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ORIGINAL REPORT

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IMMEDIATE AFFECTIVE RESPONSES OF GAIT TRAINING IN NEUROLOGICAL REHABILITATION: A RANDOMIZED CROSSOVER TRIAL

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Objective: To examine the immediate effects of physical therapy and robotic-assisted gait training on affective responses of gait training in neurological rehabilitation.

Design: Randomized crossover trial with blinded observers.

Patients: Sixteen patients with neurological disorders (stroke, traumatic brain injury, spinal cord injury, multiple sclerosis).

Methods: All patients underwent 2 single treatment sessions: physical therapy and robotic-assisted gait training. Both before and after the treatment sessions, the self-report Mood Survey Scale was used to assess the effects of the treatment on distinct affective states. The subscales of the Mood Survey Scale were tested for pre–post changes and differences in effects between treatments, using non-parametric tests.

Results: Fourteen participants completed the study. Patients showed a significant increase in activation ($r=0.55$), elation ($r=0.79$), and calmness ($r=0.72$), and a significant decrease in anger ($r=0.64$) after robotic-assisted gait training compared with physical therapy.

Conclusion: Affective responses might be positively influenced by robotic-assisted gait training, which may help to overcome motivational problems during the rehabilitation process in neurological patients.

Key words: affect; fatigue; Lokomat; motivation; rehabilitation; robotics.

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Patients with neurological impairment are known to have reduced quality of life and increased risk for depressive symptoms, which may hinder their ability to perform daily rehabilitation programmes, such as physical therapy (PT) or robotic-assisted gait training (RAGT) (1). During the continuum of rehabilitation it is necessary to consider factors such as choice and enjoyment in order to determine specifically how an individual would participate in rehabilitation programmes. The inclusion of participation scales is recommended when assessing the outcome of rehabilitation programmes (2). According to Self-Determination Theory (3), positive affective responses (e.g. activation, elation, or calmness) are connected with high intrinsic motivation and are an important regulation process in human behaviour. Therefore affective responses to the treatment sessions, as defined by Ekkekakis & Petruzello (4), might be important predictors of motivation, adoption, and maintenance of treatment regimes in the rehabilitation process.

Fatigue is a common and distressing complaint among people with neurological impairment (5). Patients often are afraid that engagement in exercise may increase fatigue (6). In patients with traumatic brain injury, "lack of energy" was rated as 1 of the top 5 problems for participation (7). Therefore it is important to emphasize that it is more likely that a higher level of energy will be achieved after exercise (8, 9). Although not yet a widely recognized determinant of exercise behaviour, affective valence is viewed in psychology and behavioural economics as one of the major factors in human decision-making (10). Findings from exercise psychology have demonstrated that the affective components of pleasure and activation might be crucial for bridging the intention–behaviour gap at the beginning of engagement in exercise (10). Regular participation in physical activity, in the long-term, may be mediated by an individual's belief in the exercise–psychological wellbeing association. It may also lead to anti-depressive effects (11). Both PT and RAGT can be considered as forms of physical activity; therefore one might speculate that the effects mentioned above could be transferred to neurological patients. While increases in energy and mood in response to a single bout of moderate intensity exercise have been shown in healthy people and several risk-groups (6, 8, 9), no such study has been carried out involving neurological patients.

To our knowledge, only 2 studies concerning RAGT and psychological effects have been published. Koenig et al. (12) described a method to observe mental engagement during RAGT. Recently, Calabro et al. (13) reported positive long-term effects of RAGT on mood and coping strategies in a case study. To our knowledge, apart from these studies, affective responses have not been researched in PT or RAGT.

Thus, the aim of this study was to determine, for patients with neurological impairment: (*i*) whether a single session of PT and RAGT has immediate effects

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on affective responses (e.g. activation, elation, or calmness) and; (*ii*) whether possible affective responses differ between PT and RAGT.

