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Integrative Upper-Limb Rehabilitation with *BrightArm Duo*™ in the Early Sub-Acute Phase of Recovery Post-Stroke

Gregory House*,‡, Grigore Burdea*, Namrata Grampurohit*, Kevin Polistico*, Doru Roll*, Frank Damiani†

*Bright Cloud International Corp, 29 L'Ambiance Court, Highland Park, NJ 08904, USA

†Roosevelt Care Center, 118 Parsonage Road, Edison, NJ 08837, USA

The *Bright Arm Duo* is a low-friction robotic rehabilitation table that adaptably trains dual arm movement and grasp through interaction with serious games. In early sub-acute phase post-stroke, $N = 3$ experimental group received conventional rehabilitation plus 12 *BrightArm Duo* sessions, each inducing up to 600 arm and hand repetitions. $N = 9$ control group received conventional rehabilitation only. Improvement for the experimental group was better than controls across 11 of 12 functional metrics and activities of daily living ($p = 0.006$).

Keywords: Sub-acute stroke; virtual rehabilitation; robotic table; occupational therapy.

1. Introduction

Stroke is the foremost cause of adult disability in United States [1]. The individuals who survive a stroke commonly experience a loss of upper limb function resulting in substantial problems with activities of daily living [2]. The functional use of upper limbs is very difficult to retrain in rehabilitation [3]. Traditional retraining approaches have not been proven effective for upper limb recovery [4].

Most of the functional recovery of the upper limb occurs in the first 6–11 weeks after a stroke, and only some recovery continues beyond this time span [5]. Thus, rehabilitation efforts should be intensified in the early recovery phase, so as to maximize upper extremity functional gains. Research has shown that early intervention in the initial phase of stroke recovery can be enhanced by high intensity task-specific training [6–8]. Robotic devices offer an opportunity for such high intensity training of the upper limb [9].

In a systematic review by Prange and colleagues (2006), robotic devices were reported to improve short and long-term motor control of the upper limb more than conventional or standard of care therapy in sub-acute and chronic phase of rehabilitation [10]. However, more recently, the benefit of robotic training over usual therapy and intensive 12-week therapy not involving robotics, has been questioned by Lo and colleagues (2010) [11]. Furthermore, improvement in functional ability has not been established with robot-assisted rehabilitation [9]. To further enhance robotic rehabilitation, these authors believe that it should be coupled with virtual reality (VR). A robotic+VR training should make training fun and engaging for the patient [12]. A case study did in fact have encouraging results when robotics and VR were combined in sub-acute phase of stroke rehabilitation [13]. This combined effect needs to be studied in a larger sample.

Long-term outcome of upper limb function is tied to developing both upper and lower arm function for reaching and grasping movements, and training bimanual

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Email Address: ‡*gregoryphouse@gmail.com*

function [14]. Thus, BrightArm Duo was developed for training arm and hand (grip) movements bimanually. *BrightArm Duo* is a novel integrative rehabilitation system developed by Bright Cloud International Corp (BCI) with funding from the National Institutes of Health [15, 16]. It has shown promising results in an enhanced maintenance training program for elderly chronic post-stroke residing at skilled nursing facilities (SNF) [17, 18]. The BrightArm Duo VR interface makes it different from other robotic devices such as MIT-Manus [19] that provides a two-dimensional uni-manual interface and Bi-Manu-Track [20] that has no visual interactive display and provides bimanual training. The grip training feature of BrightArm Duo makes it unique in its use compared to robotic devices like NeReBot [21] that have been studied in sub-acute phase of rehabilitation.

The authors believe that adding BrightArm Duo therapy to standard of care in the early sub-acute phase post-stroke will enhance the recovery for a large cohort of stroke survivors. Therefore, the purpose of this pilot study was to investigate the feasibility of the *BrightArm Duo* enhanced rehabilitation for subjects in the *early* sub-acute phase post-stroke.

2. Materials and Methods

2.1. *BrightArm duo rehabilitation system*

The *BrightArm Duo* rehabilitation system (Fig. 1) integrated cognitive and physical rehabilitation through custom designed 3D games. The game avatars were controlled by uni-manual or bimanual arm controllers. The controllers provided a unique range of supported motion and grasp capability for a combination of proximal and distal upper limb.

The robotic rehabilitation table offered the capabilility of modulating gravity loading on the affected arm. It had two actuators to lift or lower the tabletop from 26" to 34", enabling the height to be adjusted so the work surface comfortably supported the forearms of the subject [16]. Two additional linear actuators adjusted the table tilt from 15° below horizontal to 20° above horizontal, enabling modulation of gravity assistance/resistance during training. Tilting upwards provided resistance for stronger arms when moving away from the trunk. Tilting downwards assisted the movement of weaker arms.

The occupational therapist (OT) adjusted the table height and tilt through a retractable HP ENVY 17" laptop (on right in Fig. 1(a)). Subject's forearms were placed onto low-friction supports outfitted with two 770 nm LED towers and a rubber pear bulb. Subjects' grasp of the rubber pear was measured by an internal differential pressure sensor readings communicated wirelessly to the laptop station at a rate better than 40 Hz. The laptop tracked arm support positons to 0.5 mm accuracy using two overhead cameras with 760 nm high-pass filters which imaged that LED towers (Fig. 1(a)). Subjects interacted with 3D virtual reality simulations through arm movements across the table surface and hand grasps. Rehabilitation games were rendered by the laptop's mid-range GeForce GT 750M graphics card and the output was displayed on a 27" monitor.

