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Original Research

The Critical Period After Stroke Study (CPASS) Upper Extremity Treatment Protocol

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List of abbreviations: ACS, Activity Card Sort; ADL, activity of daily living; ARAT, Action Research Arm Test; CPASS, Critical Periods After Stroke Study; RCT, randomized controlled trial; UE, upper extremity.

Trial registration number: https://clinicaltrials.gov/ct2/show/NCT02235974.

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KEYWORDS
Clinical Trials as topic;
Occupational therapy;
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Upper extremity

Abstract *Objective:* To present the development of a novel upper extremity (UE) treatment and assess how it was delivered in the Critical Periods After Stroke Study (CPASS), a phase II randomized controlled trial (RCT).
Design: Secondary analysis of data from the RCT.
Setting: Inpatient and outpatient settings the first year after stroke.
Participants: Of the 72 participants enrolled in CPASS (N=72), 53 were in the study groups eligible to receive the treatment initiated at ≤30 days (acute), 2-3 months (subacute), or ≥6 months (chronic) poststroke. Individuals were 65.1±10.5 years of age, 55% were women, and had mild to moderate UE motor capacity (Action Research Arm Test=17.2±14.3) at baseline.
Intervention: The additional 20 hours of treatment began using the Activity Card Sort (ACS), a standardized assessment of activities and participation after stroke, to identify UE treatment goals selected by the participants that were meaningful to them. Treatment activities were broken down into smaller components from a standardized protocol and process that operationalized the treatments essential elements.
Main Outcome Measure(s): Feasibility of performing the treatment in a variety of clinical settings in an RCT and contextual factors that influenced adherence.
Results: A total of 49/53 participants fully adhered to the CPASS treatment. The duration and location of the treatment sessions and the UE activities practiced during therapy are presented for the total sample (n=49) and per study group as an assessment of feasibility and the contextual factors that influenced adherence.
Conclusions: The CPASS treatment and therapy goals were explicitly based on the meaningful activities identified by the participants using the ACS as a treatment planning tool. This approach provided flexibility to customize UE motor therapy without sacrificing standardization or quantification of the data regardless of the location and UE impairments of participants within the first year poststroke.

Most (~80%) of the individuals with stroke experience some impairment of the upper extremity (UE).[1] Occupational (OT) and physical therapies (PT) are the primary treatments to address UE problems; however, an effective treatment protocol has not been established.[2–8] Stroke rehabilitation randomized controlled trials (RCTs) have examined timing, dosing, and content of UE treatments early (eg, ≤9 months post)[2,5,8–15] and later (eg, ≥9 months post)[2,16–19] poststroke and have shown variable outcomes.[2–5,8,9,10,11,14,15,17,20] Consequently, people with stroke are left with lasting UE impairments leading to persistent long-term disability.[6,7,21–25] Thus, there is still a compelling need for more effective UE motor treatments poststroke.[11,26,27]

The EXCITE[13] and VECTORS[9] trials laid the foundation for recent studies of UE recovery poststroke.[28] Findings from these trials indicate that dose and timing of UE training influences motor recovery. The Critical Periods After Stroke Study (CPASS) expanded upon these findings; however, it differed because it examined if there was an optimal time, or critical period, for intensive UE motor training poststroke.[28] Participants in 3 of the 4 study groups received an additional 20 hours of intensive, task-specific, UE motor therapy based on self-selected, meaningful, daily activities using principles from rodent motor recovery literature[29–32] and recent stroke rehabilitation trials.[9–11,13,16] The CPASS study demonstrated that persons with stroke were preferentially more responsive to intensive UE motor therapy when it was initiated within 1-3 (acute and subacute groups) months poststroke compared with the control group that received prescribed, standard OT and PT.[28] These findings provide preliminary evidence that the CPASS treatment was an effective UE motor intervention poststroke. Therefore, targeted efforts need support translation of the treatment into future stroke rehabilitation trials and real-world clinical practice.

This study was a secondary analysis of data collected from the CPASS RCT.[28] The aims were to (1) describe the development of the principles, processes, and core elements of the CPASS treatment and (2) evaluate the feasibility (eg, content) of delivering the treatment in a variety of clinical settings and the influence of contextual factors (eg, treatment session duration and location) on adherence when the treatment was delivered to the 3 study-related treatment groups in the CPASS RCT.

Methods

Overview

CPASS was a phase II, single-blind, 4-group, RCT.[28] Three study groups received an additional 20 hours of UE motor training initiated at ≤30 days (acute), 2-3 months (subacute), or ≥6 months (chronic) poststroke.[28] Details of the trial design, inclusion criteria, and measurements have been reported.[28] The trial was approved by the MedStar-

Georgetown University IRB. Recruitment occurred between 2014 and 2018 at MedStar National Rehabilitation Hospital (NRH), an inpatient rehabilitation facility (IRF), potential participants provided informed consent.

Participants

Individuals were enrolled ≤28 days onset of an ischemic or hemorrhagic stroke (confirmed by neuroimaging), with mild to moderate UE motor impairment,[33–35] and minimal cognitive impairment (score of ≤10 on the Short Blessed Test).[36] After the baseline assessments, participants were adaptively randomized into 1 of 4 study groups based on the participants age, stroke type, stroke severity, motor capacity (Action Research Arm Test [ARAT] score),[37,38] days since stroke onset, and hand dominance in order to maintain equivalence on these variables at baseline among the groups. The final study cohort included 72 individuals (n=53 in the treatment groups, n=19 control group),[28] the retention rate was 97%.[28]

Procedures

The CPASS treatment protocol was developed by an interdisciplinary team including a stroke neurologist (A.W.D.), an experimental psychologist (D.F.E.), an OT (J.B.), a PT (K.B.), and a motor system neuroscientist (S.G.). A standardized protocol and process was designed to deliver the CPASS treatment. The length and location of treatment sessions varied to account for participant differences in activity tolerance, scheduling availability, and discharge disposition among the groups. CPASS therapy was started as close as possible to the first day of the group-specific (time post-stroke) treatment window and ended within 42 days of the first session.[28]

Outcome measures

Participants completed primary and secondary assessments at baseline, pre- and post-treatment, 6-month, and 1-year timepoints. Trained PTs blinded to the treatment group performed the motor assessments.[28] Table 1 includes selected measures and variables to describe participants' UE capacity, stroke severity, and treatment sessions.

