

RESEARCH PAPER

## Integrative rehabilitation of residents chronic post-stroke in skilled nursing facilities: the design and evaluation of the BrightArm Duo

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### Abstract

**Purpose:** To describe the novel *BrightArm Duo* bimanual upper extremity (UE) rehabilitation system; to determine its technology acceptance and clinical benefit for older hemiplegic participants. **Methods:** The system table tilted to adjust arm gravity loading. Participants wore arm supports that sensed grasp strength and wrist position on the table. Wrist weights further increased shoulder exertion. Games were designed to improve UE strength, motor function, cognition and emotive state and adapted automatically to each participant. The system underwent feasibility trials spanning 8 weeks in two skilled nursing facilities (SNFs). Participants were evaluated pre-therapy and post-therapy using standardized clinical measures. Computerized measures of supported arm reach, table tilt and number of arm repetitions were stored on a remote server. **Outcomes:** Seven participants had significant improvements in their active range of shoulder movement, supported arm reach, shoulder strength, grasp strength and their ability to focus. The group demonstrated higher arm function measured with FMA ( $p = 0.01$ ) and CAHAI ( $p = 0.05$ ), and had an improvement in depression (Becks Depression Inventory, II). *BrightArm Duo* technology was well accepted by participants with a rating of 4.4 out of 5 points. **Conclusions:** Given these findings, it will be beneficial to evaluate the *BrightArm Duo* application in SNF maintenance programs.

### Keywords

Bimanual interaction, integrative rehabilitation, stroke, skilled nursing facility, virtual reality

### History

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### ► Implications for Rehabilitation

- Integrative rehabilitation that addresses both physical and cognitive domains is promising for post-stroke maintenance in skilled nursing facilities.
- Simultaneous bilateral arm exercise may improve arm function in older hemiplegic patients several years after stroke.
- Virtual reality games that adapt to the patient can increase attention and working memory while decreasing depression in elderly.

### Introduction

Stroke is the leading cause of disability in the US, with 795 000 Americans having one each year [1]. While the mortality rate from stroke keeps declining [2], only 5% of adults post-stroke recover full upper extremity (UE) function [3]. Thus, millions of Americans in the chronic phase post-stroke [4] face a life of disability. Stroke is affecting quality of life, often causing depression [5]. Apart from personal cost, the societal direct and indirect costs associated with stroke are also significant, being estimated at \$105 billion annually [6].

Traditional physical rehabilitation of the paretic arm involves passive movement, compensatory training on the less involved UE, electrical stimulation [7] and constraint induced therapy to combat learned non-use of the hemiplegic hand [8]. These are uni-manual training approaches that do not take into account the prevalence of activities of daily living (ADLs), which involve both arms. Another drawback of uni-manual training is diminished neural cross talk to mirror motor areas associated with bimanual activities. A meta-analysis of 48 stroke studies to determine the cumulative effect of bilateral arm training on motor capabilities post-stroke [9] did however find a significant effect post-training involving bimanual repeated reach movements timed to auditory cues.

Another argument in favor of bilateral training is a randomized controlled study of stroke patients at the end of outpatient

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therapy [10]. Researchers found, for the first time, that training the healthy arm (in a peg-board filling task) resulted in a 23% functional improvement in the non-trained *paretic* arm. Researchers also observed improvement in bilateral tasks performance in the experimental group. The control group, which did not train, had no significant difference from baseline. These studies point to the untapped advantages of bilateral training and motivate the study described here.

In the current managed care model, post-stroke therapy ends at 6–9 months from the neural accident. Neuroscience has shown, however, that UE function can be improved years post-stroke, as long as activities are task-oriented, repeated and well attended [11]. Naturally, traditional therapy should be augmented with computerized therapy systems in order to efficiently provide this additional practice, in view of the large number of potential clients.

Repetition, while necessary to induce brain plasticity, can lead to lack of engagement (attendance to task) by the patient. Second only to the amount of practice, feedback on performance is a key element in motor training [12] and a way to engage the patient. Knowledge of performance feedback can be provided by the therapist, or through graphics in a virtual rehabilitation setting [13]. Virtual rehabilitation benefits attention, motivation and provides intensive training.

Long-term skilled nursing facility (SNF) residents post-stroke with a combination of motor, cognitive and emotive disabilities could benefit from therapy which addresses all these domains. Current standard of care addresses these domains separately, with therapy provided by different clinicians [physical therapist, occupational therapists (OT), neuro-psychologists, psychiatrists and others]. In contrast, integrative rehabilitation addresses the motor, cognitive and emotive deficits in a single-point-of-care approach. Integrative virtual rehabilitation uses custom therapeutic games in which the participant is asked to solve cognitive problems (such as making decisions on object sequences or remembering the location of image pairs) through physical exertion (arm movement and grasping). The emotive domain is addressed by making the integrative rehabilitation custom games always winnable and by lavishly congratulating for success. Based on prior studies using related technology [14,15], the authors believe that this approach can increase self-esteem, provide a feeling of accomplishment and may lead to reduced depression.

Bright Cloud International developed the BrightArm, a low-friction symmetrical table that was wheelchair accessible, and electrically lifted or lowered to accommodate different body types. Two quiet electrical linear actuators tilted the table to allow gravity modulation so that weak arms were assisted and stronger arms resisted during game play. To minimize friction, participants placed their hemiplegic forearm on a low-friction support incorporating grasp sensing. The forearm support enabled the participants to exercise by interacting with 3D virtual reality simulation games. The BrightArm transparently stored game performance into a database on a secure clinical server. The BrightArm underwent a feasibility trial on five SNF residents who were chronic post-stroke [15]. This article presents the design characteristics of the *BrightArm Duo* system, a follow up to BrightArm, as well as its first feasibility study on a group of residents of two SNFs in New Jersey, USA, who were in the chronic phase post-stroke.

## Methods

### The BrightArm Duo rehabilitation system

The BrightArm Duo system (Figure 1a) consisted of a self-contained motorized training table, a pair of instrumented forearm supports, a high-definition monitor on an adjustable stand, a remote clinical server and a library of custom designed rehabilitation games. Unlike the BrightArm which required room modifications to install overhead cameras and a TV display [15], BrightArm Duo integrated the cameras on an overhead trestle. It also included a retractable laptop station into a more self-contained table configuration. From the participant's standpoint, the core functional improvements were the capability to train both arms simultaneously, a more ergonomic table surface and greater game choices.

### Tabletop ergonomic design

The BrightArm Duo table top was 80" by 52" and had a lima bean shape with the inside U-shaped cutout facing the participant. The shape and size of the tabletop contour was designed to support simultaneous movements of both forearms within a hemisphere in front of the participant. The table surface contour exceeded the outer reach of both arms of a 90th-percentile adult male [16].

