Socially Assistive Robot for Stroke Rehabilitation: A Long-Term in-the-Wild Pilot Randomized Controlled Trial

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Abstract—Socially assistive robots (SARs) have been suggested as a platform for post-stroke training. It is not yet known whether long-term interaction with a SAR can lead to an improvement in the functional ability of individuals post-stroke. The aim of this pilot study was to compare the changes in motor ability and quality of life following a long-term intervention for upper-limb rehabilitation of post-stroke individuals using three approaches: 1) training with a SAR in addition to usual care; 2) training with a computer in addition to usual care; and 3) usual care with no additional intervention. Thirty-three post-stroke patients with moderate-severe to mild impairment were randomly allocated into three groups: two intervention groups – one with a SAR (ROBOT group) and one with a computer (COMPUTER group) – and one control group with no intervention (CONTROL group). The intervention sessions took place three times/week, for a total of 15 sessions/participant; The study was conducted over a period of two years, during which 306 sessions were held. Twenty-six participants completed the study. Participants in the ROBOT group significantly improved in their kinematic and clinical measures which included smoothness of movement, action research arm test (ARAT), and Fugl-Meyer upper-extremity assessment (FMA-UE). No significant improvement in these measures was found in the COMPUTER or the control groups. 100% of the participants in the SAR group gained improvement which reached – or exceeded – the minimal clinically important difference in the ARAT, the gold standard for upper-extremity activity performance post-stroke. This study demonstrates both the feasibility and the clinical benefit of using a SAR for long-term interaction with post-stroke individuals as part of their rehabilitation program. *Trial Registration:* ClinicalTrials.gov NCT03651063.

Index Terms—Human-computer-interface, human-robotic-interaction, neurorehabilitation, personalization, upper-limb.

I. Introduction

TO MAXIMIZE recovery of a stroke-affected upper-limb (UL), and to promote training-induced motor cortical representation [1], [2], clinicians should apply intensive, continuous task-specific practice [3], [4], [5], using tasks and tools that are both meaningful and familiar to the person with stroke [6], [7]. Winstein et al. [8] showed that a higher amount of training was correlated with a greater change in the motor activity log (MAL). To date, there is no agreement in the literature on the desired number of repetitions or the intensity of the training that is needed to gain clinical and functional improvements either in the subacute or the chronic stages of stroke [1], [9]. Current evidence shows that in order to achieve improvement in arm function an average of more than 300 repetitions per practice session may be required [9], [10]. Michaelsen et al. [1] and Birkenmeier et al. [9] both showed significant improvement following 15- and 18-session training, respectively, with a one-month follow-up.

Patient cooperation and active involvement in the rehabilitation process are essential for achieving successful rehabilitation results [11] and frequently a lack of motivation may be one of the main reasons for poor rehabilitation outcomes [12]. One of the methods that have been reported to increase motivation and intensity of practice post-stroke was the use of competitive and cooperative gamified tasks either when playing with another person with stroke [13] or when the partner was a healthy individual [12]. This effect may also be achieved by using competitive elements while using rehabilitation robots.

An advantage of rehabilitation robots is that they can be used to help the patient repeat a defined task in a

highly consistent and controllable environment [14]. However, two systematic meta-analysis [15], [16] reported that use of exoskeletons or end effectors often failed in demonstrating improvement in the person's ability to perform activities of daily living (ADL). A multi-centered study that compared three interventions, including robot-assisted training for the UL post-stroke and usual care, reported no difference between the groups in the Action Research Arm Test (ARAT), which was defined as the primary outcome measure [17].

Another type of robots that has been suggested for this purpose is the Socially Assistive Robot (SAR) [18], [19], [20], [21]. According to Fassola & Mataric, "SARs employ hands-off interaction strategies, including the use of speech, facial expressions, and communicative gestures to assist in accordance with the particular healthcare context" [22]. SARs have often been designed as a partner or a coach to assist with a particular activity [18], [19], [20], [21], [23], [24], [25], [26], [27], [28].

The COVID-19 pandemic seemed to boost the incorporation of SARs into medicine [29], and they will likely enter the realm of rehabilitation in the future. Previous works [18], [19], [20], [21], which included one-session training with a SAR, demonstrated the feasibility of such an interaction with post-stroke individuals and laid the foundations for further research in this field. However, one question that remained unanswered to date is whether a *long-term* interaction with a SAR can improve the *functional* ability of individuals post-stroke. To study this, we developed a platform for post-stroke UL rehabilitation which includes seven exercise sets, designed to train reach, grasp, and manipulation of everyday objects. The platform, whose technical details are fully described in [30], has two configurations: one with a SAR and one with a computer. It is designed to complement the individual sessions with the therapist and to assist both the clinician and the patient attain variable repetitions of a task-specific training in an engaging and motivating manner. In previous studies we showed that this platform was accepted by both expert clinicians [25], [26] and post-stroke individuals, [25], [30] as was evaluated by the usability satisfaction evaluation questionnaire (USEQ) [31] and by custom-made questionnaires, as well as in individual interviews [32].

The aim of the current work was to compare the changes in motor and functional ability, as well as self-efficacy, resulting from a long-term intervention for UL rehabilitation of post-stroke individuals using three approaches: (1) training with a SAR in addition to usual care; (2) training with a computer in addition to usual care; and (3) usual care. In this setup, the SAR served as a training coach: it provided instructions to users on the exercises they should perform, and feedback on their success on the task; it also provided encouraging statements. In the computer-based training, identical instructions, feedback and encouraging statements were provided by the computer.

We hypothesized that post-stroke individuals who engage in a long-term intervention with a SAR, compared to an intervention with a COMPUTER, and compared to a CONTROL group with no additional intervention, would show a significant clinical improvement in their motor function as measured by: 1) clinical measures; 2) kinematic measures; and 3) self-efficacy questionnaires.