CPASS treatment protocol

Overview

The design of the CPASS UE treatment included the motor learning principles from rodent studies of critical period neuroplasticity after stroke[29,44–51] and it incorporated evidence supported neurorehabilitation principles of massed practice,[30–32,52] dose/duration,[27,30,31,53,54] task-specific practice,[27,30–32,55] increased difficulty,[27,31,53,54] explicit feedback and knowledge of results,[30,52,56] and psychological theories of intrinsic motivation.[55,57–65] It used a single modality: shaping,[47,48] which involved sequential motor training where a new behavior is learned in progressive steps.[48] Treatment focused on shaping tasks based on graded functional activities that were selected by the participants to improve their functional independence and to facilitate their participation in their desired meaningful daily activities.[66,67] A standardized protocol and process was designed to operationalize the essential core elements of the protocol for fidelity and reproducibility.

Figure 1 presents the CPASS specific shaping procedures including: top-down activity-analysis and grading,[68–71] massed practice,[51,72,73] positive reinforcement,[45,47,50,74] and intrinsic motivation,[46,48,70] and table 2 presents the operationalization of the essential elements. Figure 2 presents the dynamic and iterative therapeutic process used to deliver the treatment, and figure 3 presents an example of how an activity was broken down into sub-categories and tasks from a top-down, hierarchical approach.[12,69,75] A detailed example of one Activity Card Sort (ACS) treatment activity is provided in Supplementary Appendix A.

Analysis

A per-protocol approach was used for this analysis and all data were analyzed in R (Version 4.0.1).[a] Participants were included in the analysis if they met the following criteria for adherence to the CPASS treatment defined as completion of ≥15 hours of study-related therapy within 42 days of the first session.[28] Feasibility (ie, UE activities practiced or content) of delivering the treatment to participants in the three study groups and contextual factors that influenced adherence were assessed by treatment session durations, locations, and the number UE activities practiced by participants across the study groups. Continuous variables are presented as means and standard deviations (SD) when normally distributed, or by medians and ranges if skewed. Categorical variables (treatment location and activities) are presented relative to the percentage of therapy hours. One-way ANOVAs were computed to determine treatment group differences on the critical variables. If the overall F-ratio was significant, Tukey HSD post hoc[76] tests were calculated to examine pairwise differences between treatment groups. An a priori criteria of $P \leq .05$ was used to determine significance.

Results

Participants

A total of 49 participants (92%) in the three study groups adhered to the CPASS treatment (≥15 hours) and are included in this analysis. Figure 4 presents the adapted CONSORT diagram which highlights those excluded. Table 3 includes the demographics and baseline and pre-treatment clinical characteristics of the participants included in the present analysis.[28] Participants were randomized into treatment groups at 15.1±4.4 days poststroke, all participants had poor to limited UE capacity[77,78] (ARAT=17.2±14.3) at baseline and participants in the subacute (ARAT=32.0±17.0) and chronic (ARAT=41.2±18.1) groups had limited UE capacity at the pre-treatment assessment.[77]

Duration of treatment sessions

Table 4 presents the median and ranges treatment session duration variables. The total sample required 11.2±2.6

Table 1 CPASS treatment outcome measures

Outcome Measure	Description	Construct	Scoring/Quantification
Primary and secondary measures			
Action Research Arm Test (ARAT)[37,38]	Standardized measure assessing UE functional ability for activity	UE capacity for activity	Scores ranges from 0 to 57, higher values indicated greater UE function.
National Institute of Health Stroke Scale (NIHSS)[39]	Standardized measure of global stroke severity	Stroke severity	Scores range from 0 to 42, lower scores indicate less severe stroke overall and scores ≥21 indicate severe stroke.
Treatment activities[*]			
Activity Card Sort (ACS)[40–42]	Psychometrically robust, interview-based assessment of activity and participation after stroke. The ACS was modified to include only activities that required UE performance.	Participation	Participants were shown pictures of activities and indicated if it was completed prior to their stroke.
Functional Independence Measure[†] (FIM)[43]	Observer based assessment of level of disability and change in status with rehabilitation.	Level of assistance	NA
Treatment sessions			
Session duration	Treatment session durations were quantified by 1. Total number of sessions 2. Number of days to complete treatment 3. Total session hours 4. Per session length a. Session lengths were quantified in 1-hour increments (eg, 0.25=15 minutes) b. Session length=total treatment hours/total number of treatment sessions		
Session location	CPASS treatment sessions were delivered at 4 locations: 1. IRF at NRH 2. Subacute nursing facility (SNF) 3. Outpatient rehabilitation clinic 4. Participant's home. Transportation was provided for participants to the outpatient research clinic, or the therapists traveled to SNFs and participant's home.		

Abbreviations: FIM, functional independence measure

[*] Participants identified pre-stroke activities from the ACS, UE FIM items, and other items not included in either measure. Participant-selected activities were collapsed into the 4 main categories of the ACS (instrumental, low-demand leisure, high-demand leisure, social) plus a category for ADLs. Other identified UE activities were categorized within 1 of the 5 activity domains by the treating therapist.

