be calculated and paid if a participant withdraws. If any participant will receive a single payment more than $100, or $600 or more in one calendar year, refer to Harvard University Financial Policy on Human Subject Payments.

Compensation and apparel for the Pilot Studies and Clinical Trial are described below.

PILOT COMPENSATION*

Baseline Survey **Completed within 14 days of receiving the REDCap link*	$10 Wicking T-shirt
Comprehensive Survey **Completed within 14 days of receiving the REDCap link*	$15
Weekly Survey Completion Bonus * *A survey counts toward this bonus if completed within 7 days of receiving the REDCap link* * *Must complete ≥75% of surveys (e.g., 3/4 surveys) each month* * *If a participant is on vacation or sick, they must still submit the Weekly Survey within 7 days (i.e., before the next survey is released)*	$15* Awarded Monthly

Maximum Compensation: $55

Note on Pilot 1 Participants: Participants in Pilot 1 who completed Weekly Surveys within the above timeframes will be compensated retroactively.

CLINICAL TRIAL COMPENSATION*

4-Hour Demonstration *Compensated for completion, independent of study enrollment*	$0 Branded Water Bottle
Baseline Survey	$20 Amazon Gift Card Branded Apparel
1st Monthly Survey	$20 Amazon Gift Card
2nd Monthly Survey	$20 Amazon Gift Card Branded Apparel
3rd Monthly Survey	$20 Amazon Gift Card
4th Monthly Survey	$20 Amazon Gift Card Branded Apparel
**A survey is eligible for compensation and apparel if completed within 28 days of receiving the REDCap link (i.e., before the next survey is released). The Exosuit Group*	

must also wear the exosuit >64 hours over 2 months (e.g., ~4 days/week for >2 hours/day) to be eligible for the branded apparel. Exceptions can be made for participants who have recorded AEs that made it difficult for them to achieve 64 hours within the past 2 months.

If a participant is withdrawn from the Exosuit Group due to discomfort issues that are severe or reoccurring and the participant is advised not to continue, they will still be eligible for branded apparel upon eligible completion of the Monthly Survey.

Maximum Compensation: $100

18. Sharing Study Results ☐ **N/A.** *Skip to next section.*

18.1. Describe the plan to share study results with individual participants, the participant group/community, and/or others.

PROGRESS REPORTS
De-identified or anonymous group aggregate data may be reported to study collaborators (e.g., the Industrial Partner, Liberty Mutual) and Verve Motion.

EXOSUIT GOAL-SETTING
Verve Motion may discuss exosuit data (e.g., weight offloaded, hours used, days retrieved) with participants to help with individual exosuit goal setting. The aim is for Verve Motion to ensure suit comfort, identify barriers to suit use, and determine if retraining is needed. For example, if the weight offloaded by the suit is low, it could indicate the individual is keeping the suit in slack mode, which may indicate they need to be retrained on the suit controls. If data suggests the suit was only retrieved a few days, that could correspond to the employee not returning the exosuit at the end of their shift. This task is within their role as a vendor.

EMPLOYEE-FACING RESULTS
The study team may share aggregate study data (e.g., exosuit use, weight offloaded, survey completion) with employees onsite via a poster, monitor, or PCM in the workplace. This aggregate data may be broken down by site, so participants can see how their site compares to other sites.

CLINICALTRIALS.GOV
Results may be shared on clinicaltrials.gov, in accordance with NIH policy.

19. Research Related Injuries ☐ **N/A.** *Skip to next section.*

19.1. Describe plans for medical care and compensation for research-related injuries.

If physical injury resulting from participation in this research should occur, Harvard's policy is not to provide compensation. The participant's insurance carrier may be billed for the cost of such treatment.

20. Reportable Events

20.1. Outline plans for communicating reportable events to the IRB, Sponsor, or others as applicable (e.g., adverse events, unanticipated problems involving risks to participants or others, breach of confidentiality).

Definitions

Adverse Device Effect (ADE): Any adverse event that is related or possibly related to the device.

