**Statement of Need**

Down syndrome is the most commonly occurring chromosomal condition, with incidence between 1 in 1,000 to 1 in 1,100 live births worldwide1, 4. It affects an estimated 250,000 families in the United States alone, with one in every 691 U.S. babies born with Down syndrome2, 4. These individuals experience mild to moderate cognitive delays and low muscle tone along with increased risk of hearing deficits (60-80% of individuals), congenital heart disease (40-45% of individuals), intestinal abnormalities, obesity, and thyroid dysfunction.4 However, despite its prevalence and impact, Down syndrome is the least funded genetic condition by the NIH3. According to the World Health Organization, in the early 1900’s, babies with Down syndrome weren’t expected to live until their 10th birthday; however, now 80% of individuals with Down syndrome reach their 50th birthday.4 Much of this progress is due to the steps that have been taken to improve quality of life and health in individuals with Down syndrome, such as regular check-ups with health care providers and interventions with physical therapy, counseling, and/or special education.4

The health issues associated with Down syndrome affect these individuals’ day-to-day lives. Congenital heart disease (CHD), which affects nearly half of all babies born with DS, can lead to pulmonary hypertension (high blood pressure in the lungs), an inability of the heart to effectively and efficiently pump blood, and cyanosis (blue skin from low oxygen) 5. A diagnosis of CHD can be obtained with an echocardiogram and requires that an individual with Down syndrome should have regular imaging along with medication and, in some cases, surgery5. Down syndrome can also adversely affect the immune system, hearing, and vision, and may be accompanied by sleep disorders, epilepsy, gum and dental disease, blood disorders, digestive problems, celiac disease, and mental and emotional health problems (such as Attention Deficit Hyperactivity Disorder, depression, or anxiety), all of which require additional health screening, care, and/or medication 4,5,8. Moreover, individuals with Down syndrome may have atlantoaxial instability (unstable spine just below the base of the skull) that can cause problems if an undiagnosed child has surgery or participates in certain sports or activities3,5. Down syndrome may further limit that activities that individuals decide to participate in due to the decreased muscle tone and low strength (known as hypotonia) that accompany it and contribute to the delays in rolling over, sitting up, crawling, and walking5. Likewise, individuals with Down syndrome may also have hypothyroidism, a condition in which the thyroid gland does not produce enough thyroid hormone, which can lead to decreased metabolism and weight gain 3,4,5. These various conditions along with the medications individuals may take in order to manage them can often lead to a lifestyle that is centered on medical care rather than relationships and enjoyment. These individuals are less likely to be involved in physical activity and other social activities due to their condition and additional complications5, which ultimately may lead to decreased quality of life or further emotional and mental obstacles. However, by increasing physical activity in a safe and social environment, physical therapy may play an integral role in maintaining and supporting health and wellness in individuals with Down syndrome across the lifespan.

In most of North Carolina, early intervention programs that include physical therapy are designed to help parents and families with children who are born with Down syndrome. Physical therapists work with these children in a variety of ways to help promote trunk strengthening, gross and fine motor skill acquisition, and to foster respiratory health. While many of these programs take place in homes or day-care facilities, there is in addition a free community-based group in the Triangle for children zero to three years old that partners with local physical therapists and is focused on activities and offers suggestions caregivers to work with kids at home10. However, as children transition to school age, emphasis may also shift, with community programs at museums for ages eight to twelve and social activities for ages thirteen to nineteen10. Physical activity-based interventions become less common and focus turns to more cognitive and social aspects of development. Nevertheless, physical activity in individuals with Down syndrome, particularly adolescents, is extremely important. Physical development in terms of exercise and muscle strength is vital for individuals with Down syndrome as they move into adulthood due to the fact that muscle strength may be reduced in individuals with Down syndrome and workplace activities in which they find themselves employed may require physical skills. Furthermore, adults with Down syndrome tend to have a higher occurrence of being overweight or obese7 and, despite screening for obesity and hypothyroidism. Even with the recommendations for exercise given by primary care physicians, adherence to physical activity and preventative care has been shown to be inconsistent at best11.

And at this point in time, there are no physical fitness or community exercise programs for adolescents or adults with Down syndrome in the Triangle, despite the fact that in North Carolina there is a higher prevalence of obesity in individuals with Down syndrome14. Therefore, a community-based Training and Resistance Exercise for Down Syndrome program (TREDS) would provide an opportunity to engage in preventative care exercise in specialized, multifaceted group designed to connect, educate, and empower individuals with Down syndrome in our local area10. The goal of the TREDS program is to teach adolescents and adults with Down syndrome healthy exercise habits while fostering an environment that allows for learning and encouragement. By empowering participants with positive exercise experiences in a social environment and providing the opportunity for self-improvement, growth, and self-advocacy, TREDS aims for each participant leaves with knowledge and practical skills for continuing exercise throughout their lifetime.

