NeuroBall™
Clinical Evidence Summary

1 Introduction

NeuroBall™ is an innovative, all-in-one upper extremity, digital therapy device with applications ranging from clinic to home. Designed with the input of over 300 therapists and stroke survivors, NeuroBall enables patients to perform increasingly challenging exercises and activities, with supervision and on their own. Easy to use and engaging tablet-based software encourages intense, high dose repetition in a wide range of patients. The "smart" NeuroBall software learns and adapts to the patient's ability, allowing them to advance their therapeutic goals.

Numerous studies have demonstrated the benefits of high dose, high intensity therapy in improving upper extremity functional outcomes and quality of life in stroke survivors[1,2,3]. However, conventional arm therapy sessions typically have low levels of opportunity for intensity and repetition. NeuroBall offers independent, highly repetitive movements in the same therapy time, which leads to improved outcomes.

NeuroBall has been studied in two clinical trials that validated its a) usability and acceptability by stroke survivors in a clinical setting and b) feasibility, safety and independent home use over 7 weeks. The methods and results of these trials are described in this paper.

NeuroBall with its associated tablet and software are easy to use and suitable for a wide range of patient severity.

2 In-Clinic Usability Study[4]

Method

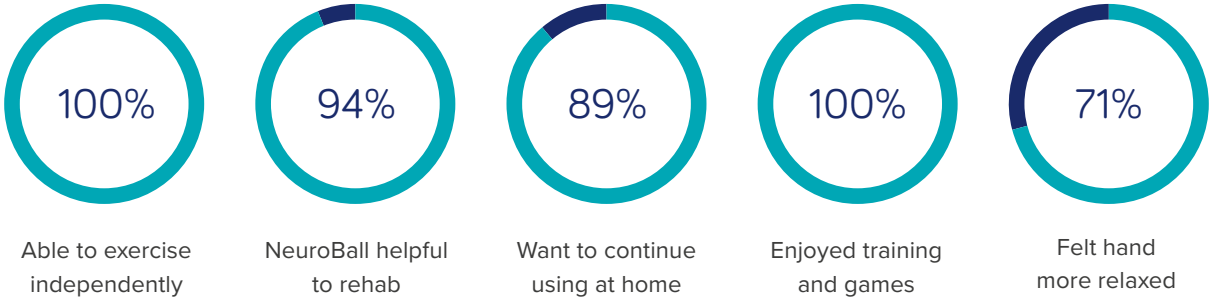
18 stroke survivors performed therapist-supervised upper extremity activities using NeuroBall for one hour at Brunel University London (UK). Patients were then asked to respond to a series of questions about their experience. This study included patients from a very wide range of age, time post-stroke and upper limb impairment:

AGE RANGE:
39 to 74
TIME POST-STROKE:
2 – 28 years
UPPER LIMB IMPAIRMENT:
Mild to severe (FMA-UE scores 9 to 59 out of 60)

“ [NeuroBall] stimulates you to use the affected wrist and fingers more. Not just squeezing a ball which is boring and doesn’t give you results. With NeuroBall you can see what is happening. Feedback on movement is immediate and this encourages you to train even more. – Usability Study Participant