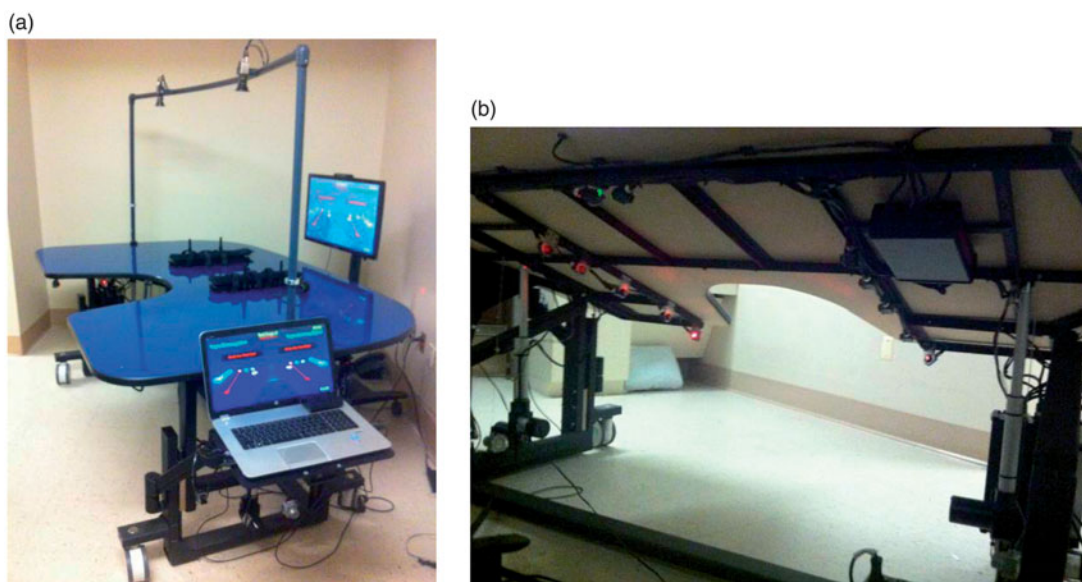


Figure 1. The BrightArm Duo integrative rehabilitation system: (a) system view; (b) frame under table top showing linear actuator and safety sensors. © Bright Cloud International Corp. Reprinted by permission.

The inner contour accommodated the torso based on waist circumference of 95th-percentile for both men and women in the target age group [16]. The width of the inner contour was greater than most wheelchair seats (20" wide or less) at the depth of the table tilt axis, and gradually widened at a 75° angle towards the back of the table to facilitate participant entry. The table top was produced from a composite light-weight material with a glossy blue Formica finish. This material was chosen for low surface friction to facilitate participant's forearm support movement, low noise generation and ease of cleaning. Along the outer edge of the table were embedded five 770 nm infrared (IR) light-emitting diodes (LED), which pointed upwards and were imaged by two overhead cameras, part of the vision tracking system described later. The LEDs were positioned flush with the top surface so as not to hinder forearm movement.

#### *Table support frame and actuators*

The table top was supported by a welded steel frame sitting on 4" hospital grade wheels for ease of transport (Figure 1b). The mechanical structure housed four electrical actuators with matching string pot position sensors and a custom electronic controller with external power supply. The four actuators were identical DC-powered linear motors (Firgelli FA-200-L-12-8) placed symmetrically about the table's central axis. Two actuators raised or lowered the table top (from 26" to 34") to accommodate different body types from pediatric to the 90th-percentile adult male. The other two actuators controlled the table tilt from 15° below horizontal to 20° above horizontal. Each linear actuator had built-in position limit switches. In addition, the table structure was retrofitted with a pair of string potentiometers (Celesco SP-12-3). One potentiometer was used to measure the amount of table lift and the other measured the amount of table tilt. Tilting the table surface downwards benefitted lower functioning participants with spasticity by adding gravity pull during the more difficult arm movement away from the trunk. Conversely, tilting the table top upwards challenged the higher functioning participants to move their arms against gravity.

#### *Table control circuit*

The BrightArm Duo, like its predecessor, was designed so that the tilt axis passed through the participant's trunk along the coronal plane when seated at the table. This design feature made it unnecessary to lift or lower the participant's trunk as a function of table tilt, allowing the use of regular wheelchairs. A key difference with the original BrightArm version was the computer platform communication with the electronic table controller through a wireless serial channel. After power up, the electronic controller guided the table through a calibration procedure that registered potentiometer readings with actual tilt and lift table positions. Subsequently, the therapist could instruct the electronic controller (through the laptop station) to move the table to set height and tilt values, with millimeter precision. Alternately, only incremental height and tilt changes were permitted when the participant safety circuit (detailed below) detected a participant who was sitting at the table. Feedback of the table current status was made available to the therapist at the laptop station or output display.

#### *Table safety circuit*

Participants were protected through an electronic collision detection system (Figure 1b). This was comprised of a multiplexer box wired to six electro-optic transmitter and receiver pairs mounted to the underside of the table top support frame (Figure 1b): one sensor beam detected the participant's trunk positioned in the table cutout; two sensor beams, angled along the

sides of the table cutout, detected pinch points on either side of the participant; three horizontal sensor beams detected potential pinch points in front of the participant from the torso to the knees. If the safety sensor beams were interrupted by contact interference from the participant's body while the table was being lowered or tilted, the electronic controller immediately halted movement and signaled an audible alarm. This arrangement prevented injury due to human error, while at the same time assuring maximum work envelope corresponding to a participant's anatomy.

#### *Instrumented forearm supports*

Participants sitting at the table placed each arm on a forearm support (shown on top of the BrightArm Duo table in Figure 1a). Each support consisted of a lima bean shaped shell made of Nylon 66 housing a custom electronics assembly, rechargeable batteries and a wireless transmitter/receiver. The forearm support instrumentation included a solid-state, differential pressure sensor used to measure the pressure exerted by participants when grasping a rubber pear connected to the forearm support. Optical proximity sensors were located to the underside at each end of the forearm support and detected unwanted lifting of the forearm off the table. Two upward-pointing cylindrical 5" towers were located on the outer edge of the shell. Each tower contained a 770 nm LED (with 80° viewing angle) for overhead camera tracking. A wireless transmitter/receiver inside the forearm support provided bi-directional communication with a laptop at a data rate  $\geq 40$  packets/second. Every 40 ms the laptop alternately instructed one of the forearm supports (left or right) to strobe its LEDs. The corresponding forearm support responded with information on the participant's grasp strength, lift sensor status and remaining battery charge level. When not in use, the forearm supports were charged using a standard 12 V wall charger, providing at least 8 h of continuous use per charge.

The top of the forearm support was covered with a removable memory foam pad encased in a soft breathable material. Each participant had personalized pads (coded underneath) to reduce the risk of skin disease transmission. The front area under the participant's fingers was covered with a smooth nylon material to prevent fingernails from digging into the foam pad and thus preventing accurate grasp strength sensing. The forearm support was secured to the participant's arm by three Velcro loops of such dimensions and spacing to accommodate the placement of wrist weights. The underside of the forearm support plastic shells had felt pads to lower contact friction when the participants moved their arms on the tabletop surface.

