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Research Article

The Effect of a Physical Exercise Package on the Motor Proficiency of Students with Down Syndrome

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Abstract

Objectives: The purpose of this study was to evaluate the feasibility and potential effect of a physical exercise package on the motor proficiency of children and adolescents with Down syndrome.

Methods: In this research, an experimental design was conducted in two special schools to evaluate the effectiveness of this package and identify its strengths and weaknesses. Forty students with Down syndrome were selected and randomly divided into intervention and control groups. A total of 36 (22 male and 14 female) students out of 50 at two special schools for children with special needs between October 2020 and March 2021 were recruited for the study. Participants were aged 12.888 \pm 2.375 (12.954 \pm 2.609 for boys and 12.785 \pm 2.044 for girls) years. The 18 students in the intervention group participated in the exercise sessions, 2 or 3 sessions per week for 12 weeks. Pre- and post-tests were performed on both groups. The Physical Exercise Package included the principles of exercise, the preferred exercise methods, and the details of exercise planning for Down syndrome individuals (FITT-VP) based on the etiology of Down syndrome and the characteristics of people with this syndrome. Motor proficiency was measured using the Bruininks Oseretsky Test of Motor Proficiency (BOT-2).

Results: The results of the study showed that the designed exercise package was adhered to with all the participants attending 93.2% of the sessions, and participants significantly improved their total motor proficiency score, manual dexterity, upper-limb coordination, strength, balance, upper-limb coordination, running speed and agility and fine motor Integration (P < 0.05). However, the exercises did not significantly change the bilateral coordination and fine motor precision (P > 0.05).

Conclusions: the current study result shows that developing and implementing the individualized exercise package and observing the principles set out in the program could have significant positive impacts on the motor proficiency of students with Down syndrome.

Keywords: Down Syndrome, Sport Rehabilitation, Motor Development, Special Education

1. Background

Down syndrome (DS) is a common neurodevelopmental disorder that causes significant delays in various aspects of development, intellectual disability, and numerous health and mental problems. The prevalence of this disorder has been reported to range from one in 650 births to one in 1200 births (1-5). Down syndrome has received more attention from researchers than any other chromosomal disorder. Indeed, Down syndrome has long been among the most popular behavioral and educational research subjects. Thanks to advances in this field, some individuals with Down syndrome attend university classes (6). Over the past 30 years, the life expectancy of Down syndrome individuals has also increased significantly, to the point that it is now only a few years shorter than the life expectancy of the general population (7, 8).

One of the essential prerequisites for designing an exercise for people with a disorder is to perfectly understand the problems and limitations that result from that disorder. In the case of Down syndrome, such an understanding can be gained from the countless studies conducted on this subject. Research has shown that people with Down syndrome are highly more likely to suffer from poor physical fitness (9), foot structure and ankle problems (10-12), balance problems (12-16), atlantoaxial instability, ligamentous laxity and joint instability (17-20), poor bone mineral density (21, 22), low muscle strength and hypotonia (23-26), shortness of arms and legs (27), overweight, obesity,

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and body composition problems (28-30), low reaction time (31), neurological or psychological issues and nerve growth problems (32-34), anomalous dominance (35, 36), information processing problems, poor cognition and memory (6, 37, 38), Alzheimer's disease (39), and cardiovascular problems (40, 41).

Another common characteristic of these individuals is inactivity. Various studies have shown that Down syndrome individuals have lower levels of physical activity than people without Down syndrome and even people with other disabilities (42-44). This inactivity can lead to health issues, debilitated motor development, and less social engagement.

Down syndrome affects fine and gross motor skills (45-48). According to Beqaj et al., children with intellectual disabilities, especially those with Down syndrome, have significantly delayed motor development compared to other children. It has been reported that children with intellectual disabilities have even poorer motor development than children with other disabilities (49). This problem is noticeably worse in children with Down syndrome because of their differently structured central nervous system (due to chromosomal abnormalities) and their unique learning style (50). By disrupting cognitive processes and impairing all aspects of growth, Down syndrome also delays the onset of motor skill development. Another difference between individuals with and without Down syndrome is in the pattern of motor activities. Motor disorders that tend to affect motor development of children with Down syndrome adversely include decreased muscle tone in the posturesupporting muscles (a neuromuscular symptom), inadequate posture control and response, inadequate muscle contractions around the joints, impaired depth perception, and hyperactivity of the joints (50). All these problems result in poor motor development and inactivity and weakness in performing sports skills and even daily activities, which can significantly reduce the overall quality of life of these individuals.