[†] UE items: self-feeding, grooming, upper body (UB) bathing, UB dressing, lower body dressing, toileting, and functional transfers. FIM scores are not considered for treatment activities. Participants could add items from the FIM and other activities not.

treatment sessions to complete 20 hours of therapy which differed significantly across the groups ($F_{(2,46)}$=12.4, P<.001). The acute group required more sessions than the subacute (P<.001) and chronic (P<.001) groups. There were no significant differences in the number of treatment sessions between the chronic and subacute groups (P=.90).

The total sample required 32.4±9.7 days to complete 20 hours of treatment which differed across the study groups ($F_{(2,46)}$=3.6, P=.04). The chronic group required fewer days than the subacute group (P=.04) to complete treatment. There were no significant differences in number of days to complete treatment between the chronic and acute group (P=.15) or the subacute and acute groups (P=.90).

The total sample completed 20.0±0.8 hours of treatment, there were no significant differences in the total hours between the study groups ($F_{(2,46)}$=1.4, P=.25). Finally, treatment sessions lasted 1.9±0.4 hours, there were significant differences in the lengths of treatment sessions across the groups ($F_{(2,46)}$=10.5, P<.001). The acute group sessions were significantly shorter than the subacute (P<.001) and chronic (P<.001) treatment sessions. The average time spent in each treatment session was similar for the subacute and chronic treatment groups (P=.99).

Location of treatment sessions

Table 4 presents the locations where the CPASS treatments were delivered, and Figure 5 presents the percentage of

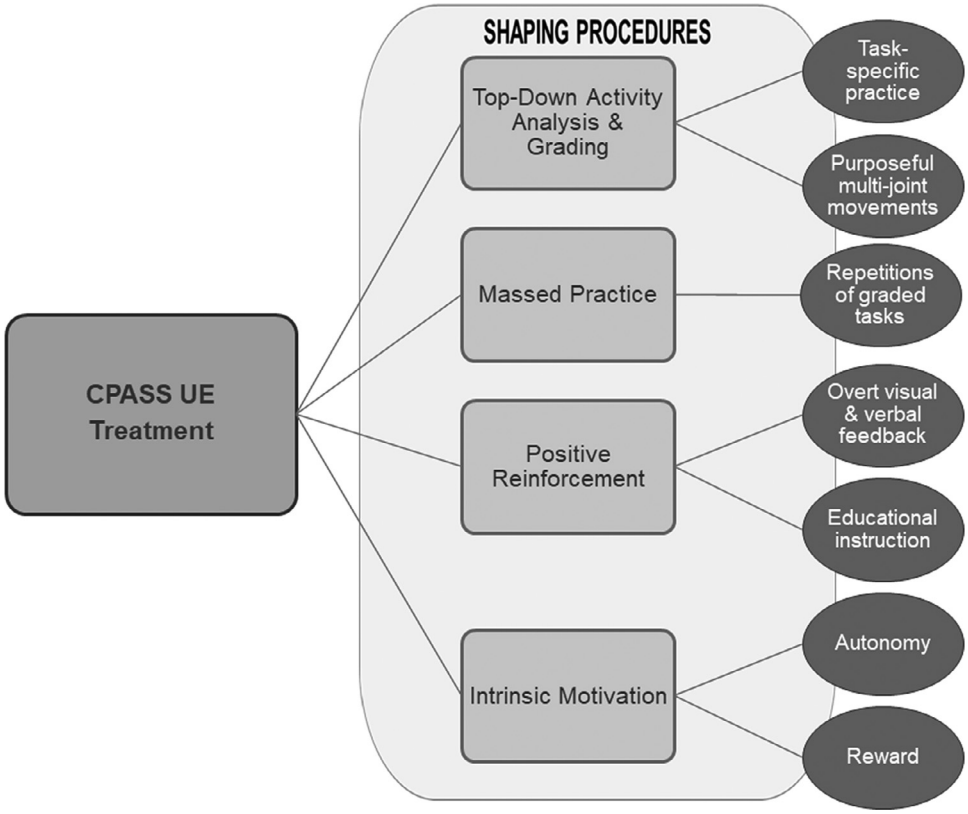

Fig 1 Essential elements of the treatment protocol. Schematic of the essential elements of the treatment protocol used in the CPASS trial. The 4 specific shaping procedures used to deliver the treatment are presented in the middle of the figure and the strategies used to for their operationalization are in the gray circles.

total treatment hours by location and study group. Most therapy hours were delivered in the outpatient clinic, followed by the IRF at NRH, then at participant's homes, and the lowest percent was delivered in a SNF. Across experimental study groups, the subacute group (91%) received most of their treatment hours at the outpatient clinic, while the acute group (56%) had the least. Additionally, 63% of the sample received the treatment at a single location, 33% required 2 locations, and 5% required 3, separate locations.

Treatment activities

Figure 6 presents the categories of UE activities (UE ACS and activities of daily living [ADLs] items) practiced across the study groups as a percent of the total therapy hours. The types of activities practiced during therapy hours varied across the treatment groups. All the treatment groups spent the least percent of treatment hours practicing social activities, such as eating at a restaurant or traveling.