#### *Overhead camera trestle*

Forearm support tracking was done by a pair of Edmund Optics CMOS machine vision cameras with 3 mm wide-angle lenses and 760 nm high-pass filters. They were mounted above the table surface on a U-shaped tubular structure supported by the tabletop frame. The camera trestle kept the cameras perpendicular to the table top regardless of tilting angle. The height was adjusted so that each camera imaged slightly more than half of the BrightArm Duo work surface with 1 mm/pixel resolution.

The cameras were connected via gigabit Ethernet cabling to a gamer laptop that ran a C++ custom image processing program. The software calibrated the camera position relative to the five LED's embedded in the table top. It tracked the image location of LED pairs for both forearm supports in either camera view at a rate of 25 frames per second. The computed locations of participant's hands on the arm supports were transmitted to the gaming application using table coordinates. As compared to the original BrightArm, the compact mounting solution used in

BrightArm Duo increased forearm tracking accuracy by 50% while improving overall system mobility.

#### *Retractable Laptop station*

The therapist controlled the BrightArm Duo through an HP ENVY 17 laptop running Windows 8 (64 bit) operating system. The laptop was located on a configurable support arm towards one side of the table. The laptop processed the IR camera image pair to track the participant's arms, rendered the real-time game graphics and interactive sound, and automatically stored game data during each rehabilitation session. The laptop 4th generation Intel Core i7-4702MQ processor allowed it to process camera image pairs in real-time, and do file management and internet communication. The real-time game graphics were rendered by the laptop mid-range NVIDIA GeForce GT 750M 2048 MB graphics card at a rate of 60 frames/second.

#### *Remote clinical server*

At the end of each game, software stored performance related measures into an Oracle MySQL database on the laptop. At the completion of each rehabilitation session, the local database was backed up (via a wireless Internet connection) to a remote HP C300 clinical server, for permanent storage and further analysis.

#### *Custom rehabilitation games*

A major advantage over off-the-shelf games was the ability of BrightArm Duo simulations to adapt to each participant each day. This made games winnable even for low-functioning participants. The adaptation was based on arm reach and grasp strength baselines performed at the start of each rehabilitation session.

During supported arm reach baseline the participant saw an avatar of the BrightArm Duo table and was instructed to move one arm at a time as far as possible, but without lifting it off the table and without trunk leaning. The surface reached by the participant was visualized by a change in color, providing easily understood visual feedback. Arm reach depended on whether the affected or unaffected arm was measured, whether wrist weights were used and whether the table was flat or tilted. Thus, baseline data stored on the laptop included left or right arm specification, the reach envelope shape and area for that arm (as measured by the overhead cameras), the table tilt angle, wrist weight worn (if any) and session date. The arm reach baseline in turn determined the placement of virtual objects in the game, such that they were reachable by the participant, no matter how small the achievable physical movement.

Subsequent to supported arm reach baseline the participant was asked to move the arm to a comfortable location on the table and then to exert maximum grasp on the arm support rubber pear. Grasp pressure was sensed by the arm support instrumentation, transmitted to the laptop and displayed on the HD monitor as a virtual thermometer gauge. The gauge consisted of a color bar of a height proportional to the participant's grasp strength and provided easily interpretable feedback. The grasp strength measurement was repeated three times and averaged to provide the grasp strength baseline value.

Each of the custom games describe below had some settings that required reach and grasp dual-tasking. For momentary grasp, used only when a virtual object was picked up, thresholds were set at 25% of the baseline grasp strength of that day. For settings which required sustained grasp once the virtual object had been picked up, the threshold was set to 10% of maximum. These values were in line with studies comparing maximum and sustained grasp [17]. This was intended to prevent arm discomfort observed in earlier trials with participants chronic post-stroke [18].

In the current study, the BrightArm Duo therapy sessions consisted of up to nine custom games written in Unity 3D [19]. Of these, *Pick-and-Place*, *Card Island*, *Treasure Island* and *Breakout 3D* were bimanual versions of the uni-manual games previously developed for BrightArm [15]. In order to encourage the use of both arms, their scenes were divided vertically into halves, one for each arm avatar. Therefore, both arms needed to be used to play the games, so to combat learned non-use.

*Remember that Card*, *Musical Drums* and *Xylophone* were games previously developed for the BrightBrainer portable system [14,20] and adapted for use with the BrightArm Duo. The adaptation referred to the different controllers used in game interactions, namely, the Razer Hydra [21] for the BrightBrainer versus the arm supports of the BrightArm Duo. The movement of the BrightBrainer controllers was in 3D space, while the movement of the arms in BrightArm Duo system was confined to the tabletop surface. In addition, dual-tasking with the BrightBrainer involved pressing the controller button with the index finger while for BrightArm Duo dual tasking was realized through power grasping of the arm support rubber ball sensor. Apart from these hardware differences, the game graphics and tasks were essentially the same.

*Arm Slalom* (Figure 2 left column) was a new game that trained task sequencing (left and right pole planting), hand-eye coordination (negotiating the gates), arm endurance, motor memory and shoulder/grasp strengthening. The participant was told to guide a skier avatar through a downhill ski course consisting of five gates. Moving the arm supports forward to back when grasping increased the speed of the avatar, and turning the direction of the arm supports changed the avatar skiing direction. Game difficulty was increased by updating the slope of the course to require a greater effort for forward motion, and by distributing the gates so larger directional changes were needed.

*Avalanche* (Figure 2 right column) trained arm endurance, shoulder/grasp strengthening, task sequencing and executive function. The patient was instructed to clear a series of ice walls to free skiers trapped by an avalanche in a lodge. The ice had to be hit with the pick axe (left arm support) before being cleared with the shovel (right arm support). Arm support movement change location of tools on the ice wall, while grasps triggered the pick axe and shovel actions. Game difficulty was increased by reducing the amount of ice cleared with single pick axe and shovel operations.

Each of the nine games included summative performance feedback, and rewards (fireworks, congratulatory text and/or applause), which provided positive reinforcement and were meant as morale boosters.

#### **Controlled study design**

A longitudinal controlled study commenced in Summer 2014 to gauge the use of the BrightArm Duo in a maintenance therapy for SNF residents in the chronic phase post-stroke. The protocol provided for an experimental group undergoing an initial intensive rehabilitation period of 8 weeks (16 sessions), followed by periodic booster sessions. The control group continued with their normal maintenance programs offered by the SNFs. The intensive rehabilitation part of the study completed by the experimental group is the subject of this article. A follow on publication will outline experimental results for the booster session component of the BrightArm Duo maintenance program, and will detail both group characteristics and include results for the control participants.

The inclusion criteria for this study were residency in a SNF, hemiplegia due to stroke, time since stroke longer than 12 months and being older than 60. English speaking and good mental awareness were required so to be able to comprehend the consent



Figure 2. *Arm Slalom* and *Avalanche* scenes: (a) start, (b) mid-game and (c) end-game. © Bright Cloud International Corp. Reprinted by permission.

form, cognitive evaluation questionnaires and the simulation exercise demands. Additional criteria included motor involvement with the UE (Fugl–Meyer Assessment – FMA [22] score of 5–45); some ability to actively move the UE (~15° of total active range or better for shoulder and elbow flexion/extension); at least 4 months after casting or Botox injections.

