Effectiveness of interactive computer play on trunk control and gross motor function in children with cerebral palsy: a pilot randomized controlled trial

NCT number: NCT02975804

Document date: April 10, 2018

Document revised date: July 18, 2019

PROPOSED RESEARCH PROJECT

a) Title:

Effectiveness of interactive computer play on trunk control and gross motor function in children with cerebral palsy: a pilot randomized controlled trial

b) Introduction:

Cerebral palsy (CP) is the most common physical disabilities in childhood, affecting 2 to 2.5 per 1000 live-births worldwide[1] and about 1.3 per 1000 live-births in Hong Kong.[2] It is a non-progressive lesion of the developing central nervous system affecting the control of movements and postures in the children.[3] Children with CP are usually classified using the Gross Motor Function Classification System (GMFCS) according to age-specific gross motor function.[4] It is an ordinal grading system of five levels (I to V), in which self-initiated movements, such as sitting, standing or walking, are described in relation to different age groups. Distinctions between levels I to V are based on assessment of functional abilities and reliance on assistive devices (such as walking aids or wheeled mobility). Children of levels I and II can generally walk without aids while children of level III can walk with aids for short distances but usually choose wheeled mobility in community settings. Children at level IV have limited motor ability in assisted standing, stepping, and transfers. Children classified as level V are completely dependent on others for transportation in a wheelchair and lack antigravity postural control.[4] Numerous studies have shown that children with CP, regardless their GMFCS levels, demonstrate problems in their postural control in sitting[5] and standing[6] positions, which in turn affect their function and participation in daily life. The main deficits in postural control in sitting for children with CP are lack of ability to recruit direction-specific muscles in more severe children (GMFCS levels IV and V) or inability to fine-tune the degree of muscle contraction according to specific situations in less disabled children when their sitting balance is challenged.[5] Excessive contraction of antagonists is a common compensatory strategy.[5] In standing, for those more abled children with CP, i.e. GMFCS levels I to II, when their balance is challenged, the children will use more proximal muscles in the hips to maintain their balance.[6] As in sitting, contraction of both agonist and antagonist muscles around the joint is a common compensation for poor postural control in standing. These ineffective strategies to compensate their balance in sitting or standing positions will affect the children’s daily function such as desk work at school, transfers and ambulation.[7]

Postural control involves controlling the body’s position in space for stability and motility.[7] Good postural control around the trunk or ‘trunk control’ in short, allows an individual to perform different tasks in an upright and vertical posture without losing the balance.[7] The control of trunk to maintain balance in either sitting or standing positions is usually tested in the following three conditions: (1) static balance- an ability to maintain a static posture without external support; (2) anticipatory balance- an ability to maintain the posture after internal perturbations such as self-initiated reaching movements; and (3) reactive balance- an ability to regain balance after external perturbations.[7] Assessment of trunk control in children is commonly part of a motor assessment such as Peabody Developmental Motor Scale or Bruininks-Osteretsky Test of Motor Proficiency.[7] The main limitation of these motor assessments is that the trunk is considered a one unit during a motor act, despite that there are different segments in the spine.[8] For example, it is unable to differentiate which region of trunk control, namely upper, middle or lower thoracic, upper or lower lumbar or full trunk, needs to be developed before a child is able to use his hands in sitting in play or feeding activities without losing balance. Preliminary findings in very young infants have shown that infants with lumbar control had better movement quality in reaching actions when compared to those with thoracic control only.[9] It seems that specific outcome measures on trunk control are necessary to demonstrate improvement in movement quality like this. There are specific outcome measures assessing balance, an indication of trunk control in recovering stability after internal or external perturbations such as Pediatric Reach Test (PRT), Pediatric Balance Scale (PBT), Trunk Control Measurement Scale, Segmental Assessment on Trunk control (SATCo) and Sitting Assessment for Children with Neuromotor Dysfunction (SACND). It has been found very few of the commonly used outcome measures on balance have covered assessing all three aspects of balance as mentioned above.[10] Most of these outcome measures require the children to be able to sit independently with or without hand support, making it unsuitable for children with CP of GMFCS levels IV and V.[10] Furthermore, most of these outcome measures have the same limitation in considering the trunk as one whole unit, not consisting of different regions. Among all the commonly used assessment of trunk control, SATCo is a recently refined assessment on segmental trunk control in children.[8] The child's trunk control is examined by progressively reducing the trunk support from the shoulder girdle to the pelvis in order to assess the head control, upper thoracic, mid-thoracic, lower thoracic, upper lumbar, lower lumbar and full trunk control.[8] The trunk control is tested under 3 different conditions in sitting: to maintain the posture (static control), during voluntary head movements (active control) and recovery of trunk control after a disturbance of balance by a nudge (reactive control).[8] The preliminary results of the SATCo showed a high inter-rater reliability (ICC $\geq$ 0.8) and moderate to good correlations with other established motor assessments (r from 0.65 to 0.88).[8] Besides assessing the trunk in different segments, SATCO is one of the rare ones being able to assess reactive balance.[10] It has been recommended that to increase the comprehensiveness in assessing the balance mechanism in children with CP, researchers can use the SATCo in combination of outcome measures assessing more dynamic sitting balance, such as the PRT.[10]

