Efficacy of a Forearm Rotation Orthosis for Persons with a Hemiparetic Arm

Study Protocol

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Background and Rationale for Study

Functional use of the upper limb during tasks requires coordination of joints of the upper extremity (van Andel, Wolterbeek, Doorenbosch, Veeger, & Harlaar, 2008). Persons with central nervous system (CNS) dysfunction often have difficulty incorporating their affected limb effectively and efficiently into functional activities due to muscle weakness and/or spasticity (Gillen, 2011). Poor functional use of the affected limb and/or motor recovery may lead to development of learned nonuse of the affected limb (Taub, Uswatte, & Pidikiti, 1999), compensatory movement patterns (Mackey, Walt, & Stott, 2006) as well as muscle or joint contracture (Milazzo & Gillen, 2011). This may further interfere with their occupational performance and restrict life roles.

Traditional rehabilitation interventions emphasize motor training on the reduction of spasticity (Gillen, 2011). However, active movement and muscle strength of forearm supination are found strongly associated with motor function recovery, rather than spasticity (Braendvik, Elvrum, Vereijken, & Roeleveld, 2010; O'Dwyer, Ada, & Neilson, 1996). In contrast, task-oriented functional training trials, such as the occupational therapy (OT) task-oriented approach (Almhdawi, 2011; Flinn, 1995) and the Constraint-Induced Movement Therapy (Page, Levine, & Leonard, 2005; Page, Levine, Leonard, Szaflarski, & Kissela, 2008; Taub, Uswatte, & Elbert, 2002; Taub et al., 2006; Wolf et al., 2008), have demonstrated promising evidence that persons with CNS dysfunction benefit from the training in improvement of increase functional use and motor function of the affected limb. However, the role of forearm movements is not addressed in rehabilitation interventions literature.

Occupational therapists often employ orthotic interventions for persons with CNS dysfunction (Milazzo & Gillen, 2011; Watanabe, 2004). Most orthotic designs are static and aimed at the wrist and/or hand with purposes of spasticity reduction, correction or prevention of deformity (Milazzo & Gillen, 2011). However, the effects remain controversial (Lannin & Herbert, 2003). Given that static orthoses may interfere with functional performance and may further develop muscle or joint contracture, compensatory movements or learned nonuse of the affected limb (Mell, Childress, & Hughes, 2005; Milazzo & Gillen, 2011), a dynamic or mobilization orthosis can be considered to assist or enhance functional use of the affected limb during functional tasks (Dunning et al., 2008; Farrell, Hoffman, Snyder, Guiliani, & Bohannon, 2007; Hoffman & Blakey, 2011; Lannin & Ada, 2011; Pitts & O'Brien, 2008). However, research evidence regarding the effects of an orthosis that assists forearm movements for this population found in the literature is limited.

The proposed research project will use a randomized clinical trial to investigate the efficacy of a forearm rotation orthosis combined with the OT task-oriented approach for persons with a hemeparetic arm on functional performance, motor function, and range of motion. We expect that the results would significantly improve participants' functional performance and motor function as well as prevent or reduce secondary complications due to CNS dysfunction. The results may also benefit the rehabilitation professions in developing treatment protocols for this population.

Methodology

Study design

This study will employ a randomized, single-blinded, two-group, repeated measure design (Table 1).

Table 1. *Experimental design of the internal pilot study*

Group/Week			Week 1	Week 2-7	Week 8	Week 9-14	Week 15
M	R	A	O1	Orthosis	O2	Orthosis+OTTO	O3
M	R	B	O1	No treatment	O2	OTTO	O3

Note. M = matching with severity of motor function of the upper extremity; R = random assignment; O1,2,3 = time points for outcomes measures; Orthosis = six weeks of forearm rotation-assist orthotic intervention; OTTO = six weeks of OT task-oriented approach intervention.

Objectives

The primary purpose of this study is to investigate the efficacy of a forearm rotation orthosis combined with the OT task-oriented approach for persons with a hemiparetic arm. Hypotheses of this study are that 1) participants who wear the forearm rotation orthosis will demonstrate significantly greater improvement in functional performance and active range of motion of forearm rotators compared to those who do not; 2) all participants who receive the OT task-oriented approach intervention will demonstrate significant improvement in functional performance; and 3) all participants who receive the OT task-oriented approach intervention will demonstrate significant improvement in motor function of the upper extremity.

Study endpoints

The primary endpoint is the functional improvement. "Functional improvement" represents improvement in the performance of everyday activities. The secondary endpoints are active range of motion and muscle strength, including grip and pinch, of the involved upper extremity as well as orthosis compliance.