In order to maximize this opportunity and influence as many individuals as possible, TREDS would utilize a comprehensive socioecological approach to health and wellness. This approach first investigates possible intrapersonal, interpersonal, institutional, community, and public policy factors that influence a health-related behavior change; then, taking these factors into account, the socioecological approach targets individual, social, and environmental influences for health promotion interventions12. Owing to its basis in multiple levels of behavior-specific influence that interact with one another, this socioecological model is thought to be one of the most effective in health behavior change13. In the TREDS program, intrapersonal factors include the internal motivation for physical activity, which will be emphasized in the monthly educational sessions detailing the benefits of exercise and the fun of being involved in a physical activity program. Interpersonal connections will bring a social component to the TREDS program, as adolescents and young adults with Down syndrome will be able to interact and engage with their peers during the weekly resistance training sessions. Furthermore, as a program held at the local YMCA and involving Triangle area physical therapists, personal trainers, and Down syndrome friends/advocates, TREDS will also appeal to the community/organizational factors influencing health behaviors. TREDS will also strive to garner support from the Triangle Down Syndrome Network (TDSN) as well as community 5k events, the Special Olympics, TDSN Buddy Walk, National Down Syndrome Awareness Month events, and other community events and public programs. By bringing awareness to the importance of strength training and physical activity for individuals with Down syndrome, TREDS may also be able to affect community and local government policy, creating a feed-forward system of influence. In this way, and by providing a safe and welcoming environment for adults with Down syndrome to experience weight lifting on a variety of equipment with their friends and community members, TREDS considers and incorporates not only intrapersonal and interpersonal factors but also community and organizational factors in a comprehensive socioecological approach to health and wellness.

**Background**

In North Carolina, the U.S., and across the globe there are consistently higher prevalence rates of being overweight and obesity in individuals with Down syndrome, during childhood, adolescence, and adulthood14, 15. In fact, obesity is often considered to be a feature of youth with Down syndrome16; however, despite the negative effects obesity can have on the health and wellness of individuals in the long run (i.e. increased risk of diabetes, hypertension, heart disease, etc.) 14, it’s not just body mass index (BMI) or body fat percentage that is an issue. Studies have shown that adolescents and young adults with Down syndrome actually have lower overall levels of fitness than age-matched adolescents without Down syndrome in fitness tests16. Certainly this could partly be due to the fact that individuals with Down syndrome tend to be overweight or obese, but it is likely also influenced by the fact that individuals with Down syndrome often have hypotonia, leading to reduced strength and aerobic capacity and making it more difficult for them to participate in recreational sports and other physical activities18. However, by limiting physical activity, they are only furthering their fitness deficits and making it more challenging to keep up with their peers or engage in functional physical activities. In addition, limitations in physical fitness impedes the ability of adults with DS to perform functional tasks of daily living18 This feed-forward cycle of muscular weakness leading to inactivity leading to increased weakness and inactivity may ultimately limit their ability to perform functional tasks for employment or even activities of daily living18. Therefore, it is important for physical therapists, other healthcare professionals, and caregivers to step in and encourage exercise and physical activity as much as possible – specifically during adolescence and young adulthood when routines and activities are being established for the rest of one’s life.