METHODS

Design and procedure

The project was designed as a crossover study with blinded observers, in which all participants were exposed to 2 treatment sessions in a randomized order: a single session of PT and a single session of RAGT. PT was based on Bobath principles and comprised mobilization, strengthening, and sensomotoric-stimulating techniques. Exercises for improving postural control (e.g. facilitated activation), for improving core stability (e.g. differentiated tasks from sitting to standing), for improving gait ability (e.g. overground gait training), and for regulating the alignment of hip, knee and ankle joint were selected according the current therapy goal of the patient. For RAGT, an exoskeleton device (Lokomat, Hocoma AG, Switzerland) was used (14). This device has been described previously (e.g. 15). Body weight support (15–50%), speed (1.2–2.0 km/h), and guidance force (30–100%) were adjusted to the patients' daily condition. Visual feedback was not used in any of the therapy sessions. Because affective responses might be affected by external stressors (e.g. changes in the daily routine) (9), no modifications were made to the therapy sessions to increase the ecological validity of the study. The duration of the treatment sessions was 1 h, including a set-up time of approximately 10 min (RAGT) and 30–60 min (PT), respectively.

In each treatment session, 2 assessments were conducted: the first immediately before treatment, and the second immediately after treatment. Group 1 started with RAGT on the first day and continued with PT on the second day. Group 2 started with PT on the first day and continued with RAGT on the second day. Consequently, the washout phase between the treatments was 24 h. A crossover design was used to reduce error variance associated with inter-individual differences and to increase statistical power. PT and RAGT were conducted by therapists who were not involved in the measurements or analyses.

Measurements consisted of a pencil-and-paper questionnaire and were done in a separate quiet room. Two independent persons, who were not involved in further analyses, were precisely instructed and supported the patients during completion of the questionnaire. The timeline (total assessment time approximately 5 min) remained the same for all assessments.

All therapy sessions and assessments were conducted at the State Hospital Hochzirl and took place in December 2012. The study was approved by the Board for Ethical Questions in Science of the State Hospital Hochzirl and all participants signed an informed consent form. Trial registration: Trial registration in ClinicalTrials.gov; number: NCT02767466.

Participants

All 24 patients with neurological disorders receiving RAGT during the 3rd week of December 2012 at Hospital Hochzirl were screened for eligibility and were recruited on a voluntary basis. Sixteen patients were randomized, starting with PT or RAGT, respectively. Block randomization (block size 2) was carried out by a clinician not involved in further assessments or analyses. The detailed participant flow is shown in Fig. 1. According to a power analysis only large effect sizes ($r > 0.5$) could be detected as significant on the assumed power of 80% by a sample size of 16. Exclusion criteria were: (*i*) lack of communication ability; (*ii*) impaired consciousness; and (*iii*) inability to speak German. All patients had previous experience with both PT and RAGT. On average the therapy observed was the 11th session (median).

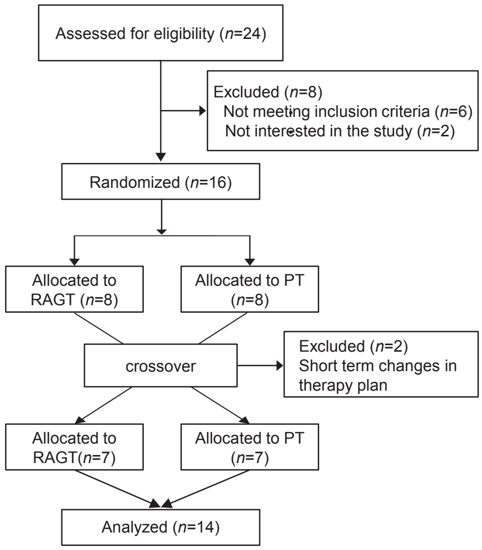

Fig. 1. Participant flow diagram. PT: physical therapy; RAGT: robotic-assisted gait training.