With the advances in computing technology, interactive computer play (ICP) has become popular in rehabilitation for people with motor impairments, including children with CP.[11-14] During an ICP, a child interacts and plays with virtual objects in a computer-generated environment, through the use of a computer console or platform and the software, allowing the child to control the games through certain body movements.[13] Because the computer games are fun and enjoyable, the child will repeat the required body movements in numerous times so as to get a high score in the game without losing the interest. These numerous repetitions (essentially mass practice) and feedback from the game scores (knowledge of performance and results) are important in motor learning and enhancing neuroplasticity.[15] Hence, ICP may be a feasible way to improve trunk control in children with CP, in addition to the conventional therapies. Up to date, there are six published studies using ICP or virtual reality in improving balance in children with CP.[16-21]

In a small randomised controlled trial (RCT) (n=6), children with CP were randomly allocated to an intervention group, who received two sessions of ICP for 90 minute per session for 4 weeks when the control group received the regular therapies.[21] All three children in the intervention group showed improvement in their postural control in terms of postural tone, proximal stability, postural alignment and two of them showed extra improvement in their balance as measured using the SACND. No statistical analysis was performed in this study due to small sample size.[21] In the case study by Deutsch et al (2008),[16] a 13-year-old boy with CP received 11 training sessions over 4 weeks with 60 to 90 minutes per session using a commercially available ICP (Nintendo Wii). It was found that his postural control was improved in increasing more symmetrical weight-bearing on both lower extremities and decreasing in body sway after the intervention.[16] Sharan and colleagues (2012) used the Nintendo Wii Fit as an intervention for a group of 16 children with CP, 3 times per week for 3 weeks along with their conventional rehabilitation modalities in their RCT.[19] Both the intervention and control groups improved significantly in their scores in the PBT and the intervention group had significantly higher score than the control group.[19] In another small RCT by Wade and Porter (2012), 13 children with CP of GMFCS levels IV and V were randomly allocated to the intervention and control groups and then crossed over.[20] Children in the intervention group practised active trunk movements through a purposely built force platform connected to computer games in sitting for 3 months (no intervention dosage provided). Significant differences were found in the shoulder girdle position and spinal profile and significant increase in the overall scores at rest (specifically associated postural reaction) and during reaching (specifically the proximal stability rating) according to the SACND after intervention.[20] The Nintendo Wii Fit was used again in a repeated-measure multiple single-subject study conducted by Jelsma and colleagues (2013).[17] A group of 14 children with hemiplegia CP of GMFCS levels I and II were randomly allocated to start the intervention first or 2 weeks later. During the intervention, the children received training using the console, four times a week for 25 minutes per session for three weeks. Significant improvement in balance, as measured with the modified Bruininks-Osteretsky Test of Motor Proficiency Version 2 (BOT2), was found immediately and 2-month post-intervention but no changes were found in the running, agility and speed in the BOT2 and Timed up and downstairs.[17] However, in a small RCT, 18 children with CP of GMFCS levels I or II were randomised into an intervention group and a control group and then crossed over after five weeks.[18] The children received practice on the Nintendo Wii Fit Balance games at least 30 minutes, five days a week during the intervention period. No significant difference was found in the change of centre of pressure during the modified Sensory Organization Test, in the muscle responses after perturbations and in the control of anterior-posterior and medial-lateral directions in the rhythmic weight shift test between the intervention and control groups.[18] In summary, promising though conflicting results were found among these studies whether ICP is effective in improving trunk control in children with CP. The main limitations of these studies are the overall low levels of study quality, small sample sizes and heterogeneous population groups under the umbrella term CP. In fact, similar conclusions for future studies with larger sample sizes and rigorous study designs have been echoed from four recent systematic reviews on the topic.[11-14]