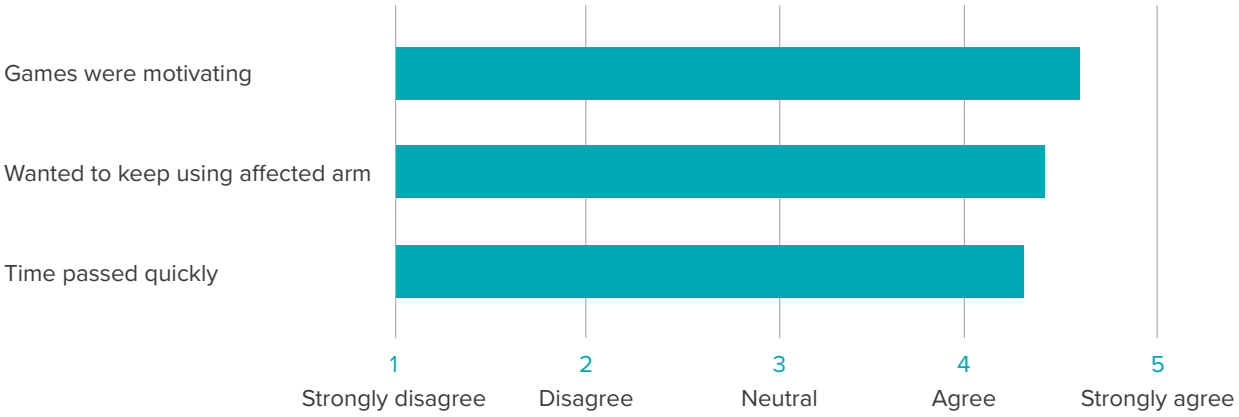
Results

Patients overwhelmingly reported positive feedback. All were able to exercise independently and enjoyed the training and game activities.



Participants were also asked to rate their agreement with a series of statements about their experience with NeuroBall.

Fig. 1: Average patient acceptance of NeuroBall



3 At-Home Feasibility Study: RHOMBUS I[5]

Method

After completion of the Usability Study, extensive user feedback collected during the study was used to improve the NeuroBall device and software. The improved design was then used in a larger Feasibility trial to evaluate acceptability, safety and clinical outcomes based on at-home use. In the RHOMBUS I (Rehabilitation via HOMe Based gaming exercise for Upper limb post-Stroke) study, after a brief at-home training session, 30 community dwelling stroke survivors were each provided a device and a tablet with activity software to use at home for 7 weeks.

This independent non-sponsored study was conducted by Brunel University of London [UK] and led by Dr. Cherry Kilbride, a leading specialist in upper extremity rehabilitation after stroke.

This study also included patients from a very wide range of age, time post-stroke and upper limb impairment:

AGE RANGE:
36-85 years
TIME POST-STROKE:
1 – 28 years
UPPER LIMB IMPAIRMENT:
Mild to severe (FMA-UE scores 8 to 63 out of 66)

Qualitative and quantitative assessment tools were used to evaluate patient acceptance, satisfaction and quality of life, as well as time spent training, number of movement repetitions, improvements in range of motion and functional outcomes such as participants' ability to perform simple daily tasks. Assessments were performed at baseline and at 8 weeks (immediately post-intervention) and 12 weeks (4 weeks after the intervention ended).

Feasibility study participant training at home with earlier version of NeuroBall.

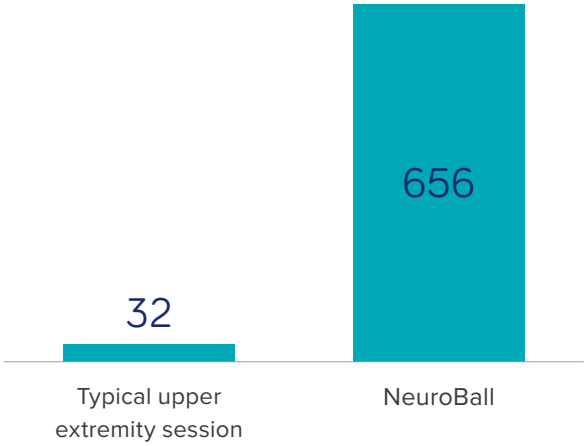
Results

High Dose and Intensity

Participants performed high dose, high intensity activities throughout the 7 week study period, training an average of nearly 3 hours per week, or over 23 minutes per day. The top 10 participants averaged over 4 ½ hours per week or 40 minutes per day. Engagement was very high; participants trained on average 4 days a week, with the top 10 participants training 6 days a week.

The average number of daily repetitions in the study was over 20 times that seen in a typical upper extremity session [Fig. 2][6]. Studies have consistently shown that the number of movement repetitions is highly correlated with improvement in functional tasks[1,2,3].

Fig. 2: Average number of repetitions per day



Arm Impairment Improvements

Statistically significant improvements were seen in:

– Fugl-Meyer Assessment for Upper Extremity (FMA-UE) scores. Participants benefited from a statistically significant reduction in their upper limb impairment. FMA-UE is the gold standard used in most clinical trials. This improvement is in line with randomized controlled trials which evaluated the importance of high dose, high intensity therapy in upper limb recovery.