The *BrightArm Duo* system included a library of 11 custom games written in Unity 3D [22]. Of these, six

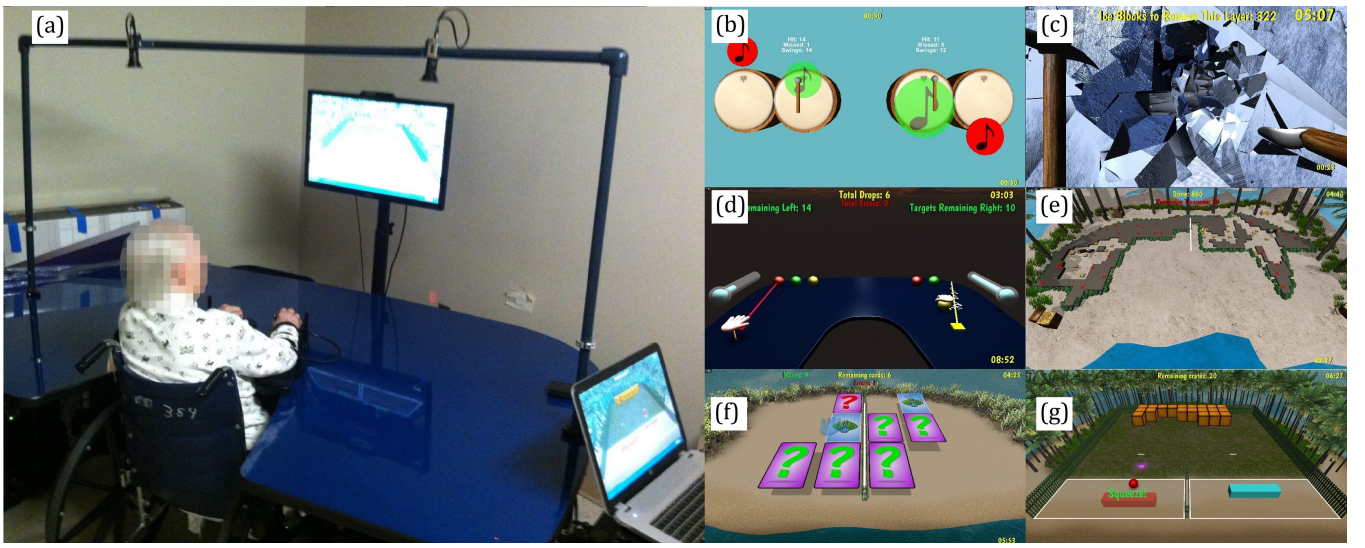

Fig. 1. (a) *BrightArm Duo* rehabilitation system with a subject sub-acute post-stroke training using both arms and screen shots of the games in the protocol: (b) *Musical Drums,* (c) *Avalanche,* (d) *Pick-and-Place,* (e) *reasure Hunt*, (f) *Card Island*, and (g) *Breakout 3D*. © Bright Cloud International Corp. Reprinted by permission.

were used in the study and are shown in Fig. 1(b). The game *Musical Drums* involved subject striking a series of notes that drifted across (up to) four drums. To do so, the subject used mallet (drum stick) avatars controlled by hand grasps and arm movements. This was a *BrightArm Duo* adaptation of a game originally created for the more compact *BrightBrainer* rehabilitation system [23, 24]. For the game *Avalanche,* subjects used grasps and arm movements to control a pick axe and a shovel avatars. These were used to clear a series of ice walls to free skiers trapped in a lodge by an avalanche.

In *Treasure Hunt*, subjects controlled one or two shovel avatars to clear sand and uncovered a number of buried treasures. They had to do so before the periodic occurrence of sand storms which would burry some treasures again. *Breakout 3D* involved the use of one or two paddle avatars to bounce a virtual ball towards an array of crates. Moreover, this game included left–right and in–out versions to encourage arm movement primarily in abduction/adduction or in shoulder flexion/extension directions, respectively. Subjects manipulated the left and right paddle avatars through movement of their left and right arms/hands. At higher level of difficulty, subjects had to remember to squeeze the rubber pear, lest the ball passed through the paddle avatar and was lost.

Card Island challenged the subject's short-term visual and spatial memory in a 3D scene of a tropical island. Subjects used left and right hand avatars to flip cards in order to find matches. For *Pick & Place*, the subject grasped and moved virtual balls to a fixed target of matching color. *Pick & Place* included left–right and in–out versions to encourage arm movement in both directions. A barrier in the middle of the scene prevented hand avatars from crossing it, insuring both hands were used to clear the board in *Pick & Place*and *Card Island* games.

A key advantage of *BrightArm Duo* simulations over off-the-shelf games was the capability to adapt to the physical limitation of the subject each day. A baseline of supported arm reach and grasp strength was measured at the beginning of each rehabilitation session. Subjects traced the largest circles that can be comforably reached with either arm. The extent of the arm positioning was then used to map the individual physical arm movement on the table to the virtual movement of the corresponding avatar in the rehabilitation games.

The grasp strength baseline involved measuring the maximum grasp using the rubber pear on the arm support. Thresholds for momentary and sustained grasp during games were set at 25% and 10% of the maximum grasp values, respectively. These thresholds were consistent with prior studies comparing maximum and sustained grasp [25], and had been used in the past with post-stroke subjects to avoid discomfort [26].

The *BrightArm Duo* stored transparently de-identified game performance into an Oracle MySQL database on the laptop. The data was backed up via a wireless Internet connection to a remote HP C300 clinical server for further analysis. Custom reporting software produced session reports that summarized the data captured for the current session and compared the data to a previous session. The reporting software also generated progress summaries that tracked the experimental subject's performance over the course of the pilot study.

The *BrightArm Duo* rehabilitation system was installed at the Roosevelt Care Center (RCC), a SNF located in Edison, NJ.

2.2. *Controlled study subjects*

Four experimental subjects were enrolled into the current pilot study, one dropped (due to early discharge from the SNF) and $N = 3$ largely completed the protocol in a minimum of 25 days. The inclusion criteria were less than 6 months since first-ever stroke, some minimal movement in both arms (not flaccidity), 30 years of age or older, and admitted as an inpatient undergoing subacute rehabilitation at RCC. Basic mental awareness and speaking English were required to understand the consent form and the exercise simulations.