Exclusion criteria were total lack of active movement in the hemiplegic arm, blindness, severe cognitive dysfunction and dementia, a history of violence in the 6 months prior to enrollment, receptive aphasia and uncontrolled hypertension (190/100 mmHg). Participants were residents of two SNFs in Central New Jersey. The Western Institutional Review Board and the JFK Health System Institutional Review Board reviewed and approved this controlled study in accordance with Federal Guidelines. Eighty seven potential participants were screened for inclusion in the study. Of these only 13 were considered suitable, and were subsequently consented. Participants were randomized into an experimental group ( $n=8$ ) and a control group ( $n=5$ ). One participant from the experimental group and two from the control group subsequently dropped, leaving an experimental group of  $n=7$  and a control group of  $n=3$  to continue the study.

Two BrightArm Duo systems were subsequently installed, one each at the Roosevelt Care Center and at JFK Hartwyck Edison Estates, two SNFs in New Jersey, USA. The systems were placed in dedicated rooms and then pre-tested with older healthy volunteers. Subsequently, the experimental group underwent rehabilitation on the BrightArm Duo during summer of 2014.

#### Experimental group characteristics

The demographic and medical history information for the seven experimental subjects is summarized in Table 1. This includes vital statistics, months since stroke, affected side, FMA initial score, depression level, cognitive functioning, ambulation, comorbidities, language primarily spoken and years of formal education.

The experimental group contained 5 male and 2 female participants with a mean (standard deviation) age of 69.7 (13) years. They were an average of 98 (45) months post-stroke. The motor impairment was rated severe for three participants and moderate for four participants based on their initial UE FMA score. Depression levels (according to Beck's Depression Inventory [23]) were generally minimal among participants with only one categorized as having moderate depressive symptoms. The mean education level was 11.7 years (high school) as three participants finished in 8th or 9th grade, three completed high school, and one having a post-secondary graduate degree. Four were native English speakers, two were native Spanish speakers and one was a native French speaker. Cognitively, four participants initially exhibited severe impairments in attention or memory (or both), while one participant had less severe cognitive impairments. All participants had multiple medical comorbidities, with four having Diabetes Mellitus, four having a heart condition, three had hypertension and two had a history of anemia. Six participants ambulated in wheelchairs within the SNF.

#### Data collection instruments

The intensive rehabilitation portion of the study used an ABA protocol, data being collected pre- (A), during training (B) and post- (A) the 8 weeks of therapy. Training consisted of 16 sessions, with each participant attending two sessions per week.

Table 1. Participant characteristics and medical history pre-intervention for group ( $N=7$ ) of chronic post-stroke SNF residents.

Variables	Group statistics
Age	69.7 SD 13.3
Gender	5 Male, 2 Female
Race	4 White, 2 Hispanic, 1 Afr American
Months since stroke	98 SD 44
Affected side	4 Left, 3 Right
UE Functional Level	3 Severe, 4 Moderate
Beck-II Depression Level	6 Minimal, 1 Moderate
Co-morbidities	Diabetes mellitus (4), Heart condition (4), Hypertension (3), Anemia (2)
Ambulation	6 Wheelchair bound, 1 Independent
Primary language	4 English, 2 Spanish, 1 French
Years of formal education	11.7 SD 3.7

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Therapy session data consisted of arm reach and grasp strength baselines, as well as game performance data. At the end of the 8 weeks of training, the participants rated their experience on a subjective evaluation paper questionnaire with nine questions. Ratings used a 5-point Likert scale, from 1 (least desirable outcome) to 5 (most desirable one).

The pre- and post-clinical evaluations involved data collection of standardized UE motor and functional measures (by a blinded senior OT not involved in the training of study participants), and of neuropsychological measures of attention/concentration, processing speed, learning and memory and executive functioning. Cognitive testing was performed by a qualified research assistant (graduate student in neuropsychology) who was blinded to the research methodology and scope. The cognitive evaluations were supervised by a board certified neuropsychologist who was familiar with the BrightArm technology and is a co-author of this article.

The UE motor impairment evaluations for each subject were performed pre- and post-therapy. This included measuring affected shoulder strength (by placing weights on the wrist), grasp strength (using a mechanical Jamar dynamometer) and finger pinch strength (with a mechanical pinch gauge). The shoulder and elbow active range of motion were determined through the use of a mechanical goniometer. The arm and hand function were measured with the Jebsen test of hand function [24], the Chedoke Arm and Hand Inventory [25] and the UE subset of the FMA test.

Emotive state evaluations were conducted using the standardized Beck Depression Inventory, Second Edition (BDI-II) [23]. The Neuropsychological Assessment Battery [26] (NAB) Attention Module (Digits and Dots sub-tests, respectively) was used to assess verbal (Digit Span Forward and Digit Span Backward) and visual attention (Dots). The Hopkins Verbal Learning Test, Revised (HVLTR) [27], Trials 1–3, was used to assess verbal learning and memory of each subject while the Brief Visuospatial Memory Test, Revised (BVMT-R) [28], Trials 1–3, was used to assess visual learning and memory. The Trail Making Test A was used to assess processing speed, while the Trail Making Test B [29] was used as a measure of executive functioning (set-switching). The Neuropsychological Assessment Battery [26] (NAB), Executive Functioning Module (Word Generation subtest) was used to assess generation and verbal fluency.

### Experimental protocol

Each session was assisted by an OT and a system technician. At the start of the session, the OT measured and logged the participants' blood pressure and pulse. Subsequently, she stretched the participant's affected arm and fingers and when

needed assisted arm movements during play. The OT also made sure the arms were positioned properly on the forearm supports. The initial participant's preparation was followed by baseline measurements of reach distance and grasp strength of the arm(s) being exercised in that session. The first 2 weeks of the intensive therapy component of the maintenance program the participants trained their affected arm in uni-manual mode, as the games were simpler to comprehend. For the remaining 6 weeks of intensive therapy, the play was bimanual so baseline measurements for each arm reach and grasp strength were gathered at the session start. The duration of the therapy increased from 20 min of actual play per session in Week 1, to 25 min in Week 2, 30 min in Week 3 and 4, to 40 min in Weeks 5 and 6 and 50 min in Weeks 7 and 8. Session training intensity was similarly increased, primarily by gradating the BrightArm table tilt angle, which was 0° (horizontal) in Weeks 1 through 3, then 10° in Weeks 4 and 5, 15° in Weeks 6 and 7 and 20° of upward tilt in Week 8. During each session, the participants played a sequence of up to 9 games (described earlier), in a set order. In week 1, for example, the order was *Pick-and-Place*, followed by *Breakout 3D*, then *Card Island*, followed by *Pick-and-Place*, *Breakout 3D* and *Treasure Island*. By week 8, the game sequence lengthened to *Pick-and-Place*, *Remember that card* (part 1), *Breakout 3D*, then *Arm slalom*, *Card Island*, *Avalanche*, *Pick-and-Place*, *Breakout 3D*, *Card Island*, *Remember that Card* (part 2), *Xylophone*, *Treasure Island* and ending with *Musical Drums*. These sequences were repeated as needed to achieve the prescribed session duration specified for that week.

