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RESEARCH ARTICLE

Task-oriented arm strength training in children with cerebral palsy. A randomized controlled trial protocol and exercise program for functional strength training based on progressive resistance exercise principles

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ABSTRACT

Objective: To compare the effectiveness of Task-Oriented Arm Strength training in children with Cerebral Palsy (TOAST-CP), using Progressive Resistance Exercise principles with manual skill learning in improving the performance of manual daily activities in children with spastic Cerebral Palsy.

Methods/Design: This multicenter randomized controlled trial investigates the effectiveness of TOAST-CP in children with spastic Cerebral Palsy, involving 50 participants aged 8-18 years. Participants are recruited from rehabilitation centers. Eligible participants are randomly allocated to either TOAST-CP or usual care related to manual skill learning.

Intervention: The participants of the intervention group performed a TOAST-CP program, based on individual goals and guided by a progressive resistance exercise algorithm. The control group receives the usual care related to the manual skill learning program. TOAST-CP consists of an individual-based 30-minute session, three times a week over 16 weeks. A specific exercise program is developed.

Outcome: Outcome is measured at baseline at eight weeks, 16 weeks (end of training), three, and six months after training.

As a primary outcome, the Assisting Hand Assessment is used. Secondary outcomes are task-oriented strength measures and muscle strength measures of the upper limb. The Observation and Scoring of Arm Hand Skills (performance and amount of use of both hands), the ABILHAND (-Kids), and the Jebsen Taylor Hand Function test (speed of hand use) are measured. The most important needs and goals for the child and his/her parents are scored by Canadian Occupational Performance Measure and Goal Attainment Scaling.

Keywords: task-oriented arm strength training- TOAST-CP-, strength, cerebral palsy, upper limb, functional therapy

Introduction

Cerebral palsy (CP) is the most common cause of movement disability in childhood. The incidence is 1.5-2.5 per 1000 live-born children and has remained stable over recent years.[1] Children with CP experience limitations in motor activities and participation in the community, predominantly caused by impairments in muscle function. Aside from abnormal posturing due to spasticity, muscle weakness can significantly contribute to impaired muscle function and there is increasing evidence that muscle weakness significantly impairs upper limb motor function and the ability to perform manual tasks in children with CP. [2-5]

Studies in the last decade have shown that muscle weakness, *not* spasticity, is the greatest limiting factor of motor function in children with CP.[6,7] This is shifting the focus from spasticity management towards strength training in children with CP. Consequently, strength training is expected to reduce limitations in activities and participation of children with CP.[8-13]

When strength training is applied, the guidelines of the National Strength and Conditioning Association (NSCA) should be used.[14,15] According to the NSCA, an individualized approach to strength training is recommended after seven years of age.[14] Strength training should involve a progressive intensity, thereby stimulating strength gains that are greater than those associated with normal growth and development. This is known as the Progressive Resistance Exercise (PRE).[8,16,17] This method of strength training has previously demonstrated efficacy in children with CP without injury or problems with compliance during a 12-week program, using a training load of 8-15 repetitions in three sets with a rest period of 90 seconds.[7,8]

In the most recent review on upper limb strength training studies (2014) five strength training studies of varying methodological quality are identified, including three Randomized Clinical Trials and two Clinical Trials. All studies demonstrated a positive effect on strength, but no effect on manual performance of daily activities is shown. In these five studies strength training is performed with single-joint exercises for the wrist, elbow, and shoulder.[18]

In rehabilitation of the upper limb motor skill learning, combined with goal-directed therapy has become the most important part of the treatment in children with CP. This has been defined as a *functional approach*.[19,20]

We are especially interested in developing a method of strength training to improve manual performance of everyday activities and participation in children with CP and compare this task-oriented strength training with usual care related to manual skill learning.