A de-identified search of medical records within the 2013–2015 time span was conducted at RCC. It was determined that there were $N = 9$ inpatients in the subacute phase of recovery who met inclusion criteria and received conventional therapy over at least a 25-day period. The aggregate statistics of the $N = 9$ inpatients served as the retrospective control group for this study, and are shown in Table 1. As seen, the control group is three times the size of the experimental group. This is consistent with prior literature [27] indicating the power of a study improves by increasing the control group's size up to 4 times that of the experimental group if the experimental group is small.

The experimental group ($N = 3$) averaged 31.3 days (Standard Deviation [SD] 22.7) post-stroke and 76 years (SD 8.0) of age. The subjects received conventional therapy that included occupational therapy for upper limb rehabilitation. This was done daily (except Sundays) up to a maximum of 2 hours/day, over an average period of 37.3 days (SD 20.2). The experimental subjects received additional *BrightArm Duo* training for 12 sessions (3×4 weeks).

The control group ($N = 9$) were previous inpatients of the same facility, averaging 74.6 years of age (SD 12.3) and 18.0 days (SD 7.4) post-stroke at admission. The subjects from this group received only conventional therapy that included upper limb rehabilitation over an average period of 34.0 days (SD 15.4).

Table 1. Subjects characteristics for sub-acute stroke control group and experimental group. © Bright Cloud International Corp. Reprinted by permission.

Variable	Control group ($N = 9$)	Experimental group ($N = 3$)
Gender	6 Male, 3 Female	2 Male, 1 Female
Race	7 Caucasian, 1 Hispanic, 1 African Am.	3 Caucasian
Years of age	74.6 (D 12.3)	76 (SD 8.0)
Days post stroke at admission	18.0 (D 7.4)	31.3 (SD 22.7)
Conventional therapy period in days	34.0 (D 15.4)	37.3 (SD 12.1)
Affected side	5 Left, 4 Right	2 Left, 1 Right

2.3. *Study design*

The training of experimental subjects using the *BrightArm Duo* system was supervised by an OT who set the optimal height and tilt of the *BrightArm Duo* tabletop for each subject. Blood pressure, pulse and blood oxygen levels were measured and recorded at the beginning and the end of each session. The OT stretched the experimental subject's affected arm and fingers and assisted if needed in arm movements during game play. The subject's arms were carefully positioned on the forearm support to maximize comfort. The initial subject's preparation was followed by baseline measurements of reach and grasp strength of the arm(s) being trained in that session.

The progression of games in the 4-week experimental protocol is shown in Table 2. The duration of actual game play in each session increased weekly: 15 min (Week 1), 20 min (Week 2), 25 min (Week 3) and 30 min (Week 4). Training frequency was set at 3 sessions/week with preferably alternating rest days. Exercise difficulty also increased during the four weeks of therapy by progressively changing the game settings from frequent cognitive cues with minimal grasp requirements to no cognitive cues, faster pace of play and more extensive use of grasp.

Training started in uni-manual mode that only involved gameplay with the affected arm. Bimanual training was expected to begin on session 7. The protocol specified the table to be kept horizontal for at least the first two weeks as subjects were expected to have little gravity bearing capability, and to increase to 5° tilt during weeks 3 and 4. The actual timing of the tilt change

Table 2. Four-week game protocol for training subjects in the early sub-acute phase post-stroke. © Bright Cloud International Corp. Reprinted by permission.

Week 1 15 min 0° tilt Uni-manual	Week 2 20 min 0° tilt Uni-manual	Week 3 25 min 5° tilt Bimanual	Week 4 30 min 5° tilt Bimanual
BASELINE (affected arm)	BASELINE (affected arm)	BASELINE (both arms)	BASELINE (both arms)
PICK & PLACE left/right Text cue	PICK & PLACE left/right Text cue	PICK & PLACE left/right No cue	PICK & PLACE left/right No cue
	MUSICAL DRUMS 1 drum	MUSICAL DRUMS 2 drums	MUSICAL DRUMS 4 drums
BREAKOUT 3D left/right Speed 7, No grasp	BREAKOUT 3D left/right Speed 7, No grasp	BREAKOUT 3D left/right Speed 8, Grasp	BREAKOUT 3D left/right Speed 9, Grasp
		AVALANCHE	AVALANCHE
CARD ISLAND 2 pairs	CARD ISLAND 4 pairs	CARD ISLAND 6 pairs	CARD ISLAND 8 pairs
2 MIN BREAK	2 MIN BREAK	2 MIN BREAK	2 MIN BREAK
PICK & PLACE in/out Text cue	PICK & PLACE in/out Text cue	PICK & PLACE in/out No cue	PICK & PLACE in/out No cue
BREAKOUT 3D in/out Speed 7, No grasp	BREAKOUT 3D in/out Speed 7, No grasp	BREAKOUT 3D in/out Speed 8, Grasp	BREAKOUT 3D in/out Speed 9, Grasp
TREASURE HUNT Cues, No Storms	TREASURE HUNT No Cues, 1 Storm	TREASURE HUNT No Cues, 1 Storm	TREASURE HUNT No Cues, 2 Storms
			MUSICAL DRUMS 4 drums

was at the discretion of the OT and depended on how the subject progressed during the first two weeks of training.

The *BrightArm Duo* sessions were set to involve playing four to six custom games in a fixed order, and with a short rest period in-between. The sequence of games was to be repeated until the predefined total exercise time was reached for that session. The decision to increase the number of executed games from 4 to 5 (week 2) and from 5 to 6 (week 3) was made in order to keep the subjects interested. The game difficulty was also to be progressed over the four weeks of training. For example, in the *Card Island* (BCI short-term memory game), the number of card pairs was to increase from 2 in week 1 to four pairs (week 2), six pairs (week 3) and finally eight pairs in week 4. More details on the game number and difficulty progression are specified in the protocol shown in Table 2.

