Individual Comparison Study

Nocturnal Protocols for Individuals with Secondary Upper Extremity Lymphedema

Therapist’s Information & Participation Package
Comparison Study General Overview

Description:
We are asking you to consider participating in an individual comparison study. The general purpose of this study is to compare two types of nightly lymphedema management protocols.

Protocol A will have the participant learn to self-apply traditional multi-layer lymphedema bandaging ("MLLB", i.e.: digit wraps as necessary, stockinette, cast padding, foam roll or padding, short stretch bandages) and don the MLLB nightly for wear while sleeping.

Protocol B will have the participant learn to don and wear a Tribute Nightwear garment each night while they sleep.

Procedures:
To participate, you will select a patient participant based on our limited inclusion and exclusion criteria. The patient’s identity will remain confidential; a fictitious name will be selected and used consistently in all study documentation both by you and by the participant. The majority of the information we will be asking for is included in your Standard Initial Evaluation documentation.

Time Involvement:
The study period is expected to last six (6) weeks, which includes your Phase 1 intensive therapy with your selected patient participant and assumes that Phase 1 is equal to two (2) weeks. The tasks related to the study are anticipated to require between 1-5 hours of your professional time over the six (6) week period. A study timeline overview with estimated professional time commitment is enclosed.

We estimate that it will take you thirty (30) minutes to gather and document the initial information.

To qualify your patient for the study, you will be required to administer brief cognitive screening test (enclosed), which should take less than five (5) minutes to administer and an additional ten (10) minutes to learn if you are unfamiliar with the test.

In addition to any measurements and/or photo-documentation you might normally perform in conjunction with treatment, you will be asked for the purpose of this study to measure and record affected limb girths three (3) times and take affected limb photographs three (3) times during the study:

1) Before Protocol A begins, on the last day of intensive phase therapy,
2) After Protocol A (two weeks) concludes, and before Protocol B begins, and
3) After Protocol B (two weeks) concludes.

We estimate that it will take you fifteen (15) minutes for each measuring and photographing session.

Additionally, you will be asked to track and record the number of minutes spent on instructing the participant during the intensive phase of therapy on how to effectively use MLLB, until the patient is competent in MLLB self-application in your professional opinion. Likewise, we will ask you to track and record the time spent on instructing your participant on how to self-apply their Tribute garment.

Risks and Benefits:
There are no significant risks associated with this study. Slight skin irritation or a lingering red tone on your patient’s skin may occur. Discontinue the protocol if either condition lasts longer than thirty (30) minutes after removing the products from your patient’s arm. You will not receive any direct benefit from participation.

Payments:
You will not be paid to participate in this study. We will provide each participating therapist with the core information we have collected. We will publish the outcomes in our Solaris Newsletter and give credit by name to the therapists who have participated.

Background:
Solaris, Inc. is the manufacturer of the Tribute Nightwear Garment. This product line consists of custom manufactured medical devices which require a medical professional to select an appropriate style and submit specific patient
measurements on standardized forms. The product line is dispensed predominantly to individuals diagnosed with lymphedema. Lymphedema occurs when the lymphatic system is impaired, resulting in visible swelling and induration of the affected body part. Lymphedema is treated by specialized medical personnel in restorative therapy. Lymphedema is incurable and requires the patient to be compliant to a self-management program for the rest of their life. There is no medical consensus outlining a comprehensive self-management program. Many patients are expected to perform a daily skin care routine, wear compression garments during the day and self-administer a multi-layer lymphedema bandaging protocol (“MLLB”) each night before sleeping. The specific aim of this study is to compare the Tribute Nightwear garment to the multi-layer bandaging nocturnal protocol for lifelong self-management of lymphedema.

**Objectives:**

i. To examine the relationship between nocturnal home programs and quality of life;
ii. To document the individual’s time commitment necessary to comply with nocturnal self-management programs;
iii. To compare the individual's ability to maintain gains made in intensive phase therapy by changing nocturnal home program;
iv. To examine the relationship between nocturnal protocols and patient compliance during their self-management program; and
v. To document disruptions to sleep or sleeping posture.

**Inclusion Criteria (must meet ALL):**

i. Diagnosis of upper extremity secondary lymphedema,
ii. No prior history of lymphedema treatment,
iii. Intact cognition and sensation,
iv. Normal ACTIVE ROM in shoulder, elbow and wrist,
v. Multi-layer bandaging must be taught to patient in intensive phase therapy.

