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治療性音樂結合荷重坐站阻力運動對雙邊痙攣型腦性麻痺兒童之療效

Effects of Therapeutic Music Combined with Loaded Sit-to-Stand Resistance Exercise for Children with Spastic Diplegia

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本論文係汪子瑄君（R96428003）在國立臺灣大學物理治療學系暨研究所完成之碩士學位論文，於民國九十八年七月二十四日承下列考試委員審查通過及口試及格，特此證明

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中文摘要

背景與目的：雙邊痙攣型腦性麻痺兒童因其肌肉力量和動作控制能力之缺損，在動作功能及日常生活參與常受限制。過去研究顯示居家荷重坐站阻力訓練可增進輕度雙邊痙攣型兒童的肌力及動作功能，然兒童對參與肌力訓練的動機較低。由過去經驗可知音樂具有提昇運動意願的效果，而利用不同的音樂元素達到提示動作目的之「音樂模組知覺動作提昇法」(Patterned Sensory Enhancement，簡稱 PSE)，可用來改善動作控制能力；然目前尚未有研究探討 PSE 音樂用於腦性麻痺兒童肌力訓練的效果。本研究主在探討以治療性音樂結合六週居家荷重坐站阻力訓練，對於輕至中度雙邊痙攣型兒童的身體功能、活動及日常生活參與的成效，以及音樂對兒童阻力訓練參與程度之影響。**方法**：本研究共徵召 22 位 5 到 13 歲可獨立坐到站的雙邊痙攣型兒童，依其年齡和嚴重度分層後，隨機分派至 PSE 音樂組(12 位)和無音樂組(10 位)。由不知分組狀況的測試者評估以獲取訓練前後荷重坐站一次最大阻力、粗大動作功能量表分數、兒童生活功能評估量表的移動性和自我照顧領域的量表分數及行走功能的變化資料；並利用動作分析系統評估兒童執行坐站動作的平順度、直接程度和動作時間等動作控制參數。實驗組兒童接受為期六週，每週三次，結合 PSE 音樂的居家荷重坐站阻力訓練。PSE 音樂由物理治療師與音樂治療師參考受試者在評估時的荷重坐站動作表現一起設計，由音樂治療師預先錄製以提昇運動興趣且增進坐站動作表現為目的之個人化音樂交由兒童使用，並於每兩週更新。控制組兒童亦接受強度相同的居家荷重坐站阻力訓練，然不提供音樂。針對上述成果變項，以重複二維多因子變異數分析比較兩組兒童之改變；此外，兩組兒童均記錄其運動參與情形，並在訓練後以動機量表評估其運動動機，利用獨立樣本 t 檢定或曼-惠特尼 U 檢定分析兩組之間的差異。顯著水準設在 α=0.05，單尾檢定。**結果**：經過六週後，PSE 音樂組兒童在功能性肌力(P=.038)、粗大動作功能量表之目標分數(P=.026)上較無音樂組有顯著進步，但 PSE 音樂組兒童並未較無音樂組在生活功能評估量表分數、行走功能和坐到站的動作

控制參數上有更多進步，然所有兒童的前後測結果相比皆有顯著的時間主效應。在運動參與程度上，兩組兒童的運動動機無顯著差異，然 PSE 音樂組兒童完成的總運動次數有較多的趨勢(*P*=.057)。**討論與結論**：本研究成功將 PSE 音樂和居家荷重坐站阻力訓練做結合，並證實 PSE 音樂可協助輕至中度雙邊痙攣型兒童增進其荷重坐站一次最大阻力和粗大動作功能，PSE 音樂組在運動參與程度上也有較多的趨勢。無論有無音樂，經阻力訓練後，所有兒童的生活參與情形、走路速度與坐站動作控制在訓練後皆有增加。未來研究可將不同類型的功能性活動與 PSE 音樂結合，以增進腦性麻痺兒童的日常生活表現。

關鍵詞：腦性麻痺、肌力訓練、音樂治療、動機、動作控制

Abstract

Background and Purpose: Children with spastic diplegia (SD) usually have limitations in mobility functions and daily participation due to muscle weakness and poor motor control. A previous study proved that a home-based loaded sit-to-stand (STS) resistance exercise program could improve their functional muscle strength and gross motor function. However, the exercise motivation for resistance training is usually poor in children. Music was reported to be used to increase adherence for exercise. Also, the Patterned Sensory Enhancement (PSE) technique of music therapy uses different elements of music to cue body movements and could improve motor control immediately. However, no studies investigated the effects of PSE music with resistance exercise for children with CP. The purpose of this study was to investigate the effects of the loaded STS resistance exercise with PSE music on body functions, activities, participation, and exercise involvement for children with SD. **Methods**: Twenty-two children with SD who could stand up independently were recruited for this study. Participants were stratified by their age and severity and then randomly assigned to the PSE music (PSE) group (n=12) and the non-music (NM) group (n=10). A blinded tester evaluated the children to obtain data of one-repetition maximum (1-RM) of the loaded STS test, Gross Motor Function Measure (GMFM) goal score, scaled scores of Pediatric Evaluation of Disability Inventory (PEDI) Mobility and Self-Care domains, and walking parameters at pre- and post-training. The motion analysis of the STS movement was also conducted to gather motor control variables, including jerk index, directness, and movement time of STS. Children in the PSE group received a home-based loaded STS exercise combined with PSE music, 3 times a week for 6 weeks. The individualized PSE music was designed by the physical therapist and the music therapist, and composed by music therapist based on the recorded video of loaded STS movement. This PSE music was aiming to increase fun and promote the exercise performance and was renewed every 2 weeks. Children in the NM group received the 6-week loaded STS exercise without music. All above outcome measures were compared between groups using two-way mixed analysis of variance. In addition, the exercise adherence and volume were gathered by logbook. The motivation was assessed by the Intrinsic Motivation Inventory after training. The above 3 variables were compared between groups with independent t test or Mann-Whitney U test. The alpha level was set at 0.05 for one-tailed test. **Results**: Children in the PSE group improved more in the 1-RM of the loaded STS test and goal score of GMFM than the NM group after 6-week training (P = .038 and .026, respectively). There were no time × group interaction effects for scores of PEDI, walking parameters, and motor control variables of STS, but there were significant main time effects while considered all subjects as a whole. The exercise motivation did not differ significantly between groups. However, children in the PSE group tended to complete more loaded STS repetitions than the NM group (*P* = .057) during the training period. **Discussion and conclusion**: In the present study, we successfully incorporated PSE music with the home-based loaded STS exercise for children with mild to moderate SD. The PSE music significantly improved the functional muscle strength and gross motor function, and had a tendency to increase the exercise volume. For all subjects as a whole, improvements were found in daily participation, walking speed, and motor control of STS. Future studies might combine PSE music with various functional activities in order to improve the performance in daily activities for children with CP.

Key Words: Cerebral palsy, Resistance training, Music therapy, Motivation, Motor control

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Chapter 1. Introduction

Children with cerebral palsy (CP) are usually characterized by impaired movement functions and restricted participations in home, school, and leisure activities (Rosenbaum et al, 2007). Among them, spastic diplegia (SD) is the most common subtype of CP (Andersen et al, 2008; Westbom et al, 2007). Children with SD usually have limitations in mobility activities, such as sit-to-stand (STS) transfer and walking. For children who have to walk with device, it was proved that their motor function started to decline after the age of 8 year (Hanna et al, 2009). The mobility limitation may be due to the muscle weakness problem and poor motor control function (Eek and Beckung, 2008; van der Heide et al, 2005). Recent reviews of exercise programs for children with CP showed that after receiving lower extremity (LE) resistance exercise, children with CP could increase their ability to generate muscle force and improve gross motor function (Fowler et al, 2007; Verschuren et al, 2008). However, there were few studies measured the training effects on the participation level and required further investigations (Fowler et al, 2007; Verschuren et al, 2008).

It is suggested that the training effects would be prominent while the resistance exercise is carried out in a task-specific, functional movement pattern in which the motor control function is highlighted (Blundell et al, 2003; Liao et al, 2007). For example, it is proved that a 6-week, home-based loaded STS resistance exercise program with the load at 50% of 1-repetition maximum of the loaded STS (1-RM STS) can improve the gross motor function and walking efficiency with a small to medium effect size for children with SD who can walk independently without device, aged between 5 to 12 years old (Liao et al, 2007). Further study found that while children with SD executing the loaded STS exercise, they tended to perform the STS movement in a smoother way than the unloaded condition (Lin, 2005). Although the loaded STS exercise program is beneficial for children with SD who can walk independently, the exercise has not been applied to children who has to walk with device because of the difficulties and the great exertion of the task. The high demand of exertion during the loaded STS exercise may also negatively affect the exercise motivation and exercise involvement of children who can or cannot walk independently.

It is proposed that listening to music could provide an interesting environment and various movement cues when combining with exercise (Hayakawa et al, 2000; Likesas and Zachopoulou, 2006; Thaut, 2005). Previous study has demonstrated that music combined with exercise can elevate motivation for children developing typically (Likesas and Zachopoulou, 2006). In addition, music is used to improve movement functions for children with CP and other neurological patients (Thaut et al, 1998; Thaut et al, 2002). Previous studies have investigated the effects of music rhythm on walking performance for children with CP (Kwak, 2007; Thaut et al, 1998). In the previous study conducted in our laboratory, the immediate effect of one kind of therapeutic music on the performances and motivation of the loaded STS movement was studied. The therapeutic music, following the Patterned Sensory Enhancement (PSE) principles, was proved to improve motor control and motivation for children with SD (Peng, 2008). However, the effect of a 6-week loaded STS exercise program with PSE music on motor ability and functions for children with SD needs further study.

Overall, the purpose of present study is to investigate the effects of PSE Music with a "home-based" loaded STS exercise program on the functional strength, gross motor function, daily participation, exercise involvement, motor control, and gait speed for children with SD.

1.1 Research Problem

Does pre-recorded therapeutic PSE music combined with a home-based functional resistance exercise program have a better effect than resistance exercise program alone for children with SD, aged 5-13 years, and classified as level I to III by the Gross Motor Function Classification System (GMFCS)?

1.2 Define Research Questions

Primary Outcomes

1. Do children with SD in the “loaded STS resistance exercise with PSE Music (PSE) group” improve more on the 1-RM STS than children in the “non-music (NM) group” after the 6-week program?
2. Do children with SD in the PSE group improve more on the goal total score of Gross Motor Function Measure (GMFM) than children in the NM group after the 6-week program?
3. Do children with SD in the PSE group "improve more on the scaled score of Pediatric Evaluation of Disability Inventory (PEDI) Mobility and Self-Care domains than children in the NM group after the 6-week program?

Secondary Outcomes

4. Do children with SD in the PSE group are superior in exercise involvement (motivation, adherence, and volume) than children in the NM group during the 6-week program?
5. Do children with SD in the PSE group improve more on the kinematic motor control related variables (smoothness, directness, and movement time of STS movement) than children in the NM group after the 6-week program?
6. Do children with SD in the PSE group improve more on the gait parameters (speed, cadence, stride length) than children in the NM group after the 6-week program?

1.3 Study Hypotheses

Primary Outcomes

Hypothesis 1

Null hypothesis (H_0): Children with SD in the PSE group would not improve differently on the 1-RM STS from children in the NM group after the 6-week program.

Alternative hypothesis (H_1): Children with SD in the PSE group would improve more on the 1-RM STS than children in the NM group after the 6-week program.

Hypothesis 2

Null hypothesis (H_0): Children with SD in the PSE group would not improve differently on the goal total score of GMFM from children in the NM group after the 6-week loaded STS exercise program.

Alternative hypothesis (H_1): Children with SD in the PSE group would improve more on the goal total score of GMFM than children in the NM group after the 6-week program.

Hypothesis 3

Null hypothesis (H_0): Children with SD in the PSE group would not improve differently on the scaled score of PEDI Mobility and Self-Care domains from children in the NM group after the 6-week program.

Alternative hypothesis (H_1): Children with SD in the PSE group would improve more on the scaled score of PEDI Mobility and Self-Care domains than children in the NM group after the 6-week program.

Secondary Outcomes

Hypothesis 4

Null hypothesis (H_0): Children with SD in the PSE group would have no difference in exercise involvement (motivation, adherence, and volume) from children in the NM group during the 6-week program.

Alternative hypothesis (H_1): Children with SD in the PSE group would have more exercise involvement (motivation, adherence, and volume) than children in the NM group during the 6-week program.

Hypothesis 5

Null hypothesis (H_0): Children with SD in the PSE group would not improve differently on the kinematic motor control related variables (smoothness, directness, and movement time of STS movement) from children in the NM group after the 6-week program.

Alternative hypothesis (H_1): Children with SD in the PSE group would improve more on the kinematic motor control related variables (smoothness, directness, and movement time of STS movement) than children in the NM group after the 6-week program.

Hypothesis 6

Null hypothesis (H_0): Children with SD in the PSE group would not improve differently on the gait parameters (speed, cadence, stride length) from children in the NM group after the 6-week program.

Alternative hypothesis (H_1): Children with SD in the PSE group would improve more on the gait parameters (speed, cadence, stride length) than children in the NM group after the 6-week program.

1.4 Operational Definitions

1.4.1 Children with Spastic Diplegia (SD)

In this study, children with SD were defined as children with spastic CP who have arm involvement less than leg involvement, were classified as GMFCS level I-III, and aged 5-13 years. The GMFCS level was used to classified children with CP based on their gross motor function (Palisano et al, 2008). Children classified as level I could walk without limitations. Children classified as level II walk with limitations. Children classified as level III walks using a hand-held mobility device.

1.4.2 Loaded Sit-to-Stand (STS) Resistance Exercise Program

The loaded STS exercise program is a functional progressive resistance exercise with STS movements. The program consists of a set of loaded STS with a load at 50% 1-RM STS until voluntary fatigue and 2 sets of loaded STS with a load at 20% 1-RM STS for 10 repetitions. The exercise was usually implemented at home with a frequency of 3 times a week for 6 weeks. The rate of progression was every 2 weeks.

1.4.3 The PSE Music (PSE) Group

Children in this group participated in a 6-week loaded STS exercise program with a set of pre-recorded, individualized therapeutic PSE music. They were instructed to exercise with therapeutic PSE music which was aimed to increase fun and enhance motor control during the 18 scheduled sessions. In addition, they also received their routine treatment program, including physical therapy, occupational therapy, etc.

1.4.4 The Non-Music (NM) Group

Children in this group participated in a 6-week loaded STS exercise program without music. In addition, they also received their routine treatment program, including physical therapy, occupational therapy, etc.

1.4.5 PSE Music

The PSE music in this study was defined as a pre-recorded synchronous music designed individually to increase fun and enhance the loaded STS movement of the subject. The music was composed using the Patterned Sensory Enhancement (PSE) technique with a faster tempo than the baseline loaded STS performance which aimed to improve the transfer between horizontal to vertical momentum during chair rising. The PSE technique will be discussed in more detail in Chapter 2 and 3.

1.4.6 One-Repetition Maximum of the Loaded Sit-to-Stand (1-RM STS)

The 1-RM STS represents the functional muscle strength and was defined as the maximal load one is capable of carrying while standing up 1 time without falling and was measured by the loaded STS test (Gan and Liao, 2002). The detailed procedure will be discussed in Chapter 3.

1.4.7 Gross Motor Function Measure (GMFM) Goal Total Score

Scores of GMFM were used to represent the "motor capacity" in the present study. The term "capacity" is used to describe what a person can do in a standardized, controlled environment defined by Holsbeeke et al (Holsbeeke et al, 2009). The GMFM is a standard criterion-referenced test designed to measure change in gross motor function in persons with CP(Russell et al, 2002). The standing dimension (D) and the walking, running & jumping dimension (E) was chose as the goal dimensions in this study. The scaled score of GMFM-66 computed from the Gross Motor Ability Estimator (GMAE) was also used to measure gross motor function of participants.

1.4.8 Pediatric Evaluation of Disability Inventory (PEDI) Mobility and Self-Care Domains

Scores of PEDI were used to represent the capability and performance in the present study. The PEDI is a standardized assessment of the functional ability of children. Two of the 3 domains were used in this study, which were the Mobility and the Self-Care domains. For each domain, scaled scores of Functional Skills scale and Caregiver Assistance scale were calculated after assessing the child's "capability" and the "performance" of daily functional activities (Haley et al, 1992). "Capability" is defined as what a person can do in his/her daily environment. "Performance" is used to describe what a person actually does do in his/her daily environment (Holsbeeke et al, 2009).

1.4.9 Exercise Motivation

The motivation is defined as "the mental functions that produce the incentive to act; the conscious or unconscious driving force for action" (World Health Organization, 2007). In this study, the exercise motivation was assessed using the Intrinsic Motivation Inventory-Chinese version (IMI-C) after the 6-week loaded STS exercise (http://www.psych.rochester.edu/SDT/measures/ intrins.html).

1.4.10 Exercise Adherence

Adherence is defined as "the extent to which the patient follows medical instructions" (Sadate, 2001). The exercise adherence in this study was defined as the percentage of suggested exercise sessions completed during the 6 weeks loaded STS exercise program.

1.4.11 Exercise Volume

The exercise volume was defined as "the total repetitions of loaded STS exercise with a load at 50% 1-RM STS completed during the 6-week program". The exercise repetitions were recorded using the exercise logbook by the main caregiver.

1.4.12 Kinematic Motor Control Related Variables (Smoothness, Directness, and

Movement Time of STS Movement)

In this study, the motor control function of STS movement were represented by the smoothness and directness of center of mass (COM) during STS, and time one took to complete STS from movement initiation to full upright standing. Smoothness of the STS movement was assessed by the jerk index, which is the rate of change of acceleration normalized by the movement duration and distance of the total body's COM (Takada et al, 2006). Higher jerk index is related to poor movement control (Sjolander et al, 2008). Directness of the STS movement was defined as the ratio of actual path length of COM to distance between the starting and termination point of the COM. Smaller ratio is associated with more direct and efficient movement. Movement time was regarded an integral component of motor control. Longer movement time of STS was reported in children with CP and was related with compensatory movement strategy (Hennington et al, 2004; Park et al, 2003; Savelberg et al, 2007). Further detail will be discussed in Chapter 3.

1.4.13 Gait Parameters

The gait speed was defined as the self-selected gait speed and was calculated using the time it took the child to walk the 10-m distance converted to meters per minute. The cadence was defined as steps walked per minute. The stride length was distance travelled in two steps.

Chapter 2. Literature Review

2.1 Children with Cerebral Palsy (CP)

Cerebral palsy (CP) describes a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain (Rosenbaum et al, 2007). CP is a heterogeneous condition and is usually divided into 3 groupings by their predominate neuromotor abnormalities, categorized as spastic, dyskinetic or ataxic (Surveillance of Cerebral Palsy in Europe, 2000). The prevalence rate of CP has been reported between 1.5 and 3 per 1000 live birth (Andersen et al, 2008). Moreover, the spastic diplegia (SD), which is defined as the lower limbs more affected than the upper ones, is the most common subtype of CP with the prevalence rate as 34% to 38% in CP group (Andersen et al, 2008; Westbom et al, 2007).

Children with CP are recognized by delayed gross motor development and the concomitant activity restrictions attributed to neuromuscular deficits (Beckung et al, 2007; Rosenbaum et al, 2007). These impairments include weakness, spasticity, abnormal movement patterns, decreased movement speed, and poor coordination (Giuliani, 1991; Østensjø et al, 2004). Latest study found that the gross motor function of children who could not walk independently might begin to decline after the age of 7 years 11 months (Hanna et al, 2009). Thus, the primary goal of rehabilitation interventions is to maximize children’s functioning. This goal may be accomplished by changing factors related to the activity and participation domain based on the framework of World Health Organization’s International Classification of Functioning, Disability and Health (ICF) model (World Health Organization, 2007).

