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Optimizing Hand Crank Configuration for Therapeutic Use of Amtrykes® for Children with Upper Extremity Motor Deficits

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OPTIMIZING HAND CRANK CONFIGURATION FOR THERAPEUTIC USE OF AMTRYKES® FOR CHILDREN WITH UPPER EXTREMITY MOTOR DEFICITS

by

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ABSTRACT

OPTIMIZING HAND CRANK CONFIGURATION FOR THERAPEUTIC USE OF AMTRYKES® FOR CHILDREN WITH UPPER EXTREMITY MOTOR DEFICITS

by

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The University of Wisconsin- Milwaukee, 2013
Under the Supervision of Roger O. Smith

Objective

The purpose of this research study was to create a model to assist therapists, that determines the optimal positioning of the hand cranks when fitting a child for an AmTryke® with a disability that limits upper body strength, such as a brachial plexus injury.

Method

A fitting model was developed by testing the amount of force required to start moving the hand cranks on the AmTryke® when various amounts of weight were applied to the seat of the device. The data collected inserted into a table. A questionnaire developed and emailed to a convenient sample of pediatric physical and occupational therapists.

Results

Data from the fitting model display a linear growth in the amount of force required as weight increases. Data also showed that as the length of auxilliary hand crank is increased, the amount of force required decreases. Results from the survey indicate that the majority of participants have not used the AmTryke® in practice.

Conclusion

Data reveals that the greater the weight of the rider, the more force required. The longer the hand crank, the less force required. This data contributes to a manual for therapists to

use when determining which arrangement will create optimal use of the AmTryke® for a child. The survey suggests that occupational and physical therapists within the convenience sample used, are not using the AmTryke® as a therapeutic intervention. While the low response rate in this study precludes generalization, this information is important to guide further study as well as to shape efforts to increase occupational and physical therapist's prevalence of use of the AmTryke® in a pediatric setting.

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I wish to extend a heartfelt "thank you" to Fred Sammons and his team at AMBUCS for their support and their resources to perform data collection using the AmTryke®. Also, thank you to my advisor, Roger O. Smith, for his support and guidance throughout the thesis process. It is with his guidance and words of wisdom that I was able to remain motivated to conduct research in the large capacity that I did. To the other members of my committee, Cynthia Clough and Brooke Slavens, thank you for your suggestions and support. Thank you for pushing me to continue working hard on my research and for being open and optimistic to the changes that were made throughout the process.

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PART I: INTRODUCTION TO THE THESIS

Overview

This thesis consists of three parts: 1) the thesis introduction, 2) the research manuscript, and 3) the appendices. Part I introduces a brief description of the thesis, the purpose of the research, and the time frame of the study from developing a fitting manual and protocol to surveying practitioners on the usefulness of the AmTryke® and the fitting manual. Through this section, readers can understand the formation of the thesis. Part II is a research manuscript that includes the entire content of the study, from the literature review to the limitations and recommendations for future research. A version of this chapter will be submitted to scholarly research journals such as the American Journal of Occupational Therapy (AJOT). Part III consists of ten appendices to provide detailed information about the fitting manual that was developed, the instruments used, and the IRB.

Chronology of the Study

The process and steps of this study were created and recorded in a journal format within Microsoft Office Word. This journal was used as a means of documenting necessary changes in procedure as well as documentation of struggles encountered throughout the research process.

The development of the fitting manual began in August, 2012. It took approximately five months to develop the procedure for data collection after literature review. Upon presentation of proposed research at the Wisconsin Occupational Therapy Association (WOTA) conference in November, 2012, further opportunities presented themselves after discussion with AmTryke® creator, Fred Sammons.

The proposal was presented to the committee on November 30th, 2012 and was approved. Appendix B presents the proposal of the study. Committee members discussed the proposal and suggested revising it in terms of procedure of data collection, and participation of children with disabilities. These suggestions were dependent upon success in the development of the fitting model.

Research utilizing the AmTryke® for the purpose of creating a fitting guide began in December, 2012. Throughout the process of data collection, journal entries were completed. Changes that had to be made to the original proposal were documented. A full listing of these changes can be found in Appendix C. Upon completion of data collection, a survey was developed that targeted practitioners in the fields of Occupational and Physical Therapy. This complete survey can be found in Appendix F. All materials were submitted to the Institutional Review Board (IRB) in July, 2013. The IRB panel accepted the proposed research in July, 2013. Appendix G presents submitted documents and the approval letter from the IRB. Following acceptance, the survey was sent out to thirty practitioners. Data was collected using Qualtrics software.

PART II: RESEARCH MANUSCRIPT

OPTIMIZING HAND CRANK CONFIGURATION FOR THERAPEUTIC USE OF AMTRYKES® FOR CHILDREN WITH UPPER EXTREMITY MOTOR DEFICITS

Introduction

The AmTryke® device is a theraputic tricycle allowing for people of all disabilities and ages to be mobile. AmTryke® is created by AMBUCS™, a non-profit service organization dedicated to creating mobility and independence for people with disabilities (AMBUCS.com, n.d.). The device was created in 1994 and the company has distributed over 15,300 AmTryke® vehicles to date. AmTrykes® can be adjusted and designed for adults and children with many diagnosis and impairments. This makes the AmTryke® an appropriate therapeutic intervention for children who have upper extremity motor impairments or brachial plexus injuries.

The brachial plexus is the group of nerves that branch out to the muscles in the hand and arm. Each of the sixteen nerves is responsible for different muscles in the anterior and posterior sides of the arm. Typically the "muscles of the shoulder and elbow are affected and hand movement is retained" (Pendleton, H. & Schultz-Krohn, W., 2006). When a patient is diagnosed with a brachial plexus injury, they receive occupational and/or physical therapy services to regain function. Therapy options are vast and can be adjusted based upon individual need .

Advantage of Mobility and Motivation

Therapy with the AmTryke® allows for kids to maintain motivation due to the natural way that the device promotes the occupation of play. Children engage in the occupation of play the most throughout their childhood years. Because riding a bike is one typical play occupation (Lyon, 2007), children are able to function within the

community, socially interact, and play with their peers while riding the AmTryke. These skills allow for children to interact with their environment (Missiuna & Pollock, 1991).

Recreational mobility is a fundamental component in a child's ability to function in the "occupations of self-care, work, and leisure and is essential to quality of life" (Case-Smith, J. & O'Brien, J., 2010). The development of mobility results in learning experiences and allows for children to influence their own environment through exploration. It also results in intrinsic motivation through children altering their environment by their actions (Case-Smith, J. & O'Brien, J., 2010).

Often times, children with physical disabilities have difficulty achieving motor control independently and become deprived of opportunities that are self-initiated (Case-Smith, J., & O'Brien, J., 2010). Therefore, the child's sensorimotor and developmental activities are not at the same stage as their peers. "Restricted experiences and mobilility during early childhood can have a diffuse and lasting influence" (Hundert, J., & Hopkins, B., 1992). Minimal recreational mobility on a device can cause a lack of ambulation restricting the child's "opportunities to practice decision making, thus giving him or her no reason to express an opinion or desire" (Butler, C., 1986) to be mobile.

However, recreational mobility devices provide the means for a child with a physical disability to become engaged in their environment through exploration. They also can facilitate "psychosocial, language, and cognitive development" (Case-Smith, J., & O'Brien, J., 2010). Within a population of children with complex developmental delays, research has shown that powered mobility increases the number of self-initiated movement occurances and affects initiation with peers and adults (Deitz, J., Swingth, Y., & White, O., 2002). When parents allow for their children to take risks within their

environment, the child works towards independence by taking responsbility for their actions (Kriegsman, K & Palmer, S., 2013). Research has focused mainly on the age at which children should be able to receive mobility devices. Controvery exists into the lasting effects that can come from providing a mobility device too soon. Conversely, "research continues to substantiate the fact that children as young as 18 months can achieve independent skills in powered mobility" (Furumasu, J., Guerrette, P., & Tefft, D., 1996).

When examining the use of mobility devices in a mainstream school setting, there are greater psychosocial barriers that exist. The environment in which the device is being utilized must be examined (Dell, A., Newton, D., & Petroff, J., 2012) in order to determine that the device will engage the student both at home and at school.

Common Interventions

Besides the AmTryke®, other treatment options include: constraint induced movement therapy (CIMT), surgical intervention, and botulinium toxin type A injections. This study focuses on the use of the AmTryke® to determine optimal hand crank length to aide therapists in fitting children with upper extremity motor impairments, such as brachial plexus injuries. However, it's also important to understand how other interventions relate to this population.

Constraint induced movement therapy

Constraint- induced movement therapy (CIMT) has been used for many years on a wide range of populations who experience hemiparesis, varying in age from infants to the elderly. This form of therapy facilitates use of the affected arm by preventing the unaffected arm from partaking in the task at hand. In adults, this is commonly seen in the stroke population. Within the pediatric population, this is commonly used for children

with cerebral palsy or brachial plexus injuries. The AmTryke® is a natural form of CIMT due to the use of both arms in the task and the ability for the therapist to adjust the hand cranks to function in different ways.

The concept of constraint induced movement therapy, according to Grotta et al., "is based upon the theory of "learned non-use." (2004). Various forms of CIMT exist that range in intensity. CIMT sometimes involves a large amount of time and can be demanding for patients to follow protocol. In the short term, it has been shown to be an effective treatment method for people of all ages with hemiparesis.

Prior studies are limited by a lack of follow-up to determine if the functional gains made were due to the CIMT or natural healing. Also, because there isn't a set protocol, studies employ different forms of CIMT ranging from five hours of use for six weeks (Gilmore et al., 2010), to thirty minutes per day for fourteen weeks (Vaz et al., 2010), to six hours per day for three weeks (Buesch et al., 2010). In two of the three instances, participants commented on the lack of comfort as well as the difficulty in completing daily tasks. However, these studies presented positive results in an increased amount of movement and function (Cope, S., Forst, H., Bibis, D., & Liu, X., 2008) (Dickerson, A. & Brown, L., 2007) through increased independence in self-cares, grip strength, and gross motor play (Martin, A., Burtner, P., Poole, J., & Phillips, J., 2008). Research into the carry-over of gains made is lacking, with the exception of one study, that followed up after six months in a population of children with cerebral palsy, and found that there existed maintenance of positive effects in multiple performance areas (Case-Smith, J., DeLuca, S., Stevenson, R., & Ramey, S., 2012).

Surgical intervention

Surgery involves nerve repair and can be done as early as 3-6 months of age. Isolated nerve repairs can occur at approximately 18 months of age. If muscles haven't been reconnected to nerves within 18 months, they may "weaken to the point where re-innervation may no longer be possible" (Cincinnati children's hospital, 2009). Other surgical "procedures may include tendon transfers, muscle transfers and osteotomies to correct muscle imbalances that limit function" (Cincinnati children's hospital, 2009). Information regarding the procedure to complete the surgery, such as incision locations, is widely accessible (Thatte, 2011). However, besides the immediate success that can be found in research (Palti, R., Horwitz, M.D., Smith, N.C., & Tonkin, M.A., 2011), little follow-up research exists.

Botulinum toxin A injections

The botulinum toxin A injections consist of injecting the affected muscle with a fluid that chemically denervates the muscle, thus making surrounding muscle groups more active. This intervention is used to diminish hypertonicity and to prevent contractures, thus making the hypertonic muscle weak or flaccid (Pendleton, H. & Schultz- Krohn, W., 2006). Injections are done in peopple with spasticity due to am upper or lower extremity motor impairment. Commonly, injections are placed in the biceps and triceps, subscapularis, and brachioradialis. The injections typically last several months. Similar to surgical intervention, immediate success is evident in research (Heise, C.O., Goncalves, L.R., Barbosa, E.R., & Gherpelli, J.L, 2005), however long-term follow-up research has not yeilded these same results (Rollnik et al., 2000). When working with a child in therapy, the therapist must be made aware covarients, such as

botulinum toxin A injections, which can impact how the AmTryke® is arranged and integrated.

Biomechanics of Motion with Children

Evaluation of biomechanics required in assisted mobility is a growing field. Currently a lack of research has led to new models used to characterize "upper extremity kinematics and kinetics during pediatric wheelchair mobility" (Paul, A., Slavens, B., Graf, A., Krzak, J., Vogel, L., & Harris, G., 2012). Results of these models incorporate the joints in the arm and the newest models are undergoing pilot studies to determine the clinical application. Ideally, the model will give insight into ways to "improve wheelchair prescription, training and long term care of children with orthopedic disabilities" (Paul et. al, 2012).

Prior Research

Up until this point, little research has been done that examines the effectiveness of the AmTryke® device in therapy. Brachial plexus injuries vary in severity and type, so no two treatment plans are the same. It is known that there are different treatment options available to children with this type of injury; however, the AmTryke® is the only intervention that gives the child the opportunity to play, to be mobile, and to interact with their peers in the way that the AmTryke® does.

Previous studies have shown that children may compensate for lack of upper body stength by moving their trunk (Children's hospital of Boston, 2002). With a decreased amount of strength, the caregiver may have to aide the child in moving the AmTryke®, limiting the child's independence.

AmTryke® Device as Therapeutic Intervention

The AmTryke® device allows for the therapist and rider to determine which hand crank arrangement they prefer, whether or not they would like to use hand or foot pedals, what type of seat they will ride on, and what accessories are added. The options are diverse for each rider and the therapist can choose how to use the AmTryke® with their client (AMBUCS.com, n.d.).

There is a lack of research on specific fitting guidelines for determining how to most effectively fit a person with an AmTryke® that they will be able to use comfortably and independently. AmTryke® has published one form that is used by occupational and physical therapists when fitting a particular client. This form gathers information about height, weight, arm measurements, leg measurements, helmet size, and the type of device that they would like (AMBUCS.com, n.d.). A copy of this form can be found in Appendix H. However, the form does not contain information to help assist the therapist in determining optimal position of the hand cranks based upon the client's upper body strength. When completing research, previous studies using this device have used strength as an outcome measure (Lyon, R., 2007) (Wickham, J., 2009) but have not looked into the correlation between hand crank placement and the ability to make the AmTryke® move.

AmTryke® devices are produced with generic hand crank arrangements, but settings are vast. There is an option of purchasing additional auxilliary hand cranks, which make the diameter of the arm of the AmTryke® longer. Auxilliary hand cranks come in two forms: 2.5" cranks and 4" cranks, which can be combined with one another to create 6.5" cranks and 8" cranks.

In order to allow for the child with limited strength and mobility to be able to move the hand cranks, adjustments can be made in three ways. First, the length of the crank can be changed. Second, there is a capability of making one hand crank stationary, thus making one arm do all of the work to move the AmTryke®. This creates a form of constraint, thus integrating a version of CIMT. Third, hand cranks can be arranged to move in two ways: (1) a reciprocal motion, where both hands are moving the same direction, or (2) in a contralateral motion where one hand is pushing while the other is pulling.

Typically, when used in therapy there are different activities that can be completed while riding the AmTryke®. Typically, the hand cranks are arranged in a reciprocal pattern, allowing the rider to push and pull at the same time in order to move the device. Activities typically integrated into practice vary from simply riding the AmTryke® to obstacle courses. The freedom to arrange hand cranks allows for therapists to further customize the device by increasing the radius for sizing purposes or for strength purposes.

This model was conceptualized based upon the literature that suggested further evidence is needed to appropriately fit a child with upper extremity weakness (brachial plexus injuries in particular), for an AmTryke® device.

Purpose of Research and Hypotheses

The purpose of the research was to create a model allowing for therapists to adjust the hand cranks on the AmTryke®, optimizing the use and progress that can be made by children who have upper extremity motor impairments that impact strength, such as brachial plexus injuries. This study tested three hypotheses: 1) The greater the weight of

the rider, the more force will be needed to move the AmTryke®; 2) The greater the diameter of the hand crank, the less force will be needed to move the device, thus making the AmTryke® easier to move for children with upper extremity weakness or impairment, and; 3)The model will be useful in aiding therapists in determining hand crank length based upon rider's weight and upper body strength.

Methods

This study was completed in two phases, which are illustrated in Table 1 and Appendix A. Phase I developed a model for therapists to fit children for the AmTryke®. This model was based upon the child's uppper body strength when measured by pull force using a spring scale. Phase II developed a survey for pracitioners to determine whether or not the model is relevant in practice. This survey also collected data regarding the frequency of use of the AmTryke® in pediatric practice from practitioners. The study was approved by the Institutional Review Board at the University of Wisconsin at Milwaukee (IRB No. 14.020).

