

Neurorehabilitation of severe acquired brain injury in the time of COVID-19: impact of the absence of caregivers

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Abstract

Introduction. During the COVID-19 pandemic, several restrictions were imposed to limit the circulation of the infection within communities. Hospitals denied access to the family and friends of inpatients, and thus to caregivers. This observational study evaluated the impact of the physical absence of caregivers during the lockdown period due to the COVID-19 emergency on the rehabilitation of inpatients with severe acquired brain injury (sABI).

Methods. The functional outcome at discharge was measured in 25 inpatients with sABI through the Disability Rating Scale (DRS), Glasgow Outcome Scale (GOS), and Levels of Cognitive Functioning scale (LCF) after neuropsychological rehabilitation in an Adult Inpatient Neurorehabilitation Unit for Patients with sABI. Fourteen patients were directly assisted by their informal caregivers physically present in the neurorehabilitation ward. Eleven patients were indirectly supported via remote connection because during the lockdown period (from March to July 2020) caregivers could not be admitted to the rehabilitation hospital. The Caregiving Impact on Neuro-Rehabilitation Scale (CINRS) was also used to evaluate both the change since the admission and the impact of the caregiver from the perspective of the cognitive therapist. Demographic characteristics, time since injury, injury severity (duration of impaired consciousness measured by the time to follow commands), level of functioning at the beginning of the rehabilitation, and duration of the rehabilitation treatment were comparable between the groups.

Results. Both groups improved after the treatment; however, the improvement was consistently greater in the group directly assisted by the caregivers. The results showed that although the caregivers ensured their virtual presence at distance, their physical absence played a role in hindering the functional outcome of the patients.

Conclusions. The role of the caregiver of patients with sABI is underlined in being not only a person handing out generic aid, cares, and affection, but also an integral part of the rehabilitation process.

Key words

- brain injury
- neurorehabilitation
- informal caregiver
- COVID-19 pandemic
- SARS-CoV-2
- lockdown

INTRODUCTION

A recent observational study [1] examined the role played by informal caregivers in the neurorehabilitation setting of patients with severe acquired brain injury (sABI), focusing on the relationships between the quality of caregiving and the psychological status of caregivers. On that occasion, the Authors developed the Caregiving Impact on Neuro-Rehabilitation Scale (CINRS), a scale based on a brief questionnaire completed by cognitive rehabilitation therapists to evaluate the *quality* and *amount* of informal caregiving.

The informal caregiver ("caregiver" from now on) is considered each person who, voluntarily and without

receiving any payment, provides care and support to a loved one who is not self-sufficient in his/her family or social network [2].

In clinical practice, the importance of a global rehabilitation approach in many populations of patients (e.g., after sABI, spinal cord injury, neurodegenerative or oncologic diseases, etc.) is well known. Moreover, from a biopsychosocial perspective [3], it is necessary to implement a specific rehabilitation protocol with the support of the caregiver, who is a very relevant piece of the puzzle composed by the rehabilitation team as a whole.

However, the literature about the role of caregiving

in rehabilitation settings is not ample and has produced contrasting results about the actual effectiveness of caregiving during the rehabilitation period or after discharge. For example, caregiver availability can be associated with a better outcome (e.g., a better motor improvement after treatment was found when caregivers were involved [4]), but alternatively it was hypothesized that either unavailability of caregivers can be associated with a better outcome (presumably because the awareness of the absence of any kind of help after discharge makes the motivation rise), or caregivers availability may hamper the outcome because their overprotection may reduce the patient's motivation to cooperate to the rehabilitation process [5]. Also, Ong and co-workers [6] explored how caregiving affects the rehabilitation outcome in sub-acute stroke and concluded that the primary caregiver identity (that is, whether he/she was a foreign domestic worker or an informal caregiver such as spouses), as well as their availability, seem to affect the rehabilitation outcome. In particular, there seemed to be a negative association between hired non-professional caregivers and the outcome at discharge.