Outcome measures for the primary endpoint include the *Canadian Occupational Performance Measure* (COPM) for self-perceived functional performance and satisfaction with performance, the *Wolf Motor Function Test* (WMFT) for quantitatively measuring the motor function of the upper extremity, and the *Motor Activity Log* (MAL) for measuring participants' actual use of the involved arm in the real world.

Outcome measures used for the secondary endpoints include goniometric measurements for active and passive range of motion (ROM), hand-held dynamometry and manual muscle testing for muscle strength of the upper extremity, Jamar Dynamometer for grip strength, pinch gauge for pinch strength, as well as information collected by the Nike+ FuelBand regarding numbers of hours they wear the orthosis everyday throughout the study period for adherence with the orthosis.

Treatment allocation

Participants who are eligible and willing to participate in this study will first be matched with the severity of the motor function of the involved upper extremity measured by the upper extremity subscale of the Short Form Fugl-Meyer Motor Function Assessment. Participants will be classified as mild, moderate, and severe groups. Participants in each group will then be randomized in a 1:1 allocation ratio to either the Group A or B (Figure 1). The primary investigator, Chih-Huang Yu, will randomly assign eligible participants at the screening session using sealed envelopes with an equal number of both intervention

conditions to balance group size (10 for each matched group with 5 Group As and 5 Group Bs).

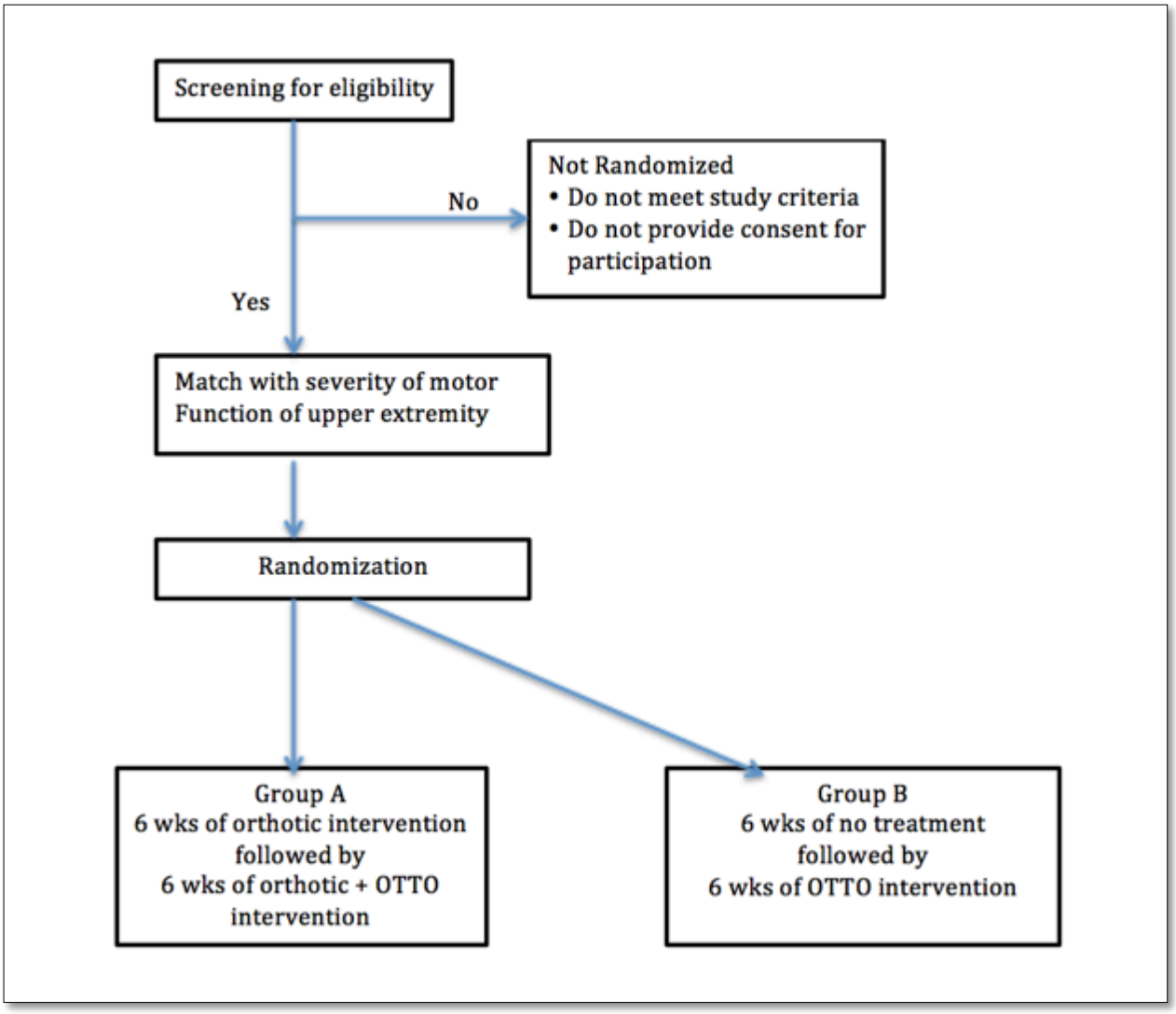

Figure 1. Study schematic for treatment allocation.