Discussion

This report describes the principles and logistics used to deliver the UE motor treatment in the CPASS RCT. Results demonstrate feasibility to implement the essential elements of CPASS treatment protocol in a variety of clinical settings and the contextual factors that influenced adherence to the treatment in the context of a single-site RCT poststroke in humans.[28] Most (92%) of the participants adhered to the treatment and completed 20 hours of study-related therapy within their group specific treatment window, relative to the time poststroke, in addition to standard rehabilitation therapies. The flexibility and individualization of the treatment protocol may have maximized engagement and motivation for the intensive motor training and treatment processes similar to the reward-based mechanisms of salient reinforcement (eg, food) used in animal models of poststroke motor recovery.[28]

Duration and location of treatment sessions

Delivery of an individualized UE motor intervention in a clinical trial required flexibility of the therapists, participants, and the treatment environment (ie, contextual factors) for adherence.[11,79] We provide the exact breakdown of numbers of treatment sessions and the typical location sites of therapy needed to complete this trial with patients receiving highly personalized and standardized UE rehabilitation. Our findings and the overall success of the CPASS trial can inform clinical trialists and clinicians providing UE rehabilitation within the first year poststroke. Our results suggest that people with stroke, who meet the CPASS inclusion criteria, can tolerate ~90-minute treatment sessions. However, the acute group required more sessions of shorter durations compared with the subacute and chronic groups, likely due

Table 2 Operationalization of the essential elements of the CPASS treatment protocol

Essential Element of Protocol	Operationalization
Individualized treatment goals	Timing: Pre-treatment assessment, before the first session Step 1: • Participants were informed by the therapist that their treatment would be guided by daily activities that they wanted to work on. • The therapist administered the ACS that was modified to include only UE activities (n=65). • Participants were shown pictures of the UE ACS activities and were asked if each activity was completed before their stroke (Yes/No). • Participants added any additional UE items such as: ○ UE FIM items (e.g., upper body bathing) ○ Other UE activities (e.g., medication management) Step 2: • Participants identified and ranked their top 10 most important pre-stroke activities. • This list of top 10 activities was reviewed at the start of each treatment session to determine which activity(ies) to practice.
Identification of shaping tasks from individually selected activities	Timing: At the start of each treatment session and as completion, regression, or advancement of tasks occurs. Step 1: • From the top 10 activity list, the therapist and participant collaborated to determine the appropriate complexity, practice order, and level of UE challenge for that session. • Once an activity was agreed upon, the participant attempted to complete the whole activity, regardless of complexity. Step 2: • For each activity, therapists completed a detailed tasks analysis to break the chosen activity into a series of progressively more difficult tasks or steps. ○ The participants provided information about how an activity was performed prior to their stroke including: □ the environment (e.g. kitchen or bathroom) □ their position (e.g. sitting or standing) □ the materials (e.g. type of trash bag or height of trash can) used to complete the activity. • Activities were broken down into sub-categories and tasks from a top-down hierarchical approach (Figure 3). Step 3: • The therapist deconstructed (broke down) the activity sub-categories through observation and task-analysis skills into tasks that targeted a specific joint and motion impairment that affected successful task completion. ○ The portions of the activity that were limited by joint and movement impairments became the shaping tasks which were the targets for therapy. Step 4: • Activities were replicated using the exact items from home if possible. ○ For example, if a participant wanted to chop vegetables, they were encouraged to bring in their own kitchen items and the therapist purchased vegetables for that session. • Tasks were simulated with objects available in the treatment setting as needed.
Task analysis and grading to progress treatment	Timing: During each treatment sessions, for each shaping task. Step 1: • Therapists adjusted aspects of the treatment activity to make it more/less difficult within the activity set-up. • Shaping tasks challenged UE movements in need of improvement but were feasible given the participant's UE impairments. • Shaping tasks were graded either more or less difficult by changing the objective and one quantifiable task parameters that included: 1. participants' position 2. position of the material 3. height, weight, speed, or size of material or object

(*continued*)

Table 2 (*Continued*)

Essential Element of Protocol	Operationalization
	• Grading methods remained constant throughout the task and session until the task was advanced, regressed, or completed. Step 2: • A task was completed if a participant performed two sets (one set = 10 repetitions) of the task within either: ○ the chosen parameter (e.g., weight, time, or height) ○ equal performance compared to the non-affected UE. • Regression occurred if a task was impacted by pain, lack of range of motion, or lack of strength. Step 3: • Problem areas that limited UE performance were addressed with different shaping tasks that targeted multiple impairments and motions of affected limb. • Learning was demonstrated when they could perform the task in different contexts. Step 4: • If an activity was mastered, the therapist challenged them by changing the activity context (i.e., folding clothes in a seated position to a standing position).
Integration of massed practice and positive reinforcement	Timing: During each treatment session, for each shaping task. Step 1: • Multiple repetitions were built into graded steps to meet the levels needed for motor learning that facilitated progression towards the successful performance of the desired whole activity. • Therapists determined the optimal number of sets needed to provide sufficient repetitive practice while guarding against fatigue and frustration. Step 2: • The shaping tasks were reinforced by positive feedback from the therapist and the satisfaction felt by the participant when they used their impaired hand or arm to perform a component of a desired activity. • CPASS therapists used different approaches for positive reinforcement: 1. Verbal feedback: ○ "great job" ○ "that reach was much better" 2. Visual feedback: ○ video recording to show the participant their motion during the task performance. 3. Educational instruction about task performance: ○ Is a step further than verbal or visual feedback. □ it provided information about the quality of movement observed during task performance. □ explicit information about how to improve the task performance.

to their inpatient rehabilitation status that necessitated frequent breaks likely because of poststroke fatigue[80–82] and the required ≥3 hours of daily inpatient therapy. Whereas participants in the subacute and chronic groups completed longer sessions, thus requiring fewer sessions over fewer days.

The design of stroke rehabilitation treatment trials need to accommodate the typical course of poststroke care as patients discharge across settings (ie, contextual factors). We found that the CPASS treatment could be effectively delivered at multiple locations depending on the study group (time poststroke). Most of the participants received the treatment at a single location (63%). Most of the participants (94%) in the acute group required 2 or 3 locations, fewer participants in the subacute (18%) and chronic (5%) study groups required 2 locations. Future, poststroke trials should budget and plan for treatments to follow study participants after discharge from acute care or inpatient rehabilitation and include the costs of transportation needed to bring participants to an outpatient rehabilitation treatment setting.