As shown, upper limb strength training focused on specific muscle groups (single joint training) will not improve everyday activities.[18] Furthermore, it is shown that in the first 6-18 weeks of strength training, little adaptation of muscle tissue will occur, but mainly specific neural adaptation will take place during this training period.[21-23] Based on the strength training guideline from the NSCA, it is concluded that motor learning theory should be incorporated into strength-training practice.[14,15,24] Based on both the guidelines for strength training and the fact that neural adaption will occur mainly in the first 8-12 weeks of training, we developed Task Oriented Arm Strength Training in children with CP (TOAST-CP). In TOAST-CP we performed the strength training with loaded objects from daily life such as a bucket, a measuring cup, a belt, and a crate, to ensure the specificity of the neural adaptation for the trained activities.[25] The strength tasks are meaningful tasks in the correct environment, which will enhance the possibility for an increase in the transfer of the trained activities to activities of daily life. The most important criteria for improved performance in everyday activities are the use of both hands during bimanual tasks and the speed of performance.[20,26]

In TOAST-CP the PRE training method will be used because it appears to be a safe training method for children with CP.[8]

The effect of TOAST-CP on the performance of daily activities will be compared with the effect of manual skill learning on the performance of daily activities.

Both programs will improve everyday activities and the use of both hands, but the TOAST-CP program will possibly lead to a faster improvement in the performance of everyday activities. This effect can decrease the period of upper limb treatment. Furthermore, the increased strength after the TOAST-CP will ensure that everyday activities will be more easily executed compared to solely manual skill learning, increasing the long-lasting independent use of both hands in everyday activities.

Aims of the study

a. To develop specific task-oriented arm strength exercises based on the needs and goals of the child.
b. To compare the effect of TOAST-CP in children with CP on the ability to use both hands in bimanual tasks with the effect of usual care (manual skill learning – MSL-).
c. To compare the effect of TOAST-CP in children with CP on upper limb strength with the effect of usual care (MSL).

This article describes both the design and training protocol of TOAST-CP exercises to assess the effectiveness of TOAST-CP on bimanual ability and strength in children with CP compared to MSL

Material and Methods

Participants

50 children with CP, from 8 rehabilitation centers, are recruited. All are identified by the rehabilitation teams, based on encountering problems in performing upper limb activities and decreased upper limb muscle strength.

Inclusion criteria are age 8-18 years, Spastic Cerebral Palsy, Gross Motor Function Classification System (GMFCS) I-IV, Manual Ability Classification System (MACS) I-III, Hand function impairment Zancolli grade I- IIB, to be able to comprehend tasks and perform the measurements and training, able to communicate in Dutch or English. Realistic problems performing manual activities, reduced upper limb strength, and strength difference between the left and right arm of at least 20%. Exclusion criteria are severe impairment of hand function: no active hand function (Zancolli III), upper limb hand surgery within the last six months, Botulinum toxin-A injection of the upper limb and/or an upper limb specific strength training program within the last three months.