*NB.: your selected patient should also be able to commit to a course of therapy with you that will include: intensive phase therapy followed by adherence to both Protocol A and Protocol B at the appropriate times, keeping a daily journal as set out in the study documentation, making and keeping the necessary follow-up appointments with you to provide, check fit, receive instruction and perform a donning time trial of the Protocol B Tribute garment, then return for a final appt at the conclusion of Protocol B to complete final study documentation.*

**Exclusion Criteria (any ONE of):**

i. Prior lymphedema treatment,
ii. Active cancer, currently receiving radiation or chemotherapy,
iii. Enrollment in another medical trial or study,
iv. Venous Insufficiency,
v. Open ulcers or wounds,
vi. Dependent ADL status,
vii. Grade 3 Protective and greater loss of sensation,
viii. Limited or compromised ACTIVE ROM,
ix. Compromised cognition.

**Informed Consent:**

An informed consent document will be provided to each participant. The document includes details about the comparison study, including purpose, duration, required procedures, potential risk, benefits and key contacts. After carefully reading the informed consent form the participant decides whether or not to sign the document and participate in the study. Informed consent is not a contract and the participant may withdraw from the study at any time.

**Confidentiality Regarding Study Participants:**

Confidentiality will be maintained including the patient participant’s personal identity and all personal medical information. The participant’s consent to the use of records is limited to inclusion criteria, medical history with date of onset, the therapist evaluation, and the daily journal or study specific answers to questions. Fictitious participant names will be used. Therapists will ensure the confidentiality of their patient’s identity.
### Solaris Comparative Study Projected Timeline & Overview of Estimated Time Commitment for Participating Therapist

<table>
<thead>
<tr>
<th>Study Day</th>
<th>Therapy Phase</th>
<th>Study Phase</th>
<th>Task¹</th>
<th>Est. Time in Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Min</td>
</tr>
<tr>
<td>DAY 1</td>
<td>1-Intensive</td>
<td>Qualification</td>
<td>Qualify new patient against inclusion/exclusion criteria²</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Administer Mini-Cog Cognitive Screening²</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Complete Standard Initial Evaluation²</td>
<td>5</td>
</tr>
<tr>
<td>DAY 1-14³</td>
<td>1-Intensive</td>
<td>Therapy</td>
<td>Record time, if any, spent training on MLLB self-application</td>
<td>14</td>
</tr>
<tr>
<td>DAY 14³</td>
<td>1-Intensive</td>
<td>Protocol A</td>
<td>Protocol A/MLLB Time Trials (3x donning sessions, timed)</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>First measurements and photos</td>
<td>10</td>
</tr>
<tr>
<td>DAY 15-29</td>
<td>2-Maintenance</td>
<td>Protocol A</td>
<td>No study time requirement</td>
<td></td>
</tr>
<tr>
<td>DAY 30</td>
<td>2-Maintenance</td>
<td>Protocol B</td>
<td>Second measurements and photos</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Protocol B/Tribute Fitting &amp; Care Session</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Protocol B/Tribute Donning/Doffing Instruction Session, timed</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Protocol B/Tribute Time Trials (3x donning sessions, timed)</td>
<td>6</td>
</tr>
<tr>
<td>DAY 31-44</td>
<td>2-Maintenance</td>
<td>Protocol B</td>
<td>No study time requirement</td>
<td></td>
</tr>
<tr>
<td>DAY 45</td>
<td>2-Maintenance</td>
<td>Conclusion</td>
<td>Final measurements and photos</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Complete all study documentation</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Collect patient's study documentation</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Seal &amp; mail completed study to Lymphedema Depot</td>
<td>5</td>
</tr>
</tbody>
</table>

**Total Min / Max expected time commitment:** 96 (1hr 36m) | 313 (5hr 13m)

¹Estimate is for time spent on performance of tasks unique to the study, i.e.: in addition to any tasks ordinarily associated with therapy

²Consideration, qualification & documentation for inclusion in the study can happen in any of the first few days of Phase 1 intensive therapy

³Assumes that Phase 1 intensive therapy is equal to 2 weeks. Longer or shorter Phase 1 durations are also acceptable.
Participant (fictitious) Name: ___________________________ Date__________________
Therapist Name: ___________________________ Date__________________

Demographics:
Check the boxes that reflect the participant’s demographics:
Gender:  □ Female  □ Male
Age Range:  □ 18 - 30  □ 31 – 40  □ 41 - 50  □ 51 – 60  □ 61 - 70  □ 71+

Medical History:
Check the box that correctly identifies the participant’s diagnosis
□ Medical History for Dx Code 457.0, “Post Mastectomy/Lumpectomy”
□ Medical Intervention History for Dx 457.1, “Other Lymphedema”

Complete date information as appropriate. Check the boxes that reflect the participant’s medical history:
Surgical Date: ___________________________ Lymphedema Onset Date: ___________________________

Affected Arm:  □ Right  □ Left
Surgical History:  □ Mastectomy  □ Lumpectomy  □ Lymph node dissection
Additional Treatments:  □ Radiation  □ Chemotherapy  □ Hormone Therapy
□ Other ___________________________

Initial Evaluation Findings Relevant to this Comparison Study:
Please document the following information from the participant’s Initial Evaluation:
Arm Sensation Status:  □ Grade 1 Normal  □ Grade 2 Less than normal  □ Grade 3 Protective
□ Grade 4 Total loss  □ Localized post surgical numbness
* If results are Grade 3 or 4 the participant cannot be included in this comparison study.

