Movement Therapy of the Upper Extremities with a Robotic Ball in Stroke Patients: Results of a Randomized Controlled Crossover Study

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Bibliography
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ABSTRACT
Background Stroke is associated with motor impairments of the upper extremities. The defining goal of rehabilitation is independent execution of activities of daily living. New therapy procedures use different hardware components to implement digital therapy contents. These can be useful complements to established therapy protocols.

Objectives The aim of this study was to examine the effect of movement therapy with a robotic ball on motor function parameters in stroke patients.

Materials and Methods 25 patients (60.0 ± 10.0 years, 172.5 ± 13.8 cm, 79.5 ± 13.8 kg, 89.8 ± 72.6 months post-stroke) took part in this crossover study. The intervention and control periods comprised 12 weeks each. Training with the robotic ball was done in addition to standard therapy two times a week for 45 min each. Different game activities were carried out with the help of a tablet and a smartphone.

Results Isometric grip strength improved by 4.5 ± 3.6 kg (p = 0.000), and unilateral dexterity increased by 7.5 ± 6.3 successful tries (p = 0.000) in the round block test. The self-reported disabilities of the arm, shoulder and hand were assessed using the QuickDASH questionnaire and showed improvements by 12.4 ± 13.0 points (p = 0.001).

Conclusions Additional therapy using the robotic ball improved upper extremity motor function and self-perceived health status in chronic stroke patients. However, performance stagnated when standard therapy was implemented alone. Moderately affected patients seem to benefit the most. The presence of very severe motor or cognitive symptoms led, in part, to some dropouts. The results need to be verified using larger patient populations.

Introduction
In Germany, up to 75% of the approx. 196,000 initial and 66,000 repeated strokes are survived [1–4]. For the affected patients, it is often the trigger for persistent physical limitations, which in 85% of the cases are manifested by the cardinal symptom of spastic or flaccid hemiparesis of the upper extremities. Restriction or even loss of function of the hand and arm drastically impacts the daily life of the affected individual [1, 5–7]. Demographic change has increased the incidence of stroke. Improved acute care has enabled more people to survive the event, resulting in a greater number of patients and a growing demand for therapy [1, 2, 6]. Reduced range of motion, pain, sensory disturbances and increased muscle tone are characteristic patient symptoms [8, 9]. Loss of arm function is the consequence in about half of stroke cases [8], unlike rehabilitation of independent mobility, which can be achieved in up to 85% of patients [10]. Consequently, relatively less time is devoted to re-
covery of hand and arm function [11]. In addition to effects on motor function there are often psychological and social consequences [12]. A variety of physical activity measures should contribute to the compensation and restoration of skills and abilities [13, 14]. Since it is still possible to make progress even weeks after a stroke, it is imperative to develop more effective therapeutic methods, especially in the case of sustained loss of upper extremity function [8]. Thus the severity and location of the cerebral insult as well as comorbidities are decisive for the further rehabilitation process [15, 16]. The success of Constraint-induced Movement Therapy (CIMT) [7, 17–24] demonstrates the necessity and possible benefit of using the upper extremities during training and everyday life.

In this context as well as due to innovative developments in technology-supported concepts and components [25–30] in the field of stroke rehabilitation such as exergaming, [31–34] the “Sphero 2.0” robotic ball was reviewed in combination with game-playing applications as a supplemental therapeutic activity [35]. The potential benefit for stroke patients regarding improving motor parameters has been documented in review articles on technology-supported therapeutic measures [36, 37]. Hardware and software components from the entertainment industry or telecommunications are used to develop new therapy activities. There are examples of the Microsoft Kinect webcam used in stroke rehabilitation [30, 38–44] as well as for game consoles such as the Nintendo Wii [45–47], Sony Playstation [48] or Microsoft XBox [44]. In addition, smartphones [34], tablets [49–52] or virtual reality goggles [53] are being used to employ generally commercially available games with potential therapeutic benefits, or to use their sensor systems for movement detection and control. Therapeutic content can be found in commercial video games such as Wii Sports [54] or Kinect Sports [44] as well as games programmed specifically for therapeutic applications [42, 55]. Their common element is the required use of the affected body half to achieve the respective game objective. The activity can reflect daily activities such as grasping and moving a glass [56], cooking [38], or striking selected piano keys [38, 49].