Table 1: Research Design

	Phase I	Phase II
Title of Phase	Testing of AmTryke® Forces & Developing Model using Table of Values	Examining Perceived Value of Model
Hypothesis being tested	1) The greater the weight of the rider, the more force will be needed to move the AmTryke®; 2) The greater the diameter of the hand crank, the less force will be needed to move the device, thus making the AmTryke® easier to move for children with upper extremity weakness or impairment	3)The model will be useful in aiding therapists to determine hand crank length based upon rider's weight and strength
# of Participants	No participants	7 occupational and physical therapists
Method	Force Spring Gauge (See Figure 4)	Survey (See Appendix F)

Phase I: Testing of AmTryke® Forces and Developing Model using Table of Values

In phase I, a model to be used in practice was developed. The model was designed to test Hypothesis #1 and Hypothesis #2. Various steps were followed to collect and interpret accurate data values.

Figure 1
AmTryke® AM-12 Small

Data Testing and Apparatus

In order to test the AmTryke®, the following materials were obtained: the model AM-12 Small AmTryke® as shown in Figure 1; a Cabela's 20 pound spring scale (Item #IK- 016365) as shown in Figure 2; 2.5" and 4" auxilliary hand cranks (Figure 3); callibrated CAP Olympic Barbell weights (45 pounds, 20 pounds, 10 pounds, and 5 pounds); laptop computer with Microsoft Excel software; 9/16" socket wrench to be used to remove bolts holding hand cranks in place; and, pin to insert into AmTryke® in order to lock steering (Figure 4).

Figure 2
Spring Force Scale
www.cabelas.com

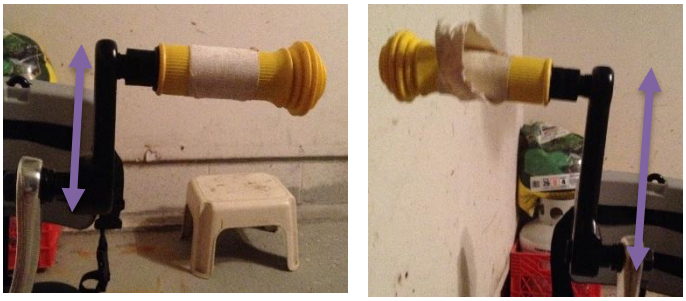


Figure 3
2.5" Auxiliary Hand Crank (Left)
4" Auxiliary Hand Crank (Right)

Figure 4
AmTryke® Pin

Testing Procedure

To ensure that data collection was completed in a concise manner, there were six steps followed between each hand crank arrangment trial. At the beginning of data collection, the AmTryke® was positioned on a level, concrete floor with the pin placed below the hand cranks to lock steering. Location of the pin can be seen in Figure 4. From that point, the following six steps were employed during data collection:

1. The AmTryke® hand cranks were positioned upwards, perpendicular with the concrete floor as shown in Figure 5. This position was selected for repeatability purposes.
2. Calibrated free weights were applied to the seat in increments of 10 pounds. Weight was positioned in an upward position and centered on the seat shown in Figure 6. Sand bags are not recommended due to the difficulty in securing them in place to prevent shifting.
3. The safety harness on the AmTryke® (Figure 6) was engaged around the weights ensuring that they remain in place during trials.
4. The force gauge was attached to the hand crank by inserting it into a piece of tape that was wrapped around the handle (Figure 3) and force was applied to pull the AmTryke®. Pull force was applied parallel to the ground

Figure 5
AmTryke® Handles Perpendicular

Figure 6
AmTryke® Safety Harness

for all trials. Enough force was applied to begin movement of the AmTryke®, however, sudden big pulls were not applied. Slow pulls were not applied either, as these affect the results of the force reading.

5. The tricycle was re-positioned between each trial so that the hand cranks were perpendicular to the ground and the spring scale was parallel to the ground.
6. After three trials were performed on a particular hand in each of the hand crank arrangements, data values were typed into the computer. These values represented the amount of force (in pounds) that must be applied in order to begin moving the AmTryke®.

Data were collected for weight increments from zero-130 pounds. This span of 130 pounds was recommended by AMBUCS™. The level of the hand cranks was assessed between each arrangement.

Data Reporting

Data was collected on the total force needed to move the AmTryke® by completing three trials measuring force using the Pull Steering Bar in the front that moves the entire AmTryke® and functions as a way to pull the device for parents (Figure 7). Data values were collected on the right hand and left hand for each of the following hand crank arrangements: both handles standard (4" radius); right hand standard (4" radius), left hand 2.5" additional crank (6.5" radius); right hand standard (4" radius), left hand 4" additional crank (8" radius); right hand standard (4" radius), left hand 6.5" additional crank (10.5" radius); both handles 2.5" additional crank (6.5" radius); both handles 4"

Figure 7
AmTryke® Handle

additional crank (8" radius); and, both handles 6.5" additional crank (10.5" radius). Figure 3 shows the Standard Crank, 2.5" crank, and 4" crank. Force was not calculated for any larger crank arrangements due to the radius being too wide to functionally ride the AmTryke®. The force was not calculated for the stationary position due to the inability to make the AmTryke® move when cranks are arranged this way. The standard handle with the AM-12 is a 4" crank, therefore by adding additional crank lengths, the radius increased the crank length to 6.5" (by adding the 2.5" crank), 8" (by adding the 4" crank), and "10.5" (by adding the 6.5" crank).

To assess inter-rater reliability of the data collection procedure, an additional rater (novice rater), who was a male and the same age as the first rater (expert rater). Training was ten minutes and length and included observation of testing position, observation of AmTryke® adjustment, and three trials completing the measuremnts. After that time, the novice rater completed three trails for each weight increment with the standard hand crank position (4" radius), the 2.5" auxiliary crank position (6.5" radius), and the 4" auxiliary crank position (8" radius).

Methods: Phase II Examining Perceived Value of Model through Survey Research

Phase II was designed to test Hypothesis #3. It consisted of development of a survey and distribution of the survey to pediatric practitioners.

Survey Development

A survey was developed within the Qualtrics software. The questionnaire was reviewed by a variety of faculty members and peers who have experience with the AmTryke® device. Feedback resulted in clarification of how to use the mini-manual and more specific questions. The purposes of the questionnaire were: (a) to identify the

extent to which therapists currently use the AmTryke® in practice; (b) to gather therapists perceptions of how easily the AmTryke® can be adjusted to meet the needs of the child; and (c) to determine whether or not therapists found the fitting guidelines helpful in determining optimal hand crank arrangements.

The questionnaire totaled fifteen items and was composed of both short answer and multiple choice questions. A copy of the survey can be found in Appendix F. Questions within the survey asked for (a) further information into the current procedures therapists use to make adjustments to the cranks; (b) more information regarding the therapist's background in pediatrics; (c) input into the effectiveness of the fitting guide that was developed prior; and (d) information into what populations benefit most from the AmTryke® as a therapeutic intervention.

Survey Procedure

After a survey was developed that incorporated the data collected in Phase I, a population sample was created. To generate the sample, email addresses were collected via convenience sampling. The survey was distributed to thirty pediatric occupational and physical therapists via email. A follow-up email was sent two days and four days after distribution of the survey. Survey data was collected and summarized within the Qualtrics software and a summary of raw data can be found in Appendix I.

Results: Phase I

Upon completion of data collection, the data was summarized in Table 2. For the purposes of size, the table has been divided into three parts. The table is divided based upon the different hand crank arrangements that were researched. Within each hand crank arrangement, all three trials on the left and right hand are shown. Values are expressed in pounds.

Table 2: Raw Data (Part I)

AmTryke® Hand Crank Data Collection Table									
Weight applied to seat	Both hand cranks standard (4" radius)						Total force (weights)		
Trial	Trial 1 Left	Trial 2 Left	Trial 3 Left	Trial 1 Right	Trial 2 Right	Trial 3 Right	Trial 1	Trial 2	Trial 3
0lb	7	7	8	7	6	7	8	8	7
10 lb	6	8	8	6	7	8	9	8.5	8.5
20 lb	7	8	8	8	8	9	10.5	9.5	9.5
30 lb	8.5	9.5	8	9.5	8.5	8	10	11.5	11
40 lb	10	10	10	9.5	9	10	12	11.5	12
50 lb	10.5	10.5	10	10	10	10.5	12	12	12.5
60 lb	11	10.5	12	10.5	11	11	13	12.5	13
70 lb	11	11	11	11	11	11	12	14	13
80 lb	11	11.5	11	12	11	11	13.5	14	14
90 lb	12	13	12	13	12	12	14	15	14.5
100 lb	12	13	14	13	12	12.5	14	14.5	15
110 lb	14	13	13	14	13.5	14	16	16	15.5
120 lb	14.5	14.5	15	14.5	14.5	14	16	16	16.5
130 lb	16.5	15.5	16	16	16	16	17	17	17

Table 2: Raw Data (Part II)

AmTryke® Hand Crank Data Collection Table

Weight applied to seat	Both 2.5" crank (6.5" radius)						Both 4" crank (8" radius)						Both 6.5" crank (10.5" radius)					
Trial	Trial 1-left	Trail 2-left	Trial 3-left	Trial 1-Right	Trial 2-Right	Trial 3-Right	Trial 1-left	Trial 2-left	Trial 3-left	Trial 1-Right	Trial 2-Right	Trial 3-Right	Trial 1-left	Trial 2-left	Trial 3-left	Trial 1-Right	Trial 2-Right	Trial 3-Rigth
0lb	6	5	6	6	6	5	4	4.5	4	4	4	4	4	3.5	3.5	3.5	3	3.5
10 lb	6	6	6	6	6	6	4	4.5	4.5	4	5	5	4	4	4	4	4	3.5
20 lb	6.5	7	7	6.5	6.5	7	5.5	4	5	5.5	5	5	5	5	5.5	5	4	4
30 lb	7.5	7.5	7	7	7.5	8	6	5.5	6.5	5	6	7	5	4.5	5	5	4.5	5
40 lb	10	8	8	10	8	7.5	7	6	5.5	7.5	5.5	6	6	5	6	4.5	5	5
50 lb	9	9.5	9	9	10	9	6	6	7	6	7	6	6	6	6	6	6	6
60 lb	11	8	7	10	8	8	7	7	7	8	7	7	6	7	7.5	6	6	6.5
70 lb	10	9	9	9	9	9.5	6	7	7	9	7	7	7	7	7	8	6.5	7
80 lb	10	10	10	10.5	10	9.5	7	7.5	8	7.5	7	8	8	7	8	8	7.5	7.5
90 lb	10	10	10.5	10	10	10	8	7	8	8	8	7	7	7.5	8	8	7.5	8
100 lb	12	10	11	11.5	10	12	9	8	8	9	9	8	8	9	8	7.5	7.5	8.5
110 lb	12	10	12	12	10	12	10	9	8	11	9	8.5	8.5	8	7	7	8.5	8
120 lb	12	12	11.5	10	11	11.5	10	10	8	10	10	10.5	8	8	10	10	8.5	10
130 lb	12	12	13	12	12	12	10	9	10	10	9	10	10	10	10	10	10	10

Table 2: Raw Data (Part III)

AmTryke® Hand Crank Data Collection Table																		
Weight applied to seat	Left Hand 2.5" crank (6.5" radius), Right Standard (4" radius)						Left Hand 4" crank (8" radius), Right Standard (4" radius)						Left Hand 6.5" crank (10.5" radius), Right Standard (4" radius)					
Trial	Trial 1- left	Trial 2 Left	Trial 3 Left	Trial 1 Right	Trial 2 Right	Trial 3 Right	Trial 1- left	Trial 2- left	Trial 3- left	Trial 1 Right	Trial 2 Right	Trial 3 Right	Trial 1- right	Trial 2- left	Trial 3- left	Trial 1 Rigth	Trial 2 Right	Trial 3 Right
0lb	4.5	4.5	5	6	6.5	5.5	4.5	4	4	6.5	6	5.5	4	3	3.5	6	6	5.5
10 lb	5	5	5	6	6	6	4	5	5	6.5	6	7	4	4	4	6	6	6.5
20 lb	6	5.5	5	6	7	6	6	6	6.5	7	7	7	4	4.5	4	8	6.5	6
30 lb	6	5.5	5.5	7	6	7	6.5	6	6	8	7	8	5	5	5	8	7	7
40 lb	7.5	7	6.5	8	8	8	7	6	6	8	8	8.5	6	4.5	5	8	7	8
50 lb	6	7	6	7.5	8	8	7.5	7	7	9	8	8	7	7	5	9	9	7
60 lb	8	8	7	8	8	9	8	7.5	8	9	9	8	7	6	6	9	9	8
70 lb	8.5	8	8	8	8.5	9	8	8	8.5	10	9	9	8	7	6.5	9	8.5	9
80 lb	9	9	8	9	9	10	8	7.5	8	9.5	9.5	9.5	7	8	6	9	10	10.5
90 lb	10	10	10	10.5	11.5	11	7.5	8	8	10.5	9.5	9.5	8	7	7	11	10	10
100 lb	11	10	10.5	11	11	12	10	9	10	10.5	10	11	8	8	7	12	10	10
110 lb	10.5	10.5	11.5	12	12	12.5	11	10	10.5	11	11	11	10	8	7	13	11	11
120 lb	12	10.5	10.5	13	13	12	10	11	10	12	12	11	9	8	7.5	10	12	11
130 lb	13.5	11.5	11.5	14	14.5	14	12	10	10	13	12.5	13	9	8	8	12	11.5	12.5

Data Reduction

Upon completion of data collection, the three data values for each hand and each crank arrangement were averaged and scaled down into Table 3. This table represents the mean force for three trials for each crank length needed to move the AmTryke® at each weight increment in pounds.

Table 3: Mean Force

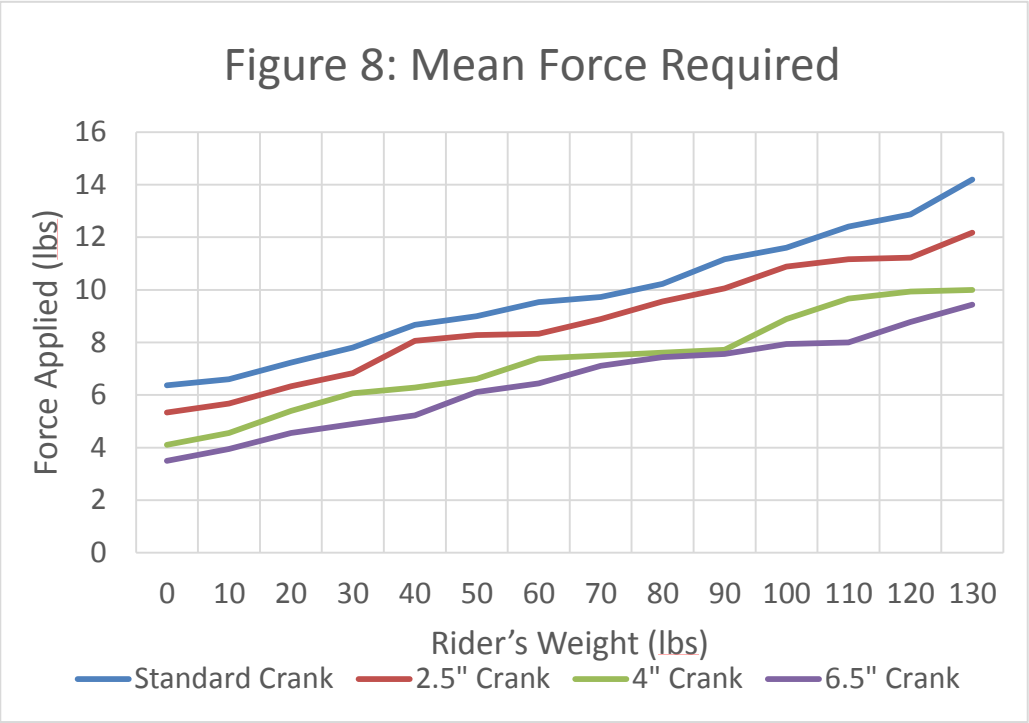
AmTryke® Mean Force															
Bilateral Symmetrical Hand Cranks															
		Both Hand Cranks Standard (4" radius)		Left 2.5" (6.5" radius), Right Standard (4" radius)		Left 4" (8" radius), Right Standard (4" radius)		Left 6.5" (10.5" radius), Right Standard (4" radius)		Both 2.5" Crank (6.5" radius)		Both 4" Crank (8" radius)		Both 6.5" Crank (10.5" radius)	
Rider's Weight (lbs)	Total Pull	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE
0	7.67	7.33	6.67	4.67	6.00	4.17	6.00	3.50	5.83	5.67	5.67	4.17	4.00	3.67	3.33
10	8.67	7.33	7.00	5.00	6.00	4.67	6.50	4.00	6.17	6.00	6.00	4.33	4.67	4.00	3.83
20	9.83	7.67	8.33	5.50	6.33	6.17	7.00	4.17	6.83	6.83	6.67	4.83	5.17	5.17	4.33
30	10.83	8.67	8.67	5.67	6.67	6.17	7.67	5.00	7.33	7.33	7.50	6.00	6.00	4.83	4.83
40	11.83	10.00	9.50	7.00	8.00	6.33	8.17	5.17	7.67	8.67	8.50	6.17	6.33	5.67	4.83
50	12.17	10.33	10.17	6.33	7.83	7.17	8.33	6.33	8.33	9.17	9.33	6.33	6.33	6.00	6.00
60	12.83	11.17	10.83	7.67	8.33	7.83	8.67	6.33	8.67	8.67	8.67	7.00	7.33	6.83	6.17
70	13.00	11.00	11.00	8.17	8.50	8.17	9.33	7.17	8.83	9.33	9.17	6.67	7.67	7.00	7.17
80	13.83	11.17	11.33	8.67	9.33	7.83	9.50	7.00	9.83	10.00	10.00	7.50	7.50	7.67	7.67
90	14.50	12.33	12.33	10.00	11.00	7.83	9.83	7.33	10.33	10.17	10.00	7.67	7.67	7.50	7.83
100	14.50	13.00	12.50	10.50	11.33	9.67	10.50	7.67	10.67	11.00	11.17	8.33	8.67	8.33	7.83
110	15.83	13.33	13.83	10.83	12.17	10.50	11.00	8.33	11.67	11.33	11.33	9.00	9.50	7.83	7.83
120	16.17	14.67	14.33	11.00	12.67	10.33	11.67	8.17	11.00	11.83	10.83	9.33	10.17	8.67	9.50
130	17.00	16.00	16.00	12.17	14.17	10.67	12.83	8.33	12.00	12.33	12.00	9.67	9.67	10.00	10.00

This table was further scaled down in order to find the average force needed in each of the positions of hand cranks. To complete this, the averages of each specific arrangement were taken from Table 3 and the total averages were found.