It has been shown that early interventions can be very effective in enhancing the motor development of Down syndrome individuals. In other words, Down syndrome individuals who receive early interventions tend to score better on their performance tests than their peers (51). Tomporowski et al. showed that exercise could improve the physical, emotional, and social development of children with Down syndrome and boost their physical and mental performance (52).

Despite outstanding advances in medical science and the development of numerous interventions for children with Down syndrome, these individuals still suffer from significant developmental delays compared to their peers (53). In a review paper by Gonzalez-Aguero et al., where they examined the literature on health-related physical fitness of children with Down syndrome, it was concluded that the exercise programs tested by many studies have not been as effective as expected in improving the physical fitness of these individuals. Therefore more research is needed to clarify the issue (54).

While there is no doubt about the effectiveness of exercise in improving the motor skills and health of children with Down syndrome (55-60), there is still no complete exercise package designed to meet the specific needs of these individuals, and teachers and caregivers tend to get confused as to which exercises are more suitable for these children (61). International studies have shown that while the number of disabled students who attend a special school or regular education is on the rise, many physical education (PE) teachers in these schools are still ill-prepared to work with these students. A major problem for these teachers in working with children with disabilities is the lack of adequate educational resources. To resolve this issue, it is critical to develop multidimensional yet sufficiently simple instructions for public use as a guideline for planning exercises for people with different disorders.

Physical education specialists are duty-bound to develop specialized exercises for special needs individuals based on the etiology and characteristics of each disorder in order to equip sports coaches and physical education teachers with the knowledge that they need to provide professional training and exercise services to these individuals. In pursuit of this goal, after reviewing the numerous studies conducted on people with Down syndrome, research team in the Sport Sciences Research Institute (SSRI) designed an individualized exercise package specifically for students with syndrome down.

2. Objectives

This study aimed to evaluate the effect of physical exercise packages for students with Down syndrome on the motor proficiency of these students. Upon the verification of the effectiveness of the program and its benefits for Down syndrome individuals, it can serve as a guideline for researchers, PE teachers, sports coaches, parents, and caregivers to help them plan exercises for people with Down syndrome through a specific methodology based on the principles of exercise science.

3. Methods

This randomized controlled trial study was conducted in two phases: 1- developing the exercise package; 2- measuring the effectiveness of the package and making the necessary modifications.

3.1. Population, Sample, and Sampling Method

In this research, an experimental design was conducted in two special schools (one all-boys school and one all-girls school) to investigate its effectiveness, discover its strengths and weaknesses. Special schools are those that provide an education for children with a special educational need or disability.

After obtaining written consent (from students' parents), the students who met the inclusion criteria (having Down syndrome, IQ between 55-75, being able to move and follow instructions, having no disability other than Down syndrome, having no severe physical disability, and being willing to participate in an exercise program) were included in the sample. The subjects, were randomly divided into two groups, intervention and control. Also those students who were not able to complete the exercise program or attend the post-test session were excluded, reducing the sample size to 36. Overall, the students of the two groups had a mean age of 12.888 \pm 2.375 (12.954 \pm 2.609 for boys and 12.785 \pm 2.044 for girls). In the intervention group, the students had a mean age of 12.555 ± 2.770 (12.250 ± 2.800 for boys and 13.167 \pm 2.857 for girls). students in the control group had a mean age of 13.222 ± 1.927 (13.800 ± 2.201 for boys and 12.500 \pm 1.309 for girls). The youngest participating student was 9, and the oldest was 17.

3.2. Measurement Tools

Motor skill development was measured by the Bruininks Oseretsky Test of Motor Proficiency (BOTMP) (BOT-2). This test consists of eight subscales that measure gross and fine motor development. BOTMP is a set of normreferenced tests. BOT-2 has been used in many studies to assess the psychomotor abilities of healthy children aged 4.5 to 14 years. Bruininks created this test in 1978 by modifying the Oseretsky motor proficiency test. Bruininks standardized the test on a sample of 756 children selected based on age, gender, race, population size, and geographic area according to a census conducted in 1970. In a 2009 study by Wuang and Su, they confirmed the reliability and responsiveness of the Bruininks-Oseretsky test of Motor Proficiency-Second Edition (BOT-2) for children with intellectual disabilities (ID) (62). Weight and height were measured with standard instruments (digital scales and tape measure).

