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(Established - 1978)

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Medical Rehab Guidance Cell

E. D. A.
Education for Differently Abled

Founder President Emeritus
DR. NANDU CHHABRIA (P.T.)

Founder Secretary
DR. MAYA NANAVATI (O.T.)

25/6/18

END OF CLINICAL TRIAL - REPORT

The Vestibulator is a patented scientific therapeutic device invented by Industrial research Center of IIT Mumbai and co patented by Transpact Enterprises Private Limited. It aims to provide vestibular stimulation to pediatric population affected by conditions like cerebral palsy , autism and ADHD. It can provide the following movements :

- **Anteroposterior tilts** – the client can be moved through a maximum of 30 degrees from the horizontal both in anterior as well as posterior directions. The client can be given treatment to focus on both tilts simultaneously or only in one direction.
- **Lateral tilts** -The client can be moved 30 degrees to the right and left or either one depending on the requirement.
- **Rotations** – the client can be provided clock wise as well as anti clockwise rotations
- **Horizontal accelerations** – the client can be provided a maximum of 280 mm of movement in a sliding motion (forward and backward)
- **Vertical accelerations** – the client is provided with an up and down movement to a maximum of 140 mm .

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The speed of these movements as well as the number of cycles can be modified depending on the requirement.

The client can be provided these movements in a variety of positions – supine , prone , chair sitting , long- sitting , cross legged sitting ,kneeling , crawling as well as standing.

Personalized treatment combinations can be stored as patient data for purpose of monitoring and comparing.

5 point harnessing system and emergency stop switches are provided to ensure safety of the client.

Title of Clinical trial

To study the effects of vestibular stimulation using the Vestibulator on muscle tone and reflex responses in children with cerebral palsy

Selection of children

- Children between 3-11 years of age
- Confirmed diagnosis of cerebral palsy
- Children with active epileptic episodes were not taken in the study
- Children with severely impaired cognitive abilities were also excluded from the study

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Number of children

- A target of 30 children was set , however only 24 children were finally enrolled . Over the course of the trial 3 children opted out due to various reasons bringing the final number of children to 21.

Population characteristics

Spastic quadriplegia - 4

Spastic diplegia – 6

Hypotonia- 4

Hemiplegia- 3

Ataxia-3

Athetoid – 1

Gender ratio

Girls to boys = 8:13

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Process of Consent

A meeting was held before the trail with the parents of the participating children to explain the nature of the clinical trial , the product that was going to be investigated and how it was likely to impact their children . All questions pertaining to the same were answered to the parents' satisfaction. A video of the product was also shown at the time. The parental consent form was signed after one trial session as per the parent's request.

Assessment Protocol

The physiotherapist involved in the clinical trial used the following standardized tests to measure the outcomes –

- *Modified Tardieu Scale* – it has been found to be a valid, reliable and sensitive abridged version of the Tardieu Scale . The angle of catch at most rapid velocity (R1) and the joint angle when muscle length is maximum (R2) when moved using slow passive movement. The difference in degrees between R2 and R1 is referred to as the dynamic component of spasticity.
- *Early clinical assessment of balance* – It quantifies deficits in balance that may be present in specific pediatric populations
- *Pediatric balance scale* – It examines functional balance in the context of every day tasks in the pediatric population. Steady state and anticipatory balance activities are performed with and without visual inputs

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These assessments were done at the beginning of treatment and repeated after the 12th and 24th session.

The respective therapists were also provided with an assessment form to be filled at the beginning of the clinical trial , after 12 sessions and at the end of 24 sessions.

Treatment Protocol

- *Frequency of sessions* : Treatment sessions were provided twice a week for 3 months thus making a total of 24 sessions
- *Position of the child* : The position of the child was progressed from postures with wide base of support – for example , sitting and crawling to those with narrow base of support like kneeling and standing
- *Support* : The support provided to the children was gradually decreased as treatment progressed-for example standing with support to the back was progressed to standing without support at the back.
- *Range of motion* : The treatment began with small magnitude and was gradually progressed depending on the response of the child.

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- *Speed of the vestibular stimulation* also progressed appropriate to response of the child
- *Reducing visual stimuli*- The children were also provided treatment with their eyes closed once they had responded well with their eyes open.
- *Assistive devices* like AFO s , pediwraps , shoes with compensation were used depending on the need of the child during the treatment session
- A questionnaire was provided to the parents at the end of each session to document the safety of the machine and any adverse reactions that may have occurred during the treatment.