By finding the mean for each crank length, the table was summarized into Table 4 and illustrated in Figure 8. The essential data was pulled out and summarized into this table. With this information, it does not matter which hand crank must be adjusted; variations of crank arrangments can be created. It is assumed that a data collection in CIMT hand crank arrangement would result in similar findings.

Table 4: AmTryke® Sizing Guide- Essential Data with weight and force (lbs)

AmTryke Sizing Guide (Essential Data)				
Hand Crank Length				
Rider's Weight	Standard Crank (4” radius)	2.5" Crank (6.5” radius)	4" Crank (8” radius)	6.5" Crank (10.5” radius)
0	6.37	5.33	4.11	3.50
10	6.60	5.67	4.56	3.94
20	7.23	6.33	5.39	4.56
30	7.80	6.83	6.06	4.89
40	8.67	8.06	6.28	5.22
50	9.00	8.28	6.61	6.11
60	9.53	8.33	7.39	6.44
70	9.73	8.89	7.50	7.11
80	10.23	9.56	7.61	7.44
90	11.17	10.06	7.72	7.56
100	11.60	10.89	8.89	7.94
110	12.40	11.17	9.67	8.00
120	12.87	11.22	9.94	8.78
130	14.20	12.17	10.00	9.44



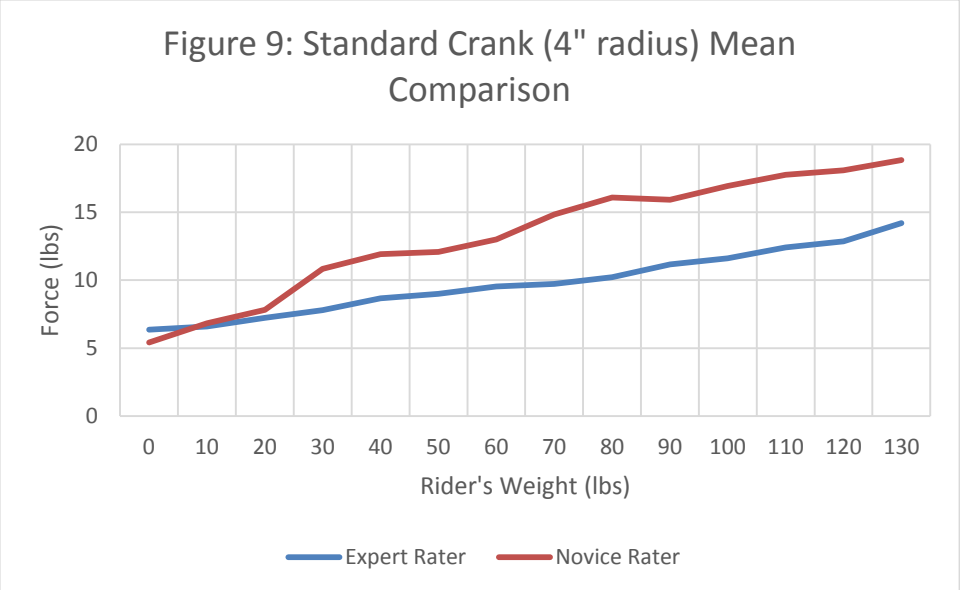
Inter-rater Reliability

To assess inter-rater reliability, data points from the three trials were averaged and inserted into a table with data collected from initial trails completed by the expert rater (Table 5). Novice rater's data were compared to initial data collected. The mean of both raters are graphed below. Figure 9 displays the means for the standard crank length (4" radius), Figure 10 displays the means for the 2.5" auxiliary crank (6.5" radius), and Figure 11 displays the means for the 4" auxiliary crank (8" radius). Pearson Product Moment was calculated within Microsoft Excel software. When comparing the Standard Crank (4" radius) to one another, there was a high level of covariance (r=0.961). Similar covariance was calculated with 2.5" crank (6.5" radius) where r=0.986 and for the 4" crank (8" radius) where r=0.975 (Portney, L., & Watkins, M., 2009). Figure 12 displays the correlation plot for the standard crank (4" radius), Figure 13 displays the correlation

plot for the 2.5” crank (6.5” radius), and Figure 14 displays the correlation plot for the 4” crank (8” radius).

Table 5: Expert and Novice Rater Data Means

Expert and Novice Rater Data Means						
Rider’s Weight	Standard (4” radius) (Expert Rater)	Standard (4” radius) (Novice Rater)	2.5” Crank (6.5” radius) (Expert Rater)	2.5” Crank (6.5” radius) (Novice Rater)	4” Crank (8” radius) (Expert Rater)	4” Crank (8” radius) (Novice Rater)
0	6.37	5.42	5.33	4.33	4.11	3.17
10	6.6	6.83	5.67	4.5	4.56	3.5
20	7.23	7.83	6.33	5	5.39	4.33
30	7.8	10.83	6.83	6.33	6.06	5.33
40	8.67	11.92	8.06	7.5	6.28	6
50	9	12.08	8.28	7.83	6.61	7.5
60	9.53	13	8.33	9.5	7.39	7.83
70	9.73	14.83	8.89	10	7.5	8
80	10.23	16.08	9.56	10	7.61	9.33
90	11.17	15.92	10.06	11.67	7.72	10
100	11.6	16.92	10.89	11.5	8.89	11
110	12.4	17.75	11.17	12.5	9.67	11.33
120	12.87	18.08	11.22	13.17	9.94	11.33
130	14.2	18.83	12.17	13.83	10	11.5



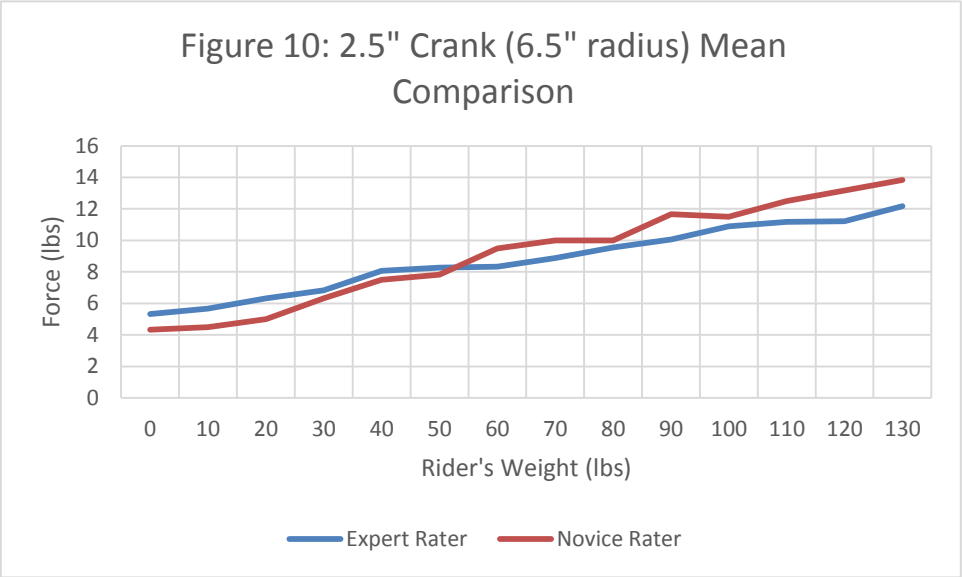


Figure 10: 2.5" Crank (6.5" radius) Mean Comparison
Force (lbs)
16
14
12
10
8
6
4
2
0
0 10 20 30 40 50 60 70 80 90 100 110 120 130
Rider's Weight (lbs)
Expert Rater
Novice Rater

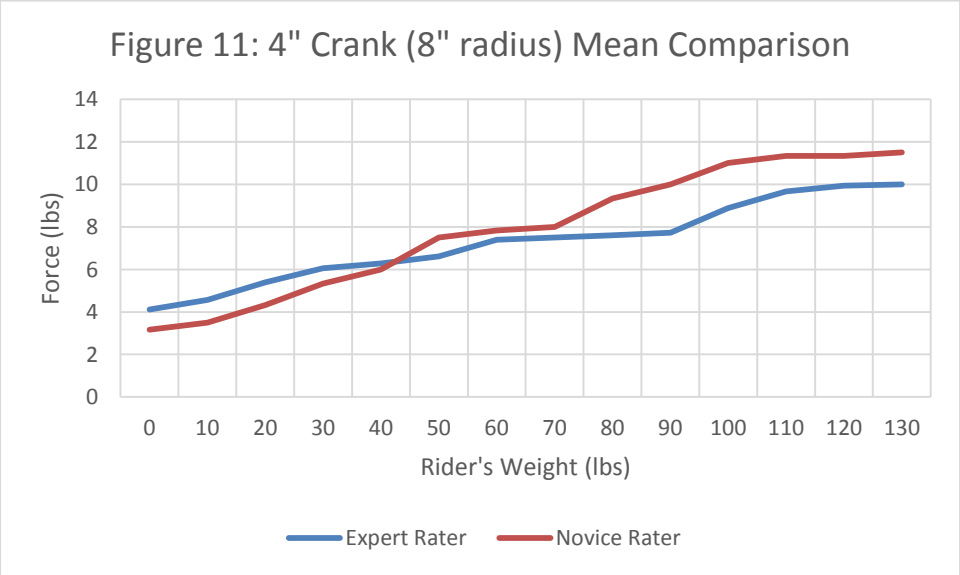


Figure 11: 4" Crank (8" radius) Mean Comparison
Force (lbs)
14
12
10
8
6
4
2
0
0 10 20 30 40 50 60 70 80 90 100 110 120 130
Rider's Weight (lbs)
Expert Rater
Novice Rater

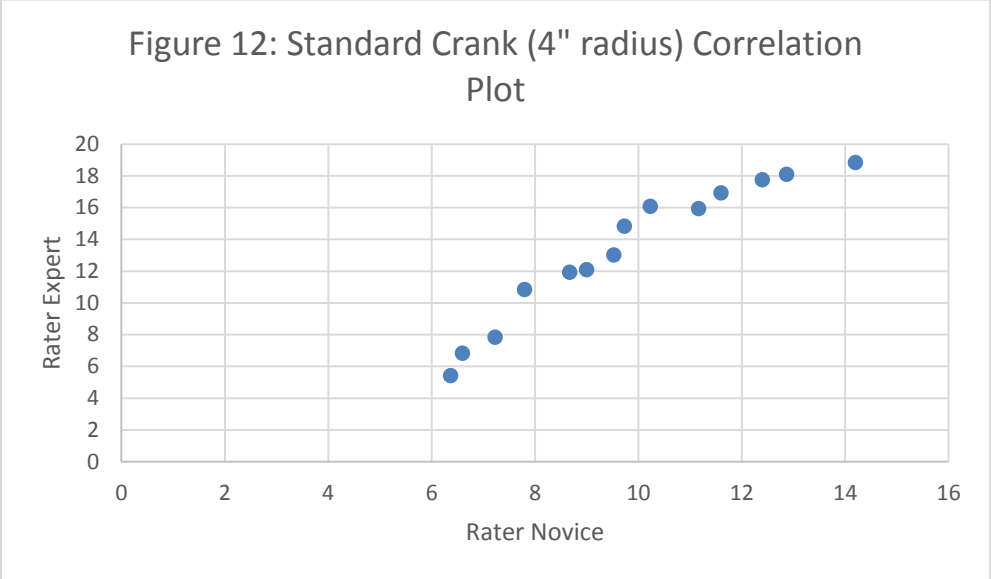


Figure 12: Standard Crank (4" radius) Correlation Plot
Rater Expert
Rater Novice
0
2
4
6
8
10
12
14
16
18
20

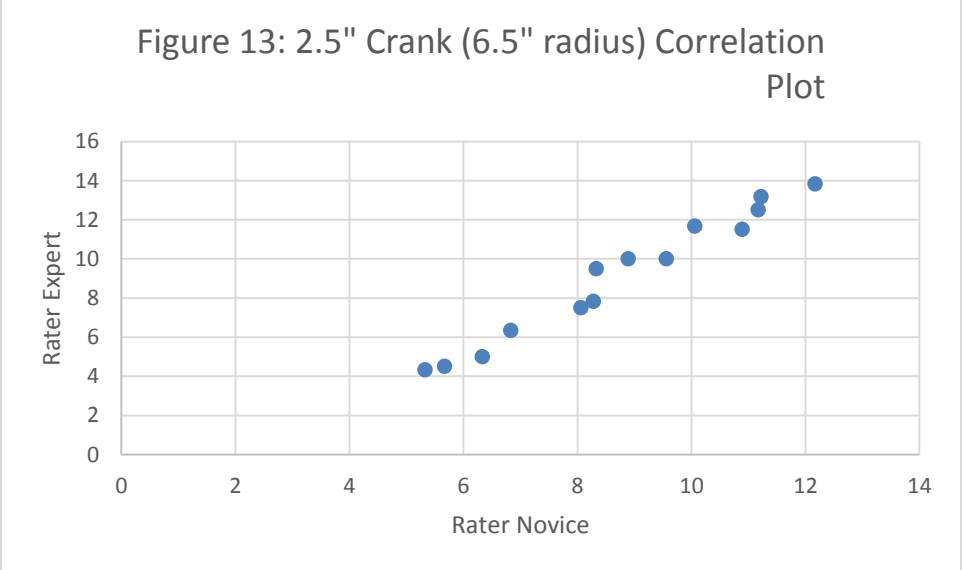
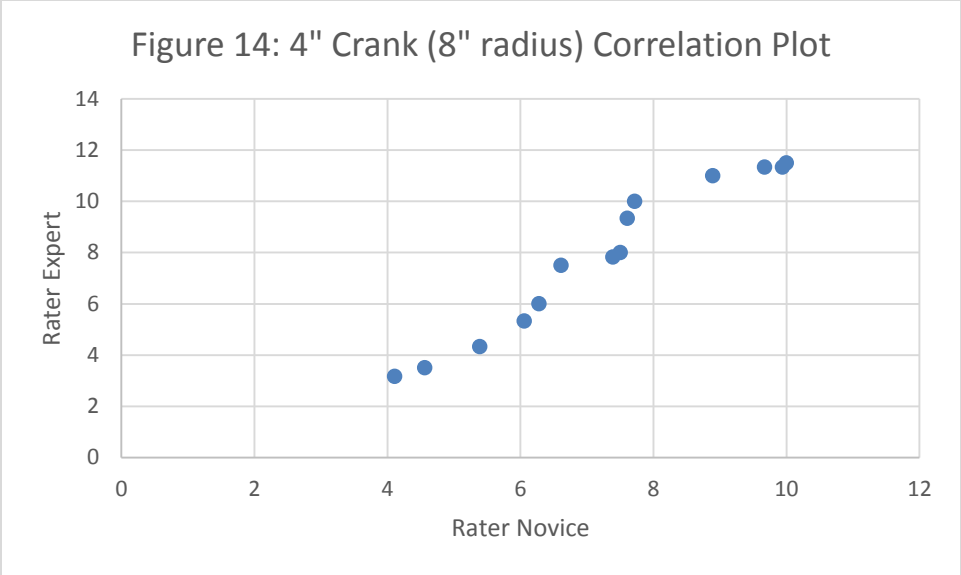


Figure 13: 2.5" Crank (6.5" radius) Correlation Plot
Rater Expert
Rater Novice
0
2
4
6
8
10
12
14
16



Following assessment, standard deviation was calculated to find the difference between both raters (Table 6).