Adverse Event (AE): Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

Serious Adverse Event (SAE): Any Adverse Event that (1) results in death; (2) is life-threatening (places the subject at immediate risk of death from the event as it occurred); (3) results in inpatient hospitalization or prolongation of existing hospitalization; (4) results in a persistent or significant disability/incapacity; (5) results in a congenital anomaly/birth defect; or (6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Unanticipated Adverse Device Effect (UADE): Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Unanticipated Problem (UP) Involving Risk to Participants or Others: Any information that is (1) unanticipated; (2) related or possibly related to participation in the research; and (3) indicates that participants or others are at increased risk of harm.

Protocol Deviation: Any departure from our IRB-approved research protocol.

Harvard IRB Requirements

If a deviation in data collection/usage, adverse or unanticipated event involving risks to participants or others, or a breach in confidentiality is suspected or found, the incident will be reported to the IRB either immediately, within 5 business days via an RNI, or at continuing review depending on the severity of the event.

FDA Policy

Unanticipated Adverse Device Effect (UADE) Reporting

The study team will immediately conduct an evaluation of the adverse device effect (ADE) to determine if it is an UADE. If the study team determines that it is a UADE, the study team will terminate the activities that present that risk as soon as possible – no later than 5 working days

after making this determination and no later than 15 working days after receiving notice of this effect. The terminated activity may not resume without IRB and FDA approval (21CFR812.46)

UADEs will be reported to the IRB using either the SAE Form or UP Form (whichever is applicable for the event) and will be submitted to the FDA via the following link https://www.accessdata.fda.gov/scripts/medwatch/index.cfm within 10 working days after receiving notice of the effect. Additional reports may be submitted as requested by the IRB and FDA (21CFR812.150(b)(1)).

21. Regulatory Compliance

21.1. Describe plans for monitoring regulatory compliance. The monitoring plan should include how you will ensure proper record keeping, retention of required regulatory documents and participant files, and adherence to the IRB-approved protocol and/or IRB policies and procedures. Monitoring plans should describe 1) who is responsible for file maintenance, 2) what will be maintained, 3) how often files will be reviewed and using what method, and 4) where documentation will be retained (for both Regulatory Documents and Participant files). The IRB recommends the use of QIP's Study Management Tools to monitor regulatory compliance and organize study documents.

See Section 5.13.

22. Data or Biospecimen Sharing ☐ **N/A.** *Skip to next section.*
If you plan to establish a repository, please submit a separate application using the HLC Repository Protocol Template.

22.1. Describe the plan to send data/specimens to research collaborators outside of Harvard.
☐ **N/A**

See Section 15.4.

22.2. Describe the plan to receive data/specimens from collaborators outside of Harvard.
☐ **N/A**

See Section 3.3.

23. Clinical Trials ☐ **N/A.** *Skip to next section.*
Complete this section for clinical trials, including NIH funded clinical trials or applicable clinical trials (ACT) under the FDA Amendments Act. To determine if a study meets the definition of a clinical trial, follow the guidance in the "Preparing the Research Protocol" section of the Investigator Manual.

23.1. Describe how this study meets the definition of a clinical trial.

Our trial meets all four of the NIH's criteria of a clinical trial:

1. **Does the study involve human participants?**

Yes.

2. **Are the participants prospectively assigned to an intervention?**
   Yes.
3. **Is the study designed to evaluate the effect of the intervention on the participants?**
   Yes.
4. **Is the effect being evaluated a health-related biomedical or behavioral outcome?**
   Yes.

Source: https://grants.nih.gov/policy/clinical-trials/definition.htm

23.2. Describe plans for registering this project in a clinical trials registry, e.g., clinicaltrials.gov. If available, provide the registry record number.

The study will be registered on clinicaltrials.gov no later than 21 days after the first Trial participant is enrolled.

23.3. Describe plans for posting the clinical trial consent form on a publicly available federal website per federal requirements in the Common Rule (45§46.116(h)).