Objective and Issues Addressed

The effect of movement therapy of stroke patients utilizing a robotic ball based on selected motor parameters will be investigated using a crossover study design. The motor functionality of the upper extremities will be quantified using subjective and objective assessments. The aim is to investigate the effect of a robotic ball with various play activities in addition to standard therapy.

Methodology

Study design

The study was conducted based on a crossover design. Group 1 started in Phase 1 with standard therapy, supplemented by robotic ball therapy; Phase 2 used only standard therapeutic procedures. The process for Group 2 was reversed (Fig. 1). Training with the robotic ball involved 24 units for each patient, two times per week, each 45 min in duration. Standard therapy (generally 1–2 applications during 1–2 sessions per week) included physiotherapy and occupational therapy, and as needed, logotherapeutic activities. These included classical physiotherapeutic approaches such as remedial gymnastics for neurological diseases (Bobath, Vojta and PNF) as well as neuromuscular electrostimulation. Furthermore, mobilizing therapy exercises with heat application (fango, ultrasound, hot roller), classical massages or manual therapy were used; edema was treated with lymph drainage. Occupational therapy included motor-functional, sensomotor-perceptive, psychological as well as neuropsychological treatment measures. The study was reviewed and approved by the local ethics committee (VS-129-HS).

Sampling

After prior verbal and written disclosure, 25 stroke patients volunteered for the study which was conducted in an outpatient rehabilitation center, respecting patient privacy (Table 1). Twenty-three of the patients had experienced a stroke more than 6 months prior to the study [57].

Hardware/software

Supplemental training employed the “Sphere 2.0” robotic ball (Orbotix, Colorado, USA) using firmware ver. 3.73 (Fig. 2). The applications were controlled using a Cubot X15 smartphone (Android
5.1) as well as an Apple Mini 2 iPad (iOS 9.2–10.2). In addition, a specially-developed holder was used as an aid in grasping the smartphone [35]. The therapeutic actions were implemented using the “Sphero” and “Sphero Chromo” apps.

**Therapeutic activities**

By moving the upper extremities, especially the hand, the patient actively tries to achieve the objectives of the respective game. The robotic ball is either held in the hand and turned in various directions (Chromo app) (Fig. 3) or remotely controlled by moving the smartphone (Sphero app) (Fig. 4). The study director performs device setup, configures motion tasks and provides support during patient training.

In addition to the wrist, the patient also partially moves the elbow and shoulder joints to involve the complete hand-arm-shoulder chain. Another challenge is the ability to grasp and turn the ball in a variety of ways. Numerous exercise variations allow a wide range of therapeutic options depending on symptom manifestation. Simple aids (tenpins, floor mats, bars) can also be used to create new movement tasks (Fig. 4).

**Test procedures**

Patient cognitive status was determined using the Montreal Cognitive Assessment. A result greater than 26 points is considered "normal" [58]. Motor function was determined using isometric grip strength for 1–2 s (starting with the affected side, 3 attempts; healthy side as reference in 2 attempts). This parameter is used as a marker for global functionality of the upper extremities as well as a measurement of rehabilitation progress [59, 60]. The round block test was selected to determine unilateral dexterity of gross motor
movements. Within 60 s, as many cylinders as possible (diameter 6.5 cm, thickness 2 cm) are turned with one hand into recesses (0.5 cm) on a wooden board (starting with the affected side, 3 attempts; healthy side as reference in 2 attempts). In addition, the QuickDASH questionnaire assessed the subjective perception of the affected person with regard to their current state of health (0 points ≥, no impairment up to 100 points ≤, maximum possible restriction) of the upper extremities [61, 62]. A difference of at least 14 points is considered clinically relevant [63].

In order to carry out a differentiated data analysis, three performance classes were formed for the parameters grip strength, unilateral dexterity and personal health perception. Grouping patients as “severely affected”, “moderately affected” and “mildly affected” should help to specify the suitability of the therapy concept and to make apparent any differences depending on the degree of impairment. Classification was done after randomization in percentage relation to the healthy half of the body (grip strength, round block) or to the lowest score as a measure of no impairment (QuickDASH). Severely affected ≤ 20 %, moderately affected 20 to ≤ 75 % and mildly affected > 75 %.