3.3. Intervention

The students in the control group continued their routine educational program, which of course included routine daily physical activities of special schools (equal to the experimental group). The students in the intervention group attended 1-hour exercise sessions, 2-3 sessions per week for 12 weeks in addition to their routine physical activities. The exercise program was planned based on the developed training-exercise package for rehabilitation of students with Down syndrome (SSRI package). Unfortunately, because of the frequent closure of schools in the autumn and winter of 2019, over the three-month scheduled semester, students were able to attend only 21 exercise sessions (in addition to 7 sessions dedicated to pre- and posttesting.

3.4. SSRI Exercise Package for Students with Down Syndrome

Sport Sciences Research Institute exercise package for students with Down syndrome was designed in a research project by Kashi and Sarlak in 2020 (63). The details of the exercise program (frequency, intensity, type, time, volume and progression) were planned based on the findings of previous studies. According to American College of Sports Medicine (ACSM), all exercise programs should consist of a series of basic elements, including aerobic, strength, balance, and flexibility exercises (64); the exercise program was designed on this basis. The exercise package was developed in three parts. The first part was dedicated to the principles of exercise for students with Down syndrome. These principles are the basic exercise guidelines for Down syndrome individuals and the essential psychosocial, emotional, and motor knowledge that teachers need to work with these individuals. The second part was devoted to the preferred exercise methods for Down syndrome individuals, and the third part was dedicated to the details of prescribing exercise programs for these individuals. More detailed information in this regard is provided in the first part of results.

3.4.1. Principles of Exercise for Down Syndrome Individuals

According to the SSRI exercise package, PE teachers and coaches that are working with Down syndrome students are recommended to learn these principles and try to follow them when planning exercises or recommending exercise programs for these individuals:

1- Providing specialized sports exercises on top of the games played in PE classes with due attention to the principles and fundamentals of sports exercise

2- Following the principles of adaptive physical education with a supportive and group-oriented approach.

3- Teaching fundamental motor skills (FMS) and strengthening them in all exercise sessions.

4- Using visual instructions in exercises and evaluations.

5- Facilitating the attendance of Down syndrome students in PE classes.

6- Expanding inclusive education in the educational programs for Down syndrome students.

7- Developing educational and exercise programs for Down syndrome students based on the etiology of this syndrome and with attention to the syndrome's specific impacts in each person.

8- Teaching parents to give extra-school exercises.

9- Teaching school teachers how to work with Down syndrome students.

10- Integrating groups of students with different disabilities in PE classes and not separating them from public programs.

11- Creating motivation for participation in PE classes based on each student's interests.

12- Promoting participation in Special Olympics programs as an extracurricular special sport activity for Down syndrome individuals.

These principles are basic guidelines to help teachers, even those with unrelated education, to understand the essentials of working with Down syndrome students and take positive steps in boosting physical activity and the rehabilitation of these students.

3.4.2 Preferred Exercises for Down Syndrome Individuals

The exercise mentioned in Table 1, are recommended for students with Down syndrome acording to the SSRI package. The training instructor or teacher needs to plan the exercise sessions, of course with adherence to the principles of exercise for Down syndrome students, in a way that all ten categories get covered over the course of each planning window. Naturally, it is impossible to include all of the ten categories in each session. Thus, for example, if the students are scheduled to attend 24 sessions per semester, these 24 sessions must be planned with attention to the capacity of students, school facilities, and the cooperation of colleagues, parents, and students in such a way as to have a diverse combination of these exercises throughout the semester and achieve the maximum possible improvement in motor development at the end of the semester. The plans can also be adjusted to overcome unforeseen disruptions, for example, by shifting to remotely supervised home exercises during the pandemic.

3.4.3. Details of the Implementation of the Exercise Program for Down Syndrome Individuals

The developed exercise package should be at least 12 weeks long to have significant effects. It is recommended to continue the exercises as long as possible and incorporate them into the daily routine to have lasting effects. This package proposed that having 2 - 3 sessions a week, each lasting 45 to 60 minutes, would be a good choice for students with Down syndrome. Also, it is recommended to start the developed exercise program at low intensity,

gradually raise the intensity of exercises to a moderate level, and introduce a few high-intensity exercises once students show improved cardiovascular performance. However, considering the limitations of the cardiovascular and metabolic systems in Down syndrome individuals, highintensity exercises must be used with extreme caution.

3.5. Data Analysis Methods

The descriptive statistical analysis was conducted by the use of mean, standard deviation, and frequency distribution tables and graphs. For the inferential statistical analysis, the analysis of covariance (ANCOVA) was used to test the hypotheses on the presence of significant relationships between research variables.