Outcomes

A self-report multi-item questionnaire, based on the Circumplex model (16), was used to assess affective responses. Distinct affective states were assessed with a short version of the German Mood Survey Scale (MSS (17)), an adjective list of originally 40 items ("At this moment, I feel…") with a 5-point Likert response mode ("not at all" to "very"). Eight subscales (activation, elation, contemplation, calmness, fatigue, depression, anger, excitement) are each calculated from 5 items. Each subscale ranges from 5 (lowest value) to 25 (highest value). Internal consistency is reliable (Cronbach's $\alpha = 0.70–0.86$). Other psychometric properties of convergent and divergent validity can be found in Abele-Brehm & Brehm. (17). The MSS can be compared with the Profile of Mood State (18), but has the advantage of providing 4 positive subscales, compared with 1 in the Profile of Mood State. Considering the patient's condition, it is important to provide a short questioning time, to use understandable items, and not to lose information. Therefore, the 40 items of the original scale were reduced to 21 items by eliminating the neutral subscale (contemplation) and by using only 3 rather than 5 items per subscale. The 7 remaining subscales were: anger, activation, elation, calmness, fatigue, excitement and depression. This approach has been used previously in psychiatric patients (19). Cronbach's α values for internal consistency of the MSS in the present study ranged from 0.72 to 0.91. For detailed results see Table I.

Walking ability was assessed using the Functional Ambulation Category (FAC; 20). Test–retest reliability and inter-rater reliability of FAC are excellent, with a κ of 0.95 and 0.91, respectively (21).

Primary outcome parameters of the study were the subscales of the MSS.

Table I. Cronbach's α of the first survey

Anger	Excitement	Activation	Elation	Calmness	Fatigue	Depression
0.91	0.76	0.80	0.90	0.72	0.86	0.85

Statistical analyses

All statistical analyses were performed using SPSS v.20 (IBM, New York, USA). Due to the low sample size, non-parametric methods (Wilcoxon tests) were used in the analysis, as suggested by Bortz & Lienert (22).

To test for possible period and carry-over effects, as suggested by Senn (23), the sums (period effect) and differences in post-values (carry-over effect) were tested for differences between the 2 groups, using Mann–Whitney *U* tests.

To test for possible changes, the following analyses were performed: (*i*) the differences in variables (post–pre) of the subscales were calculated and tested for possible differences in effects over time between the 2 treatments; (*ii*) to test for differences in only one treatment, pre- and post-values of the according treatment session (PT or RAGT) were used.

To determine the magnitude of the effects, effect size *r* was calculated, as suggested by Field (24). A positive value of *r* indicates an increase, while negative values mark decreases.

The level of significance was set at $p<0.05$ (2-tailed). Data are presented as median (interquartile range) unless specified.

The study was approved by the Board for Ethical Questions in Science of the State Hospital Hochzirl. All participants signed an informed consent form.

RESULTS

Sample and treatment session description

Fourteen patients with a median age of 71.5 years (age range 57.2–77.3 years) completed the study (14% female). Median walking ability was 2.5 (range 0.8–4.3) on the FAC. The following incidents were represented: stroke (71.4%), traumatic brain injury (14.3%), spinal cord injury (7.1%), and multiple sclerosis (7.1%) (1 patient each). The incident occurred a median of 77 days previously (range 37–285 days, 2 outliers: 3 and 20 years). Two patients dropped out for reasons not connected with the study (short-term change in therapy plan). The median duration of PT was 45 min (range 35–48 min). RAGT had a median duration of 49 min (range 45–53 min), median distance of 1,293 m (range 1,182–1,481 m), median speed of 1.7 km/h (range 1.5–1.8 km/h), median body weight support of 25% (range 21–36%), and median guidance force of 78% (range 50–100%). No harmful event was observed in any of the sessions.