Sample size estimation

We plan to enroll 30 participants in the study. Based on anticipated number of screen failures and/or withdrawals, the maximum number of participants whom we will consent in order to achieve the scientific objectives of this study is 40. Note that the number of participants described above is a rough estimate of the sample size needed, since there is no evidence to address the primary question of interest. This proposed project involves pilot/preliminary investigation, which will be used to calculate the effect sizes that need to be used for the future study.

Participant selection

The target population for this study is stroke patients who have a hemiparetic arm. Subjects will be recruited from a) local hospitals and institutions in the Twin Cities metro area, including advertising at Fairview hospitals and the stroke center at the North Memorial Hospital and b) the Onsite clinic at the University of Puget Sound at which the PI was a graduate from the occupational therapy program.

Inclusive criteria in this study include:

Participants

1) Have a diagnosis of stroke for at least three months,
2) Be 18 years of age or older,
3) Have sufficient cognitive function to follow three-step verbal instruction and provide independent consent,
4) Have appropriate trunk and lower extremity function that does not interfere with performance of the upper extremity,
5) Have at least minimum voluntary movement in the upper extremity (10

degrees of shoulder flex/abduction, 10 degrees of elbow flexion/extension), and

6) Not receive any rehabilitative interventions concurrent with the study.

Exclusive criteria include:

1) Severe joint deformities or contractures of the affected upper extremity that limit range of motion required for functional tasks,
2) Capability of voluntarily extending the wrist and fingers through the full range,
3) Have serious uncontrolled medical problems, such as seizures and visual impairment.

Interested persons, who begin pharmacological treatments for management of spasticity, such as Botox and Baclofen, before the study and sustain these throughout the study period, will be permitted to participate. Interested persons who use pharmacological treatment for spasticity reduction, such as Botox or Baclofen, and then stop treatment, are excluded until they are at least 4 months past their last use of the medications. Persons who enroll in the study while using Botox or Baclofen will be **removed** from the study if they stop that treatment during the study period. Timeline for consenting is illustrated in Figure 2.