Despite these examples of contrasting results, if one considers the increase in population ageing and the increased incidence of ABI, there is general agreement that there will be an increasing need for caregiving. In particular, caregiving is essential in the care of patients with sABI who, along with complex, multi-professional, and long-lasting rehabilitation programs, need constant assistance by a caregiver (e.g., [7]).

In many rehabilitation centres, before the COVID-19 pandemic, caregivers actively participated in the individual rehabilitation project (IRP) that is elaborated, as project manager, by the physician expert in physical and rehabilitation medicine (a psychiatrist or other rehabilitation equipollent physician such as a neurologist, orthopaedic, rheumatologist, geriatrist, etc.), in coordination with the other professionals of the team. The caregiver cooperated with the team in many ways, for example, facilitating the communication of the patients' needs to the rehabilitation team, as well as engaging the patient in tasks and exercises in the intervals between formal rehabilitation sessions [8]. As COVID-19 became pandemic, several restrictions were imposed to limit the circulation of the infection within communities. In 2020, during the first wave of the COVID-19 pandemic, Italian hospitals denied access to the family and friends of inpatients, and thus to caregivers [9]. Our neurorehabilitation hospital (Santa Lucia Foundation, Rome) had to restrict any access of family members from 10 March to July. Consequently, during that lockdown period, newly admitted inpatients could not be directly assisted by any caregiver, while the caregivers of inpatients admitted before that date had to interrupt their assistance "in presence". Therefore, during the lockdown, the patients could be supported only indirectly by their caregivers, who were contacted by the patients' cognitive therapists (in the presence of the care recipient) on average two-three times per week, by a 15-minute lasting video call (via tablet).

The present study involved two groups of adult inpatients with sABI matched for demographic and clinical

variables, admitted to a Neurorehabilitation Unit for Post-Coma patients. All patients were admitted with the diagnosis of sABI in the acute phase, that is, they were all suitable for an intensive rehabilitation program. Both groups underwent an IRP by a multi-professional rehabilitation team, according to the biopsychosocial approach [3], which emphasises the central figure of the patient and caregiver. The patients of one group were admitted before the COVID-19 outbreak and directly assisted by caregivers who were physically present in the neurorehabilitation ward for the whole length of stay. The patients of the other group were admitted during the COVID-19 outbreak and assisted during their stay by remotely connected caregivers. In particular, the caregivers who were physically present in the ward had daily contact and actively interacted with the cognitive therapists and the rehabilitation team. These caregivers directly assisted their care recipients, spending most of the day with them, thereby helping them in generalizing outside the rehabilitation setting the behaviours and daily activities focussed during the intervention. Conversely, the caregivers who were active during the lockdown could only participate through a remote modality and could not physically interact with their loved ones. Therefore, the peculiar though anguishing circumstances that occurred under the COVID-19 pandemic determined an exceptional forced condition, allowing us to evaluate what happens when caregivers cannot be physically present in the hospital. In fact, despite the cognitive therapists supplying both groups of caregivers with the same kind of indications along the IRP, the caregivers of the patients admitted during the lockdown had only a poor chance to implement them because their care recipients could only be contacted by video calls of short duration.

This observational study aims to examine the impact of the physical absence of the caregivers in the hospital on the outcome of inpatients with sABI. On one hand, the outcome at discharge was measured by standard instruments for evaluation of sABI (Disability Rating Scale: DRS; Levels of Cognitive Functioning scale: LCF; Glasgow Outcome Scale: GOS) and compared between the groups of inpatients. On the other hand, to evaluate the quality and amount of caregiving afforded by the physically present and the remote caregivers, the groups were compared using the Caregiving Impact on Neuro-Rehabilitation Scale (CINRS) [1].