Statistics

Statistical analysis was performed using IBM SPSS Statistics version 24. The significance level was defined as α = 5 %. The pre/post comparison of the results used the nonparametric Wilcoxon test measurement method and sign test. The results were calculated according to Cohen’s d effect size [64].

\[
d = \frac{MV_{t2} - MV_{t1}}{SD_{pool}}
\]

This is interpreted in the following intervals: 0.2–0.5 ≤ small effect, 0.5–0.8 ≙ medium effect, > 0.8 ≤ large effect. ANOVA was used to verify the influence of the therapy form (standard therapy and additional robotic ball training) as well as the group affiliation (sequence of the therapy application) on differences in the assessments.

Furthermore, the root-mean-square error (RMSE) was calculated in order to include the minimum effect for the underlying sample in the interpretation based on the variability of the data after several measured attempts (grip strength, round block).

\[
\text{Effect}_{\text{min}} = \text{RMSE} \times 2.77
\]

The confidence interval for the effect was formed in order to further classify the results, thus allowing specification of a value range within which the true value for the effect for the population can be determined with 95 % confidence.

\[
\text{Effect}_{\text{CI}} = \text{Mean Difference} \pm (1.96 \times \text{Standard error})
\]

Results

Twenty of 25 patients could complete the intervention in its entirety. There were dropouts in both Group 1 (n = 2) and Group 2 (n = 3). In four cases this was due to the severity of symptoms (particularly finger flexion spasticity), and in one case, too severe cognitive impairments. On the whole, grip strength increased by 4.5 ± 3.6 kg (p = 0.000), corresponding to an improvement of 43.9 ± 30.4 to 53.8 ± 33.8 % relative to the healthy body half. Group 2 showed a lower initial level of grip strength compared to Group 1. Moderately affected patients (n = 11) improved by 5.4 ± 2.8 kg (p = 0.003), corresponding to an improvement of 16.0 ± 9.1 % relative to the unaffected upper extremity. Mildly affected (n = 4) patients improved by 7.3 ± 2.9 kg (≤ 5.5 ± 5.9 %), and the severely affected (n = 5) improved by 0.1 ± 0.5 kg (≤ 0.0 ± 0.7 %). In the round block test as a measure of unilateral dexterity, the subjects were able to improve by 7.5 ± 6.3 successful attempts per minute (p = 0.000), corresponding to an improvement of 29.6 ± 20.9 to 40.2 ± 25.9 % relative to the healthy body half. Regarding this parameter, Group 2 demonstrated a weaker initial level compared to Group 1. Moderately affected patients (n = 14) improved by 10.0 ± 6.0 attempts were again the strongest group (p = 0.000), corresponding to an improvement of 13.5 ± 9.9 % relative to the unaffected upper extremity. Severely affected patients (n = 8) improved by 1.9 ± 1.6 successful attempts per minute (≥ 3.5 ± 3.8 %). Subjective health perception improved among all subjects by 12.4 ± 13.0 points (p = 0.001), although the clinically relevant difference of 14 points [63] was narrowly missed. The group of moderately affected patients (n = 15) reached this threshold with 16.8 ± 11.9 points (p = 0.000). Severely affected patients (n = 2) improved by 3.4 ± 4.8 points; mildly affected patients (n = 3) improved by 0.0 ± 2.3 points. Group 2 demonstrated fewer changes than Group 1 (Tab. 2).