Treatment activities

Beginning treatment with a modified version of the ACS, prompted a dialog between the therapist and participant to efficiently select and prioritize UE treatment goals from complex, daily activities that aligned with their individual, functional needs and priorities.[83,84] In the CPASS treatment, we used the ACS, to drive the design of the intensive motor training. This is the first stroke rehabilitation trial that we know of to base the design of the treatment on the individual activity, participation needs, and preferences of the study participants.[51] UE rehabilitation after stroke is the

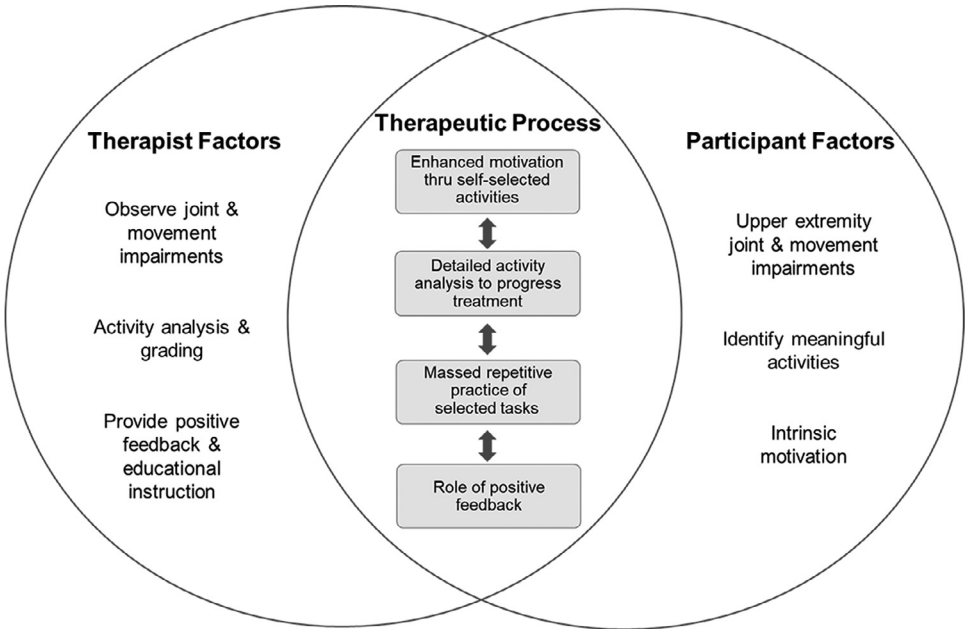

Fig 2 Process to deliver the treatment protocol. Schematic of the dynamic, iterative process used to deliver the CPASS treatment protocol. A standardized and individualized approach was designed that accounted for the therapist and participant factors that gave rise to a highly collaborative therapeutic process. The double-headed arrows reflect the fluidity between each and all steps.

most effective when the therapeutic interventions are individually tailored to reflect each person's unique goals and priorities and help to maximize participation and activity engagemnt.[85] This presents a huge challenge when designing a feasible, protocol-driven approach to treatment in RCTs, which demands both standardization and quantification.[79,86–88] In the CPASS study, the activities selected by participants varied; however, the approach to the treatment was standardized to be reproducible across therapists. The results of this analysis demonstrate feasibility of the CPASS treatment and show that when participants can select their goals for UE therapy, they will choose activities across all 5 domains (UE ACS items and ADLs) regardless of their impairments or time poststroke. In the United States, the current standard delivery of post-acute stroke care has led to OTs/PTs beginning interventions to reduce UE impairments around 3-6 months of stroke and can extend into the chronic phase, when recovery plateaus.[89,90] Typically, time poststroke, rehabilitation setting, and the reimbursement mechanisms have substantial influence on therapy goals.[91] When individuals are hospitalized, therapy goals and the interventions delivered to patients can often be influenced by length of stay restrictions rather than the needs or preferences of the individual.[91–93] As a result, therapy goals tend to target

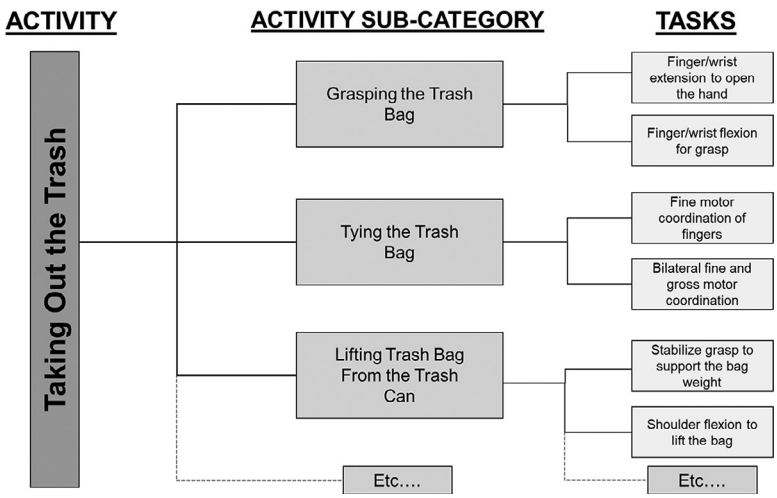

Fig 3 Identification of shaping tasks from an ACS activity. Example of how one ACS instrumental activity, "taking out the trash," was broken down into sub-categories and shaping tasks from a top-down, hierarchical approach after observation of task performance and collaboration between the therapist and participant. The sub-categories were deconstructed into shaping tasks that targeted a specific UE joint and motion impairment. Of note, the activity sub-categories and tasks varied across participants based on their individual goals and UE problems.