Several studies have examined the relationships between impairments, activities and participation for children with CP. For example, the positive correlation between lower extremity (LE) muscle strength and function has been recognized in previous studies (Damiano and Abel, 1998; Damiano et al, 2000; Damiano et al, 2001; Eek and Beckung, 2008; Goh et al, 2006; Kramer and MacPhail, 1994; Liao et al, 2005; Ross and Engsberg, 2007). Recently, a cross-sectional study evaluated the strength and spasticity simultaneously of 97 ambulatory children with SD CP showed that the aggregate strength of LE is highly related to gross motor function measured by the 66-item Gross Motor Function Measure (GMFM) ($r=.83$, $p<.01$) and there is no significant relationship between spasticity and gross motor function ($r=.27$, $p>.05$) (Ross and Engsberg, 2007). With regard to the participation of daily activities usually assessed by the Pediatric Evaluation of Disability Inventory (PEDI) in children with CP, it is found that the GMFM-66 score is a very strong predictor, accounting for 88% of the variance in Mobility, 76% in Self-Care, and 57% in Social Function of the PEDI in children with CP aged between 2 to 8 years (Østensjø et al, 2004). The importance of motor control function has been noticed by researchers as well. It is proved that the movement quality of reaching in children with CP is significantly correlated with functional performance in daily life. For children with bilateral spastic CP, the smoothness and directness of reaching movement is positively correlated with the total score of PEDI ($r=.49-.77$, $p<.05$), especially with the Self-Care domain (van der Heide et al, 2005). To summarize, muscle weakness and poor motor control are highly associated with the level of activity limitation and participation restriction in children with CP. Because recent studies have suggested that increasing LE muscle strength has positive effects for children with CP (Fowler et al, 2007), the following session will review studies focused on the effects of LE resistance exercise in this population.

2.2 Lower Extremity (LE) Muscle Resistance Exercise for Children with CP

LE resistance exercise was defined as prescribed exercises for the lower limbs, with the aim of improving strength and muscular endurance, that are typically carried out by making repeated muscle contractions resisted by body weight, elastic devices, masses, free weights, specialized machine weights, or isokinetic devices (Verschuren et al, 2008). For children with spastic CP, since previous studies have proved that the spasticity and muscle coactivation do not increase after resistance exercise (Damiano et al, 1995b; Fowler et al, 2001; Healy, 1958), there has been growing importance placed on the resistance training in physical therapy intervention. Consequently, this session will focus on issues pertinent to the effects and protocols of research on resistance training. Studies focused on investigating effects of LE resistance exercise for children with CP were listed in Table 1. Data of participants, study design, prescribed exercise program, and outcome of training were extracted.

2.2.1 Effect of LE Resistance Training for Children with CP

The review identified 15 articles reporting 12 resistance training protocols (Table 1). Most of the studies were a single group, repeated-measures design. There were only 7 studies included a non-strengthening control group. Almost all studies reported positive effects on the body function and structure components of the ICF, such as improvements in muscle strength, gait, energy expenditure, and self concept. Among the 14 studies assessed the increments in strength or training load, there was only 1 study showed no significant increase in strength compare with the control group. This result may be due to the insufficient training intensity provided to the post-operation participants (Patikas et al, 2006). For outcome measures from gait analysis, all studies showed an improvement in crouch gait (Damiano et al, 1995a; Damiano and Abel, 1998; Engsberg et al, 2006; Lee et al, 2007; Unger et al, 2006). Two of 3 studies reporting energy expenditure as outcome showed a positive effect (Eagleton et al, 2004; Liao et al, 2007). In recent 2 studies, changes in self concept after receiving resistance training program were investigated and revealed inconsistent results (Dodd et al, 2004; Unger et al, 2006). Contrary to the positive effect of a school-based resistance training program on body image discovered in adolescent with CP, a home-based program focused on school-aged children revealed a significant decrease in scholastic competence and social acceptance compared with the control (Dodd et al, 2004; Unger et al, 2006). The authors of the latter study suggested that the detrimental impact of exercise on self concept might be due to reduced time for doing homework or interacting with others (Dodd et al, 2004).

The most frequently used outcome measures in the activity component of ICF were GMFM, gait speed, stride length, and cadence. Six of 8 studies showed a positive improvement in score of GMFM (Damiano and Abel, 1998; Engsberg et al, 2006; Lee et al, 2007; Liao et al, 2007; MacPhail and Kramer, 1995; Morton et al, 2005). However, effect of resistance training on walking performance is inconsistent. There were 3 out of 11 studies reported an increase in gait speed (Damiano and Abel, 1998; Eagleton et al, 2004; Lee et al, 2007).

Only 2 studies investigated the effect of resistance training on psychological aspect (quality of life and well-being) and reported a positive influence (Engsberg et al, 2006; McBurney et al, 2003).

From the above, it was concluded that resistance training can increase LE strength, improve gait pattern, and promote gross motor function for children with CP. However, there was no study investigated effects on participation.

2.2.2 Prescription of LE Resistance Exercise for Children with CP

Generally, there are 5 components of exercise prescription, which are mode, intensity, frequency, duration, and rate of progression (American College of Sports Medicine, 2000). The training guidelines, announced by the Canadian Society for Exercise Physiology, indicated that the resistance training for children and adolescents should be done 2 to 3 times per week on non-consecutive days, with moderate intensity (50-60% 1-RM) and higher repetitions (15-20 repetitions) for 1-2 sets initially, progressing to 4 sets of 8-15 repetitions for 8-12 exercises (Behm et al, 2008). The training session should begin with a 5 to 10 minutes dynamic warm-up period and cool-down with less intense activities and static stretching (Behm et al, 2008).

For children with neurological disorders such as CP, despite there is little evidence to identify the optimal mode, frequency, intensity, and duration of the resistance training program (Verschuren et al, 2008), there are some consensus on resistance training prescription. It is noticed that there are generally 2 main kinds of resistance training programs according to the exercise mode. Traditionally, resistance exercise is designed as a single-joint, open-kinetic chain movement. As increasing emphasis is placed on the concept of task-specific training, there were increasing studies assigned resistance exercise in a more functional movement pattern. This resistance training program which focused on multiple-joint, closed-kinetic chain movements is known as the functional resistance training program (Blundell et al, 2003).

In order to determine the mode of resistance exercise in the present study, 7 RCTs of the effectiveness of resistance exercise for children with CP were reviewed, considering that the results of RCTs are most unlikely to be inflated. Among them, 6 studies incorporated functional resistance training programs and all demonstrated a positive training effect (Dodd et al, 2003; Dodd et al, 2004; Lee et al, 2007; Liao et al, 2007; Patikas et al, 2006; Unger et al, 2006). The effect size I proposed by Cohen of each RCTs were calculated and listed in Table 2. It is found that there were a small to medium effect on strength, a small to medium effect on gait pattern, a small effect on GMFM, and a medium to large effect on gait speed and stride length (Dodd et al, 2003; Lee et al, 2007; Liao et al, 2007; Unger et al, 2006). Programs that brought out larger effects are characterized by specifying the procedure to determine the training load (Liao et al, 2007).Therefore, the loaded sit-to-stand exercise mode in which the resistance can be quantified objectively was chosen for the present study.

Other components of the functional resistance training programs provided in previous studies are as follows. The training intensity is different across studies, and ranged from the lowest 50% 1-RM to 6 to 12-RM (about 57-75% 1-RM) for children with CP (Gan, 2000). Frequency and duration is 3 times per week for 5-8 weeks. The progression rate is usually every 2 weeks. For each training session, it usually takes 20 to 60 minutes to complete. Furthermore, it is suggested that children younger than 5 are less likely to consistently produce maximal effort and are not appropriate to participate a resistance training program (Damiano and Abel, 1998). These factors were all considered while designing the loaded STS exercise in the present study.

2.2.3 Effects of Load on STS Performance for Children with CP

STS transfer is a fundamental movement in daily activity. The ability to rise from chair is a prerequisite for independent walking and children with CP is known to have difficulty standing up. However, not until recently have researchers investigated the biomechanical characteristics of the STS movement in children with spastic CP. The kinematics results obtained from motion analysis revealed that children with CP take longer time to stand up than typically developed children (Gan, 2000; Hennington et al, 2004; Park et al, 2003). They also produce more anterior pelvic tilt and hip flexion during STS (Park et al, 2003). Thus, it is suggested that children with spastic CP perform STS transfer with a different movement strategy. Furthermore, it is found that the smoothness of STS movement on the horizontal plane is poorer (Lin, 2005). As for the kinetic data, the extension moment and power of knee joint are lower in children with CP (Lin, 2005; Park et al, 2003). These results may be explained by the impaired motor control and muscle weakness in this population.

The immediate effects of providing loads during STS movement were analyzed and it was found that there was a significant increase in hip and knee extension moment and a trend of improved smoothness of STS movements along the anterior-posterior direction under the loaded condition (Lin, 2005). The smoothness of movement was represented by the number of movement units (MUs). An MU consists of 1 acceleration and 1 deceleration in the joint velocity profile. According to Lin's study, for children developed typically, aged between 5 to 12 years, the MUs of the total body center of mass (COM) on the horizontal direction were ranged between 1 and 2 and there was only 1 MU on the vertical direction (Lin, 2005). For children with CP, there were 7 out of 10 subjects performed the STS movement with more than 2 MUs in the horizontal plane and 3 subjects with more than 1 MU on the vertical plane in the natural condition (Lin, 2005). In the loaded condition, the smoothness over the horizontal plane improved in 4 subjects (Lin, 2005). In sum, external loads could increase the extension moment during STS and probably have the potential to improve motor control for children with CP.

2.2.4 Summary

Although evidence supported the training effects of loaded STS exercise, the long term effects and effects on improving participation need further investigation. In addition, the compliance of a conventional home-based exercise for school-aged children is not very good and it is proposed that the exercise program should be meaningful and interesting to increase compliance (Bryanton et al, 2006). It has been suggested that listening to music during exercise can promote psychophysical well-being and may be able to increase exercise adherence (Karageorphis and Terry, 1997). Hence, the following session will introduce the effects of music during exercise.

2.3 Effects of Therapeutic Music when Combining with Exercise

Throughout history, it is considered that music has positive effect on human mind and body. Listening to music can affect emotional behavior and stimulate physical response. The psychophysical effect of music in sport and exercise has been examined extensively. Researchers have identified improved motor performance, increased endurance and enhanced exercise experience and mood while exercising with music (Karageorphis and Terry, 1997). Recent studies on the field of Neurological Music Therapy also showed improved motor control while incorporating music or music components with physical rehabilitation programs for neurologically impaired patients (Thaut et al, 1999). Hence, the effects, proposed mechanisms, and principles of combining music with exercise to enhance exercise motivation and motor performance will be reviewed.

2.3.1 Psychological Effect of Music when Combining with Exercise

Music has the potential to make exercise enjoyable (Dyrlund and Wininger, 2008). In the field of sport psychology, music provided during exercise can be divided into 2 kinds, synchronous and asynchronous music. The asynchronous background music can evoke music-related emotional response, but it shows inconsistent effect on improve motor performance due to diverse individual perceptions of the motivation quality of music (Karageorghis et al, 2006; Karageorphis and Terry, 1997). Moreover, music which is not compatible with movement in meter, rhythm, and tempo cannot be used in guiding movement. Therefore, only synchronous music will be discussed and prescribed in the present study. The tempo of synchronous music matches to the physical activity, and can improve mood and enhance work output (Anshel and Marisi, 1978; Hayakawa et al, 2000). However, few studies have investigated the effects of synchronous music. The studies inspected the psychological effects of synchronous music while combining with exercise were listed on Table 3.

Eight studies were reviewed and 7 of them showed that combining synchronous music with exercise has positive effects, such as increased exercise motivation, improved mood, and exercise adherence (Hayakawa et al, 2000; Johnson et al, 2001; Likesas and Zachopoulou, 2006). In 2 studies, questionnaires were used to assess the effects of motivation or mood state while exercise with music, and found better response for the music condition than the non-music condition (Hayakawa et al, 2000; Likesas and Zachopoulou, 2006). There are 2 studies measured exercise adherence while incorporating synchronous music and came up with positive results (Johnson et al, 2001; Marrero et al, 1988). Synchronous music was also reported to increase the speed of sprint running (Simpson and Karageorghis, 2006). Two studies measured the time to exhaustion during cycle ergometer exercise with synchronous music and proved that music can elicit longer exercise endurance (Anshel and Marisi, 1978; Karageorphis and Jones, 2000). The study which aimed to evaluate the influence of music on pain perception during exercise turned out to be no significant effect (Kim and Koh, 2005). Whereas, the subjective reports from participants supported the use of music to increase fun, interest, and positive feelings during exercise (Kim and Koh, 2005; Marrero et al, 1988).

The underlying mechanism of the positive effect of synchronous music is still unclear. It is proposed that rhythm was pleasurable to the individual because it replicates ‘natural forms’ of physical activity (Karageorphis and Terry, 1997). In addition, incorporating music with exercise may divert attention from the perception of difficulty, exertion, boredom, fatigue, and discomforts associated with exercise and promote a more positive mood state and overall engagement (Johnson et al, 2001; Karageorphis and Terry, 1997).

Based on the review, it is regarded that music has important implication as a way to increase exercise motivation, adherence, and number of repetitions. However, most studies focused on the effect of music on single session aerobic exercise for adults. Therefore, we inspected the long-term training effects of synchronous music on exercise adherence and motivation during the functional resistance exercise program for children with CP.

While prescribing music to improve exercise motivation, it is suggested that the effect of music neither depends upon personal preference and familiarity of music, nor the motivational qualities of music (Johnson et al, 2001; Simpson and Karageorghis, 2006). Accordingly, the above principles were considered while composing the therapeutic PSE music in the present study.

2.3.2 Motor Effect of Music when Combining with Exercise

The concept of using music to elicit movement in patients with movement disorders is extended from the work on rhythmic auditory stimulation (RAS). The RAS is 1 of 3 techniques in Neurological Music Therapy for sensorimotor rehabilitation. The auditory rhythm can provide timing information for the patient and help to regulate the temporal and spatial control of movement (Thaut et al, 1999). Studies have shown that RAS can entrain and guide gait patterns for patients with neurological disorders, such as stroke patients, patients with Parkinson's disease, and children with CP (Hausdorff et al, 2007; Kwak, 2007; Thaut et al, 1998; Thaut et al, 2007) (Table 4). Thaut and his colleagues (1998) demonstrated that children with CP can be entrained by the RAS with a tempo 5% faster than the subject's normal cadence. In the first part of their study, the immediate effect of RAS was noted by significantly increases in walking velocity and swing symmetry ratio. In the second part, 6 children underwent a 30-minute daily gait training program at home with pre-recorded RAS tapes. After 3 weeks training, the uncued gait velocity improves 21.2% (Thaut et al, 1998). In Kwak's study, 25 subjects with spastic CP, aged between 6 to 20 years-old were divided into 3 groups and received a 3-week training program. In the "therapist-guided training" group, the music therapist was actively involved in the RAS gait training program. Children of the "self-guided training" group were instructed to execute a gait training program with taped RAS at the first session. After that, the therapist did not actively intervene the training. Participants of the control group had conventional PT. Although the paired t-test showed a significant increase in the stride length, velocity, and symmetry after RAS training in the "therapist-guided training" group, statistical analysis on the improvements of gait parameters revealed no significant difference between the 3 groups (Kwak, 2007). Based on the results of Kwak's study, pre-recorded music was used for the present study.

The RAS technique can only be used in facilitating rhythmic movements. For regulating discrete movements, such as STS and stand-to-sit, the movement patterns need to be first translated into music and then used the musical elements to provide information for feedforward control. The use of music to translate and entrain the temporal, spatial, and force parameters of movement is called the patterned sensory enhancement (PSE) (Thaut, 2005). This Neurological Music Therapy technique incorporates pitch, loudness, sound duration, and harmony for spatial cueing. The tempo, meter, rhythmic patterning, and form of the music are used for temporal cueing. The loudness, harmony, timbre, and tempo can be applied for cueing force (Thaut, 2005).

There are few studies scrutinize the utilization of the PSE technique. Hamburg and Clair (2003) recruited 14 older adults in a movement with music program for 14 weeks. New music was composed to cue movement duration, speed, number of repetitions, and movement dynamics of a set of whole-body movement program. In the middle of the training program (the sixth week), assessment showed a significant improvement in one-leg standing balance and gait speed, and the improvement was maintained throughout the training program (Hamburg and Clair, 2003) (Table 4). The limitations of Hamburg and Clair's study are lacking of control group and no outcome measures assessing the improvement of motor control. In the present study, a control group was included and the motor control of STS transfer was analyzed.

In the previous study conducted in our laboratory, the immediate effect of PSE music on the motivation and movement of the loaded STS is investigated (Peng, 2008). The study compared the performance of children with CP between the PSE music condition (5% increased speed) and the non-music condition. Higher exercise motivation measured by IMI-C is noted. And the children also performed the loaded STS movement with larger knee peak extension power, decreased movement time, and smoother movement analyzed by 3-dimensional movement analysis system (Peng, 2008). There was no obvious carry-over effect immediately after the music was switched off (Peng, 2008). From this study, we found that the loaded STS movement of children with CP can be influenced by the PSE music. However, the long-term training effect is still unclear. Thus, the effect of PSE music after a 6-week loaded STS training was investigated in this study.

2.3.3 Musical Information Processing and Movement Synchronization

As mentioned above, listening to appropriate music can affect the exercise performance. The information containing in a piece of music is abundant and involves different brain areas to process (Stewart et al, 2006). In fact, the areas related to rhythm analysis, which could be regarded as one kind of temporal information, are closely matched to areas controlled movement (Lewis and Miall, 2003). This interaction between auditory and motor functions may be responsible for the emergence of movement synchronization to music (Chen et al, 2006).

Based on the review article of Stewart and his colleagues (2006), present knowledge about music processing is discussed (Stewart et al, 2006). Music is processed from the VIIIth cranial nerve through the ascending auditory pathway to the auditory cortex, like sounds. The auditory cortex is located in the superior-temporal plane within the Sylvian fissure. The Heschl's gyrus runs anterolaterally within the superior-temporal plane which contains the primary auditory cortex (Area 41) in the medial side and the secondary auditory cortex (Area 42) in the lateral side. Behind the Heschl's gyrus lies the planum temporal, which can be considered the auditory association area (Area 22) (Stewart et al, 2006).

The musical information can be divided into several components, such as rhythm, pitch, timber, and emotion (Stewart et al, 2006). Rhythm perception and reproduction is mostly related to lateral cerebellum and basal ganglia (Molinari et al, 2003; Stewart et al, 2006). While listening to time intervals that were in integer ratios, the cerebellar anterior lobe is activated as well (Sakai et al, 1999). Other motor regions were also recruited, such as the supplementary motor area and mid-premotor cortex (Chen et al, 2008). Perception of the pitch may be encoded in the secondary auditory cortex (Stewart et al, 2006). During analyzing the sequences of variable pitch, bilateral brain activation was noted in the lateral Heschl's gyrus, the anterior and posterior superior-temporal gyrus with a degree of right lateralization (Patterson et al, 2002). Timber, the sound-color, is mainly processed in the bilateral posterior superior-temporal lobes and the right superior-temporal gyrus (Stewart et al, 2006). Emotional reaction triggered by music may be due to the activation of the amygdala, ventral striatum, orbitofrontal cortex, and mesiolimbic areas (Stewart et al, 2006). In sum, the temporal organization, melodies, and emotional response of music appear to be processed in different pathways. In order to further understand the brain areas related to synchronizing movement to musical rhythm, studies using the rhythm production paradigm will be reviewed.