Thus the program TREDS was formed in order to help tackle the need for physical activity and exercise programs that are tailored to individuals with Down syndrome and foster functional performance in both work and recreational environments. The program is run by dedicated physical therapists, physical therapy students, and highly qualified instructors who are specially equipped to work with adolescents and adults in order to teach them about exercise, train them in the proper utilization of gym and resistance equipment, and encourage them to maintain healthy lifestyles. The TREDS program is designed for individuals with Down syndrome age 15 and up and will combine a monthly educational health session on lifting techniques, safety, cardiovascular exercise, and nutrition with a weekly focus on resistance training in a gym. The program was structured with these two components in order to motivate patients intrapersonally to become healthier first through education12 and then provide a chance for them to engage in strength exercises and become healthier, given the evidence that resistance training is beneficial for improving strength and work task performance, encouraging weight loss and fitness, and improving mucosal immunity response in adolescents and young adults with Down syndrome9. Although the benefits of cardiovascular exercise will be stressed in the educational sessions with participants being encouraged to go on walks and bike rides with their family and friends, the weekly exercise sessions will focus on resistance training – something that is often less accessible outside of a program or gym membership. Twenty-five minutes of guided resistance exercise three times a week can lead to significant improvements in hip extensor, hip flexor, knee extensor, knee flexor, hip abductor, and ankle plantarflexor strength along with improved agility in only six weeks for adolescents with Down syndrome23. Therefore, TREDS weekly lifting/resistance exercises will incorporate core workouts along with both upper and lower extremity strength training, using a mixture of body weight resistance and movement-controlled resistance machines. Studies have shown that young adults with Down syndrome experienced improved leg strength and stair-climbing ability following 10 weeks of resistance training twice a week, 6 indicating that regular resistance training strength translated into functional ability, which is important for young adults moving into the work force. Although children have also showed a statistically significant improvement in knee extensors strength, hip flexor strength, and balance following 6 weeks of progressive resistance exercise training19 the program will begin at age 15 in order to ensure safety within the weight room. Furthermore, exercise habits tend to wear off as people enter adolescence, meaning that exercise habits should be promoted and preserved especially in adolescence27. TREDS is a 20 week program, which should be adequate time to not only see an affect on individuals’ health and fitness 6,9,23 but also should provide enough time for participants in the program to learn safe lifting techniques and have exercise become more of a habit or routine in their lives. For that reason, although the program takes 5 months to complete, individuals may remain in the program and come to the weekly training sessions for as long as they desire.

This program is likely to be an effective way to improve strength and fitness in individuals with Down syndrome for a number of reasons. First, it incorporates intrapersonal motivation for fitness and fun by means of the educational sessions with interpersonal and community social motivation in accordance with the socioecological model12. A randomized controlled trial of a similar program involving a 10-week community-based progressive resistance-training program for individuals with DS found that those who underwent 10 weeks of resistance training had increased their upper and lower limb strength after the program21. Physical activity and lower leg strength gains persisted another 14 weeks following cessation of the program, indicating that progressive resistance training is a safe and feasible fitness option that can improve muscle strength and endurance in adults with Down syndrome21,26. Even programs led by physical therapy students as opposed to licensed physical therapists have demonstrated improvement in lower limb muscle strength after 10 weeks of resistance exercise24. Furthermore, muscular strength items, especially leg strength, have been shown to significantly predicted functional performance in both men and women with Down syndrome17, indicating that appropriate training programs can be tailored for this population and lead to not just gross strength gains but improvements in performance of *functional* activities. But strength gains are not the only benefit of a resistance program for young adults with Down syndrome. In addition, studies have shown there may be significant improvements in both the VO2 peak and heart rate recovery following exercise and physical activity in adults with Down syndrome following a resistance program22. Furthermore, resistance training has been shown to significantly decrease inflammatory markers of infection along with improved fat-free mass and decreased waist circumference20. This means that a resistance training program like TREDS for adolescents and young adults could influence strength, aerobic capacity, cardiac recovery, inflammation, and obesity. Moreover, the consequences of *not* providing such a program in our area for adolescents and young adults may be more harmful than anyone might expect. One study found that adolescents and young adults who did not engage in resistance training or aerobic training demonstrated significant *increases* in body fat percentage, while those who did train maintained their body composition25. And in addition to the physical benefits of the program, TREDS will help to establish patterns of health behavior that extends past the duration of the program. By addressing the more subjective factors that affect behaviors according to social cognitive theory and health belief models, such as the “perceived benefits,” “self-efficacy,” and “observational learning.” 28,29 TREDS educational sessions enlighten the participants about the many benefits of exercise and healthy eating, while seeing themselves learn to use the machines and seeing their progress will improve self-efficacy. In addition, by partnering with their peers and working together in the weight room, holding one another’s feet for sit-ups, etc., the participants will also be exposed to peer modeling that is so important in observational learning and exposure29. Therefore, a program like TREDS is an important first step in helping to maintain the health and wellness of individuals with Down syndrome in our community.

**Program Description**

*Program Objectives*

1. All participants will demonstrate proper use of all resistance machines sanctioned for their individually tailored program after 20 weeks.
2. Participants will achieve an increase in lower body strength as indicated by >/= 25% increase in weight lifted during their normal sets/reps compared to baseline on a basic leg press machine after 20 weeks.
3. Participants will have decreased body mass index by 20 weeks.
4. Participants will have improved number of sit-ups completed in 1 minute by >/=10% of baseline after 20 weeks.
5. Participants will have composed a written plan for continuing fitness and for the next 3 months either with TREDS or outside TREDS at completion of program.
6. More than 70% of participants who have completed the program will have improved self-efficacy for resistance exercise from baseline at the beginning the TREDS program based on short questionnaire.
7. More than 80% of participants who have completed the program will they are in better health since beginning the TREDS program based on short questionnaire.

