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ORIGINAL REPORT

DYNAMIC STANDING EXERCISE USING THE INNOWALK DEVICE IN PATIENTS WITH GENETIC AND ACQUIRED MOTOR IMPAIRMENTS

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Objective: **For individuals with motor impairments, dynamic standing has been proposed as an opportunity for regular daily physical activity. The aim of this study was to analyse patient characteristics, indications, intensity of usage, desired objectives and outcomes of dynamic standing in daily clinical practice in order to form the basis for research regarding this treatment option.**

Setting: **Data were analysed from standardized questionnaires completed prospectively before supply of a home-based medical device for dynamic standing (Innowalk; Made for Movement GmbH, Langenhagen, Germany) and at the time of individual adaptations.**

Participants: **In a retrospective chart analysis, records of 46 patients (50% cerebral palsy; 50% diverse syndromes) were evaluated.**

Intervention: **The Innowalk had been prescribed for either home-based use ($n = 31$), in therapeutic institutions ($n = 8$), or other settings ($n = 7$). Dynamic standing was performed for 10–30 min as a single session ($n = 8$) or for 20–60 min 11 [4–21] weeks in 36 patients.**

Results: **Improvements were found for: passive assisted motion (79%), stimulation of intestinal functions (71%), body stability (64%), joint mobility (56%), secure means of allowing supine position (52%), and revision of abnormal motion patterns (48%).**

Conclusion: **Thus, this systematic approach shows usage patterns, indications, desired goals and clinical outcome of dynamic standing in daily clinical practice and forms the basis for the design of a prospective, randomized controlled trial.**

Key words: dynamic standing; cerebral palsy; neuromuscular rehabilitation; medical device; exercise.

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LAY ABSTRACT

This study analysed usage patterns, safety, desired goals and the effects of the Innowalk, a medical device that enables a patient to stand in a weight-bearing position while stimulating active use of upper thigh and torso muscles in order to maintain patient's balance. In addition, the characteristics of patients who used this device were summarized and described. Half of the included patients employed the Innowalk due to cerebral palsy. The positive effects after usage of the Innowalk were noticed to occur in passive assisted motion, stimulation of digestive function, body stability, joint mobility, secure means of allowing horizontal body position, and correction of abnormal motion patterns. No negative effects were noticed. Use of the Innowalk was safe. Further research is needed to verify the effectiveness of the usage of the medical device.

Neuromuscular disorders, such as cerebral palsy (CP), are characterized by loss of functional skeletal muscles (1), spasticity, contractures and joint dysfunction (2, 3). However, there is a lack of high-quality studies addressing therapies aimed at improving overall neuromuscular function of the primary underlying condition. With unavailability of causal treatment, symptomatic approaches include a mix of orthopaedic devices, assistive devices, physiotherapy, behavioural therapy, occupational and speech therapy with proven subsequent benefits. Depending on the level of disability, the aims of all therapies include improvement of function, compensation for pathology, prevention of secondary conditions through pathological movement patterns, growth and postural management in lying, sitting and standing, as well as improvement in quality of life of patients and caregivers (3).

To deliver home-based exercise several times per week, the Innowalk (Made for Movement, Langenhagen, Germany) has been widely prescribed for patients with neuromuscular disorders in Germany and internationally. The Innowalk is an innovative, home-based medical device for so-called dynamic standing (4). This entails patients standing in a weight-bearing position whilst their legs are passively moved in a gait-like pattern. Thus, patients are forced to actively use upper thigh and

torso muscles to keep their balance as much as they individually can. This muscle activation counteracts the downsides of sole passive standing. In addition to the well-established standing devices used for verticalization of patients, the Innowalk offers passive motion of the lower extremities under weight-bearing conditions, with the possibility of active training of trunk, neck and upper extremities. A demonstration of the device is shown in the Supplementary material, video 1.

Since 2009, approximately 700 Innowalk devices have been prescribed in Germany. However, no information has yet been gathered systematically regarding indications, disability level, type of impairment, delivery of the intervention, appropriate outcome measures and perceived benefits in order to develop further evaluative research regarding dynamic standing in young people with motor impairments.

Therefore a systematic retrospective analysis of prospectively completed consecutive report forms was performed, with the aim of analysing patient's baseline characteristics as well as outcome measures of dynamic standing training. The results will form the basis for a design of prospective, randomized, single-blinded multicentre trial to prove short- and long-term medical benefit and determine potential risks associated with this form of therapy.