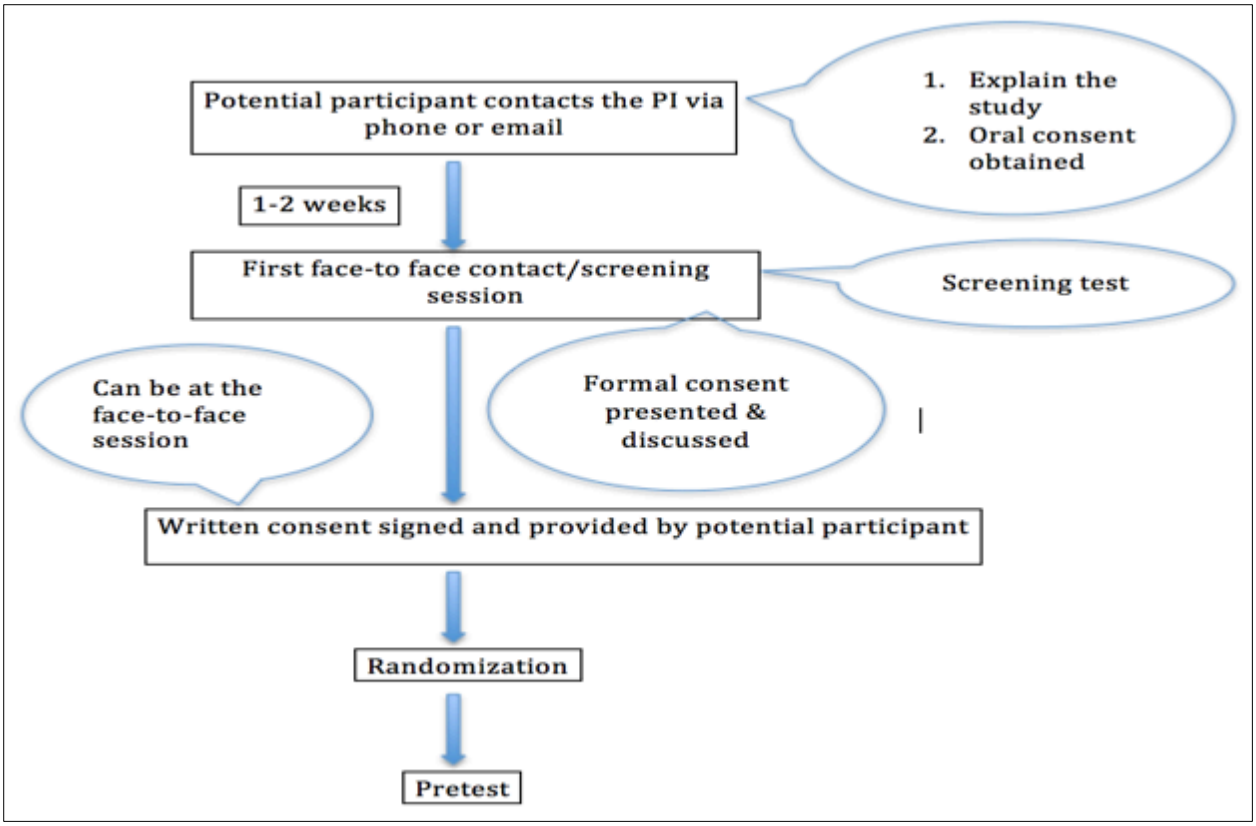

Figure 2. Timeline for consenting.

Study plan

Intervention. Participants in the Group A will experience the orthotic intervention followed by the orthosis plus OT task-oriented approach intervention. Participants in the Group B will first undergo a period of no treatment followed by the OT task-oriented approach only (Figure 3).

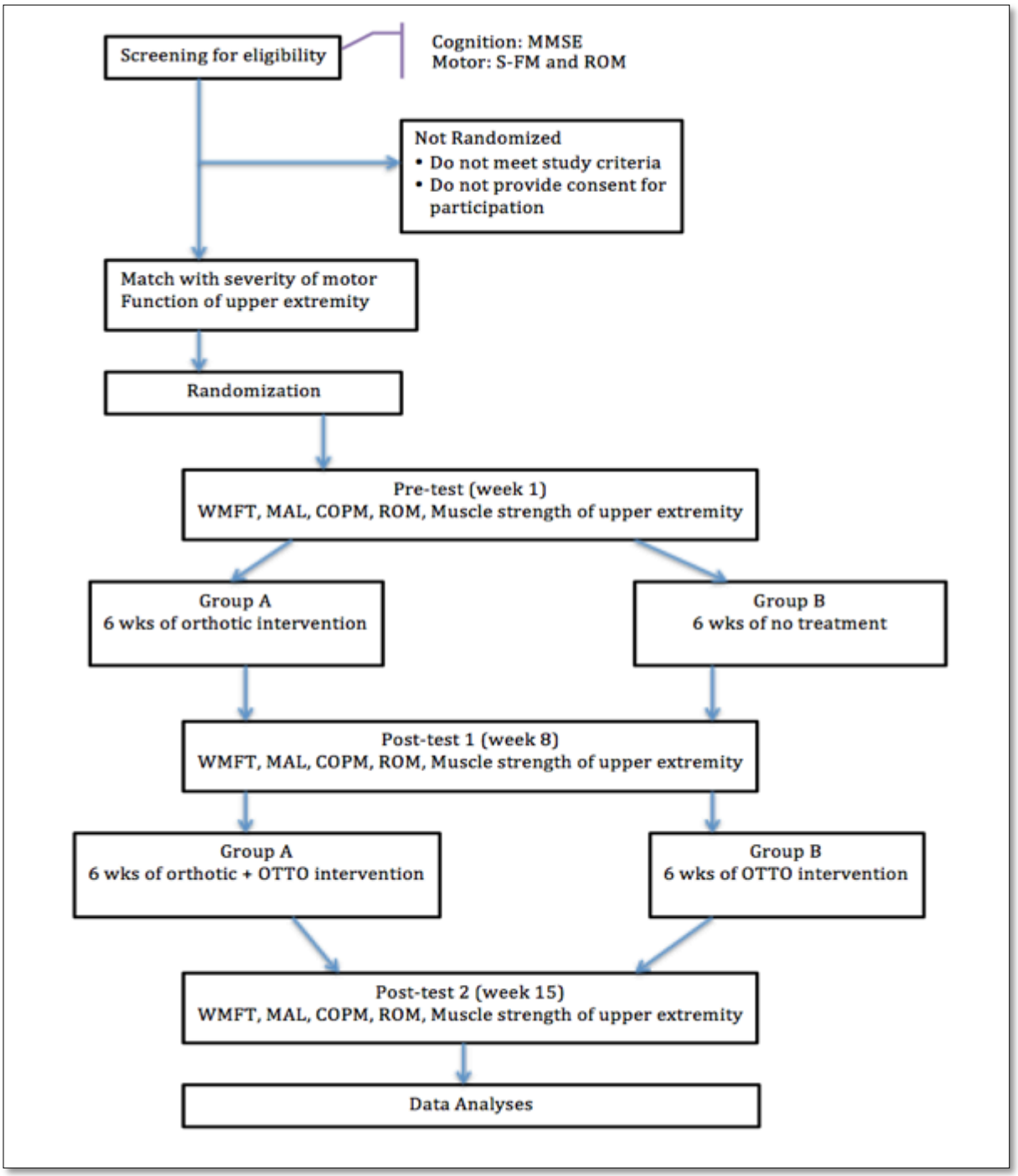

Figure 3. Flowchart for the proposed protocol.