Table 6: Standard Deviation Inter-rater

Standard Deviation Between Raters			
Weight	Standard Crank (4” radius)	2.5" Crank (6.5” radius)	4" Crank (8” radius)
0	0.67	0.71	0.66
10	0.16	0.83	0.75
20	0.42	0.94	0.75
30	2.14	0.35	0.52
40	2.30	0.40	0.20
50	2.18	0.32	0.63
60	2.45	0.83	0.31
70	3.61	0.78	0.35
80	4.14	0.31	1.22
90	3.36	1.14	1.61
100	3.76	0.43	1.49
110	3.78	0.94	1.17
120	3.68	1.38	0.98
130	3.27	1.17	1.06

Development of Sizing Guide

After data collection was complete and data tables were summarized, a sizing guide was created that details steps on how to adjust the hand cranks of the AM-12 in order to make necessary adjustments. This sizing guide talks through the steps to adjusting the AmTryke® and includes graphs and tables of information along with instructions on how to determine the arrangement that will work best for the child. The manual can be found in Appendix E, however, the detailed steps are displayed below. The AmTryke® Fitting Model based upon arm strength is a tool for Occupational and Physical Therapists who work within a pediatric setting. The purpose of this tool is to aide therapists in determining which hand crank length will benefit children the most.

When using the AmTryke® Fitting Model for the model AM-12 Small AmTryke® based upon arm strength, there is a series of steps that must be followed.

1. Measure the upper extremity strength by attaching the spring scale to a solid object that will not move when they pull. Ask the child to pull forcefully but do not allow for them to continue to pull for greater than one second. This will allow you to measure the capacity of force that will be necessary to start moving the AmTryke®.
2. Determine child's weight.
3. Using the table below, locate the nearest weight class of the child.
4. Locate the child's upper extremity strength within the table.
5. Arrange hand crank crank length according to the appropriate recommendation shown in Table 2.

6. If none of the arrangements match ideal formatting, use the averages in Table 3 that incorporate averages from Table 2.
7. If the child's weight and strength fall between averages, use Figure 8 to determine where the child most closely fits.

Examples:

1. Ben is a 10 year old child with a brachial plexus injury. He is 77 pounds and has a force of 10.2 pounds in his right arm and 7.3 pounds in his left arm. Based upon these measurements, Table 2 indicates that the right arm should be arranged in a standard format and his left arm should be arranged with a 6.5" crank.
2. Cary is a 4 year old child who suffered bilateral arm fractures. She weighs 40 pounds and has 6.5 pounds of force in both arms. Based upon the recommendations in Table 2, Cary's AmTryke® will have both hand cranks arranged with 4" cranks.

Hypothesis #1: The greater the weight of the rider, the more force will be needed to move the AmTryke®.

Data supports this hypothesis based upon the force values that were required to move the AmTryke®. Confirmation of this can be found in Tables 2, 3, and 4, which show that there is a linear increase in the amount of force required to move the device as the weight increases in ten pound increments. At each additional weight increment, the force needed inceased.

Hypothesis #2: The greater the diameter of the hand crank, the less force will be needed to move the device, thus making the AmTryke® easier to move for children with upper extremity weakness or impairment.

This hypothesis was supported by the force values summarized in Tables 2, 3, and 4. As the length of the hand crank increased, there was a decrease in the amount of force needed to move the AmTryke®. These findings suggest that the longer the hand crank, the less upper extremity strength is needed to successfully make the device move.

Results: Phase II

Hypothesis #3: The model will be useful in aiding therapists when determining hand crank length based upon a rider's weight and strength.

Seven survey responses were recorded. The majority of respondents (86%) reported not having experience with using the AmTryke® as a therapeutic intervention.

In regards to the fitting diagram, the therapist stated that the fitting diagram corresponded with how they previously had fit children (by looking at strength). They also determined that individual arm force with various crank lengths is more appropriate than using total force. However, the responding therapist selected that they have not used other crank lengths when working with children with brachial plexus injuries.

When asked about other modifications that affect the success of the AmTryke®, the therapist commented that the straps applied to handles and pedals are essential when working with children with neurological deficits and tone (Hardy, J., 2013). The most difficult part about adjusting the AmTryke® is that "the child has to be off the bike [during the adjustment]" (Hardy, J., 2013) according to the responding therapist.

When asked whether home therapy programs or programs within the clinic were more effective, the therapist chose therapy within the clinic. It was noted that significant progress towards meeting the child's goals typically occurs in less than one month, however, signficant results are not always evident.

Therefore, due to a low response rate, it is unknown whether or not the fitting model is an accurate tool for therapists who practice in a pediatric setting because data can not be generalized or be found statistically significant.

Discussion

The results from Phase I indicate that a fitting model based upon a child's weight and strength is directly affected by the length of the crank that is attached. When examining data tables, it can be seen that there is a general decrease in the amount of strength required for a child to move the AmTryke® as the length of the hand crank is increased. This implies that potential for a child to be mobile increases when the crank length is increased.

Hyphotheses #1 and #2 are supported by data in this instance. This leads to the conclusion that the AmTryke® presents itself as an option for therapeutic intervention.

In the instance of a CIMT type of hand crank arrangement, the cranks would be arranged in a way that prevents one of them from moving by creating a zero degree range of motion. The child's hand may be strapped to the handle. When using this form of therapy, there is a "Brachial Plexus Kit" that be purchased from AMBUCS™. The use of this kit would allow for therapists to prevent motion in the affected arm, and to determine if the other crank needs adjustment as well in order to compensate for the inability to use both arms to power the device. Although there is not an external constraint that is required, the AmTryke® presents as a natural form of constraint because it requires the child to actively hold the handle to make the device move.

If this research were repeated, there are multiple factors that could influence yielding the same results. The surface of the testing is a key component simply because there is different amounts of friction produced on various surfaces. Also, if the ground is not completely flat, there is the chance that the uneven surface can make it harder or easier to move the AmTryke®. A third component that can result in different data values

is the use of different researchers. Human error can result in pulling the force gauge differently from one study to the next and can even change between trials. It is important to note that when pulling on the force gauge, consistency is vital to the success in attaining accurate numbers that represent the population of children with upper extremity strength deficits.

Unfortunately, Hypothesis #3 was not able to be accurately assessed within this study. The lack of survey repsonse indicates that there is not a common knowledge base that exists among practitioners about the AmTryke®. Survey responses indicate that 86% of therapists do not have any experience with the AmTryke®, indicating that AmTryke® use appears to be geographically spotty. However, therapists who do have experience using the device have indicated that strength is a common factor in the assessment and determination of adjustments to be made to the device. This indicates that the fitting model created in Phase I has potential to be of great use to therapists in practice.

Repeating the survey would result in more successful data collection by using more aggressive recruitment methods as well as earlier start of survey distribution. Research into the geographical areas in which the AmTryke® is used would allow for survey distribution to be more focused on therapists who have AmTryke® experience.

Implications for practice

The results from the data survey indicate that there is room for great improvement in the understanding of the benefits of using the AmTryke® as a therapeutic intervention. The use of the fitting model in practice is both practical and quick. The force that a child has in each of their upper extremities is simple to measure. Thus, these measurements

can then be used to determine which crank size is appropriate for a child. By using this manual, therapists can quickly and easily find which arrangement will help the child to increase their strength, rather than by trial and error.

Occupational therapy is unique in that it does not have strict guidelines for how to conduct intervention on clients. When searching for things such as "OT manual" on the internet, one will be directed to the *Occupational Therapy Practice Framework* that was created by the American Occupational Therapy Association (2008). Within this framework, there are key terms and important items to consider when conducting therapy with a client, such as therapeutic use of self or evidence-based practice. However, occupational therapy does not view each diagnosis as having a certain protocol which results in a lack of detailed information or manuals on how to conduct therapy. For therapists who are presented with a client who is unique to their skill-set, this can be challenging. By creating this model, this is a small step towards therapists feeling confident in the decisions for fitting that they are making.

Limitations

Limitations to this study include the amount of individual judgement used when pulling the device forward. There was no blinding that occurred when completing the trials. However, interrater reliability shows that when comparing two raters, there is a high Pearson Product-Moment Correlation Coefficient. In real use, bilateral hand crank motions are typical. Within this study, hand cranks were arranged unilaterally to ensure that both cranks were perpendicular to the ground during all trials. Another limitation is a lack of participants. This was caused by lack of time to collect survey entries as well as a lack of knowledge of the AmTryke® device and its therapeutic value. Data was collected

in 10 pound increments. Although this isn't relatable for all riders, graph models can be used by following the linear line as shown in Figure 8. Another limitation is that averages were found using a spring scale alone and there was no mechanical means to pulling the scale. Use of more technology, such as force sensors, would have created a more accurate representation of what the force applied is.

Suggestions for future research

Future research with the AmTryke® is essential in increasing the knowledge about the device as well as in increasing its usefulness to practitioners. Suggestions include using force sensors to determine an exact measurement of force applied in both directions. Also, research can be done into different arrangements that include manipulating the hand cranks so they are in various locations to increase or decrease a child's range of motion. For example, research into the arrangement in which cranks are positioned perpendicular to one another, may yield different results. A third suggestion is to gather data using children with brachial plexus injuries by having them use the device rather than putting free weights on the seat.

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PART III: APPENDICES

Appendix A: Overall Research Design

	Phase I	Phase II
Title of Phase	Testing of AmTryke® Forces & Developing Model using Table of Values	Examining Perceived Value of Model
Hypothesis being tested	1) The greater the weight of the rider, the more force will be needed to move the AmTryke®; 2) The greater the diameter of the hand crank, the less force will be needed to move the device, thus making the AmTryke® easier to move for children with upper extremity weakness or impairment	3)The model will be useful in aiding therapists to determine hand crank configuration based upon rider's weight and strength
# of Participants	No participants	7 occupational and physical therapists
Instrumentation	Force Gauge (See Figure 4)	Survey (See Appendix F)

Appendix B: Research Proposal

I. PURPOSE

Brachial plexus injuries (BPI) occur in 1.5 out of every 1000 births (Cincinnati children's hospital, 2009) and can manifest themselves in two forms: severe and mild. The form is dependent upon the type of injury, as well as how damaged the brachial plexus becomes following the injury. Treatment time and the amount of healing is unique to each patient, making it difficult to determine the amount of time it will take to heal from a brachial plexus injury. Many forms of therapy have been utilized in treatment. Many of the children affected by brachial plexus injuries are treated using surgical interventions, if symptoms haven't healed quickly on their own. To avoid surgical intervention, new research is needed on various interventions that can help stimulate nerve healing.

One such intervention is the AmTryke®, which is a hand powered tricycle that makes it easier to move by having adjusted hand cranks and push or pull bars that are adjusted for each patient. This device gives the therapist the opportunity to let the child play and interact with their environment while working on the deficits caused by the brachial plexus injury. One issue that emerges is that there is limited research using the AmTryke®. Therefore, there is a need to better understand the therapeutic benefits while riding the AmTryke® as well as research to determine which AmTryke® device and accessories can be created to allow for the person to be as independent as possible. The purpose of this research is to create a model to be used by therapists that illustrates the optimal positioning of the hand cranks when fitting a child for an AmTryke®.

II. INTRODUCTION AND LITERATURE REVIEW

The Brachial Plexus

The brachial plexus is the group of nerves that branch out to the muscles in the hand and arm. Each nerve is responsible for different muscles and if an injury affects that nerve, it's possible that only a few muscles of the arm will be affected. The brachial plexus can be seen in Figure 1. It consists of sixteen nerves that branch to reach the anterior and posterior muscles of the arm and hand.

When a patient is diagnosed with a brachial plexus injury, they receive occupational therapy services to help regain function. Therapy options are vast and can be adjusted based upon the individual scenario. One such option that has been introduced in the past few years is the AmTryke® created by AMBUCS™, which is a non-profit service organization that is dedicated to creating mobility and independence for people with disabilities. (AMBUCS.com, n.d.) This device was created in 1994 and the company has distributed over 15,300 AmTryke® vehicles to date. This device can be adjusted and designed for adults and children with many diagnosis and impairments. Although this form of therapy can be used in a variety of settings and with a large population, there is yet to be published research that explores the results of this device on children, specifically those with brachial plexus injuries.

Brachial Plexus Injury Assessments

Therapy options for therapists are extensive and sometimes making therapeutic decisions can be difficult, even for experienced therapists, due to the intricacy of injuries. Assessments have been created to help therapists know where the child is functionally performing. These assessments include the Mallet Classification (Nath, R.K.,

Somasundaram, C., Melcher, S.E., Bala, M., & Wentz, M.J., 2009) and the Active Movement Scale (AMS) (Akel et. al., 2012). These concepts relate very closely to range of motion (ROM) and manual muscle test (MMT), which are common assessments used in occupational therapy. By using these, therapists can determine baseline measurements and measuresments throughout intervention without causing as much pain as when ROM and MMT are assessed.

Motivation and Play

The AmTryke® device presents a form of therapy that would allow for kids to maintain motivation due to the natural way in which the device promotes the occupation of play, which is one area in which children engage the most throughout their childhood years. Because riding a bike is one typical play occupation (Lyon, 2007), children will be able to function within the community, socially interact, and play with their peers while riding the AmTryke. These skills that are developed allow for children to interact with their environment, (Missiuna & Pollock, 1991) which is lacking in several other forms of intervention.

Treatment Approaches and Evidence

Besides the AmTryke®, there are four different treatment approaches for brachial plexus injuries that are worth additional discussion. These include no therapy, constraint induced movement therapy (CIMT), surgical intervention, and botox injections. Because "[a]pproximately two-thirds of children with brachial plexus palsy get better on their own with minimal treatment. Most children benefit from therapy" (Cincinnati children's hospital, 2009). This study focuses on the use of the AmTryke® to determine optimal hand crank arrangements to aide therapists in fitting the device for children with brachial

plexus injuries, however, it's also important to understand how other interventions relate to this population.

Constraint induced movement therapy

When determining which intervention will be used with a client who has a BPI, one common intervention is constraint induced movement therapy (CIMT). CIMT is a form of therapy that has been used for many years on a wide range of populations who experience hemiparesis, varying in age from infants to the elderly. This form of therapy involves facilitating use of the affected arm by preventing the unaffected arm from partaking in the task at hand. In adults, this is commonly seen in the stroke population. Within the pediatric population, this is commonly used for children with cerebral palsy or brachial plexus injuries. The concept of constraint induced movement therapy, according to Grotta et al., "is based upon the theory of "learned non-use." (2004). CIMT involves a large amount of time and can sometimes be demanding for patients to follow protocol. In the short term use, it has been show to be an effective treatment method for people of all ages with hemiparesis.

Prior studies present limitations. The amount of time wearing the glove can be very long and it becomes a taxing process for the child affected. In prior research, there was not a follow-up to determine if the functional gains made were due to the CIMT or natural healing. Also, because there isn't a set protocol found, all three studies employ different forms of CIMT.

A study completed by Gilmore et al. in 2010, CIMT was used with a group of 32 kids in a day camp setting by having students perform various activities using the glove. During the process of treatment, children had to participate in a camp for six hours per

day, five days per week, for two weeks. Upon analysis of interviews with the children, three themes were discovered: "glove experience, "doing" the camp, and gains" (Gilmore et al., 2010). Children commented that the glove was "annoying" (Gilmore et al., 2010) and that it was very tiring to have to complete all activities using only one hand. However, upon completion, students had improved function with their affected arm.

Similar to this study, a single subject design study was completed by Vaz et al. in 2010 evaluated the effects of CIMT used after two years of receiving physical therapy. In this study, the child participated in CIMT for 30 minutes per day for a total of fourteen weeks, with the child being able to choose three activities to do during treatment. Activities involved "reaching, prehension and manipulation with the affected hand" (Vaz et al., 2010). In this instance, the child completed the activities with less assistance after time.