Design and procedure

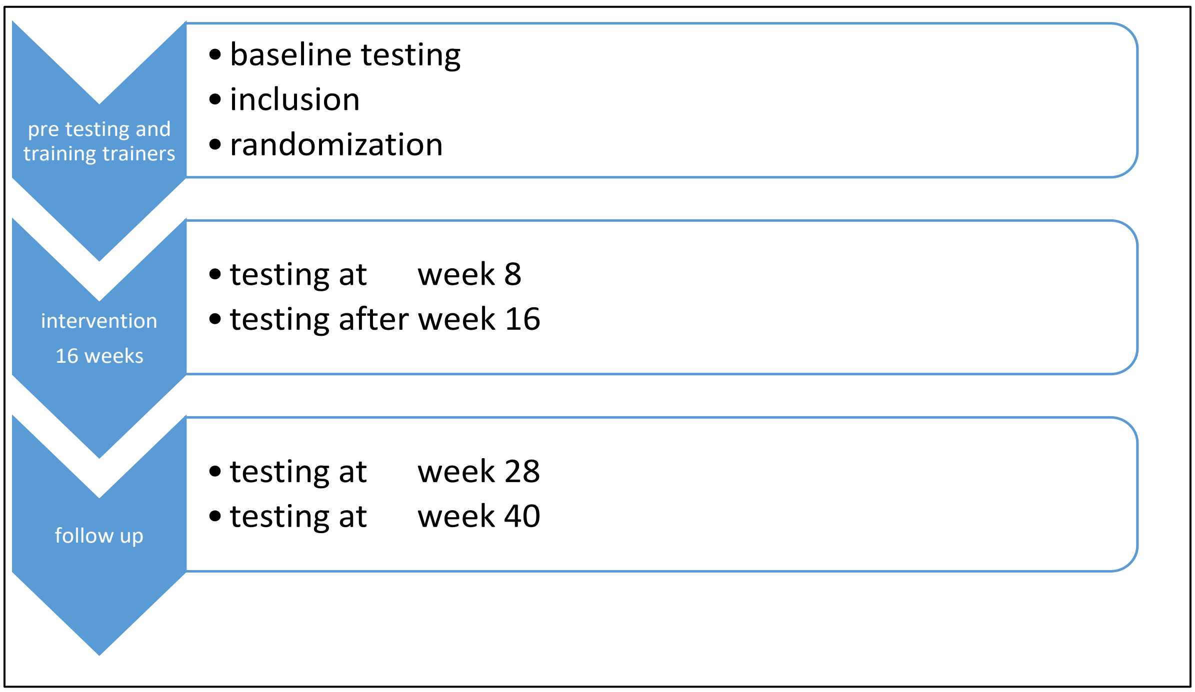
A multicenter randomized controlled trial design is used. The ethical committee of Maastricht University approved the study (NL4981801514). The trail is registered NL4533 (NTR4668)

Evaluation procedure

Participants are assessed by blinded testers at baseline, after eight weeks of training, after completion of the intervention period at 16 weeks, and at three and six months after the treatment, to assess the long-term outcome of the intervention. See Figure 1.

Testers are trained to perform all tests, they receive eight hours of training to perform the tests and practice with four children all tests.

Figure 1. Test design and procedures



Randomization and allocation concealment

Inclusion and randomization are performed by an independent physician and ER, based on videos of the most important needs of the child and the strength data. After inclusion, the participants are randomly allocated to either TOAST-CP (experimental group) or MSL (usual care) using a block allocation of four. Three independent trained blinded testers and randomized allocation of the research trainers to the TOAST-CP or MSL group will guarantee optimal allocation concealment.

Specific TOAST-CP and MSL trainers are labeled and both are completely uninformed about each other's program. The TOAST-CP therapists are trained (12 hours) before the commencement of the study to guarantee a uniform use of the PRE training principles and task-oriented approach and administration. The MLS trainers received only information about the task-oriented approach and administration (4 hours).

Study parameters/Measurements

Measurements across all domains of the International Classification of Functioning, Disability and Health for Children and Youth (ICF-CY) are used to answer the research questions. All measures are administered and scored by raters blinded for group assignment.

Activity Level

Primary outcome measure:

The Assisting Hand Assessment (AHA) measures the typical performance of a child's assisting hand in a range of bimanual activities. The AHA measures the ability and performance of the use of the affected hand in bimanual play by standardized video observation. It is validated for children with unilateral CP, aged 1.5 to 12 years. The interrater reliability of the sum scores is excellent (0.97 (0.91-0.99).[28,29]

Secondary outcome measures:

Activity Level

The Observation and Scoring of Arm hand Skills (OSAS) is a video-based observation system to observe the spontaneous use of the affected limb in standardized bimanual fine and gross motor tasks (threading beads task, construction tasks small and large, making sandwich tasks and stacking cylinder tasks). These tasks have shown very good interrater reliability of 87% -91% agreement and interrater reliability of 72% -84% agreement in children with unilateral CP (prepared to submit). The OSAS will be scored by one blinded assessor. Duration of the use of the affected hand in these bimanual skills will be scored.[30]

The ABILHAND-Kids is a 21-item questionnaire based on existing scales and expert advice. The ABILHAND-kids is a functional scale specifically developed to measure manual ability in children with CP (up to 12 years). A high reliability (R = 0.94), and good reproducibility over time (R = 0.91) have been shown. The original ABILHAND will be used for adolescents (12-18 years), which has shown good reliability and reproducibility.[31]