The difficulty of each exercise was progressively increased from easier games with no required grasping in Weeks 1 and 2, to most difficult ones requiring sustained grasping in Weeks 7 and 8. Game difficulty was further increased during the last 4 weeks of therapy by asking participants to wear wrist weights on both arms. The weights were 0.5 lb in Week 5, 1 lb in Week 6 and 2 lbs in Weeks 7 and 8. The OT had the authority to deviate from the set game level progression in case it proved too difficult, or not challenging enough for a participant. In that case, the technician operating the BrightArm Duo would alter the game settings for tabletop tilt, or grasping condition, etc.

### Statistical methods

Pre- and post-therapy comparisons of continuous variables were implemented by paired  $t$ -tests. Two-sided  $p$  values less than 0.05 were deemed to be statistically significant. The results were expressed as 95% confidence intervals to document the precision of all statistical estimates. Although low statistical power (due to the small  $n$ ) made negative statements less reliable, any positive statistically significant findings implied the findings were robust and not obscured by the small sample size. Data that approaches

significance for the small sample size of may be significant among a larger subject pool, and so lay the foundation for future research with larger  $n$  sizes.

Though power may be low for any individual measure, one can take advantage of the multiple measures performed on each patient. The tests done in the physical domain were tabulated and an observation was made of how many were in the direction of improvement. A binomial sign test was then used to test the hypothesis that there were no more differences between pre and post in the improved direction than in the reverse. All analyses were conducted using SAS 9.4 (SAS Institute, Inc., Cary, NC) [30].

## Results

### Upper extremity range and strength outcomes

#### Shoulder and hand strength

The experimental group made progress in the strength of their affected UE (Table 2). The most significant improvement was in grasp strength of the affected arm from an average of 7.6 N pre-therapy to 17.2 N post-therapy. This represents an average gain of 9.5 N, a value above the repeatability of the Jamar dynamometer [31]. Shoulder strength improved by more modest margins; mean Shoulder Lateral Deltoid strength increased by 1.3 N while the Shoulder Anterior Deltoid strength increased by 0.3 N. The mean pinch strength for the thumb with second finger and 3-fingertip grip tests were 1 and 0 N, respectively.

#### Shoulder and elbow active range of motion

Training on the BrightArm Duo resulted in an increase in shoulder active range of motion for the affected arm (Table 2). The greatest improvement was in shoulder extension, with mean pre-therapy value of 18.7° and post-therapy value of 33.3°. The 14.6° range increase was statistically significant ( $p=0.05$ ). Shoulder abduction increased on average 3.4° ( $p=0.44$ ) from 68.0° to 71.4°. There were modest improvements in shoulder flexion (increasing by 1.1°) and shoulder internal rotation (increasing by 0.6°). There were increases on average in elbow flexion (5.9°) and elbow extension (4.8°), but the measured improvements do not meet criteria for statistical significance.

### Upper extremity functional outcomes

Due to participants' elbow and finger spasticity, none of the participants was able to perform the timed tasks of the Jebsen test with the affected arm. Improved shoulder strength and increased affected arm use resulted in more improvement in the Fugl-Meyer assessment and Chedoke Arm and Hand Activity Inventory (CAHAI). As seen in Table 2, the groups mean FMA UE score for the affected arm pre-therapy was 15.6, and increased to 16.9 post-therapy. The 1.3 point improvement was statistical significant ( $p=0.01$ ). For the CAHAI test, the pre-therapy mean score of 11.9 increased to 14.0 post-therapy. This 2.1 point gain was statistically significant ( $p$  value of 0.05).

The binomial sign test was performed on the data in Table 2 with 11 of 13 measures showing improvement. Rejecting the hypothesis of no difference between pre- and post-scores was statistically significant ( $p=0.02$ ).

There were tangible benefits observed in the functional abilities of subjects. As seen in Figure 3a), one subject was able to demonstrate use of the affected arm to open a door, something he had not been able to do before the BrightArm Duo training. This corresponds to an increase in the subject's affected hand grip strength from 0 N to 89 N, which is above the minimal clinically important difference of 49 N [32]. A second subject displayed the new found ability to use both arms simultaneously in the *Arm Slalom* and *Avalanche* games (Figure 3b). This corresponds to an increase of CAHAI from 18 to 24, which is approximately the minimal clinically important difference of 6.3 points [33].

### Emotive and cognitive outcomes

Table 3 presents the group statistical analysis for the emotive and cognitive measures taken pre-and post-BrightArm Duo 8-week therapy. Paired  $t$ -tests were used in the comparison across testing sessions (pre- versus post-intervention). Testing variables included emotive state assessment and neuropsychological measures of attention, processing speed, learning, memory and executive functioning (as measured by the aforementioned neuropsychological instruments).

Mood generally improved post-training. The group mean depression score saw a reduction of 3.1 points ( $T_2 - T_1 = -3.1$ ), but the result was not statistically significant ( $p=0.17$ ). One participant depression severity dropped 13 points into the minimal

Table 2. Group statistical analysis of shoulder and hand strength (N), range of motion (degrees) and inventory metrics for affected arm of seven participants before ( $T_1$ ) and after ( $T_2$ ) 8 weeks of training.

Variables	$T_1$	$T_2$	$T_2 - T_1$	95% CI: $T_2 - T_1$	$p$
Shoulder and hand strength					
Ant. Deltoid	6.7 SD 5.3	7.0 SD 6.1	0.3*	(-1.5, 2.1)	0.68
Lat. Deltoid	6.7 SD 3.9	7.9 SD 5.3	1.3*	(-1.1, 3.6)	0.23
Hand Grip	7.6 SD 13.3	17.2 SD 33.1	9.5*	(-23.4, 42.5)	0.51
Shoulder range of motion					
Flexion	42.4 SD 42.5	43.6 SD 33.7	1.1*	(-13.6, 15.9)	0.86
Extension	18.7 SD 16.9	33.3 SD 5.9	14.6*	(-0.4, 29.6)	<b>0.05</b>
Abduction	68.0 SD 16.7	71.4 SD 15.8	3.4*	(-6.7, 13.6)	0.44
Internal rot.	49.3 SD 15.0	49.9 SD 8.7	0.6*	(-11.0, 12.1)	0.91
Elbow range of motion					
Flexion	130.1 SD 10.4	136.0 SD 11.4	5.9*	(-21.0, 14.0)	0.21
Extension	68.7 SD 31.6	63.9 SD 26.2	-4.8*	(-16.4, 6.7)	0.34
Pronation	40.0 SD 38.7	39.4 SD 39.5	-0.6	(-5.0, 3.8)	0.76
Supination	17.9 SD 25.8	14.3 SD 31.7	-3.6	(-20.2, 13.0)	0.61
UE function and inventory					
FMA	15.6 SD 11	16. SD 11.5	1.3*	(0.4, 2.2)	<b>0.01</b>
CAHAI	11.9 SD 3.6	14.0 SD 5.8	2.1*	(0.0, 4.3)	<b>0.05</b>

Bold  $p$  values indicate statistical significance. \*Indicates improvement over time. © Bright Cloud International Corp. Reprinted by permission.