Buesch et al. conducted a study in 2010 that included two single subject case studies with 12 year old males. In each study, the boys were given a set time to wear the mitt. One wore the mitt for six hours per day for three weeks and the other wore the mitt four and a half hours per day for four weeks. Inclusion criteria required that the boys be able to lift their arm against gravity (indicating MMT grade 3) and to have minimal grip strength and assessments including the Melbourne Assessment of Unilateral Upper Limb Function, the Assisted Hand Assessment, and the Nine Hole Peg Test. Results indicated that there was an increase in scores between baseline and follow-up stages for both boys in all assessments except for the Nine Hole Peg Test. Similar to other studies, a diary was kept by each of the boys and it was found that they didn't like the intervention because it was extremely difficult and cumbersome.

Surgical intervention

Surgery involves nerve repair and can be done as early as 3-6 months of age. Isolated nerve repairs can occur at approximately 18 months of age. If muscles haven't been reconnected to nerves within 18 months, they may "weaken to the point where re-innervation may no longer be possible" (Cincinnati children's hospital, 2009). Other surgical "procedures may include tendon transfers, muscle transfers and osteotomies to correct muscle imbalances that limit function" (Cincinnati children's hospital, 2009). Commonly, an incision is made in the supraclavicular and infraclavicular aspects of the shoulder. This produces a flap that allows surgeons to view all regions of the brachial plexus as well as "rapid access" (Thatte, 2011). In a study done in 2011, three children received surgical interventions for their brachial plexus injuries (Palti, R., Horwitz, M.D., Smith, N.C., & Tonkin, M.A.). For all three children, a posterior glenohumoral dislocation was being corrected. Each child had good shoulder function following surgery. This study suggests there was an effect; however, it does not go into detail about how evaluations were made following the surgery.

Botulinum toxin A injections

The botulinum toxin A injections consist of injecting the affected muscle with a fluid that essentially paralyzes the muscle, thus making surrounding muscle groups more active. It is the goal of this intervention to decrease spasticity in patients suffering from a brachial plexus injury. Commonly, injections are placed in the biceps and triceps. A study completed in 2005 with eight children resulted in none of the children requiring a second set of injections after 3-18 months post injection because in the cases where Botox was injected into the bicep, it appeared that elbow extension increased. Results

were much less observable in two of the children who received injections in the triceps due to secondary disorders. (Heise, C.O., Goncalves, L.R., Barbosa, E.R., & Gherpelli, J.L, 2005)

Another study that involved injections into the triceps showed an immediate change in range of motion, however, "after a 1-year follow-up, there was no clinical recurrence" (Rollnik et al., 2000). This study recommended that further research include whether or not the effects of the injection could be seen over a longer period of time.

AmTryke® Research

Up until this point, little research has been done that examines the effectiveness of the AmTryke® device in therapy. Brachial plexus injuries vary in severity and type, so no two treatment plans are the same. It is known that there are different types of treatment options avaiable to children who have this type of injury, however, the AmTryke® is the only intervention that gives the child the opportunity to play, to be mobile, and to interact with their peers in the way that the AmTryke® does.

The AmTryke® device allows for the therapist and rider to determine which hand crank arrangement they prefer, whether or not they would like to use hand or foot pedals, what type of seat they will ride on, and what accessories and attachments they can add. The options are diverse for each individual rider and there are choices for the therapist in determining how to use the AmTryke® with their client (AMBUCS™, n.d.).

There is currently a lack of research on specific fitting guidelines when determining how to most effectively fit the person with a device that they will be able to use comfortably and independently. AmTryke® has published one form that is used by occupational and physical therapists when fitting a particular client. This form gathers

information about height, weight, arm measurements, leg measurements, helmet size, and the type of device that they would like (AMBUCS.com, n.d.). However, the form doesn't contain information to help assist the therapist in determining the optimal position of the hand cranks based upon the upper body strength of the client. When completing research, previous studies using this device have used strength as an outcome measure but none have looked into the correlation between hand crank placement and the ability to make the AmTryke® move.

Importance of Hand crank Settings

AmTryke® devices are produced with generic hand crank arrangements but hand crank settings are vast. There is an option of purchasing additional hand cranks, which make the diameter of the arm of the AmTryke longer, thus allowing for less force to be applied to move the device. These hand cranks come in two forms: 2.5" cranks and 4" cranks. These can also be combined with one another to create 6.5" cranks and 8" cranks. This small change can give the child the power to move the AmTryke without requiring as much force. Therefore, the child can operate the device without having large amounts of arm strength.

The AmTryke® offers children the opportunity to receive an assistive device that is rehabilitative in nature. One can adjust the handles and location of the seat, making it useful throughout various ages and stages in a child's life. In addition, there is an opportunity for the client to receive a device that has been custom fitted to meet their needs. There are tricycles that are strictly hand-powered, those that are foot-powered, and those that use both hands and feet.

In order to allow for the child with limited strength and mobility to be able to move the AmTryke, there are cranks that can be added to the device, enabling it to be moved easier and with less force. Three main adjustments are possible. First, the length of the crank can be changed, which implies that this can be adjusted depending upon the amount of power exerted by the child. Second, there is a capability of making one hand crank stationary, thus making one arm do all of the work to move the AmTryke®. Third, hand cranks can be arranged to move in a reciprocal motion, where both hands are moving the same direction, or in a contralateral motion where one hand is pushing while the other is pulling.

It is vital to the success of the child in therapy to determine the best hand crank fit for them. Literature and observations suggest that there are five possible negative consequences that can result if a child is using the AmTryke® with the incorrect hand crank settings. The table below illustrates possible negative effects of having the wrong settings.

Negative Effects of Wrong Hand crank Configuration
Compensation of upper body and trunk to move (Children's hospital of Boston, 2002)
Need additional support through a pull or push from therapist or caregiver
Pain
Decreased motivation caused by pain
Unable to move device

Previous studies have shown that children may compensate for lack of upper body stength by moving their trunk (Children's hospital of Boston, 2002). Also, with a

decreased amount of strength, it is possible that the caregiver will have to aide the child in moving the AmTryke®, which limits the amount of independence the child experiences. Pain can be seen in patients with brachial plexus injuries (Children's hospital of Boston, 2002), which can play a large role in how motivated a child will be to use the device. If it hurts their arm to move, the child will not want to utilize the device and this may result in them not being able to move the AmTryke® at all without assistance. In an extreme example, a child with a brachial plexus injury may not be able to move their arm at all without pain. In this case, hand cranks could be staged in a way that requires the child to exert extreme amounts of force to move the device. In this case, pain would result and the child may no longer be motivated to ride the AmTryke®.

Conceptualization of the Model

This model was conceptualized based upon the literature that suggested further evidence is needed to appropriately fit a child with upper extremity weakness (brachial plexus injuries in particular), for an AmTryke® device. Previous research, or lack thereof, suggests implies that there is more to learn about this device and its potential therapeutic value. By making the fitting process easier for therapists, it is hypothesized that finding the just-right fit will be easier to obtain.

III. METHODS

Research Design

This study aims to create a protocol for optimally configuring AmTryke® hand cranks for configuration for children with brachial plexus injuries. This research design uses two phases: the first to create the model and the second to determine the practical

application of the model through a survey administered to practicing occupational and physical therapists.

Research Hypothesis It is hypothesized that the model will help aide therapists in determining optimal hand crank arrangements to create the just-right force necessary to encourage children to work hard to move the AmTryke®.

Participants

The table below illustrates when participants will be utilized by phase.

Phase I	Phase II
No participants	30 occupational and physical therapists

Participants in the second phase of this study will include 30 occupational and physical therapists that have experience working in a pediatric population. Inclusion criteria for participants will require that the therapist is currently practicing in the field of pediatrics and that they have experience using the AmTryke® as a therapeutic intervention.

Instrumentation

The instruments used in this study by phase can be seen below.

Phase I	Phase II
Force gauge (fish scale)	Survey (see Appendix C)

In order to determine the strength of the biceps, triceps, and lower arm muscles, there are a few assessments that are typically done. These assessments will then be used to determine which hand crank configuration is optimal for a given child based upon the amount of strength that they have to get the AmTryke® moving.

Pull Strength

In order to quantify the force that is applied in order to make the AmTryke® move, a fish scale will be used to gather data in pounds. Because forces are equal and opposite, the strength during pull is the same as the push strength. ("Newton's Third Law of Motion, n.d.) This scale will simply measure the force that the child is using to pull on the spring, when it is used in a real life setting. In order to standardize this value, scale will be set according to instructions. The hook will then be attached to a stationary object in order to measure the child's pull force in pounds. For the purposes of data collection, the hook will simply be attached to the AmTryke® at the hand crank.

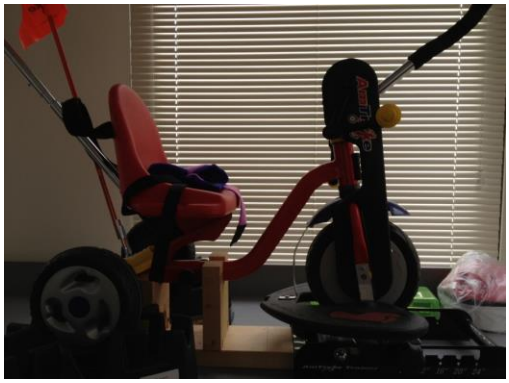

Figure 3
AmTryke® Device

Procedure

The procedure will be broken into two phases. This will allow for analysis of the original findings and the data collected to then be formed into a model that will allow therapists to fit children to the optimal hand crank arrangement.

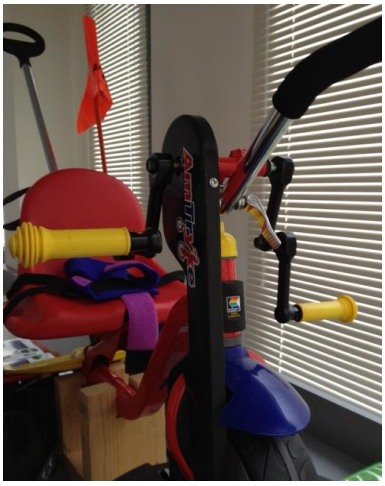

Figure 4
AmTryke® Device Hand cranks

Phase I

1. Materials will be gathered and all scales will be tested to validate the measurements.

Materials will include: a fish scale, a model AM-12 Small Hand cycle from AmTryke® (shown in Figure 3), a brachial plexus kit which includes additional sizes of hand cranks, and various free weights. An example of a 2.5" crank that comes in the kit can be seen in Figure 4 on the left-hand side of the picture. An example of a 4" crank can also be seen in Figure 4 on the right-hand side of the picture.

2. A ten pound weight will be applied to the seat. Using this weight, there are several hand crank configurations that will be assessed. Table 1 illustrates these options.
3. Hand cranks will be arranged so that both cranks are upwards, aiming toward the ceiling.
4. Forces will be measured using the fish scale on the left hand crank to get the AmTryke® started with just that hand, as well as on the front pull bar that will measure the total force required. This will be done three times and an average will be taken.
5. The previous step will be reassessed using the following increments of weight: 10lb., 20lb, 30 lb., 40 lb., 50 lb., 60 lb., 70 lb., 80 lb., 90 lb., 100 lb., 110 lb., 120 lb., & 130 lb.
6. Data will be recorded and a model will be formed that utilizes the data collected.

Table 1: Hand crank Configurations

Hand crank Arrangement											
	Normal Configuration							CIMT Configuration			
Weight applied to seat	Both handles standard	Left 2.5" crank, Right standard	Left 4" crank, Right standard	Left 6.5" crank, Right standard	Both 2.5" crank	Both 4" crank	Both 6.5" crank	Left standard, Right stationary	Left 2.5" crank, Right stantionary	Left 4" crank, Right stationary	Left 6.5" crank, Right stationary
0 lb											
10 lb											
20 lb											
30 lb											
40 lb											
50 lb											
60 lb											
70 lb											
80 lb											
90 lb											
100 lb											
110 lb											
120 lb											
130 lb											

Phase II (A draft will be evaluated by the committee and will be piloted in a small group of six peers to get usability feedback)

1. An electronic survey will be developed using Qualtrics software.
2. Survey will be sent to 30 pediatric occupational and physical therapists in the states of Wisconsin and Michigan.
3. Therapists will complete the survey that contains regarding their use of the AmTryke® in practice as well as their current fitting guidelines when working with children who have disabilities that limit upper body strength.

Figure 5
AmTryke® Device Safety Harness

Figure 6
AmTryke® Device Foot pedals

Ethics and Protection of Human Subjects

Prior to the start of the survey, consent will be obtained. Participants will have the opportunity to remove themselves from the study at any point should they deem it necessary.

Future Research Recommendations

It is recommended that future research utilize this model with various assessments such as the Active Movement Scale and the Carroll Quantitative Test of Upper Extremity Function.

Active Movement Scale (AMS)

The AMS measures muscle strength without the use of manual muscle testing. Through the use of scores that are indicative of active and passive ranges, the amount of muscle strength can be assessed. "The AMS is an ordinal 8-grade scale designed to capture changes in arm movement. This scale offers a number of advantages over other classification systems and can be used to grade movement in entire upper extremities of infants and young children, and it does not require the child to perform tasks on command" (Akel, Oskay, Oksuz, Firat, Karahan, & Leblebicioglu, 2012). In order to measure the strength of the muscles that will be used, just the following movements will be measured: Shoulder flexion, elbow flexion, and elbow extension. A copy of this can be found in Appendix B.

Carroll Quantitative Test of Upper Extremity Function

This six-part assessment is used to observe the effect of hand dysfunction on the use of the hand during activities of daily living (ADLs). "It is based upon the assumption that complex upper extremity movements used to perform ordinary ADLs can be reduced to specific patterns of grasp and prehension of the hand, supination and pronation of the forearm, flexion and extension of the elbow, and elevation of the arm" (Pendelton & Schultz- Krohn, 2006).

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Appendix C: Executive Summary of Changes

The following is a list of changes that were made in the proposed research design throughout the data collection:

1. Original research included crank lengths of 8” in addition to the 4” standard crank. This data point was eliminated because the AmTryke® hand cranks were not able to move due to the large diameter.
2. Research included data points up to 150 pounds. This was reduced to 130 pounds due to the lack of stability in the seat when greater than 130 pounds was added.
3. Total pull force was intended to be collected for each arrangement. This was eliminated because the total force was unchanged by the hand crank configuration due to the force being measured by the bar that was attached to the front, rather than the individual hand cranks.
4. The original survey was significantly altered. The survey originally was based upon finding out why therapists choose to use the AmTryke®. The current survey gathers information more related to the fitting models and current use of strength assessments in practice.
5. Initially, the proposal planned on testing this model with children. This was eliminated due to time and lack of funding.
6. Similarly, original research proposed the use of force sensors to be added to the hand cranks in order to gain valuable data with higher level technology. This was eliminated due to lack of funding.