METHODS

Participants

Forty-three inpatients with sABI consecutively admitted to the Neurorehabilitation Unit for Post-Coma of Santa Lucia Foundation in Rome (Italy) from February 2019 to May 2020 and their caregivers were enrolled on this observational study according to the inclusion criteria reported below. After having matched for gender, age, educational level, time since injury, injury severity (measured by time to follow commands, TFC), and level of disability at admission the groups of patients directly assisted and those not directly assisted by the caregivers, only twenty-five inpatients were included in the final sample. Fourteen patients were directly as-

sisted by their caregivers (who thereby were physically present, "Caregiver-IN") from February to December 2019, while 11 patients were only indirectly supported by their caregivers (group with a physically-out caregiver, from here on, "Caregiver-OUT") from March to July 2020.

The study was approved by the local Ethics Committee. All patients and their caregivers provided their written consent after being informed about the use of their data for the study.

Patients were selected according to the following inclusion criteria: 1) age ≥ 18 years; 2) diagnosis of severe ABI (Glasgow Coma Scale, GCS, score ≤ 8 in the acute phase); 3) presence of a primary caregiver who was involved by the cognitive therapist in the rehabilitation project of their loved one, whether he/she was physically present or not.

The inclusion criterion for both groups of caregivers was the absence of any current or previous severe neurological or psychiatric disorder.

The group of patients with Caregiver-IN consisted of 11 males and 3 females, with a mean age of 46.7 years (SD = 14.2), a mean educational level of 12.3 years (SD = 2.7), a mean time since the injury of 164.5 days (SD = 56.8), a mean TFC of 15.9 days (SD = 22.4), and a mean length of stay of 106.8 days (SD = 33.1). As for their aetiology, 6 suffered from TBI, 7 from vascular brain injury, and one from anoxic brain injury due to cardiac arrest. Caregivers-IN were 2 males (1 father and 1 husband) and 12 females (4 mothers, 6 wives/partners, 1 sister, and 1 granddaughter), with a mean age of 53.9 years (SD = 14.0), and a mean educational level of 12.2 years (median = 13.0; SD = 4.8). The group of patients with Caregiver-OUT consisted of 8 males and 3 females, with a mean age of 52.5 years (SD = 15.1), a mean educational level of 12.5 years (SD = 3.3), a mean time since the injury of 168.5 days (SD = 35.7), a mean TFC of 26.9 days (SD = 22.4), and a mean length of stay of 86.9 days (SD = 27.2). Three of them suffered from TBI, 4 from vascular brain injury, 1 from hypoxic coma due to a cardiac arrest, 1 from neurosurgical intervention of brain tumour removal, and 2 from meningo-encephalitis. Their caregivers were 1 male (a husband) and 10 females (1 mother, 5 wives/partners, 2 daughters, and 2 sisters), with a mean age of 46.8 years (SD = 9.0), and a mean educational level of 13.9 years (median = 13.0; SD = 3.0).

Measures

Patients' functional scores upon admission and discharge

Glasgow Outcome Scale (GOS). GOS [10] assesses the patients' functional recovery by 5 points, from 1 ("Death") to 5 ("Good Recovery", referring to light damage with minor neurological and psychological deficits).

Levels of Cognitive Functioning scale (LCF). LCF [11] assesses the cognitive and behavioural functioning levels of the patients. The score ranges from 1 (no response) to 8 (purposeful-appropriate).

Disability Rating Scale (DRS). DRS [12] assesses the level of disability in 8 areas of functioning: eye-opening, verbalization, motor response, levels of cognitive ability

for feeding, toileting, and grooming, level of independence, and employability. The overall score can range from 0 to 29, with 0 representing intact functioning and 29 representing a vegetative state.