II. MATERIALS AND METHODS

We conducted the study in-the-wild [33], in the out-patient unit of the "Adi-Negev" Rehabilitation Center. This randomized, parallel trial was conducted at a single site, approved by the institutional Helsinki ethical committee for clinical trials (SMC-5273-2018) and prospectively registered in the NIH ClinicalTrials.gov database (NCT03651063). Participants gave their written informed consent after receiving a detailed explanation of the study.

A. Inclusion/Exclusion Criteria

Inclusion criteria were: (1) First unilateral stroke, confirmed by imaging; (2) age: 18-85; (3) Mini-Mental State Examination (MMSE) score $\geq 24/30$ (for participants $\geq$ 65yrs) [34] or the equivalent Montreal Cognitive Assessment (MoCA) score $\geq$ 23/30 (for participants < 65 yrs) [35]; (4) Fugl-Meyer Upper Extremity Assessment (FMA-UE) [36], [37] score $\geq 16/60$ (higher score indicates less impairment; a score $\leq 16/60$ indicates the patient does not have the capacity to reach and grasp objects); (4) no excessive pain in the UL, defined as $\leq$ 4 on the visual analog scale (VAS).

Exclusion criteria were: (a) other neurological or musculoskeletal conditions affecting UL movement (e.g., Parkinson's disease, unilateral neglect); (b) severe vision or sensory deficits affecting UL movements as reported in their medical records; and (c) aphasia impeding comprehension of simple instructions.

B. Procedure

The RCT was conducted in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement [38]. Participants were out-patients in the ambulatory unit of the rehabilitation center. This was a consecutive sample, where whoever met the inclusion criteria was available to arrive according to the protocol of the study, and gave their consent, entered the study. Participants who entered the study were randomly allocated to one of three groups:

1. SAR intervention group (the "ROBOT group", see Fig 1A). The robot used for this configuration was the Pepper robot (SoftBank Robotics), which served as a training coach: the instructions and the feedback on performance were displayed on the robot's tablet screen, and the accompanying voice instructions and feedback were given via the robot's integrated speakers and accompanied by gestures made by the robot.

2. Computer intervention group: (the "COMPUTER group", see Fig. 1B). Instructions, feedback and encouraging statements (identical to those used in the ROBOT group) were displayed on a 28-in computer screen, and the accompanying voice instructions and feedback were given via the computer's integrated speakers.

3. Control group: Participants received a conventional therapy program, composed of at least three types of therapeutic
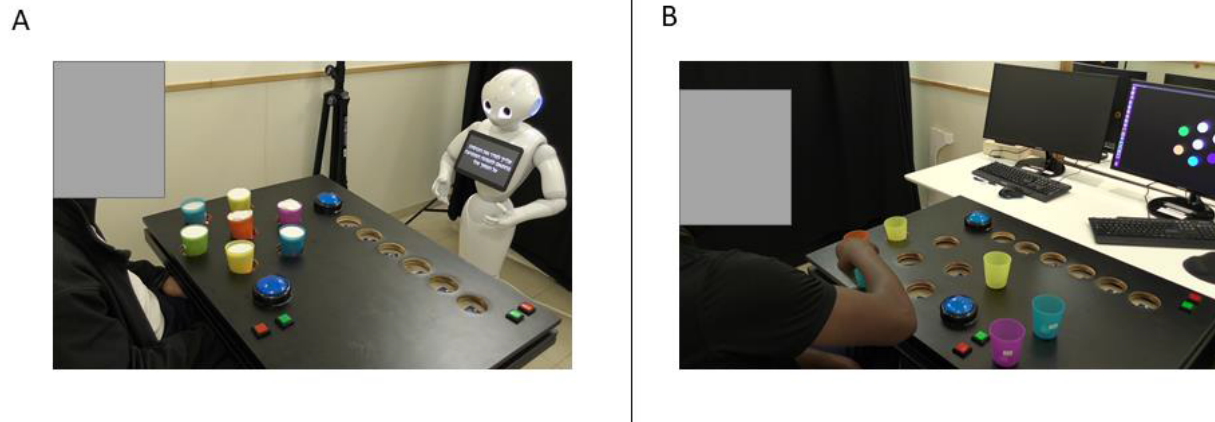
Fig. 1.   The experimental setup. A. Participant in the ROBOT group. The social robot Pepper gives instructions and feedback to the patient, which are presented both on the robot's tablet screen and verbally. B. Participant in the COMPUTER group. The instructions and feedback are presented both on a computer screen and verbally.

sessions, two to three times a week, with no additional intervention.

All the participants in the three groups received the conventional therapy of the rehabilitation center that was delivered by the multidisciplinary clinical team who were not part of the research team. This program consisted of physiotherapy, occupational therapy, hydrotherapy, speech therapy, gym, etc. The participants in the two intervention groups received additional exercise sessions with either the computer system or the robotic system (SAR).

Evaluations were conducted at two time points: two 45-minute sequential evaluation sessions (held within 48 hours of each other) upon entrance to the study, before randomization (T1); one 90 minutes evaluation session following 15 intervention sessions (T2); MMSE and FMA-UE scores were recorded as screening tools. FMA-UE was used both as a screening tool and as a primary outcome measure [39], as detailed below.

C. Intervention Protocol

The flow chart of the study is shown in Figure 2.