2.4. *Data collection instruments*

The *BrightArm Duo* system automatically captured a wide range of metrics during each training session. Three measures that have been used to track improvements of the experimental subjects included the arm reach and grasp baselines, arm movement repetitions and hand grasp repetitions. The area of arm reach measured by the baselines provided insight into change in the range of motion for the experimental group over the 4-week protocol. The arm repetitions tracked physical arm activity each session by counting the number of times that each arm was moved a distance corresponding to the arm reach baseline. Finally, hand grasp repetitions tracked hand activity each session by totaling the number of times the grasp threshold was exceeded.

The three experimental subjects were also evaluated pre- and post-therapy for strength of grip and pinch (three jaw chuck with the thumb, index and middle fingers; and tip-to-tip pinch with the thumb and index fingertips). These were measured for both hands using a Jamar dynamometer and a pinch meter, respectively. Jamar dynamometers and pinch meters are commonly used instruments for grip and pinch strength evaluation [28]. The subjects completed the Upper Extremity Functional Index (UEFI-20) Questionnaire at the start and end of the therapy. UEFI-20 is a standardized questionnaire with excellent reliability and validity [29].

Functional metrics and ADL's were extracted from OT reports tracking therapy of the experimental and control groups. Therapists in sub-acute setting commonly rate the patient performance into categories of "Poor," "Fair," and "Good," similar to the muscle testing scale [30]. These ratings reported in therapy documentation were converted to a 6-point scale (0: Unable to do, 1: Trace, 2: Poor, 3: Fair, 4: Good, 5: Normal) to be consistent with upper extremity (UE) strength measures. The functional metrics were strength of the upper limb, static sitting balance, dynamic sitting balance, and static standing balance. Standing was reported in minutes.

Table 3. Conversion of OT ADL assistance rating to a 7-point scale based on FIM. © Bright Cloud International Corp. Reprinted by permission.

Scale	OT ADL Assistance rating
7.0	Independent
6.0	Modified Independent
5.0	Stand by Assist or Minimum Cognitive Assist
4.0	Minimum Assist
3.5	Minimum to Moderate Assist
3.0	Moderate Assist
2.5	Moderate to Maximum Assist
2.0	Maximum Assist (1 × person) or Moderate Assist (2 × persons)
1.0	Dependent
0.0	Activity did not Occur

The therapy documentation reported activities of daily living (ADL) difficulty in terms of assistance needed by the individual with the Functional Independence Measure™ (FIM) scale as the basis [31]. FIM has excellent reliability and validity reported in the literature and is the most commonly used measure in sub-acute and inpatient rehabiliation facilities. Table 3 illustrates the conversion of OT ADL assistance ratings to a 7-point scale based on FIM. This modified FIM rating has intermediate levels of 2.5 and 3.5, identified by the therapists at RCC to reflect intermediate level of assistance to create a more sensitive measure of ADL assistance.

BrightArm Duo technology acceptance by the experimental group was sampled using a subjective evaluation questionnaire. The custom questionnaire consisted of 10 questions, with answers rated on a 5-point Likert scale. Aresponse of 1 was the least desirable outcome and 5 was the most desirable outcome. The 10 questions were "1. The instructions given to me were useful," "2. The system was easy to use," "3. The games were interesting," "4. I had no muscle pain or discomfort," "5. I was fatigued by the end of the therapy," "6. I was not bored while exercising," "7. The length of exercising in a day was appropriate," "8. There were few technical problems," "9. I would encourage other patients to use it," and "10. I liked the system overall." Subjects had to fill the evaluation form once, at the end of the 4 weeks of experimental training.

2.5. *Statistical analysis*

Pre- and Post-therapy comparisons of continuous variables were implemented using paired t-tests. However, the $N = 3$ sample size for the experimental group was not sufficient to generate statistically significantly results

($p < 0.05$) for individual metrics. When available, improvements in individual metrics were benchmarked against the Minimal Clinically Important Difference (MCID) for that measure.

The results for multiple measures were analyzed together to make comparisons between the control and experimental groups. Functional metrics and ADL's were grouped and observations were made of how many variable improvements for one group exceeded the other. A binomial sign test was then used to evaluate the hypothesis that there was no difference between improvements in the experimental group versus improvements of the control group.

All experimental subjects signed an approved written informed consent. Western Institutional Review Board (Independent review board overseeing research involving human subjects) reviewed and approved the protocol for this study in accordance with Federal Guidelines.

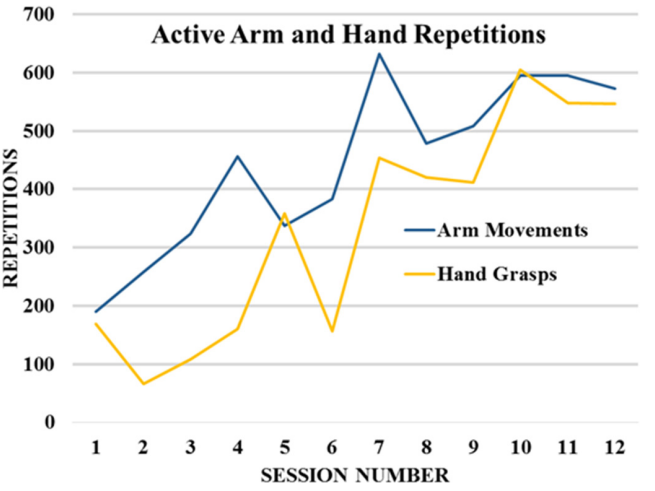

Fig. 2. Mean active arm and hand repetitions by session number for the experimental group of $N = 3$ subjects sub-acute post-stroke. © Bright Cloud International Corp. Reprinted by permission.