Depending on the group at the respective study phase, the data clearly indicate that the greatest changes were achieved by both groups during the supplementary robotic ball training phase (Fig. 5). In addition, the data trend of Group 1 shows that the training effects during standard therapy did not persist, and in fact, even declined slightly (p = 0.005, d = 0.24). Twelve weeks after the intervention, grip strength, unilateral dexterity as well as subjective perception of health were still greater than the initial level. The form of therapy had a highly-significant influence on the differentials in grip strength (ANOVA, p = 0.000) and unilateral dexterity (ANOVA, p = 0.000) Group affiliation (sequence of therapeutic applications) had no significant influence on the differences in grip strength (ANOVA, p = 0.346) or unilateral dexterity (ANOVA, p = 0.269). Regarding grip strength and health perception, both groups were at the same level, although initially Group 1 performed better in the round block test (Fig. 5). The subjective health perception (QuickDASH) of both groups significantly improved during the robotic ball training phase (p = 0.001, d = -0.60) although the mean difference of 12.4 ± 13.0 varied substantially. If only moderately affected patients are analyzed, the mean difference increases to 16.8 ± 11.9 points (p = 0.000, d = 1.01) which is clinically relevant [63]. Analysis of grip strength (p = 0.000, d = 0.33) and unilateral dexterity (p = 0.000, d = 0.47) after robotic ball training showed minor effects for the entire random sample. Both parameters showed greater improvement for moderately affected patients. Grip strength improved up to 66.6 ± 15.2 % (p = 0.003, d = 0.76), and unilateral dexterity increased to 53.4 ± 18.0 % (p = 0.000, d = 0.78) of the capacity of the unaffected body half. The differential between grip strength and unilateral dexterity showed no statistically significant relationship (p = 0.099, r = 0.38). The contrast to
the difference in unilateral dexterity (p = 0.5, r = -0.16), median grip strength was significantly related to the difference in subjective health perception (p = 0.042, r = -0.459).

Individual case analysis illustrates the heterogeneity of the sample performance level. In particular, the group of severely affected patients demonstrated fewer changes in the assessments in the course of the study (Fig. 6). At the start of the intervention, strong correlations (p = 0.000, R² = 0.768, d = 1.82) between health perception and grip strength or unilateral dexterity could be measured for the entire sample. In addition, an initially high level of performance seemed to be improvable in some cases (Fig. 6). On average, Group 1 showed higher performance in terms of grip strength, and after completion of training, demonstrated greater effects (p = 0.007, d = 0.52) compared to Group 2 (p = 0.018, d = 0.25). With approximately equal effects in the round block test (Group 1: p = 0.002, d = 0.45 and Group 2: p = 0.008, d = 0.49), the differing grip strength was decisive for the large distinction between the two groups in terms of subjective health perception (Fig. 5). Group 1 showed a clinically-relevant change of 14 (p = 0.002, d = -1.16), whereas in Group 2 only a small effect (p = 0.289, d = -0.38) was achieved (Fig. 5). The correlation between the difference in the perception of health and the differences between gripping strength and unilateral dexterity was not statistically significant (p = 0.133, R² = 0.118, d = 0.37).

For the most part the data show a similar progression with few to no changes occurring in the standard therapy phase and distinct changes occurring with supplemental robotic ball therapy. Comparison of the standard therapy phases shows that the higher level of grip strength in Group 1 did not persist as a consequence of robotic ball training (−2.16 kg), whereas in Group 2 the differences in grip strength during the standard therapy phase were minimal (−0.4 kg) (Fig. 7). The median differentials in this phase differed
significantly in this phase \(p = 0.004\). Grip strength and unilateral dexterity increased; analogously the QuickDASH score declined, indicating improved subjective health perception.

**Discussion**

The data show that improved grip strength, combined with better everyday functioning, had a positive effect on the patients’ subjective health perception. The strength of the hand when grasping is considered a prognostic indicator as well as a measure of the damage to the upper extremities in stroke patients [60]. This parameter is also a marker for estimating indication-specific mortality for middle-aged and older people and can be used as a predictor of morbidity, infirmity and functional impairment [65, 66]. However, a relevant change in the subjective perception of health among either severely or mildly affected patients due to additional therapy was not achieved. Severely pronounced symptoms could not therefore be improved so significantly that the patients’ general health perception was positively influenced. In mildly impaired patients, the potential for improving health was low even before initiation of robotic ball therapy. Noticeable group differentials in grip strength, unilateral dexterity and health perception are due to the randomized and thus varying group distribution of the subjects. The number of severely affected patients was greater in Group 2, which may explain the reduced effects. Differentiated analysis suggests that the therapy concept is not equally suitable for all stroke patients, but can complement the therapy, especially in moderately affected patients. In addition, non-specific effects should be taken into account which may have influenced the causes of the effects. On the one hand, patients may have been particularly motivated by the innovative and previously completely unknown therapy opportunity. Furthermore, the intensity and scope of the therapy were significantly increased. The new and unique training stimulus had a particularly favorable effect on the therapy results (Fig. 7).