During synchronization to musical rhythms, interactions between the auditory and premotor cortex was found (Chen et al, 2006). While the ability to perceive and estimate brief interval is crucial for motor control, the underlying mechanism of motor timing was investigated (Mauk and Buonomano, 2004). As for the rhythm perception, it is actually processing the temporal information. Thus, there may be an inherent link between the motor and auditory systems because they both involve in the measurement of time. It is hypothesized that the synchronization of movement to sub-second intervals is related to the motor control system which can measure time with less attention demand (Lewis and Miall, 2003). A review identified the bilateral supplementary motor area, left sensorimotor cortex, right cerebellum, lateral premotor area, left thalamus, basal ganglia, and the right superior temporal gyrus were all involved in this sub-second timing task (Lewis and Miall, 2003). Because the connection between auditory rhythm and motor control system is strong, the unconscious responses to auditory rhythmic stimulation may have the potential to guide movement.

2.3.4 Guiding STS Movement with Music for Children with CP

There are 2 common strategies of STS transfer, the momentum transfer strategy and the stabilization strategy (Hughes et al, 1994). The former is the most efficient way to rise from a chair and predominantly adopted by most healthy people (Scarborough et al, 2007). During the momentum transfer strategy, forward momentum produces by upper-body transfer smoothly into vertical momentum under coordinated control of the whole body. The latter strategy is usually seen in subjects with movement disorders or muscle weakness and is characterized by exaggerated trunk flexion before seat-off. The increasing trunk flexion may help individuals to place their center of mass over their feet before extension and minimize the demanding on balance (Hughes et al, 1994). However, the conservative strategy sacrifices the transfer of momentums and may demand more hip extensors strength, probably leads to failed STS transfer (Savelberg et al, 2007). As mentioned above, children with spastic CP stand up with longer time and more trunk flexion, corresponded with the description of the stabilization strategy. Therefore, the primary goal of guiding STS movement with PSE music should be promoting the controlled transition between horizontal momentum and vertical momentum in order to increase successful rising from a chair.

There are some considerations while combining music with STS movement. In Kwak's work, the details of RAS delivery techniques in gait training for children with CP were described (Kwak, 2007). There may be some useful information while designing the PSE music in the present study. First, the whole-body movement pattern in children with CP is unique and an individualized program was required (Kwak, 2007). Second, deformity of bones and contracture of joints may influence the treatment effect, as well as the balance and equilibrium abilities (Kwak, 2007). Therefore, children with obvious musculoskeletal abnormalities were excluded and participants were stratified by their gross motor function. Third, the assistive walking device used by the subject might alter the application of RAS (Kwak, 2007). It is important to incorporate appropriate assistive device in the training program, such as the footwear, orthosis, and chair height in the present study. During the loaded STS exercise, footwear and orthosis were not used unless necessary. Appropriate chair height was selected based on child's ability. Finally, the self-discipline, family support, and personality may all be responsible for the training effects (Kwak, 2007). Therefore, children were encouraged to complete the exercise program and kept an exercise logbook in this study.

2.3.5 Summary

To sum up, it is contended that synchronous music and PSE technique have influence on exercise motivation and motor control. Previous studies indicated that children with CP respond to auditory rhythm. Hence, there is a possibility to motivate and entrain children with SD using synchronous music composed to guide the movement of loaded STS exercise migrating to a more efficient movement pattern and increasing motor abilities.

2.4 Factors Influencing the Effects of Resistance Exercise

There are some potentially confounding factors which may influence the training response of the loaded STS exercise, such as age, sex, and severity. However, there were no study compared the effect of resistance exercise for children with CP in different age groups, gender, or gross motor function. Reviews of the resistance exercise programs for children developing typically suggested that the relative gain in strength of pre-pubertal children was greater than or equal to late pubertal and young adult men (Faigenbaum, 2000; Malina, 2006). Nevertheless, the absolute strength gain was smaller for the pre-pubertal children (Faigenbaum, 2000; Malina, 2006). The review also implied that the sex difference in response to resistance training is generally small (Malina, 2006). Since the muscle strength is different between GMFCS levels for children with CP, increments of strength after resistance training is probably varied (Eek and Beckung, 2008). Accordingly, subjects in the present study were stratified by their age and GMFCS level and then randomly assigned to either experimental or control group.

The resistance training response is direct related to the number of training session completed and the training volume (Behm et al, 2008). The training volume is determined by the number of repetitions per set and number of sets per exercise. Consequently, the training volume completed by participants was documented in the exercise logbook. Moreover, previous resistance training status may affect the training response. A meta-analysis of 140 studies on dose-response for strength development in healthy adults revealed that the treatment effects are different between trained and untrained participants (Rhea et al, 2003). The effect size is significant smaller for the participants who have been weight training for at least 1 year before the study (Rhea et al, 2003). Thus, the resistance exercise components in routine physical therapy, occupational therapy or vigorous physical activity, such as swimming or physical education class, may also have influences on the training effects, and were recorded. For children with CP, the unfavorable impact of resistance training on self-concept scholastic competence was noted (Dodd et al, 2004). For this reason, the time spent for doing homework was also recorded.

2.5 Measurements of the Effects of PSE Music

2.5.1 Loaded Sit-to-Stand (Loaded STS) Test

The loaded STS test is developed to measure the maximal load a child is capable of carrying while standing up 1 time without falling, which is referred to the 1-RM STS. The testing procedure is standardized and has high test-retest (ICC=.94) and interrater reliability (ICC=.94) for children with SD (Gan and Liao, 2002; Liu et al, 2004). The 1-RM STS normalized by body weight is the index of STS functional muscle strength. The validity of the normalized 1-RM STS is developed via the fair to high correlations with LE isometric muscles strength (r=.40-.78, p<.05). The normalized 1-RM STS was correlated with both the GMFM total scores and goal dimension scores (r=.76-.80, p<.01) for children with mild SD (Liao et al, 2005). The correlation of the normalized 1-RM STS with gait speed and energy efficiency was also significant (r=.37-.39, p<.05) (Gan and Liao, 2002). The 1-RM STS showed a medium effect size of 0.70 after a 6-week loaded STS exercise program for children with SD (Liao et al, 2007).

2.5.2 Gross Motor Function Measure (GMFM) Dimension D and E

The GMFM is a standard criterion-referenced test designed to measure change in gross motor function in persons with CP (Russell et al, 2002). The GMFM-88 has 88 items and is grouped into 5 dimensions: (A) lying and rolling, (B) sitting, (C) crawling and kneeling, (D) standing, and (E) walking, running & jumping. The psychometric properties of GMFM have been examined extensively and showed good to excellent reliability (Harvey et al, 2008). The validity was also supported by evidence (Harvey et al, 2008). The GMFM dimension D and E score showed a small effect size I of 0.24 after a 6-week loaded STS exercise program for children with SD (Liao et al, 2007).

2.5.3 Pediatric Evaluation of Disability Inventory (PEDI) Mobility and Self-Care Domains

The PEDI is a clinical assessment instrument that evaluates functional capabilities and performance in young children (age below 7.5 year-old) and children with disabilities whose functional abilities are expected to fall below the 7.5 year-old level (Haley et al, 1992). The PEDI has 3 domains: Self-Care, Mobility, and Social Function. For each domain, 3 independent scaled scores ranged from 0 to 100 can be calculated from raw score to reflect the capability and performance of the child in his or her daily environment. The 3 scaled scores are Functional Skills, Caregiver Assistance and Modifications (Haley et al, 1992). The PEDI is administered by a trained professional based on either personal familiarity with the child or a structured interview of the parent (Haley et al, 1992). The reliability and validity of the Chinese version of PEDI were examined, and the results supported its use in children with CP (Chen et al, 2009). A review investigated the psychometric properties of PEDI for children with CP and discovered that the Mobility domain performed better than the Self-Care and Social Function domains for reliability and concurrent and discriminative validity (Harvey et al, 2008). For the responsiveness of PEDI, the scaled scores of Functional Skills and Caregiver Assistance for both Mobility and Self-Care domains are reported to have a large effect size ranging from 0.74 to 0.98 after a functional therapy program for children with CP (Vos-Vromans et al, 2005).

2.5.4 Intrinsic Motivation Inventory-Chinese Version (IMI-C)

The original Intrinsic Motivation Inventory is a multidimensional measurement device intended to assess participants' subjective experience related to a target activity in laboratory experiments and contains 6 subscales, which are participants' interest/enjoyment, perceived competence, effort, value/usefulness, felt pressure and tension, and perceived choice while performing a given activity. In the present study, the loaded STS exercise was the target activity and the interest/enjoyment subscale was translated to Chinese and used to measure the self-reported exercise motivation. The interest/enjoyment subscale has 7 items and the internal consistency assessed by Cronbach alpha was 0.78 (McAuley et al, 1989). The 1 week test-retest reliability of the interest/enjoyment subscale for undergraduate students after an endurance field test was 0.86 assessed by intraclass correlation coefficient (Tsigilis and Theodosiou, 2003). In our previous study, the test-retest reliability of the IMI-C for children with SD after 8 repetitions of loaded STS exercise was 0.86 assessed by intraclass correlation coefficient (Peng, 2008).

2.5.5 Exercise Adherence and Volume

Exercise adherence and volume are generally measured in either a subjective or objective way. Objective measure may be more accurate, but needs some electronic devise, such as accelerometer. Parental-report or self-report adherence is more accessible, but the results may be overestimated (World Health Organization, 2003).

2.5.6 Motor Control Variables of the STS Movement

Kinematic motor control variables were collected by motion analysis system. The control of total body's COM (jerk index and directness) was used to represent movement smoothness and efficiency. The movement time of a single STS was used to represent the temporal component of STS control.

To measure movement smoothness, the jerk cost, which is the rate of change of acceleration, was used (Hogan, 1984). Because the jerk cost increases with movement duration and distance, so time- and distance-normalized jerk cost is used and expressed as the jerk index (Kitazawa et al, 1993). The reliability of the jerk index for chewing movement in healthy adults was examined and there was no significant difference in 2 separate sessions (Takada et al, 2006). The validity of the jerk index was supported by comparing the reaching movement between different age groups and between patients with neurological disorders and control subjects (Cozens and Bhakta, 2003; Yan et al, 2000). As for the responsiveness, the jerk index showed a significant difference between the loaded STS movement with PSE music and loaded STS movement without music in children with SD (Peng, 2008).

The directness was calculated by dividing actual path length by distance. The ration was usually used for evaluating motor control of upper extremities (Wu et al, 2007). The validity of using directness in STS movement was partly supported by

Peng's study (Peng, 2008).

The movement time of STS was the most common used variables while analyzing the STS movement of children with CP (Hennington et al, 2004; Park et al, 2003). Previous studies found significant longer movement time for this population (Hennington et al, 2004; Park et al, 2003). The immediate effect of PSE music on movement time of STS was found in Peng's study (Peng, 2008).

Chapter 3. Methods

3.1 Experimental Design

This was an experimental study with single blind, randomized block design to investigate the effects of PSE Music with the loaded STS exercise. Participants were stratified by their age (5 - 8.4 year-old and 8.5 - 13 year-old) and gross motor function (GMFCS I-II and III) first, and then randomly assigned to the "PSE Music (PSE) group" and the "non-music (NM) group". For children in the PSE group, individualized therapeutic music based on the PSE principle was incorporated with the 50% 1-RM loaded STS exercise for 18 sessions during the 6-week program. For children in the NM group, they executed loaded STS exercise without musical cues for the 18 scheduled sessions. Children and their parents were informed of the 2 possible allocations.

3.2 Participants

After calculating the effect size of motivation (ES I= 1.3) from the work of Likesas and Zachopoulou and the effect size of single leg support and gait speed improvements (ES I= 0.8-1.0) from the work of Hamburg and Clair (Hamburg and Clair, 2003; Likesas and Zachopoulou, 2006), the sample size in this study was calculated as 24 participants with alpha set at 0.05 for a one-tailed test, power at 0.8, and attrition considered as 10%.

The inclusion criteria of this study were: (1) children with SD, aged 5 to 13 year-old, and GMFCS level between I to III, (2) able to stand up from a chair independently and maintain standing for more than 2 seconds without falling, (3) able to follow verbal instructions, and (4) parental commitment to allow participation without altering current therapy or activity. The exclusion criteria were (1) have orthopedic surgery, selective dorsal rhizotomy, or use of a baclofen pump within 6 months, (2) have orthopedic problems or other medical conditions preventing the child from joining the resistance exercise program, such as obvious LE joint contractures, uncontrolled epilepsy, or cardiopulmonary problems, (3) hearing loss or using hearing aid, and (4) have mental disorders, such as pervasive developmental disorders and attention-deficit and disruptive behavior disorders.

3.3 Experimental Procedures

The experimental procedure was illustrated in Figure 1. After obtaining signed consent forms that were approved by the Human Subjects Review Committee at National Taiwan University Hospital, Taiwan, participant were stratified and randomly assigned to the PSE group or NM group by drawing, which was executed by a person who was not involved in this study.

Participants were evaluated by the same blind tester (Y-C Peng, PT) on 2 separate days and basic information was gathered, such as body weight, body height, previous resistance exercise experience, frequency and content of current rehabilitation programs and physical activities. On the first day, the movement analysis of STS was completed in the Orthopedic Engineering and Movement Analysis Laboratory to evaluate the motor control of STS movement. On the second day, the results of GMFM, PEDI and gait speed were gathered at the Laboratory for Pediatric Studies. The load of 1-RM STS was also measured by the loaded STS test. Six repetitions of loaded STS exercise with a 50% 1-RM STS load were complete by the subjects and the baseline exercise motivation was evaluated using the IMI-C. Also, the movement of loaded STS exercise with a 50% 1-RM STS load was video-recorded using a digital video camera and analyzed by the main investigator (T-H Wang, PT) who was responsible for conducting the exercise and the music therapist (Y-L Chen, MT). For children in the PSE group, the PSE music was composed based on the pattern and temporal characteristics of the movement with a 5% increased in tempo. Finally, an assessment of musical aptitude was conducted by using the Primary Measures of Music Audiation (PMMA) (Gordon, 1986). The results were served as a potential confounding factor.

The 6-week loaded STS exercise was introduced by the main investigator on a home visit. For the PSE group, the body vest, free weights, and individualized therapeutic music CD were given to the caregiver. The maximal training load was set at

50% of 1-RM STS based on the review. The main investigator instructed the child how to play music and conduct the loaded STS exercise with music at home. Caregivers also received instructions to supervise or help child. One exercise session was completed under the supervision of the main investigator and caregiver. The exercise logbook was handed into the caregiver to record the date, weight, repetition number, adverse effects of the exercise, and time spent for exercise and homework (Appendix 4).

Every 2 weeks, the loaded STS test was conducted during a home visit to modify the training load. To modify the PSE music, 6 repetitions loaded STS exercise with the load at 50% of 1-RM STS was performed by the children and the sagittal plane movement videotape. After analyzing the recorded movements, a pre-recorded PSE music with appropriate meter was selected and the tempo of the music was adjusted to fit the child's movement using the Cool Edit 2000 software (Syntrillium Software Corp.). Then, the children executed 1 exercise session under the supervision of the caregiver. The main investigator checked the quality of the loaded STS exercise and helped the children and caregiver to do the exercise in a proper way. Telephone interview was done every week to ensure exercise adherence.

For the NM group, the procedure was similar to the PSE group except that the NM group did not have music during the exercise sessions.

The post-training evaluation was performed after the completion of the exercise program by the same blind tester. The procedures, locations, and the diurnal time of the test were the same as the pre-training evaluation except that there was no need to record the 6 repetitions of loaded STS. In addition, the exercise motivation and adherence for the past 6-week training were gathered (Figure 1).

3.3.1. Loaded STS Resistance Exercise Program

Participants of both groups were asked to carry out the loaded STS exercise at home, 3 times a week for 6 weeks, under the supervision of the caregivers. The height of the chair was set at 100% lower leg length (knee joint line to the floor) of the child. For children classified as GMFCS level III, who have difficulties to stand up, a higher chair of 120% lower leg length was used to make the exercise easier. A secured desk was placed in front of the child to prevent falling if necessary.

Each training session began with a 10 minutes warm-up exercise, including a set of dynamic warm-up exercise and gentle stretching of lumbar extensors, hip adductors, hamstrings, and ankle plantar flexors. The dynamic warm-up exercise contained a stepping or walking activities for 1 to 2 minutes and a controlled STS or squat to stand activities for 5 to 10 times with or without external support. The stretching exercise contained two sets of 15-second stretching movements for 3 times (Appendix 1 and

Appendix 2).

Then, the subject performed the loaded STS exercise with the load at 20% of 1-RM STS for 10 repetitions. After a 1 to 2 minutes rest, the child performed loaded STS with the load at 50% of 1-RM STS repeatedly without stopping until fatigue. Caregivers were asked to encourage the child to perform as many repetitions as possible. After another 2 to 3 minutes rest, the child performed the loaded STS exercise with the load at 20% of 1-RM STS for 10 times again. The session ended with a cool-down static stretching exercise of quadriceps and ankle plantar flexors similar to the warm-up. The training load was progressed every 2 weeks according to the results of the latest loaded STS test.

3.3.2. PSE Music

While executing the second set of the loaded STS exercise program, the PSE group performed the 50% 1-RM loaded STS exercise program with the individualized therapeutic music which was composed following the principles of PSE. The specific components of the music were designed based on video recorded movement of the loaded STS with a load at 50% of 1-RM STS. The STS movement could be divided into 2 phases. The phase I is from the initiation of the STS movement to the moment of seat-off. The phase II begins after seat-off until the body reaches the standing posture. In order to facilitate momentum transfer from horizontal to vertical, the phase I duration was reduced while prescribing the PSE music. Principles of prescribing the PSE music are described as follows:

(1) The PSE music was taped music with a 20- to 30-second prelude for children to prepare the movement.

(2) The tempo of the PSE music was increased 5% above the average speed of phase I. Two to three successful STS trials with shorter phase I durations were selected from the 6 assessment trials. If the variability of phase 1 duration was large (coefficient of variance > 15%), the shortest one was used to determine the tempo. The tempo was determined by shortening the phase I duration in order to speed up the initiation of STS movement and reduce excessive trunk flexion. For example, if a child's average phase I duration is 0.75 seconds, we then took 0.75 seconds as "a beat" and calculated the 5% increased tempo as (60/0.75) * 105% = 84 beats per minute.

(3) The meter of PSE music were 2/4, 3/4, 4/4, or others depending on the proportion of phase I and phase II. For example, if the proportion is 1:1, the music meter is 2/4; if the proportion is 1:2, the music meter is 3/4; if the proportion is 1:3, the music meter is 4/4. The ratio of phase II/phase I was

rounded into integer following at the 10th position after the decimal point. The rhythm contained short and running notes to cue the initiation of seat-off.

(4) The pitch of PSE music were descending scales using a narrow register for Phase I, ascending melodic line using a broad register for Phase II, and descending melodic line using a broad register for stand-to-sit according to the COM movement.

(5) Increasing loudness with an accent on the turning point from Phase I to Phase II during STS and decreasing loudness during stand-to-sit.

(6) The harmony of PSE music was simple in order not to complicate the comprehension of the synchronization between the music and the movement. It was increasing spacing of the chord progression during STS, emphasizing on the seat-off with a most rich chord and then decreasing spacing of the chord progression during stand-to-sit.

(7) The timbre of PSE music was the sound modeled from an electric piano by the GarageBand software (Mac, Apple. Inc.).

(8) The individualized PSE music duration was lasted for 20 minutes at least. To add interest, the PSE music was embedded with well-known melodies from children songs, musicals, and classical music, such as “Twinkle Twinkle Little Star”, “Edelweiss”, and “Bach Minuet in G Major”.