Appendix D: Raw Data Tables

AmTryke® Hand Crank Data Collection Table									
Weight applied to seat	Both handles standard (4” radius)						Total force (weights)		
Trial	Trial 1 Left	Trial 2 Left	Trial 3 Left	Trial 1 Right	Trial 2 Right	Trial 3 Right	Trial 1	Trial 2	Trial 3
0lb	7	7	8	7	6	7	8	8	7
10 lb	6	8	8	6	7	8	9	8.5	8.5
20 lb	7	8	8	8	8	9	10.5	9.5	9.5
30 lb	8.5	9.5	8	9.5	8.5	8	10	11.5	11
40 lb	10	10	10	9.5	9	10	12	11.5	12
50 lb	10.5	10.5	10	10	10	10.5	12	12	12.5
60 lb	11	10.5	12	10.5	11	11	13	12.5	13
70 lb	11	11	11	11	11	11	12	14	13
80 lb	11	11.5	11	12	11	11	13.5	14	14
90 lb	12	13	12	13	12	12	14	15	14.5
100 lb	12	13	14	13	12	12.5	14	14.5	15
110 lb	14	13	13	14	13.5	14	16	16	15.5
120 lb	14.5	14.5	15	14.5	14.5	14	16	16	16.5
130 lb	16.5	15.5	16	16	16	16	17	17	17

AmTryke® Hand Crank Data Collection																		
Weight applied to seat	Left Hand 2.5" crank (6.5" radius), Right Standard (4" radius)						Left Hand 4" crank (8" radius), Right Standard (4" radius)						Left Hand 6.5" crank (10.5" crank), Right Standard (4" radius)					
Trial	Trial 1-left	Trial 2 Left	Trial 3 Left	Trial 1 Right	Trial 2 Right	Trial 3 Right	Trial 1-left	Trial 2-left	Trial 3-left	Trial 1 Right	Trial 2 Right	Trial 3 Right	Trial 1-right	Trial 2-left	Trial 3-left	Trial 1 Rigth	Trial 2 Right	Trial 3 Right
0lb	4.5	4.5	5	6	6.5	5.5	4.5	4	4	6.5	6	5.5	4	3	3.5	6	6	5.5
10 lb	5	5	5	6	6	6	4	5	5	6.5	6	7	4	4	4	6	6	6.5
20 lb	6	5.5	5	6	7	6	6	6	6.5	7	7	7	4	4.5	4	8	6.5	6
30 lb	6	5.5	5.5	7	6	7	6.5	6	6	8	7	8	5	5	5	8	7	7
40 lb	7.5	7	6.5	8	8	8	7	6	6	8	8	8.5	6	4.5	5	8	7	8
50 lb	6	7	6	7.5	8	8	7.5	7	7	9	8	8	7	7	5	9	9	7
60 lb	8	8	7	8	8	9	8	7.5	8	9	9	8	7	6	6	9	9	8
70 lb	8.5	8	8	8	8.5	9	8	8	8.5	10	9	9	8	7	6.5	9	8.5	9
80 lb	9	9	8	9	9	10	8	7.5	8	9.5	9.5	9.5	7	8	6	9	10	10.5
90 lb	10	10	10	10.5	11.5	11	7.5	8	8	10.5	9.5	9.5	8	7	7	11	10	10
100 lb	11	10	10.5	11	11	12	10	9	10	10.5	10	11	8	8	7	12	10	10
110 lb	10.5	10.5	11.5	12	12	12.5	11	10	10.5	11	11	11	10	8	7	13	11	11
120 lb	12	10.5	10.5	13	13	12	10	11	10	12	12	11	9	8	7.5	10	12	11
130 lb	13.5	11.5	11.5	14	14.5	14	12	10	10	13	12.5	13	9	8	8	12	11.5	12.5

AmTryke® Mean Force															
		Both Handles Standard (4" radius)		Left 2.5" (6.5" radius), Right Standard (4" radius)		Left 4" (8" radius), Right Standard (4" radius)		Left 6.5" (10.5" radius), Right Standard (4" radius)		Both 2.5" Crank (6.5" radius)		Both 4" Crank (8" radius)		Both 6.5" Crank (10.5" radius)	
Rider's Weight (lbs)	Total Pull	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE
0	7.67	7.33	6.67	4.67	6.00	4.17	6.00	3.50	5.83	5.67	5.67	4.17	4.00	3.67	3.33
10	8.67	7.33	7.00	5.00	6.00	4.67	6.50	4.00	6.17	6.00	6.00	4.33	4.67	4.00	3.83
20	9.83	7.67	8.33	5.50	6.33	6.17	7.00	4.17	6.83	6.83	6.67	4.83	5.17	5.17	4.33
30	10.83	8.67	8.67	5.67	6.67	6.17	7.67	5.00	7.33	7.33	7.50	6.00	6.00	4.83	4.83
40	11.83	10.00	9.50	7.00	8.00	6.33	8.17	5.17	7.67	8.67	8.50	6.17	6.33	5.67	4.83
50	12.17	10.33	10.17	6.33	7.83	7.17	8.33	6.33	8.33	9.17	9.33	6.33	6.33	6.00	6.00
60	12.83	11.17	10.83	7.67	8.33	7.83	8.67	6.33	8.67	8.67	8.67	7.00	7.33	6.83	6.17
70	13.00	11.00	11.00	8.17	8.50	8.17	9.33	7.17	8.83	9.33	9.17	6.67	7.67	7.00	7.17
80	13.83	11.17	11.33	8.67	9.33	7.83	9.50	7.00	9.83	10.00	10.00	7.50	7.50	7.67	7.67
90	14.50	12.33	12.33	10.00	11.00	7.83	9.83	7.33	10.33	10.17	10.00	7.67	7.67	7.50	7.83
100	14.50	13.00	12.50	10.50	11.33	9.67	10.50	7.67	10.67	11.00	11.17	8.33	8.67	8.33	7.83
110	15.83	13.33	13.83	10.83	12.17	10.50	11.00	8.33	11.67	11.33	11.33	9.00	9.50	7.83	7.83
120	16.17	14.67	14.33	11.00	12.67	10.33	11.67	8.17	11.00	11.83	10.83	9.33	10.17	8.67	9.50
130	17.00	16.00	16.00	12.17	14.17	10.67	12.83	8.33	12.00	12.33	12.00	9.67	9.67	10.00	10.00

AMTRYKE Hand Crank Configuration Data Table																		
Weight applied to seat	Both 2.5" crank (6.5" radius)						Both 4" crank (8" radius)						Both 6.5" crank (10.5" radius)					
Trial	Trial 1-left	Trail 2-left	Trial 3-left	Trial 1-Right	Trial 2-Right	Trial 3-Right	Trial 1-left	Trial 2-left	Trial 3-left	Trial 1-Right	Trial 2-Right	Trial 3-Right	Trial 1-left	Trial 2-left	Trial 3-left	Trial 1-Right	Trial 2-Right	Trial 3-Right
0lb	6	5	6	6	6	5	4	4.5	4	4	4	4	4	3.5	3.5	3.5	3	3.5
10 lb	6	6	6	6	6	6	4	4.5	4.5	4	5	5	4	4	4	4	4	3.5
20 lb	6.5	7	7	6.5	6.5	7	5.5	4	5	5.5	5	5	5	5	5.5	5	4	4
30 lb	7.5	7.5	7	7	7.5	8	6	5.5	6.5	5	6	7	5	4.5	5	5	4.5	5
40 lb	10	8	8	10	8	7.5	7	6	5.5	7.5	5.5	6	6	5	6	4.5	5	5
50 lb	9	9.5	9	9	10	9	6	6	7	6	7	6	6	6	6	6	6	6
60 lb	11	8	7	10	8	8	7	7	7	8	7	7	6	7	7.5	6	6	6.5
70 lb	10	9	9	9	9	9.5	6	7	7	9	7	7	7	7	7	8	6.5	7
80 lb	10	10	10	10.5	10	9.5	7	7.5	8	7.5	7	8	8	7	8	8	7.5	7.5
90 lb	10	10	10.5	10	10	10	8	7	8	8	8	7	7	7.5	8	8	7.5	8
100 lb	12	10	11	11.5	10	12	9	8	8	9	9	8	8	9	8	7.5	7.5	8.5
110 lb	12	10	12	12	10	12	10	9	8	11	9	8.5	8.5	8	7	7	8.5	8
120 lb	12	12	11.5	10	11	11.5	10	10	8	10	10	10.5	8	8	10	10	8.5	10
130 lb	12	12	13	12	12	12	10	9	10	10	9	10	10	10	10	10	10	10

Appendix E: Mini Manual for Practitioners (Version 2.0)

The AmTryke® Fitting Model based upon arm strength is a tool for Occupational and Physical Therapists who work within a pediatric setting. The purpose of this tool is to aide therapists in determining which hand crank length will benefit children the most. Version 2.0 was created after review by experts in the field.

When using the AmTryke® Fitting Model for the model AM-12 Small AmTryke® based upon arm strength, there is a series of steps that must be followed.

8. Measure the upper extremity strength by attaching the spring scale to a solid object that will not move when they pull. Ask the child to pull forcefully but do not allow for them to continue to pull for greater than one second. This will allow you to measure the capacity of force that will be necessary to start moving the AmTryke®.
9. Determine child's weight.
10. Using the table below, locate the nearest weight class of the child.
11. Locate the child's upper extremity strength within the table.
12. Arrange hand crank crank length according to the appropriate recommendation shown in Table 1.
13. If none of the arrangements match ideal formatting, use the averages in Table 2 that incorporate averages from Table .
14. If the child's weight and strength fall between averages, use Figure 1 to determine where the child most closely fits.

Examples:

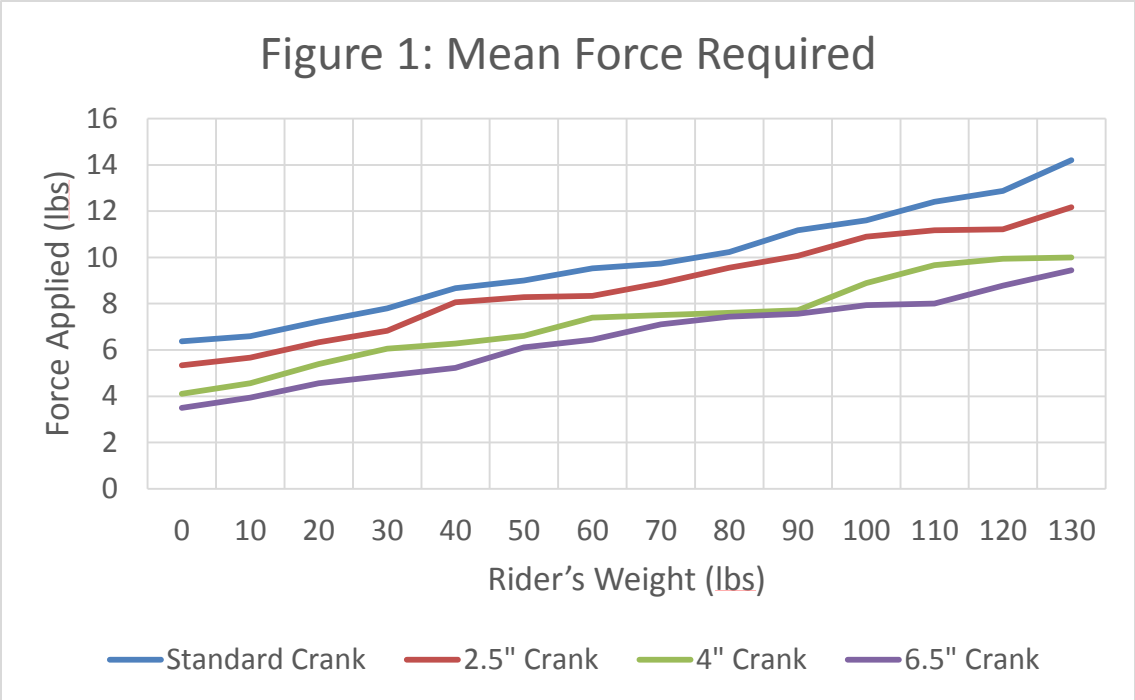
3. Ben is a 10 year old child with a brachial plexus injury. He is 77 pounds and has a force of 10.2 pounds in his right arm and 7.3 pounds in his left arm. Based upon these measurements, Table 2 indicates that the right arm should be arranged in a standard format and his left arm should be arranged with a 6.5" crank.
4. Cary is a 4 year old child who suffered bilateral arm fractures. She weighs 40 pounds and has 6.5 pounds of force in both arms. Based upon the recommendations in Table 2, Cary's AmTryke® will have both hand cranks arranged with 4" cranks.

Table 1: AmTryke Sizing Guide Based upon Pull Strength. Averages are shown in pounds (lbs) for each hand crank arrangement assessed. In order to view the table, select the child's weight and determine the crank length based upon the upper body strength of the child.

AmTryke Sizing Guide- Average Pull Strength															
Hand Crank Length															
		Both Handles Standard (4" radius)		Left 2.5" (6.5" radius), Right Standard (4" radius)		Left 4"(8" radius), Right Standard (4" radius)		Left 6.5" (10.5" radius), Right Standard (4" radius)		Both 2.5" cranks (6.5" radius)		Both 4" cranks (8" radius)		Both 6.5" cranks (10.5" radius)	
Rider's Weight (lbs)	Total Pull	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE	Left UE	Right UE
0	7.67	7.33	6.67	4.67	6.00	4.17	6.00	3.50	5.83	5.67	5.67	4.17	4.00	3.67	3.33
10	8.67	7.33	7.00	5.00	6.00	4.67	6.50	4.00	6.17	6.00	6.00	4.33	4.67	4.00	3.83
20	9.83	7.67	8.33	5.50	6.33	6.17	7.00	4.17	6.83	6.83	6.67	4.83	5.17	5.17	4.33
30	10.83	8.67	8.67	5.67	6.67	6.17	7.67	5.00	7.33	7.33	7.50	6.00	6.00	4.83	4.83
40	11.83	10.00	9.50	7.00	8.00	6.33	8.17	5.17	7.67	8.67	8.50	6.17	6.33	5.67	4.83
50	12.17	10.33	10.17	6.33	7.83	7.17	8.33	6.33	8.33	9.17	9.33	6.33	6.33	6.00	6.00
60	12.83	11.17	10.83	7.67	8.33	7.83	8.67	6.33	8.67	8.67	8.67	7.00	7.33	6.83	6.17
70	13.00	11.00	11.00	8.17	8.50	8.17	9.33	7.17	8.83	9.33	9.17	6.67	7.67	7.00	7.17
80	13.83	11.17	11.33	8.67	9.33	7.83	9.50	7.00	9.83	10.00	10.00	7.50	7.50	7.67	7.67
90	14.50	12.33	12.33	10.00	11.00	7.83	9.83	7.33	10.33	10.17	10.00	7.67	7.67	7.50	7.83
100	14.50	13.00	12.50	10.50	11.33	9.67	10.50	7.67	10.67	11.00	11.17	8.33	8.67	8.33	7.83
110	15.83	13.33	13.83	10.83	12.17	10.50	11.00	8.33	11.67	11.33	11.33	9.00	9.50	7.83	7.83
120	16.17	14.67	14.33	11.00	12.67	10.33	11.67	8.17	11.00	11.83	10.83	9.33	10.17	8.67	9.50
130	17.00	16.00	16.00	12.17	14.17	10.67	12.83	8.33	12.00	12.33	12.00	9.67	9.67	10.00	10.00

These results can be generalized into Table 2. In this table, pull strength would be assessed on each arm and then the arrangement would be made based upon the amount of strength in pounds (lbs) as shown below. In this instance, stationary positions are not shown because they are not capable of making the AmTryke® move. Please use the graph below fo rfurther guidance when unsure of crank arrangment.

Table 2: AmTryke Sizing Guide				
Hand Crank Length and Formatting				
Rider's Weight	Standard Crank (4" radius)	2.5" Crank (6.5" radius)	4" Crank (8" radius)	6.5" Crank (10.5" radius)
0	6.37	5.33	4.11	3.50
10	6.60	5.67	4.56	3.94
20	7.23	6.33	5.39	4.56
30	7.80	6.83	6.06	4.89
40	8.67	8.06	6.28	5.22
50	9.00	8.28	6.61	6.11
60	9.53	8.33	7.39	6.44
70	9.73	8.89	7.50	7.11
80	10.23	9.56	7.61	7.44
90	11.17	10.06	7.72	7.56
100	11.60	10.89	8.89	7.94
110	12.40	11.17	9.67	8.00
120	12.87	11.22	9.94	8.78
130	14.20	12.17	10.00	9.44



Appendix F: Survey for Practitioners

Occupational Therapist Survey of the AmTryke®

1. **Do you have experience with using the AmTryke as a therapeutic intervention in a pediatric population?**
2. **In your opinion, which population of people is best suited for use of the AmTryke?**
3. **When working with a child with a brachial plexus injury, what do you typically measure to fit them for the AmTryke?**
4. **What device(s) do you use when determining a child's current level of strength?**
    a. **Hand-held dynamometer**
    b. **Manual muscle testing**
    c. **Other:**
5. **When using the fitting diagram, did the criteria go with or against your previous methods to fit a child for the AmTryke®?**
    a. **With previous philosophies**
    b. **Against previous philosophies.**
    c. **Other:**
6. **When determining which hand crank arrangement is most appropriate, is it more helpful to utilize the total force or each individual arm pressure with various lengths of crank?**
    a. **Total force**
    b. **Individual arm pressure with various lengths.**
    c. **Other:**
7. **In a brachial plexus scenario, what is the radius length that you find to be most successful (in addition to the 4" standard length)?**
    a. **2.5" crank**
    b. **4" crank**
    c. **6.5" crank**
    d. **I have not used other crank lengths.**
    e. **Other:**
8. **Which radius length was ineffective?**
    a. **2.5" crank**
    b. **4" crank**
    c. **6.5" crank**
    d. **All were effective.**
    e. **All were ineffective.**

f. **I have not used other crank lengths.**

9. **Are there any other modifications to the AmTryke that affect success of its use?**

10. **What is the most difficult part about adjusting the AmTryke?**

11. **How long do you implement the AmTryke before seeing significant progress towards meeting the child's goals?**

    a. **Less than one month**
    b. **Between one and two months**
    c. **Greater than two months**
    d. **Other:**

12. **Do you always see significant results?**

    a. **Yes**
    b. **Sometimes**
    c. **No**

13. **Which location of AmTryke intervention yields the greatest results?**

    a. **Within the child's home**
    b. **Within the clinic**
    c. **Other:**

14. **Describe your clinical background with the pediatric population.**

Appendix G: IRB Documents

UNIVERSITY of WISCONSIN
UWMILWAUKEE

Jessica Rice
Institutional Review BoardIRB Administrator
Department of University Safety & Assurances Engelmann 270
P. O. Box 413
Milwaukee, WI(414) 229-3182 *phone*53201 -0413
(414) 229-6729 *fax*
http://www.irb.uwm.edricej@uwm.edu u

New Study - Notice of IRB Exempt Status

Date: July 24, 2013

To: Roger Smith, PhD
Dept: Occupational Science and Technology

Cc: Jennifer Hardy

IRB#: 14.020
Title: Optimizing Hand crank Configurations for Therapeutic Use of AmTrykes® for Children With Brachial Plexus Injuries

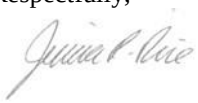
After review of your research protocol by the University of Wisconsin – Milwaukee Institutional Review Board, your protocol has been granted Exempt Status under Category 2 as governed by 45 CFR 46.101(b).