3. Results

3.1. *Bimanual training and table tilt deviation from protocol*

There were deviations from the protocol shown in Table 2, so as to accommodate individual subject's functional level. Bimanual training was started in session 6 for subject 1, session 3 for subject 2 and session 7 for subject 3. The supervising therapist's judgement of subject's readiness contributed to the earlier start of bimanual training than originally planned. For example, the therapist determined that subject 2 had bilateral upper limb weakness and would derive most benefit from early start of bimanual training.

Introduction of table tilt for adding resistance against gravity also varied for the three subjects and was at the discretion of the supervising therapist. Subject 1 trained on the table kept horizontal for 10 sessions and at 10-degree upwards tilt the last two sessions. Subject 2 trained with the table at 0 degree tilt for six sessions, 5-degrees tilt for four sessions and 10 degree upwards tilt in the last two sessions. Subject 3 trained with a horizontal table throughout all sessions. Thus, the *BrightArm Duo* rehabilitation system was adapted to the subject's needs for the optimal amount of challenge.

3.2. *Experimental group arm repetitions & baselines*

The *BrightArm Duo* system automatically captured physical metrics that tracked the intensity of the exercising of the experimental group. Figure 2 shows the total number of active arm reach and hand grasp repetitions by session number. The arm repetitions started at about 200 in session 1 and increased to an average about 600 total arm movements by session 12. The slope of the linear fit for arm repetitions was statistically significant ($p = 0.0002$).

The hand grasp repetitions started at 170 and generally increased with session number to almost 600 total grasps towards the end of the therapy protocol. The slope of the linear fit for the grasp repetitions was also statistically significant (p=0.00006).

The reach baselines for both arms were determined at the beginning of every session for all three experimental subjects. The size of the baselines captured reflect the range of motion for subject's arms in that session. The area of the affected arm baseline increased by 275% from an average minimum of 171 cm^2 (SD 99 cm^2) to an average maximum of 640 cm^2 (SD 768 cm^2). The area of the unaffected arm baseline increased by 535% from an average minimum of 164 cm^2 (SD 91 cm^2) to an average maximum of 1042 cm^2 (SD 779 cm^2). Although demonstrating notable gains in arm range of movement, neither the affected ($p = 0.39$) arms nor the unaffected ($p = 0.17$) arms had statistically significant increases in their reach baselines.

3.3. *Experimental group UEFI-20 & hand grip strength*

The experimental participants completed the UEFI-20 questionnaire before and after the *BrightArm Duo* therapy protocol. The UEFI-20 improved from 29.3 (SD 23.8) to 48.3 (SD 10.6), a 19 points difference (p=0.14). This is well above MCID of eight points [29].

Figure 3 displays the affected and unaffected hand grip, three jaw chuck and tip-to-tip pinch for the experimental group. The average values for the affected hand

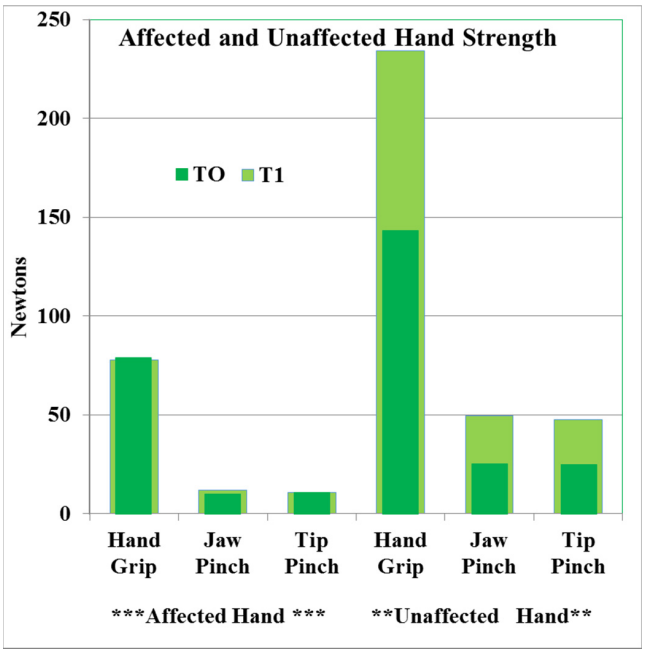

Fig. 3. Affected and unaffected hand grip, three jaw chuck and pinch strength of control and experimental group of participants early sub-acute post-stroke ($N = 3$) before (T0) and after (T1) therapy. © Bright Cloud International Corp. Reprinted by permission.

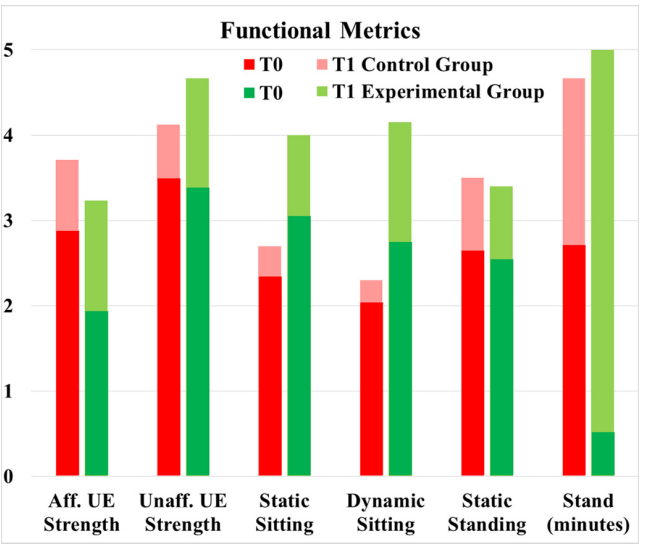

Fig. 4. Functional Metrics for control (red) and experimental (green) groups of sub-acute stroke participants (0–5 scale). Average values computed from participants with both T0 and T1 measurements. © Bright Cloud International Corp. Reprinted by permission.