Caregiving evaluation

Caregiving impact on neurorehabilitation scale (CINRS)

The CINRS is an Italian questionnaire collecting information on the role of the caregiver in the neurorehabilitation process of adult patients with sABI [1]. The questions of Section A measure the *amount* of participation of the caregiver in the neurorehabilitation process and the *quality* of his/her caregiving. The final question (Section B) allows the cognitive therapist to subjectively evaluate the *general improvement* of the patient at the end of a period of rehabilitation. In detail, Section A measures the time spent in the hospital by the caregiver (item A1), the frequency of participation in the therapy sessions (A2), the level of participation/cooperation in the neurorehabilitation process (A3), and the availability of the caregiver when the therapist needs to communicate with him/her (A7). Moreover, it evaluates the possible presence of substituting attitude by the caregiver (A4), how much the patient cooperates when the caregiver is present (A5), and how much the caregiver trusts the neurorehabilitation process (A6). Finally, the therapist evaluates whether the global influence of the caregiver facilitated or hampered the whole neurorehabilitation process (A8). High scores in Section A indicate a high amount and better quality of caregiving. Section B is a 10-point scale, ranging from 0 ("no improvement") to 10 ("as much improved as possible") assessing the relative change from the beginning of the treatment. Further details about the response options for each item of the CINRS and the scores range are described in [1].

In the present study, the cognitive therapists responded to the CINRS to evaluate the caregiving of both the patients with Caregiver-IN and the patients with Caregiver-OUT. For this latter group, the cognitive therapists conveniently took into account the remote presence of the caregiver and responded to item A8 considering the influence globally played by the physical absence of the caregiver on the patient's rehabilitation.

Procedure

The observations for the comparisons between the groups were recorded at two time points: t0 and t1. The demographic and clinical baseline measures were taken at t0, immediately before the beginning of the rehabilitation period.

t1 was the time-point when the outcome was measured for both groups of patients at discharge (i.e., at the end of their rehabilitation). A neurologist administered the functional assessment (i.e., DRS, GOS, and LFC scales) to the patients at t0 and t1. A psychologist administered the CINRS at t1 to the cognitive therapist involved in the rehabilitation of the related patient.

Despite the pandemic and the lockdown period, standard rehabilitation protocols were maintained because the medical and rehabilitation staff did not undergo any change in the amount of personnel involved with respect to the pre-COVID-19 period, therefore both

groups of inpatients were treated in the same way, except for the absence of the caregivers in the ward during the lockdown in the case of the Caregiver-OUT group of patients.

Data analysis

Data analysis was carried out using SPSS software (version 27). Descriptive statistics were used to illustrate the demographic and clinical characteristics of the patients and caregivers.

Shapiro-Wilk normality test was used to determine if the variables (demographical and clinical data, standard scales scores, and CINRS scores) followed a normal distribution. Two-tailed t-tests for independent samples were run to compare the groups for normally distributed variables (age, time since injury, length of stay, and DRS at t0); Mann-Whitney tests were used for non-parametric analysis (educational level, TFC, GOS, LCF). For within-group comparisons between time points, t-tests and Wilcoxon tests for repeated measures were used for parametric and non-parametric analyses, respectively. As for DRS score, a one-way ANCOVA was used to compare the groups at t1 using the DRS at t0 as a covariate to control for a possible effect of the initial disability on the final score. As for the CINRS, differently from Bivona *et al.* [1], the total score did not include three items of Section A (A4, A5, and A6, concerning the trust of the caregiver in the rehabilitation process, his/her tendency to substitute for the patient, and the cooperation of the patients when the caregiver is remotely connected, respectively) because these were not fully applicable in the Caregiver-OUT group. Moreover, item A1 (time spent in the hospital by the caregiver) was excluded because it scored by default 1 for all the patients with Caregiver-OUT. Therefore, only the scores of the items A2, A3, A7, and A8 were summed up for both groups. This composite score as well as the score of Section B were submitted to parametric analysis for the group comparisons. Individual items of the CINRS Section A (except the items A4, A5 and A6 for the abovementioned reason) were singly compared between the groups with non-parametric tests.

