PHASE 2
INTRODUCTION

The Phase 1 of the study identified that across groups, the response abilities of children vary with the complexity of tasks at hand. The response abilities, in terms of RT and RF in various task conditions, are different among those who are typically developing when compared to children with IDD and DS. The response abilities of children with DS and IDD were found to be comparable across experimental settings. Therefore, Phase 2 of the study was designed to assess if the response abilities in terms of RT and RF of children with IDD and DS can be trained. Since the performance of IDD and DS groups were comparable, we included both in one group, i.e. IDD, which was inclusive of children with DS.

Object control skills are a component of fundamental movement skills. We hypothesized that training the ability to control objects and progressing the training by focusing on faster performance of these activities, would influence the response abilities of participants by improving their timing and ability to control activities. We operationally defined object control skills training as “training participants to control and manipulate objects using activities like sorting, throwing, catching, pressing, pinching, molding and beading, with progression in the speed and repetition of the tasks.”

Video game training has been used for training cognitive functions and RT among children with IDD. However, the influence of video game training on RF and on response abilities (i.e. RT and RF) has not been assessed. We hypothesized that use of video games which had tasks that emphasized faster performance and modulating the
pressure on the mouse to achieve goals would help reduce their response time and improve their ability to control and modulate the force with which they respond.

**AIM:** To compare the effect of training with object control skills or video game based training interventions on response abilities in terms of response time and response force among children with IDD.

**OBJECTIVE**

**Primary objective**
- To compare the effect of object control skills training and video game based training against no training, on response time and response force across task conditions among children with IDD

**Secondary objective**
- To compare the effects of object control skills training and video game based training against no training on response time using the ruler drop test among children with IDD
- To compare the effects object control skills training and video game based training against no training on upper limb speed and dexterity among children with IDD.
Chapter 6

METHODOLOGY
6 METHODOLOGY

6.1 STUDY SETTING

Permission to conduct the study was taken from the school incharge and administrative authorities. Based on the information derived from phase 1 of the study, the Manasa centre for Rehabilitation, Pamboor, Shirva, Udupi district, was the school chosen for phase 2 using convenience sampling. Compared to other schools in Udupi district, this center schooled the largest number of children with disabilities and had both residential and day scholar facilities. Choosing this school for phase 2 enabled us to keep the study setting constant thereby reducing the possible confounders and variability in data which could occur with multiple study settings. The school provided a room near its classrooms where the participants could be brought during school hours to perform the study. The school engaged their students with a one to one teacher student training. The participants were brought in for the assessment and training, either before or after completion of their teacher-student sessions, without disturbing their regular schooling schedule.

6.2 STUDY DESIGN

Multiple arm parallel-group randomized controlled trial. Equal randomization was performed and participants were randomly assigned to one of the three parallel groups by a 1:1:1 ratio. The study received ethical clearance from the Institutional Ethics Committee (IEC 499/2014). The trial was registered on Clinical Trial Registry - India (CTRI/2015/04/005724). There were no changes in the trail design after commencement of the trial.
6.3 SAMPLE SIZE

6.3.1 Estimation

Sample size was calculated using the formula for repeated measures

\[
n = \frac{2}{\delta^2} \left[ (\sigma^2_b + \sigma^2/k) [1 + (k - 1) \rho] \right] \left[ Z_{\alpha/2} + Z_{\beta} \right]
\]

With a 5% level of significance and power of 80%, the minimum sample size in each group was 18. With a 20% drop out rate the estimated sample size was 22 in each group i.e. a total sample size of 66.

6.3.2 Analysis or stoppage

No interim analysis was performed and the study was stopped after the sample size was met.