largely remained the same for the hand grip (from 79 N to 78 N), three jaw chuck (from 10.4 N to 11.9 N) and tip-to-tip pinch (from 11.3 N to 10.7 N). For the unaffected hand, the average values for three jaw chuck and tip-to-tip pinch increased 24 N (from 26 N to 49 N) and 22 N (from 25 N to 47 N), respectively. The greatest improvement was in the average unaffected hand grip strength which increased 91 N from 143 N to 234 N, a difference which is above the MCID of 49 N [32]. The results were not statistically significant ($p > 0.05$) with the small ($N = 3$) sample size. However, the improvement in unaffected hand strength exceeded MCID for two of three subjects. Subject 1, pre-training had virtually no grasp ability and post-training had unaffected hand grip strength of 242 N.

3.4. *Functional group comparisons*

Figure 4 shows functional metrics for control and experimental groups of subjects early sub-acute post-stroke. Typically, T0 (pre) and T1 (post) occurred within one day of admission and discharge from the SNF, respectively. The functional metrics used a 0–5 point scale. The amount of improvement in five metrics was larger for the experimental group than the control group.

The arm strength improvements were much higher for the experimental group than for controls. For the experimental subjects, the affected and unaffected upper extremity (UE) strength increased 1.3 (from 1.9 to 3.2) and 1.4 (from 3.3 to 4.7) points, respectively. By comparison, the control group strength changes were more modest 0.9 (from 2.8 to 3.7) and 0.7 (from 3.4 to 4.1) points, respectively.

The sitting functional metrics were likewise better for the experimental group. For the control group, the static and dynamic sitting metrics improved 0.4 point (from 2.3 to 2.7) and 0.3 point (from 2.0 to 2.3), respectively. By comparison, the experimental participants improved a much higher 2.0 points (from 3.0 to 5.0) and 1.5 points (from 2.7 to 4.2), respectively for static and dynamic sitting.

The static standing improved 0.9 points for both the control group (2.6 to 3.5) and the experimental group (from 2.5 to 3.4). The length of standing improved 2 min (from 1.5 to 3.5) for the control group, which is less than the 4.5 min increase (from 0.5 to 5.0) for the experimental group. Unlike static standing, standing time measures endurance and includes upper extremity involvement as is usually administered with a walker.

3.5. *Comparison of group ADL independence*

Figure 5 illustrates OT evaluations of eight different ADLs for both groups across the therapy. The average values were computed using group members with both T0 (pre) and T1 (post) measurements (0–7 FIM scale). The experimental group improved more in ADL independence for 6 of 8 daily activities. The exceptions are grooming, where the control group increased by 2.0 points (from

2.0 to 4.0) and the experimental group only increased by 1.3 points (from 3.7 to 5.0), and bed mobility where both groups improved by 1.5 points.

For the experimental group, Dress Upper, Dress Lower and Toilet ADL's improved 1.7 (from 3.7 to 5.3), 1.7 (from 2.7 to 4.3) and 2.3 (from 2.7 to 5.0) points, respectively. The corresponding control group ADL's independence increased a lower amount of 1.4 (from 3.2 to 4.6), 1.5 (from 3.3 to 4.8) and 1.1 (from 2.7 to 3.8) points for those daily activities.

For the control group, Functional Transfers, Supine to Sit, and Sit-to-Stand ADL's improved 1.1 (from 2.7 to 3.8), 0.0, and 0.5 (from 2.5 to 3.0) points. The experimental group improved more, namely 1.5 (from 3.0 to 4.5), 2.0 (from 3.0 to 5.0) and 2.0 (from 3.5 to 5.5) points.

There was a consistent trend in favor of the experimental group when viewing the totality of the 14 metrics in Figs. 4 and 5. The mean value for the experimental subjects was larger than the control subjects for only seven of the metrics pre-therapy, but increases to 11 metrics post-therapy. When comparing directly the mean change of each metric, the experimental group improvement exceeded controls for 11 outcomes whereas the control group exceeded the experimental group for only one outcome (ADL grooming). The improvement for both groups was the same for two outcomes (ADL Bed Mobility and functional metric Static Standing). As 11 of 12 comparisons for binomial sign test favor the experimental group, rejection of the null hypothesis that there is no difference in improvement among the groups is statistically significant ($p = 0.006$).

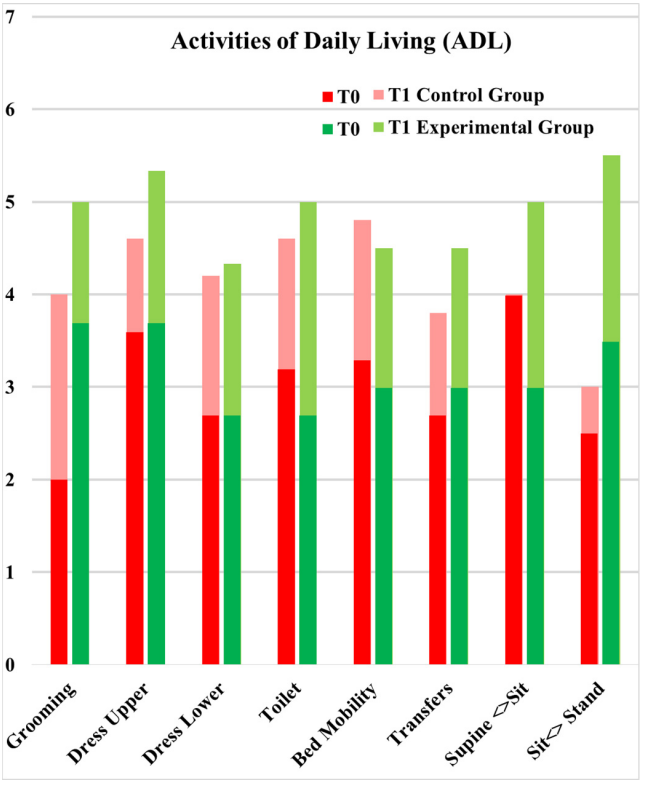

Fig. 5. ADLs for control and experimental groups of sub-acute stroke participants (0–7 scale based on FIM). Average values computed from participants with both T0 and T1 measurements. © Bright Cloud International Corp. Reprinted by permission.