One of possible reasons for the conflicting conclusion on the use of ICP in rehabilitation for children with CP may be lack of sensitive outcome measures to capture the specific changes in the trunk control post-intervention. The above-mentioned studies were either using general motor assessments or outcome measures with unknown psychometric properties to assess the posture of the participants. Besides, when the child received the ICP intervention in a standing position, compensatory strategies, due to uncontrolled degrees of freedom in lower limbs, might be used to maintain their trunk control in this more challenging position than a sitting position. These compensatory strategies may in turn, water down the overall effect of the ICP intervention on the trunk control. This may have explained the negative results from the study by Ramstand et al (2012).[18] Most of these studies examined only one or two aspect of the trunk control as testing the static or anticipatory balance of the children. Furthermore, the commercially available gaming consoles, such as Nintendo Wii Fit, are not specifically developed for children with CP to elicit targeted movements to overcome their impairment and the software may not be sensitive enough to translate the subtle movement changes to an increase in the game scores as well to an adequate challenge for these children.[15]

Tymo (Tyromotion, Austria, www.tyromotion.com) is a wireless force plate detecting the movement of the centre of pressure, either in a sitting or standing position. Force and weight distribution can be measured using the software provided with the Tymo in these two positions. During the assessment, the user will move the trunk forward, backward and sideways as far as they can. The amplitude of the force and weight distribution between the two sides of the body will be recorded. This information will be used when the user uses the Tymo as a balance training module, in which the user will move the trunk forward, backward and sideways to participate in a computer game. For example, the user will move their trunk in different directions so as to manoeuvre a basket to catch the falling apples or manoeuvre the hot-air balloon through an obstacle course (Tables 1 and 2). The difficulties of the game will be adjusted according to the information provided during the assessment so that the user needs to move their body accordingly in different directions without losing their balance. This equipment is specially designed for rehabilitation for people with movement disorders, hence unlike the commercial games, there are no flashing lights or sudden noises during the games. To our best knowledge, there has been no study published using Tymo as an intervention for training trunk control in children with CP.

c) Aims and Hypotheses to be Tested:

Conducting a pilot single-blinded randomised controlled trial (RCT), the overall objective is to investigate the effect of a 6-week training programme using an interactive computer play training tool on the segmental trunk control, sitting and/or standing balance and gross motor function in children with CP.

The hypotheses to be tested are:

(1) That after 6 weeks of training using the interactive computer play training tool, Tymo, the children with CP will show significant improvement in their segmental trunk control as demonstrated in the SATCo.

(2) That after 6 weeks of training using the interactive computer play training tool, Tymo, the children with CP will show significant improvement in their balance in sitting and/or standing positions as demonstrated in the PRT.

(3) That after 6 weeks of training using the interactive computer play training tool, Tymo, the children with CP will show significant improvement in gross motor activities as demonstrated in the GMFM 88.

(4) That after 6 weeks of training using the interactive computer play training tool, Tymo, children with CP, who are able to ambulate independently with a walking aid, will show a significant improvement in the distance covered in 2 minutes.

d) Plan of Investigation:

(i) <u>Subjects</u>

Selection criteria:

(1) Children with a diagnosis of CP will be of GMFCS levels III to IV, who in general, require walking aid (level III) during ambulation and with limited walking ability (level IV).[4] Aiming to achieve a higher homogeneity of the recruited children, for those with level III, only those requiring physical assistance to climb stairs will be recruited and so it is believed that only those with lower motor ability, i.e. similar to level IV, will be included.

(2) Children, with non-CP physical disabilities, will have similar gross motor function as in (1).

(3) Aged from 6 to 12 years old and

(4) Able to follow instructions to interact in simple computer games

Sample size calculation: There is no previous published study using the primary outcome measure (see below under Methods) to examine the effect of the ICP on trunk control in this population group, hence, no sample size calculation is possible based on previous data. Thus it is estimated that 20 children with 10 children in each arm for this pilot RCT is appropriate and feasible. The sample size will be the largest among the previous studies in this area.