The Jebsen-Taylor Hand Function Test scores the velocity of the use of the affected hand in functional standardized tasks. For the dominant hand, the test-retest reliability in patients with stable hand disorders is high (R=0.89 to 0.99), except for the writing subtest (R=0.67). With the non-dominant hand, the simulated feeding subtest is the least reproducible (r=0.60). The test seems to be sensitive enough to detect changes in hand function in patients with different impairments.[32]

Participation Level

The Canadian Occupational Performance Measure (COPM) is a semi-structured interview for children or their parents. It identifies the child's perceived problems in activities of self-care, play, and leisure, and performance and satisfaction scores are the features of the COPM used. COPM has shown good test-retest reliability of 0.69-0.89.[33]

For five needs involving problems with bimanual skills, treatment goals will be established.

The *three most important goals* are scaled using Goal Attainment Scaling (GAS). GAS has good interrater reliability (0.96) and moderate to good interrater reliability 0.51-0.95.[34] All baseline GAS constructs will be formulated by the same testers.

The domain frequency of use of the Children's Assessment of Participation and Enjoyment

(CAPE) and Preferences for Activities for Children (PAC) is used to document this outcome. The CAPE/PAC has been developed to determine the outcome of participation once per three months. This aims to evaluate the effect of training in a child's typical environment (in the family, with friends, at home, at school, in sports and hobbies). The CAPE / PAC has a moderate to good test-retest reliability (0.68-086) and moderate to good interrater reliability 0.47-0.99.[35]

Enjoyment of the child during the training is assessed using the Youth Rating Scale of the Behavioral and Emotional Rating Scale Second Edition (BERS-2).[36]

The test-retest reliability coefficient of the Parent Rating Scale Composite Strength Index (r = .87) with subscales ranges from 0.82 to 0.92. The Youth Rating Scale Composite Strength Index (*r* = 0.91) with subscales ranging from 0.84 to 0.91. BERS-2 can be used from 5-18 years of age. For younger children, the Smiley Face five rating satisfaction scale will be used.

Body function/Body structure

At the body function/ structure level (ICF-CY), measurement of muscle strength, spasticity, and active and passive range of movement is performed.

Measurement of strength includes both dynamic and isometric components of strength and the next tests are performed:

Grip and pinch strength are measured using the E-link from Biometrics (isometric strength) (http://www.biometricsltd.com/REHAB.htm). Grip and pinch strength measurements in CP are shown to be very reliable (test-retest and inter-rater reliability.[4]

The isometric strength of wrist and elbow muscles is measured using Hand Held Dynamometry (HHD). The Microfet-2 is used, using the make method.[37] HHD strength measurements in CP are showing to be very reliable (test-retest and inter-rater reliability (http://www.biometrics.nl/produkten.php?ms_id=196&Instrumenten/Spierkracht/MicroFET_2.)

Task-oriented strength is measured during the performance of specific tasks related to their three defined goals: two examples are the box task (bimanual lifting) and the cup task (unimanual lifting). Strength is expressed as the number of Kg lifted and kept in one standardized described position for five seconds Box and cup strength measurements are shown to be very reliable (test-retest and inter-rater reliability).[30,38,39]

Goniometry is used to measure an angle of catch (AOC) (high-velocity stretch) presenting a measure for spasticity. Furthermore, goniometry is used to measure active and passive Range of Motion (ROM) of the wrist, elbow, and shoulder. A Lafayette Gollehon extendable goniometer (model 01335) is used to measure ROM. (http://www.lafayetteevaluation.com/product_detail.asp).

A standardized protocol with standardized positions is used. The protocol has been used in the Botulinum Toxin Bimanual Skills study (BoBiVa).[40] A schematic overview of the measurements is given in Table 1.