(9) For children who had difficulties in maintaining balance after standing (more likely to step forward and loss balance), one measure was added after the preexistent music to encourage standing.

(10) For children who cannot sit down with control (sit down abruptly) or for children whose STS time was disproportionally longer than the time for stand-to-sit, durations of stand-to-sit were also considered while designing the PSE music. For children who usually crashed onto the chair, longer note, broader register, and decreased loudness were used to encourage sit down slowly. For children whose rising time was far longer than the sit-down time, shorter measure was used to facilitate synchronization.

The main investigator instructed the children how to do loaded STS exercise with PSE music during each home assessment. Children listened to the music for 2 minutes to get familiar with the music. Then, the main investigator demonstrated the STS movement for 4 times first and asked the child to follow 4 times with a 50% 1-RM load. After the practice, children executed the exercise by themselves. Children were reminded that they can wait for the next cue to stand up if they mismatched with the rhythm. During the exercise, the main investigator monitored the exercise condition and gave prompt if the children cannot match their movement to the music. The main investigator used verbal cue, visual cue, and modeling to prompt the child when to stand up and sit down.

For the PSE group, the main caregiver was not allowed to provide any cue during the following 5 exercise sessions. But they could remind the child to sit and wait for appropriate timing to stand up. The caregiver was also asked not to play the PSE music in occasions other than exercise.

3.4 Experimental Equipments

3.4.1 Equipments for the Loaded STS Test and the Loaded STS Exercise

For the Loaded STS Test, self designed body vests with different sizes and several pockets were used. Lead weights of 0.25, 0.5, and 1 kg were also prepared. The chair used in the loaded STS test was height adjustable without armrests and backrest. A rope was set up at the child's body height as a cue for full extension of the whole body.

For the loaded STS exercise, a chair at child's home and with suitable height (100% of lower leg length for GMFCS I-II, and 120% of lower leg length for GMFCS III) was used. A rope was also set up at the child's body height as a cue for full extension.

3.4.2 Equipments for Designing, Producing and Playing Music

During assessment of the loaded STS movement, a digital video camera recorder

(DCR-TRV6, SONY) was set up on the side of the child and used to record the sagittal-view of the loaded STS movement. The video was exported to the computer. Movement time and phase durations were analyzed by the PowerProducer software (CyberLink).

The Garageband software (by Mac mini, Apple Inc.) was used to export and edit the music played on the electric piano (YAMAHA) by the music therapist. The music was then converted into a mp3 file. During home-visit assessment, the music was edited by a laptop computer and saved in a CD. During the home exercise period for the PSE group, the music was played by the CD player or computer depends on the equipment the child's family has. The volume was adjusted to about 70 to 80 decibels measured by the decibelmeter (TENMARS TM-102).

3.4.3 Motion Analysis System for STS Movement

The Vicon system contains 7 infrared cameras (VICON512, VICON Motion Systems Ltd., UK) with sampling rate at 60 Hz, controlling hardware modules, and the software Vicon Workstation 4.0. The system captures the 6 degree-of-freedom motion (3 translations and 3 rotations in anatomical planes and their axes). Reflective spherical markers with 1 cm in diameter were placed on the bony landmarks based on the OEMAL marker set: C7, sternal notch, bilateral ear traguses, acromion processes, arm, radial side of elbow axis, ulnar side of elbow axis, ulnar styloid, radial styloid, ASIS, PSIS, iliac crest, greater trochanter, thigh, medial femoral condyle, lateral femoral condyle, tibial tuberosity, fibular head, medial malleolus, lateral malleolus, navicular tuberosity, 5th metatarsal base, 2nd metatarsal head, and heel (Lu, 1997). We added a pelvis marker cluster and 4 wands over thighs and legs to prevent data loss.

3.5 Experimental Measures

3.5.1 The Loaded STS Test

The test began with a dynamic warm-up and stretching exercise and then the tester explained the procedure and demonstrated the STS movement. The chair height was set at 100% lower leg length. For children who were classified as GMFCS level III, the chair height was adjusted to 120% lower leg length to make the task easier. A rope was set up at the child's height to mark the ended position. The starting position was closed to hip flexion at 90°, knee flexion at 105°, and feet flat on the floor. Child was instructed to sit with feet parallel, trunk erect, and arm crossing the chest. Children performed the STS independently in bear feet, without the use of hands. Subjects were allowed to practice STS without load and then with light load for 3 to 4 times in order to familiarize themselves with the movements. The weights were added into the body vest initially as a load equaling to 30% body weight. Children were asked to stand up twice at a comfortable speed and then sit down after 2 seconds. The instruction was “Stand up without moving your feet and waving your arms at your comfortable speed, hold this standing position for 2 seconds, and then sit down slowly. No falling. If you try but cannot stand up, just let us know. It is OK.” The attempt was considered a failure if subjects were: (1) swaying their trunk back and forth several times to initiate the task of standing up, (2) moving their feet out of the force plates, (3) losing balance, (4) unable to maintain a standing position for 2 seconds after standing, or (5) standing up with an obviously asymmetrical posture during test. Based on the ease of performing STS movements, the following trial’s load (increase or decrease by 0.5 to 4kg each trial) was determined. All children took a break of at least 2 minutes between test trials. The weight that the child could carry in the body vest and stand up only once was defined as the 1-RM STS of that child. The 1-RM STS was determined within 10 trials to prevent fatigue.

3.5.2 Gross Motor Function Measure (GMFM) Dimension D and E

The GMFM dimension D and E was conducted as instructed in the GMFM manual. Each item is scored using a 4-point Likert scale (0, does not initiate; 1, initiates; 2, partially completes; 3, completes). Total score from each dimension was divided by the total possible points to produce a percentage score. Both percentage scores of dimension

D and E were averaged to yield a goal total score and was used as the primary outcome. The GMFM-66 computer scoring program, the Gross Motor Ability Estimator, was also used to calculate the scaled score for each participant based on the 37 items tested.

3.5.3 Pediatric Evaluation of Disability Inventory (PEDI) Mobility and Self-Care Domains

The PEDI is a standardized instrument used to measure the capability and performance of functional activities in daily life situations. The Chinese version of PEDI was used in this study through a structured interview with the caregiver. The Functional Skills scale is used to assess whether the activities can be performed or not in most situations. The items are scored as 0 (unable or limited capability) or 1 (capable in most situations).The Caregiver Assistance scale is used to measure the degree or amount of physical assistance required and scored from 0 (total assistance required) to 5 (independent). The raw score of the Functional Skills scale and the Caregiver Assistance scale of the Mobility and Self-Care domains were converted into the scaled score ranging from 0 to 100 and used as the primary outcome.

3.5.4 Intrinsic Motivation Inventory-Chinese Version (IMI-C)

The IMI-C was used to measure the exercise motivation and was assessed during the pre-training evaluation to assess the baseline motivation immediately after a set of 6 repetitions loaded STS exercise. The IMI-C was also assessed in post-training evaluation to evaluate the exercise motivation for the past 6 weeks training. Children were asked to answer the 7 items in the IMI-C based on their feelings. Each item contains a sentence to describe motivation toward the loaded STS exercise with a seven-point Likert scale ranging from 1 (not at all true) to 7 (very true) (Appendix 4). After instructing the children to pick up the best answer described their feelings, the tester read the sentence aloud to them using an interview format to ensure they understand the sentence. There were 2 reverse questions in the IMI-C, and the scores of these 2 items were obtained by subtracting the original score from 8. Then, the average score across the 7 items was calculated.

3.5.5 Exercise Adherence and Exercise Volume

The exercise adherence and volume were measured by self-report of sessions completed during the training program using the logbook recorded by the caregiver.

3.5.6 Motor Analysis of STS Movement

The motor control of STS movement was assessed using the motion analysis system described in 3.4.2. The body weight, body height, leg lengths, and shoulder circumferences was measured. The leg length was defined as the distance between the ASIS to the inferior border of the medial malleolus in supine position. The shoulder circumference was defined as the circumference from the acromion through the axillary fossa and then to the acromion. The data was used to calculate the shoulder joint center. Children were asked to wear only undershirt and underpants to allow attachment of markers. The test began with a dynamic warm-up and stretching exercise then the tester explains the procedure and demonstrates the STS movement. The chair height was set at 100% lower leg length. For children who cannot stand up successfully, chair height was adjusted to 120% lower leg length to make the task easier. The starting position and the rope were the same as the loaded STS test described above. After placing the markers, children were allowed to practice the STS motion 2-3 times to familiar with the task. Then, data of 5 successful STS trials were gathered. The instruction was "Stand up without moving your feet and waving your arms at your comfortable speed, hold this standing position for 2 seconds, and then sit down slowly. No falling." The attempt was considered a failure as described in the loaded STS test.

3.5.7 Ten-Meter Walking Test

Gait speed in meters per minute was calculated using the time it took the child to walk the 10-m distance in the most familiar way. An extra distance of 2.5-m were set before the starting line and after the finished line for acceleration and deceleration. Participants used the same walking devises or orthoses across testing sessions. Before the test, the tester had given the children instruction, such as "I'd like you to walk in the way you would normally do." The average velocity of 3 separate trials was used as the self-selected speed. Average number of steps for 10-m was also counted. Cadence was calculated by dividing average time (min) by average number of steps for 10-m. Stride length was calculated by dividing 2 × 1000 (cm) by average number of steps.

3.5.8 Gross Motor Function Classification System (GMFCS)

The GMFCS was used to classify the gross motor ability of children with CP. Children who classified as level I can walk without limitations. The level II can walk with limitations. As for the children in level III, they walk using a hand-held mobility device. The detailed procedure of classification will follow the Gross Motor Function Classification System Expanded and Revised (Rosenbaum et al, 2008).

3.6 Data Reductions

For calculating the movement time, jerk index and directness of the COM from motion analysis, markers were identified and labeled off line and transformed to their 3-dimensional coordinate using workstation 4.0 software. The global coordinate of the laboratory was presented with x and z axes corresponding to the anterior-posterior and vertical directions of the child. Marker coordinates were then generalized, cross-validatory spline smoothing and differentiation in MATLAB 7.0 (Mathworks, Inc., Natick, Massachusetts, USA). The total body's COM was based on the 13-segment model. The proportion of segments was measured by the norm formula (Winter, 2005).

The movement time of one STS was defined by velocity profile of the COM. The starting point of the STS movement was defined as the last frame in which the horizontal velocity of the COM is zero before reaching peak value. The end point of the STS was defined as the first frame that the vertical velocity of the COM is zero after reaching peak value.

The jerk index was calculated by the following equation,

$$\text{Jerk index} = \text{sqrt} \quad \frac{\left(0.5 \int_{T1}^{T2} \left(x'''(t)\right)^2 + (y'''(t))^2 + (z'''(t))^2 dt\right) \times t^5}{(\text{Actual path length of COM})^2}$$

Where T1 was the starting point of STS, T2 was the end point, and t was the movement time of the STS movement. The x'''(t) indicated the 3^{rd} derivative of the displacement of x-axis, and so forth.

As for directness, the actual path length of COM was divided by distance between the starting point and the end point in sagittal plane.

3.7 Statistical Analysis

SPSS 13.0 (SPSS Inc., Chicago, USA) was used for statistical analysis. Demographic data and all outcome measures were analyzed first using descriptive statistics. The normality of the interval and continuous variables were examined by the Shapiro-Wilks test. For examination of the differences of baseline characteristics between the PSE group and the NM group, independent t tests were used for normally distributed variables, Mann-Whitney U tests were used for variables without normal distribution, and chi-square tests were used for nominal variables. For the outcome measures, the IMI-C and exercise adherence were compared between the 2 groups with independent t test. The GMFM, PEDI, and the 1-RM STS were compared between the groups using the 2-way mixed analysis of variance (ANOVA) (group × time). The music aptitude tested by PMMA was considered as covariates if it correlated linearly with the changes of outcome variables. If the covariate is found, repeated-measures analysis of covariance (ANCOVA) was used. The alpha level was set at 0.05, one-tailed because the hypotheses were unidirectional. Effect size indices for ANOVA (ES_f) were estimated for outcome measures. The ES_f was calculated by the following formula,

$$ES_f = \sqrt{\frac{SSb}{SSe}}$$

Where SSb was the interaction sum of squares form the ANOVA summary table, and the SSe was the within subjects error sum of squares. Criteria for judging the estimated ES_f were as follows: a large effect size is .40 or over, a medium effect size is .25 to .39, and a small effect size is .10 to .24 (Cohen, 1988). Power analysis was done if there was no statistically significant effect.

Chapter 4. Results

Participants were recruited from January 2009 to April 2009. Most of them were recruited from hospitals in northern Taipei or the Cerebral Palsy Association of ROC. A total of 26 participants were assessed for eligibility for this study (Figure 2). Two of the children did not meet the inclusion criteria (not able to follow verbal instructions / suspect mental disorder), one chose not to participate for time reasons. Of the 23 participating children, 12 of them were randomly allocated to the PSE music (PSE) group and 11 to the non-music (NM) group after stratification by age and gross motor function. One child in the NM group had discontinued the loaded STS exercise for 4 weeks because of upper respiratory infection and concomitant respiratory distress. Data of this participant was not used for further analysis. Baseline demographic data (age, gender, body weight, body height, body mass index), gross motor function (GMFCS levels), and previous resistance exercise experience of the remaining participants are listed in Table 6. No significant differences between two groups were found before training. Mean baseline exercise motivations for loaded STS exercise were not different between the PSE group (4.7 ± 1.8 points) and the NM group (4.0 ± 2.2 points) assessed by the IMI-C (*P*=.43, independent t test).

According to the exercise logbook, children in both groups executed the loaded STS exercise at least 3 times every 2 weeks, and 8 children exercised more than 3 times a week. One participant in the PSE group suspended exercise for 1 week due to influenza. For children who had recorded time spend for loaded STS exercise, the average duration of each exercise session for the PSE group was 29.4 ± 9.7 minutes (n=9) and 27.5 ± 9.0 minutes for the NM group (n=6). With program progress, the mean 1-RM STS ± standard deviation increased from 11.5 ± 5.2kg, to 15.0 ± 6.5kg, to 17.0 ± 6.8kg in the PSE group every 2 weeks and increased from 12.4 ± 7.6kg, to 13.6 ± 6.1kg, to 14.3 ± 5.6kg in the NM group. Therefore, the mean load used for loaded STS exercise of the PSE group during the first 2 weeks was 5.8kg (range, 1-11.5kg), the load for the following 2 weeks was 7.5kg (range, 2-13.5kg), and the load for the last 2 weeks was 8.5kg (range, 1.5-14kg). The temporal elements of the PSE music used in the training period were listed in Appendix 6. The mean load used for loaded STS exercise of the NM group during the first 2 weeks was 6.2kg (range, 1-12.75kg), the load for the following 2 weeks was 6.8kg (range, 3-11.5kg), and the load for the last 2 weeks was 7.1kg (range, 4.3-12kg). Six participants (3 in PSE group, 3 in NM group) reported discomfort caused by the body vest and weight during the initial session and were resolved after modification of the vest. Muscle soreness of quadriceps or trunk extensors occurred in 5 children in the PSE group and 1 child in the NM group. All symptoms had been relieved in 1 to 2 days.

There was no significant difference in PT service frequency between groups

(P=.44, Mann-Whitney U Test). In the PSE group, 2 children received PT 3 times a week, 2 children twice a week, 6 children once a week, and 2 children once every 2 weeks. In the NM group, 1 child received PT 5 times a week, 2 children 3 times a week, 1 child twice a week, 5 once a week and 1 received no PT at all. During the study period, there was no change in children's regular therapy. Average time spent for physical activities, such as treadmill walking, stairs climbing, walking outdoors, tricycle riding, horse riding, swimming were not significant different between groups (P=.82, Mann-Whitney U Test). For children in the PSE group, the mean raw score of PMMA Tonal test was 31 ± 8, mean raw score of PMMA Rhythm test was 27 ± 5, and the Composite score was 59 ± 12. Since there were no significant correlations between PMMA and changes in primary outcomes, the PMMA was not used as a covariate.

4.1 Effects of PSE Music on Functional Strength

Table 7 shows the results from the two-way ANOVA with repeated measures for 1-RM STS. There were significant main effect of time ($F_{1,20}$ = 29.4, $P_{(\text{one-tailed})}$ < .001) and significant time × group interaction ($F_{1,20}$ = 3.5, $P_{(\text{one-tailed})}$ = .038). For participants in the PSE group, the 1-RM STS improved by 55%, whereas the NM group improved by 24%. Results indicated that, a 6-week loaded STS exercise combined with PSE music resulted in significantly greater gains in 1-RM STS compared with gains in the

NM group. The ES_f was .42, which was a large effect size.

4.2 Effects of PSE Music on Gross Motor Capacity

Percent scores of GMFM dimension D, E, and goal dimensions followed by the scaled score of GMFM-66 obtained from GMAE were listed in Table 7. There was a significant interaction between group and time on GMFM-goal total score and the GMFM-66 scaled score ($F_{1,20}$ = 4.2, $P_{(\text{one-tailed})}$ = .026 and $F_{1,20}$ = 3.1, $P_{(\text{one-tailed})}$ = .047, respectively). The PSE group, compared with the NM group, had a greater improvement in GMFM-goal total score (8% vs. 3%) and GMFM-66 (3% vs. 1%). The effect size indices *f* were large (ES_f =.46 and .39, respectively). Both GMFM-D and -E improved significantly across time for whole group ($F_{1,20}$ = 6.4, $P_{(\text{one-tailed})}$ = .010 and $F_{1,20}$ = 12.2, $P_{(\text{one-tailed})}$ = .001, respectively), but there were no significant interactions between group and time ($F_{1,20}$ = 2.0, $P_{(\text{one-tailed})}$ = .09 and $F_{1,20}$ = 18.0, $P_{(\text{one-tailed})}$ = .13, respectively). The effect size indices *f* were medium (ES_f = .31 and .26, respectively).

4.3 Effects of PSE Music on Functional Capabilities and Performance (PEDI)

All 4 scaled scores of PEDI used in this study increased significantly within groups ($F_{1,20}$ = 7.0-24.9, $P_{(\text{one-tailed})}$ < .008), but there were no significant interactions between group and time ($F_{1,20}$ = 0.2-1.2, $P_{(\text{one-tailed})}$ = .14-.32) (Table 7). For the Self-Care and

Mobility domains in Functional Skills scale, the PSE group improved by 2.5% and 4.3%, while the NM group improved by 1.8% and 3.5%. For the Self-Care and Mobility domains in Caregiver Assistance scale, the PSE group improved by 1.4% and 6.4%, while the NM group improved by 7.8% and 4.3%, respectively. The effect size indices $_f$ were small (ES_f = .10-.24).

4.4 Effects of PSE Music on Exercise Involvement

4.4.1 Motivation

There were 1 child in the PSE group and 2 children in the NM group could not understand how to answer the IMI-C and could not give consistent answers. Answers from remaining participants were analyzed by independent t test. Results showed that there was no significant difference in exercise motivation for the 6-week program between the PSE group (5.0 ± 1.8) and the NM group (3.9 ± 1.9) (t = 1.3, $P_{(\text{one-tailed})}$ = .11, independent t test) (Table 8).

4.4.2 Adherence

As shown in Table 8, participants in the PSE group completed 103 ± 9% of the 18 scheduled exercise sessions, and the NM group completed 99 ± 21%. There was no significant difference between 2 groups in terms of adherence ($P_{(\text{one-tailed})}$ = .26, independent t test).