Active Range of Motion (ROM):
Check the boxes that reflect the participant’s active ROM function level:
Elbow Flexion/Extension:  □ Normal/Functional  □ Limited/Compromised
Supination/Pronation:  □ Normal/Functional  □ Limited/Compromised
Wrist Flexion/Extension:  □ Normal/Functional  □ Limited/Compromised
MCP Flexion:  □ Normal/Functional  □ Limited/Compromised
DIP/PIP Flexion:  □ Normal/Functional  □ Limited/Compromised
* If results of any one active ROM are Limited/Compromised, the participant cannot be included in this comparison study.
Activities of Daily Living (ADL) Status:
Check the box that most accurately describes the participant:

ADL Status:  □ Independent   □ Independent with Adaptation/Modification   □ Dependent

*If result is Dependent, the participant cannot be included in this comparison study.

Mini-Cog Cognitive Screening:
This brief cognitive screen is a two-part test of executive function (ability to plan, manage time, organize activities, and working memory).

The test can be administered on any day prior to the start of Protocol A.

PART ONE: ask the patient to listen carefully to, remember, and then repeat three unrelated words you will say.

Your words are:  □ 1.____________ □ 2.____________ □ 3.____________

Check the boxes for the words that were remembered after Part Two (the clock drawing test).

*Patient must have remembered 2 of 3 words following the clock drawing test in order to be included in this comparison study. Word re-ordering is OK.

PART TWO: Clock drawing test. Check off only those activities that the patient was UNABLE to complete.

Provide the participant with a blank sheet of paper and a pencil/pen.

□ Ask the patient to draw a large circle on the paper to make a clock face.
□ Ask the patient to write the hour numbers on the face of the clock.
□ Then ask the patient to draw hands on the clock for this specific time:  11:10

Any check marks would mean a compromised cognition level for this comparison study. Attach the testing sheet to your evaluation materials being returned to Solaris.

After the clock drawing test, ask the participant to repeat the three words you spoke to them previously and check the box next to each word correctly recalled.

*If the participant can recall two to three words and was able to complete two to three parts of the clock drawing test, this equals a normal cognitive screening result.

Check the box that represents the results of the Mini-Cog test:

RESULTS:  □ Normal   □ Compromised

*If results are compromised, the participant cannot be included in this comparison study.
1. **Circumferential Girth Measurements:**

**WHEN TO MEASURE:** Record the date for each measuring session in the chart below.

a. Please measure your patient's affected limb on the **last** day of intensive phase therapy prior to beginning Protocol A (self applied MLLB)***

b. Repeat measurements two weeks later, prior to beginning Protocol B (wearing the Tribute overnight instead of bandaging).

c. Take the final measurements at the end of Protocol B

*Please try to measure around the same time of day for each of the measuring sessions.*

***Note these measurements will need to be submitted to Lymphedema Depot Ltd. ASAP after being taken on the provided Measuring/Order form in order to have your patient’s custom Tribute garment manufactured & delivered in time for use during Protocol B.

**HOW TO MEASURE:** With the patient in supine or standing position (please choose one position and measure in that position consistently throughout the study) complete the following information in the second column, below, "Lengths in Centimeters.”

a. "B" Length (MCP's): measure the length from the wrist crease to the volar MCP of the third digit. Enter this length into the column below, “Lengths in Centimeters,” across from “B – MCP’s”

b. Using a water-based marker, dot the arm at the largest girth point of the forearm and the largest girth point of the mid-biceps. Place the tape measure on the wrist crease and gently lay the tape on the arm following the contouring. Document the length from the wrist to the dotted largest girth point of the forearm and enter this as your “D – Forearm” length.

c. Continue to measure proximally, keeping the zero/starting measuring point at the wrist crease.

d. Enter each of the remaining landmark lengths in the “Length in Centimeters” column.

e. Take circumference measurements at these same landmark lengths at each of your three measuring sessions, entering the measurements in the corresponding column each session.