4. Results

The Down syndrome students that participated in this research were in the age range of 9-17 years and had a mean age of 12.888 \pm 2.375 (12.954 \pm 2.609 for boys and 12.785 \pm 2.044 for girls) years.

Based on sample size calculation using GPower, 36 participants were included in this study to give 1 - beta = 0.95, alpha = 0.05 and effect size $|\rho| = 0.50$ and allocated into either the intervention or the control group.

4.1. Adherence to Exercise Intervention

All the participants completed the exercise sessions with no more than three sessions absent. On average, participants attended 93.2% of the sessions, and 100% completed the pre and post-assessments.

4.2. Effects of the Exercise Program on Body Composition and Body Mass Index

The mean weight of the control group changed from 41.44 \pm 15.617 in the pre-test stage to 41.111 \pm 15.593 in the post-test stage. In the intervention group, the mean weight changed from 37.228 \pm 15.664 in the pre-test stage to 37.111 \pm 14.556 in the post-test stage. The mean body mass index (BMI) in the control group changed from 22.4837 \pm 4.705 to 22.217 \pm 4.733, and in the intervention group changed from 20.565 \pm 4.541 to 20.573 \pm 4.044. For both weight and BMI, the results of ANCOVA showed no significant difference between the post-test weight or BMI of the two groups after controlling for their pre-test values (P > 0.05), meaning that the exercises had no significant effect on the weight or BMI of the students.

Recommended Exercise Methods	Details				
Perception-action exercises	Receiving, throwing and hitting exercises, folk dances and rhythmic movements, exercises that improve reaction time and cognitive processing				
After school exercises	Exercising on sloping surfaces, using machines such as treadmill and stationary bicycle, swimming, massage, and horseback riding				
Balance exercises	Using BOSU ball and its exercises, rotational strengthening and stabilizing exercises, exercising on movin fixed and unstable surfaces				
Virtual games	Using Xbox Kinect and Nintendo Wii games				
Muscle endurance exercises	Increasing the level of physical activity, repetitive contractions, and Swedish exercises				
Whole-body vibration machines	Whole-body vibration at low to high frequencies				
Aerobic exercises	Cardiovascular endurance improvement through aerobic exercises, running, cycling, etc., increasing heart rate in stationary exercises throughout the session				
Exercise with wheeled equipment	Cycling, skating, using power pump or any kind of wheeled equipment that involve maintaining balance and controlling muscle contraction				
Strength exercise and its complementary exercises	Strength-balance exercises, strength-aerobic exercises, strength-agility exercises, exercises that strengthen core stability muscles, strength and depth perception development exercises, plyometric exercises, community-based strength exercises, exercising with weight, and two-person exercises				
Yoga and gymnastics exercises	Special yoga cards, stories, games for Down syndrome individuals, special gymnastic moves for Down syndrome individuals (avoid those moves that put pressure on the neck and atlantoaxial joint)				

4.3. Effects of the Exercise Program on Motor Proficiency

The results of this study showed that (Table 2) the exercises significantly improved the total motor proficiency score (F = 28.766, P = 0.000, Eta = 0.750). The exercise program had a significant impact on different dimensions of motor proficiency, including manual dexterity (F = 28.118, P = 0.000, Eta = 0.466), upper-limb coordination (F = 6.009, P = 0.020, Eta = 0.154), strength (F= 11.128, P = 0.002, Eta = 0.252), balance (F = 9.369, P=0.004, Eta = 0.221), upper-limb coordination (F = 15.905, P = 0.000, Eta = 0.325), running speed and agility (F = 6.251, P = 0.018, Eta = 0.159) and fine motor Integration (F = 6.009, P = 0.020, Eta = 0.154). However, the exercises did not significantly change the bilateral coordination (F = 1.878, P = 0.180) and fine motor precision (F = 1.617, P = 0.212) score of the students (P > 0.05).

After identifying the weaknesses of this exercise package (i.e. the areas where improvements were insignificant), necessary modifications were made based on previous reports and findings and the principles of exercise science to finalize the proposed exercise guidelines for students with Down syndrome (Figure 1).