– Range of motion in finger extension, wrist extension, and shoulder external rotation [Fig. 3], with approximately 60% of participants having improved their range of motion due to NeuroBall training.

Arm Function Improvements

Statistically significant improvements in functional activities were measured using the Motor Activity Log (MAL). Participants reported that the quality and amount of movement improved and they were using their affected arm and hand more in a wide range of Activities of Daily Living (ADLs), including:

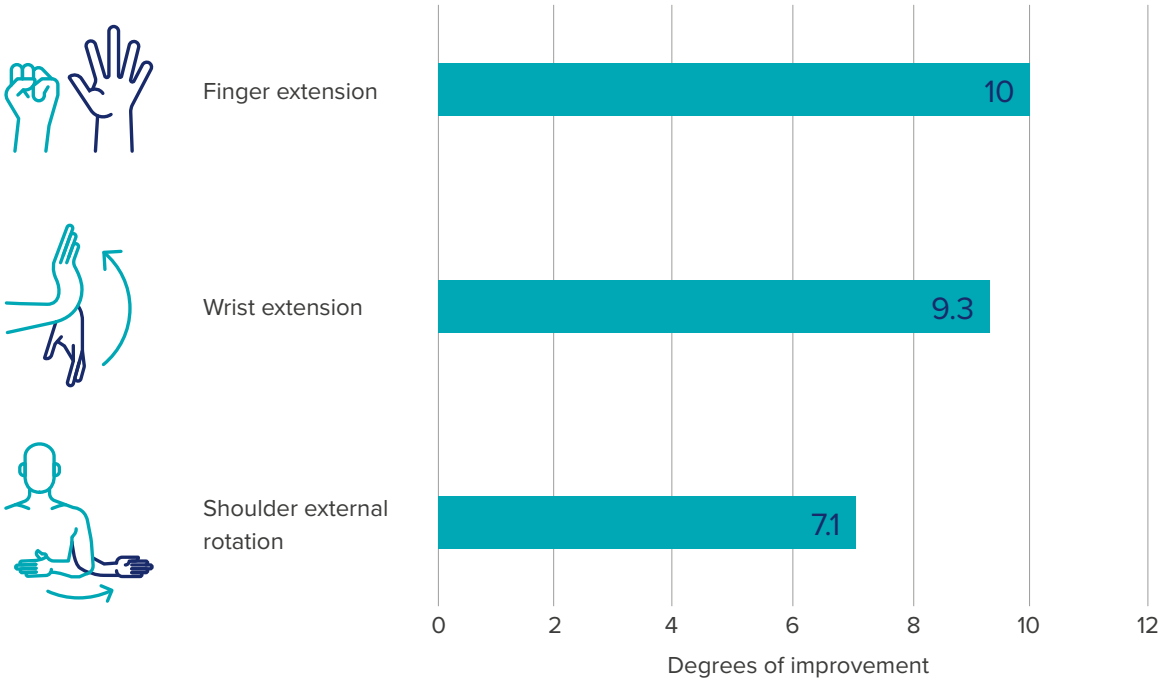
Using a knife and fork,

Buttoning a shirt,

Washing pots and pans.

“ It has helped using a knife and fork. There is a change. I feel that I can move my fingers more easily now [after using NeuroBall].
– RHOMBUS I Study Participant

Fig. 3: Range of motion improvements



Reduction in Shoulder Pain

Importantly, after the 7 week intervention, the probability of shoulder pain (assessed using a standard VAS pain score) declined by nearly 50% compared to baseline. One month after completing the study, the majority of patients maintained improvements in range of motion, as well as the reduction in shoulder pain.

High Patient Acceptance and Satisfaction

Throughout the study, NeuroBall provided high dose, high intensity therapy and patients reported high overall satisfaction with all aspects of NeuroBall.