Use of the Nike + FuelBand as monitor ~~and placebo~~. The Nike+ FuelBand will serve as a monitor for all participants throughout their study period. The FuelBand is a commercially available wristband designed to measure activities throughout a day. The

wristband is available in three sizes. Researcher will adjust the length for each participant, by removing 8mm link or adding up to 16mm to each wristband.

All participants will wear the Nike+ FuelBand at the wrist level throughout the study period and will be informed that the wristband is used to monitor their use of the arms during a day. Participants experiencing the orthotic intervention (Group A) will wear the forearm rotation orthosis on top of this wristband. All participants will receive weekly phone calls from the investigator reminding them to recharge the wristband because the wristband needs to be recharged by connecting to a computer or any device with USB port every 4-7 days.

Conditions involving OT task-oriented approach intervention consists of 18 hours of intervention time (three one-hour or two 1.5-hour session per week) of functional and motor training. Each session will concentrate on how to engage the affected arm actively, effectively, and efficiently in functional tasks that are meaningful to the participant. Suggested evaluation and intervention procedures for the OT task-oriented approach are illustrated in Figure 4 and 5.

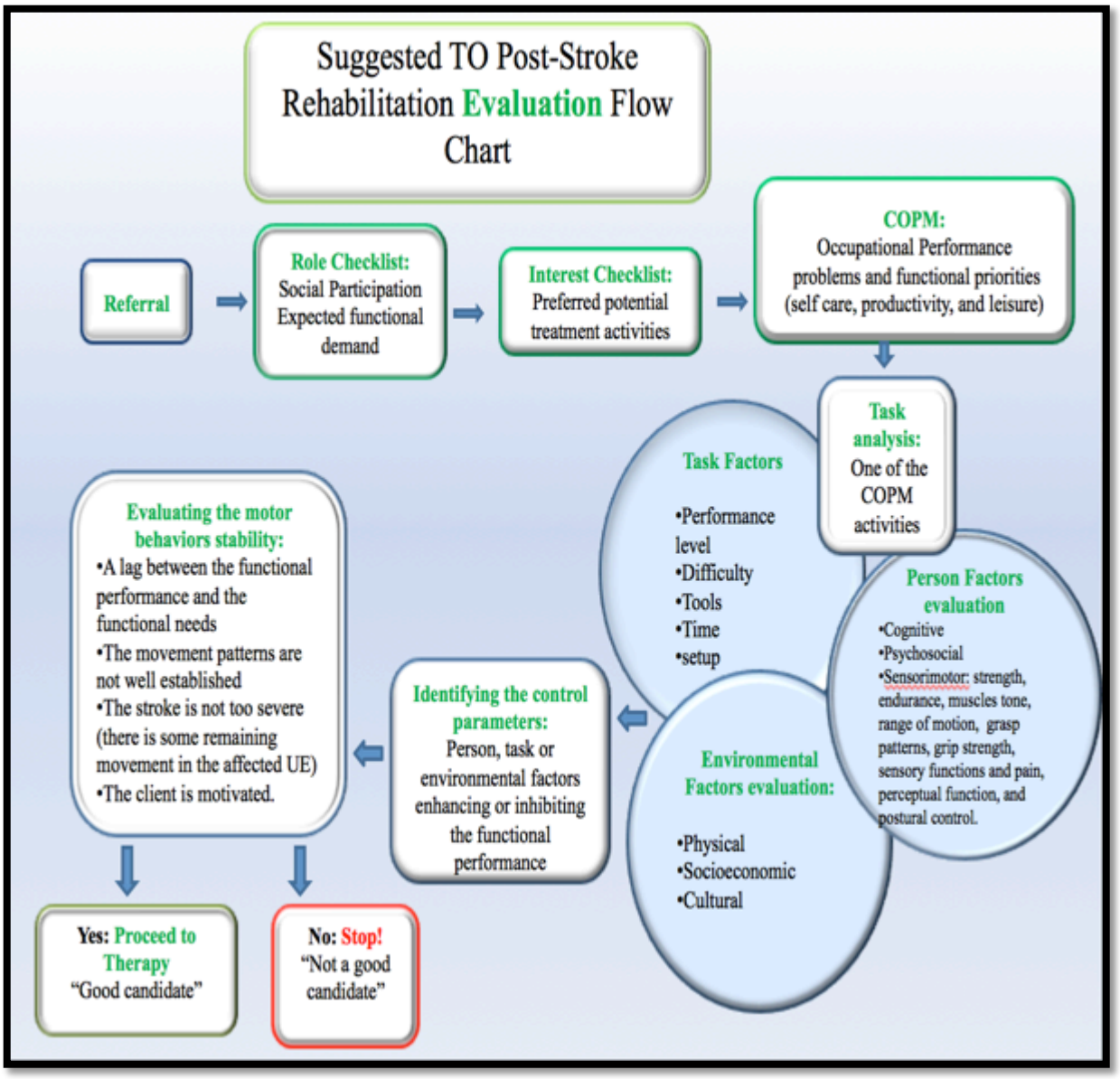

Figure 4. Flowchart for suggested evaluation procedure for OT task-oriented approach.

Copied from Almhdawi (2011) with permission.

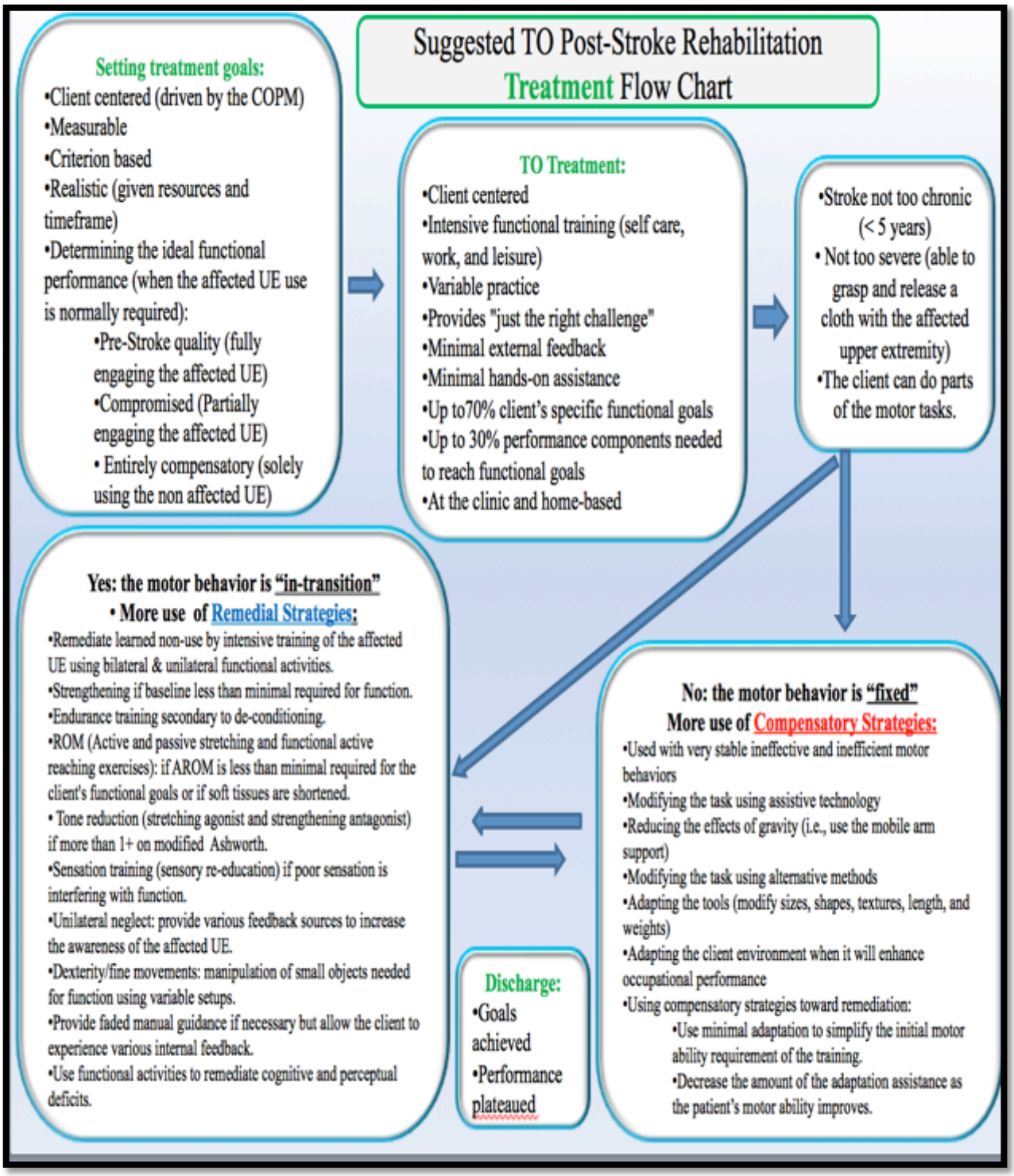

Figure 5. Flowchart for suggest treatment for OT task-oriented approach. *Copied from Almhdawi (2011) with permission*.