Exclusion criteria:

(1) Children with epilepsy/ seizures that could be elicited by flashing lights or sudden loud noises from computer screens

(ii) <u>Methods</u>

Outcome measures (OM) used in this proposal include:

Primary study outcome:

(1) Segmental Assessment on Trunk control (SATCo)[8] assessment on the child's segmental trunk control by progressively reducing the trunk support from the shoulder girdle to assess the

head control, through support at the axillae (upper thoracic), inferior scapula (mid-thoracic), lower ribs (lower thoracic), below ribs (upper lumbar), pelvis (lower lumbar) and no support to measure full trunk control.[8] The trunk control is tested under 3 different conditions in sitting: to maintain the posture (static control), during voluntary head movements (active control) and recovery of trunk control after a disturbance of balance by a nudge (reactive control).[8]

Secondary study outcomes:

(2) Pediatric Reach Test (PRT)[22] assessment on balance in sitting and standing positions. The distance how far the child can reach forward, to right and to left will be measured in sitting and standing. High construct validity has been shown between the PRT in standing and a laboratory test of steadiness in quiet stance (r= 0.79) and age (r= 0.83) in a group of 19 typically developing children. High construct validity has also been shown between the total PRT score and GMFCS level (r= 0.88) among a sample of 10 children with cerebral palsy. Test-retest reliability and inter-tester reliability with children with cerebral palsy was moderate to high (intraclass correlation coefficients= 0.54 to 0.88 and 0.50 to 0.93 respectively)[22] and

(3) Gross Motor Function Measure 88 (GMFM 88)[23] assessment on general gross motor function in various positions including lying, sitting, 4-point kneeling, high kneeling and standing. The intra- and inter-rater reliability of the GMFM 88 have been shown to be very high (ICC= 0.99 in both cases).[23]

(4) 2-minute walk test[24] distance covered in a period of 2 minutes with self-chosen comfortable speed will be measured. The walk test has been shown to have high test-retest, intra- and inter-rater reliability.[24]

(5) The height and weight of the children

(iii) <u>Study design</u>

20 children with CP or similar physical disabilities will be recruited from 2 special schools for children with physical disabilities in Hong Kong for this pilot RCT (see ‘Existing facilities’ for details). Informed consent will be sought from the parents or guardians before the study will commence. After the initial assessment, all study children will be randomly allocated into a control group or treatment group (10 children in each arm) using a ‘draw card from the hat’. The randomization will be separately done in each school so as to take into account the heterogeneity of the children and treatment regime in each school. The children in the treatment group will receive training on their trunk control using the Tymo in sitting 4 times per week for 20 minutes per session. The treatment will last for 6 weeks. All study children will continue their usual therapies at school but will be asked to stop playing any interactive computer play, which is designed to train balance such as Nintendo Wii balance board, during the study period. As there is no strong research evidence that commercial computer games are effective in improving the balance for children with CP and this type of commercial computer play is not a routine training exercises for balance in the treatment sessions at the schools, it is believed that discontinuing this type of ‘training’ for 6 weeks would not cause detrimental effect on the balance of the study children.

All the assessment will be carried out by a blinded assessor (PA), who is not aware of the group allocation of the children. All the children will be assessed at the beginning, and 3, 6 and 12 weeks after the commencement of the intervention. The last assessment aims to examine the medium-term effect on their trunk control post-intervention.

Intervention:

All participating children will be calibrated using the Tymo in a static sitting position in each treatment session by the research staff. Force and weight distribution will be calibrated by asking the child to move the trunk forward, backward and sideways as far as s/he can. The amplitude of the force and weight distribution between the two sides of the body will be recorded. These information will be used to set up the Tymo as a balance training module (the intervention) by the software, in which the child will move the trunk forward, backward and sideways to participate in a computer game in a sitting position (Tables 1 and 2). The child will be allowed to choose which game they want in each treatment session and they have to stay on the same game for at least 10 minutes before changing to another game. In other words, the child will have a maximal choice of 2 computer games in each treatment session. All children will start at a medium level of difficulty. Only if the child is unable to score any point in 3 trials in a row, the difficulty level will be reduced to one level down. Similarly, if the child scores full points in 3 trials in a row, the difficulty level will be increased to one level up. The progression of the intervention will then be closely monitored by the research staff. A logbook will be used for each child to record the level of difficulty in each treatment session, the number of treatment sessions, duration of each session and general comments on the child in each session during the intervention phase. The intervention will be supervised by a research assistant, who will be employed for the study.

(iv) Data processing and analysis

Statistical analyses: SPSS for Windows (version 20) will be used to analyse the results. Mann Whitney U test will be used to compare the results of the OM(1) between the intervention and control groups and independent t-test for OM(2) to OM(5). The statistical significance level is set at $p < 0.05$.