<table>
<thead>
<tr>
<th>Measuring Landmarks</th>
<th>Lengths in Centimeters</th>
<th>Circumferences at each Length Landmark</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Date:</td>
</tr>
<tr>
<td>G - Axilla</td>
<td>cm</td>
<td>cm</td>
</tr>
<tr>
<td>F - Mid-Biceps</td>
<td>cm</td>
<td>cm</td>
</tr>
<tr>
<td>E - Elbow</td>
<td>cm</td>
<td>cm</td>
</tr>
<tr>
<td>D - Forearm</td>
<td>cm</td>
<td>cm</td>
</tr>
<tr>
<td>C - Wrist</td>
<td>0 (zero) cm</td>
<td>cm</td>
</tr>
<tr>
<td>B - MCP's</td>
<td>cm</td>
<td>cm</td>
</tr>
</tbody>
</table>

*Remember to take photographs at each measuring session. See next page.
2. Visual Documentation and Photographs:

When taking the three (3) sets of circumferential measurements, please use the following instructions to visually document the girths and results for your patient participant.

WHEN TO PHOTOGRAPH: Take the necessary photographs each time that you take the participant’s circumferential measurements.

   a. Please photograph the participant on the last day of intensive phase therapy, just prior to beginning two (2) weeks of Protocol A (self-applied MLLB).
   b. Repeat the photographs two weeks later, just prior to beginning two (2) weeks of Protocol B (Tribute garment).
   c. Take the final photographs at the end of Protocol B.

*Please try to take the photographs around the same time of day for each set.

HOW TO PHOTOGRAPH: When photographing the patient participant please use the following guidelines.

   a. Attach the included sheet of graph paper to a wall.
   b. Have the participant place their arm at a forty-five (45°) degree angle from the trunk, as close as possible to the center of the graph paper where the X and Y axis meet.
   c. Be sure to not include anything except the participant’s arm in order to ensure their privacy.
   d. Take one photograph with the participant facing the camera, palm of hand also facing camera.
   e. Take one photograph with the participant facing the wall/graph, palm of hand facing wall.

Please photograph the participant’s arm as detailed above each time you take a set of circumferential girth measurements.

Please try to ensure that lighting is as bright and even as possible to help avoid deep or dark shadows in your photographs.
3. Nighttime Compression Protocols Instruction Time with Participant:

Record the time it takes the participant to become educated and competent in donning and doffing for each of the study protocols for nighttime compression. Please observe and record the times in minutes and seconds.

Protocol A refers to traditional MLLB. Please include the clinical instruction time required during intensive phase therapy for the participant to become competent in self-application of the multi-layer bandaging.

Protocol B refers to the clinical instruction time spent with the participant to become competent in self-application of the Tribute Nightwear garment.

<table>
<thead>
<tr>
<th>Protocol A</th>
<th>Date:</th>
<th>Date:</th>
<th>Date:</th>
<th>Date:</th>
<th>Date:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(MLLB)</td>
<td>Time:</td>
<td>Time:</td>
<td>Time:</td>
<td>Time:</td>
<td>Time:</td>
<td>Time:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Protocol B</th>
<th>Date:</th>
<th>Date:</th>
<th>Date:</th>
<th>Date:</th>
<th>Date:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Tribute)</td>
<td>Time:</td>
<td>Time:</td>
<td>Time:</td>
<td>Time:</td>
<td>Time:</td>
<td>Time:</td>
</tr>
</tbody>
</table>

4. Nighttime Compression Protocols Donning/Doffing Time Trials with Participant:

Near the end of the intensive phase of therapy, when the patient has become competent in self-application of the MLLB, but prior to commencement of Protocol A and the maintenance phase, please conduct a time trial session with your participant. Ask the participant to completely apply, and then remove, the MLLB three times. Record the amount of time in minutes and seconds for each time trial in the table, below.

When the participant returns to your office two weeks into the maintenance phase to receive their Tribute garment and Protocol B instructions, and once you have completed the donning/doffing instruction for the Tribute and the patient is competent to self-apply the garment, please ask the participant to completely apply, and then remove, the Tribute Nightwear garment three times. Document the amount of time in minutes and seconds for each time trial in the table, below.

<table>
<thead>
<tr>
<th>TIME TRIAL 1</th>
<th>TIME TRIAL 2</th>
<th>TIME TRIAL 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>MLLB Self-Application</td>
<td>Date:</td>
<td>Date:</td>
</tr>
<tr>
<td>(near end of intensive phase, prior to commencing Protocol A)</td>
<td>Time:</td>
<td>Time:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TIME TRIAL 1</th>
<th>TIME TRIAL 2</th>
<th>TIME TRIAL 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tribute Self-Application</td>
<td>Date:</td>
<td>Date:</td>
</tr>
<tr>
<td>(just prior to commencing Protocol B, after donning/doffing training)</td>
<td>Time:</td>
<td>Time:</td>
</tr>
</tbody>
</table>
Thank you for completing this comparison study.

Please return all materials in the supplied return envelope, including your documentation, your participant’s documentation and the disposable camera with your study photographs.

Please give us your feedback on how we could have improved this study for the therapist administering the evaluation.

Please give us your feedback on how we could have improved this study in regard to the therapist's documentation.

Any additional comments you would like to share?