Unless specifically where the change is necessary to eliminate apparent immediate hazards to the subjects, any proposed changes to the protocol must be reviewed by the IRB before implementation. It is the principal investigator's responsibility to adhere to the policies and guidelines set forth by the UWM IRB and maintain proper documentation of its records and promptly report to the IRB any adverse events which require reporting.

It is the principal investigator's responsibility to adhere to UWM and UW System Policies, and any applicable state and federal laws governing activities the principal investigator may seek to employ (e.g., FERPA, Radiation Safety, UWM Data Security, UW System policy on Prizes, Awards and Gifts, state gambling laws, etc.) which are independent of IRB review/approval.

Contact the IRB office if you have any further questions. Thank you for your cooperation and best wishes for a successful project

Respectfully,



Jessica P. Rice
IRB Administrator

IRBManager Protocol Form

Instructions: Each Section must be completed unless directed otherwise. Incomplete forms will delay the IRB review process and may be returned to you. Enter your information in the **colored boxes** or place an **"X"** in front of the appropriate response(s). If the question does not apply, write **"N/A."**

SECTION A: Title

A1. Full Study Title:

Optimizing Hand crank Configurations for Therapeutic Use of AmTrykes® for Children With Brachial Plexus Injuries

SECTION B: Study Duration

B1. What is the expected start date? *Data collection, screening, recruitment, enrollment, or consenting activities may not begin until IRB approval has been granted. Format: 07/05/2011*

07/22/2013

B2. What is the expected end date? *Expected end date should take into account data analysis, queries, and paper write-up. Format: 07/05/2014*

08/12/2013

SECTION C: Summary

C1. Write a brief descriptive summary of this study in Layman Terms (non-technical language):

This study will create a model that can be used to assist Occupational and Physical therapists when implementing the AmTryke as a therapeutic intervention. The study will use a survey of practitioners in the field to assess how well the model relates to practice.

C2. Describe the purpose/objective and the significance of the research:

The purpose of this study is to create a model that can be used by practitioners in the fields of Occupational and Physical Therapy in order to determine which hand crank arrangement of the AmTryke device will be the best fit for a child, based upon their upper body strength.

C3. Cite any relevant literature pertaining to the proposed research:

AMBUCS™. (n.d.) *AmTryke*® ®. Retrieved from http://www.AMBUCS™.org/AmTryke® /
Arndorfer, A., Brumbaugh, A., Cochran, M., & Voss, T. (n.d.). Effectiveness of the AmTryke therapeutic tricycle as an intervention for children with hemiplegic cerebral palsy: A pilot study. Retrieved from www.ambucs.com
Cindy, L. (2001). Use of therapeutic tricycles to increase activity in an underserved population: Description of an AmTryke® demonstration project. Retrieved from www.ambucs.com
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Lisenby, J. & Spooner, A. (2001). The effects of therapeutic tricycle riding on gait and endurance for three children with spastic diplegic cerebral palsy. Retrieved from www.ambucs.com
Lyon, R. (2007). The effect of therapeutic tricycle riding on upper extremity function in children with unilateral neglect. Retrieved from www.ambucs.com
Wickham, J. (2009). A fitness program for a 4-year old child with spina bifida myelomeningocele that utilizes an AmTryke® therapeutic tricycle combination hand/foot drive A fitness program. Retrieved from www.ambucs.com

SECTION D: Subject Population

Section Notes…

- D1. If this study involves analysis of de-identified data only (i.e., no human subject interaction), IRB submission/review may not be necessary. Visit the Pre-Submission section in the IRB website for more information.

D1. Identify any population(s) that you will be specifically targeting for the study. Check all that apply: (Place an "X" in the column next to the name of the special population.)

	Not Applicable (e.g., de-identified datasets)		Institutionalized/ Nursing home residents recruited in the nursing home
	UWM Students of PI or study staff		Diagnosable Psychological Disorder/Psychiatrically impaired
	Non-UWM students to be recruited in their educational setting, i.e. in class or at school		Decisionally/Cognitively Impaired
	UWM Staff or Faculty		Economically/Educationally Disadvantaged
	Pregnant Women/Neonates		Prisoners
	Minors under 18 and ARE NOT wards of the State		Non-English Speaking
	Minors under 18 and ARE wards of the State		Terminally ill
X	Other (Please identify): occupational therapists and physical therapists who are currently practicing		

D2. Describe the subject group and enter the total number to be enrolled for each group. For example: teachers-50, students-200, parents-25, parent's children-25, student control-30, student experimental-30, medical charts-500, dataset of

1500, etc. Enter the total number of subjects below.

Describe subject group:	**Number:**
Occupational therapists	25
Physical therapists	25
TOTAL # OF SUBJECTS:	50
TOTAL # OF SUBJECTS (If UWM is a collaborating site):	

D3. List any major inclusion and exclusion criteria (e.g., age, gender, health status/condition, ethnicity, location, English speaking, etc.) and state the justification for the inclusion and exclusion:

Therapists must currently be practicing in a pediatric setting where they have exposure to working with children who have various disabilities.

SECTION E: Informed Consent

Section Notes…

- E1. Make sure to attach any recruitment materials for IRB approval.
- E3. The privacy of the participants must be maintained throughout the consent process.

E1. Describe how the subjects will be recruited. (E.g., through flyers, beginning announcement for X class, referrals, random telephone sampling, etc.). If this study involves secondary analysis of data/charts/specimens only, provide information on the source of the data, whether the data is publicly available and whether the data contains direct or indirect identifiers.

Subjects will be recruited through referrals and through research into pediatric therapists via websites for various healthcare agencies throughout the nation.

E2. Describe the forms that will be used for each subject group (e.g., short version, combined parent/child consent form, child assent form, verbal script, information sheet): If data from failed eligibility screenings will be used as part of your "research data", then these individuals **<u>are</u>** considered research subjects and consent will need to be obtained. Copies of all forms should be attached for approval. If requesting to waive documentation (not collecting subject's signature) or to waive consent all together, state so and complete the "Waiver to Obtain-Document-Alter Consent" and attach:

The study requests to waive documentation of consent. By clicking "Next" in order to complete survey, participant will be consenting to participate. Waiver is attached.

E3. Describe who will obtain consent and where and when consent will be obtained. When appropriate (for higher risk and complex study activities), a process should be mentioned to assure that participants understand the information. For example, in addition to the signed consent form, describing the study procedures verbally or visually**:**

Consent will be obtained within the survey developed using Qualtrics. It will be obtained prior to starting the survey.

SECTION F: Data Collection and Design

Section Notes…

- F1. Reminder, all data collection instruments should be attached for IRB review.
- F1. The IRB welcomes the use of flowcharts and tables in the consent form for complex/ multiple study activities.

F1. In the table below, chronologically describe all study activities where human subjects are involved.

- In **column A**, give the activity a short name. E.g., Obtaining Dataset, Records Review, Recruiting, Consenting, Screening, Interview, Online Survey, Lab Visit 1, 4 Week Follow-Up, Debriefing, etc.
- In **column B**, describe in greater detail the activities (surveys, audiotaped interviews, tasks, etc.) research participants will be engaged in. Address where, how long, and when each activity takes place.
- In **column C,** describe any possible risks (e.g., physical, psychological, social, economic, legal, etc.) the subject may ***reasonably*** encounter. Describe the **safeguards** that will be put into place to minimize possible risks (e.g., interviews are in a private location, data is anonymous, assigning pseudonyms, where data is stored, coded data, etc.) and what happens if the participant gets hurt or upset (e.g., referred to Norris Health Center, PI will stop the interview and assess, given referral, etc.).

A. Activity Name:	**B. Activity Description:**	**C. Activity Risks and Safeguards:**
Recruiting	To be completed based upon referrals and randomized emails to current physical and occupational therapy practitioners.	
Consenting	To be obtained within survey but prior to beginning to answer questions.	Risk that participant does not consent. Safeguard will be to ensure data is anonymous, assigning pseudonyms, and store data within locked file cabinet.
Online Survey	Survey to be completed via online using Qualtrics.	Risk that participant does not complete survey due to lack of knowledge about AmTryke Safeguard will be to give references to places where participant can seek additional information.

F2. Explain how the privacy and confidentiality of the participants' data will be maintained after study closure:

Confidentiality will be maintained after closure by not including participant's names and by deleting all surveys after they are completed on Qualtrics and are analyzed.

F3. Explain how the data will be analyzed or studied (i.e. quantitatively or qualitatively) and how the data will be reported (i.e. aggregated, anonymously, pseudonyms for participants, etc.):

Data will be coded and sorted based upon responses to survey. Data will be analyzed qualitatively due to many questions being open-ended. Data will be reported with anonymously.

SECTION G: Benefits and Risk/Benefit Analysis

Section Notes…

- Do not include Incentives/ Compensations in this section.

G1. Describe any benefits to the individual participants. If there are no anticipated benefits to the subject directly, state so. Describe potential benefits to society (i.e., further knowledge to the area of study) or a specific group of individuals (i.e., teachers, foster children). Describe the ratio of risks to benefits.

Benefits to participant include broadening the research base around the AmTryke device and furthering the knowledge of therapists who use the device as a therapeutic intervention.

G2. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of how the anticipated risks to participants and steps taken to minimize these risks, balance against anticipated benefits to the individual or to society.

Risks to the survey include not having a solid research base around the AmTryke due to it being new in the field of therapy. The benefits outweigh the costs because of the knowledge that will be gained. Although there is a risk, the risk will not affect the individual participant's well-being in any way.

SECTION H: Subject Incentives/ Compensations

Section Notes…

- H2 & H3. The IRB recognizes the potential for undue influence and coercion when extra credit is offered. The UWM IRB, as also recommended by OHRP and APA Code of Ethics, agrees when extra credit is offered or required, prospective subjects should be given the choice of an equitable alternative. In instances where the researcher does not know whether extra credit will be accepted and its worth, such information should be conveyed to the subject in the recruitment materials and the consent form. For example, "The awarding of extra credit and its amount is dependent upon your instructor. Please contact your instructor before participating if you have any questions. If extra credit is awarded and you choose to not participate, the instructor will offer an equitable alternative."
- H4. If you intend to submit to the Travel Management Office for reimbursement purposes make sure you understand what each level of payment confidentiality means **(click here for additional information).**

H1. Does this study involve incentives or compensation to the subjects? For example cash, class extra credit, gift cards, or items.

[__] Yes
[_X_] No [SKIP THIS SECTION]

H2. Explain what (a) the item is, (b) the amount or approximate value of the item, and (c) when it will be given. For extra credit, state the number of credit hours and/or points. (e.g., $5 after completing each survey, subject will receive [item] even if they do not complete the procedure, extra credit will be award at the end of the semester)**:**

H3. If extra credit is offered as compensation/incentive, an alternative activity (which can be another research study or class assignment) should be offered. The alternative activity (either class assignment or another research study) should be similar in the amount of time involved to complete and worth the same extra credit.

H4. If cash or gift cards, select the appropriate confidentiality level for payments (see section notes):

[__] Level 1 indicates that confidentiality of the subjects is not a serious issue, e.g., providing a social security number or other identifying information for payment would not pose a serious risk to subjects.

- Choosing a Level 1 requires the researcher to maintain a record of the following: The payee's name, address, and social security number and the amount paid.
- When Level 1 is selected, a formal notice is not issued by the IRB and the Travel Management Office assumes Level 1.

- Level 1 payment information will be retained in the extramural account folder at UWM/Research Services and attached to the voucher in Accounts Payable. These are public documents, potentially open to public review.

[__] **Level 2** indicates that confidentiality is an issue, but is not paramount to the study, e.g., the participant will be involved in a study researching sensitive, yet not illegal issues.

- Choosing a Level 2 requires the researcher to maintain a record of the following: A list of names, social security numbers, home addresses and amounts paid.
- When Level 2 is selected, a formal notice will be issued by the IRB.
- Level 2 payment information, including the names, are attached to the PIR and become part of the voucher in Accounts Payable. The records retained by Accounts Payable are not considered public record.

[__] **Level 3** indicates that confidentiality of the subjects must be guaranteed. In this category, identifying information such as a social security number would put a subject at increased risk.

- Choosing a Level 3 requires the researcher to maintain a record of the following: research subject's name and corresponding coded identification. This will be the only record of payee names, and it will stay in the control of the PI.
- Payments are made to the research subjects by either personal check or cash.
- Gift cards are considered cash.
- If a cash payment is made, the PI must obtain signed receipts.
- If the total payment to an individual subject is over $600 per calendar year, Level 3 cannot be selected.

H5. If Level 2 or Level 3 Confidentiality is requested, please provide justification.

SECTION I: Deception/ Incomplete Disclosure (INSERT "NA" IF NOT APPLICABLE)

Section Notes…

- If you cannot adequately state the true purpose of the study to the subject in the informed consent, deception/ incomplete disclosure is involved.

I1. Describe (a) what information will be withheld from the subject (b) why such deception/ incomplete disclosure is necessary, and (c) when the subjects will be debriefed about the deception/ incomplete disclosure.

NA

IMPORTANT – Make sure all sections are complete and attach this document to your IRBManager web submission in the Attachment Page (Y1).

University of Wisconsin – Milwaukee
Consent to Participate in Online Survey Research

Study Title: Optimizing Hand crank Configurations for Therapeutic Use of AmTrykes® for Children With Brachial Plexus Injuries

Person Responsible for Research: Jennifer Hardy, Master's Student in Occupational Therapy; Roger O. Smith, Thesis Advisor

Study Description: The purpose of this research study is to create a protocol for optimally configuring AmTryke® hand cranks for configuration for children with brachial plexus injuries. Approximately 50 subjects will participate in this study. If you agree to participate, you will be asked to complete an online survey that will take approximately 30 minutes to complete. The questions will ask of your experience as a clinician using the AmTryke as a therapeutic intervention. They will also ask of your procedures for determining which hand crank arrangement will best suit a child's needs.

Risks / Benefits: Risks to participants are considered minimal. By participating, you risk having a lack of understanding about the concepts if you have never indeed used the AmTryke as a therapeutic intervention. Collection of data and survey responses using the internet involves the same risks that a person would encounter in everyday use of the internet, such as breach of confidentiality. While the researchers have taken every reasonable step to protect your confidentiality, there is always the possibility of interception or hacking of the data by third parties that is not under the control of the research team.

There will be no costs for participating. Benefits of participating include learning more about the fitting procedures that are currently being created, assisting in research to help the AmTryke to become a more widely used therapeutic intervention, and helping therapists in the field to know more about the AmTryke's benefits.

Limits to Confidentiality

Identifying information such as your name, email address, and the Internet Protocol (IP) address of this computer will not be asked or available to the researchers. Data will be retained on the Qualtrics website server for 30 days and will be deleted by the research staff after this time. However, data may exist on backups or server logs beyond the timeframe of this research project. Data transferred from the survey site will be saved on a password protected computer for 60 days. Only the student primary investigator (Jennifer Hardy) and primary investigator (Roger O. Smith) will have access to the data collected by this study. However, the Institutional Review Board at UW-Milwaukee or appropriate federal agencies like the Office for Human Research Protections may review this study's records.