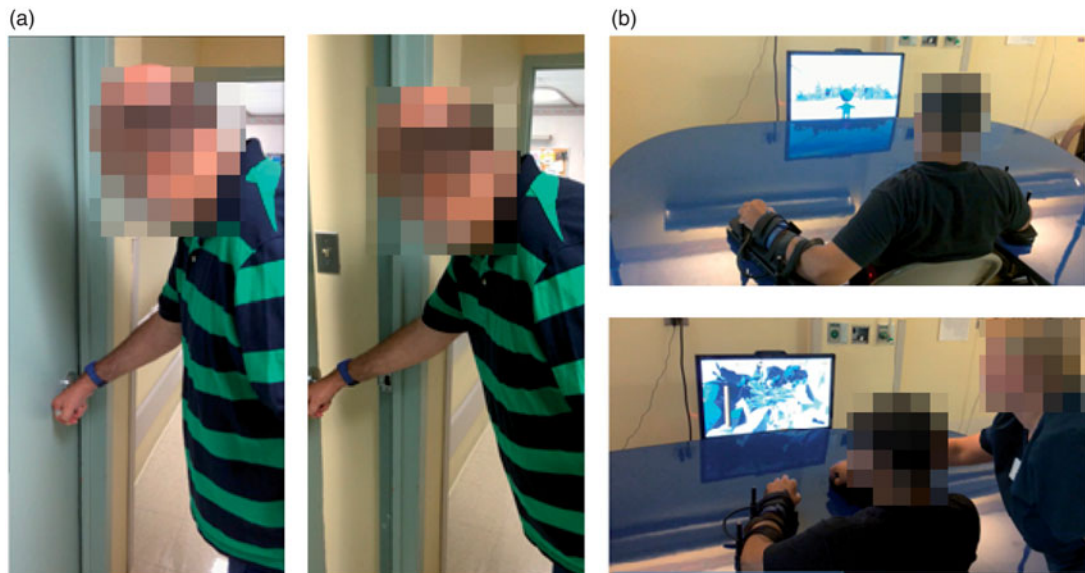


Figure 3. (a) Subject able to open door with affected arm, something he was unable to do prior to training on BrightArm Duo. (b) Second subject playing *Arm Slalom* and *Avalanche* using both arms. © Bright Cloud International Corp. Reprinted by permission.

Table 3. Group statistical analysis of emotive and cognitive outcomes for seven participants chronic post-stroke before ( $T_1$ ) and after ( $T_2$ ) 8 weeks of VR training.

Variables	$T_1$	$T_2$	$T_2 - T_1$	95% CI: $T_2 - T_1$	$p$
BDI-II	8.0 SD 7.0	4.9 SD 8.5	-3.1*	(-8.0, 1.7)	0.17
NAB Digit Forw	4.6 SD 2.1	4.3 SD 2.6	-0.3	(-1.9, 1.4)	0.69
NAB Digit Back	1.3 SD 1.5	2.9 SD 2.0	1.6*	(0.3, 2.9)	<b>0.02</b>
NAB Dots	2.1 SD 2.5	2.7 SD 2.1	0.6*	(-1.9, 3.1)	0.60
TMT-A	90.9 SD 38	94.6 SD 30	3.7	(-5.8, 13.3)	0.38
HVLT-R Trials	15.1 SD 7.9	14.9 SD 6.8	-0.3	(-4.9, 4.4)	0.89
BVMT-R Trials	5.9 SD 5.5	10.1 SD 10	4.3*	(-3.3, 11.9)	0.22
TMT-B	255 SD 80	229 SD 91	-26*	(-81, 27.8)	0.27
NAB Word Gen	3.9 SD 4.4	3.0 SD 3.7	-0.9	(-3.2, 1.5)	0.40

Bold  $p$  values indicate statistical significance. \*Indicates improvement over time. © Bright Cloud International Corp. Reprinted by permission.

range (13–0), while another had a 7-point reduction in depression severity from 8 to 1 on the Beck's Depression Inventory II scale [23].

Statistically significant improvement was seen on the NAB Digits Backwards test ( $T_2 - T_1 = 1.6$ ,  $p = 0.02$ ), a cognitive measure related to verbal attention and working memory. There were non-statistically significant changes in the improvement direction in visual attention (NAB Dots  $T_2 - T_1 = 0.6$ ,  $p = 0.6$ ), memory (BVMT-R Trials  $T_2 - T_1 = 4.3$ ,  $p = 0.22$ ), and set shifting (Trail Making Test B  $T_2 - T_1 = -26.6$ ,  $p = 0.27$ ). Executive function, through NAB Word Generation test ( $T_2 - T_1 = -26.6$ ,  $p = 0.27$ ) and attention/processing measured with TMT A test ( $T_2 - T_1 = 3.7$ ,  $p = 0.38$ ) showed no improvements.

### Exercise intensity and arm movement repetitions

The BrightArm Duo tracked session performance information including session duration, exercise duration (session duration–rest time) and movement repetitions for each arm. Figure 4(a) shows the increase in number of arm movement repetitions per session when repetitions of both arms are summed up. As can be seen the participants group achieved a mean of above 1200 arm repetitions/session by the end of therapy. The increase in standard deviation which occurred with the increase in session difficulty is indicative of less uniformity in performance among the group.

Figure 4(b) graphs the number of arm repetitions *per minute* for both arms, as a measure of training intensity. The unaffected arm started being trained in session 5 corresponding to the switch to bimanual training. The plots increased by 2/3 over the course of the study, with the slopes statistically different from zero (null hypothesis) for both affected ( $p = 0.007$ ) and unaffected ( $p = 0.003$ ) arms. This corresponds to the increase in game difficulty toward the end of the study. The group was able to increase physical effort required by more intense training, indicative of increased endurance manifested in both arms.