The forearm rotation orthosis (Figure 6) is consisted of a commercial fabric wrist orthosis and a Latex-free neoprene strap. This orthosis is designed to assist forearm rotation without limiting functional elbow flexion and extension. During the phase of orthotic intervention only, participants will be asked to wear the orthosis on top of the Nike+ FuelBand of their affected arm during functional tasks within their context. The primary investigator will make three bi-weekly phone calls during the experiment phase for enhancing adherence with orthosis and reminding them to recharge the wristband. Participants will also be asked to wear the orthosis and the wristband for the following experiment phase, including research visits, and will be encouraged to continue wear it within their context. However, they will be asked not to wear the orthosis at evaluation sessions to maintain the integrity of the design.

Figure 6. The forearm rotation orthosis.

Potential risk of the orthosis. No risks regarding using the neoprene for a dynamic orthosis were identified in the literature. Using the forearm rotation orthosis for the

proposed study, we hypothesize that possible risks may include but not be limited: 1) skin irritation over contact areas, 2) increased muscle soreness when increased use of the arm, and/or 3) movement restriction of the involved upper extremity during functional tasks. Participants will need to remove the orthosis immediately and report to the primary investigator if any of above symptoms develops. Information regarding possible risks of use of the orthosis is included in the consent form as well as the written instructions (Appendix A). The primary investigator will provide verbal education and written instructions regarding orthosis use and care to the participants after orthosis fabrication.

Data collection plan and schedule. The timing of screening, randomization, and follow-up visits are illustrated in Figure 2. The primary investigator will screen potential participants' eligibility using the Mini-Mental Status Examination (MMSE), the Short Form Fugl-Meyer (S-FM), and ROM. There will be three time points for data collection (pretest, posttest 1, and posttest 2). Trained occupational therapy students recruited from the University of Minnesota and University of Puget Sound will serve as the blinded evaluators to implement all assessments except the COPM for each research site. The primary investigator will administer the COPM to obtain information that will be used to guide future interventions.

Evaluation

Data analysis

The *R* software will be used for data analyses. Descriptive statistics will be used to analyze the demographic data, baseline information, and adherence with orthosis wearing. The linear mixed-effects model regression will be used as the omnibus test for examination of effect of intervention involving orthosis across time in comparison of that without. The

systematic or fixed effects of this study are group assignment and time. Main effect of the two factors and the interaction effect between the two will be explored. Study participants will be considered and added into the model as the random effects.

General linear regression model will be used to determine effects of experimental conditions between the two groups. Data obtained from the pretest will first be used to examine if there are differences in outcome measures between the two groups. It will also serve as a covariate while examining difference between the two groups at the posttest 1. Data from the posttest 1 will serve as a covariate while examining difference between the two groups at the posttest 2. The *paired t* test will be used to examine difference within each group for each intervention period across time.

Interim monitoring of the data will occur after 16 participants complete the study. If the study results indicate a significant decline in functional performance for either group across the 12-week study, the study will be terminated. If there are serious adverse effects, the study would be terminated.

Data monitor

The academic advisor, Virgil Mathiowetz, is the founder of the OT task-oriented approach. He will monitor study procedures to ensure fidelity to the OT task-oriented approach. The academic advisor will work closely with the study investigators for safety monitoring throughout the study period. He will supervise the primary investigator, Chih-Huang Yu, with the development and implementation of the treatment plan for study participants. The principle investigator will train the blinded evaluators of both sites on all assessment tools until total agreement is achieved. The blinded assessor will execute all evaluations and the primary investigator will complete the data entry accumulatively. The

academic advisor will also check and monitor the accuracy of data collection, data entry, and data analyses.

All information gathered for the study will be converted into digital files and uploaded within 24 hours to the "Box" secure storage operated by the University of Minnesota. The Box is an online storage space that allows storing Protected Health Information (PHI). Only the principle investigator has the access to "Box" as it requires duo-factor authentication to log in. Information on the "Box" is at http://box.umn.edu

Subjects' name and contact information will be kept in a separate file from the data gathered from the study using an ID code. All printed documents will be converted into digital files and uploaded to Box. Printed documents will then be immediately shredded.