Table 1: Primary and secondary outcome measures and timeline measurement

ICF-CY	Measurement	Domain	Baseline	8 weeks	16 weeks	28 weeks	40 weeks
Primary outcome							
Activity							
	AHA Assisting Hand Assessment	Performance assisting hand	x	x	x	x	x
Secondary outcome							
Activity							
	OSAS Observation and Scoring of Arm hand Skills	Percentage use of both hands	x	x	x	x	x
	Abilhand-kids	Manual ability	x	x	x	x	x
	Jebsen Taylor Hand Function Test	Capacity Speed	x	x	x	x	x
Participation							
	COPM Canadian occupational performance measurement	Performance	x	x	x	x	x
	GAS Goal Attainment Scale	Performance	x	x	x	x	x
	CAPE Children's Assessment of Participation and Enjoyment	Performance	x		x		x
Personal Factor							
	Youth rating scale	Performance	x	x	x	x	x
Body Function & structures							
	Grip/pinch strength/ HHD Handheld dynamometry	Capacity	x	x	x	x	x
	Functional crate task /pitcher task	Capacity	x	x	x	x	x
	Spasticity, AROM Active Range of Motion, PROM Passive Range of Motion	Capacity	x		x		x

Interventions

Both groups

TOAST-CP and MSL treatment are based on the three selected goals and *an analysis of the task performance* has been made of each of these three goals. The *results of the task analysis serve as the basis for the individualized treatment of participants* allocated to the TOAST-CP group.

All TOAST-CP participants receive individual 30-minute contact sessions three times a week over 16 weeks. Based on earlier research, it is established that three goals can be trained in 30 minutes.[40]

The MSL group receives individual usual care, without any strength intervention, 3 times a week over 16 weeks.

Therapists' adherence to the treatment protocol is supported by structured forms, instructional guides, and weekly audits. The therapists used a registration booklet to record all activities performed in blocks of five minutes of training. These booklets will be scanned and e-mailed each week to the principles investigator.

After the end of the treatment period of 16 weeks, the participants receive their usual care without a specific focus on upper limb treatment. The focus will be on lower limb treatment, speech therapy, or sports.

Due to the period of 16 weeks of training and the holidays in the Netherlands, each training period contains one week of a holiday or two separate weeks of holiday. No training will be provided during holidays of one week and is added at the end of the training period to ensure the 16 weeks of training.

Experimental group

Task-oriented strength training protocol - TOAST-CP program-

The exercises in TOAST-CP are based on 1) the *three defined goals,* 2) the *outcome of the analysis of the task performance and* 3) a *specific strength analysis* is performed based on the chosen exercises.

The Repetition Maximum (RM) model is used to determine the load.[8,16,17] All exercises based on the task analysis are loaded with weight to determine the 8-15 RM. According to the nature of task-oriented strength exercises, a set of muscles required to perform the functional task are trained and targeted.[15,16] Examples of these tasks are lifting a bucket, carrying a tray, making a sandwich, fastening a belt, and lifting a mug.

The training method is Progressive Resistance Exercise (PRE). This method of strength training has previously demonstrated efficacy in children with CP without injury or problems with compliance during a 12-week program.[16] Using the NSCA guidelines, a training load of 8-15 RM, three sets with a 90-second rest period is used.[14,15]

The PRE training lasts 16 weeks. The first two weeks consist of unloaded task-oriented exercises, with a focus on the quality of the performance of the task. To determine the load of 8-15 RM, measurement takes place after the *second week. In the third and fourth weeks,* the load of the task-oriented exercises increases up to the level of their individual 8-15 RM. At the start of week five, the 8-15 RM training starts, and after each week, the load will be re-measured and adapted.

From week five to week 16 (12 weeks) the load increases 10-20% per week if a block of three sets of 8-15 RM is possible.[17] See Figure 2.

Figure 2 RCT program TOAST-CP study

Inclusion	
Week 1 Task analysis & treatment plan based on three goals	
TOAST-CP 16 weeks 3 times a week	MSL 16 weeks 3 times a week
Week 2-3 Unloaded performance training for three goals	Week 2-16 Unloaded performance training for three goals
Week 4-16 PRE-training 15 RM of three goals Increasing load per week by 10-20% if possible	

Abbreviations: TOAST-CP = task-oriented arm Strength Training in Cerebral Palsy; MSL= Manual Skill learning, PRE = Progressive Resistance Exercise

A detailed program has been developed and adapted based on pilot training sessions. In this program examples of exercises, based on the most frequently chosen goals in usual are described. This program is very useful for therapists to perform strength training.