4.4.3 Volume

The median total number of repetitions during the loaded STS exercise in the PSE group was 1341, and the inter-quartile range was 686-1706. As for the NM group, the median repetition number was 762, and the inter-quartile range was 546-1145. There was no significant difference in training volume between 2 groups ($P_{(one\text{-}tailed)}$ = 0.057, Mann-Whitney U test) (Table 8, Figure 3).

4.6 Effects of PSE Music on Motor Control Variables of STS

For 10 children in the PSE group and 10 children in the NM group, motion analyses of STS movement were conducted before- and after-training. Two children (GMFCS level III) in the PSE group were excluded from motion analysis because they could not stand up without wearing orthoses. Successful rate of the initial 5 attempts was calculated to represent the motor ability of STS. The definition of a failure trial was stated in 3.5.6. During pre-training assessment, median and inter-quartile range of STS successful rate in the PSE group was 20% (15-100%), and 40% (0-100%) for the NM group. During post-training evaluation, median and inter-quartile range of STS successful rate in the PSE group was 80% (35-100%), and 70% (30-85%) for the NM group. There was no significant difference in the successful rate changes (post-training successful rate minus pre-training successful rate) between 2 groups (PSE group: 10% (0–45%), NM group: 0% (-5-40%); $P_{\text{(one-tailed)}} = 0.15$, Mann-Whitney U test).

Results of motion analysis were not available for 1 participant in the PSE group and 2 participants in the NM group due to low successful rate of STS (<10%). All of them were classified as GMFCS level III. Therefore, only 9 children in the PSE group and 8 children in the NM group were included in this part of analysis. The demographic data is listed in Table 9.

Values of jerk index were logarithm-transformed (log) owing to the positively skewed distribution. Jerk index, movement time of STS, and directness were all decreased significantly within groups ($F_{1,15}$ = 6.2-8.1, $P_{\text{(one-tailed)}}$ = .006-.013), but there was no significant interaction between group and time ($F_{1,15}$ =.10-1.2, $P_{\text{(one-tailed)}}$ = .15-.38) (Table 10, Figure 4, Figure 5). The mean value of jerk index decreased 39% in the PSE group, and 24% in the NM group. The movement time of STS was shortened by 30% in the PSE group, and by 28% in the NM group. For the directness of COM, the PSE group improved by 10%, while the NM group improved by 5%. The effect size indices *f* of smoothness and directness were medium (ES_f = .24-.28). The effect size index *f* of movement time was less than small (ES_f = .08).

4.7 Effects of PSE Music on Gait Parameters

As shown in Table 11, ANOVA for comfortable walking speed and stride length demonstrated a significant time effect ($F_{1,18}$ = 4.7, $P_{(\text{one-tailed})}$ = .022 and $F_{1,18}$ = 10.7, $P_{(\text{one-tailed})}$ = .002, respectively), but there was no interaction between group and time ($F_{1,18}$ = .05, $P_{(\text{one-tailed})}$ = .41 and $F_{1,18}$ = .52, $P_{(\text{one-tailed})}$ = .23, respectively). Walking speed increased by 10.2% in the PSE group, and 12.5% in the NM group. Stride length increased by 10.4% in the PSE group, and 6.5% in the NM group. For cadence, there was no significant main or interaction effect ($F_{1,18}$ = .55, $P_{(\text{one-tailed})}$ = .23).

Chapter 5. Discussion

The present study found that a 6-week loaded STS exercise combined with PSE music program could significantly improve the functional muscle strength and gross motor capacity than those without PSE music for children with SD. For all subjects as a whole, loaded STS exercise with and without music showed significant effects in capability and performance in daily living, motor control of STS transfer without load, and gait speed. However, the PSE music could not significantly improve participants' daily activity and participation, neither the motor control function in STS movement. The exercise motivation and volume for loaded STS exercise might be enhanced by PSE music.

This was the first RCT study combined PSE music with functional resistance exercise, and investigated the short term effect of PSE music on body functions (muscle strength, exercise motivation, motor control) as well as activity and participation in daily life (motor function, walking speed, functional mobility and self care function) for children with CP. While PSE music with loaded STS exercise was applied at home settings, the effect was apparent in improving muscle strength and gross motor function over and above the effect gained through loaded STS exercise without PSE music. To our knowledge, there has been no previous study that investigates the effects of PSE music with resistance exercise program for clients with disabilities. In the present study, the individualized PSE designed by music therapist and PT according to the STS performance of each child could allow children to conduct loaded STS exercise at home under the supervision of parents. Although no significant difference in IMI-C between two groups was found, the PSE music had the tendency to increase exercise involvement for children in this study ($P_{(one\text{-}tailed)} = 0.057$). In addition, this study suggested that loaded STS exercise with or without music could be applied to improve motor capacity in children with SD, even for children classified as GMFCS level III, whose gross motor function are commonly declined after the age of 8 years (Hanna et al, 2009). However, the improvement in basic motor capacity (GMFM) brought by PSE music did not transfer to capability (Functional Skills Scale of PEDI) and performance (Caregiver Assistance Scale of PEDI). Changes of daily participation may be relied on more than improvement of basic motor skills. Therefore, the necessity of functional oriented approach merged into the resistance exercise needs to be considered in future studies.

5.1 Effects of PSE Music on Functional Strength

In this study, the 1-RM STS of the PSE group showed a significant increase after training compared with the NM group. One explanation for this might be that the PSE music could immediate shorten the time it takes to complete a loaded STS movement

(Peng, 2008). Previous studies suggested that resistance exercise with fast movement velocities were more effective on increasing muscle strength than slow velocities (Kraemer and Ratamess, 2004; Morrissey et al, 1998). Children in the PSE group might exercise with a higher velocity and developed more functional muscle strength. The effect of PSE music on immediate increasing knee extensor power may also help to explain the greater strength gained in the PSE group after 6-week training (Peng, 2008).

Another possible explanation for the greater increase of 1-RM in the PSE group might lie in the dose-response effect of resistance exercise. Children in the PSE group had a tendency to complete more exercise volume (total number of repetitions) than the NM group. The increased repetitions might be explained by psychological effect of PSE music which could help children to distract the uncomfortable feeling and fatigue sensations during exercise (Johnson et al, 2001; Karageorphis and Terry, 1997). In two guidelines for progressive resistance exercise, increasing repetitions is one way to progress the training program (American College of Sports Medicine, 2000; Kraemer and Ratamess, 2004). The dose-response of resistance training suggested that higher repetitions might get more strength. Thus, we hypothesized that the PSE music increased the training volume and in turn increased functional muscle strength.

5.2 Effects of PSE Music on Gross Motor Capacity

A significant improvement in gross motor function for children in the PSE group was found in this study. To authors' knowledge, there is no previous RCT to investigate the effects of PSE music with resistance exercise program for clients with disabilities. Only one single group quasi-experimental design study showed that after a 14-week exercise program with music, which composed to reflect movements, improved one-leg standing balance and gait speed for healthy elderly (Hamburg and Clair, 2003). Since loaded STS exercise is a functional resistance exercise, the GMFM could improve along with the increase in functional strength, which was significantly improved by the PSE music. The result was similar to Engsberg's study that they found correlation between ankle muscle strength changes and GMFM-66 changes was 0.67 ($P = 0.048$) (Engsberg et al, 2006).

Previous studies reporting GMFM score changes after resistance exercise were compared with the present study by calculating the effect size *I* (ES *I*) proposed by Cohen because ES_f of previous studies were not available (Cohen, 1988). Criteria for judging the effect size *I* are as follows: a large effect size is 0.80 or over, a medium effect size is 0.40 to 0.79, and a small effect size is 0.20 to 0.39 (Cohen, 1988). The ES *I* after a 6-week loaded STS exercise program was 0.24 calculating from GMFM goal total score (Liao et al, 2007). The result is similar to the NM group (ES $I = 0.10$) in the present study, but smaller than the PSE group (ES *I* = 0.47), which might suggest that the present study successfully reproduce previous findings by Liao et al. even though this time we included severer children classified as GMFCS level III. Comparing the present study with an ankle-joint strengthening exercise, Engsberg and his colleagues found the ES *I* computed from GMFM-66 score was 0.10 after the 12-week program (Engsberg et al, 2006). The ES *I* of Engsberg et al.'s study was smaller than the PSE group (ES *I* = 0.34) in the present study and similar to the findings in the NM group (ES *I* = 0.10). In Dodd et al's study, children aged 12.7 ± 2.8 years received a 6-week functional strengthening program. The ES *I* in GMFM Dimension D was 0.35, Dimension E was 0.14, and the goal total score was 0.19 (Dodd et al, 2003). These results are comparable to the present study, but their participants were older than the children in the present study. Future studies are needed to investigate the effectiveness of functional strengthening program for children and adolescents with different ages.

5.3 Effects of PSE Music on Functional Capabilities and Performance (PEDI)

Score of PEDI for children in the PSE group did not differ significantly from NM group, which probably imply that the improvement in motor capacity (GMFM) brought by PSE music did not translate to capability (Functional Skills scale of PEDI) and performance(Caregiver Assistance scale of PEDI). These results could be explained by considering the complex relations between capacity, capability, and performance (Holsbeeke et al, 2009; Wright et al, 2008). Changes of capability and performance in daily environment may be relied on more than improvement of basic motor skills. Holsbeeke and her colleagues investigated relations between capacity, capability, and performance by administrating GMFM-66, PEDI Functional Skills scale, and PEDI Caregiver Assistance scale for children with CP aged 30 months (Holsbeeke et al, 2009). The correlations were high (r = 0.84 – 0.92) between the 3 constructs. However, they found a large variation in motor performance between children with the same level of capacity (Holsbeeke et al, 2009). They proposed that the environmental factors and personal factors influenced the relationships between capacity and performance, which are in line with the International Classification of Functioning, Disability and Health (ICF) model (Holsbeeke et al, 2009; World Health Organization, 2007). For children with older age, the relationships may be smaller because the variability of both environmental factors and personal factors would be larger (Holsbeeke et al, 2009).

Despite the fact that there was no difference in scores of PEDI between PSE and NM group, there were still significant main effects of time for all PEDI outcomes in the present study. As far as we know, this is the first study investigated the effects of functional resistance exercise on daily activities and participation for children with CP and yielded a positive result.

5.4 Effects of PSE Music on Exercise Involvement

5.4.1 Motivation

The results of the present study did not support the hypothesis that music can increase exercise motivation for loaded STS exercise. The results of this study were contrary to the result of previous study that found more interest and pleasure while learning movements with music in school-aged children (Likesas and Zachopoulou, 2006). One possible explanation may lay in the different approaches that applying music. The music was pre-recorded in the present study, and the children listened receptively to the PSE music. While there may not have sufficient interactions between children, caregiver, and music, the music did not make the exercise more fun and enjoyable.

The sample size estimation in the present study was performed based on results of healthy children and elderly because there was no previous study investigated the training effect of music on children with CP. Therefore, a post hoc analysis for the independent t test was performed in order to estimate the chance of making a type II error and the sample size. The statistical power was calculated as 0.35 under this sample size (n=11 in PSE group and n=9 in NM group) with alpha set at 0.05, one-tailed test. Thus, 36 children in each group will be needed to provide an 80% chance to detect significant difference.

5.4.2 Exercise Adherence

The exercise adherence was also not influenced by the presence of PSE music. For most school-aged children, the most important factors affecting participation in resistance training reported by caregiver are time and academic pressure. Although we wanted to document time spent in doing homework, it is hard to keep records for parents. Therefore, the relations between exercise adherence and homework load were still unclear. The adherence was also influenced by caregiver's attitude toward exercise. Therefore, comprehensive explanations about the importance of physical activities and resistance exercise may be necessary.

5.4.3 Exercise Volume

There was no significant difference in exercise volume between groups. However, there was a trend of more exercise repetitions for the PSE group ($P_{\text{(one-tailed)}} = 0.057$), which was similar with previous studies. In a study examined the effects of music on increasing exercise repetitions for elderly people, researchers noted that strong, rhythmic pulsed, instrumental music could increase exercise repetitions in 2 out of 14 exercises (Johnson et al, 2001). For patients with COPD underwent a pulmonary rehabilitation program, playing self-selected background music during a walking regimen significantly increased the cumulative walking distance for the music group than the control group (Bauldoff et al, 2002). As for music during resistance training, 93.8% weightlifters reported that they more often experienced the desire to repeat an exercise under musical stimulation (Kodzhaspirov et al, 1986). It was suggested that rhythm may make the exercise more pleasurable because it replicates 'natural forms' of physical activity and music may help to divert attention from the perception of difficulty, exertion, boredom, fatigue, and discomforts associated with exercise (Karageorphis and Terry, 1997). These potential influences of music might explained the larger repetitions completed by children in the PSE group.

5.5 Effects of PSE Music on Motor Control Variables of STS

Three kinematic variables were chose to represent motor control function during the natural, uncued, STS transfer without resistant loads, which were the jerk index and directness of COM and movement time. Previous study worked on immediate effects of PSE music on loaded STS exercise for the same population found that the PSE music could decrease jerk index of COM and shorten the STS time (Peng, 2008). However, children in the PSE group did not improve significantly in these motor control variables than the NM group. There was no obvious transfer of learning from loaded STS with

PSE music to STS without load and music (Magill, 2006).

STS movement was chose as the target movement in this study because children performed STS transfer in a non-load, discrete form in their daily activities. Sit-to-stand is a common activity in everyday life (around 60 STS movements per day for healthy adults) and is also difficult for people with muscle weakness (Dall and Kerr, 2009; Hughes et al, 1996). Most children with CP use compensatory strategies during STS and spend more time (Hennington et al, 2004; Park et al, 2003). The loaded STS exercise program with PSE music was aimed to increase functional strength and modify movement strategy because PSE music might help to regulate movement during loaded STS exercise. However, results of the present study did not strongly support the use of PSE music with loaded STS to improve motor control during STS. There was only a tendency that children in the PSE group increased their successful rate and movement smoothness of STS more than the NM group ($P_{(one\text{-}tailed)} = 0.15$). The effect size index, *f,* for the jerk index was 0.23. According to the criteria proposed by Cohen (Cohen, 1988), this effect size was considered a small effect size value (0.10 – 0.25). The number of participants necessary to detect a true difference of this effect size while the alpha level set at 0.05, two-tailed, power at 0.8 is 64 children per group.

There were some methodological difference between the present study and the study conducted by Peng (Peng, 2008). In the previous study, the resistance load was determined as 50% 1-RM of STS estimated by the rate of five-time-sit-to-stand test and the trunk extensor isometric muscle strength, which may be underestimated. The previous experiment was completed in a laboratory setting under supervision of 2 PTs and only 8 repetitions were performed. In the present study, loaded STS exercise was mostly executed at home under supervision of the main caregiver and children had to work until volitional fatigue. The less restrictive environment of clinical settings may lead to more distractions during exercise (siblings doing leisure activities nearby, family members watching TV or making phone calls), less cues to help children entrained by the music (insufficient verbal cues, visual cues, and modeling provided by therapists), and may interfere the effect of PSE music, which may partially explain the inconsistent results. The large number of repetitions requested also made it more difficult to synchronize with music due to fatigue. But considered all children as a whole, the successful rate of STS and motor control variables were improved significantly after 6-week loaded STS exercise program.

5.6 Effects of PSE Music on Gait Parameters

The gait parameters of children in the PSE group did not improved significantly greater than the NM group. The PSE music used to enhance and guide loaded STS movement did not have influences on gait performance because of the different properties of STS and walking tasks. In the field of motor control, STS is classified as discrete task and walking is a continuous movement. Each of them might be controlled by distinct timing control mechanisms (Huys et al, 2008). Further studies incorporated different PSE music translated from gait pattern of children with CP may be needed.

In the present study, self-selected walking speed and stride length were increased significantly for all subjects as a whole. The results were not congruent with previous study investigated effectiveness of loaded STS exercise (Liao et al, 2007). One possible explanation for this was that children in the present study walked slower (mean speed = 45.9 m/min) than previous study (mean speed = 56.9 m/min). Buchner and his colleagues proposed that there was a non-linear relationship between lower extremity muscle strength and walking speed (Buchner et al, 1996). For people with severe functional impairment, increase little capacity might result in great change in function; for healthy or less disabled people, large change in capacity might only lead to little improvement (Buchner et al, 1996). Thus, the incremental functional strength might bring more changes in walking functions for participants in the present study.

The result of increased speed by only increased in stride length but not cadence was consistent with previous studies (Damiano et al, 1995b; Lee et al, 2007), but conflicted with the other. (Damiano and Abel, 1998). Lee reported a decrease in double support phase, increased stride length, and walking speed after 5-week strengthening exercise (Lee et al, 2007). The improvement might be related with increase extensor strength and improved single limb support (Lee et al, 2007). The effect of resistance exercise on gait performance was still controversial. Further studies are needed to delineate the effect of different kinds of strengthening exercise on walking performance for children with different motor capacity.

5.7 Study Limitations

There were several limitations in the present study. First, the treating therapist who was responsible for load progression during each home visit was inevitably aware of group allocation, but bias might be minimized because the exercise program and 1-RM STS tests were supervised by the main caregivers. Second, the participants and their caregivers were not blinded to their treatment assignment because it was difficult to design a sham music that definitely not has a psychological effect. This could introduce bias into the study by affecting exercise compliance and self-reporting exercise logbook in the NM group and by increasing caregivers' enthusiasm for training in the PSE group. However, both groups received similar exercise sessions at home that may decrease the bias. Third, in order to adapt the loaded STS exercise with PSE music program to the less-structured home settings, pre-recorded PSE music was used and instructions about music entrainment were only provided during the presence of therapist. Thus, the PSE music might not always be appropriate for children's movement. Also, the quality of exercise may be affected by the ability of the caregiver supervising and interacting with the child. In the profession of Neurological Music Therapy, improvisatory music is suggested while using the PSE music to guide movement (Thaut, 2005). Immediate modifications can be made by the music therapists to serve as a feedback for the patient. In spite of the disadvantages of using pre-recorded music, participants gained a lot of profit from exercising at home, such as making exercise more convenient, saving cost and time for transportation, and reducing professional manpower requirements. Finally, we found some different clinical characteristics between children classified as level I-II and level III, but the small sample size did not allow a subgroup analysis of the effect of PSE music on motor capacity. Moreover, motion analysis data of STS were difficult to gather for children classified as GMFCS level III even with chair height elevated to 120% lower leg length.

5.9 Recommendations for Future Studies

From the present study, effects of PSE music on functional strength and gross motor capacity were confirmed. Improvement on the above 2 variables might be associated with the specificity of practice hypothesis that the amount of transfer of learning would be greater between 2 similar tasks (Magill, 2006). The loaded STS exercise was more similar with the testing situations of loaded STS test and GMFM. Thus, further studies are needed to investigate the effectiveness of PSE music combined with functional resistance exercise and task-oriented approach on motor capability and performance in daily activities for children with CP. This can be done by incorporating other functional related activities into the functional resistance exercise with the PSE music. Since it is suggested that the resistance exercise program should be varied systematically and should consider all major muscle groups and core muscles to achieve maximal gains (Behm et al, 2008), simple but well-designed circuit training of different functional activities which can be executed at home are needed to facilitate translations between body functions and participation. As for the music delivery method, PSE music combined with additional visual cues presented by a monitor may be more fun and easier to understand for children with CP while exercising without therapist nearby.

Chapter 6. Conclusion

In the present study, we successfully applied PSE music into the home-based loaded STS exercise program for children with SD, GMFCS level I-III via collaboration between music and physical therapist. This was the first RCT study to investigate the effect of PSE music on body functions, activities and participation in daily life. The PSE music significantly improved the functional strength and gross motor function over and above the effects gained through loaded STS exercise alone, even for children classified as GMFCS level III. We also observed a tendency of increased exercise involvement for children in the PSE group. However, the PSE music could not significantly improve participants' capability and performance in daily life, or the smoothness of STS transfer during the non-load condition. Therefore, future studies may be needed to assess the effectiveness of "home-based", functional oriented program merged with various functional resistance exercises with PSE music for children with CP.