RESULTS

Comparisons between Caregiver-IN and Caregiver-OUT groups

The groups of patients were comparable for gender ($X^2_{(1, N=25)} = 0.115$, $p = 0.734$), age ($t_{(23)} = 0.97$, $p = 0.343$), educational level ($U = 71.5$, $p = 0.767$), time since injury ($t_{(23)} = 0.21$, $p = 0.839$), TFC ($U = 52.0$, $p = 0.183$), and duration of rehabilitation ($t_{(23)} = 1.61$, $p = 0.121$). The demographical features of the caregivers were comparable between the groups: there were no differences of gender $X^2_{(1, N=25)} = 0.157$, $p = 0.692$), age ($t_{(23)} = 1.46$, $p = 0.158$), or educational level ($U = 62.0$, $p = 0.434$).

Standard scales at baseline (t0)

The groups of patients were comparable at t0 for all the standard scales assessing the disability level (Table 1). In particular, both the GOS and the LCF scores were comparable between the groups (Mann-Whitney $U = 58.5$, $p = 0.317$ and $U = 65.0$, $p = 0.536$, respectively)

ly) as well as the DRS score ($t_{(23)} = 1.08$, $p = 0.290$). The data points in correspondence of t0 in Figure 1 show the DRS scores at the baseline for the two groups.

According to the baseline scores (see Table 1), both groups of care recipients were characterized by a severe disability (median GOS equal to 3 for both groups and average DRS scores equal to 14.4 and 16.7, for the patients with Caregiver-IN and OUT, respectively) and by a confused-appropriate level of cognitive functioning needing moderate assistance for daily living activities (median LCF score equal to 6.0).

Standard scales after rehabilitation (t1)

Groups were comparable (see Table 1) for the GOS ($U = 58.0$, $p = 0.317$) and LCF outcome scores ($U = 51.5$, $p = 0.166$). In the case of the DRS score, the ANCOVA run controlling for the initial disability level showed a significant effect of group ($F_{(1,22)} = 4.95$; $p < 0.05$) with a large effect size (partial $\eta^2 = 0.18$), indicating that the patients with Caregiver-IN showed a better outcome than those with Caregiver-OUT (see in Figure 1 the data points in correspondence of t1).

Baseline vs outcome comparisons

Comparisons between t0 and t1 were run for the standard scales score, separately for the patients with Caregiver-IN and Caregiver-OUT, to verify that there was an improvement at the end of the rehabilitation period. For all the scales, the comparisons showed that both groups significantly improved after treatment (see Table 1). In Figure 1, the slopes of the two lines connecting t0 with t1 show that both groups improved over time.

Synthesis of standard scales results

The level of disability severity at t0 was comparable between the groups; then both the Caregiver-IN and the Caregiver-OUT patients showed a statistically significant better performance at t1 with respect to t0 for all the standard scales. However, in terms of functional improvement after the neurorehabilitation treatment, the change in the field pictured by the GOS scale was only marginal and showed that patients did not reach a moderate level of disability (therefore both the groups still needed to be assisted by someone for daily life activities). The LCF scale at t1 showed that the Caregiver-IN group stepped towards level 7, meaning automatic/appropriate behaviour, which is characterized by minimal assistance for daily living skills, while the change for the Caregiver-OUT patients did not allow them to make a similar step towards. Finally, the DRS score improved significantly for both groups from t0 to t1, but while the patients with Caregiver-IN improved to a level of moderately severe disability (passing from 14.4 to 7.2), the patients with Caregiver-OUT, despite having passed from 16.7 to 12.6, remained at the initial severity category.

Overall, besides statistically significant changes, the Caregiver-OUT group did not change the level of disability severity, while the Caregiver-IN group passed to a level of moderately severe disability.