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e) Existing Facilities:

Both the PA and co-applicant are very experienced paediatric physiotherapists with over 20 years of experience in managing young children with movement disorders. The mother institution of the PA is the only University in Hong Kong running the undergraduate degree in Physiotherapy and the Department of Rehabilitation Sciences at the Hong Kong Polytechnic University has abundant experiences in conducting research studies on individuals with movement disorders. Space will be provided for data storage (both hard and soft data) and statistical software will be provided for the present study. The co-applicant is the developer of the SATCo and is active in conducting research studies with collaborating researchers in USA and Denmark in examining trunk control in children with CP.

The Medical Technologies Ltd is the sole agent in Asia, which manages the Tymo Therapy plate. The agent will provide training and support in using the Tymo Therapy plate to all relevant personnel in this study in Hong Kong, as part of their quote on the equipment.

Initial contact has been made with the physiotherapists in-charge at 3 special schools in Hong Kong, namely the John F Kennedy Centre, the Red Cross Princess Alexandra School and Pui Oi School (all are special schools for children with physical disabilities), who all show interests to participate in the study. Specifically, the study children will be recruited from the first two schools and these schools will accommodate the Tymo Therapy Plate on site during the intervention phase. The physiotherapists in-charge tentatively believed that recruitment of 20 children with CP or similar physical disabilities is feasible in the first 2 schools. In case the recruitment falls short or a substantial drop-outs during the study period, Pui Oi School would be approached for further recruitment.

f) Justification of Requirements:

Staffing- a Physiotherapist will be employed to supervise the children to carry out the ICP at respective schools. Salary for this personnel is set as point 19 (median point of Physiotherapist II) of MPS, i.e. $32,560 per month + $1,500 MPF per month for 6 months= $204,360 because the personnel is required to have experience in managing paediatric clients with physical disabilities and has understanding of postural control in children.

Equipment- hiring Tymo Therapy plate and associated equipment= $61,405. The Medical Technologies Ltd is the sole agent in Asia, which manages the Tymo Therapy plate and this is the only equipment, as far as the PA knows, that provides this type of training on trunk control using the concept of ICP. The quote provided by the agent includes assembling, transporting and disassembling the equipment across the 2 special schools.

Travel cost for intervention= $100 per returned trip X 5 days X 16 weeks = $8,000

Travel cost for blinded assessments= $100 per returned trip X 4 assessments per child X 10 trips (assessing 2 children per day)= $4,000

Gifts to participating children= $20 X 20 children = $400

External hard drive for data storage= $500

Total= $278,665

g) Purpose and Potential:

Cerebral palsy (CP) is the most common physical disability in childhood, affecting about 1.3 per 1000 live-births in Hong Kong. Regardless the severities of the disability, children with CP have inadequate control in their trunk, affecting their balance in maintaining their posture in sitting and standing positions and regaining their balance if challenged in both positions. With the advance in computing technology, interactive computer play (ICP) has become popular in rehabilitation for people with motor impairments, including children with CP. During an ICP, a child interacts and plays with virtual objects in a computer-generated environment, through the use of a computer console or platform and the software, allowing the child to control the games through certain body movements. Because the computer games are fun and enjoyable, the child will continuously repeat the required body movements so as to get a high score in the game without losing the interest. The numerous repetitions and feedback from the game scores fulfil the principles of motor learning. Hence, ICP may be a feasible way to improve trunk control in children with CP, in addition to the conventional therapies. Up to date, there is controversial evidence in using ICP or virtual reality in improving balance in children with CP. The main reasons for inconclusive effectiveness of ICP in improving trunk control on this population group include low quality of research study designs, small sample sizes and insensitive outcome measures. In addition, use of commercial ICP may not be able to specifically train the trunk control and translate the improvement in the trunk control into the game scores.

The present study is designed to overcome these shortfalls. It is a single blinded controlled trial with 20 children with CP in each arm. The intervention, ICP is a specifically designed balance training tool for rehabilitation (www.tyromotion.com). One of the outcome measures used is an assessment of segmental trunk control, which will capture subtle changes in trunk control in different segments, instead of considering the whole trunk as one unit. The targeted children with CP are relatively homogeneous. It is the first of the series in using ICP for children with movement disorders. If the intervention is proven to be effective, ICP may be an adjunct to the conventional Physiotherapy to children with movement disorders. With the future Hong Kong Children's Hospital in mind, the ICP may be an essential piece of equipment in the rehabilitation program in the wards. Furthermore, future studies on different population groups with movement disorders, such as Developmental Coordination Disorders and children with preterm birth, will be conducted using the ICP.