Voluntary Participation: Your participation in this study is voluntary. You may choose to not answer any of the questions or withdraw from this study at any time without penalty. Your decision will not change any present or future relationship with the University of Wisconsin Milwaukee.

Who do I contact for questions about the study: For more information about the study or study procedures, contact Jennifer Hardy at jlhardy@uwm.edu or (414)430-1581.

Who do I contact for questions about my rights or complaints towards my treatment as a research subject? Contact the UWM IRB at 414-229-3173 or irbinfo@uwm.edu

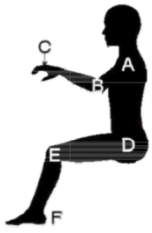
Research Subject's Consent to Participate in Research:
By entering this survey, you are indicating that you have read the consent form, you are age 18 or older and that you voluntarily agree to participate in this research study.

Appendix H: AmTryke® Fitting Guidelines

AMTRYKE SIZING CHART

MOTION CONTROLLED	MODEL	RIDER LEG LENGTH (Inches) (Center of hip to bottom of shoe)	RIDER ARM LENGTH (Inches) (Middle of shoulder to center of digit crease)	RIDER WEIGHT (lbs)	RIDER MAX. HEIGHT (Inches)	TRYKE WEIGHT (lbs)	WHEEL SIZE (Inches)	FRAME HEIGHT (Inches) (Without seat)	TOTAL LENGTH (inches) (With push bar add 24")	TRYKE WIDTH (Inches)
Hand/Foot	AM-9XXS	10-15	10-14	150	36	55	Front 9 Rear 6.5	11	26	19.5
Hand/Foot	AM-9XS	11-18	11-14	150	36	33	Front 9 Rear 6.5	11	26	19.5
Hand/Foot	AM-9S	16-19	15-17	150	36	33	Front 9 Rear 6.5	11	26	19.5
Hand/Foot	AM-12S	16-20	12-14.5	150	40	45	12	8	36	21
Hand/Foot	AM-12	17-27	14-18	150	47	45	12	11	39.5	25
Hand/Foot	AM-16	24-32	18-26	175	66	55	Front 16 Rear 12	12.5	45	31
Foot	Oceana	16-19	14-18	150	36	33	Front 9 Rear 6.5	11	26	19.5
Foot	Snappy	17-22	9-13	150	42	45	12	11	36	24
Foot	1412/1512	21-26	14-22	125	42	72	12	13	43	27
Foot	1416/1516	24-32	14-22	175	60	74/85	16	16.5	53	28
Foot	1420/1520	27-35	18-28	250	72	74/85	20	18.5	64	30
Foot	2701/2707	28-34	20-24	275	62	72	20	25	66	29.5
Foot	2721/2727	32-36	22-26	275	72	74	24	28	72	29.5
Foot	JT-2000	30-41	20-28	250	74	80	Front 16 Rear 20	17	72	29.5
Hand	Swirlygig	16-26	14-20	150	36	65	12	9	36	23
Hand	1424	22-41	22-26	250	72	74	20	14.5	64	29.5
Hand	HP-1000		22-26	250	74	80	Front 16 Rear 20	14.5	64	29.5

A Center of Shoulder
B Center of Elbow
C Center of Digit Crease
D Center of Hip
E Center of Knee
F Bottom of Foot



RIDER'S MEASUREMENTS

Arm Measurements (inches) Total Length

Left	A to B	B to C
Right	A to B	B to C
Trunk	A to D	

Leg Measurements (inches) Total Length

Left	D to E	E to F
Right	D to E	E to F

HELMET SIZING

Youth Sizes	Head Circumference Inches
XXS	18.5 to 19.5
XS	20.5 to 22
SM	22 to 23 5/8
L	23 5/8 to 25 3/4

Adult Sizes	Head Circumference Inches
S/M	22 to 23 5/8
L/XL	23 5/8 to 25 3/4

Appendix I: Survey Raw Data

Initial Report

Last Modified: 07/25/2013

1. 1. By clicking "Next" you are indicating that you consent to completing the following survey, that you are age 18 or older, and that you voluntarily agree to participate in this research study.

#	Answer		Response	%
1	Next		7	100%
2	I do not wish to participate.		0	0%
	Total		7	100%

Statistic	Value
Min Value	1
Max Value	1
Mean	1.00
Variance	0.00
Standard Deviation	0.00
Total Responses	7

2. 2. Do you have experience with using the AmTryke as a therapeutic intervention in a pediatric population?

#	Answer		Response	%
1	Yes, I have experience.		1	14%
2	No, I do not have any experience.		6	86%
	Total		7	100%

Statistic	Value
Min Value	1
Max Value	2
Mean	1.86
Variance	0.14
Standard Deviation	0.38
Total Responses	7

3. 3. In your opinion, which population of people is best suited for use of the AmTryke?

Text Response
I feel that the neurological patient is best suited for the amtryke. I do like to use this intervention with orthopedic children that need to gain ROM as it is a fun way to stretch.

Statistic	Value
Total Responses	1

4. 4. When working with a child with a brachial plexus injury, what do you typically measure in order to fit them for the AmTryke?

Text Response
I have not worked with a child with a brachial plexus injury

Statistic	Value
Total Responses	1

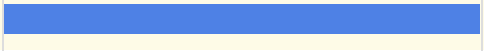
5. 5. What device(s) do you use when determining a child's current level of strength?

#	Answer		Response	%
1	hand-held dynamometer		0	0%
2	manual muscle testing		1	100%
3	other		1	100%

other
function against gravity

Statistic	Value
Min Value	2
Max Value	3
Total Responses	1

6. 6. When using the fitting diagram did the criteria go with or against your previous methods to fit a child for the AmTryke? Amtryke Fitting Guide

#	Answer		Response	%
1	With previous philosophies.		1	100%
2	Against previous philosophies.		0	0%
3	Other		0	0%
	Total		1	100%

Other

Statistic	Value
Min Value	1
Max Value	1
Mean	1.00
Variance	0.00
Standard Deviation	0.00
Total Responses	1

7. 7. When determining which hand crank arrangement is most appropriate, is it more helpful to utilize the total force or each individual arm pressure with various lengths of crank?

#	Answer		Response	%
1	Total force		0	0%
2	Individual arm pressure with various lengths		1	100%
3	Other		0	0%
	Total		1	100%

Other

Statistic	Value
Min Value	2
Max Value	2
Mean	2.00
Variance	0.00
Standard Deviation	0.00
Total Responses	1

8. 8. In a brachial plexus scenario, what is the radius length that you find to be most successful (in addition to the 4" standard length)?

#	Answer		Response	%
1	2.5" crank		0	0%
2	4" crank		0	0%
3	6.5" crank		0	0%
4	I have not used other crank lengths.		1	100%
5	Other		0	0%
	Total		1	100%

Other

Statistic	Value
Min Value	4
Max Value	4
Mean	4.00
Variance	0.00
Standard Deviation	0.00
Total Responses	1

9. 9. Which radius length was ineffective?

#	Answer		Response	%
1	2.5" crank		0	0%
2	4" crank		0	0%
3	6.5" crank		0	0%
4	All were effective		0	0%
5	All were ineffective.		0	0%
6	I have not used other crank lengths.		1	100%
	Total		1	100%

Statistic	Value
Min Value	6
Max Value	6
Mean	6.00
Variance	0.00
Standard Deviation	0.00
Total Responses	1

10. 10. Are there any other modifications to the AmTryke that affect success of its use?

Text Response
the straps on the handles and the straps on the foot pedals. These are almost a necessity when children have neurological deficits or tone.

Statistic	Value
Total Responses	1

11. 11. What is the most difficult part about adjusting the AmTryke?

Text Response
the child has to be off the bike

Statistic	Value
Total Responses	1

12. 12. How long do you implement the AmTryke before seeing significant progress towards meeting the child's goals?

#	Answer		Response	%
1	Less than one month		1	100%
2	Between one and two months		0	0%
3	Greater than two months		0	0%
4	Other		0	0%
	Total		1	100%

Other

Statistic	Value
Min Value	1
Max Value	1
Mean	1.00
Variance	0.00
Standard Deviation	0.00
Total Responses	1

13. 13. Do you always see significant results?

#	Answer		Response	%
1	Yes		0	0%
2	Sometimes		0	0%
3	No		1	100%
	Total		1	100%

Statistic	Value
Min Value	3
Max Value	3
Mean	3.00
Variance	0.00
Standard Deviation	0.00
Total Responses	1

14. 14. Which location of AmTryke intervention yields the greatest results?

#	Answer		Response	%
1	Within the child's home		0	0%
2	Within the clinic		1	100%
3	Other		0	0%
	Total		1	100%

Other

Statistic	Value
Min Value	2
Max Value	2
Mean	2.00
Variance	0.00
Standard Deviation	0.00
Total Responses	1

15. 15. Describe your clinical background with the pediatric population.

Text Response
I have been working in peds for 3 years and have used the Amtryke extensively when i was in TX. I have been working in Milwaukee for about 1.5 years, and I have not been able to find a provider or the ability to get some loaner bikes.

Statistic	Value
Total Responses	1

Appendix J: Equivalent Text Descriptions

1. Table 1 EqTD
    a. Table 1 Research Design
    b. Brief Description: Table illustrating research design with information regarding phase title, hypotheses, number of participants, and instrumentation.
    c. Essential Description: This table is broken into columns labeled Phase I and Phase II. Within each column are four rows: title of phase, hypotheses being tested, number of participants, and instrumentation.
2. Figure 1 EqTD
    a. AmTryke® AM-12 Small
    b. Brief Description: Image showing model AM-12 Small AmTryke® that was used in data collection.
    c. Essential Description: Image shows an AmTryke® model AM-12 Small on concrete floor with footplate and pull bar attached.
3. Figure 2 EqTD
    a. Spring Force Scale
    b. Brief Description: Photo showing spring scale used in data collection.
    c. Essential Description: Photo shows a green Cabela's spring scale with hook at one end and bar to pull on other end.
4. Figure 3 EqTD
    a. Auxiliary Hand Cranks
    b. Brief Description: Photo showing 2.5" hand crank and 4" hand crank added to standard 4" hand crank during data collection. Also illustrates strap used to attach spring scale during each trail.
    c. Essential Description: Photo shows 2.5" auxiliary hand crank on left side and 4" auxiliary hand crank on right side. Both are attached to the standard 4" crank. On each handle is a piece of tape that was wrapped around so that the hook from the spring scale could be looped through.
5. Figure 4 EqTD
    a. AmTryke® Pin
    b. Brief Description: Photo showing pin inserted into shaft of AmTryke® to lock steering during data collection.
    c. Essential Description: Photo shows rater inserting pin into a small hole on the shaft approximately 4" above the front wheel in order to lock steering.
6. Figure 5 EqTD
    a. AmTryke® Perpendicular Hand Cranks
    b. Brief Description: Photo illustrating arrangement of hand cranks in 90 degree perpendicular position.
    c. Essential Description: Photo shows AmTryke® on concrete surface with both hand cranks in a position that is perpendicular to the floor.
7. Figure 6 EqTD
    a. Safety harness
    b. Brief Description: Photo showing safety harness to hold weights into place on seat.

    c. Essential Description: Photo displays safety harness that is arranged around the CAP calibrated weights to hold them in an upright position on the seat.
8. Figure 7 EqTD
    a. Pull Handle
    b. Brief Description: Photo showing pull handle to be used when measuring total force.
    c. Essential Description: Photo displays handle that is attached to the front shaft of the AmTryke®. This handle allows for parents to pull their child on the trike and also was used for collecting data on total force.
9. Table 2 EqTD
    a. Raw Data Table
    b. Brief Description: Table is broken into three parts for the purpose of size and illustrates force value collected in each of three trials for every hand crank arrangement.
    c. Essential Description: Table has nine columns (weight applied to seat, both handles standard, total force, both 2.5" crank, both 4" crank, both 6.5" crank, left hand 2.5" crank and right standard, left 4" crank and right standard, and left 6.5" crank and right standard). These columns are then divided into six smaller columns that include data for three trials on the right hand and three trials on the left hand. The column has 14 rows that include weight increments from 0-130 pounds.
10. Table 3 EqTD
    a. Mean Force Table
    b. Brief Description: Table shows average force for each hand crank arrangement at every weight increment.
    c. Essential Data: Table has 8 columns of data (total pull force, both handles standard, total force, both 2.5" crank, both 4" crank, both 6.5" crank, left hand 2.5" crank and right standard, left 4" crank and right standard, and left 6.5" crank and right standard). Data is split into right and left hand by finding the mean values from the three trials in Table 2. The table has 14 rows that include weight increments from 0-130 pounds.
11. Table 5 EqTD
    a. AmTryke® Sizing Guide: Essential Data
    b. Brief Description: Table shows average force values based upon hand crank length for each weight increment.
    c. Essential Description: Table has 5 columns (rider's weight, standard crank, 2.5" crank, 4" crank, and 6.5" crank) and 14 rows that display the weight increments from 0-130 pounds. Data shows the mean of all data for a specific crank length.
12. Figure 9 EqTD
    a. Essential Data Graph
    b. Brief Description: Graph illustrates relationship between weight and force based on crank length.
    c. Essential Description: The y-axis represents force applied in pounds. The x-axis represents rider's weight in pounds. Each hand crank length means

(standard crank, 2.5" crank, 4" crank, & 6.5" crank) are graphed and show a linear relationship between weight and force.

13. Table 5 EqTD
    a. Expert and Novice Rater Data Means
    b. Brief Description: Table compares data collected by two raters for multiple crank arrangements.
    c. Essential Description: Table has seven columns (rider's weight, expert standard crank, novice standard crank, expert 2.5" crank, novice 2.5" crank, expert 4" crank, & novice 4" crank). There are 14 rows with each of the weight increments from 0-130 lbs. Data represent means from three trials in each crank length for both raters.
14. Figure 9 EqTD
    a. Standard Crank (4" radius) Mean Comparison
    b. Brief description: Graph shows data from expert rater and novice rater while assessing standard crank (4" radius) position.
    c. Essential Description: Graph illustrates relationship between means for expert and novice rater when testing standard crank (4" radius) length using a line graph. The y-axis represents force (lbs) and the x-axis represents rider's weight (lbs).
15. Figure 10 EqTD
    a. 2.5" Crank (6.5" radius) Mean Comparison
    b. Brief description: Graph shows data from expert rater and novice rater while assessing 2.5" crank (6.5" radius) position.
    c. Essential Description: Graph illustrates relationship between means for expert and novice rater when testing 2.5" crank (6.5" radius) length using a line graph. The y-axis represents force (lbs) and the x-axis represents rider's weight (lbs).
16. Figure 11 EqTD
    a. 4" Crank (8" radius) Mean Comparison
    b. Brief description: Graph shows data from expert rater and novice rater while assessing 4" crank (8" radius) position.
    c. Essential Description: Graph illustrates relationship between means for expert and novice rater when testing 4" crank (8" radius) length using line graph. The y-axis represents force (lbs) and the x-axis represents rider's weight (lbs).
17. Figure 12 EqTD
    a. Correlation Plot for Standard Crank (4" radius) between Expert and Novice Rater
    b. Brief Description: Graph shows scatterplot showing correlation between expert and novice rater when testing standard crank (4" radius) length.
    c. Essential Description: Graph is a scatterplot that shows the Pearson Product-Moment calculation for the standard crank (4" radius) length. The y-axis is representative of the expert rater and the x-axis is the novice rater.
18. Figure 13 EqTD

a. Correlation Plot for 2.5” Crank (6.5” radius) between Expert and Novice Rater
b. Brief Description: Graph shows scatterplot showing correlation between expert and novice rater when testing 2.5” crank (6.5” radius) length.
c. Essential Description: Graph is a scatterplot that shows the Pearson Product-Moment calculation for the 2.5” crank (6.5” radius) length. The y-axis is representative of the expert rater and the x-axis is the novice rater.

19. Figure 14 EqTD
    a. Correlation Plot for 4” Crank (8” radius) between Expert and Novice Rater
    b. Brief Description: Graph shows scatterplot showing correlation between expert and novice rater when testing 4” crank (8” radius) length.
    c. Essential Description: Graph is a scatterplot that shows the Pearson Product-Moment calculation for the 4” crank (8” radius) length. The y-axis is representative of the expert rater and the x-axis is the novice rater.
20. Table 6 EqTD
    a. Standard Deviation Table
    b. Brief Description: Table shows standard deviation between values in Table 5.
    c. Essential Description: Table contains 4 columns (rider’s weight, standard crank, 2.5” crank, and 4” crank) that display the standard deviation between the expert and novice rater at each of the 14 weight increments and for each of the three hand crank lengths assessed.