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Tables

Table 1. Programs of lower extremities resistance exercise for children with CP

Study	Subjects	Design	Resistance Training Program					Results		
			Mode (Resistance)	Target Muscles or Movements	Intensity and Repetitions	Rate of Progression	Frequency and Duration	Body Function and Structure	Activity	Participation
Damiano, Kelly et al., 1995 Damiano, Vaughan et al., 1995	Age: 6-14 N= 14 SD Gross motor function: Walk independently: 11 Walk with device: 3	Before-after trial	OKC (free weight)	KE	65% 1-RM by approximation 5 rep×4 sets	1 wk	3 times/wk ×6 wk	Sig. increase in isometric KE strength, knee flexion angle at heel-strike in free speed NS change in isometric KF strength, max. knee extension angle during stance phase	Sig. increase in stride length in free and fast speed NS change in gait speed & cadence in free and fast speed	-
MacPhail and Kramer, 1995	Age: 12-20 N= 17 (SD/SQ/SH=7/1/9) Gross motor function: All walk independently	Before-after trial with 3 months FU	OKC (isokinetic dynamometer)	KE & KF	Max. voluntary effort at 90°/s 5 rep×3 sets	NA	3 times/wk ×8 wk 45 min/sess.	Sig. increase in isokinetic total strength of KE & KF NS change in spasticity & EEI	Sig. number of subjects shows increase in GMFM-D/E (9/17) NS change in gait speed	-
Damiano and Abel, 1998	Age: 6-12 N= 11 (SD/SH=6/5) Gross motor function of SD: All walk with device	Before-after trial	OKC (free weight)	2 weakest LE muscles	65% 1-RM 5 rep×4 sets	2 wk	3 times/wk ×6 wk	Sig. increase in isometric strength of target muscles and percent time of double support in fast speed NS change in EEI,	Sig. increase in GMFM-E, gait speed & cadence in free and fast speed NS change in GMFM total score, and stride	-

								percent time of double support in free speed	length in free and fast speed	
Blundell, Shepherd et al., 2003	Age: 4-8 N= 8 (SD/SQ=7/1) Gross motor function: Ambulatory	Before-after trial with 2 months FU	CKC (body weight)	Treadmill walking, standing balance exercise, forward & lateral step up/off, STS, leg press, heel raise/lower	Complete max. number of rep	NA (progressed by increasing number of rep. or exercise difficulty)	2 times/wk ×4 wk 60 min/sess.	Sig. increase in isometric LE strength	Sig. increase in lateral step up test, STS, & stride length NS change in gait speed & cadence	-
Dodd, Taylor et al., 2003	Age: 8-18 N= 21 SD Gross motor function: GMFCS I/II/III Exp: 2/2/7 Control: 5/3/2	Randomized clinical trial with 3 months FU	CKC (free weight in backpack)	Heel raise half squat, step up/off	8-12 RM Complete 8-10 rep×3 sets	2 wk	3 times/wk ×6 wk 20-30 min/sess.	Sig. increase in training load and combined KE and APF strength NS change in isometric strength of HE, KE, and APF	NS change in GMFM-D/E and total score, timed stair test, and gait speed	-
McBurney, Taylor et al., 2003	Age: 8-18 N= 11 SD Gross motor function: GMFCS I/II/III: 2/2/7	Qualitative study	CKC (free weight in backpack)	Heel raise half squat, step up/off	8-12 RM Complete 8-10 rep×3 sets	2 wk	3 times/wk ×6 wk 20-30 min/sess.	Perceptions of improved strength, flexibility, posture, balance, and circulation	Perceptions of improved mobility	Perceptions of improved participation in school, leisure, social, and family events

Dodd, Taylor et al., 2004	Age: 8-16 N= 17 SD Gross motor function: GMFCS I/II/III Exp: 2/2/6 Control: 4/2/1	Randomized clinical trial	CKC (free weight in backpack)	Heel raise half squat, step up/off	8-12 RM Complete 8-10 rep×3 sets	2 wk	3 times/wk ×6 wk 20-30 min/sess.	Sig. increase in training load Sig. decrease in self-concept for scholastic competence and social acceptance NS change in LE isometric strength	-	-
Eagleton, Iams et al., 2004	Age: 12-20 N= 7 Gross motor function: Ambulatory	Before-after trial	OKC (free weight or weight machine)	Trunk, hip, knee, and ankle flexors and extensors and hip abductors	80% 1-RM Complete 8-10 rep	1 wk (progressed by increasing the load or/and repetitions)	3 times/wk ×6 wk	Sig. decrease in EEI	Sig. increase in gait speed, step length, and cadence	-
Morton, Brownlee et al., 2005	Age: 6-12 N= 8 bilateral spastic CP Gross motor function: GMFCS III	Before-after trial with 1 month FU	OKC (free weight)	KE & KF	65% 1-RM by approximation Progress the rep from 5 rep×4 sets to 10 rep×3 sets	2 wk	3 times/wks ×6 wk	Sig. increase in isometric strength of KE and KF Sig. decrease in spasticity	Sig. increase in GMFM-E and cadence in free speed NS change in GMFM-D gait speed, step length in free and fast speed	-
Engsberg, Ross et al., 2006	Age: 9.7±3.3 N= 12 SD Gross motor function:	Randomized clinical	OKC (isokinetic dynamomet	ADF & APF	> 80% of max. voluntary	NA	3 times/wk ×12 wk	Sig. increase in target muscle strength Sig. decrease in spasticity	Sig. increase in GMFM-E NS change in GMFM	-

	GMFCS I/II/III ADF: 1/1/1 APF: 2/1/1 ADF+APF: 1/1/0 Control: 1/2/0	trial	er)		effort at 90°/s ADF & APF: 30 rep ADF+APF: 60 rep			and max. knee flexion angle during walking NS change in kinematic data of ankle and max. ankle PF moment during walking	total score, gait speed, stride length, and cadence	
Patikas, Wolf et al., 2006	Age: 6-16 N= 39 SD Gross motor function: GMFCS I/II/III Exp: 6/11/2 Control: 6/7/7	Rando mized clinical trial	OKC and CKC (elastic band & body weight)	7 training drills targeting trunk and LE muscles	5 rep ×2 sets	NI (progressed by eliminating the external support)	3 times/wk ×9 months 30-45 min/sess.	NS difference in strength and spasticity	NS difference in GMFM	-
Unger, Faure et al., 2006	Age: 13-18 N= 31 (SD/SH=15/16) Gross motor function: Exp: walk independently: 19 walk with device: 2 Control: walk independently: 10	RCT	OKC and CKC (free weight, elastic band, & body weight)	28-station circuit targeting upper and lower limbs and trunk muscles	From 6-10 rep×1 set to 12 rep×3 sets	When 12 rep×3 sets was reached	3 times/wk ×8 wk 40-60 min/sess.	Sig. increase in a more upright posture and the perception of body image NS change in functional competence	NS change in gait speed, stride length, and cadence	-

Lee, Sung et al., 2007	Age: 4-12 N= 17(SD/SH=9/8) Gross motor function: GMFCS II-III Exp: 9 Control: 8	RCT with 1.5 month FU	OKC and CKC (free weight, isokinetic machine & body weight)	OKC exercise focused on LE muscles; squat to stand, lateral step up and down	10 rep×2 sets	NI	3 times/wk ×5 wk	Sig. increase in HE strength, max. moment of HF during walking Sig. decrease in percent time of double support NS change in HF, HAbd, HAdd, KE, KF strength and percent time of single support	Sig. increase in squat to stand test, GMFM-D/E, gait speed, and stride length NS change in lateral step up test, GMFM total score, and cadence	-
Liao, Liu et al., 2007	Age: 5-12 N= 20 SD Gross motor function: GMFCS I/II Exp: 4/6 Control: 6/4	Randomized block design	CKC (free weight in body vest)	Loaded STS	50% 1-RM until fatigue	2 wk	3 times/wk ×6 wk 20-30 min/sess.	Sig increase in 1-RM STS Sig. decrease in EEI NS change in isometric KE strength	Sig increase in GMFM goal dimension NS change in gait speed	-

Abbreviation: ADF, ankle dorsiflexor; APF, ankle plantar flexor; CKC, closed-kinetic chain; EEI, energy expenditure index; FU, follow-up; GMFCS, Gross Motor Functional Classification System; GMFM, Gross Motor Function Measure, HAbd, hip abductor; HAdd, hip adductor; HE, hip extensor; HF, hip flexor; KE, knee extensor; KF, knee flexor; NA, not applicable; NI, no information available; NS, non-significant; OKC, open-kinetic chain; RM, repetition maximum; rep, repetition; SD, spastic diplegia; sess, session; SH, spastic hemiplegia; Sig, significant; SQ, spastic quadriplegia; STS, sit-to-stand; wk, week.

Table 2. Effect size I of outcome measures in randomized clinical studies on lower extremities resistance exercise for children with CP

Study	Program	Effect Size I of Outcome Measures		
		Body Function and Structure	Activity	Participation
Dodd, Taylor et al., 2003	CKC (free weight in backpack)	Combined KE and APF strength: Post-training/FU: 0.25/0.46	-	-
Engsberg, Ross et al., 2006	OKC (isokinetic dynamometer)	Target muscle strength: 0.57-0.71 Max. knee flexion angle during walking: 0.27	GMFM-E: 0.11	-
Unger, Faure et al., 2006	OKC and CKC (free weight, elastic band, & body weight)	Sum of the ankle, knee, and hip angles at midstance: 0.29 Perception of body image: 0.49	-	-
Lee, Sung et al., 2007	OKC and CKC (free weight, isokinetic machine & body weight)	HE strength: Post-training/FU: 0.43/0.57 Max. moment of HF during walking: FU: 0.67 Percent time of double support: Post-training/FU: 0.52/0.33	Squat to stand test Post-training/FU: 0.27/0.35 GMFM-D Post-training: 0.01 GMFM-E Post-training: 0.03 Gait speed Post-training/FU: 0.65/0.77 Stride length Post-training/FU: 0.80/0.98	-
Liao, Liu et al., 2007	CKC (free weight in body vest)	1-RM STS: 0.70 EEI: 0.29	GMFM goal dimension: 0.24	-

Abbreviation: APF, ankle plantar flexor; CKC, closed-kinetic chain; EEI, energy expenditure index; FU, follow-up; GMFM, Gross Motor Function Measure, HE, hip extensor; HF, hip flexor; KE, knee extensor; OKC, open-kinetic chain; PedsQL, the Pediatric Quality of Life Inventory; RM, repetition maximum; rep, repetition; STS, sit-to-stand.

Effect size I equal to the difference between pre- and post-test means divided by the pooled standard deviation. The effect size I of 0.2 is small effect size, 0.5 is medium effect, and 0.8 is large effect.

Table 3 Psychological effects of synchronous music while combining with exercise

Study	Participants	Exercise & Music	Conditions or Procedures	Results	Subjective Report
Anshel and Marisi, 1978	32 undergraduates Age: 19-22y	Cycle ergometer to exhaustion (intensity: HR=170 bpm, pedaling rate: 50 rpm) Synchronous music	Conditions: a. Synchronous music b. Asynchronous music c. No music control	<u>Time to exhaustion:</u> Synchronous > asynchronous = no music (ES I= 0.63)	
Marrero, Fremion et al., 1988	10 adolescents with insulin-dependent DM Age: 12-14y	30 min aerobic exercise Movement to Music	Before-after trial: 3 times/wk ×12 wk exercise program with patient education	Report 87% completion of the requested 36 sessions	All reported that the exercises were fun
Hayakawa, Miki et al., 2000	16 middle-aged women Age: 32-60y	30 min bench stepping exercise (intensity: 60-90% max HR, stepping rate: 30 cycles/min) Music tempo:120 bpm	Conditions: a. Synchronous music b. Asynchronous music c. No music control with metronome	<u>Profile of Mood Scales</u> <u>Vigor</u>: synchronous > asynchronous = no music (ES I= 0.45) <u>Fatigue</u>: synchronous = asynchronous < no music (ES I= 0.03) <u>Confusion</u>: synchronous < asynchronous = no music (ES I= 0.44) <u>Depression</u>, <u>Anger</u>, <u>Tension</u>: NS across conditions	
Karageorphis and Jones, 2000	20 sport science undergraduates volunteers Age: 21±3y	Cycle ergometer to exhaustion (intensity: 75% max HR, pedaling rate: 65 rpm) Music tempo:130 bpm	Conditions: a. Synchronous music b. Asynchronous music c. No music controls	<u>Time to exhaustion:</u> Synchronous = asynchronous > no music <u>Heart rate prior to exhaustion:</u> Synchronous > asynchronous = no music	
Johnson, Otto et al., 2001	19 residents with physical frailties of care centers Age: 65-90y	20 min physical therapy program of 14 movements Movement to Music (music was paired with exercise according to compatibility with the meter, rhythm, and tempo)	Conditions a. Instrumental synchronous music b. Live vocal synchronous music c. No music	<u>Movement repetitions as adherence:</u> Instrumental > no music in 2 exercises (supination/pronation and marching) Vocal > no music in 1 exercise No music > vocal (and instrumental) in 2 (1) exercises NS in other 8 exercises	Verbally indicated their enjoyment of music in exercise
Kim and Koh, 2005	10 chronic stroke patients of a daycare center Age: 61-73y	5 groups of upper extremity exercise movements Movement to Music (double meter, moderate tempo,	Conditions a. Synchronous song b. Synchronous karaoke accompaniment	<u>Pain perception by VAS:</u> NS across conditions	Expressed interest in music and positive feelings from

		and clear beat)	c. No music		listening to music
Likesas and Zachopoulou, 2006	232 elementary school students Age: 6-11y	22 Greek dance lessons for 45 min Music and movement teaching model (modern synchronized music)	Clinical trial Trained group: music and movement education and creative child-centered teaching Control group: instructional or guided method	Intrinsic Motivation Inventory Effort-interest: synchronous music > non-music (ES I= 1.3) Pleasure: synchronous music > non-music (ES I= 2) Perceptual ability: NS across groups	
Simpson and Karageorghis, 2006	36 male volunteers Age: 20.4±1.4y	400-m sprint Music tempo:135-140 bpm for 6 running ability groups	Conditions a. Synchronous motivating music b. Synchronous oudeterous music c. No music	400-m sprint time: Synchronous motivating = synchronous oudeterous < no music	

Abbreviation: bpm, beats per minute; DM, diabetes mellitus; ES, effect size; HR, heart rate.

Table 4 Effects of therapeutic music on motor functions for elderly people and children with CP

Study	Participants	Study design	Exercise & Music	Program	Results
Hanburg & Clair, 2003	14 healthy elderly Age: 65-78y	Single group quasi-experimental design	Laban Movement & Motivation Moves Music	20 min/session 1 session/wk × 14 wks	Improve one-leg standing balance and gait speed No significant change on functional reach test
Thaut et al.,1998	6 CP with SD Age: 9.8±1.5y	Single group quasi-experimental design	Home-based gait training with RAS	30 min/day 7 days/wk × 3 wks	Improved gait velocity by 21.2% Increase hip and knee range of motion during walking Improve smoothness of velocity profile of hip and knee trajectory
Kwak, 2007	25 spastic CP Age: 6-20y	Multiple groups quasi-experimental design	Gait training with RAS in clinical setting	30 min/day 5 days/wk × 3 wks	No significant difference in gait speed, cadence, and stride length across groups

Abbreviation: CP, cerebral palsy; SD, spastic diplegia; RAS, rhythmic auditory stimulation; wk, week.

Table 5 Randomized after stratification by age and gross motor function

Subject Numbers (PSE group / NM group)		Gross Motor Functional Classification System	
		Level I or II	Level III
Age (years)	5 - 8.4	3 / 3	2 / 1
	8.5 - 13	4 / 3	3 / 3

Table 6 Baseline characteristics of the participants

	PSE group (n=12)	NM group (n=10)	*P*
Demography			
Male/female (no.)[1]	8/4	7/3	.87
Age (years)	8.9 ± 2.1	9.1 ± 2.5	.85
Body weight (kg)	26.2 ± 8.1	27.7 ± 10.0	.70
Body height (cm)	123.4 ± 10.3	125.6 ± 11.5	.64
BMI (kg/m^2)	16.9 ± 3.4	17.0 ± 3.2	.94
Motor function and strength related factors			
GMFCS level (I/II/III, no.)[1]	3/4/5	4/2/4	.69
Received resistance exercise before study period (yes/no, no)[1]	3/9	3/7	.79
Motivation for loaded STS resistance exercise at baseline (points)[2]	4.7 ± 1.8	4.0 ± 2.2	.43
Frequency of PT intervention received during study period (times/week)[3]	1.0 (1.0-2.0)	1.3 (1.0-3.0)	(.44)
Average amount of physical activity during study period (hours/week)[3]	1.5 (1.0-4.6)	2.3 (1.5-3.6)	(.82)

Abbreviations: PSE = Patterned Sensory Enhancement; NM = non-music; no. = number; BMI = body mass index; GMFCS = Gross Motor Function Classification System; STS = sit-to-stand.

Values are mean ± SD, median (inter-quartile range) or number.

P Values derived from independent t test.

[1] *P* Values derived from Chi-Square test.

[2] n= 11 in the PSE group, and n= 9 in the NM group.

[3] *P* Values derived from Mann-Whitney U Test.

Table 7 Comparisons of primary outcomes in two groups at pre- and post-training

	PSE group (n=12)		NM group (n=10)		Time	Group	Time*Group	ES
	Pre-training	Post-training	Pre-training	Post-training	$P_{(one-tailed)}$	$P_{(one-tailed)}$	$P_{(one-tailed)}$	f
Functional strength								
1-RM STS (kg)	11.5 ± 5.2	17.8 ± 7.6	12.4 ± 7.6	15.4 ± 6.7	.001*	.39	.038*	.42
Gross motor capacity								
GMFM-D (% score)	74.5 ± 13.6	79.4 ± 8.6	78.3 ± 11.9	79.7 ± 9.3	.010*	.33	.09	.31
GMFM-E (% score)	50.3 ± 19.0	55.5 ± 18.7	56.0 ± 26.9	58.6 ± 26.3	.001*	.33	.13	.26
GMFM-goal total score (% score)	62.8 ± 15.5	67.7 ± 13.3	67.4 ± 18.9	69.4 ± 17.3	.001*	.32	.026*	.46
GMFM-66 (scaled score)	63.7 ± 5.6	65.6 ± 5.7	66.7 ± 9.4	67.6 ± 9.4	.001*	.22	.047*	.39
Functional capabilities and performance (scaled score of PEDI)								
Functional Skills in Self-Care	75.2 ± 14.3	77.1 ± 13.3	76.7 ± 10.6	78.1 ± 11.4	.002*	.41	.32	.10
Functional Skills in Mobility	67.5 ± 10.0	70.4 ± 9.6	71.4 ± 13.8	73.9 ± 12.8	.001*	.23	.33	.10
Caregiver Assistance in Self-Care	71.8 ± 11.8	74.7 ± 12.2	69.6 ± 9.9	75.0 ± 12.4	.001*	.42	.14	.24
Caregiver Assistance in Mobility	69.8 ± 9.5	74.3 ± 15.0	71.3 ± 9.8	74.4 ± 9.3	.008*	.43	.33	.10

Abbreviations: PSE = Patterned Sensory Enhancement; NM = non-music; ES = effect size; 1-RM STS = one-repetition maximum of the loaded sit-to-stand; GMFM = Gross Motor Function Measure; PEDI = Pediatric Evaluation of Disability Inventory

Values are mean ± SD.