Results

Tone :

Cerebral palsy is classified into four broad categories -- spastic, athetoid, ataxic, and mixed forms -- in accordance with the type of movement disturbance. In spastic cerebral palsy the muscles are stiff and permanently contracted . Athétoid, or dyskinetic, cerebral palsy is characterized by uncontrolled, slow, writhing movements which affect the hands, feet, arms, or legs and, in some cases, the muscles of the face and tongue, causing grimacing or drooling. Ataxic cerebral palsy affects the sense of balance and depth perception. Affected persons often have poor coordination; walk unsteadily with a wide-based gait, placing their feet

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unusually far apart and experience difficulty when attempting quick or precise movements, such as writing or buttoning a shirt. It is common for patients to have symptoms of more than one of the previous three forms. The most common mixed form may include spasticity and athetoid movements.

Spasticity develops when an imbalance occurs in the excitatory and inhibitory input to alpha motor neurons which is caused by damage to the spinal cord and/or central nervous system. Ataxia is an outcome of damage to the cerebellum or its connections while athetoid cerebral palsy results from damage to the basal ganglia.

As mentioned earlier the Modified Tardieu scale measures the dynamic component of spasticity. The post test results of the Modified Tardieu Scale have shown a decrease in the dynamic component in the hamstrings as well as TA in most children (highlighted in red) as compared to the dynamic component present before the trial .

It is to be noted that children with no change in dynamic component (highlighted in blue) fell under 2 categories – those whose passive Range of Motion had increased or those whose muscles were already in contracture.

It is also to be noted that 2 children showed an increase in the dynamic component of the hamstrings on one side while 1 showed an increase in the dynamic component of the TA also on one side.(highlighted in green). Both children had missed considerable sessions on the Vestibulator as well as with their respective therapist.

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The MTS - hamstrings

Sr no	name	Muscle	Pre test R2	Post test R2	Pre test R1	Post test R1	Pre test R2-R1	Post test R2-R1
1	faizan	Lt hamstrings	120	130	100	130	20	0
		Rt hamstrings	120	150	100	150	20	0
2	vihang	Lt hamstrings	110	125	90	115	30	10
		Rt hamstrings	120	135	90	125	30	10
3	raunak	Lt hamstrings	140	130	90	115	50	15
		Rt hamstrings	140	110	120	110	20	0
4	sansiya	Lt hamstrings	140	170	120	170	20	0
		Rt hamstrings	140	170	110	170	30	0
5	soham	Lt hamstrings	120	120	120	105	0	15
		Rt hamstrings	130	110	90	90	40	20
6	atharva	Lt hamstrings	90	150	75	150	15	0
		Rt hamstrings	75	130	75	130	0	0
7	Sadaf	Lt hamstrings	125	140	65	135	60	5
		Rt hamstrings	95	120	60	110	30	10
8	astha	Lt hamstrings	160	150	160	125	0	25
		Rt hamstrimgs	120	150	90	125	30	25
9	Sarthak r	Lt hamstrings	120	130	90	110	30	20
		Rt hamstrings	130	135	110	120	20	15
10	jhanvi	Lt hamstrings	90	150	90	150	0	0
		Rt hamstrings	130	170	130	170	0	0
11	krishna	Lt hamstrings	120	170	100	170	20	0
		Rt hamstrings	NA					
12	samiksha	Lt hamstrings	NA					
		Rt hamstings	130	150	130	150	0	0

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The MTS -plantar flexors (TA)