The intervention program consisted of 15 individual therapy sessions, two-to-three times a week, 45-60 minutes each, over a period of five-seven weeks [1] (for a total of 306 sessions over all participants). The intervention protocol consisted of seven gamified exercise sets which train Reach-To-Grasp (RTG) movements by using objects of everyday life. The technical specifications of the seven gamified exercise sets are fully detailed in [30]. For each participant, the specifics of the RTG practice exercise (which exercise set to start with, the weight of the objects, the location of the objects on the table, and the height of the table) were determined by the clinician based on their impairment level as was identified by the clinical tests, upon admission to the study (T1). In five of the games the participant was asked to arrange a set of real objects of everyday use (such as cups or jars) according to an image displayed on the screen of the robot or the computer. The other two games were interactive (e.g., a Black Jack card game). In the first five sets there were several difficulty levels which increased by changing the height of the platform, as well as the weight and the number of the objects.
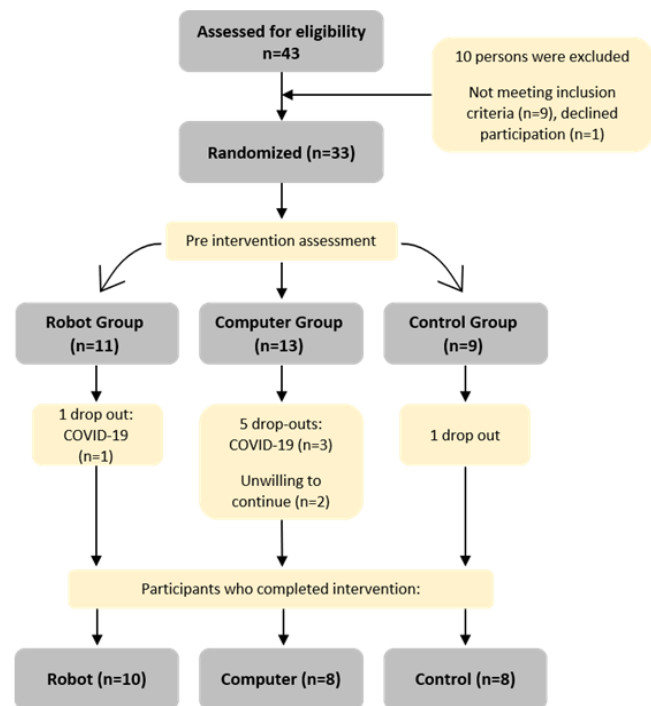
Fig. 2.   Group-allocation flow chart.

After setting up the game parameters, a clinician (physiotherapist) or research assistant was present in the room for safety reasons only and did not intervene in the interaction with the system, or in the progression of the exercise set.

D. Sample Size Estimation, Randomization and Blinding

Since this study was defined as a pilot Randomized Controlled Trial (RCT), no sample size estimation was implemented. Randomization into one of the three groups was performed by a custom-written MATLAB script code using a 1:1:1 randomization, employing a permuted block design. Following the initial evaluation (T1), the researcher would

run the MATLAB code; The output of the code was one of three numbers indicating the group to which the participant has been assigned. Enrollment into the study was done by author RFP, and assignment of participants to interventions was done by one of three researchers who ran the intervention. The analysis of the kinematic 3D measurements was performed by a researcher who was blinded to the randomization, the intervention, the number of assessment and to the clinical results.

E. Outcome Measures

1) Primary Outcome Measures: We followed the international classification of function (ICF) framework introduced by the World Health Organization (WHO) criteria [40] and the recommendation of the Stroke Recovery and Rehabilitation Roundtable (SRRR) [41].

1. To assess the *body structures and function* level we used the FMA-UE [36]. Since it was reported that FMA-UE can be measured without the 6 points of reflexes, a maximum score of 60 was used [37]. The minimal clinically important difference (MCID) of the FMA-UE was reported as 8% of the highest possible score (i.e., 5.25 points) [42].

2. To assess the *activity* level we used the ARAT [43], which was recognized as an activity gold standard measure [44], [45] The MCID of the ARAT was reported as 6% from the highest score (i.e., 4 points) [46].

3. To assess the *participation* level we used the Motor Activity Log (MAL) [47], where the person rates their amount of use and the quality of movement of the affected UL in a variety of everyday tasks; and the Hebrew version [48] of the Stroke Impact Scale (SIS) version 3.0 [49], assessing self-reported impact of stroke in eight domains of everyday life and self-rated the general perceived recovery since the onset of stroke on a scale ranging from 0 to 100 [47]. The MAL-28 is a structured interview during which patients are asked to rate how much (amount of use [AOU] scale) and how well (Quality of Movement [QOM] scale) their more-impaired arm was used to accomplish each of 28 activities of daily living [47].

As it was most important for us to document changes in the clinical and participation aspects of the rehabilitation process, these were defined as the primary outcome measures.

The minimal detectable change and the MCID for the SIS hand function subscale are 25.9 points and 17.8 points, respectively. The MCID for the total rating is 10-15% [42].

2) Secondary Outcome Measures: Recovery of the motor system is best measured with kinematics [41], which were also shown by [50] as biomarkers which predict UL recovery after robotic training. Therefore, each participant was asked to perform six reaching movements to a cup of two weights (either empty or full of water) located at a standard table height (75 cm) in front of them, and then grasp and lift it to a 5-cm shelf located on the table (for details see [51]).

The kinematic measurement set was previously described in [52] and in [51]. In brief, position of the UL joints was recorded using the V120:Trio portable motion-capture system (OptiTrack, USA), which includes three cameras (120 Hz). Eleven reflective markers were placed on the upper body

and three additional markers were placed on the cup. The kinematic measures included velocity of movement (mm/sec), smoothness of movement (normalized jerk), and trunk displacement (TD) (cm). The details of where each marker was placed, as well as how each of the kinematic measures was calculated are listed in the Supplementary Materials.

Participants were asked to inform the researcher of any inconvenience which they felt during the training session, however these data were not systematically collected or scaled.

F. Statistical Analysis

Data were analyzed using SPSS (Chicago IL, v 26.0) and a custom-written MATLAB script (Mathworks, MA, v.R2018b).