Identifying materials such as the consent forms gathered from the University of Minnesota site will be kept in a locked file cabinet in the rehabilitation science graduate student office, which requires security code for access. Personnel from the department have access to the office. However, only the primary investigator has access to locked file cabinet that keeps the study information. Identifying materials such as the consent forms obtained from the onsite clinic at the University of Puget Sound will be kept in a locked file in the Occupational Therapy Department at the University of Puget Sound, WEY 106. Data collected from this study will be maintained for three years after completion of the study, then shredded.

Treatment Fidelity

Project personnel training

Interventionists. The principle investigator, Chih-Huang Yu, serves as the primary interventionist. He will provide the Occupational Therapy Task-Oriented Approach (OTTO)

based interventions for most participants throughout the study period. He will work closely and regularly with Dr. Virgil Mathiowetz, the theorist behind the OTTO approach and the academic advisor, to ensure fidelity to the OTTO, monitor safety during the study period, and supervise the primary interventionist for the development and implementation of the OTTO based treatment plan.

The primary interventionist will develop treatment plans for all participants using the *Canadian Occupational Performance Measure*. The secondary investigator, Matthew White, functions as a backup therapist when the primary interventionist is not available. He is a certified occupational therapist working at the Courage Kenny Research Institute and has participated in the previous clinical trial of OTTO.

Prior to data collection, the primary and the secondary investigators will discuss the concepts and procedures of OTTO based interventions. The primary interventionist will observe the backup therapist implementing the first one or two sessions for each study participant and discuss the content of treatment afterwards. The two will communicate via face-to-face and email discussions. If the secondary investigator becomes unavailable during the period of study, a third therapist will be sought and the same training procedure will be implemented.

Blinded evaluator. The blinded evaluators are occupational therapy students at University of Minnesota and University of Puget Sound. Each evaluator will conduct all evaluations for the same study participants, except the *Canadian Occupational Performance Measure*. The primary investigator will work with blinded evaluators on the implementation of the Wolf Motor Function Test, Motor Activity Log, ROM, and strength assessments. Inter-rater reliability: Prior to enrollment of the first participant,

measurements between the primary investigator and the blinded evaluators will be within the standard error of measurement for each outcome measure prior to the enrollment of the first participant.

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Appendix A

Instructions for orthosis/splint use and care

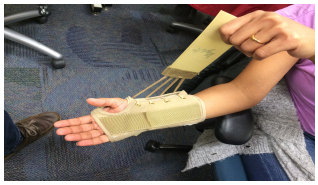
The forearm rotation splint that you will wear on your weaker arm combines a wrist splint and a neoprene strap

- The wrist splint has a single pull lace closures. It allows you to easily put it on and adjust with one hand.
- The neoprene strap is Latex-free. This elastic strap will assist the forearm rotation movement of your weaker arm.

How to put on the splint:

- 1st Put on the wrist splint and fasten the Velcro strap of the splint. (Figure 1 and 2)
- 2nd Attach one end of the strap to the wrist splint at the **wrist level** of the *pinky side*. (Figure 3)
- 3rd Straighten your elbow with your palm facing the ceiling. (Figure 4)
- 4th Wrap the strap at an angle around the forearm, continuing up to the elbow. (Figure 5) **Do not wrap the strap too tight**. You don't want to restrict circulation.
- 5th Attach the end of the strap to itself. (Figure 6)


Figure 1.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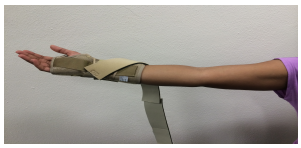
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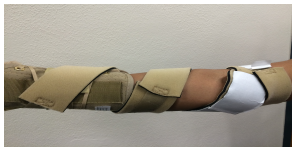
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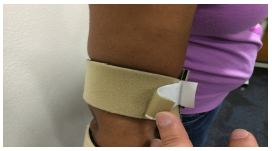
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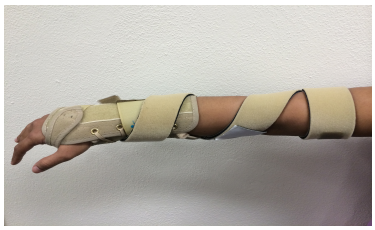

Stop using the splint if you have:

- Swelling of the weaker arm, or
- An allergic reaction producing redness, itching, burning or other skin problems, or
- Find the splint uncomfortable, or
- Have an open wound that would come in contact with the splint.

If you have any of these problems, please also contact the researcher, Chih-Huang (Jeffrey) Yu, immediately at (425)-985-5517.

Care and cleaning:

- Please hand wash the splint in ***warm water and mild soap*** as needed.
- **Do not wring**. Lay flat on towel. Dry at room temperature. Be sure the material is completely dry before reapplying.
- **Do not use ointments or oils** under the material.