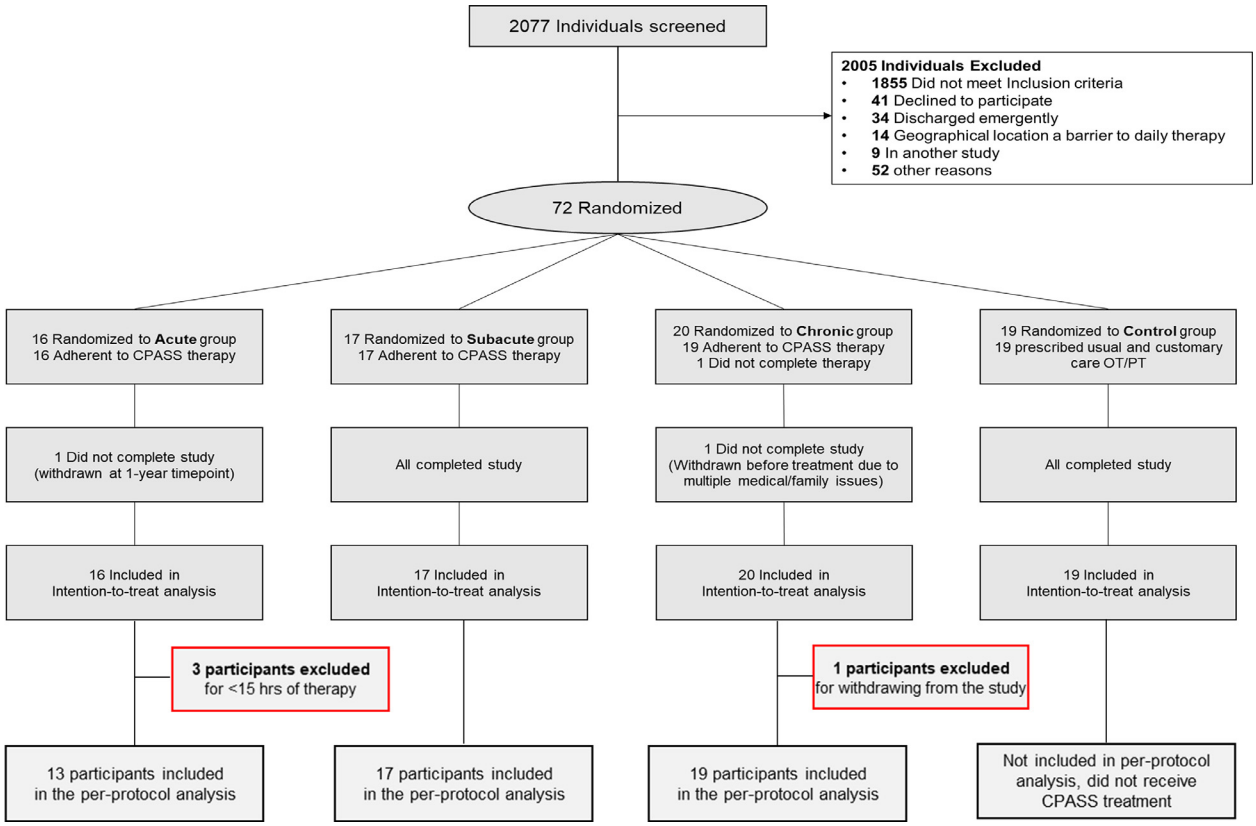

Fig 4 Adapted CORSORT diagram of the per-protocol analysis. CONSORT diagram from the CPASS trial that has been adapted for this analysis. In the CPASS RCT, participants in 3 of the 4 study groups received an additional 20 hours of UE motor training initiated at ≤30 days (acute), 2-3 months (subacute), or ≥6 months (chronic) poststroke. In this per-protocol analysis, participants were excluded if they completed ≤15 hours of CPASS treatment within 42 days of their treatment start date. The boxes with red outlines toward the bottom of the figure highlight the participants excluded from the per-protocol analysis. Excluded participants were from the acute (n=3) and chronic (n=1) study groups. The acute group participants were unable to complete the study-related treatment due to factors unrelated to the treatment and the chronic participant withdrew from the study after baseline assessments. The number of participants included in the pre-protocol analysis from each of the study groups are presented in the gray boxes at the bottom of the figure.

maximizing independence with ADLs and functional mobility to prepare for discharge to the next level of care.[91–93] In the CPASS study, all of the study groups spent most of their UE therapy practicing instrumental activities (eg, cooking dinner or laundry); however, the next most practiced activities were very different across the groups. Interestingly, across the study groups, 60% of the total therapy time was spent practicing a combination of ADLs and low- and high-demand leisure activities, while <10% of time was allocated to social activities. We believe that allowing participants to self-select their preferred UE treatment activities for shaping procedures may have maximized engagement, motivation, and potentially provided a sense of autonomy and reward for the participants within each of the study groups (and notably, time poststroke). The CPASS treatment challenged current approaches to UE therapy by focusing on the participants preferred activities to create the treatment goals. Future UE rehabilitation trials can further challenge the delivery of rehabilitation services with this approach by providing more treatment around the time when patients typically discharge home in the current system.