1) Baseline Characteristics: Descriptive data analysis and tests for the assumption of normal distribution (Shapiro-Wilk test) were examined for all variables. Baseline characteristics were compared among the three groups using univariate ANOVA for continuous variables (age, time from stroke onset), Kruskal-Wallis H test for ordinal variables or variables with non-normal distributions (FMA, ARAT, SIS, MAL) and Chi-squared test for categorical data (gender, lesion type, stroke side).

2) Clinical Outcomes and Questionnaires: For ordinal variables (FMA-UE, ARAT, SIS, MAL) we used the Friedman test to analyze changes over time, and the Kruskal-Wallis H test to analyze changes across groups. We used Wilcoxon signed-rank test for exploratory post-hoc analyses within each group separately; post-intervention and pre-intervention (T2-T1) differences were computed, and we used the Kruskal-Wallis H to analyze changes across groups and the Mann-Whitney U test to compare this difference between each two groups. Significance level was set at $p \leq 0.05$. Due to multiple comparisons the P value indicating significance was adjusted to $p \leq 0.01$, using the Bonferroni correction. Effect size was calculated using the Kendall's W (Coefficient of Concordance), where, as in Cohen's interpretation guidelines for rehabilitation treatment effects presented by Kinney et al., 0.14 indicates a small effect, 0.31 indicates a moderate effect, and 0.61 or above indicates a strong effect [53].

For each group, the proportion of participants who achieved improvement equal to or beyond the MCID of each measure was calculated [46], excluding the participants whose score at baseline (T1) was higher than the maximal possible score minus the MCID.

3) Kinematic Outcome Measures: For each kinematic outcome measure, we used a linear mixed model (LMM) to analyze the results of the longitudinal assessments [51], [54] across the two time points and the three groups with a between-subject factor (i.e., group: ROBOT/COMPUTER/ CONTROL), two within-subject factors (i.e., time: T1/T2; and weight: empty/full), and the interaction between these factors. For all post-hoc tests, the *p* values were adjusted using the Bonferroni correction for multiple comparisons.

4) Availability of Data and Materials: The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

	Robot Group (n=11)	Computer Group (n=13)	Control Group (n=9)	P-value
Age (±SD) in years	54.3 (±12.7)	62.0 (±14.5)	57.3 (±12.7)	0 .29a
Gender (M/W)	6/5	7/6	6/3	0.81c
Time from stroke onset (±SD) in days	108 (±56)	104 (±33)	92 (±42)	0.66a
Stroke side (R/L)	5/6	3/10	4/5	0.44c
Lesion type (I/ H)	8/3	9/4	6/3	0.87c
FMA/60 (range)	42 (17-53)	41(17-54)	39 (18-58)	0.96b
ARAT/57 (range)	36 (15-51)	38 (6-57)	33 (17-53)	0.56b

Values are mean (±SD) for continuous variables and median (range) for ordinal/non-normally distributed variables. Abbreviations: Gender, M-man, W-woman; Lesion type, I-ischemic, H-hemorrhagic; FMA-Fugl-Meyer Assessment; ARAT-Action Research Arm Test; a Univariate ANOVA, b Kruskal-Wallis H, c Chi-square, *p<0.05

III. RESULTS

A. Participants

The baseline characteristics per group are presented in Table I. Thirty-three sub-acute to early-chronic stage post stroke individuals who met the inclusion criteria (mean age 58.3±12.8 years, 14 women, 19 men, mean days since stroke onset 105±45) entered the study over a period of 28 months, between May 2019 and August 2021 (Figure 2). Table I describes the baseline characteristics of the participants in the study. The Rehabilitation Unit was locked down from mid-March 2020 to mid-May 2020 due to COVID-19. At that time, there were four participants in the middle of intervention: one in the ROBOT group, and three in the COMPUTER group. These participants were therefore excluded from the study. Five participants did not complete the intervention in the COMPUTER group (three were excluded due to the COVID-19 lockdown, and two dropped out since they did not wish to continue the intervention).

Twenty-six participants (ten women, 16 men, aged 30-80 years, mean 58.0±12.9 years; 42-245 days from stroke onset, mean 105±45 days; FMA score 17-58/60; ROBOT group: n=10, COMPUTER group: n=8, CONTROL group: n=8) completed the study. Demographic and clinical characteristics of the participants who completed the study are provided in Table S1. In both intervention groups participants attended all 15 training sessions; some of them (ROBOT group: n=3; COMPUTER group: n=3) completed the intervention in seven weeks due to technical constraints (e.g., in-hospital medical examinations and/or procedures, difficulties arriving due to lockdown, etc.). To match the conditions across groups, we verified that also three participants in the CONTROL group were evaluated (T2) seven weeks after the first one (T1).

B. Primary Outcome Measures: Clinical Scores

The clinical outcome measures are summarized in Table II.

1) Fugl-Meyer Upper Extremity Assessment (FMA-UE): We found a significant effect of time and a moderate effect size for the FMA-UE ($\chi^2(1) = 10.714$, $p = 0.001$, ES = 0.446). The ROBOT group improved significantly between T1 and T2, while no significant effect of time was found for the computer or the control groups. A significant group-by-time interaction (H = 13.03, $p = 0.001$) was found in the between-group analysis, with a significant effect between the ROBOT and the CONTROL group ($z = -3.48$, $p < 0.001$), and between the COMPUTER and the CONTROL group ($z = -2.68$, $p = 0.007$), but not between the ROBOT and the COMPUTER ($z = -0.223$, $p = 0.829$, see Fig. 3).

Minimal Clinical Importance Difference (MCID): In the ROBOT group, 9/10 participants (90%) showed an improvement ≥ six points. In the COMPUTER group, 5/8 participants (63%) showed improvement ≥ the MCID. None of the participants in the CONTROL group showed an improvement of six points or more in the FMA-UE.