*Methods*

Training and Resistance Exercise for Down Syndrome is a community-based exercise program designed to connect, educate, and empower individuals with Down syndrome in the Triangle area. The program is run by dedicated physical therapists and highly qualified instructors who are specially equipped to work with adolescents and adults in order to teach them about exercise, train them in the proper utilization of gym and resistance equipment, and encourage them to maintain healthy lifestyles. The program designed for teens and young adults with Down syndrome age 15 years and up, and it is comprised of two parts: First, a monthly educational session in which participants will be instructed in the correct techniques for weight lifting and exercise along with tips for healthy living and goal-setting. Second, participants will meet once a week for hour-long group weight-lifting and resistance exercise training. Both components of the program will be held at the Downtown Durham YMCA given that the location is a community-friendly building, has both a gym and smaller meeting rooms, and is located in the heart of the Triangle, between Chapel Hill and Raleigh.

Given that research has shown that individuals are more likely to make and stick to health behavior changes when they have intrapersonal motivation12, the educational component of TREDS is an important piece of the program and will help increase individuals’ knowledge and motivation to continue physical activity. These educational sessions will meet monthly for between 45 minutes and an hour, just prior to the first weight lifting session of the month. The meetings will be held in either an empty exercise room or community meeting room based upon the YMCA schedules. Principles and topics that will be explored and discussed vary slightly from session to session but will include health topics such as physical activity, nutrition, injury-prevention, goal-setting, and self-efficacy/self-esteem as well as encouragement and ideas for cardiovascular activity each day. In addition, there will be a review of correct lifting techniques with an emphasis on safety prior to going to the training session. Educational session speakers will vary based upon topic and areas of interest, and participants will be encouraged to ask/answer questions throughout. Over the course of the program, individuals will receive specific instruction in goals and planning for continued, lifelong physical activity. This will include learning how to set SMART goals and tips for incorporating physical activity into daily life. In order to be eligible to “graduate” from the program after 20 weeks, the participants will be required to attend at least 3 monthly educational sessions and have a written plan for continued physical activity and wellness.

Based on the evidence that community-based resistance exercise programs can lead to overall increases in strength and functional performance in individuals with Down syndrome17, the weekly lifting/resistance exercises in the gym at the YMCA will incorporate core workouts along with both upper and lower extremity strength training, using a mixture of body weight resistance and movement-controlled resistance machines. For every weekly training session, all resistance and lifting activities will occur under the supervision certified physical therapists and/or personal trainers but will include a group warm-up comprised of simple stretches, jumping jacks, and toe-touches led by a different participant each week to encourage the social and interpersonal aspect of the program. During each participant’s first week of training, a special one-on-one intake session will occur under the supervision of a certified physical therapist and/or personal trainer. That participant’s specific exercise/lifting program will be individualized in order to keep everyone safe, and all activities will be completed with either body-weight only (i.e. body weight lunges, squats, sit-ups, push-ups, etc.) or using movement-controlled resistance machines (i.e. leg press, hamstring curl, leg extension, shoulder press, etc.) in order to minimize risk of injury. The lifting sessions will be supervised by at least 1 physical therapist or personal trainer for every 3 participants in order to ensure safety. As the program grows and increases in number, the goal is to likewise increase physical therapist and personal trainer volunteers to help speak at educational sessions and oversee training sessions. In addition, participants will be instructed to use the machines in pairs so that they can encourage one another and “spot” their peers throughout the training session (although they will not be using free weights, as is usually the case when one needs a “spotter”). The “basic program” for each participant will generally be comprised of the following exercises but weight, repetitions, and sets will be tailored to that individual as necessary:

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| **Core**   * Sit-ups (partner holding feet) * Plank * Supine bridge holds (progress to marching) |
| **Upper-Body**   * Shoulder press * Lat pull-down * Row * Push-ups |
| **Lower-Body**   * Leg press * Hamstring curl * Leg extension * Calf raises |