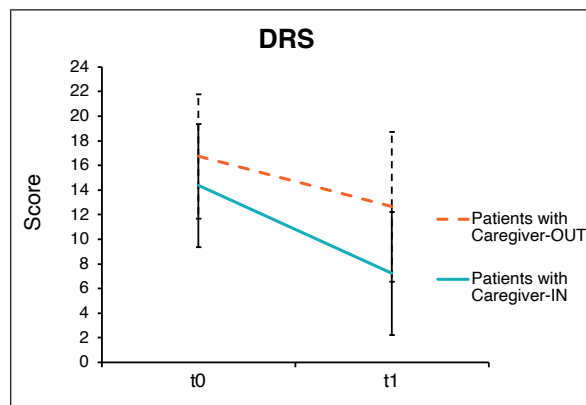
Finally, for the DRS, the direct comparison between the groups upon discharge, controlling for the possible

Table 1

Results for the standard scales scores (GOS, LCF, and DRS) measured at t0 (baseline) and t1 (outcome). Descriptive statistics are reported separately for the groups of patients with Caregiver-IN and with Caregiver-OUT. The results of the group comparisons performed separately at t0 and t1 are reported in the last two columns. The comparisons evaluating the difference between t0 and t1 are also reported separately for each group, in the time point columns. Significant comparisons are highlighted in bold

	Patients with Caregiver-IN				Patients with Caregiver-OUT				Group comparisons	
	Time point	Mean	Median	SEM	Time point	Mean	Median	SEM	Test	p-value
GOS	t0	3.1	3.0	0.07	t0	2.8	3.0	0.12	U = 58.5	0.317
	t1	3.6	3.0	0.20	t1	3.2	3.0	0.18	U = 58.0	0.317
Test	Z = 2.07				Z = 2.00					
p-value	< 0.05				< 0.05					
LCF	t0	5.4	6.0	0.39	t0	5.0	6.0	0.49	U = 65.0	0.536
	t1	6.7	7.0	0.34	t1	5.9	6.0	0.48	U = 51.5	0.166
Test	Z = 3.49				Z = 2.12					
p-value	< 0.001				< 0.05					
DRS	Time point	Mean	SD	Time point	Mean	SD	Test	p-value		
	t0	14.4	5.7	t0	16.7	5.0	$t_{(23)} = 1.08$	0.290		
	t1	7.2	5.3	t1	12.6	6.1	$F_{(1,22)} = 4.95$	< 0.05		
Test	$t_{(13)} = 7.07$				$t_{(10)} = 3.12$					
p-value	< 0.001				< 0.05					

GOS: Glasgow Outcome Scale, LCF: Levels of Cognitive Functioning scale, DRS: Disability Rating Scale.

**Figure 1**

The Disability Rating Scale (DRS) score is reported for the baseline (t0) and for the outcome (t1) separately for the group of patients with Caregiver-OUT (dashed line) and with Caregiver-IN (continuous line). Error bars represent standard deviations.

effect of the baseline DRS, showed that the patients with Caregiver-IN had a significantly better outcome than those with Caregiver-OUT.

CINRS at the outcome

The group results are presented in *Table 2*. The difference between the groups for item A1 (which refers to the frequency of the caregiver in the rehabilitation ward) was statistically significant by default because the score reflected the absence of caregivers in the ward for all the patients with Caregiver-OUT. As for the other items, only A8 showed a significant difference between the groups, while A3 failed to reach significance,

and A2, A7, and Section B did not differ between the groups. When the composite score was considered, the groups differed significantly, with the Caregiver-IN showing a better score than the Caregiver-OUT group. The Cohen's d was equal to 1.22, indicating a large effect size.

To synthesize, the contribution of the caregivers who participated in a remote modality was considered less determinant in the overall neurorehabilitation process than the contribution of the physically present caregivers. That is, even if availability and frequency of participation in the training sessions were considered comparable between the groups of caregivers, the cognitive therapists attributed an overall significant difference between them concerning their global influence on the IRP efficacy. However, the therapists judged the relative change from the beginning to the discharge with a similar score for the patients of both groups (5.9 and 5.4 points over a maximum score of 10, for the Caregiver-IN and -OUT patients, respectively).

DISCUSSION

The importance of the involvement of caregivers has been widely emphasized by the holistic and bio-psychosocial rehabilitation approach for patients with sABI [1, 3, 13]. Furthermore, in recent years, both international, as well as Italian, panels of experts and Italian legislators have also shown to be increasingly sensitive to this topic, as demonstrated by the publication of guidelines [14, 15] and the promulgation of law decrees.