6.4 SAMPLING METHOD

The list of students enrolled the school where the study was conducted was obtained from the school administration office. The list formed the sampling frame for including the participants into the study. Of the list, only those students who were 9 to 17 years of age were screened for eligibility. Participants were chosen from the school based on purposive sampling.
6.5 **Eligibility Criteria**

6.5.1 **Inclusion criteria**

Children were included in the study if they met the following criteria, i.e. children who were

- between the ages of 9 to 17 years
- could understand and follow basic one step instructions
- could understand the requirements and perform the first experiment and who could perform the simple response task

6.5.2 **Exclusion criteria**

Children were excluded from the study if they fell into the following criteria, i.e. children who

- were uncooperative
- had any cardio-pulmonary problems which would impede exercise performance
- had any deformity in upper limbs which would impede the measurement of their response abilities
- were under CNS stimulant or CNS depressant drugs

Children who met the inclusion criteria were given consent forms seeking approval of their parents or guardians. After parental consent, the participant's assent was obtained. The participants were then familiarized with the equipment to assess their response time and response force. The participants were given instructions and
demonstrations explaining how the task had to be performed. Further, if the child could perform the simple response task, the child was included in the study. For those who could not perform the simple response task inspite of adequate familiarization with the testing procedure, two more attempts were made on separate occasions. If the participant could perform the test at the second or third attempt, then they were included in the study, else they were excluded.

6.6 INTERVENTIONS

6.6.1 No training group

Participants allocated to the no training group received standard care given by the Community Based Physiotherapy team from Department of Physiotherapy, SOAHS. The team visited the school twice weekly and provided training for a period of one hour to all children studying in the school. The training was in the form of group exercises and sport specific training.

6.6.2 Intervention groups

The interventions were chosen to be simple and replicable. Both groups continued the physical therapy program provided by the Department of Physiotherapy. In addition to that, both the intervention groups received additional one to one training program which was performed three times a week for a period of four weeks.
The interventions were designed in a stepwise manner such that the progression was in the form of addition of more tasks to already existing tasks along with a gradual increase in complexity of tasks. There were four steps spanning across four weeks of intervention. After the first step was mastered the participant learned new activities from the second step. The second step thereby included the new activities (belonging to the second step) in addition to the activities from the first step. The third step involved new activities from the third step in addition to all the activities performed in step two. The progression of intervention, therefore, was in terms of addition of new intervention to already existing intervention, in addition to increasing the time duration for performing that intervention. Given a situation when a child could not learn the new activities in the next step, the previous step was continued with an increase in repetitions and duration.

Both intervention setups required a table with two chairs (figure 14), which was arranged in the same room within the school where the assessments were carried out.

**Figure 14: Training set up for participants**

| Object control skills training | Video game training |
6.6.2.1  **Object control skills training**

The exercise groups had four steps of intervention with increasing difficulty or complexity as the weeks progressed. The program was based on performing simple tasks using either upper limb as quickly as possible. As the weeks progressed, new tasks of greater complexity get added along with an increase in the repetitions of the previously learned task. Tasks involved sorting based on colors, shapes and arranging shapes in a sequence; alternating movements of both upper limbs and lower limbs; increasing the speed with which the learned tasks were performed (table 8, figure 15). All activities were performed first from the preferred hand and then from the other hand. Duration of the training was fifteen minutes in the first week with an addition of 10 mins with each step. With each progress in step, the participants had to learn the activities from the new step and perform the already learned activities faster and with more repetitions.

*Figure 15: Participants performing the object control skills training*
### Table 8: Object control skills training activities