Requirement: According to Sections 46.102(b) and 46.116(h) of the revised Common Rule, we are required to post an IRB-approved version of our consent form on a public federal website.

Plan: We plan to post an IRB-approved version of our consent form to our clinicaltrials.gov study record no later than 60 days following the last study visit.

Source: https://grants.nih.gov/policy/clinical-trials/informedconsent.htm

24. Device *This section should be completed if the study involves the use of any device on/in/with human subjects, and/or the use any device utilizing human specimens, which meets the FDA definition of a medical device.* ☐ **N/A.** *Skip to next section.*

24.1. Describe the device, including the generic or common name, brand name (if applicable), purpose, function/operation, and whether it is an implant. Indicate who is providing this device for research use.

Generic name: Back Exosuit or Back Exoskeleton

Brand name: Verve SafeLift

Purpose: The soft wearable robotic suit and its components are designed to improve wearer physiology, kinetics, kinematics to reduce the possibility of injury. This back exosuit has demonstrated significant reductions in back (18%), hip (11%) and knee (22%) extensor muscle activity during a 1-hour workplace simulation task when compared to lifting without a suit.

Function: The soft wearable robot is primarily composed of textiles that wrap around the body to generate anchor points on both sides of one or multiple joints. An actuating element attaches to those anchor elements to provide assistive forces while the user performs a physical activity. The soft wearable robot integrates sensing components to be able to detect user biomechanics and device function, actuating elements to provide assistive forces to the user, soft components (e.g., textiles) to anchor to the user and algorithms that use sensing information to command the actuation to appropriately time the assistance to the user.

Implant: No

Provider: Verve Motion

24.2. Indicate the FDA status of the device as it is being used for the proposed research:

☐ FDA-approved device being used "on-label" (i.e., FDA-approved purpose, population, manner).

☐ FDA-approved device that is being used "off-label" (i.e., for a different purpose, population, or in a different manner than approved).

☒ Not approved by the FDA.

24.3. Indicate the IDE Status of this device:

☐ The use of this device has an IDE.

☒ The use of the device qualifies for an Abbreviated IDE.

☐ The use of the device is exempt from the IDE requirements.

24.4. Has the FDA made a determination as to whether the device is Significant Risk or Non-Significant Risk? ☒ No ☐ Yes: *If yes, indicate the FDA's determination.*

24.5. Describe plans for storage control, and dispensing of the product so that (1) only authorized investigators will use the product; (2) the product will only be used in participants who have provided consent, and (3) there will be documented tracking of each product, including unique identifiers and any return/disposal.

DEVICE MONITORING PLAN

Device Distribution: Participants who are randomly assigned to the exosuit group will be uniquely fitted to an exosuit that they will be asked to wear for the duration of the study. The exosuit will be labeled with a unique ID number, so participants know which exosuit is theirs.

Device Monitoring: Verve Motion can track exosuit usability (i.e., when the exosuit was removed from the docking station and when it was returned) and will be responsible for device monitoring and accountability.

Device Accountability and Return: Verve Motion will be responsible for device return.

25. Drug/Biologic *This section should be completed if the study involves the use of any drug/biologic on/in/with human subjects which meets the FDA definition of a drug/biologic.* ☒ **N/A.** *Skip this section.*

25.1. Describe the drug or biologic, including the generic or common name, brand name (if applicable), dosing, route of administration, number of doses, timing of administration. Indicate who is providing the drug, biologic, supplement for research use.

25.2. Indicate the IND Status of this drug or biologic and who holds the IND: (select one)

☐	There is an IND approval from the FDA for the use of this item.
	The IND is held by:
	The IND number is:
☐	An IND application has been, or will be, submitted to the FDA.
	The IND will be held by:
	The IND number is:
☐	An IND approval is not required.

25.3. Describe how dispensing, delivery and administration will be performed, and by whom. Include information about control (e.g., locked storage), tracking (e.g., lot number, returned pills), documentation, storage, and return/disposal.

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