Results of the present study will be presented in local and overseas conferences, e.g. Hong Kong Physiotherapy Association conference, American Academy of Cerebral Palsy and Developmental Medicine conference etc. Results will also be submitted for publication in high ranking journals such as Developmental Medicine and Child Neurology (impact factor 3.292) and Journal of Physiotherapy (impact factor 2.894).

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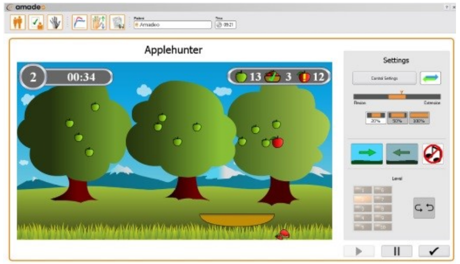
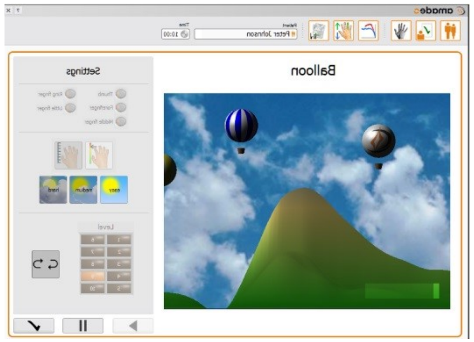
Table 1 One-dimensional therapy games

Therapy module	**Content**	**Exercise**	**Shaping**
Applehunter 	Falling apples must be caught with a basket: active repetition of a coordinated motion sequence, or application of a strength value to a selected hand function	Motion control, strength, strength control, tonus control, goal-oriented motor, coordination, attention, balance and postural control	Number and speed of falling apples, size of the basket, mirroring
Balloon 	Manoeuvring a balloon through a course and past obstacles: dynamic motion sequence, and/or the application of a strength value over a longer period of time	Motion control, motion coordination, strength control, permanent contraction, concentration, balance and postural control	Number of obstacles, flying speed, width and height of air lane, mirroring
Shooting cans	Cans move past a fixed reticule on the screen. Pulling the trigger at the right time will shoot the cans: timely activation of strength and/or motion	Triggering of motion, concentration, precise and quick application of strength, coordination, reaction,	Speed and size of the cans, mirroring

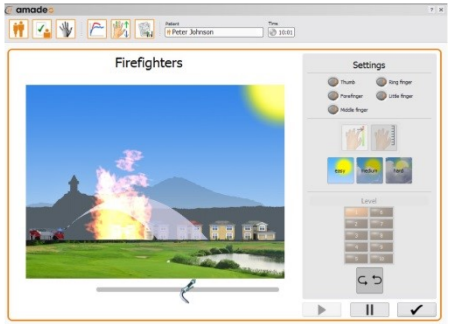
	impulses	balance and postural control	
Firefighters 	Flaring flames must be extinguished with a water jet as precisely as possible: achieving and maintaining the required strength and/or motion level	Strength control, strength rationing, coordination, goal-oriented motor, permanent contraction, attention, balance and postural control	Number of fires, duration of extinguishing the fires, width of the water jet, mirroring
Recycle 	Grabbing different pieces of waste with a gripper and depositing them in the corresponding container: achieving and maintaining the required strength and/or motion level	Strength control, strength rationing, coordination, goal-oriented motor, permanent contraction, attention, balance and postural control	Speed, number of pieces of waste, mirroring

Table 2 Two-dimensional games

Therapy module	Content	Exercise	Shaping
Farm	A chicken must be controlled while it is picking worms from the ground: achieving active and efficient motions without compensation	Goal-oriented repetitive motions, complex motions with every day-relevance, learning how to correctly control motions, prevention of compensation during the learning process, tonus control and tonus normalisation, training of spatial orientation and of reactions	Speed, number of worms, time target, mirroring
Labyrinth	A ball must be guided through a labyrinth with obstacles: achieving active and efficient motions without compensation	Goal-oriented repetitive motions, complex motions with everyday-relevance, learning how to correctly control motions, prevention of compensation during the learning process, tonus control and tonus normalisation, training of spatial orientation and of reactions	Number and complexity of obstacles, speed, time, mirroring
Set the table	Correct allocation of dishes to place mats on the table (as if the person itself is standing in front of the table): achieving active and efficient motions without compensation	Goal-oriented repetitive motions, complex motions with every day-relevance, prevention of compensation during the learning process, training of spatial orientation and of cognition	Number of dishes and place mats, spatial changes, mirror-inversion, speed, time