This program is added as: **Specific TOAST-CP program.**

Control group

Usual Care (Manual Skill Learning) (MSL)

Participants assigned to the control group received MSL.

The exercises in the control group are based on the *three main goals and* individualized MSL will be performed, without any strength training. See Figure 2.

Sample Size

In the present study, the AHA is the primary outcome measure. Based on the Botulinum Toxin Bimanual Skills study (BoBiVa)[40] and the results in the study of Eliasson et al.[29], we assume that a difference in the AHA score of one logit after treatment between groups is the minimum clinically relevant difference to be detected in our study. We also assume that the variation of the measurements in both studies will be representative of our study population. This means that with a two-sided alpha of 0.05 and a beta of 0.10 (or power of 90%), a minimum of 50 children in total is needed to detect the main effects of the two treatment comparisons. For this study, we choose to focus on the mean effects (> one logit).

A dropout of about 20% is anticipated; therefore, the study aims to recruit a total of 60 children.

Data Analysis

First, descriptive statistics for the demographical characteristics of the whole group, the experimental group, and the control group will be presented.

Second, clinical and demographical characteristics will be presented for baseline results of outcome measures and other potential confounding variables for both experimental and control groups. The level of hand function (graded by the Manual Ability Classification System and Zancolli) is considered to be a potential confounder.

Differences in results will be calculated for between-group comparison. Results will be calculated according to the intention to treat principle. Between-group analysis will include differences between baseline and follow-up measurements for each clinical outcome measure used, their standard deviation, and 95% confidence intervals. Mixed models for the baseline and follow-ups will be used. Statistical significance is set to $p < 0.05$ and clinical importance will be judged by the lower 95% confidence interval which equals the minimum effect size.

Specific TOAST-CP program

Steps

The TOAST-CP program contains five steps to follow during the training.

1. Task analysis of the personal goals, determining the parts of the task in which strength of the upper limb is important to realize that part of the task.
2. Determine the baseline load for the part-tasks derived from the goals.
3. Train the part-tasks for two weeks unloaded to finetune the performance before loading.
4. PRE training starts in the third week with a baseline load.

Uploading the weight in PRE training when 3 series of 8-15 RM has been realized. Uploading will be done with 10-20% each time.

PRE scheme

Based on the PRE training scheme the start of the training is at the 8-15 RM. Figure A.

	Load	Repetition	Series	Pause
Maximal strength	90-95%	1-3	4-8	2-4 min.
Submaximal	75-90%	8-12	3-5	1.5-2 min
Submaximal strength	50-75%	10-15	3-5	45-90 sec.
Endurance strength	<50%	10-50	3-5	↓ 45 sec.

Figure A. PRE scheme. Load of training is in the range of 8-15 RM (90-50%).(pink block)

The PRE training contains 3 -5 series of 8-15 repetitions at the level of 50-90%. The pauses in between need to be 45 sec to 2 min., depending on the number of repetitions.

Amount of weeks: total amount of 16 weeks with 12 weeks of PRE training. Frequency of training 3 times per week.

Equipment needed:

Weights

Weights from 20 gr coins to 500 gr pockets, up to 3 kg pockets or discs. Figure B.

Figure B. Weights for PRE training

Training Frame

Frame to use for PRE training for daily tasks. See figure C.

Figure C. Training frame with rolls and ropes to attach weights to the daily objects. (Artimex sport equipment).

Scale

Scale integrated in a table to measure pressure from 0.1 kg up to 20 kg. Figure D.