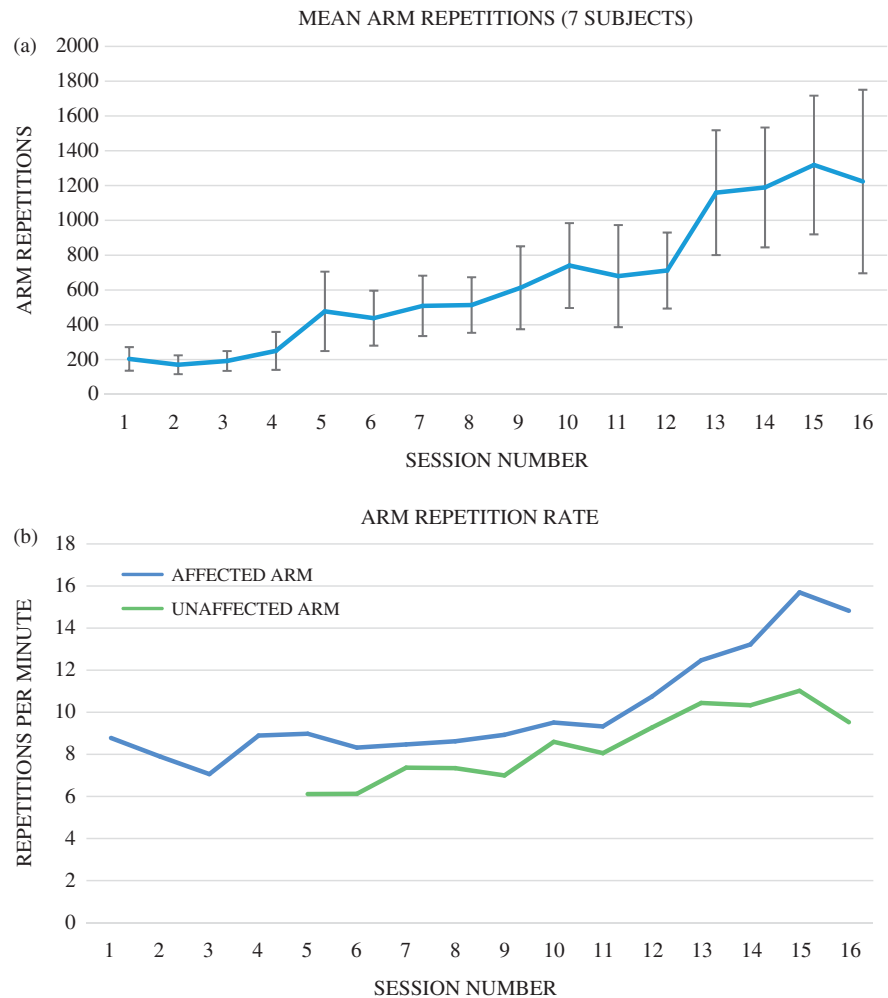
### Baseline measures of supported arm reach

A unique feature of the BrightArm Duo over the previous BrightArm system was the ability to train both arms simultaneously. The effective area of supported arm reach was measured pre- and post-therapy for both arms with the table kept horizontal. The supported arm reach baseline surface increased substantially over the course of the study for all participants. The affected arm area increased by 265% from a mean of 187 cm<sup>2</sup> (SD 187 cm<sup>2</sup>) to a mean of 682 cm<sup>2</sup> (SD 825 cm<sup>2</sup>) with  $p = 0.1$ . The unaffected arm area increased by 225% from a mean of 584 cm<sup>2</sup> (SD 316 cm<sup>2</sup>) to a mean of 1900 cm<sup>2</sup> (SD 931 cm<sup>2</sup>). This improvement was statistically significant ( $p = 0.02$ ).

Figure 5 illustrates the shape of the arm baselines for the seven experimental group participants. There is a clear difference in the size of the regions between the affected and unaffected arms.



Figure 4. (a) Total arm movement repetitions by session; (b) training intensity measured by the mean arm movement repetitions per minute of exercise. © Bright Cloud International Corp. Reprinted by permission.



The regions of both arms are comparable in size for participants ID-14-12 and ID-14-20. Apart from the quantitative improvement in terms of arm reach area, there was a qualitative improvement too. Namely, the shape of the baselines became more curved, similar to the reach of a healthy arm. The direction of the curvature depended on which arm was performing baseline measurements, curving to the left for the left arm and to the right for the right arm.

### Subjective evaluation of the BrightArm Duo

Participants gave the BrightArm Duo ease of use a score of 4.3/5. They scored lowest (2.7) for questions related to ease of playing with affected arm and degree of muscle pain/discomfort. Participants liked the system overall, giving that question the highest score (4.4/5). This was followed by the responses about technical reliability (4.3/5) and whether they would encourage others to use the system (4.1/5).

## Discussion

### Motor and function improvements

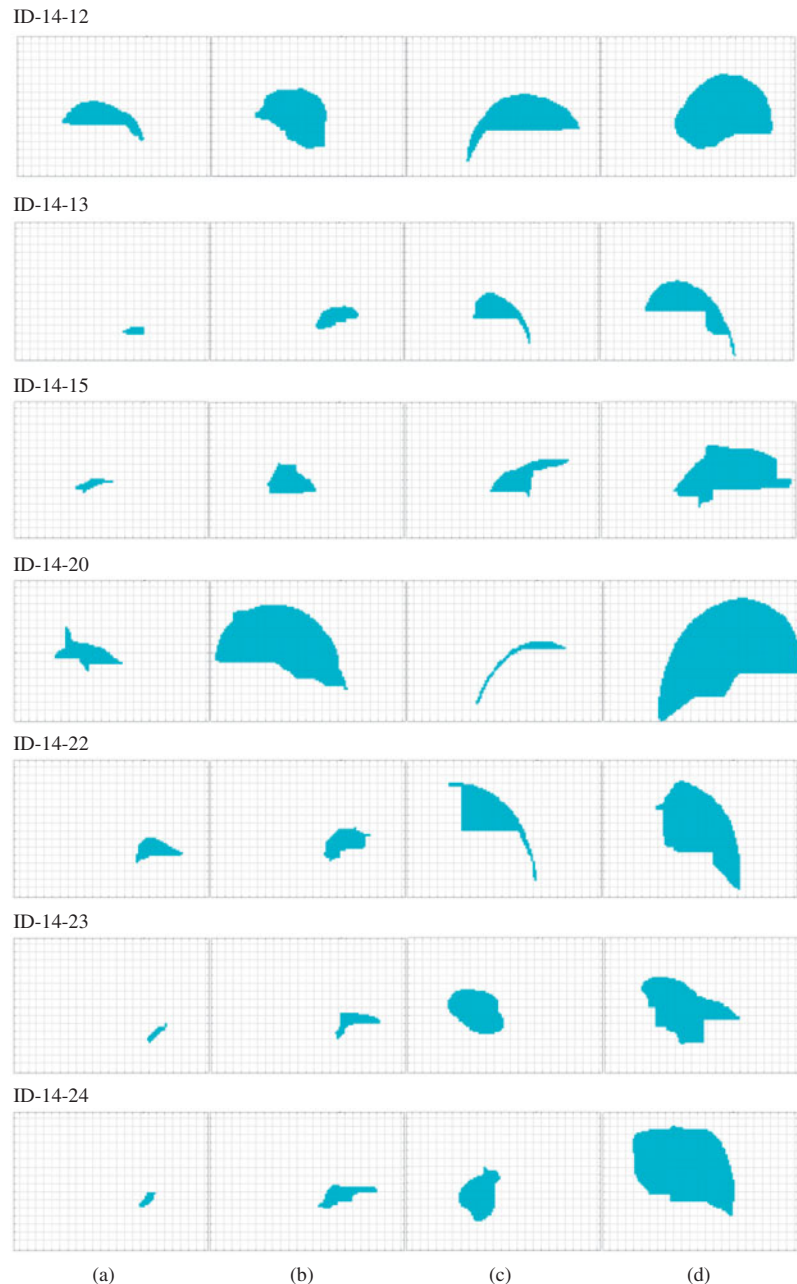
The largest strength improvement for the group undergoing BrightArm Duo therapy was a 9.5 N increase in power grasp. In comparison, participants in the prior BrightArm study averaged a slightly higher 12 N grasp strength increase [15]. This difference could be attributed to 18 therapy sessions in the BrightArm study versus 16 in the current study. The results are fairly similar