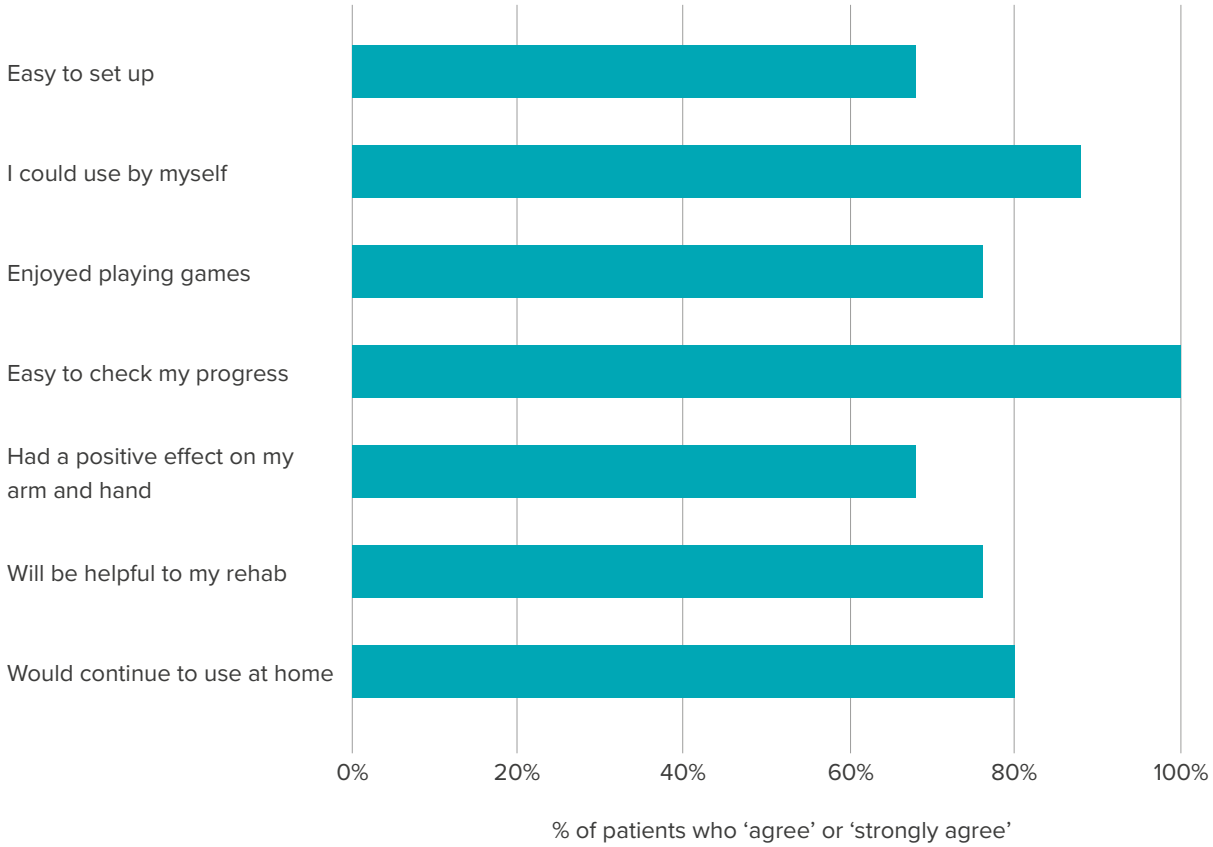
– Participants were satisfied with NeuroBall’s size, weight, ease of use, safety, durability, comfort and effectiveness. Satisfaction with these product attributes was reflected in the high Quebec User Evaluation of Satisfaction with Assistance Technology (QUEST) scores: 36 out of a possible 40.

– After the first training session with a therapist, participants felt confident in using NeuroBall independently (average score was 8 out 10 on a scale of 1-10).

– 88% reported they were overall “satisfied” or “very satisfied.” No participants reported being “dissatisfied.” 3 patients withdrew from the study due to challenges in using NeuroBall at home. These patients were either severely impaired, lacked motivation or required additional support to enable them to successfully use NeuroBall. Improvements were made to NeuroBall to address this feedback.