<table>
<thead>
<tr>
<th>Steps</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>I. Putty play</td>
</tr>
<tr>
<td></td>
<td>II. Sorting color chips</td>
</tr>
<tr>
<td></td>
<td>III. Walk – clap – walk – clap</td>
</tr>
<tr>
<td></td>
<td>IV. Reciprocal finger tapping with both hands</td>
</tr>
<tr>
<td>1</td>
<td>I. Squeezing soft ball</td>
</tr>
<tr>
<td></td>
<td>II. Matching paper clips with similar colored paper</td>
</tr>
<tr>
<td></td>
<td>III. Reciprocal movement of hands as in marching</td>
</tr>
<tr>
<td></td>
<td>IV. Catching ball with both hands with one bounce</td>
</tr>
<tr>
<td>2</td>
<td>I. Beading as fast as one can</td>
</tr>
<tr>
<td></td>
<td>II. Ringing a towel</td>
</tr>
<tr>
<td></td>
<td>III. Placing colored cloth pin on edges of box painted with similar color</td>
</tr>
<tr>
<td></td>
<td>IV. Throwing ball from one hand to another</td>
</tr>
<tr>
<td>3</td>
<td>I. Using tongs to pick up small objects, like beads and buttons</td>
</tr>
<tr>
<td></td>
<td>II. Pressing buttons into putty</td>
</tr>
<tr>
<td></td>
<td>III. Matching colored caps of different color of pens</td>
</tr>
<tr>
<td></td>
<td>IV. Skipping using a skipping rope</td>
</tr>
</tbody>
</table>
6.6.2.2 Video game training

A laptop with a mouse and an active internet connection was required for the video game training. The participants of the study were not familiar with playing video games or the use of a mouse. Therefore, games that were simpler in nature were selected for training purpose. The video game based activities were aimed at improving participant’s ability to respond quickly and to modulate and structure the force with which the participant responds. The games used were available online and therefore required connectivity to internet facility while doing the activities. The games required the participant to respond by clicking the mouse either quickly or to click and press and modulate their RF. (Table 9, Figure 16, 17)

Figure 16: Participants performing the video game training
### Table 9: Description of video game activities

<table>
<thead>
<tr>
<th>Goal</th>
<th>Description</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STEP 1A: EAT COOKIES</strong>&lt;br&gt;To finish eating the cookies by pressing the switch across the cookie.</td>
<td>There were five different shapes of cookies which would appear one after another. Each cookie would stay on screen for 5 secs followed by next one.</td>
<td>Press and release repeatedly and drag to the adjacent area.</td>
</tr>
<tr>
<td><strong>STEP 1B: MOUSE VS HAMMER</strong>&lt;br&gt;To hit the mice’s head with the hammer every time its head popped up from the hole.</td>
<td>Clicking the mouse as soon as the head of the mouse appears.</td>
<td>Pressing quickly to hit the mouse</td>
</tr>
<tr>
<td><strong>STEP 2: BRUSHING TEETH</strong>&lt;br&gt;To finish clearing the grim on teeth as soon as possible</td>
<td>The lower and upper set of teeth would appear twice and the brush had to be moved and dragged around to clear the grim</td>
<td>Press and maintain pressure and move</td>
</tr>
<tr>
<td><strong>STEP 3: SAMURAI NINJA</strong>&lt;br&gt;To slice as many fruits as possible</td>
<td>The fruits kept appearing on the screen. A horizontal movement with the pressed mouse resulted in the slicing of the fruits.</td>
<td>Press maintain pressure and move across quickly to cut the falling fruits</td>
</tr>
<tr>
<td><strong>STEP 5: JUMPING IN SWIMMING POOL</strong>&lt;br&gt;To aim and jump such that the child lands in/on the floaters</td>
<td>The floaters appeared in a constant motion and each click caused one child to jump. The jump was expected to occur at the right time coinciding with the moving floater, as only then the child would land on the floater. As the game progresses the speed of the floater’s increases. Every wrong jump results in loss of life.</td>
<td>Timed and quick press</td>
</tr>
</tbody>
</table>
Figure 17: Images of the video game training steps

<table>
<thead>
<tr>
<th>STEP 1</th>
<th>STEP 2</th>
<th>STEP 3</th>
<th>STEP 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
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<tr>
<td><img src="image1.png" alt="Image" /></td>
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<td><img src="image4.png" alt="Image" /></td>
</tr>
</tbody>
</table>
6.7 OUTCOMES

6.7.1 General description

All the outcome measures were assessed at baseline (Week 0), immediately post intervention (week 5) and at 4 weeks follow-up after completion of intervention (Week 10). All the assessments were done by the evaluator who conducted the training session.

