

**The Effect of Balance Bike Training on Balance, Physical Activity Levels, and  
Participation in Children and Youth with Down Syndrome: A Pilot Study**

**NCT #:** NCT03677245

**Date:** 9.4.2018

## RESEARCH PROTOCOL AND STATISTICAL ANALYSIS PLAN

<b>TITLE</b>	The Effect of Balance Bike Training on Balance, Physical Activity Levels, and Participation in Children and Youth with Down Syndrome: A Pilot Study
<b>ABSTRACT</b>	<p>Background: Children with Down syndrome (DS) present with hypotonia, impaired balance and poor gross motor proficiency which lead to difficulty learning new motor skills, decreased engagement in physical activity, and limited participation in home, school, and community activities. Bicycle riding is a popular childhood activity with multiple health benefits; however, children with DS often have difficulty learning to ride a standard two-wheel bike. Purpose: The purpose of this pilot study is to determine the effectiveness of the Strider “Learn to Ride” intervention when used to teach children with DS to ride a two-wheel balance bike. Additional purposes include examining the immediate effects of the five-day “Learn to Ride” intervention on the balance of children with DS and the long-term effects of completion of the intervention on the participation and physical activity levels of children with DS. Methods: An estimated 20 children between the ages of 5 and 17 years old will be recruited to participate in the quasi-experimental, pre-post-test group design study. The participants will complete the five-day Strider “Learn to Ride” intervention under the instruction of a pediatric physical therapist. The immediate effects of the intervention on distance cycled and balance, using the Pediatric Balance Scale (PBS), will be assessed. Participation and physical activity levels will be assessed at long term follow-up using the Participation and Environment Measure for Children and Youth (PEM-CY) and a parent-report questionnaire.</p>
<b>BACKGROUND</b>	<p>Bicycle riding is a popular childhood activity; however, individuals with Down syndrome (DS) often have difficulty mastering this skill. Down syndrome, a common chromosomal disorder identified in approximately 1 in 700 live births, carries the certainty of developmental delay and altered gross motor movement proficiency.<sup>1</sup> Individuals with DS present with cerebellar hypoplasia which contributes to delayed motor skills, problems with axial control, and impaired coordination.<sup>2</sup> Additionally, a reported 58% of children and adolescents with DS do not meet the Office of Disease Prevention and Health Promotion’s PA guidelines, and evidence suggests that PA levels continue to decrease as children move into adolescence.<sup>3</sup> Additional characteristics of children with DS contributing to physical inactivity and difficulty learning to ride two-wheel bikes include cognitive impairments, hypotonia, balance impairments, and reduced exercise capacity.<sup>4,5</sup> Societal and environmental barriers to PA, including limited opportunities for participation in inclusive sports and high costs of adaptive equipment also contribute to</p>

	<p>low fitness levels of this population. Identification of enjoyable, sustainable, accessible, and effective forms of PA for this population is necessary in order to promote improved overall health and participation across the lifespan. Bicycle riding has been identified as a source of moderate to vigorous PA for children and adolescents and is a noncompetitive, highly accessible activity that can be enjoyed across the lifespan.<sup>6,7</sup> However, research examining bike riding as an enjoyable and effective PA intervention for adolescents with developmental disabilities, particularly DS, is limited. One study examined the benefits of children with DS learning to ride an adaptive two-wheel bicycle.<sup>8</sup> The children participated in “Lose the Training Wheels”, an intensive, five-day program aimed at teaching the skill of riding a two-wheel bike independently.<sup>8</sup> Specially designed two-wheel adaptive bikes were used for initial training. The bikes were modified to include a push handle on the back, to be used by the instructor, and rear roller wheels to increase the bike’s base of support.<sup>8</sup> Forty-four percent of the participants were unable to learn to ride a two-wheel bike during the training period.<sup>8</sup> However, children who did complete the training program decreased their time spent in sedentary behavior by 75 minutes per day, indicating that new motor skill development might positively impact PA levels for up to 12 months following the initial intervention period.<sup>8</sup> A similar study also examined the effectiveness of the “Lose the Training Wheels” program, previously described, for children and adolescents with DS and Autism Spectrum Disorder.<sup>6</sup> The results indicated that 61% of children with DS continued to ride their bike at home after the intervention period ended, supporting transfer of an enjoyable PA to the natural environment.<sup>6</sup> However, the adaptive bikes used for the “Lose the Training Wheels” program are specially made and not commercially available, making widespread access to this intervention difficult. Strider Bikes, a brand of commercially available balance bikes, are specifically designed to be lightweight, easy to handle, and safe for use with children with disabilities. One study using Strider bikes reported that children with autism spectrum disorder demonstrated significant improvements in postural control following completion of 15 minutes of riding, three days per week for five weeks.<sup>9</sup> However, there is currently no research available that has utilized Strider bikes with youth with DS. In order to impact a large population of children with DS and create lasting, positive outcomes, a relatively inexpensive, commercially available adaptive bike and effective instructional intervention must be identified.</p>
<b>PURPOSE</b>	The purpose of this pilot study is to determine the effectiveness of the Strider “Learn to Ride” intervention on the balance of children with Down syndrome and the long-term effects of completion of