3.6. *Technology acceptance*

Technology acceptance by the $N = 3$ experimental group subjects was gauged using the subjective evaluation questionnaire. The mean response was 3.9 (SD 0.5) out of 5 (max). The response was 4.0 or better for the following seven questions: *liked the system overall*? (4.3); *would encourage others to use it*? (4.3); games were interesting? (4.3); *system easy to use*? (4.0); *not bored while exercising*? (4.0); *length of exercising appropriate*? (4.0); and *instructions useful*? (4.0). Only three out of ten questions had an average score below 4.0: *no muscle pain or discomfort*? (3.7); *not fatigued by the therapy end*? (3.0) and *few technical problems*? (3.0).

4. Discussion

4.1. *Discussion of current study outcomes*

The comparative effectiveness of adding BrightArm Duo intervention to conventional rehabilitation was in the aim of this study. The two groups were evaluated pre- (T0) and post-therapy (T1) for 14 functional metrics and activities of daily living. The initial assessment (T0) of the two groups was comparable as the experimental group values were larger than controls for only half of the measures. The improvement for the experimental group was better than controls for 11 of the 12 functional metrics and activities of daily living that differed between the groups. Functional transfers, standing and sit-to-stand were included in the metrics since all the participants used assistive devices (i.e. wheelchair, walker, or cane) for standing and coming to a stand. Typically, upper extremities were involved when using these mobility aids. BrightArm Duo intervention was better than prior studies using robotic devices that lack evidence of improvements in function [9, 37].

Conventional physical rehabilitation of the paretic arm involves passive movement, compensatory training, electrical stimulation [34], and constraint induced movement therapy [35]. These are typically uni-manual training approaches that lack bimanual activities. BrightArm Duo has advantages over conventional rehabilitation in inducing bimanual training while at the same time providing gravity assistance and resistance using the robotic table. Recent studies have indicated that bimanual gravity unloading reduces abnormal joint

coupling [36] and might be beneficial in the early sub-acute phase post-stroke.

Robotic devices have traditionally been deficient in distal UE rehabilitation [10]. This study shows that *BrightArm Duo* has the potential to target grip, three jaw chuck and tip-to-tip pinch strength in the early sub-acute phase post-stroke. There was a large gain of 91 N for the unaffected hand grip strength, which is higher than the MCID (49N) [32]. The supported and active arm reach baselines also showed sizeable gains, 275% for the affected side and 535% for the unaffected side. It is worth mentioning that the unaffected hand grip strength is not often trained in current practice. It is believed that the lack of substantial increase in affected hand grasp and affected hand pinch strength is related to the very early phase of recovery in the subjects [2]. Suzuki and colleagues [2011] point to a bilateral weakness early post-stroke, with a logarithmic recovery pattern [38]. This may also explain why the ipsilateral arm of the experimental subjects showed significant strength gains following the BrightArm Duo bilateral training. It may also be that a longer training period as well as more intense training of affected hand strength are needed for better outcomes.

The ADL measure of upper extremity (UEFI-20) found a 19-point mean difference, clearly above the MCID of eight points [29]. The *BrightArm Duo* was able to improve upper and lower arm function, although the results on the 7-point scale of functional independence did not reach statistical significance including *grooming* ($p = 0.06$), *dress upper* ($p = 0.20$), and *dress lower*($p = 0.13$). In future studies, a larger sample is warranted with effective size calculation to better study the outcomes.

The acceptance of *BrightArm Duo* technology among experimental subjects was remarkable, particularly because none of the participants had any prior experience or training with computer technology. On a Likert scale of 1–5, the only questions that had responses below 4 by the experimental subjects were related to fatigue, discomfort and technical problems. This may be due to difficulty using the weaker arm, typical of their early stage in recovery post-stroke. No adverse effects such as cyber sickness [39] were reported in this study. Subject 3 reported as a technical problem the feeling of the *BrightArm Duo* arm support 'sticking' to the table during movement. This can be attributed to the weight of the *BrightArm Duo* controller which was about 2 lbs. The ongoing development of *BrightArm Duo* technology for ease of use and added features to accommodate low and high functioning individuals should address some of these issues.

4.2. *Prior study on subjects chronic post-stroke*

The *BrightArm Duo* was the focus of a previous control study aimed at the development of a virtual reality-based maintenance program for SNFs. This earlier study targeted elderly in the chronic phase post-stroke, unlike the present study which involved those in the early sub-acute phase. In the earlier study, seven experimental subjects underwent eight weeks (2 sessions per week) of *BrightArm Duo* rehabilitation, with session durations progressing from 25 min to 50 min [16]. The baselines for their affected arm reach increased by 265%, similar to the outcome of the present study. However the unaffected arm of the group chronic post-stroke saw a baseline area increase of only 225% which was less than the comparable arm reach increase for the sub-acute group in this study (535%). One possible explanation for this different outcome was the difference in the residency of the two experimental groups. The group chronic post-stroke were long-term residents of SNF, living a sedentary life with limited use of their unaffected arm [33]. By contrast, the subjects early sub-acute post-stroke had been living in their homes up until a few weeks prior to participation in this study. These individuals were overall stronger and better fit compared to the elderly long-term SNF residents. Another possible explanation was the hyper brain plasticity of the subjects in the current study. This compared favorably to the diminished plasticity on the subjects in the earlier study who were in the chronic phase. They averaged about 100 months after their stroke [16] and thus presented with less brain plasticity.