2) Action Research Arm Test (ARAT): We found a significant effect of time and a strong effect size for the ARAT ($\chi 2(1) = 11.636$, p = 0.001, ES = 0.506). The ROBOT group significantly improved from T1 to T2, while no significant effect of time was found for the other groups. A significant group-by-time interaction (H = 7.55, p = 0.023) was found for the between-group analysis, with a significant difference between the ROBOT and the CONTROL groups ($z = -2.813$, p = 0.005), while no significant difference was found between the ROBOT and COMPUTER groups or between the COMPUTER and CONTROL groups (see Figure 3).

MCID: In the ROBOT group, 100% of participants improved to a degree equal to or beyond the MCID. Of the eight participants in the COMPUTER group, two participants had an entrance score equal to or close to the maximal possible score, and of the remaining participants, 5/6 (83.3%) showed improvement that was either equal to or exceeded the MCID. In the CONTROL group, 4/8 participants (50%) showed improvement ≥ the MCID.

3) Motor Activity Log (MAL): The total score on the MAL was analyzed from 25 participants, as one participant in the CONTROL group did not complete the scale in T2 due to logistical constraints. We found a significant effect of time and a strong effect size for the MAL-AoU ($\chi^2(1) = 21.16$, $p < 0.001$, ES = 0.846) and for the MAL-QoM ($\chi^2(1) = 17.64$, $p < 0.001$, ES = 0.706). Only the ROBOT group significantly improved in the AoU and the QoM of the affected UL between T1 and T2, with no significant improvement in these measures for the other groups, and no significant group-by-time interaction for these measures (see Figure 3).

4) Stroke Impact Scale (SIS): The total score on the SIS questionnaire was analyzed from 24 participants, as one participant in the COMPUTER group and one participant in the CONTROL group did not complete the scale in T2 due to logistical constraints. A significant effect of time and a moderate effect size were found for the total score of the SIS ($\chi^2(1) = 12.565$, $p < 0.001$, ES = 0.487). No group demonstrated significant improvement in the SIS between T1

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TABLE II

CLINICAL RESULTS

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Measure	Group	Baseline (T1)	Post 5-7 weeks (T2)	Within-group comparison T2-T1		Between-group comparison T2-T1	
				Z	p	H	p
FMA-UE (0-60)	Robot (n=10)	**43.3 (±10.6)**	**54.2 (±5.8)**	**-2.81**	**.005****	13.03	**0.001*****
	Computer (n=8)	42.1 (±12.0)	52.1 (±13.7)	-2.37	.018		
	Control (n=8)	41.2 (±10.312.9)	40.5 (±13.1)	-.17	.865		
ARAT (0-57)	Robot (n=10)	**36.6 (±11.5)**	**50 (±7.6)**	**-2.81**	**.005****	7.55	**0.023***
	Computer (n=8)	37.0 (±16.6)	47.3 (±17.6)	-2.20	.028		
	Control (n=8)	35.3 (±10.5)	37.5 (±13.2)	-.42	.673		
MAL–AoU (0-5)	Robot (n=10)	**2.5 (±1.8)**	**3.8 (±1.1)**	**-2.67**	**.005****	2.67	0.264
	Computer (n=8)	2.4 (±1.4)	3.3 (±1.5)	-2.52	.012		
	Control (n=7)	2.2 (±1.2)	3.1 (±1.5)	-1.99	.028		
MAL QoM (0-5)	Robot (n=10)	**2.2 (±1.6)**	**3.5 (±1.1)**	**-2.55**	**.007****	3.13	0.210
	Computer (n=8)	2.2 (±1.3)	3.1 (±1.5)	-2.24	.012		
	Control (n=7)	2.0 (±.9)	2.9 (±1.3)	-1.99	.028		
SIS: total score (from 100)	Robot (n=10)	68.2 (±12.2)	77.7 (±15.9)	-2.19	.028	0.33	0.849
	Computer (n=7)	59.2 (±18.0)	74.0 (±16.2)	-1.52	.128		
	Control (n=7)	59.2 (±15.2)	77.6 (±12.8)	-2.36	.018		
SIS: general perceived recovery (0-100)	Robot (n=10)	58.5 (±21.09)	68 (±22.1)	-1.69	0.091	0.18	0.915
	Computer (n=7)	59.2 (±18.0)	74.0 (±16.2)	-1.45	.147		
	Control (n=7)	59.2 (±15.2)	77.6 (±12.8)	-1.59	.112		

Listed are the mean values (±SD) for baseline (T1) and post 5-7 weeks (T2); bolded values denote a significant difference within each group. Asterisks denote the *p*-value: *p≤0.05, **p≤0.01, ***p≤0.001. After applying the Bonferroni adjustments for multiple comparisons, the adjusted within group p-value was set as p<0.01. *Abbreviations*: FMA-UE: Fugl Meyer Upper Extremity; ARAT: Action Research Arm Test; MAL: Motor Activity Log; AoU: Amount of Use; QoM: Quality of Movement; SIS: Stroke Impact Scale; logNJ: log Normalized; NS: Not significant

and T2, with no significant group-by-time interaction (see Figure 3).

Seven out of ten participants (70%) from the ROBOT group, 3/7 participants (43%) from the COMPUTER group, and 5/7 participants (71.4%) from the CONTROL group exceeded the MCID of the *hand function* domain.

C. Secondary Outcome Measures: Kinematic Parameters

The change in kinematic parameters over time and across groups was tested in secondary exploratory analysis. The kinematic results are presented in Table III.

Kinematic data were analyzed for the interaction between time (T1, T2) and group (ROBOT/COMPUTER/CONTROL) for the function as a whole (*Reach*, *Grasp* and *Lift*). Due loss of data, kinetic data were not analyzed, and the kinematic data were analyzed from 19 participants (ROBOT: n = 7; COMPUTER: n = 5; CONTROL: n = 7) for whom data exist from both time-points T1 and T2. The kinematic data of seven participants were lost due to technical problems.