In addition to the results from the quantitative data analysis, direct patient feedback was important in order to document further changes. In addition to the therapy time, the patients’ daily routine was taken into account. Behavior changes, for example in the form of additional use of the affected half of the body with more self-confidence due to increased ability, could additionally influence the effects. Individual discussions frequently revealed a patient’s readiness to increasingly use the affected body half. Positive perceptions such as increased strength and dexterity as well as a somewhat improved exercise tolerance motivated the moderately affected in particular to apply different aspects of the training to everyday life,

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**Table 1** Anthropometry of the sample and stroke characteristics.

| Gender | Age [years] | Size [cm] | Weight [kg] | Insult type | Post-stroke [months] | Symptom side | Handedness | MoCa
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>15 m, 10 f</td>
<td>60.0 ± 10.0</td>
<td>172.5 ± 13.8</td>
<td>79.5 ± 13.8</td>
<td>20I, 5H</td>
<td>89.8 ± 72.6</td>
<td>14 r, 11 l</td>
<td>24 r, 1 l</td>
<td>23.8 ± 7.1</td>
</tr>
</tbody>
</table>

* m male, f female, I ischemic, H hemorrhagic, r right, l left, MoCa Montreal Cognitive Assessment (Normal is > 26 points)
Table 2  Pre/post results after the robotic ball training phase of isometric grip strength, unilateral dexterity as well as perceived state of health.

<table>
<thead>
<tr>
<th>Group</th>
<th>Grip strength [kg]</th>
<th>Round block [number of successful attempts]</th>
<th>QuickDASH</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>IM</td>
<td>IM %</td>
<td>FM</td>
</tr>
<tr>
<td>Group 1 (intervention – standard therapy) n = 10</td>
<td>15.1 ± 8.8</td>
<td>50.9 ± 24.0</td>
<td>19.8 ± 9.3</td>
</tr>
<tr>
<td></td>
<td>p = 0.007 *</td>
<td>d = 0.52</td>
<td>Effc_tmin = 3.1kg</td>
</tr>
<tr>
<td></td>
<td>d = 0.52</td>
<td>d = 0.45</td>
<td>Effc_tmin = 5.5</td>
</tr>
<tr>
<td></td>
<td>Effc_tmin = 2.8–6.6kg</td>
<td>Diff_m = 4.7 ± 3.1kg</td>
<td>Diff_m = 6.8 ± 3.7</td>
</tr>
<tr>
<td>Group 2 (standard therapy – intervention) n = 10</td>
<td>14.6 ± 15.8</td>
<td>36.9 ± 35.7</td>
<td>18.9 ± 18.4</td>
</tr>
<tr>
<td></td>
<td>p = 0.018 *</td>
<td>d = 0.25</td>
<td>Effc_tmin = 4.2kg</td>
</tr>
<tr>
<td></td>
<td>d = 0.25</td>
<td>d = 0.49</td>
<td>Effc_tmin = 4.0</td>
</tr>
<tr>
<td></td>
<td>Effc_tmin = 1.7–6.8kg</td>
<td>Diff_m = 4.3 ± 4.2kg</td>
<td>Diff_m = 8.3 ± 8.4</td>
</tr>
<tr>
<td>Group 1 + 2 n = 20</td>
<td>14.9 ± 12.5</td>
<td>43.9 ± 30.4</td>
<td>19.4 ± 14.3</td>
</tr>
<tr>
<td></td>
<td>p = 0.000 *</td>
<td>d = 0.33</td>
<td>Effc_tmin = 3.6kg</td>
</tr>
<tr>
<td></td>
<td>d = 0.33</td>
<td>d = 0.47</td>
<td>Effc_tmin = 4.7</td>
</tr>
<tr>
<td></td>
<td>Effc_tmin = 2.9–6.1kg</td>
<td>Diff_m = 4.5 ± 3.6kg</td>
<td>Diff_m = 7.5 ± 6.3</td>
</tr>
<tr>
<td>Moderately affected n = 11 (GF) n = 14 (RB) n = 15 (QD)</td>
<td>15.6 ± 7.6</td>
<td>50.7 ± 18.1</td>
<td>21.0 ± 6.8</td>
</tr>
<tr>
<td></td>
<td>p = 0.003 *</td>
<td>d = 0.76</td>
<td>Effc_tmin = 3.1kg</td>
</tr>
<tr>
<td></td>
<td>d = 0.76</td>
<td>d = 0.78</td>
<td>Effc_tmin = 5.3</td>
</tr>
<tr>
<td></td>
<td>Effc_tmin = 3.8–7.1kg</td>
<td>Diff_m = 5.4 ± 2.8kg</td>
<td>Diff_m = 10.0 ± 6.0</td>
</tr>
</tbody>
</table>