Differences in affective responses between physical therapy and robotic-assisted gait training

The changes in affective responses in PT and RAGT, indicated by the median difference between post- and pre-, are shown in Table II. No significant period or carryover effects were observed ($Z>-2.05$, $p>0.05$). When PT and RAGT were compared directly, significantly different changes in affective responses were detected in negative affect anger. Although there was no visible effect on the median values, none of the patients showed an increase in anger after RAGT, while 7 of the patients showed larger anger values after PT. In RAGT, the values were left skewed (i.e. a reduction in anger) and in PT the values were right skewed (i.e. an increase in anger), as indicated by interquartile range values. The following positive affective states showed significant differences in PT and RAGT: activation, elation, and calmness. Activation, elation, and calmness increased after RAGT and decreased after PT.

Pre–post changes within physical therapy/robotic-assisted gait training

In PT, no significant changes were observed. However, there was a non-significant decrease in activation, elation, and fatigue. In RAGT, elation and calmness increased significantly (Table II).

Table II. Median changes in affective responses in each treatment session

Affective response	Treatment session	Median (post–pre)[a]	IQR	Pre–post changes Z	*p*-value	*r*	Treatment session differences Z	*p*-value	*r*
Anger	Robotic-assisted gait training	0.0	−0.3–0.0	−1.84	0.066	−0.49			
	Physical therapy	0.0	0.0–0.4	−0.95	0.343	0.25	−2.39	0.017	−0.64*
Excitement	Robotic-assisted gait training	0.0	−0.4–0.0	−0.74	0.459	−0.20			
	Physical therapy	0.0	−0.1–0.7	−1.12	0.263	0.30	−1.22	0.223	−0.33
Activation	Robotic-assisted gait training	0.0	−0.3–0.5	−0.42	0.675	0.11			
	Physical therapy	−0.3	−1.1–0.1	−1.92	0.055	−0.51	−2.07	0.039	0.55*
Elation	Robotic-assisted gait training	0.3	0.0–1.7	−2.00	0.045	0.53*			
	Physical therapy	0.0	−0.3–0.0	−1.93	0.054	−0.52	−2.97	0.003	0.79**
Calmness	Robotic-assisted gait training	0.3	0.3–1.4	−2.99	0.003	0.80**			
	Physical therapy	−0.2	−0.7–0.4	−0.57	0.570	−0.15	−2.68	0.007	0.72**
Fatigue	Robotic-assisted gait training	0.0	−0.7–0.0	−1.23	0.202	−0.33			
	Physical therapy	0.0	−0.8–0.0	−1.41	0.157	−0.38	−0.12	0.905	0.03
Depression	Robotic-assisted gait training	0.0	0.0–0.0	−0.45	0.655	−0.12			
	Physical therapy	0.0	0.0–0.4	−1.11	0.268	0.30	−1.27	0.203	−0.34

*$0.01 \leq p<0.05$, **$p<0.01$. [a]Values of the affective responses were calculated as the sum of all item values per affective response divided by 3 (number of items per affective response). The pre-value was then subtracted from the post-value. Positive values represent increases (maximal possible value: 4), negative values represent decreases (minimal value −4), in the affective response. IQR: interquartile range.

DISCUSSION

Changes in affect

The aim of the current study was to analyse immediate affective responses following a single session of PT and RAGT.

The main result was that, after a single session of RAGT, the positive affective states activation, elation, and calmness were increased, and the negative affective state anger was decreased compared with after a single session of PT. The study measured affective responses theoretically based on exercise psychology models (25), and is assumed to have high ecological validity due to minimal changes in the daily activities of the patients. In addition, the use of a within-subject design, allowed inter-individual variability to be controlled for by using participants as their own controls. The detected effect sizes are even larger than the previously reported low- to middle-sized effects in healthy subjects (26, 27).

An increase in positive affective states during physical activity was shown to increase the probability of maintaining previous exercise behaviour (28). Positive affective responses to a specific behaviour may increase intrinsic motivation for maintenance, and adoption of this behaviour (29). Given the high rates of fatigue in neurological patients (8) and the high importance of motivation during treatment (12), it is necessary to find treatment approaches that increase patients' motivation.

The findings after PT, although non-significant, show tendencies to decreasing positive affective states and increasing negative affective states. This contradicts previous findings of higher energy levels after exercise in healthy people and several risk-groups (6, 8, 9).