MATERIAL AND METHODS

This retrospective chart analysis includes analysis of 46 patients with various neuromuscular deficits using the Innowalk for dynamic standing as part of their treatment from September 2014 to January 2019 in Germany (see Fig. 1).

Key variables for inclusion were: identification by name and date of birth, address, International Classification of Diseases 10th Revision (ICD-10) code, height and weight, date of documentation, GMFCMS-E&R (Gross Motor Function Classification System - Expanded and Revised) level, baseline disabilities, goal, target variable, assignable signature of person who documented the data.

The report forms were completed at baseline when the Innowalk was initially tested and whenever the company's representatives and trained physiotherapists had an appointment with the child at a later time.

During the later time, inquiry regarding the goal defined at the beginning was performed and the outcome recorded. Reasons for the latter documentation were technical adjustments or end of the testing period.

This analysis was performed in accordance with the principles of the Declaration of Helsinki and was approved by the local ethics committee (Eth-15/18) Landesärztekammer Berlin (Germany). The study is registered in the German Clinical Trials Register (DRKS00014980).

Outcome measurements

Documentation of demographic data, usage patterns, duration and frequency of the Innowalk use, as well as type of Innowalk used, were summarized. All data are presented as median and interquartile range throughout the manuscript.

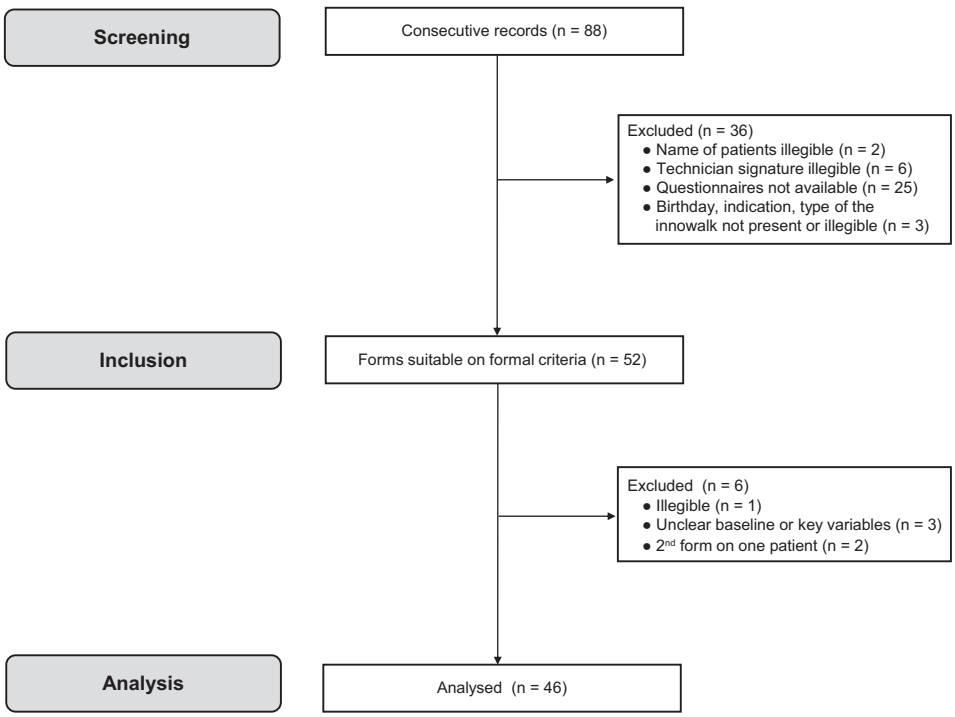

Fig. 1. Study flowchart

For patients who used the Innowalk more than once, goals were defined before initial training and results were documented at the end of the trial period with standardized questionnaires. The following goals were predefined: improvement in muscular tone, reduction in spasticity, activation and preservation of muscle strength, improvement in vital function, improvement in bowel function, improved ability to walk, better gait stability, improved weight-bearing during transfer, improved coordination and body control, improved passive joint mobility, increase in stability of trunk and neck, reduction in pathological movement patterns, improvement in passive joint mobility postoperatively, increased endurance, improved sleep patterns, decrease in right-to-left deficiency, increase in alertness and orientation, better active and secure standing, improved independent walking, better usage of upper extremities, reduction in medication and related side-effects, increased possibility of passive and active movements, easier change of position, increase in general well-being. In addition, adverse effects (yes/no) and type of adverse effects were documented as well as reasons for not using the Innowalk. This evaluation was performed by the therapist, where, for each goal set at the beginning, the following answers were offered: better/not better/not possible to answer/long-term goal at later time-points.