	<p>the intervention on the participation and physical activity levels of children with Down syndrome. Our central hypothesis is that successful completion of the Strider “Learn to Ride” intervention will provide children with Down syndrome the ability to ride a two-wheel balance bike safely and independently. We also hypothesize that balance biking will be a sustainable activity that has the potential to greatly increase the functional balance, participation, and physical activity levels of youth with Down syndrome because we propose riding Strider bikes to be enjoyable and motivating for this population.</p>
<b>SPECIFIC AIM(S)</b>	<p>Page 4 of 74/5/2019 Specific Aim(s) We plan to test our central hypothesis and meet our overall objective for this project by pursuing the following specific aims: 1. Determine the ability of youth with DS to learn to ride a Strider balance bike, within one week, utilizing the Strider “Learn to Ride” curriculum. Our working hypothesis is that youth with DS who complete the five “Learn to Ride” classes will be able to successfully and safely ride their Strider bike 100’ or more without loss of balance. 2. Determine the efficacy of balance biking on improving balance in youth with DS, as measured by the Pediatric Balance Scale (PBS). Our working hypothesis that balance will be improved in youth with DS who complete the balance biking intervention because biking is an enjoyable childhood PA that requires high levels of postural control. 3. Determine the long-term sustainability of balance biking for youth with DS, as estimated by a 3-, 6-, 9-, and 12-month follow up surveys. Our working hypothesis here is that balance biking will be a sustainable form of PA for individuals with DS that can be continued throughout the lifespan, leading to increased PA levels and decreased time spent engaged in sedentary behaviors. 4. Determine the impact of long-term participation in balance biking on home, school, and community participation levels, as measured by the Participation and Environment Measure for Children and Youth (PEM-CY). Our working hypothesis that long-term involvement in a balance biking program will lead to increased participation in home, school, and community environments.</p>
<b>STUDY DESIGN</b>	<p>The proposed pilot study is a pre-post-test design with each participant serving as his or her own control. The proposed study design will provide preliminary data towards answering the hypothesis and specific aims. Children ages 5-17 years old with a diagnosis of Down syndrome will be recruited to participate from pediatric therapy clinics, schools, and the Central Mississippi Down Syndrome Association. Each participant will be provided with a Strider balance bike to use for the intervention. On the first day of the intervention, each participant will complete the Pediatric Balance scale and the distance that each child can cycle will be recorded. Participants’ parents will be asked to complete the Participation and Environment Measure for Children</p>