For each participant’s first training session, an individualized intake occurs preceding the normal training session in order to allow for adequate one-on-one attention without removing the facilitator from the other participants and potentially jeopardizing their safety. During this intake session, the individual’s BMI, capacity on the leg press, and number of sit-ups in 1 minute will be recorded as baseline data. Furthermore, on the first training session of each month (the same day as the educational session), participants will be observed and aided in order to progress the weights or repetitions as appropriate. However, participants will only be allowed to perform exercises or utilize equipment that they have been instructed in, though trainers may add a new exercise or equipment per patient appropriateness as they progress. Participants will receive a chart of their exercises with pictures and instructions to keep with them along with places to log their sets/reps/resistance for each training session. During each subsequent weekly training session of the month, participants will have a partner in order to help one another and encourage one another. This is intended to improve individuals’ safety during training while also increasing motivation to return to TREDS each week by promoting friendship and socialization. In addition, a group cool-down led by another participant will conclude each training session and be comprised of

After 20 weeks, participants in the program will be evaluated for safe and effective lifting techniques in a final one-on-one training session with a certified physical therapist. Once he or she has demonstrated the ability to safely and effectively complete his or her own individualized training regimen and has provided the instructors with a written “plan” for continued health and fitness, the participant is considered to have “graduated” from TREDS and will receive a blue ribbon for their achievement. Although the program takes 5 months to complete, individuals may remain in the program and come to the weekly training sessions for as long as they desire. During the final training session, data will be collected on individual’s BMI, leg press weight, and number of sit-ups as outcome measures compared to baseline.

**Program Evaluation**

Following completion of the program, participants’ final training session data will be analyzed along with their individual intake baseline data in order to track progress and ensure that they are ready to “graduate” from the TREDS program. In addition, each participant will be given a short questionnaire to answer about the program in order to measure outcomes and help determine whether or not each of the program objectives for TREDS is being accomplished. The questions asked on the questionnaire will be as follows:

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| “How confident are you that you could come to the gym and do your program on your own?”  5=very confident 4=confident 3=unsure 2=not confident 1=not possible |
| “Do you feel you are more healthy since starting TREDS?”  Yes or No |
| “What was your favorite part of the TREDS program?” |
| “What was your least favorite part of the TREDS program?” |
| “Overall, how would you rate your experience in the TREDS program?”  5=excellent 4=good 3=fair 2=unsatisfactory 1=poor |
| Is there anything you would like us to change or do differently for the TREDS program? |
| Do you have any other questions or comments about TREDS? |

The data from the final training session, once analyzed compared with the baseline data from the initial intake session, will be helpful in both looking at individual progress and readiness for “graduation” as well as adjusting program objectives as needed to be more attainable. If, for example, it turns out that only twenty or thirty percent of participants are increasing their lower leg strength by more than 25% by the end of the twenty weeks, it may be necessary to change the objective to a goal of more than 15% increase in lower leg strength. Likewise, if individuals aren’t able to perform the exercises safely on their own or they are not showing a decrease in BMI at the conclusion of the TREDS program, it may be necessary to lengthen the program in order to provide participants with more time to learn and improve. Similarly, the information and feedback that participants provide on the questionnaire will be utilized to investigate program objectives for self-efficacy and perceived health and to improve the program and better the experience for everyone involved. By understanding what participants enjoyed and disliked as well as what they would change, issues that the program facilitators and directors may not even be aware of can be addressed and remedied. In addition, positive remarks, testimonials, and praise for the program that may be included on the questionnaire would be beneficial in terms of promotion for the program and garnering support.

Nevertheless, there are a few possible limitations for the TREDS program. First, it is not yet known how many individuals will be interested in participating in the TREDS program initially, and therefore it is unclear how many physical therapists and personal trainers will be needed to keep the ratio of participants to facilitators at 3:1. Having an adequate number of supervisors is extremely important in ensuring that each participant receives proper instruction and is safe in the weight room. Furthermore, given that everyone is little bit different, some of the participants may need subsequent one-on-one training session after the initial intake session before they are ready to be working with a partner under less direct supervision. Although this would not be a large issue if it is only one or two participants, but if nearly every participant needed multiple direct-supervision one-on-one training sessions then it would be very difficult to find the time and resources to accommodate that. As of right now, it is hard to know whether or not one intake session will be adequate. In addition, another possible limitation involves the use of the YMCA gym for educational sessions and resistance training sessions. Because YMCAs are community centers, there may be at times random conflicts with other groups, classes, conferences, or simply too many people in the gym. At this time, we cannot predict if or how often there may be conflicts, but a back-up plan will be necessary in order to ensure that the program is successful. Nevertheless, with enough support and community involvement, the TREDS program will effectively help to serve the individuals with Down syndrome in the Triangle area by providing a safe and empowering place to improve health, connect with community, learn about livelong health, and become empowered to achieve health and fitness goals.

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