6.7.2 Primary outcome measure

The primary outcome measure was response time and response force as measured by the response analyzer. Response time and response force was measured across simple task, active and passive dual-task and choice response task. The description of the set-up and measurements are consistent with that explained in phase 1.

6.7.3 Secondary outcome measure

The secondary outcome measure was the Ruler drop test and the Response speed and Upper-limb speed and dexterity subtest of Bruininks-Oseretsky Test of Motor Proficiency (BOTMP).\textsuperscript{165}

6.7.3.1 Ruler drop test

The ruler drop test was a basic test used to assess response time. The participant was expected to lean forward and rest the forearm of their preferred arm on the table. The examiner would hold the one-meter long ruler and release it
vertically. The participant was expected to grasp the ruler as soon as the examiner released it. The distance at which the participant grasps the ruler or the distance by which the ruler fell is measured. Ten repetitions of the test was taken and considered for analysis. The distance hereby calculated was converted into time by using the formula \[ t = \sqrt{ \frac{2d}{g} } \]; where \( t \) = time in seconds, \( d \) = the distance the ruler fell in meters and \( g \) = acceleration due to gravity (9.81 m/s\(^2\)).

### 6.7.3.2 Subtests of Bruininks-Oseretsky Test of Motor Proficiency

Hand preference of the participants was assessed based on the BOTMP Manual i.e. hand used for overhand throwing. In addition, the hand preference for the hand used for writing and eating was documented. The preferred hand was used to perform the subsequent tests. The procedure for administering and recording the test was in accordance with the BOTMP manual.\(^\text{165}\)

#### 6.7.3.2.1 Upper-limb speed and dexterity subtest of BOTMP

The upper-limb speed and dexterity subtest had eight items namely placing pennies in a box (figure 18 C), placing pennies in two boxes (figure 18 A), sorting shape cards (figure 18 E), stringing beads (figure 18 F), displacing pegs (figure 18 D), drawing vertical lines (figure 18 B), making dots in circles and making dots. The subtest assesses hand speed and arm speed along with hand and finger dexterity. (Figure 18).

#### 6.7.3.2.2 Response speed subtest

The response speed subtest, i.e. subtest 6 of the BOTMP measures the ability of a participant to respond quickly to a moving stimulus. Here the response speed stick provided in the BOTMP kit was to be held against the wall. The participant was
expected to lean forward and stop the stick from falling to the floor. The point where the participant holds the stick was measured and the raw score was calculated and converted to measured score.

**Figure 18: Participants performing the upper-limb speed and dexterity subtest of BOTMP**

6.8 RANDOMIZATION

Which group the participant would be assigned to was determined by a sequence generated by using a computer generated random number table by a professional who was not part of the study. The allocation sequence was not concealed.

Participants who met the eligibility criteria for the study were chosen from the special education school. Written informed consent was obtained from the parents of the potential participants. For students who were institutionalized, consent was obtained from their hostel warden and from their class teacher. After approval from their parent or guardians, those students who assented to perform the experiment...
were further evaluated for their ability to perform the simple response task. Those students who could perform the simple response task were considered as a participant of the study. After inclusion in the study, the outcome measures were assessed. After the baseline assessment, participants were randomly allocated into one of the three groups (i.e. object control skills training group, video game training group and no training group).

6.9 BLINDING

The study was not blinded to assessor or participants.

6.10 STATISTICAL METHODS

Data was analyzed using two-way mixed effects ANOVA for the primary and secondary outcome measures.

6.10.1 Primary outcome measures

For each of the primary outcome measures, two-way mixed effects ANOVA was performed to assess the interaction between the intervention group, time points of assessment and experimental condition.

6.10.2 Secondary outcome measures

For each of the secondary outcome measures, two-way mixed effects ANOVA was used to assess the interaction between the intervention group and time point of assessment.
6.10.3 Sub-group analysis

A sub-group analysis was performed using Pearson’s correlation coefficient to correlate the RT data obtained by different measures.