	and Youth (PEM-CY) and the PROMIS physical activity questionnaire on the first day of the intervention. Each participant will complete the 5-day Strider Learn to Ride Intervention under the supervision of a physical therapist. On the last day, each child will be reassessed with the Pediatric Balance Scale and the distance that each participant can cycle will again be recorded. Participants' caregivers will be contacted by mail from the PI to complete follow up outcome measures (PEM-CY and PROMIS questionnaire) at 3-and6-months.
<b>INCLUSION CRITERIA</b>	To be included in the study, the individuals must 1) be between the ages of 5 and 17 years old with a diagnosis of Down syndrome, 2) have the core strength and balance necessary to maintain sitting on a two-wheel bike with their feet on the ground, and 3) be able to follow simple commands.
<b>EXCLUSION CRITERIA</b>	The exclusion criteria for the study are 1) significant cardiovascular event or illness in the past 6 months and 2) another medical diagnosis, besides Down syndrome, that would limit participation in the biking intervention.
<b>NUMBER OF SUBJECTS</b>	Approximately 10 participants will be recruited to participate in the pilot study, based on the recommended number of participants for each Strider "Learn to Ride" intervention.
<b>OUTCOME MEASURES</b>	Outcome measures used will include the Pediatric Balance Scale (PBS), distance cycled, Participation and Environment Measure for Children and Youth (PEM-CY), and PROMIS questionnaire. The PBS is a valid, 14-item assessment, developed based on the Berg Balance Scale. The PBS is a criterion-based measure, with each item scored on a 0-4 scale. Distance cycled will be measured based on the longest straight-line distance, out of three trials, that the participant is able to safely and independently propel their Strider bike. The PEM-CY is a participation level outcome measure used to assess a child's engagement in activities in the home, school, and community environments. The PEM-CY is a valid and reliable measure and is completed by parent/caregiver report, making it appropriate to use with children with Down syndrome. The final outcome measure, a parent report PROMIS questionnaire to assess PA levels of participants, will also be used. Long-term follow up at 3-and 6 months, through mail, will be completed to assess long-term changes in participation and physical activity levels as well as the sustainability of the Strider bike intervention for this population.
<b>STUDY ENDPOINTS</b>	All outcomes measures will be administered on the first day of the intervention to collect pre-intervention data. Upon completion of the five-day "Learn to Ride" intervention, the Pediatric Balance Scale and distance cycled will again be administered for post-intervention data. The Participation and Environment Measure for Children and Youth and the PROMIS physical activity questionnaire will be administered, my mail, to each participants' caregiver/parent at 3-and-6-months following completion of the

	<p>intervention to assess long-term outcomes associated with the intervention.</p>
<b>STATISTICAL METHODOLOGY</b>	<p>IMB SPSS Statistics will be used to analyze all data. Dependent t-tests will be used to analyze pre-and post-test scores of the Pediatric Balance Scale, Participation and Environment Measure for Children and Youth, and distance cycled. If assumptions are not met, a Wilcoxon Signed Ranks test will be used to analyze the data.</p>
<b>REFERENCES</b>	<ol style="list-style-type: none"> <li>1. Down Syndrome Data and Statistics. Center for Disease Control and Prevention website <a href="http://www.cdc.gov/ncbddd/birthdefects/downsyndrome/data.html">http://www.cdc.gov/ncbddd/birthdefects/downsyndrome/data.html</a>. Updated June 27, 2017. Accessed July 8, 2017.</li> <li>2. Malak R, Kostiukow A, Krawczyk-Wasielewska A, Mojs E, Samborski W. Delays in motor development in children with Down syndrome. <i>Medical Science Monitor</i>. 2015;21:1904-1910.</li> <li>3. Shields N, Dodd KJ, Abblitt C. Do children with Down syndrome perform sufficient physical activity to maintain good health? A pilot study. <i>Adapted Physical Activity Quarterly</i>. 2009;26:307-320.</li> <li>4. Latash M, Wood L, Ulrich D. What is currently known about hypotonia, motor skill development, and physical activity in Down syndrome. <i>Down Syndrome Education Online</i>. <a href="http://www.down-syndrome.org/reviews/2074/">http://www.down-syndrome.org/reviews/2074/</a>. Updated 2008. Accessed July 8, 2017.</li> <li>5. Mendonca GV, Pereira FD, Fernhall B. Reduced exercise capacity in persons with Down syndrome: cause, effect, and management. <i>Therapeutics and Clinical Risk Management</i>. 2010;6:601-610.</li> <li>6. MacDonald M, Esposito P, Hauck J, Jeong I, Hornyak J, Argento A, Ulrich DA. Bicycle training for youth with Down syndrome and autism spectrum disorders. <i>Focus on Autism and Other Developmental Disabilities</i>. 2012;27(1):12-21.</li> <li>7. Physical Activity Guidelines: Children and Adolescents. Office of Disease Prevention and Health Promotion website <a href="http://health.gov/paguidelines/guidelines/chapter3.aspx">http://health.gov/paguidelines/guidelines/chapter3.aspx</a>. Accessed on July 8, 2017.</li> <li>8. Ulrich DA, Burghardt AR, Lloyd M, Tiernan C, Hornyak JE. Physical activity benefits of learning to ride a two-wheel bicycle for children with Down syndrome: a randomized trial. <i>Phys Ther</i>. 2011;91(10):1463-1477.</li> <li>9. Shim AL, Peterson S, Turbes J. Incorporating a pedal-less bicycle curriculum into a K-5<sup>th</sup> grade after school program to improve stability for ASD children. <i>Journal of Physical Education, Recreation, and Dance</i>. 2016;87(3):52-54</li> </ol>