P Values derived from 2 (group) × 2 (time) two-way mixed ANOVA.

The level of significance was set at 0.05, one-tailed.

Table 8 Comparisons of exercise motivation, adherence, and exercise volume in two groups

	PSE group	**NM group**	***t* *(Mann-Whitney U)***	***P* (one-tailed)**
Exercise motivation				
IMI-C (points) [1]	5.0 ± 1.8	3.9 ± 1.9	1.3	.11
Exercise adherence				
Percent of sessions completed (%)	103 ± 9	99 ± 21	.65	.26
Exercise volume				
Total repetitions during training (repetitions)	1341 (686-1706)	762 (546-1145)	(36)	.057

Abbreviations: PSE = Patterned Sensory Enhancement; NM = non-music; IMI-C = Intrinsic Motivation Inventory -Chinese Version.

Values are mean ± SD or median (inter-quartile range).

P Values derived from independent t test or (Mann-Whitney U test).

The level of significance was set at 0.05, one-tailed.

[1] n= 11 in PSE group, and n= 9 in NM group.

Table 9 Characteristics of participants used for comparisons of motor control related parameters

	PSE group (n=9)	NM group (n=8)	*P*
Male/female (no.)[1]	6/3	5/3	.86
Age (years)	9.4 ± 2.1	8.3 ± 2.0	.31
Body weight (kg)	28.1 ± 8.5	27.0 ± 11.1	.83
Body height (cm)	125.8 ± 10.0	123.6 ± 11.0	.67
BMI (kg/m^2)	17.5 ± 3.7	17.0 ± 3.6	.79
GMFCS level (I/II/III, no.)[1]	3/4/2	4/2/2	.69

Abbreviations: PSE = Patterned Sensory Enhancement; NM = non-music; no. = number; BMI = body mass index; GMFCS = Gross Motor Function Classification System

Values are mean ± SD or number.

P Values derived from independent t test.

[1] *P* Values derived from Chi-Square test.

Table 10 Motor control related parameters of STS in two groups at pre- and post-training

	PSE group (n=9)		NM group (n=8)		Time	Group	Time*Group	Effect Size
Motor control	**Pre-training**	**Post-training**	**Pre-training**	**Post-training**	***P* (one-tailed)**	***P* (one-tailed)**	***P* (one-tailed)**	***f***
Log (Jerk index $\times$ 10^4)	1.08 ± 0.45	0.66 ± 0.32	0.75 ± 0.42	0.57 ± 0.24	.009*	.07	.15	.28
Directness	1.45 ± 0.19	1.31 ± 0.10	1.42 ± 0.17	1.35 ± 0.10	.006*	.46	.19	.24
Movement time (sec)	2.9 ± 1.5	2.0 ± 0.4	2.5 ± 1.2	1.8 ± 0.6	.008*	.19	.38	.08

Abbreviations: PSE = Patterned Sensory Enhancement; NM = non-music.

Values are mean ± SD.

P Values derived from two-way mixed ANOVA.

The level of significance was set at 0.05, one-tailed.

Table 11 Comparisons of gait parameters in two groups at pre- and post-training

	PSE group (n=10)		NM group (n=10)		Time	Group	Time*Group	ES
	Pre-training	**Post-training**	**Pre-training**	**Post-training**	$P_{\text{(one-tailed)}}$	$P_{\text{(one-tailed)}}$	$P_{\text{(one-tailed)}}$	f
Comfortable speed (m/min)	45.7 ± 19.5	50.3 ± 18.1	46.1 ± 12.8	51.9 ± 14.3	.022*	.44	.41	.05
Cadence (steps/min)	116.1 ± 35.7	116.8 ± 35.1	117.9 ± 23.7	124.0 ± 27.5	.18	.37	.23	.18
Stride length (cm)	76.6 ± 16.4	84.5 ± 16.5	77.6 ± 10.9	82.6 ± 9.8	.002*	.47	.24	.17

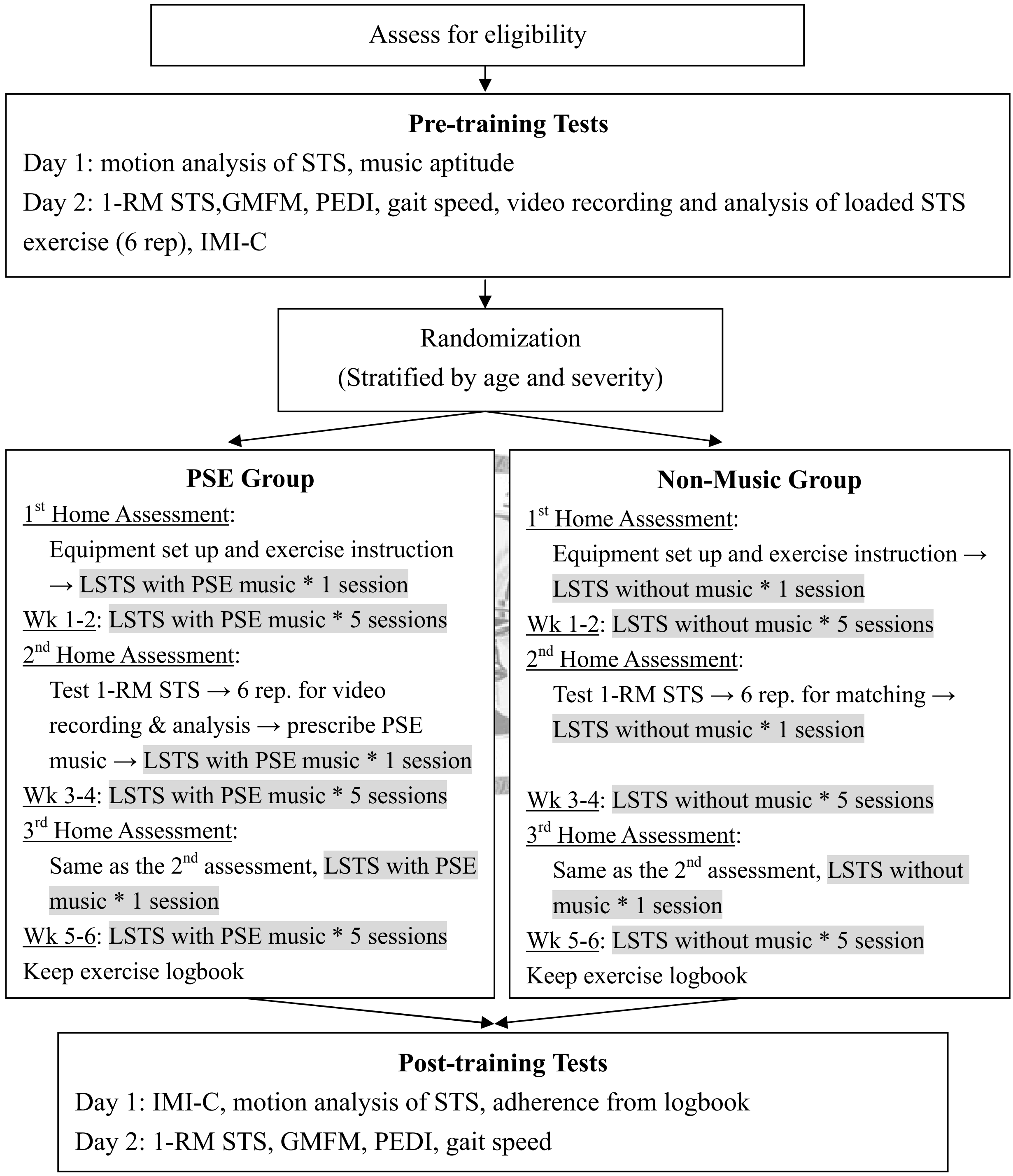
Abbreviations: PSE = Patterned Sensory Enhancement; NM = non-music; ES = effect size.

Values are mean ± SD.

P Values derived from 2 (group) × 2 (time) two-way mixed ANOVA.

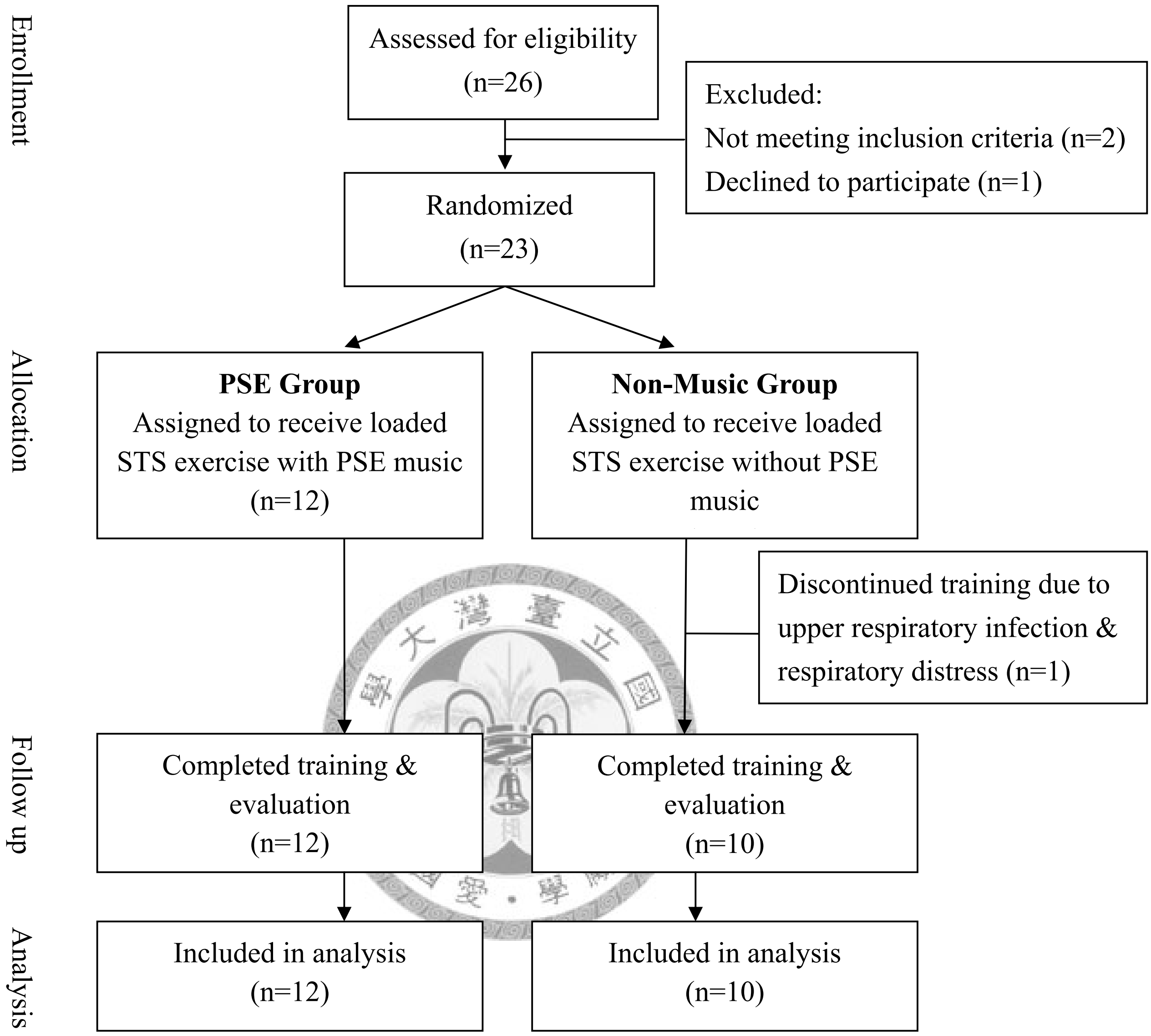
The level of significance was set at 0.05, one-tailed.

Figures



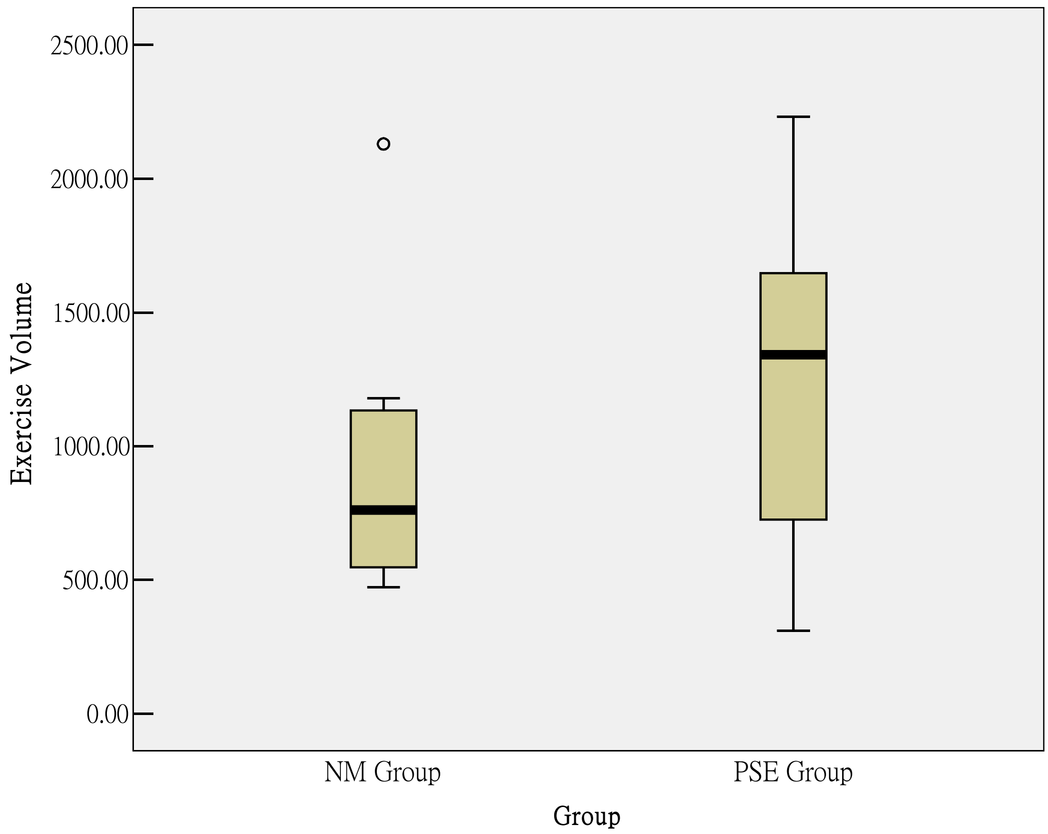
Abbreviations: GMFM = Gross Motor Function Measure; IMI-C = Intrinsic Motivation Inventory-Chinese Version; LSTS = loaded sit-to-stand; PEDI = Pediatric Evaluation of Disability Inventory; PSE = Patterned Sensory Enhancement; rep = repetition; RM = repetition maximum; STS = sit-to-stand.

Figure 1. Experimental procedure



Abbreviations: PSE = Patterned Sensory Enhancement; STS = sit-to-stand

Figure 2. Flow chart of participants' enrollment, randomization, and data analysis



Abbreviations: NM = non-music; PSE = Patterned Sensory Enhancement

Figure 3. Boxplot of exercise volume in two groups

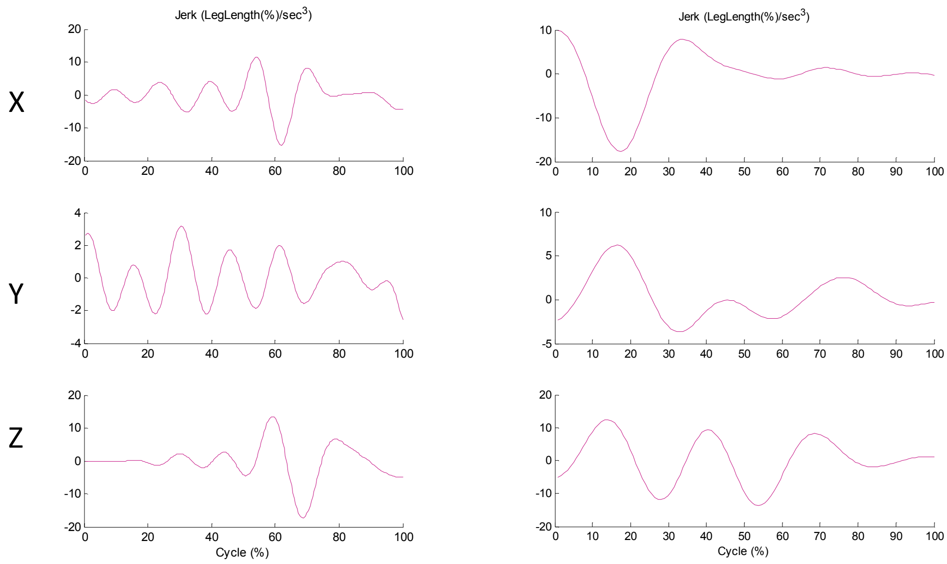


Figure 4. The jerk index of total body's COM of one child in the PSE group with GMFCS level II during pre- and post-training tests (Left: pre-training, Right: post-training)

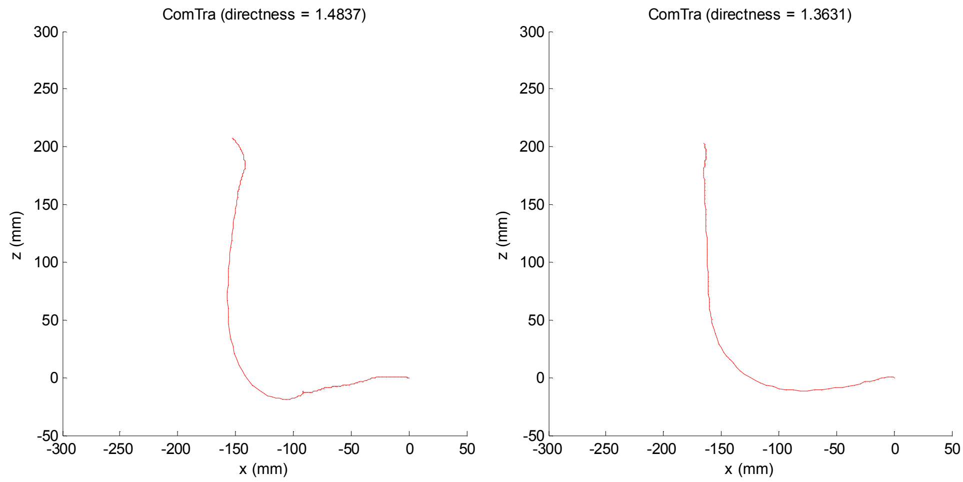


Figure 5. The directness of total body's COM of one child in the PSE group with GMFCS level II during pre- and post-training tests (Left: pre-training, Right: post-training)

Appendices

Appendix 1: Permission of Institutional Review Board and Consent Form

檔　號：
發文方式：郵寄
保存年限：

國立臺灣大學醫學院附設醫院　函

地址：100臺北市中山南路7號
承辦人：王劭慈
電話：02-2312-3456轉63157
傳真：02-2395-1950
電子信箱：NTUHREC2008@YAHOO.COM.TW

受文者：臺灣大學醫學院物理治療學系暨研究所廖華芳副教授
發文日期：中華民國97年12月17日
發文字號：校附醫倫字第0971762466號
速別：普通件
密等及解密條件或保密期限：普通
附件：

主旨：有關　台端所主持之「治療性音樂結合荷重坐站阻力運動對雙邊痙攣型腦性麻痺兒童之療效/Effects of Therapeutic Music Combined with Loaded Sit-to-Stand Resistance Exercise for Children with Spastic Diplegia」（本院案號：200811026R）純學術臨床試驗案，符合快速審查條件及研究倫理規範，通過本院研究倫理委員會審查，同意核備，並提第146次研究倫理委員會報備追認，請　查照。