Movement velocity. There was no time-by-group interaction effect ($F_{2,165} = 1.58$, $p = 0.209$) on the movement velocity.

In the ROBOT group there was an effect of time on the velocity ($F_{1,69} = 7.24$, $p = 0.009$), indicating that participants who practiced with the ROBOT performed faster movements following the intervention, with no effect of time in the other two groups (COMPUTER: ($F_{1,37} = 2.51$, $p = 0.122$; CONTROL: ($F_{1,49} = 0.042$, $p = 0.838$)).

Log-Normalized jerk (logNJ) [51]. There was a significant time-by-group interaction effect on the logNJ. The movement of the participants in the ROBOT and COMPUTER groups was significantly less jerky following the intervention compared to the CONTROL group ($F_{2,161} = 4.647$, $p = 0.011$).

Trunk Displacement (TD). There was no effect of the interaction of time-by-group on the TD ($F_{2,87} = 1.772$, $p = 0.176$). That is, there was no difference in the way participants in all three groups displaced their trunk while reaching to grasp the cup before and after the intervention.

D. Adverse Effects and Compliance

Three out of nine participants in the CONTROL group (33%) reported increased shoulder pain between T1 and T2: Two participants developed severe pain (>7/10 in the VAS) and one participant developed moderate pain (=5/10)
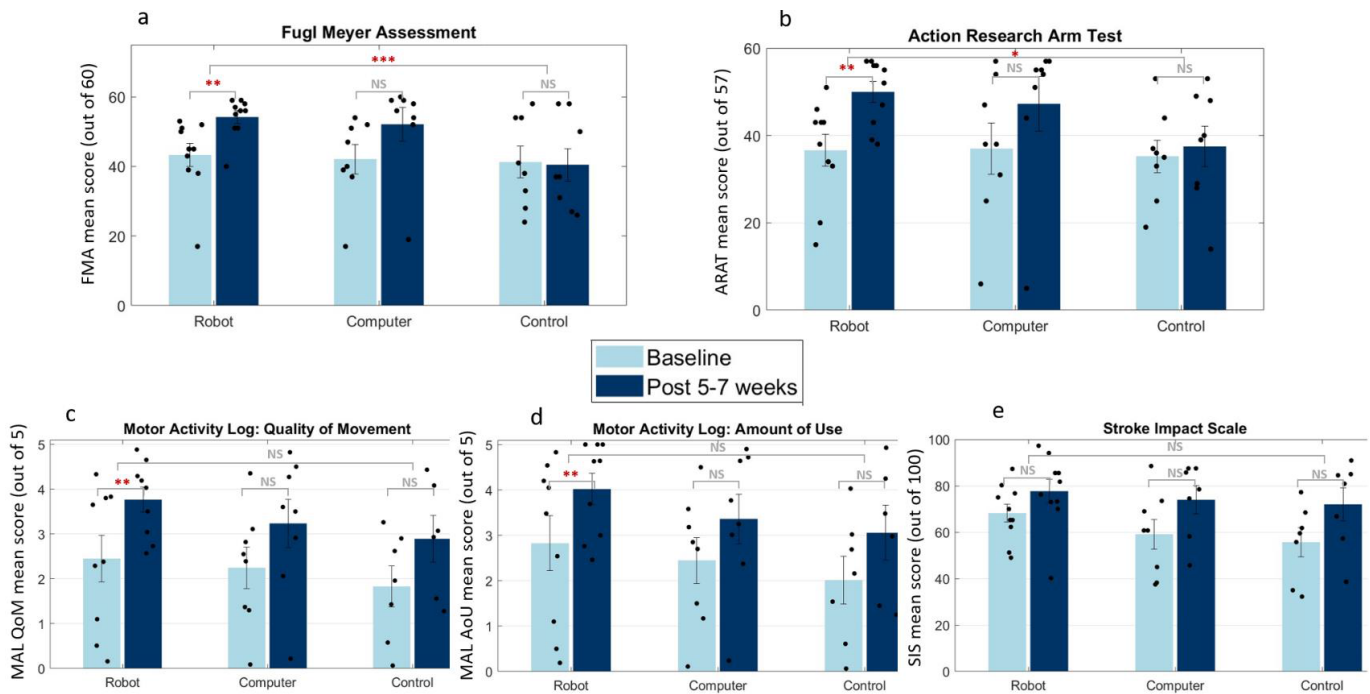
Fig. 3. Results of the Clinical Outcome Measures: a. FMA-UE (out of 60) b. ARAT (out of 57) c. MAL: AoU d. MAL: QoM. We found a significant improvement only in the ROBOT group between T1 and T2. e. SIS. Asterisks denote the *p*-value: *$p \leq 0.05$, **$p \leq 0.01$, ***$p \leq 0.001$, multiple comparisons adjusted p-value < 0.01. Error bars represent 95% confidence interval. Abbreviations: FMA-UA: Fugl Meyer Assessment Upper Extremity; ARAT- Action Research arm Test. 90% of the participants in the ROBOT group, 63% of the participants in the COMPUTER group and none of the CONTROL participants showed improvement, which was equal to, or exceeded, the MCID of the FMA-UE. 100% of the participants in the ROBOT group, 83% of the participants in the COMPUTER group and 44% of the CONTROL participants showed improvement, which was equal to, or exceeded, the MCID of the ARAT.