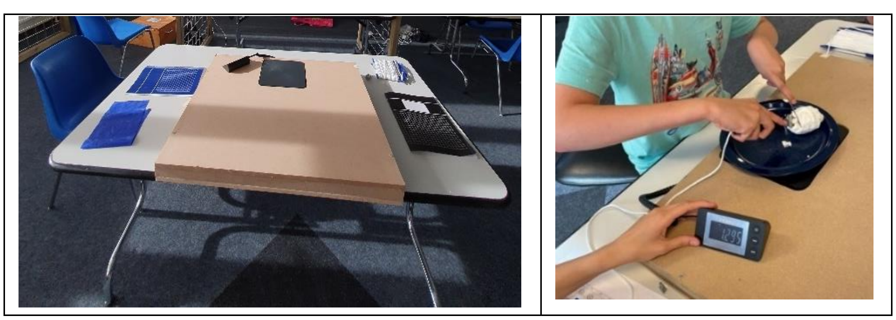


Figure D: scale and measuring unit integrated into a table. A plate can be placed on the scale to measure the pressure while cutting clay, food, etc.

Examples of tasks suitable for task-oriented PRE training

Using fork

Criteria for loading:

Amount of pressure on the scale to measure maximal force (1 RM) and the 75-90% force to realize 8 -15 repetitions by using the fork. Figure D.

Figure D. Measuring the force of when pushing the fork with the affected hand to stabilize the food.

Amount of weight attached to the fork and the training frame with a rope when holding the fork in a stable position in predefined time (5-30 sec), 8-15 repetitions. Figure E.

Figure E. Measuring the weight attached to the fork in the affected hand, by a rope when stabilizing the fork in a specific position on the plate. The weight is pulled against the pushing direction.

Shoe lacing

Criteria for loading

Amount of weight attached to a shoelace in the affected hand, using a rope and rolls connected to the training frame, that can be managed by holding the shoelace in a specific position while part of the shoe lacing can be performed. Figure F.

Figure F. Weight attached with a rope to a shoelace, that needs to be stabilized with the affected hand when performing a part of the shoe lacing task. Weight is pulling in the opposite direction of the force needed to stabilize the shoelace.

Lifting objects – box, cooker, frying pan, bottle, cup

Criteria for loading:

Amount of weight lifted to manage 8-15 repetitions. Figure G.

Figure G. Box lifting with added weights.

Holding cup

Criteria for loading:

Amount of weight in the cup, lifted by the affected hand in 8-15 repetitions. Figure H.

Figure H. Holding a cup in the affected hand while pouring water/ weights in the cup.

Making a tail

Criteria for loading:
Amount of weight pulled by the rope in the training frame, that can be managed by holding the tail in a stable position with the affected hand and elevated arm, while the preferred is doing the tail, in 8-15 repetitions. Figure I.

Figure I. Affected hand is holding the tail and getting resistance while holding the tail. The weight is pulling the stabilizing hand in the downward frontal direction against the direction needed to stabilize the tail with the hand.

Zippering

Criteria for loading:
Amount of weight pulled by the rope in the training frame, that can be managed by holding the jacket in a stretched downward position with the affected hand, with or without zippering, in a series of 8-15 repetitions. Figure J.

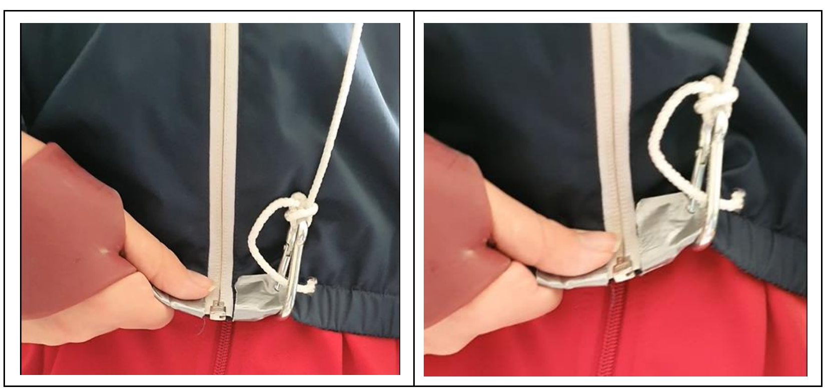


Figure J. The Affected hand is pulling the jacket downwards into a straight position, while resistance is created in the opposite direction.

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