From the perspective of the holistic approach, the present study followed up on a recent study [1], which examined the impact of caregiving in the rehabilitation setting on the outcome of patients with sABI. In that

study, it was concluded that the better the psychological status of the caregiver, the better the caregiving and the better the functional outcome of the patient.

Between March and July 2020, the exceptional restriction measures imposed to limit the COVID-19 pandemic determined the exclusion of all caregivers from the wards of the hospitals. Consequently, the absence of caregivers in the Post-Coma Unit of our neurorehabilitation hospital determined a peculiar condition that allowed evaluating the impact of the physical absence of the caregiver on the rehabilitation process. Therefore, we compared two groups of patients who were supported by their corresponding groups of caregivers: Caregivers-IN group and Caregivers-OUT group. In particular, the caregivers of the first group assisted their care recipients and participated in their rehabilitation process through daily contact with them, helping them to generalize across the whole day the intervention of the cognitive therapist. Differently, the caregivers of the Caregivers-OUT group could interact with their care recipients only poorly, because although the daily availability of remote connections was ensured, the communication between caregivers and patients lasted only fractions of hours instead of lasting the whole day.

Our results confirmed the importance of caregiving carried out under specific conditions, that is, in the presence of a person directly interacting and guiding the patient throughout the whole day before, during and after the official daily training sessions (see the comments about items A2 and A3 of the CINRS, below).

Like Caregivers-IN, also Caregivers-OUT were constantly informed and involved in the rehabilitation process; nevertheless, their physical absence in the rehabilitation setting seemed to have negatively impacted the functional outcome in the group of their care recipients. This was particularly evident if one considers the DRS score, which is the most sensitive among the standard scales used in the present study: the patients with Caregiver-OUT, despite the DRS score improved from admission to discharge, remained at the same disability category of the beginning (“severe disability”), while the group with Caregiver-IN reached a lower level of disability (“moderately severe disability”). The direct comparison between the groups, taken into account and controlled for possible group differences between the scores measured upon admission, showed that the outcomes of the groups significantly differed at discharge.

Of course, the small sample size and the lack of biomarkers for a more objective and mechanistic evaluation of the beneficial effects of caregiver physical presence can be considered as some limits of the present study. However, according to this specific result, we feel confident that the better outcome observed in the patients assisted by their Caregivers-IN could be closely related to the above-mentioned advantages determined by the physical presence of the caregivers in the rehabilitation ward. In saying this, we also lean on the fact that the medical and neurorehabilitation staff did not undergo any change in the amount of personnel in-

Table 2

Results for the CINRS measured at t1 are presented separately for each item of the questionnaire and as a composite score (sum of the items A2, A3, A7, and A8). Descriptive statistics are reported separately for the Caregiver-IN and the Caregiver-OUT groups. Group comparisons (tests and p-values) are also reported. Significant comparisons are highlighted in bold. Descriptive statistics of the items A4, A5, and A6 were not reported for the Caregiver-OUT group because of missing values for some participants, therefore the group comparisons were not run for these items