TABLE III
RESULTS OF THE KINEMATIC MEASURES FOR PARTICIPANTS WHO COMPLETED THE INTERVENTION

Measure	Group	Baseline (T1)	Post 5-7 weeks (T2)	Between-group comparison T2-T1	
				F	p
logNJ	Robot (n=7)	5.2 (±.1)	4.9 (±.1)	4.647	0.011**
	Computer (n=5)	5.3 (±.1)	4.7 (±.2)		
	Control (n=7)	4.8 (±.1)	5.3 (±.2)		
TD (cm)	Robot (n=7)	3.4 (±.4)	2.9 (±.2)	2.619	0.077
	Computer (n=5)	3.4 (±.3)	3.2 (±.2)		
	Control (n=7)	3.3 (±.4)	3.1 (±.3)		
Velocity (mm/sec)	Robot (n=7)	160.2 (±9.2)	188.9 (±8.8)	1.582	0.209
	Computer (n=5)	150.5 (±12.1)	178.9 (±11.5)		
	Control (n=7)	169.5 (±8.6)	166.8 (±11.5)		

Listed are the mean values (±SD) for baseline (T1) and post 5-7 weeks (T2); bolded values denote a significant difference within each group. Asterisks denote the *p*-value: *$p \leq 0.05$, **$p \leq 0.01$, ***$p \leq 0.001$. *Abbreviations*: logNJ: log Normalized; TD: Trunk Displacement. Measurement units: Velocity (mm/sec); TD (cm)

between T1 and T2. None of the other participants in the CONTROL group (67%) or in the intervention groups reported any discomfort or adverse effects during the study period. Two

participants in the COMPUTER group dropped out during the intervention period, being unwilling to continue, since they did not feel the intervention had helped them.

IV. DISCUSSION

This study is, to the best of our knowledge, the first comprehensive clinical study that investigates the *clinical advantages* of using a socially assistive robot for a *long-term* interaction of post-stroke patients as part of their rehabilitation program and the first to study the long-term human-robot interaction in this population in the ecological setting of a rehabilitation clinic.

Part 1 of our hypothesis (clinical outcomes) was confirmed. The participants in the ROBOT group showed greater improvement, compared to the computer group and compared to regular-care alone, in the clinical measures (FMA-UE, ARAT). Furthermore, following the intervention, a greater percentage of participants in the ROBOT group exceeded the MCID of the FMA-UE and of the ARAT than did the participants in the two other groups. Part 2 of our hypothesis (kinematic outcomes) was partially confirmed: participants in the ROBOT group demonstrated a greater improvement in the velocity of the movement post intervention, while the Reach-Grasp-Lift movement of the participants in both intervention groups was significantly smoother compared to that of the control group post 5-7 weeks. There was no significant difference among the three groups in terms of trunk displacement. Part 3 of our hypothesis (self-efficacy questionnaires) was also partly confirmed: the participants in the ROBOT group showed a significant improvement in their MAL-AoU compared to the other two groups, with no significant difference in the MAL-QoM or the SIS. When observing the results, it may seem that the two intervention groups do not significantly differ from each other. However, only the ROBOT group showed statistically and clinically significant differences when taking into account multiple comparisons. The reason for this difference may be that the results of the ROBOT group are less variable than the results of the COMPUTER group, which may reflect a higher engagement within the intervention sessions with the SAR, compared to those with the computer, resulting in more consistent improvement in functional outcomes in the ROBOT group.

Importantly, *there was no difference among the three groups in the number of therapy sessions participants received* including and excluding the number of intervention sessions (Figure S2). This, alongside with the feedback participants gave on the system – showing that they found it to be enjoyable and contributing to their UL rehabilitation [30] suggest that it was not added practice *time* in addition to the regular therapy that made the difference, but rather the *nature* of the practice itself.

Patients were at a wide range of time points post-stroke so some would be expected to improve due to spontaneous recovery processes. However, the patients were randomly allocated into three groups and there were no statistical differences among the three groups at baseline, as shown in Table I. Thus, if there was spontaneous recovery during the study, it would be manifested in all three groups. That is, spontaneous recovery, to the extent it occurred, cannot explain the differences among the three groups following the 5-7-week period between T1 and T2.

One of the interesting results of the current study is the gap – in the ROBOT group – between the improvement in kinematic and clinical measures and the relatively moderate results in the MAL and the SIS. That is, the improvement in the kinematic and clinical measures is not fully reflected in the subjective MAL and SIS questionnaires, which assess the self-efficacy of the person and how they perceive their amount of use of the affected UL both in different everyday tasks (MAL) and in their overall everyday function (SIS). The difficulty of persons with stroke to translate the improvement in their motor capacity into improvement in UL use has been reported in previous works [55], [56]; that is, even when the clinician indicated that the patients demonstrated significant clinical improvement, the patients themselves still perceived their affected UL as incapable of fully participating in ADLs [56]. In the present study, it is evident that even participants with very high scores in the FMA-UE and near-maximal scores in the ARAT (e.g., participant Cl02, with an FMA-UE score of 58, and an ARAT score of 53) still reported that their arm is "not as it used to be." Individuals who perceive their capabilities high post-stroke may perform activities that not only establish the achievements reached during rehabilitation, but may also serve to support additional progress and function over time [57]. It could be that the clinical measures that were used here, while being robust and widely used, still fail to capture the whole UL function of the post-stroke participants. Even though the difference in functional ability was not fully reflected in the MAL and the SIS questionnaires, it was reflected in the MCID of *all clinical measures*. That is, all participants (100%) in the ROBOT group exceeded the MCID of the ARAT, while their MAL QoM and SIS scores did not change significantly between T1 and T2. Another reflection of the change that the ROBOT group underwent is the decrease in normalized movement jerk. Smoothness of movement is widely regarded as a hallmark of skilled, coordinated movement [58], and movement jerk has been used as an empirical measure of this quality [59]. Thus, the results of this study imply that the kinematic and the functional improvement following the intervention, may have been accompanied by a restoration of neural networks in the cortex [58]. Having said that, the kinematic results should be referred to with caution as these data were analyzed from only part of the participants due to loss of data, which could affect the interpretation of the results. The effect of interaction with a SAR on brain plasticity should be investigated in future studies.