5. Discussion

This study aimed to evaluate the feasibility and potential effect of a physical exercise package on the motor proficiency of children and adolescents with Down syndrome. The results of numerous studies on individuals with Down syndrome have shown that participation in exercise programs, can have significant positive effects on their onset

and rate of motor skill development. Additionally, exercise programs can have profound impacts on these individuals and, most notably, on their growth (65), immune and hormonal system function (66, 67), cognitive function, neurological and psychological function(27, 68), physiological response to physical activity (5, 69), executive function (70), cardiovascular fitness (71, 72), aerobic capacity (73, 74) and body composition (30, 75), which certainly lead to improved health and quality of life.

Regarding the effect of physical activity on Down syndrome individuals, there is a consensus that exercise has remarkable benefits for these people in terms of cardiovascular, neurological, and muscular responses (59). The enhanced capability to use motor skills in adaptive activities makes Down syndrome individuals more independent in their personal and work life (5). Exercise programs developed for these individuals has to start with simple exercises to understand and fulfil theperson's need to develop a physical capacity or capability. Wang and Ju. (76) and Wang and Chang (77) showed that although physical activities such as the long jump have many benefits for Down syndrome individuals, it is not worthwhile or particularly effective to continue this type of exercise, which strengthens a particular part of the body, for a long time. Therefore, researchers have strongly recommended using exercises that improve various body parts and various dimensions of physical health. A good example of an enjoyable program that meets this requirement is the one proposed by Lin and Wuang, which uses a combination of walking/jogging and virtual reality exercises (with Wii

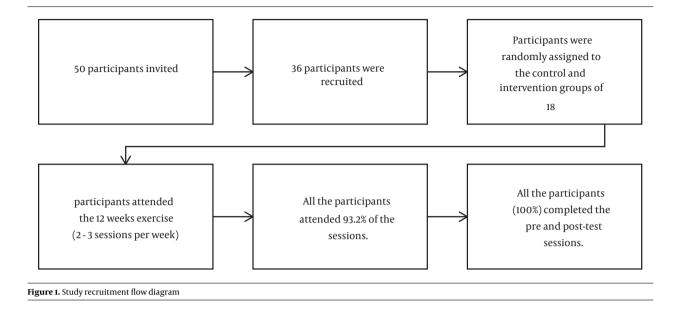
Variables and Test	Sum of Squares	df	Mean Square	f	P Value	Partial Eta Squared	Observed Power
Mean total BOTMP score							
Pre test	1916.233	1	1916.233	127.887	0.000	0.792	1
Variable	437.865	1	437.865	28.766	0.000	0.466	0.999
Running speed and agility							
Pre test	111.304	1	111.304	90.504	0.000	0.773	1
Variable	7.688	1	7.688	6.251	0.018	0.159	0.680
Balance							
Pre test	131.948	1	131.948	127.662	0.000	0.795	1
Variable	9.683	1	9.683	9.369	0.004	0.221	0.884
Bilateral coordination							
Pre test	41.818	1	41.818	106.939	0.000	0.764	1
Variable	0.734	1	0.734	1.878	0.180	0.054	0.265
Strength							
Pre test	128.384	1	128.384	69.196	0.000	0.675	1
Variable	20.647	1	20.647	11.128	0.002	0.252	0.899
Fine motor precision							
Pre test	105.422	1	105.422	201.092	0.000	0.859	1
Variable	0.848	1	0.848	1.617	0.212	0.049	0.235
Upper-limb coordination							
Pre test	195.502	1	195.502	371.057	0.000	0.918	1
Variable	3.166	1	3.166	6.009	0.020	0.154	0.663
Manual dexterity							
Pre test	108.672	1	108.672	214.529	0.000	0.867	1
Variable	14.598	1	14.598	28.118	0.000	0.466	0.999

Abbreviation: BOTMP, Bruininks Oseretsky Test of Motor Proficiency.

game console) (78). Shields et al. have introduced two different exercise interventions for Down syndrome individuals. One of these interventions is a group-based training which involves two or three Down syndrome individuals exercising with a trainer. The other program involves Down syndrome individuals exercising in groups while receiving guidance from mentors. This form of training can improve social interaction and physiological adaptation capabilities and prevent many of the problems associated with specific exercise programs (79, 80). Therefore, researchers also tried to put together different types of exercises that could benefit Down syndrome individuals instead of strengthening a specific dimension in order to reach an exercise program capable of improving the overall health of participants and alleviating the common limitations resulting from the syndrome; an exercise program that can be continued for a long period of time and lead to

lasting improvement in various indicators of health.