The CPASS treatment also empowered the study therapists to fully use their expertise in motor learning and behavioral self-management techniques to promote self-determination of the participants through choice, control, and self-monitoring enabling adherence to the treatment.[60,61,65,94–96] Here, the ACS was used to identify UE treatment goals which grounded the therapy in complex, meaningful, daily activities, such as cooking dinner or fishing rather than smaller components of associated functional tasks (eg, chopping vegetables or putting a line on a fishing reel) limited by the UE impairment. The top-down, activity-analysis, and grading systematically breakdown complex activities into treatment tasks that targeted a single joint and movement while maintaining the focus on activity-based outcomes.[69] Additionally, therapists used positive reinforcement coupled with educational instruction about task performance to provide feedback to participants. Combining these approaches may have resulted in motor learning that is more likely to be sustained over time,[45] with an increased probability of behavioral responses,[29,65,45] and behavioral change promoted through self-management.[97] Therefore, positive verbal feedback combined with personalized education about task performance from therapists was essential to the success of the shaping process which focused on facilitating specific and consistent motor movements through repeated practice of

Table 3 Participant demographics and characteristics on baseline study measures

	Combined sample in treatment groups (N=49)	Acute (n=13)	Subacute (n=17)	Chronic (n=19)
*Demographics**				
Age (years)	65.1 ± 10.5	63.1 ± 10.9	63.9 ± 10.8	67.4 ± 10.1
Sex (female)	27 (55)	10 (77)	6 (35)	11 (58)
Race				
Caucasian	7 (14)	1 (8)	2 (12)	4 (21)
African American	40 (82)	12 (92)	14 (82)	14 (74)
American Indian, Alaskan	2 (4)	0	1 (6)	1 (5)
Asian	0	0	0	0
Native Hawaiian, Pacific Islander	0 (0)	0	0	0
Dominant UE affected	23 (47)	7 (54)	8 (47)	8 (42)
Stroke type				
Ischemic	46 (94)	13 (100)	17 (100)	16 (84)
Hemorrhagic	3 (6)	0	0	3 (16)
Baseline and pre-treatment information				
Total NIHSS Baseline	4.6±1.8	4.5±1.9	4.9±2.1	4.5±1.5
Total ARAT Baseline	17.2±14.3	14.3±14.4	13.4±11.4	21.3±15.6
Total ARAT Pre-Treatment	30.9±19.7	14.3±14.4	32.0±17.0	41.2±18.1
Days from stroke onset to randomization	15.1±4 .4	15.1±4.2	14.8±4.6	15.4±4.5

* Demographics of participants who adhered to the CPASS treatment for the combined sample in the treatment groups and per each study group. Categorical variables are shown as counts and percentages, continuous variables are described using means and standard deviations.

Abbreviations: ARAT= Action Research Arm Test; NIHSS=National Institutes of Health Stroke Scale.

Table 4 Characteristics of CPASS treatment sessions

Treatment Session Duration	Total (N=49)	Acute (n=13)	Subacute (n=17)	Chronic (n=19)
Total sessions (n)	11.2±2.6 (6–19)	13.8±3.1 (10–19)	10.4±2.3 (6–16)	10.1±0.8 (9–12)
Days to complete treatment (n)*	32.4±9.7 (11–55)	34.3±8.1 (20–52)	35.8±11.4 (17–55)	28.1±7.7 (11–39)
Total session hours (hrs)	20.0±0.8 (9.5–22)	19.8±1.1 (9.5–21.25)	20.1±2.0 (19.125–20.5)	20.2±0.7 (19.125–22)
Per session length (hrs)†	1.9±0.4 (0.25–3.2)	1.5±0.4 (0.25–2.0)	2.0±0.5 (0.25–4.75)	1.9±0.1 (1.00–3.5)
Location participants received the intervention‡				
Inpatient Rehab Facility (IRF)				
% of therapy	10%	32%	0%	0%
Total therapy hours	94.1±0.1	94.1±0.1	0	0
Subacute Nursing Facility (SNF)				
% of therapy	2%	0%	0.5%	6%
Total therapy hours	21.3±0.1	0	1.3±0.1	20.0±0.1
Outpatient				
% of therapy	80%	56%	91%	88%
Total therapy hours	814.3±0.2	166.5±0.1	310.5±0.1	337.3±0.2
Home				
% of therapy	9%	12%	8.5%	6%
Total therapy hours	92.4±0.2	36.3±0.2	29.3±0.1	27.0±0.1

NOTE. Treatment session durations and locations. Treatment session durations present the mean ± SD and ranges of the variables used to quantify the treatment sessions for the whole sample and per study group. Values are counts, days, and hours. The treatment locations (lower portion of the table) provides information on the location each participant received the CPASS intervention. Treatment location is analyzed as a function of total therapy hours delivered within each location for the total sample and per treatment group. Values are hours and %. The % of therapy hours is relative to the total hours of therapy completed by that group.

* Number of days to complete treatment was the difference between the treatment end and start dates.

† Individual session lengths were the total session hours divided by the number of treatment sessions.

‡ Participants received the treatment at as many locations as needed to adhere to 20 hours of therapy.

