**COVER PAGE**

**OFFICIAL TITLE OF THE STUDY: A preliminary clinical usability study to assess design, comfort, wearability, and acceptance of Recovery Force's Deep vein thrombosis (DVT) cuff.**

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**A preliminary clinical usability study to assess design, comfort, wearability, and acceptance of Recovery Force's Deep vein thrombosis (DVT) cuff.**

## Hypothesis

The primary hypothesis for this Phase I study is following Recovery Force's DVT II cuff demonstration, participants will be strongly satisfied with design, comfort and wearability of the product. This will lead to a Phase II study, where it can be predicted that their perceived adherence to wearing the device will be high.

## Outcome Measures

Primary Outcome Measures are Wearability/Comfort and patient acceptance, which are the two key components for adherence and compliance to the product. This is evaluated through the Cuff Evaluation Questionnaire: For Assessment of cuff comfort, flexibility, temperature, ability of the cuff to remain in place on the leg, and sweatiness of the leg.

Secondary Outcome Measures are Usability and Design-Human Factors. This is designed to confirm that product and engineering requirements are in alignment. These outcome measures will provide feedback on compression, cycle sequence, target zones, materials, comfort, and mobility.

## Methods and Study Design

A single site, observational study will be conducted at the University of Southern California (USC) with participants who have and/or have had previous experience with DVT pneumatic cuffs. Study staff will examine participants overall experience, product functionality and perceived adherence to Recovery Force's DVT II cuff. About 46 participants will be recruited into the study. (Estimated recruitment duration – about 2 months)

## Study Population and Inclusion Criteria

Male or Female Age 18-65 who have had exposure with a DVT cuff on the calf within the last 6 months from a previous or current clinical condition will be enrolled to the study.

## Recruitment

Participants will be recruited from USC database, and referrals from physicians, clinicians, and vascular clinicians and staff. Study staff will obtain approval from the IRB and consent from each participant. All subjects will be consented individually in a private room. All study documents, including original signed consents, will be maintained for up to 10 years. Personal information regarding participation in this study may be disclosed if required by state law.

## Tests and Procedures

***Pre- Demonstrations Questionnaires*:** Prior to beginning the prototype demonstration, participants and study staff will have completed an inclusion questionnaire with demographic

information and a Prior DVT Cuff Experience questionnaire. Demographics information includes Age, Gender, Ethnicity, Brief Medical History, Last Month of DVT Cuff use, Type of Prior DVT Cuff/Model.

**Prior Experience with DVT Devices Questionnaire:** A series of questions used to gauge patient experience with and attitudes towards DVT devices. Major topics will include the application and availability of DVT devices, perceptions regarding bothersome and pleasurable aspects of DVT devices.

***Prototype Demonstration*:** Recovery Force will provide five DVT II prototypes for the study. Participants will test DVT II cuff prototype. Each participant will examine, wear, and remove a DVT Cuff for a total of 40 minutes test time and turn on the device for a minimum of 20 minutes. As participants try on the DVT II, they will be asked to mimic normal behavior (walking/sitting/standing/supine position).

***Post- Demonstrations Questionnaires*:** The study will include primary and secondary outcome questionnaires that access human factor engineering and usability.

***Closing interview*:** A closing interview of 20 min will be conducted by the study team. A series of follow-up post-demonstration questions using a semi-structured interview with an interpretative phenomenological analysis approach [34] will be recorded and transcribed by a study staff. This interview will focus on initial exposure to the device, user impressions, suggestions, critiques and overall appeal.

**Sample size calculation**

Using a sample power analysis (IBM SPSS), the PI determined 34 total patients will be needed, using an error margin of 0.2 points based on overall expected responses to questionnaires, assuming 10% missing data, alpha level of 95% certainty. Assuming a 25% dropout rate, the recruitment goal will increase to 46 participants.
The small sample size was also recommended as a preliminary assessment of product design and human factor usability that will provide adequate insight into clinical protocol design for future larger statistically powered clinical trials in Phase II to address patient compliance.

Overall patient acceptance will be determined by the patient's response to the final question on the End of Study Cuff Evaluation Questionnaire: "Which Cuff did you like better OVERALL?" If at least 75% of patients respond as preferring the new cuff over the traditional, then the study's primary outcome will be achieved [29].

**Potential Risks**

Risks will be explained to all participants in advance of study enrollment. The main risk is slight discomfort from improper use of shoe by over/under tightening the closures. A user manual will be provided to each participant. A second risk is the amount of pressure applied to the bottom of the foot may cause slight discomfort. Participants may opt not to participate in the study at any time; additional participants will be recruited through the pool of eligible participants.

**Potential Benefits of the Proposed Research to Human Subjects and Others**

There is no known individual benefit for participating in this study. With the information provided by the study, participants may benefit from understanding the need for patient compliance to receiving maximum therapeutic benefit by improving lower limb tissue reperfusion, pressure distribution, mobility (quality of life).

**Importance of the Knowledge to be Gained**

It is anticipated that this study will have potential benefits to society, as it will provide new insights and ultimately education to patients at risk for DVT, which may translate to actionable health outcomes. As the risks to the subject are minimal, the relation of risk to the importance of the knowledge expected is reasonable for this study. This research may provide a more effective compression therapy for patients at risk for DVT.