The grip strength of the affected and unaffected hands in the group of subjects chronic post-stroke improved by 9.5 N (7.6 N to 17.2 N) and 17 N (247 N to 265 N), respectively. Neither value was near the MCID = 49 N, similar to the results for sub-acute participants in the present study. The three-jaw chuck or tip-to-tip pinch strength did not improve for either hand for the subjects in the chronic phase post-stroke. By contrast, the unaffected hand for the subjects sub-acute post-stroke in the present study had a nearly 90% increase in three jaw chuck and pinch strength. This is indicative of greater benefit in three jaw chuck and tip-to-tip pinch when training bimanually with *BrightArm Duo* in the early sub-acute phase post-stroke.

4.3. *Limitations*

A key limitation of this pilot study is that only four experimental subjects were recruited, with only $N = 3$ subjects largely completing the 12-session protocol. Low statistical power restricted the statistical analysis that could be performed using the pre (T0) and post (T1) values for individual metrics. A follow-up study with a larger size experimental group would be beneficial.

Retrospective controls were used in this research study by applying inclusion and exclusion criteria to de-identified files at the SNF where the *BrightArm Duo* was located. This was done to address limited eligible

candidates for the study due to strict intake criteria and enable a controlled trial design versus a case-cohort study. The benefit of adding training on the *BrightArm Duo* rehabilitation system to conventional therapy could not be understood without comparison with controls. The retrospective controls methodology has been critiqued [40] for differences in conventional therapy between the experimental and control group. The influence of this bias is possible in this study. However, single site, two years of retrospective data, and same group of therapists were involved in the conventional therapy for both groups. This should reduce this bias. Future research with a randomized controlled trial is needed to fully address this potential bias.

Another limitation in the present study was that the evaluating OT (though not the OT supervising training) was not blinded to the study methods. The evaluating OT did in fact substitute for the training OT in about 1/3 of the sessions due to scheduling conflicts.

5. Conclusion

BrightArm Duo rehabilitation system is a low-friction robotic table that adaptably trains arm movement and grasp through interaction with custom serious games. With all the limitations due to small sample size and the lack of blinding, it is clear that the added *BrightArm Duo* intervention to conventional UE rehabilitation benefitted the experimental subjects. Their outcomes were better compared to the control group that had only conventional UE training. In future trials, a randomized controlled study is needed with an increased sample size so as to investigate the replication of results from the current study and generalize the findings. Longitudinal studies are also needed to see if the early dose of VR and robotics intensive training results in better outcomes in subsequent outpatient training.

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Gregory P. House PhD received his M.S. and Ph.D. degrees from Carnegie Mellon University, in 1991 and 1995, respectively. From 1998 to 2003, he was a Senior Engineer at PVI and worked on real-time augmented reality projects such as the Virtual First Down Line. From 2003 to 2010, he created measurement technologies as Director of Computer Development Integration at Cablevision. From 2010 to 2013, he facilitated various tracking projects as Chief Engineer at ESPN. Now, he is a Chief Technology Officer at Bright Cloud International Corp.

Gregory House is the author of over 20 technical publications and has been awarded 11 patents. His research interests include surveillance, real-time augmented reality, measurement technologies, and robotic virtual rehabilitation.

Grigore C. Burdea PhD received his PhD in Robotics from New York University in 1987. He is currently the President of Bright Cloud International as well as Professor in the Department of Electrical and Computer Engineering at Rutgers — The State University of New Jersey. Burdea is also the Founder of the International Society on Virtual Rehabilitation.

He is the author of over 150 technical publications spanning the fields of Haptics, Virtual Reality and Virtual Rehabilitation.

Namrata Grampurohit PhD received her PhD in Rehabilitation Science from University of Washington, Seattle, WA in 2016. From 2002 to 2014, she was at Evergreen Hospital and Medical Center, Kirkland, WA as Registered Occupational Therapist (OTR/L), where she was responsible for evaluation and treatment of patients with multiple neurological and musculoskeletal conditions. She is currently a Research Occupational Therapist at Bright Cloud International Corp., Edison, NJ.

Namrata Grampurohit is the author of three publications and licensed to practice Occupational Therapy in the States of New Jersey and Washington. Her research interests include scale development, innovative rehabilitation interventions, and advancing treatment of upper extremity disorders, particularly in neurological conditions.

Kevin Polistico B. S. received his B.S. degree in Computer and Electrical Engineering from Rutgers University, located in New Jersey. He is currently a Software Developer at Bright Cloud International.

Kevin is the author of over eight technical publications. His research interests include Virtual Rehabilitation and Assistive Technology.

Doru T. Roll MS received his MS degree in Electrical Engineering from the Polytechnic Institute of New York (now the NYU Tandon School of Engineering) in 1985. Since 1984, he has held various technical and executive positions in the aerospace, semiconductor and telecommunications industries. Since 2010, he serves as Director of Product Development at Bright Cloud International Corp. Mr. Roll has authored multiple technical publications and several patents. His current research interests include robotics, imaging and signal processing as applied to Assistive Technologies.

Frank Damiani MD received his MD degree from the University of Rome, Italy, in 1984. From 1994 to 1999, he was the Rehabilitation Director at Jackson Center, Genesis Eldercare. Since 1999, Dr. Damiani is the Director of Resident Care and Administrator at Roosevelt Care Centers, USA. From 2003 to present, he has also served as Adjunct Professor in the Department of Biology with Monmouth University, USA. Dr. Damiani research interests are virtual reality and its application in rehabilitation, an area where he has co-authored many publications.