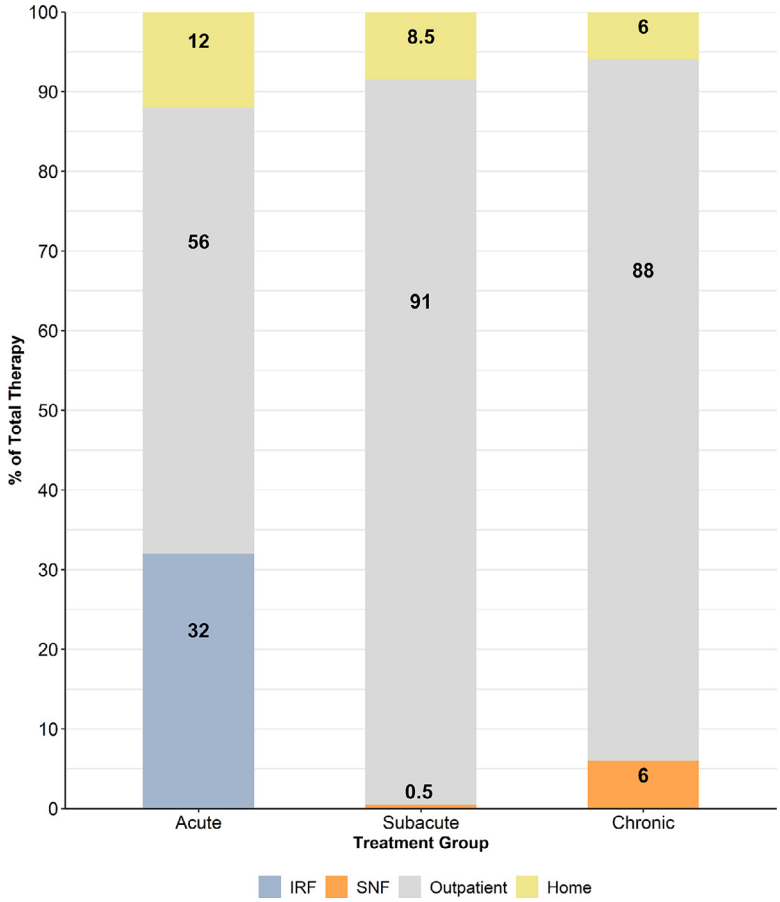

Fig 5 Percentage of total session hours delivered at the different locations. Each bar shows the percentage of session hours delivered at the inpatient rehabilitation facility (IRF), skilled nursing facility (SNF), outpatient research lab, or the participants' home for the study groups. NOTE. Subacute participants received zero hours at the IRF and 0.5% of total session hours were delivered at a SNF.

graded tasks.[60,65,98] With these approaches, participants gained an understanding of how the shaping activities used to progress the treatment emphasized purposeful, goal-directed movements that were associated with their identified UE goals.[65,91,92,99] Thus, the therapeutic process used to deliver the CPASS treatment provided the required flexibility and customization of therapy without sacrificing standardization or quantification.[79,86,88]

Limitations

There were limitations in the current study to consider when interpreting these results. First, the treatment was designed and delivered by a small group of study therapists at a single institution. Future pragmatic trials are needed to test the CPASS treatment in new groups of therapists (providers) across traditional stroke rehabilitation settings.[66,67,100] Second, participant retention (97%) and adherence to the CPASS treatment (92%) were high. However, because adherence was quantified by a total number of hours (≥15 hours), the optimal dose or intensity of therapy was not tested. Future studies are required to determine the optimal dose of the CPASS treatment to provide more information about the interaction between the timing and intensity of treatment. Despite these limitations, the CPASS study treatment provided a standardized yet highly individualized progressive UE motor intervention.

Conclusions

The CPASS treatment provided flexibility to customize therapy without sacrificing standardization of procedures, quantification of data, or intensity across groups, regardless of the location, time after stroke, and stroke severity.[26,67] The UE protocol designed for the CPASS RCT represents a philosophical and methodological shift from an impairment-driven to an activity-focused treatment. Future trials will need to build on the results of CPASS in a larger, multi-site trial, with an expanded range of inclusion criteria to determine if the effects are sustained and to further develop and implement the training and procedures needed to move the intervention from the research setting to more traditional stroke rehabilitation environments.

Suppliers

a. R Version 4.0.1; R Foundation for Statistical Computing.

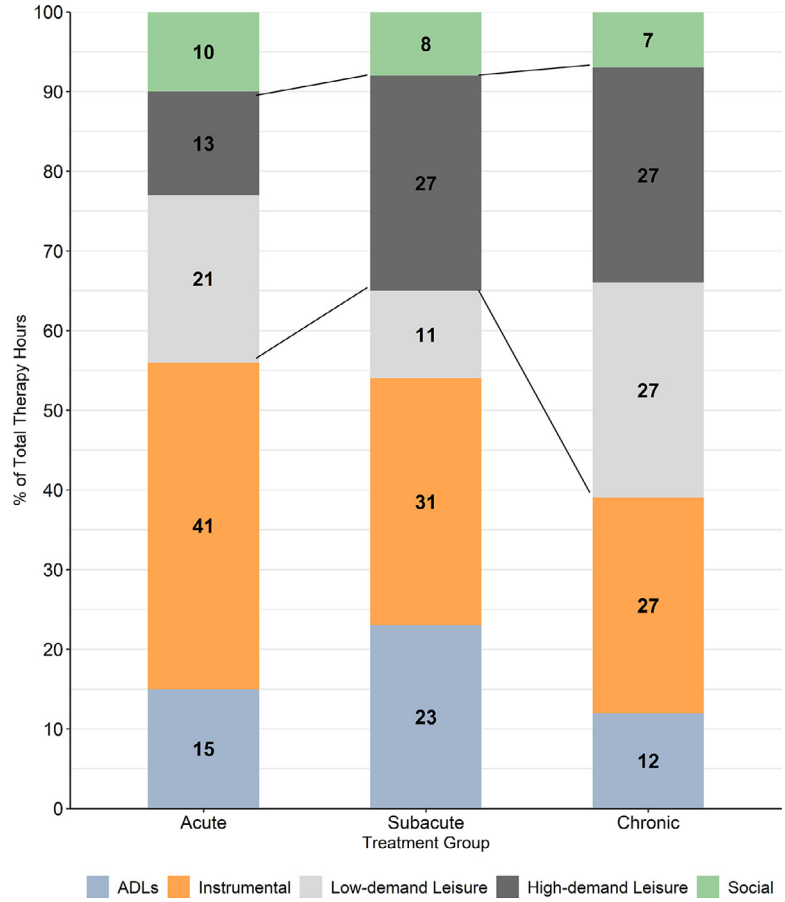

Fig 6 Percentage of total session hours training across the 5 activity domains. Each bar shows, as a percent, the total session hours spent by the acute, subacute, and chronic groups training activities within the different domains including ADLs, instrumental, low-demand leisure, high-demand leisure, and social domains of the ACS.

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