Innowalk device

The Innowalk device is a motorized, multi-functional assistive device offering the possibility of repetitive leg movements in an upright individually adjusted weight-bearing position (5). This movement induces flexion and extension of hip, knee and ankle joints. The device comprises a motor-driven gait orthosis for the legs, a weight support system, neck support, shoulder straps, side-support with a belt, and a transport trolley (for additional information see Supplementary Material and Methods).

RESULTS

The demographic and clinical characteristics of the 46 patients (33 males, median age 11 [interquartile range 7–15] years) at baseline are summarized in Table I. Of these, 91% ($n=43$), were younger than 18 years of age. Cerebral palsy was the underlying condition in 50% ($n=23$); of these the majority had spasticity, paresis and controlled epilepsy or a combination. Other underlying diagnoses were genetic syndromes, acquired brain damage, developmental disorders, neuromuscular disorders and neurological disorders (see Table I). The majority were underweight 62% ($n=23$). GMFCS E&R was classified as at least level IV in 92% ($n=22$) of evaluated patients.. Forty percent of patients had hip dysplasia. Five surgical procedures related to CP were performed on the lower extremities and 1 related to an accident with severe brain damage.

Twelve patients used the Innowalk in size small, 29 size medium, and 5 Innowalk Pro. Depending on the individual's heterogeneous underlying disease (see Table I), there was a wide variety of combination of therapies. All patients were attached to so-called sociopaediatric centres, where a multi-professional team of specialists treated the patient, including prescription of medical treatment and provision of medical aids, as individually required. In 2 cases (4%) the device was used in a hospital/institutional rehabilitation unit, whereas in 44 (96%) cases, the Innowalk was used outside hospitals, with nearly 70% at home, 17% in day care (kindergarten or school) or at medical supply store or the Made for Movement facility (11%). No recommendation regarding duration and frequency for an effective treatment can be derived from this. The reason for single testing was

Table I. Baseline characteristics and demographic variables ($n=46$)

Characteristics	Frequency (n), or median (IQR)
Age, years	11 (7–15)
Age group 1: 2–11 years	23
Age group 2: 12–17 years	19
Age group 3: 18 and older	4
Sex	
Male	33
Weight category[1], kg	
Underweight	23
Normal weight	9
Overweight	5
Indication	
CP ($n=23$)	
With spasticity	6
With spasticity and paresis	2
And epilepsy	1
No specification	13
With musculoskeletal deformities and contractures	1
Other diagnosis[2]	23
Genetic syndromes	1
Acquired brain damage	4
Developmental disorder	9
Neuromuscular disorder	8
Neurological disorder	1
GMFCS E&R Classification	
Level III	2
Level IV	12
Level V	10
Not applicable	22 (100% disability level :5)

CP: cerebral palsy; GMFCS E&R: Gross Motor Function Classification System – Expanded & Revised; IQR: interquartile range.

[1]According to (17).

[2]Trisomy 5P $n=1$, birth asphyxia $n=1$, traumatic brain injury grade 3 $n=2$, tetraspasticity after herpes encephalitis $n=1$, spina bifida $n=1$, thoracolumbar meningomyelocele $n=1$, hypoplastic left heart syndrome with epilepsy $n=1$, developmental disorder $n=2$, agenesis of the corpus callosum $n=1$, Aicardi Goutieres syndrome $n=1$, lissencephaly tetraspasticity $n=1$, porencephaly $n=1$, spinal muscular atrophy $n=2$, spastic paresis and tetraplegia $n=1$, spastic tetraparesis and tetraplegia $n=2$, bilateral spastic paresis with epilepsy $n=1$, tetraparesis $n=1$, paraplegia $n=1$, epilepsy $n=1$.

Table II. Innowalk usage

User type	*n*
Once	8
10 min	1
20 min	2
30 min	5
Long-term usage[1]	36
2–4 weeks	7
5–12 weeks	9
13–52 weeks	20
Inconclusive	2

[1]1–7 days a week; 20–60 min per session.

lack of approval by the insurance provider for further usage. The final report of the remaining 36 patients was available after 11 weeks usage of the Innowalk (not available for 2 patients). For these 36 patients, the length of training was 30 min, with a frequency of 5 per week (as shown in Table II).