Items	Patients with Caregiver-IN			Patients with Caregiver-OUT			Group comparisons	
	Mean	Median	SEM	Mean	Median	SEM	Test	p-value
A1. Frequency of caregiver in the ward	3.8	4.0	0.24	1.0	1.0	0.00	U = 0.0	<0.001
A2. Frequency of participation of the caregiver in the neuro-rehabilitation setting	2.5	2.0	0.25	3.2	4.0	0.54	U = 60.0	0.373
A3. Amount of participation/cooperation by the caregiver	3.7	4.0	0.22	2.8	2.0	0.40	U = 43.0	= 0.066
(A4). (Caregiver tendency to substitute for the patient)	4.0	4.0	0.21	-	-	-	-	-
(A5). (Cooperation of the patient when the caregiver is present)	2.0	2.0	0.11	-	-	-	-	-
(A6). (Caregiver's trust in the rehabilitation process)	3.8	4.0	0.16	-	-	-	-	-
A7. Caregiver availability/easy to find	4.4	5.0	0.17	4.3	4.0	0.24	U = 69.5	0.687
A8. Caregiver's global influence on patient's rehabilitation	4.3	4.0	0.13	1.8	2.0	0.23	U = 0.0	<0.001
	Mean		SD	Mean		SD	Test	p-value
Part B (relative change since admission)	5.9		2.2	5.4		2.6	t ₍₂₃₎ = 0.51	0.614
Composite score (A2, A3, A7, A8)	14.9		1.9	12.1		1.7	t ₍₂₃₎ = 3.04	<0.01

CINRS: Caregiving impact on neurorehabilitation scale.

volved in the two periods under observation. In fact, standard neurorehabilitation protocols were applied to both groups of patients; the only change in the neurorehabilitation protocol and setting for the patients treated during the lockdown period was the extraordinary absence of caregivers.

As for the amount and quality of caregiving, on one hand, the CINRS Section B (which was based on the therapists' subjective appraisal of the relative change from admission to discharge) recorded a change in both groups. On the other hand, the CINRS composite score recorded a group difference which accounted for the actual lower amount (item A3) of participation and lower global influence played by the remote caregivers (item A8) in the overall neurorehabilitation process. This result highlights the fact that availability (item A7) and frequency (item A2) of (remote) participation in the training sessions (in other words, the sole presence during the therapy sessions) is not enough: effective co-operation and thus effective influence is possible only if a caregiver is present all day long, not only during the specific formal training session. In the light of our experience as an integrated group of clinicians cooperating in a team made by physicians, cognitive therapists, psychologists, and nurses, we would further suggest that the significant changes that occurred in the group of patients with Caregiver-OUT would not have been possible without an exceptional effort by the cognitive therapists who (as reported by all of them) tried to compensate for the absence of all-day caregivers. Of course, only a larger sample of patients would confirm these results and the related suggestions, although the hope is that similar exceptional conditions that allowed this study will not occur anymore in the future.

CONCLUSIONS

The role of caregiver participation in the assessment of responsiveness in patients with sABI and disorders of consciousness has been recently reported [16].

The previous study of Bivona *et al.* [1] demonstrated the relevant role of caregiving in rehabilitation but did not report any data on the absence of caregivers in the same neurorehabilitation milieu. The current pandemic COVID-19 made it possible to investigate the possible difference between the physical presence *vs* absence of

caregivers in the neurorehabilitation ward in terms of the functional outcome of their care recipient.

The lockdown period has been challenging for the professionals making an effort to involve and specifically educate caregivers on the best practices, as well as psychologically sustain them in this dramatic phase of their life. However, it has undoubtedly also been challenging for the caregivers themselves, who had to temporarily manage their psychological distress, their worry about being distant, and their anticipation of the future mental and physical effort related to the care recipient's demands.

We would here underline once again the importance of integrating at least one primary caregiver in the rehabilitation project of the care recipient, to address all the functional consequences of a severe ABI. We would also suggest that, on one hand, it is important that the therapists get the compliance and the participation of the caregivers in order to educate the family (even at distance) on how to functionally behave with the care recipient. On the other hand, as suggested by the study, it is crucial to guide the caregivers when they are *in presence* so that they can immediately guide and help the patients in generalizing outside the rehabilitation setting what the patients learned during the rehabilitation sessions.

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Authors' contributions

MDL and UB: conception and design. EDA, BO, FM, GF, MI, and SL: data acquisition. VB, MDL and UB: data analysis and interpretation of results. MDL and UB: original draft. RF: project supervision and manuscript revision. All Authors read and approved the final version of the manuscript.

Conflict of interest statement

The Authors declare that they have no conflicts of interest regarding the publication of this paper.

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