說明：

一、為配合WHO之稽核及符合ICH GCP 4.10.1之規範「Where required by the applicable regulatory requirements, the investigator should submit written summaries of the trial's status to the institution. The investigator/ institution should submit written summaries of the status of the trial to the IRB/IEC annually, or more frequently, if requested by the IRB/IEC.」，凡通過本會審查之案件，需於追蹤年限1年到期前的1個月內提出持續審查申請，逾期未繳交者，不得申請新案。

二、依據國際醫學雜誌編輯委員會(The International Committee of Medical Journal Editors, ICMJE)之投稿規

第1頁　共2頁

定(http://www.icmje.org/clin_trialup.htm)，臨床試驗研究計畫投稿者，需於招募第一位受試者參與試驗前，將通過研究倫理委員會審核之臨床試驗計畫資料登錄於臨床試驗公開網站，完成登錄作業後，國際醫學雜誌編輯委員會(ICMJE)才會接受研究結果之發表。WHO對臨床試驗研究計畫之定義為任何對受試者或特定族群進行一個或多個與健康有關的介入措施(如藥物、外科處置、器材、行為治療、飲食介入及照護過程改變)以評估對健康的效益之計畫，非屬上述臨床試驗計畫，請計畫主持人自行決定是否登錄。

三、本院已向美國國家衛生研究院(National Institutes of Health, NIH) ClinicalTrials. gov 網站- Protocol Registration System (PRS https:// register. clinicaltrials.gov/)申請本院專用帳號，供本院計畫主持人(PI) 登錄所主持之臨床試驗研究計畫，登入網頁之帳號及密碼如下列：

(一)Organization：NTaiwanUH

(二)User Name：NTUH

(三)Password：NTUH99

正本：臺灣大學醫學院物理治療學系暨研究所廖華芳副教授
副本：本院研究倫理委員會

院長 陳明豐

國立台灣大學醫學院附設醫院
臨床試驗受試者說明及同意書

（為保護病人權益，請將試驗可能造成受試者危險的警示字句標示出來）

（本書表應由計畫主持人或其指定代理人親自向受試者說明詳細內容，並請受試者經過慎重考慮後方得簽名）

您被邀請參與此臨床試驗研究。這份表格提供您本研究之相關資訊，研究主持人或研究護士將會為您說明研究內容並回答您的任何疑問。

研究計畫名稱：

中文: 治療性音樂結合荷重坐站阻力運動對雙邊痙攣型腦性麻痺兒童之療效

英文: **Effects of Therapeutic Music Combined with Loaded Sit-to-Stand Resistance Exercise for Children with Spastic Diplegia**

執行單位：台大物理治療學系暨研究所 電話：**02-33228122**

主要主持人：廖華芳 職稱：副教授 電話：**02-33228136**

協同主持人：謝正宜 職稱：主治醫師 電話：**02-23123456 #67035**

協同主持人：呂東武 職稱：教授 電話：**02-33663299**

※二十四小時緊急聯絡人：廖華芳 電話：**02-33228136**

受試者姓名：

性別： 出生日期：

病歷號碼：

通訊地址：

聯絡電話：

法定代理人或有同意權人之姓名：

與受試者關係：

性別： 出生日期：

身份證字號：

通訊地址：

聯絡電話：

一、藥品、醫療技術、醫療器材全球上市現況簡介：

本計劃不涉及此項。

二、試驗目的：

本研究的目的是為了解孩童在家中進行背重量坐到站的運動時，若提供針對孩童個別情況錄製的治療性音樂，是否可以增加孩童進行運動的動機，以及是否有較佳的治療效果。

三、試驗之主要納入與排除條件：

負責本研究的物理治療師會幫您的孩子做評估，以確定您的孩子適合參加背重量坐到站的運動訓練。

受試者必須符合以下所有條件方能參加本研究：

- 以下肢肌力較弱為主的痙攣型腦性麻痺兒童，年齡為 5-12 歲，在行走能力方面至少要可以使用推車或助行器在戶外行走。
- 可獨立完成坐到站並維持站立 2 秒以上而不跌倒。
- 可以服從口頭指導、命令等，且實驗過程中合作者。
- 孩子經過您的同意可以接受在家自我運動訓練，且在三個月的研究過程中不會更動孩子目前所接受的療育服務以及活動情形者。

若有下列任何情況者，不能參加本研究：

- 近六個月有手術者，例如骨科手術、背根神經切除術等。
- 不適合進行運動訓練之醫療狀況，例如嚴重的關節變形、心肺疾病、未控制的癲癇等。
- 有聽覺問題者 (本實驗須聆聽音樂)。
- 有嚴重情緒障礙者，例如自閉症、注意力缺陷等。

四、試驗方法及相關檢驗：

整個研究期間大約三個月，預計收錄 32 人參加。向您及您的孩子解釋研究內容後，如果您同意讓您的孩子參加本研究，將由物理治療師為您的孩子進行評估，共分兩次完成，每次約需 100-120 分鐘。內容包括蒐集基本資料，如：性別、年齡、身高、體重等，以量表進行動作功能和日常生活表現的評估，測試孩子的下肢肌力，以問卷詢問孩子對進行背重量坐到站運動的運動動機（評估地點在台灣大學物理治療研究所兒童觀察實驗室），並以動作分析系統和反光球蒐集孩子在執行坐到站時的動作情形（評估地點在台灣大學醫學工程研究所

骨科工程暨動作分析實驗室)；以上之測量項目將用於分析治療效果。

而後，您的孩子將依據他的年齡及行走能力分成不同層級，每一個層級的孩子會再以抽籤的方式決定運動訓練的音樂組別。本研究共分為兩組，兩組兒童皆將在家執行每週三次，為期六週，共 18 次的背重量坐到站的運動訓練，在訓練過程中兩組會搭配不同的音樂，然此音樂皆由音樂治療師針對孩子的表現所個別錄製。在訓練開始前，物理治療師將至您的家中訪問，幫您準備運動所需要的器材以及指導您及您的孩子進行運動訓練並紀錄運動情形。之後每隔兩週，治療師會為孩子更新運動時背負的重量以及音樂。

六週訓練完成後，將會再由六週前替您的孩子評估的治療師執行與六週前相同的測試，以了解訓練之效果。經過六週的追蹤期之後，將會再替您的孩子評估動作功能、日常生活表現及下肢肌力。

五、可能產生之副作用、發生率及處理方法：

本研究所進行之評估項目均為非侵入性，包括動作功能評估、問卷評量、肌力測試以及動作分析，皆是廣泛使用於兒童的評估方法。背重量坐站運動為國內外專家學者認可的痙攣型腦性麻痺兒童下肢功能性肌力訓練方法，物理治療師會指導您及您的孩子適當的運動方式以及熱身、緩和運動，以預防可能因肌力訓練引起的肌肉酸痛。於訓練之過程中若出現不適與疲勞可立刻停止運動，並立即告知治療師，治療師將給予適當之處置以及運動劑量之調整。研究期間若有任何問題、不適或突發狀況，可隨時與研究人員聯絡，以提供相關醫療諮詢，並安排相關回診檢查，視情況依指示就醫。

六、其他替代療法及說明：

目前對於下肢肌力較弱的痙攣型腦性麻痺兒童之臨床醫療處置以肌力訓練及動作訓練為主。相較於傳統的肌力訓練和動作訓練，背重量坐到站運動合併兩種訓練的優點，在進行動作訓練的同時給予阻力及音樂，過去研究已初步證實其對於肌肉力量及動作功能有效果。

七、試驗預期效益：

您的孩子於接受六週合併治療性音樂的運動訓練後，預期在動作功能和肌力可能會有所改善。此外，研究結束後，孩童將可以養成在家持續運動的習慣，以保持其健康體適能。

八、試驗進行中受試者之禁忌、限制與應配合之事項：

於十二週的研究過程中，請盡量不要變動您的孩子的復健活動。除此之外，亦請不要在此期間安排手術或降低張力等治療。除此之外，您只需盡量配

合為期十二週的研究訓練計畫與評估。

九、機密性：

臺大醫院將依法把任何可辨識您的身分之記錄與您的個人隱私資料視為機密來處理，不會公開。如果發表試驗結果，您的身分仍將保密。您亦瞭解若簽署同意書即同意您的原始醫療紀錄可直接受監測者、稽核者、研究倫理委員會及主管機關檢閱，以確保臨床試驗過程與數據符合相關法律及法規要求；上述人員並承諾絕不違反您的身分之機密性。

十、損害賠償與保險：

若依本研究所訂臨床試驗計畫，因而發生不良反應或損害，本醫院將提供專業醫療照顧及醫療諮詢，您不必負擔治療不良反應或傷害之必要醫療費用。除此之外，本研究不提供其他形式之補償。若您不接受這樣的風險，請勿參加試驗。

十一、受試者權利：

（一）您與孩子參加本研究皆不須繳交額外費用。

（二）試驗過程中，與您的孩子健康或是疾病有關資訊，可能影響孩子繼續接受臨床試驗意願的任何重大發現，都將即時提供給您。

（三）如對試驗相關資訊或對受試者權利有任何疑問，請電詢研究倫理委員會，電話：02-23123456 轉 63155。

（四）如對試驗有關之損害有任何疑問, 可隨時聯絡研究主持人廖華芳(電話：02- 33228136)。

（五）本同意書一式 2 份，負責之研究人員已將同意書副本交給您，並已完整說明本研究之性質與目的,且已回答您有關評估、運動方式、治療性音樂等與研究相關的問題。

十二、試驗之退出與中止：

您可自由決定是否參加本試驗；試驗過程中也可隨時撤銷同意，退出試驗，不需任何理由，且不會引起任何不愉快或影響日後醫師或治療師對您的醫療照顧。試驗主持人亦可能於必要時中止該試驗之進行。

十三、利益衝突：

本試驗無利益衝突。

十四、簽章

(一) 主要主持人、協同主持人已詳細解釋有關本研究計畫中上述研究方法

的性質與目的，及可能產生的危險與利益。

主要主持人/協同主持人簽章：

日期：□□□□年□□月□□日

(二) 受試者已詳細瞭解上述研究方法及其所可能產生的危險與利益，有關本試驗計畫的疑問，業經計畫主持人詳細予以解釋。本人同意接受為臨床試驗計畫的自願受試者。

受試者簽章：

法定代理人簽章：

日期：□□□□年□□月□□日

* 受試者為無行為能力(未滿七歲之未成年人者或禁治產人)，由法定代理人為之；禁治產人，

由監護人擔任其法定代理人。

* 受試者為限制行為人者(滿七歲以上之未成年人)，應得法定代理人之同意。

有同意權人簽章：

日期：□□□□年□□月□□日

* 受試者雖非無行為能力或限制行為能力者，但因意識混亂或有精神與智能障礙，而無法進行有

效溝通和判斷時，由有同意權之人為之。前項有同意權人為配偶及直系親屬。

(三) 見證人：

姓名：

身份證字號：□□□□□□□□□□ 聯絡電話：□□□□□□□□□□

通訊地址：

簽章： 日期：□□□□年□□月□□日

*受試者、法定代理人或有同意權之人皆無法閱讀時，應由見證人在場參與所有有關受試者同意之討論。並確定受試者、法定代理人或有同意權之人之同意完全出於其自由意願後，應於受試者同意書簽名並載明日期。試驗相關人員不得為見證人。

Appendix 2: The Loaded STS Home Exercise Guideline for the PSE Group

親愛的家長您好：

整套背重量坐站運動共需持續六週，每週執行 3 次，每次間隔一天。在運動計畫開始前，物理治療師會為您的孩子進行一次評估，並且示範運動的執行過程。之後每隔兩週會進行一次測試，以作為運動強度的參考。在六週的運動結束後，會再為您的孩子進行評估。若在過程中有任何問題，請立刻與治療師聯絡。

運動執行方式：

準備器材：治療師會提供您背心及鉛塊。另需請您準備高度適當的椅子及播放音樂的設備。

步驟一、熱身運動

1. 原地踏步或走路 1-2 分鐘；
2. 拉大腿內側肌肉：坐在地上，雙腳打開，身體向前彎，維持 15 秒，做 3 次；

3. 拉小腿肌肉：站傾斜板或扶著東西蹲下，維持 15 秒，做 3 次；
4. 不背重量坐站 5-10 次。

步驟二、背重量坐站運動，共三回合，每回合中間至少休息 1-2 分鐘

第一回：______公斤， 10 下

第二回，加入音樂：______公斤，直到疲累，約___下

第三回：______公斤， 10 下

步驟三、緩和運動

1. 拉大腿前側肌肉：趴在床上，膝蓋彎曲，儘可能讓腳跟接近臀部，維持 15 秒，做 3 次；

2. 拉小腿肌肉：站傾斜板或扶著東西蹲下，維持 15 秒，做 3 次。

注意事項：

- 飯前、飯後半小時內不要做運動。
- 在第二回運動開始之前可提醒孩子若在坐站過程中沒有配合上音樂，可坐著等待下一節音樂開始；在運動開始之後也可以視需要提醒孩子，但請不要一直提示何時該站起坐下，太多的訊息也可能是種干擾。
- 運動時需適時給予鼓勵，但也不要過度勉強。

Appendix 3: The Loaded STS Home Exercise Guideline for the Non-Music Group

親愛的家長您好：

整套背重量坐站運動共需持續六週，每週執行 3 次，每次間隔一天。在運動計畫開始前，物理治療師會為您的孩子進行一次評估，並且示範運動的執行過程。之後每隔兩週會進行一次測試，以作為運動強度的參考。在六週的運動結束後，會再為您的孩子進行評估。若在過程中有任何問題，請立刻與治療師聯絡。

運動執行方式：

準備器材：治療師會提供您背心及鉛塊。另需請您準備高度適當的椅子。

步驟一、熱身運動

1. 原地踏步或走路 1-2 分鐘；
2. 拉大腿內側肌肉：坐在地上，雙腳打開，身體向前彎，維持 15 秒，做 3 次；
3. 拉小腿肌肉：站傾斜板或扶著東西蹲下，維持 15 秒，做 3 次；
4. 不背重量坐站 5-10 次。

步驟二、背重量坐站運動，共三回合，每回合中間可視需要休息 1-2 分鐘

第一回：______公斤， 10 下

第二回：______公斤，____下

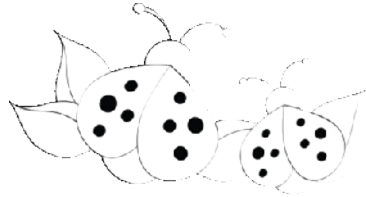
第三回：______公斤， 10 下

步驟三、緩和運動

1. 拉大腿前側肌肉：趴在床上，膝蓋彎曲，儘可能讓腳跟接近臀部，維持 15 秒，做 3 次；
2. 拉小腿肌肉：站傾斜板或扶著東西蹲下，維持 15 秒，做 3 次。

注意事項：

- 飯前、飯後半小時內不要做運動。
- 在第二回合運動開始之前提醒孩子以他記得的音樂節奏進行坐站運動，在運動中不需要給予他提示，因為太多的訊息也可能是種干擾。
- 運動時需適時給予鼓勵，且不要過度勉強。



Appendix 4: Logbook for the Loaded STS Home Exercise

建議運動內容： 1. 熱身運動

2. 背重量坐站運動：第一回：______公斤，10下；第二回：______公斤，____下；第三回：______公斤，10下

3. 緩和運動

	星期	星期	星期	星期	星期	星期	星期
日期	月 日	月 日	月 日	月 日	月 日	月 日	月 日
背重量坐站運動次數							
第一回	____下	____下	____下	____下	____下	____下	____下
第二回	____下	____下	____下	____下	____下	____下	____下
第三回	____下	____下	____下	____下	____下	____下	____下
做運動的時間	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘
寫功課的時間	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘
做完運動有沒有不舒服的感覺？	有 / 沒有	有 / 沒有	有 / 沒有	有 / 沒有	有 / 沒有	有 / 沒有	有 / 沒有
若有，是哪裡不舒服？	__________	__________	__________	__________	__________	__________	__________

日期	月 日	月 日	月 日	月 日	月 日	月 日	月 日
背重量坐站運動次數							
第一回	____下	____下	____下	____下	____下	____下	____下
第二回	____下	____下	____下	____下	____下	____下	____下
第三回	____下	____下	____下	____下	____下	____下	____下
做運動的時間	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘
寫功課的時間	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘	__小時___分鐘
做完運動有沒有不舒服的感覺	有 / 沒有	有 / 沒有	有 / 沒有	有 / 沒有	有 / 沒有	有 / 沒有	有 / 沒有
若有，是哪裡不舒服？	__________	__________	__________	__________	__________	__________	__________

Appendix 5: The Intrinsic Motivation Inventory-Chinese Version

說明： 在背重量坐站運動後我們請你回答以下問題， 答案無所謂對或錯， 我會一題一題講你的感覺， 你可以在下面1-7分中，指出句子講的感覺對不對，有1-7分可以任選，4分代表有些對，哭臉這邊1分代表非常不對，笑臉這邊7分代表非常對，如果你覺得非常對，就選笑臉這邊，覺得非常不對，就選哭臉這邊，如果覺得有些對，就選中間。

1. 我很喜歡坐站運動

1	2	3	4	5	6	7
非常不對			有些對			非常對


2. 做坐站運動很好玩

1	2	3	4	5	6	7
非常不對			有些對			非常對


3. 我覺得坐站運動是個無聊的活動

1	2	3	4	5	6	7
非常不對			有些對			非常對


4. 我會說坐站運動真的很有趣

1	2	3	4	5	6	7
非常不對			有些對			非常對

5. 我覺得坐站運動是蠻快樂的

1	2	3	4	5	6	7
非常不對			有些對			非常對

6. 當在做坐站運動的時候，我感覺我很快樂

1	2	3	4	5	6	7
非常不對			有些對			非常對

7. 坐站運動一點也不會引起我的興趣

1	2	3	4	5	6	7
非常不對			有些對			非常對

Appendix 6: Principle Components of PSE Music Design for Children in the PSE Group

Demographic Data				Week 1-2			Week 3-4			Week 5-6		
No.	Age (years)	GMFCS level	BW (kg)	1-RM STS (%BW)	Tempo (bpm)	Meter	1-RM STS (%BW)	Tempo (bpm)	Meter	1-RM STS (%BW)	Tempo (bpm)	Meter
1	6.1	I	21	28%	100	2/4	33%	94	3/4	35%	93	3/4
2	8.3	I	22	27%	37	2/4	36%	135	6/4	40%	48	2/4
3	11.8	I	44	17%	88	3/4	21%	72	3/4	21%	86	3/4
4	6.7	II	17	25%	111	6/4	41%	105	6/4	44%	78	4/4
5	8.5	II	31	23%	100	4/4	26%	117	4/4	31%	92	4/4
6	9.8	II	23	25%	67	2/4	23%	56	3/4	28%	94	4/4
7	10.7	II	26	22%	62	4/4	28%	84	4/4	40%	86	4/4
8	6.5	III	19	15%	44	2/4	23%	105	3/4	34%	56	2/4
9	7.0	III	20	5%	20	2/4	10%	90	2/4	8%	107	2/4
10	9.4	III	22	19%	16	2/4	26%	14	2/4	29%	22	2/4
11	11.0	III	33	35%	123	3/4	39%	106	3/4	42%	103	2/4
12	11.4	III	35	21%	85	4/4	39%	32	2/4	40%	34	3/4

Abbreviations: PSE = Patterned Sensory Enhancement; GMFCS = Gross Motor Function Classification System; 1-RM STS = one-repetition maximum of the loaded sit-to-stand normalized by body weight; BW = body weight; bpm = beats per minute.