As shown in Table III, all patients in whom disabilities had been recorded in detail ($n=20$), severe impairments in multiple mental, sensory and motor functions were present. All patients using the Innowalk were unable to walk or stand, 18 out 20 were unable to control their body or crawl. Only 10% were able to self-transfer or sit freely with no or only minor difficulties. Twenty percent of patients reported moderate pain before usage of the Innowalk.

For the majority (76%), improvement/activation of walking was termed as not applicable, due to their severe motor impairments. During this relatively short treatment period, improvements were found in: passive assisted motion (79%), stimulation of intestinal functions (71%), body stability (64%), joint mobility (56%), secure means of allowing supine position (52%), revision of abnormal motion patterns (48%) and postoperative joint mobility (33%), as shown in Fig. 2.

No adverse effects were reported in any of the records in these 46 patients.

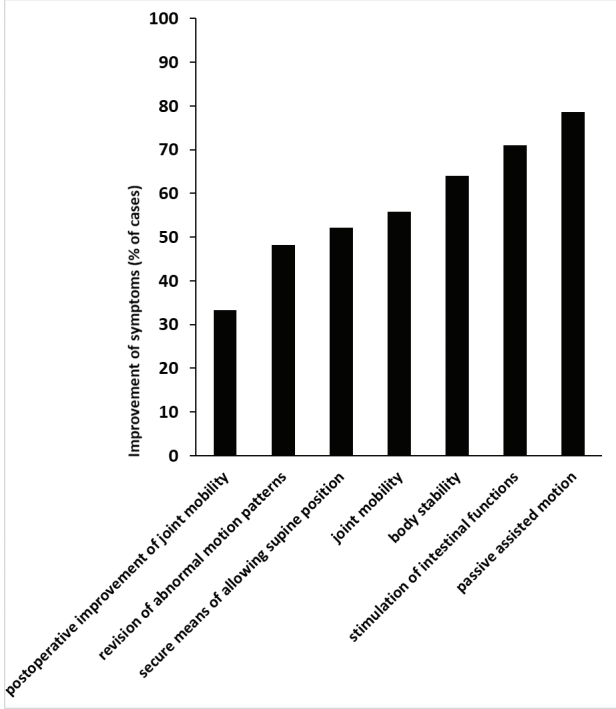

Fig. 2. Outcomes after training with the Innowalk for 10 (4–21) weeks in 36 patients.

DISCUSSION

These findings support the hypothesis that the Innowalk device for dynamic standing is effective in addition to the standard state-of-the art therapy in the treatment of people with severe motor impairments. Dynamic standing with the Innowalk allows upright positioning with individually adjusted weight bearing in combination with passive-assisted motion of lower extremities in correct axial alignment and, most likely, active muscle training. The current data show improved body stability, stimulated intestinal function and rever-

Table III. Mental, sensory and motor function impairments

Mental and sensory Impairments $n=20$	Communication	Perception	Bladder/gut function	Sleep	Respiration	Pain
Without to small (*n*)	6	8	4	10	13	13
Moderate (*n*)	4	6	6	7	6	4
Huge to impossible (*n*)	10	6	9	3	1	0
No Information (*n*)			1			3
Motor function impairment ($n=20$)	**Coordination balance**	**Body control**	**Spasticity**	**Joint mobility**	**Scoliosis**	**Head control**
Without to small (*n*)	1	2	7	4	11	6
Moderate (*n*)	4	4	4	9	2	9
Huge to impossible (*n*)	15	14	8	7	6	5
No Information (*n*)			1		1	
	Walking	**Standing**	**Self-transfer**	**Free sitting**	**Crawling**	**Hand mobility**
Without to small (*n*)	0	0	2	2	2	3
Moderate (*n*)	1	2	2	1	4	4
Huge to impossible (*n*)	19	18	16	17	14	13

Data are given in as absolute numbers of available cases, $n=20$

sed abnormal motion patterns, as well as increased joint mobility after surgical interventions.

To overcome lack of physical activity in people with severe motor impairments, dynamic standing devices have been developed. First, promising results come from small case studies (6–9). To date, there has been no information gathered systematically regarding the prescription patterns, type of indications, age and sex distribution, symptoms or severity of disease or disability level, or the type of Innowalk device used. The present study is the first to report medical benefit, impact on daily life and define risks and undesired effects from real-life routine prescriptions with the Innowalk since its introduction in 2009 in Germany.