The three groups did not differ in the quality of movement, as reflected by the similar patterns in trunk displacement (TD). This finding is not surprising, given that this aspect of the movement was not directly trained in the current intervention, as the platform did not supply the participants with feedback on the way they performed the movement ("knowledge of performance" [60]). In a previous work [51], we tested a similar reach-grasp-lift task of different heights and weights and found a correlation between TD and logNJ during the *lift* phase of the task. Some of the participants mentioned [30] the absence of such feedback, which they desired to receive in order to

improve their movement performance. We have developed an algorithm for this purpose [52], which we implemented on the rehabilitation platform [61], using a structured feedback scheme, including information on trunk displacement [62].

Increasing patient motivation preoccupies clinicians in rehabilitation daily [63], [64], [65]. Many factors may influence patients' motivation. Some of them stem organically from the brain damage, others from the former personality and life experiences of the patient, their social network support, and the ability of the patients to attribute the motor and functional improvement they are experiencing to their practicing routine. Therefore, assessing motivation of persons with stroke following intervention and differentiating the effect of a specific intervention from the other described factors affecting motivation is difficult. Thus, for the purposes of the current study, we regard the drop-out rate from the study as a proxy for the participants' motivation to perform the rehabilitation exercises with the platform. None of the participants in the ROBOT group chose to drop out, whereas two (20%) chose to drop out from the COMPUTER group (involuntary drop outs due to COVID-19-related lockdowns are not counted here). In addition, as we reported in Feingold Polak et al., where the system was fully described, [30], the participants in both intervention groups mentioned they would like to keep using the system during their rehabilitation. It is interesting to note that Rapolienė et al. [65] found that there was a correlation between the internal motivation (believing that one's health is dependent on one's own behavior) of individuals post-stroke at the beginning of rehabilitation and improvement in ADLs during the rehabilitation process.

One of the aims of the current study was to investigate whether a SAR can motivate people with stroke to persist in their exercise program. As was stressed by Warland et al. [66], and is also evident in the current study, it is not the mere use of technology and the repetitive practice itself that increased the motivation of the person to practice, thus promoting rehabilitation, but rather the nature of the intervention. This assertion is supported by the finding that participants in the ROBOT group demonstrated a significant improvement in the clinical measures and in the MAL-AoU while the other two groups did not demonstrate a significant change in those outcome measures; This is despite the fact that the training with the platform in the two intervention groups was identical, except for the non-human operator which provided the instructions and feedback (either a robot or a computer). It might have been argued that patients in the intervention groups received more training hours, and that this difference in time spent practicing underlies the difference in outcomes between the groups. However, the participants in the ROBOT and the COMPUTER groups received the same amount of training with the platform, and there was *no significant difference in the number of therapy sessions among the three groups*. We thus posit that it is the use of everyday objects in a meaningful way, and the interaction with the ROBOT that improved the patients' performance in everyday life. We argue that the clinical improvement participants experienced, as well as the improvement in MCID in all clinical measures reported here, along with the satisfaction from the intervention program

reported in [30] reflects the motivating potential of the SAR for stroke long-term rehabilitation.

We recently published a set of guidelines for incorporation of technological tools into rehabilitation. In light of those guidelines, we note that the current platform has limitations that should be taken into consideration in the context of long-term use: it requires a large amount of space and availability of technical support [67]. While there were technical errors (e.g., the platform would erroneously report that the user did not complete the task correctly), it appears this did not affect the users' acceptance of, trust of the system or willingness to continue training with the system [30], [32]. The study benefited from the presence of a multidisciplinary team, which included both clinicians and engineers, all of whom were able to respond to technical difficulties in real time. The study used outcome measures commensurate with the SRRR guidelines for post-stroke studies [41], and was performed in a clinic, rather than in a lab setting, and thus, where the system is expected to ultimately be used. When asked whether they were satisfied with the intervention, and whether they experienced an improvement in their hand function, the responses of participants who were interviewed varied, depending on the intervention: 78% in the interviewees in SAR group vs. 43% in the Computer group were satisfied with the intervention, and 78% in the SAR group vs. 29% in the Computer group reported experiencing an improvement in their hand function [32].

V. CONCLUSION

This study demonstrated that post-stroke individuals experienced significant improvement at all levels of the ICF following a robotic intervention involving gradual, personalized training, using sensor-embedded objects from everyday life. The improvement in clinical measures of the participants in the ROBOT group was greater than those of the COMPUTER and CONTROL groups. We demonstrated the feasibility of SAR for long-term interaction with post-stroke individuals as part of their rehabilitation program. These results are especially encouraging in light of the COVID-19 pandemic, when the requirement to reduce physical contact and to socially distance accentuates the benefit of non-contact technologies, such as SAR. Our results apply to individuals post stroke with even a minimal capacity to reach and grasp objects. The clinical benefit of SAR on stroke patients should be further investigated in studies with a larger number of participants.

LIMITATIONS

This was a pilot feasibility study with a small number of participants in each subgroup, conducted in one ambulatory-rehabilitation center. The significant results obtained even with a total of 26 participants indicate the great potential of SARs for post-stroke rehabilitation. Having said that, the benefit offered by the SAR-based system should be further investigated in larger studies, involving several rehabilitation centers around the world.

Blinding was applied only for the kinematic outcome measures and not for the clinical outcome measures, which could

bias the results. However, the clinical results of the study were always compared to the clinical scores given by the occupational therapists of the rehabilitation center, as reported in the patients' medical chart; The scores of the research team were consistently very similar to those of the rehabilitation center, and always within the MCID. The occupational therapists in the rehabilitation center were not part of the research team and were not familiar with the allocation to the research groups.

The outbreak of COVID-19 and the uncertainty that accompanied the ensuing two years brought made it very difficult to recruit participants to the study, to follow through the long-term intervention due to lock-downs and uncertainty, and to conduct the 6-month follow-up originally planned. For that reason, the results of the follow up are not presented here.

CONFLICTS OF INTEREST

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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