considering that at baseline only three of the seven participants in the current study registered any grasp strength at all, whereas four of five participants who had no grasp ability at baseline in the prior BrightArm study. Improvements in grasp strength were also observed in an earlier study involving four chronic stroke patients who trained on the Rutgers Arm, a precursor system to the BrightArm [17]. In another study, 10 subjects with multiple sclerosis, trained on the Armeo Spring (Hocoma AG, Zurich, Switzerland) for half-hour sessions, three times/week, for eight weeks [34]. These participants improved in arm function, but had no significant increase in muscle strength.

The greatest range of motion improvement for the BrightArm Duo study was 14.6° in shoulder extension for the affected arm which is higher than the minimal clinically important difference of 8° for the shoulder [35]. This is slightly better than the prior BrightArm study where a mean of 13° increase in shoulder extension was reported [15].

In the current BrightArm Duo study, the CAHAI improved by 2.1 points or 18% with a  $p$  value at the threshold of statistical significance ( $p = 0.05$ ). In another study, two subjects chronic post-stroke trained in virtual reality executing bimanual tasks using the YouGrabber system [36]. The intensity of training was higher than in this study, namely, 20 rehabilitation sessions over 4 weeks. The subjects' paretic arm performed 5478 and 9835 grasps, respectively, resulting in CAHAI score improvements of 4 and 13 points, respectively for the two subjects. While YouGrabber did not provide strength training, the researchers noted improvements in ADLs which were maintained at 12 weeks post-therapy.

Figure 5. Supported arm reach baseline of seven SNF residents chronic post-stroke for affected arm: (a) pre-therapy and (b) post-therapy, and for unaffected arm: (c) pre-therapy and (d) post-therapy. Areas ranged from a minimum of  $42\text{ cm}^2$  for an affected arm pre-therapy (ID-14-23) to maximum of  $3648\text{ cm}^2$  for an unaffected arm post-therapy (ID-14-20). © Bright Cloud International Corp. Reprinted by permission.



One explanation for the larger CAHAI gains in the YouGrabber study is the younger subjects (mean age 58) compared to the SNF residents in experimental group (mean age 70).

FMA scores improvement in the BrightArm Duo study was statistically significant, but fairly modest at 1.5 points. The prior BrightArm study on five post-stroke individuals posted a mean gain of 4.4 points.

### Emotive and cognitive gains

There was general improvement in the emotive state of the participants following the BrightArm Duo therapy. The mean BDI-II score dropped by 40%, which translated in a 3.1 point improvement. By comparison, the mean BDI-II score in the BrightArm study improved by 30%, or 2.6 points reduction on the BDI-II test.

For the seven participants in the BrightArm Duo intervention, verbal attention and working memory improved on average by a statistically significant 1.6 points (120% improvement over the initial value). There was a more modest improvement of 0.6 points or 30% in visual attention. By comparison, the prior

BrightArm study saw modest gains in verbal attention and strong results in the area of visual attention/focusing. This is consistent with study results that showed there were statistically significant improvements for the group playing video games which trained in 3D over popular 2D brain training games in the areas of spatial perception and skill persistence [37].

The experimental group realized improvements in memory (BVMT-R) by 4.3 points, translating to a 70% gain. There was more modest 26.6 second improvement (10%) in set shifting time (TMT-B). This is consistent with a study on 72 undergraduate students that found time spent playing video games was a predictor of improved visual memory [38]. Another randomized study of 36 elderly SNF residents showed significant improvement on memory tests when the participants were exposed to 3 months of intensive virtual reality training followed by 3 months of periodic booster sessions [39].

### Conclusions

BrightArm Duo is an advanced computerized training table that provides integrative bimanual rehabilitation using custom virtual

rehabilitation games. Like its BrightArm predecessor, the system supports weak arms, gradates gravity loading by tilting the work surface, is wheelchair accessible and stores performance data on a remote server. The new system introduced simultaneous training of both arms, increased measurement accuracy of arm movements and improved real-time grasp sensing for dual-task training. The expanded library of games automatically adapted to each participant, and games were winnable even with a minimal level of cognitive or motor function.

The BrightArm Duo trial on seven residents of two SNF who were chronic post-stroke showed clinical benefits in the motor, emotive and cognitive domains, as well as good technology acceptance by the participants. A limitation of this study is the small sample size ( $n=7$ ), due to recruitment difficulty in SNFs. Another limitation is the lack of imaging studies to determine if brain plasticity was induced by the experimental training intensity.

Despite the small sample size of the group, the NAB Digit Span Backwards finding was very robust and suggested there was a large impact on attention/working memory following training on the BrightArm Duo system.

The above results bode well for the second part of the study, namely, the use of BrightArm Duo as a maintenance system in SNFs. This second study component is a longitudinal study currently underway, where the control group will be clinically evaluated at set periods of time and compared with the experimental group that will have periodic booster sessions on the BrightArm Duo.

### Acknowledgements

Abby Eisner OT performed the motor evaluations. Daniel Saldana performed the cognitive and emotive evaluations. Pooja Joshi OT and Melissa Langewisch OT trained the participants.

### Declaration of interest

Gregory House, PhD, is CTO of Bright Cloud International Corp (BCI). Grigore Burdea, PhD, is inventor on a patent related to the technology described in this article. His is majority shareholder of BCI. Kevin Polistico is a full-time employee of BCI, Doru Roll is a part-time employee and shareholder of BCI, Jay Kim has been an intern of BCI and Namrata Grampurohit is a part-time employee of BCI. Frank Damiani, MD, is Administrator and Director of Medical Care of Roosevelt Care Center, a Skilled Nursing Facility in which the study took place. Samantha Keeler is Director of Quality & Service Delivery for JFK Hartwyck Nursing & Rehabilitation Centers, a second Skilled Nursing Facility in which the study took place. Jasdeep Hundal, PsyD, is President of Hundal Neuropsychology Group LLC. Simcha Pollack, PhD, President of Data Drive Innovation, performed bio-statistical analysis. Research reported here was made possible by grant 9R44AG044639-02A1 from the National Institute on Aging/NIH. Permission to publish photos has been given by the subjects as part of the consent process for the study. However subject names cannot be divulged due to privacy rules in the US, as imposed by our IRBs.

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