IM Initial measurement, FM Final measurement, IM % Percentage relation to the non-affected side at the time of the initial measurement, FM % Percentage relation to the non-affected side at the time of the final measurement, * Wilcoxon Test, * * Sign test, Effc_tmin minimum effect, Effc_CI Confidence interval for the effect, Diff_m mean difference, d Cohen's d effect strength, p significance (pre/post comparison), GS Grip strength, RB Round block, QD Questionnaire Disability Score
especially including gripping and using objects (e.g. hanging laundry, cooking, carrying utensils, using a keyboard). Thus, positive experiences in daily life and during training could contribute to increasing acceptance of the therapy concept and being open to new activities. Several patients demonstrated the willingness to try new movements with the injured side and to consciously integrate them more often into their everyday life.

Based on an objective data analysis in combination with subjective experience reports and observations during therapy with robotic ball training, it was possible to determine that the group of moderately-affected patients benefited the most from this measure (Tab. 2). Patients’ symptoms allowed the implementation of various game activities with tolerable challenges and intensity. Very severely affected patients were generally able to perform the robotic ball therapy; however brain damage was so severe in these cases that this movement-therapeutic measure had its limits (4 dropouts due to great motor limitations). Although these patients could perform fewer play variations, nevertheless, they profited from the therapy, reporting a noticeable relaxation of muscle tone in the hand and arm immediately after the therapy session, which continued for up to three hours after therapy. The games were particularly welcomed by patients undergoing long-term therapy who saw them as a goal-oriented, motivating and entertaining addition to the therapy routine. However, the dropouts show the limits of feasibility. Severe spasticity in the lower arm or the fingers in particular can make it impossible to hold the robotic ball or smartphone and thus perform the movements.

Prior experience with the robotic ball shows the potentials of this therapeutic concept. High acceptance by patients and therapists due to entertaining and diversified therapy activities contributed to motivation and compliance. At the same time, these activities provided a measurable benefit with respect to the patients’ motor-related parameters. It remains to be seen whether minimal setup effort and intuitive operation allow independent use by trained patients in the home environment. Furthermore, the results should be verified based on a larger patient sample. In addition, brain activation (e.g. via fMRI, fNIRS, TMS, EEG) could be investigated in order to determine the possible effect of the movements on neurophysiological processes (e.g. hemodynamics, electrical activity). It would then be possible to compare the extent and localization of brain activation with other activities and draw conclusions about processes of neurogenesis, plasticity and neuroprotection. The application of the therapy concept should be studied with respect to other pathologies, such as Parkinson’s disease or multiple sclerosis.

Summary and Outlook

1. Additional therapy using a robotic ball could profitably supplement standard therapy. Positive changes in grip strength, unilateral dexterity and subjective sense of health were apparent in the supplemental robotic ball training phase; however, performance in the standard therapy phase largely stagnated. Improvement in grip strength was related to an improved perception of health. Non-specific effects in conjunction with the new, unfamiliar training stimulus may have additionally influenced the results.

2. Objective data analysis, subjective observations as well as patient reports demonstrated the benefit of the therapy concept for moderately affected patients. Particularly in the vane of very severe symptom manifestation, not all therapeutic activities could be completely performed; therefore only minor effects could be achieved. Especially severe motor or cognitive limitations could pose insurmountable barriers for patients; therefore the therapy concept could not be employed in individual cases.

To verify the results, robotic ball therapy should be used in a larger randomized study. Single-case analysis of the data show heterogeneity within the random sample and corresponding differences in effects. Application of this approach in the home environment should be studied. Furthermore, new specific therapeutic activities should be developed for stroke patients.

Conflict of Interest

The authors declare no conflict of interest.

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