Patients were also asked to rate their agreement with a series of statements on a scale of 1 to 5: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, and 5 = strongly agree. The majority of patients found that NeuroBall was easy to use and allowed them to track their progress. They also enjoyed their rehab activities and wanted to continue using NeuroBall. Fig. 4 shows the percentage of patients who responded “agree” or “strongly agree” to each statement.

Fig. 4: Post Intervention Questionnaire about NeuroBall



Social Participation Improvements

Statistically significant improvements were seen in Subjective Index of Physical and Social Outcomes (SIPSO) scores. Participants reported improvements in their ability to reintegrate into a normal lifestyle, including in the number and quality of their activities and social interactions. SIPSO measures improvements in participants' ability to dress themselves, move around in their home and neighborhood, talk with friends, perform activities of daily living, carry the shopping bag and feel better about their appearance in public. Improvements in SIPSO scores were maintained 4 weeks after the study was completed.

Summary

A significant finding of this study demonstrated that by using NeuroBall, patients were able to do more frequent and more intense upper limb activities, but without an increase in fatigue, spasticity or pain.

4 Safety

There were no serious adverse events related to the intervention reported in either trial. Adverse events reported in the At-Home Feasibility Study (RHOMBUS I) were infrequent, mild and transient. These included muscle fatigue or soreness, which were expected from actively engaging in upper limb activities.

5 Conclusion

Two studies have shown that NeuroBall appears to be a safe and effective intervention for upper extremity rehabilitation. High patient satisfaction led to high motivation and engagement, resulting in high intensity, high dose therapy without an increase in fatigue, spasticity or pain.

The At-Home Feasibility Study (RHOMBUS I) demonstrated that after a brief training session, patients were successfully able to use NeuroBall on their own, at home, making NeuroBall an exceptionally efficient therapeutic option, freeing therapist time for other responsibilities or patients. With approximately 2 hours of therapist time for training and occasional check-ins, patients were able to use NeuroBall independently for 7 weeks, training on average 19 hours and performing over 18,000 repetitions, representing almost a 10 times return on investment of therapist time.

Study outcomes such as the high number of daily repetitions and improvements in range of motion further demonstrated NeuroBall's effectiveness and usefulness in upper extremity rehabilitation, and most importantly, in patients' improved abilities to perform activities of daily living, self-confidence and social participation.

6 Next steps

These two independent studies were designed and conducted by a leading stroke rehabilitation institution under rigorous research guidelines. They demonstrated exceptional patient acceptance, improvements in functional outcomes, and high efficiency in therapist time. Additional larger, randomized controlled trials are underway. Neurofenix is committed to ongoing clinical research and continued product innovation to help improve the lives of patients suffering from stroke and other neurological conditions.

To learn more about how NeuroBall can help improve the lives of your patients

Call: (800) 945-8132 Email: usa@neurofenix.com

www.neurofenix.com

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References:

1. Ward et al. Intensive upper limb neurorehabilitation in chronic stroke: outcomes from the Queen Square programme. Journal of Neurology, Neurosurgery & Psychiatry 90.5 (2019): 498-506.
2. McCabe et al. Comparison of robotics, functional electrical stimulation, and motor learning methods for treatment of persistent upper extremity dysfunction after stroke: a randomized controlled trial. Archives of physical medicine and rehabilitation 96.6 (2015): 981-990.
3. Han et al. Effects of intensity of arm training on hemiplegic upper extremity motor recovery in stroke patients: a randomized controlled trial. Clinical rehabilitation 27.1 (2013): 75-81.
4. Kilbride, et al. Usability, safety, and user experience of the novel Neurofenix gaming platform for upper-limb rehabilitation after stroke: a cross-sectional evaluation. Manuscript under review.
5. Kilbride, et al. Rehabilitation via HOMe Based gaming exercise for the Upper-limb post Stroke (RHOMBUS): an intervention feasibility trial. Manuscript under review.
6. Lang et al. Observation of amounts of movement practice provided during stroke rehabilitation. Archives of physical medicine and rehabilitation 90.10 (2009): 1692-1698.