It is clear that despite extensive studies in the field of sports science on people with Down syndrome, teachers and coaches still face substantial ambiguities when planning exercises for these individuals. While the Special Olympics Organization has made some recommendations on how these people should exercise, many ordinary Down syndrome individuals, especially students, need regular, easy-to-use, and diverse exercises to help them get fit and develop their motor skills rather than engage in sports activities. Experts in the field of sports science are obligated to develop such exercises to improve the physical health of these individuals so that they can enjoy a long life and play an active role in society. However, a major problem in this area is the poor readiness of PE teachers in many parts of the world to implement the developed exercise programs such that there would be an effective improve-



ment in the physical abilities of their Down syndrome students. Unfortunately, many PE teachers lack the necessary knowledge to plan exercises for students with Down syndrome and desperately need training and clear practical instructions to carry out this task. In this study, researchers tried to develop such instructions in the form of a special exercise package for Down syndrome students in order to take a step toward better physical rehabilitation of these individuals in special and public schools. After an extensive study of research conducted on this subject in different countries, the SSRC exercise package was developed based on the latest scientific findings (63). In order to make sure of its applicability, the program had to be tested in this research by several special PE teachers to identify its strengths and shortcomings. By implementing the package in two special schools, researchers ensured that the provided instructions were easy to understand and apply.

After completing the program, the participating students showed an increase in total motor proficiency scores, with significant improvement in various subscales of motor proficiency, including manual dexterity, upper-limb coordination, strength, balance, upper-limb coordination, running speed and agility and fine motor Integration (P < 0.05). Although this exercise package is being tested for the first time, this result is consistent with other studies findings (52-55, 58). This is a critical outcome as it indicates the positive impact of the exercise package for individuals with down syndrome.

Current study result demonstrated that the exercises did not significantly change the students' weight, BMI, bilateral coordination, and fine motor integration score (P> 0.05). Considering the short time intervention, this result was expected. This finding shows that longer-term intervention could be more beneficial for individuals with syndrome down.

The study strength includes the novel individualized exercise program for students with syndrome down, considering ACSM guidelines and these individuals' capabilities and interests. However, there were a few limitations in the program. For example, it was challenging to change body composition by holding two or three one-hour exercise sessions over a few months, mainly because the program was focused on improving motor function and neuromuscular coordination in the initial months. However, if continued for a more extended period of time, the program can be expected to have more significant impacts on body structure and composition. Undoubtedly, shortterm exercise programs will never be able to guarantee lasting health benefits, which is why teachers should encourage students to incorporate physical activity and exercise into their daily routines so that they can reap the benefits throughout their life. Further longitudinal studies with larger sample sizes are required to help in a better understanding of the individualized exercise program for students with syndrome down. Also, this study suggests that controlling other factors such as eating behavior, alongside the individualized exercise package, might have a better impact and benefits for individuals with syndrome down.

5.1. Conclusions

Our review of studies on Down syndrome individuals showed that they tend to suffer from problems in body

composition, fitness, motor skills, and some physical abilities, all of which negatively impact their health and quality of life. These problems can substantially limit a Down syndrome individual's opportunities for social interaction and engagement because they tend to get involved in jobs and tasks that mainly require physical health (this is because, unfortunately, they are mostly unable to do complex tasks that depend on intellectual abilities). This highlights the importance of improving the physical health of Down syndrome individuals and explains why this is among the core duties of experts in rehabilitation and sports sciences. By providing specific exercise guidelines for students with Down syndrome, researchers hope to help PE teachers, sports coaches, and parents of these students to successfully implement a multidimensional exercise program for these individuals so that they can gain the physical capabilities that they will need to have effective social engagements and move towards a more independent life of higher quality.

Footnotes

Authors' Contribution: Concept: Ali Kashi; design: Ali Kashi and Zahra Sarlak; data collection or processing: Ali Kashi; analysis or interpretation: Ali Kashi, Helen Dawes and Maedeh Mansiubi; Critical revision of the manuscript for important intellectual content: Helen Dawes, Ali Kashi and Maedeh Mansiubi; literature search: Zahra Sarlak; writing: Ali Kashi, Maedeh Mansoubi.

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Data Reproducibility: The data presented in this study are openly available in one of the repositories or will be available on request from the corresponding author by this journal representative at any time during submission or after publication. Otherwise, all consequences of possible withdrawal or future retraction will be with the corresponding author.

Ethical Approval: The research proposal was submitted in advance to the National Committee for Ethics in Biomedical Research at the Ministry of Health and Medical Education of Iran and SSRI and received permission with the code IR.SSRC.REC.1398.030.

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