Several reasons for various changes in affective states have been discussed previously. First, according to the dual-mode theory (30), affective responses are altered differently after exercise, depending on exercise intensity. In particular, a high training intensity might be accompanied by less positive affective states (31). Therefore, in the current study it is possible that the intensity was too high in PT. However, this explanation remains speculative, since physical exertion was not measured. Secondly, it is known, that individual preferences differ regarding the type of physical activity, and the surrounding environment including the therapists (32). In neurophysiological rehabilitation, in particular, therapists and patients need to establish a very close collaboration, which may have a significant influence on the affective response to physical activity. In addition, the type of physical exercise during RAGT (repetitive task of walking at moderate speed) might explain the calming and anger-reducing effect (25). In the present sample, the median anger did not differ between the 2 treatment sessions, but there was a difference in the spread of values. The Wilcoxon test not only tests median differences, but also takes into account the spread of values (33). Thirdly, satisfaction with one's own performance is known to be an influencing factor on affective responses (17). After a neurological incident, the subject's own performance is reduced abruptly to a very low level, which causes difficulties for the subject recognizing small improvements and staying motivated considering the status of their former performance. This may also partly explain the elation-enhancing effect of RAGT in contrast to PT, because it can be assumed that the subject's own performance is rated higher during RAGT due to the illusion of unassisted walking. In RAGT, the device-guided facilitation of the legs might be considered elation-enhancing. In contrast, during PT patients are repeatedly confronted with their personal limits due to maximal efforts, which might decrease elation. Fourthly, the initial situation of affective states can cause a ceiling effect (8). This refers especially to the state of fatigue, which it is important to reduce during hospital treatment (5). In the present study, the mean difference in fatigue, despite showing an improvement, did not reach a significant level, as patients did not report themselves as fatigued/depressed before the treatment session.

From a clinical point of view, a combination of both treatments seems to be desirable (34). In the continuum of rehabilitation, it is important to work specifically on the patients' weaknesses during PT and therefore to confront patients with their own limitations (35). However, the enhancing effect on positive affective responses due to RAGT could help overcome motivational problems during the rehabilitation process. This might contribute to improvements in functional outcomes, as previous studies emphasize the importance of the combination of PT and RAGT (e.g. 34).

Study limitations

The following limitations must be considered when interpreting the findings of this study. First, the sample size was fairly small. The effect sizes observed suggest that only a small sample size was needed; however, further study is required to confirm the observation in a larger sample size. Secondly, the sample was inhomogeneous. The neurological pathologies, the duration between the therapy sessions and the incident, and the sex distribution were not standardized. Although all patients were inpatients and therefore shared the danger of fatigue due to hospitalization (5), it cannot be ruled out that different neurological incidents in different rehabilitation phases have different effects on affective responses. Although there is no evidence that sex has a mediating effect on affective responses in healthy persons (36), affective responses might differ between male and female patients. Future studies should therefore consider using a homogenous sample. Thirdly, since we were interested mainly in differences between PT and RAGT, we did not include a control condition. A control condition would have enabled all external effects on affective responses (e.g. due to time or physical inactivity) to be determined. Fourthly, no measurement was made of perceived exertion or training intensity during the treatment session. As stated in previous studies, affective responses after exercise are different due to the intensity during exercise (31). Future studies should therefore consider the measurement of heart rate or a self-reported rating of physical exertion.

In conclusion, this study is a first approach to examining the immediate psychological effects of different exercise-related treatments in neurological patients. RAGT showed significantly increased elation and calmness after the treatment session. The affective responses between physical therapy and RAGT differed significantly in favour of RAGT in positive and negative affective states. If the results of this study can be replicated, patients' motivation, maintenance, and adoption might be positively influenced by RAGT. Further research should include a control condition, a homogeneous patient sample, and measurement of treatment intensity.

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Conflict of interests: AM has been part of the Scientific Advisory Board of Hocoma AG since 2010. The other authors declare that they have no competing interests to report.

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