Data were gathered consecutively using prospectively completed, standardized technical recordings for technical purposes. Hereby, selection bias has been reduced and a representative sample of diagnoses and geographical distribution over the last years obtained. Using quality-validated reports only, this study satisfies the standards of an evidence class IV of any case series design (10) and serves as a sound basis for design of a prospective controlled trial to show additional benefit of the Innowalk in evidence-based treatment of motor impairment.

The Innowalk has been prescribed for severely impaired children and adults with CP as the most common diagnosis. Severity of disability, as well as distribution of both age and diagnosis, correspond to those in other reports of the Innowalk or other dynamic standing devices (6–8). To date, no evidence-based data are available to deduct recommendations regarding disease-related and severity-of-disease-related recommendations, recommendations for frequency, duration and intensity of training. Future research needs improved methodological rigour to determine a specific set of exercise guidelines and safety considerations (11).

The improvements described in this analysis are in line with previous descriptions by case reports of dynamic standing involving improvements in passive range of motion, trunk stability, muscle strength, and intestinal functions (12). Dynamic standing with Innowalk thus provides aspects of weight bearing, passive motion as well as exercise. Since intensive training is the only intervention factor associated with improvement in gross motor function in individuals with motor impairments (13), dynamic standing is considered as an option when other forms of physical activities are rendered impossible (14).

There are other motor-driven passive or active cycling devices, with scarce scientific data proving a positive benefit/risk ratio or records for currently ongoing trials for early mobilization. Improvements have been shown in muscular function and force, cardiopulmonary parameters, cognitive skill and endurance (15, 16). These data, however, have low-evidence levels, and results from well-designed clinical trials are imperative before a definite conclusion can be drawn.

This study has several limitations, such as the retrospective design, with limited phenotypic data at inclusion documented in lean questionnaires developed by specialists together with the company restricted to the anticipated required information. With the relatively small sample size, heterogeneity may be underestimated, and a control arm is not available. We cannot exclude the possibility that patients have been included in this analysis with a bias at prescription. This, on the other hand, is an advantage, since it reflects all the so-far existing real-life prescription patterns of long-term prescribers with the urgent need to be confirmed in a well-designed and adequately powered trial. The data presented here relate to actual usage; no recommendation regarding the duration and frequency of an effective treatment can be deducted.

Further research

A more powerful study is now planned on this basis, with a large number of patients in a prospective, randomized, controlled multicentre trial, to prove evidence for concept and underlying mechanism. The trial will assess functional improvement according to individualized goal attainment quantification with the prespecified primary endpoint of hip mobility as surrogate parameter; sample size will be chosen to meet an error probability $\alpha = 0.05$ and a power $1-\beta = 0.9$; all concomitant therapy will be assessed in short intervals with standardized and validated questionnaires.

CONCLUSION

Since multidisciplinary therapy for people with severe disabilities are complex and time-consuming, the approach of weight-bearing dynamic standing with this device in a home-based environment provides a promising alternative treatment as an add-on to standard therapy.

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Author contributions

WS, UH, PB and RDB provided scientific guidance and expert opinion. JK provided assistance in data collection. AP and CS-L designed and implemented

the research, analysed the results and wrote the paper with input from all authors. All authors provided critical feedback and helped shape the research, analysis and manuscript.

Competing interests

Made for Movement holds the patent for the Innowalk (EU patent number 2134308; Norway patent number 326332). Jens Kleine and Rikke Damkjær Moen are employees of Made for Movement. Caroline Schmidt-Lucke and Ana Pekanovic are employees of MEDI-ACC, which received an honorary fee for analysis of the data and preparation of the manuscript. Employees of Made for Movement had no part in concept, analysis or writing of the manuscript.

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Data sharing statement

All data relevant to the study are included in the article or uploaded as supplementary information.

The authors have no conflicts of interest to declare.