Sr no	name	Muscle	Pre test R2	Post test R2	Pre test R1	Post test R1	Pre test R2-R1	Post test R2-R1
1	faizan	Lt TA	100	120	90	120	10	0
		Rt TA	100	120	90	120	10	0
2	vihang	Lt TA	110	120	90	120	20	0
		Rt TA	90	120	70	120	20	0
3	raunak	Lt TA	90	110	90	110	0	0
		Rt TA	90	90	90	90	0	0
4	sansiya	Lt TA	100	110	80	110	20	0
		Rt TA	110	110	90	110	20	0
5	soham	Lt TA	90	110	90	110	0	0
		Rt TA	90	110	90	110	0	0
6	atharva	Lt TA	90	90	70	90	20	0
		Rt TA	90	90	70	90	20	0
7	Sadaf	Lt TA	90	90	70	90	20	0
		Rt TA	90	115	40	115	50	0
8	astha	Lt TA	110	120	90	120	20	0
		Rt TA	110	110	90	110	20	0
9	Sarthak r	Lt TA	90	90	70	70	20	20
		Rt TA	90	70	90	70	0	0
10	jhanvi	Lt TA	90	110	90	90	0	20
		Rt TA	90	110	90	110	0	0
11	krishna	Lt TA	90	110	90	110	0	0
		Rt TA	NA					
12	samiksha	Lt TA	NA					
		Rt TA	90	110	90	110	0	0
13	twisha	Lt TA	NA					
		Rt TA	110	110	90	110	20	0
14	arnica	Lt TA	NA					
		Rt TA	110	110	110	110	0	0
15	aaricia	Lt TA	NA					
		Rt TA	90	120	90	120	0	0

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Discussion : The Vestibulator allowed to provide graded and consistent changes in the support surface. The therapist provided tactile as well as verbal inputs to the child regarding appropriate response which was correctly learned over a period of a time . The child was weaned off these inputs slowly till he/she was able to make these adjustments more automatically. In order to allow for more vestibular and somatosensory feedback to make these postural adjustments the child was blindfolded thus cutting off all visual input.

Children with cerebral palsy have an exaggerated reaction to gravity resulting in spasticity. This results in abnormal feedback from the muscles as well as joints. This combined with abnormal patterns of activation result in poor postural control thus making the child a victim of gravity. It could be thus hypothesized that learning the correct response by providing consistent and graded input would break the cycle and thus normalize the tone

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Reflex Responses

The Early Clinical Assessment of Balance

The Early Clinical Assessment of Balance consists of 2 parts. The first part consists of automatic reactions including righting , equilibrium and protective reactions .The second part consists of static as well as dynamic balance activities in sitting and standing.

Most children showed a noticeable improvement in the post test scores.

Discussion : The integration of visual , vestibular as well as somato sensory input is crucial to the development of postural control . Disruption of any one system results in disruption of postural strategies. In children with cerebral palsy one or all three systems may be affected – either primarily or secondarily. When these inputs are provided consistently and in a graded manner , correct motor output can be activated , repeated and learnt so as to become more automatic in nature.

Some crucial observations have to be noted here.

1. Children who depended heavily on their vision for balance found it very difficult to tolerate blindfolded sessions. In fact they could not be given any. On being blindfolded they responded with anxiety and a general stiffening of the body. It remains to be seen whether more sessions would have helped to activate their vestibular and somato sensory systems for participating in postural control.

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2. On the other hand there were 2 children who showed excellent response when there eyes were closed, implying that the visual system was providing conflicting visual input and thus interfering with the normal development of postural control.
3. Another important observation was pertaining to children who were unable to make postural adjustments (whether eyes open or closed) even when provided with tactile and verbal inputs from the therapist . If they did the response was momentary and not sustained. This showed that somatosensory inputs (kinesthesia and proprioception) are crucial in providing the feedback required for accurate postural reflexes. These children performed well when provided support but could not demonstrate the same response when support was removed.

Early clinical assessment of Balance

Sr no	Name	Pre test ECAB	Post test ECAB
1	Faizan	7	16
2	Vihang	22	36
3	Sansiya	22	31
4	Soham	11	18
5	Atharva	13	17
6	Sadaf	11	17
7	Astha	23	29
8	Sarthak r	62.5	64
9	Jhanvi	26	30
10	Aaricia	66.5	82.5
11	Raj	24	34
12	Sai (after 17 sessions)	14	20
13	Krishna	15	23

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Pediatric Balance Scale

The pediatric balance scale consists of static as well dynamic tests of balance with eyes open as well as closed. The post test scores reflected minimum improvement.

Discussion : Most children were able to perform all the subtests with relative ease even at the beginning. The key subtests that proved difficult for them were tandem standing, one leg standing, and reaching forward. it is important to review these subtests more critically.