REFERENCES

1. Mathewson MA, Lieber RL. Pathophysiology of muscle contractures in cerebral palsy. Phys Med Rehabil Clin North Amer 2015; 26: 57–67.
2. Boulard C, Gross R, Gautheron V, Lapole T. What causes increased passive stiffness of plantarflexor muscle-tendon unit in children with spastic cerebral palsy? Eur J Appl Physiol 2019; 119: 2151–2165.
3. Rosenbaum PL, Walter SD, Hanna SE, Palisano RJ, Russell DJ, Raina P, Wood E, Bartlett DJ, Galuppi BE. Prognosis for gross motor function in cerebral palsy: creation of motor development curves. JAMA 2002; 288: 1357–1363.
4. Schmidt-Lucke C, Käferle J, Rydh Berner BM, Ahlborg L, Hansen HM, Skjellvik Tollefsen U, et al. Effect of assisted walking-movement in patients with genetic and acquired neuromuscular disorders with the motorised Innowalk device: an international case study meta-analysis. PeerJ 2019; 7: e7098.
5. Schmidt-Lucke C, Käferle J, Rydh Berner B-M, Ahlborg L, Hansen HM, Skjellvik Tollefsen U, et al. Effect of assisted walking-movement in patients with genetic and acquired neuromuscular disorders with the motorised Innowalk device: an international case study meta-analysis. PeerJ 2019; 7: e7098.
6. Curtis DJ, Bencke J, Mygind B. The effect of training in an interactive dynamic stander on ankle dorsiflexion and gross motor function in children with cerebral palsy. Devel Neurorehabil 2014; 17: 393–397.
7. Damcott M, Blochlinger S, Foulds R. Effects of passive versus dynamic loading interventions on bone health in children who are nonambulatory. Pediatric Phys Ther 2013; 25: 248–255.
8. Palisano RJ, Rosenbaum P, Bartlett D, Livingston MH. Content validity of the expanded and revised Gross Motor Function Classification System. Devel Med Child Neurol 2008; 50: 744–750.
9. Lauruschkus K, Hallstrom I, Westbom L, Tornberg A, Nordmark E. Participation in physical activities for children with cerebral palsy: feasibility and effectiveness of physical activity on prescription. Arch Physiother 2017; 7: 13.
10. Definition of Classes of Evidence (CoE) and Overall Strength of Evidence (SoE). Evid Based Spine Care J 2013; 4: 167.
11. Rogers A, Furler BL, Brinks S, Darrah J. A systematic review of the effectiveness of aerobic exercise interventions for children with cerebral palsy: an AACPDM evidence report. Devel Med Child Neurol 2008; 50: 808–814.
12. Käferle J. Der Innowalk - Verbesserung Der Hueftgelenksbeweglichkeit Bei Icp (Paperback). Einfluss eines Bewegungstherapiegerätes auf das Hüftgelenk von Kindern mit bilateral spastischer Cerebralparese, GMFCS IV/V im Alter von sechs bis zehn Jahren eingebettet in das Konduktiv Mehrfachtherapeutische Fördersystem. AV Akademikerverlag; 2014. ISBN13: 9783639720051. 62-68.
13. Storvold GV, Jahnsen RB, Evensen KAI, Romild UK, Bratberg GH. Factors associated with enhanced gross motor progress in children with cerebral palsy: a register-based study. Phys Occupat Ther Pediatr 2018: 1–14.
14. Verschuren O, Peterson MD, Balemans AC, Hurvitz EA. Exercise and physical activity recommendations for people with cerebral palsy. Devel Med Child Neurol 2016; 58: 798–808.
15. Rocca A, Pignat JM, Berney L, Johr J, Van de Ville D, Daniel RT, et al. Sympathetic activity and early mobilization in patients in intensive and intermediate care with severe brain injuries: a preliminary prospective randomized study. BMC Neurol 2016; 16: 169.
16. Yang HC, Lee CL, Lin R, Hsu MJ, Chen CH, Lin JH, et al. Effect of biofeedback cycling training on functional recovery and walking ability of lower extremity in patients with stroke. Kaohsiung J Med Sci 2014; 30: 35–42.
17. WHO Multicentre Growth Reference Study Group. WHO Child Growth Standards based on length/height, weight and age. Acta Paediatr Suppl 2006; 450: 76–85.
18. Palisano R, Rosenbaum P, Walter S, Russell D, Wood E, Galuppi B. Development and reliability of a system to classify gross motor function in children with cerebral palsy. Devel Med Child Neurol 1997; 39: 214–223.
19. Palisano RJ, Hanna SE, Rosenbaum PL, Russell DJ, Walter SD, Wood EP, et al. Validation of a model of gross motor function for children with cerebral palsy. Phys Ther 2000; 80: 974–985.