Tandem standing – Most children scored a 2 , pre-test as well as posttest. Some progressed from being required assistance to place foot in front to be able to take step independently but were unable to hold 30 seconds. This improvement could not be captured due to the nature of the scoring. It is possible that there would have been measurable difference if treatment was continued.

One leg standing – This criterion showed little or no improvement in any of the children. It has been suggested that static balance is primarily affected by proprioceptive inputs and the vestibular system is primarily responsible for dynamic balance therefore this test would not be an ideal indicator for improvement in vestibular function

Reaching forward with outstretched arm- Most children were able to reach further than the previous assessment however this progress could not be captured due to the nature of the scoring. It can be assumed that there has been some improvement in ability to move center of gravity over base of support more

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smoothly and confidently implying emerging postural control. Again, it is possible that a measurable difference could have been noted if treatment was continued.

The pediatric balance scale

Sr no	Name	Pre test pbs score	Pot test pbs score
1	samiksha	50	52
2	Sarthak k	45	50
3	twisha	51	51
4	tatsav	49	51
5	keyur	46	51
6	manan	48	53
7	arnica	52	53

Feedback from the therapists

1) Most therapists reported a general relaxation of their patients thus handling them became easier

2) The therapists felt the children were less fearful on movable surfaces making it easier to work on their balance

3) They also reported an increased ability to maintain static postures – sitting , kneeling , crawling and standing demonstrating improved trunk control.

Feedback from parents

1) Parents too reported a general relaxation which made handling easy

2) Nine parents reported improvement in the ability to maintain sitting , kneeling ,and standing positions for a longer period of time

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3) The parents felt the children were sitting and standing straighter and taller

4) Four children reported they were falling less

5) There was noticeable improvement in academics in two children- even handwriting

6) Three parents reported walking to have improved and transitioning was also easier

Concluding Remarks : The vestibular system acts as a GPS for the body . It detects linear , vertical and rotatory accelerations via sensory receptors located in the inner ear namely the otoliths and semicircular canals. Inputs from the visual and somato sensory systems are integrated with this information to provide motor output in the form of reflex reponses to maintain static as well as dynamic equilibrium. These reflex responses are

Vestibulo – ocular reflex- the eyes are kept steady while head moves

Vestibulo – colic reflex – the head is kept steady while body moves

Vestibulo spinal reflex – adjusts posture for rapid changes in position

In children with cerebral palsy these inputs may be affected primarily or' secondarily causing abnormal tone and thus abnormal reflex responses. Stimulation of vestibular receptors in conventional therapy settings can be achieved using tilt boards and stability trainers , but this stimulation cannot be quantified , graded or consistent . Thus the response too is inconsistent making it difficult for learning to take place. Hence the automatic nature of the reflex

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response cannot be established. The Vestibulator could theoretically bridge this gap in clinical treatment settings and prove to be a useful adjunct to conventional rehabilitation protocols. Correct patient selection and sound clinical judgement is essential to achieving the desired outcomes and is thus the sole responsibility of the therapist. Once these criteria are fulfilled the Vestibulator shows great promise in providing specific inputs and thus achieving targeted results saving time and money for the client as well as the therapist. Further research is definitely required but the Vestibulator could potentially become an effective tool for therapists

Limitations of the clinical trial

1) Attendance of the participants – The children and their families were very cooperative and tried very hard to attend the sessions regularly . Unfortunately illness , exams , family constraints and other issues caused absences and thus the continuity of treatment was compromised. A few children completed only 20 sessions while one was able to attend only 17 sessions.

2) Technical issues –There were some instances when the Vestibulator faced technical issues and treatment had to be rescheduled thereby causing a break in continuity of treatment

3) Number of patients – Owing to the eligibility criteria, the number of participants that were finally enrolled was quite low. A larger sample would have been ideal

4) Novelty of the device – As this is a new product knowledge about its inherent working was limited and this could have affected the actual treatment sessions.

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The therapist was also evolving the treatment sessions as and how her knowledge of the device evolved.

Recommendations

1) It is recommended to study the effects of vestibular therapy using Vestibulator when more frequent , ideally daily sessions on the Vestibulator are provided.

2) This study involved all kinds of cerebral palsy children. The sample can be restricted to a single kind in the future.

3) Outcome measures have to be chosen with care based on the outcomes that are to be evaluated.

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