Rehabilitation after critical illness: A randomized, controlled trial

Christina Jones, PhD; Paul Skirrow, MPhil; Richard D. Griffiths, MD, FRCP; Gerald H. Humphris, PhD, M Clin Psych; Sarah Ingleby, BSc; Jane Eddleston, FRCA; Carl Waldmann, FRCA; Melanie Gager, RGN

Objective: **To evaluate the effectiveness of a rehabilitation program following critical illness to aid physical and psychological recovery.**

Design: **Randomized controlled trial, blind at follow-up with final assessment at 6 months.**

Setting: **Two district general hospitals and one teaching hospital.**

Patients: **Patients were 126 consecutively admitted intensive care patients meeting the inclusion criteria.**

Interventions: **Control patients received ward visits, three telephone calls at home, and clinic appointments at 8 wks and 6 months. Intervention patients received the same plus a 6-wk self-help rehabilitation manual.**

Measurements and Main Results: **We measured levels of depression and anxiety (Hospital Anxiety and Depression Scale), phobic symptoms (Fear Index), posttraumatic stress disorder (PTSD)-related symptoms (Impact of Events Scale), and scores on the Short-Form Health Survey physical dimension 8 wks and 6 months after intensive care unit (ICU) treatment. Memory for ICU was assessed at 2 wks post-ICU discharge using the ICU Memory Tool.**

The intervention group improved, compared with the control patients, on the Short-Form Health Survey physical function scores at 8 wks and 6 months ($p = .006$), and there was a trend to a lower rate of depression at 8 wks (12% vs. 25%). However, there were no differences in levels of anxiety and PTSD-related symptoms between the groups. The presence of delusional memories was correlated significantly with both anxiety and Impact of Events Scale scores.

Conclusions: **A self-help rehabilitation manual is effective in aiding physical recovery and reducing depression. However, in those patients recalling delusional memories from the ICU, further psychological care may be needed to reduce the incidence of anxiety and PTSD-related symptoms. (Crit Care Med 2003; 31:2456–2461)**

KEY WORDS: critical illness; rehabilitation; anxiety; depression; posttraumatic stress disorder-related symptoms; delusional memories

Intensive care unit (ICU) patients in the United Kingdom face a common core of physical and psychological problems during their recovery despite differing presenting diagnoses. Muscle wasting and weakness are common and physical recovery is slow, measured in months rather than weeks (1). Patients often display high levels of psychological distress, including posttraumatic stress disorder (PTSD) (2). Research into rehabilitation following critical illness is limited, focusing primarily on pulmonary rehabilitation (3).

Rehabilitation studies have shown that exercise regimes and psychological intervention programs have aided recovery and enhanced coping behavior in patients with widely differing diagnoses, such as chronic obstructive pulmonary disease (4), chronic fatigue syndrome (5), and myocardial infarction (6–8). Home-based programs have been shown to enhance compliance to exercise programs (9). We hypothesized that a rehabilitation program following critical illness might aid physical and psychological recovery. However, ICU patients' psychological recovery may be complicated by memories from the period of critical illness (10, 11). Because delusional memories of hallucinations or paranoid delusions are thought to be major contributors to post-ICU psychological distress, a subsidiary outcome was to examine the impact of memories for the time in ICU on psychological recovery.

The primary aim of the study was to test whether the provision of a 6-wk rehabilitation program post-ICU improves patients' physical and psychological recovery. The possible confounding effect of delusional memories from the ICU on psychological recovery was examined in a cohort of the patients.

MATERIALS AND METHODS

Protocol

The study was conducted at Whiston Hospital (Merseyside), Manchester Royal Infirmary, and Royal Berkshire Hospital (Reading), all in the United Kingdom. All three hospitals already had established follow-up clinics for patients recovering from critical illness. The individual hospitals' local research ethics committees approved the study protocol.

The inclusion criteria were that the patients had been in ICU and ventilated. Patients were excluded if they a) stayed in the ICU <48 hrs; b) were suffering burn injury (due to prolonged recovery); c) were unable to follow the manual or had language difficulties; d)

From the Intensive Care Research Group, Department of Medicine (CJ, PS, RDG), University of Liverpool, and the Intensive Care Unit, Whiston Hospital, Prescot, UK; the Department of Clinical Psychology (GHH), University of Manchester, UK; the Intensive Care Unit (SI, JE), Manchester Royal Infirmary, Manchester, UK; and the Intensive Care Unit (CW, MG), Royal Berkshire Hospital, Reading, UK.

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Address requests for reprints to Prof. Richard D. Griffiths, MD, FRCP, Intensive Care Research Group, Department of Medicine, University of Liverpool, Duncan Building, Daulby Street, Liverpool L69 3GA, UK. E-mail: rdg@liverpool.ac.uk

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were neurosurgical patients; e) had preexisting psychotic illness (confounding factor for psychological recovery); or f) were discharged for terminal care and unlikely to survive the 6-month follow-up period.

A sample size of 150 patients was required, assuming a) 33% of patients suffering psychological distress (2); b) a projected 10% loss or withdrawal rate; and c) a significance level of 5% and a power of 80%.

The study was a block randomized, controlled trial, in which routine ICU follow-up was compared with routine follow-up plus a 6-wk self-help rehabilitation program. Patients were recruited to the study 1 wk after ICU discharge when still on the general wards. Follow-up was blinded. The principle outcomes were physical and psychological recovery at 6 months post-ICU discharge.

Treatment Conditions

Control Patients: Routine ICU Follow-Up. All patients were followed up on the general wards post-ICU discharge, were contacted by telephone three times once they had gone home to ask how they were getting on, and finally were seen in a dedicated ICU follow-up clinic at 8 wks and 6 months.

Intervention: Routine Follow-Up Plus Rehabilitation Package. In addition to the routine follow-up and telephone calls, intervention patients received a 6-wk rehabilitation package consisting of 93 pages of text, diagrams, and supporting illustrations. The manual was tailored to the needs of recovering ICU patients and contained advice on a wide range of psychological, psychosocial, and physical problems. It included a self-directed exercise program. Three weekly telephone calls reinforced the use of the rehabilitation manual. The patients kept a diary to allow us to measure their use of the rehabilitation package.

The content of the rehabilitation manual was guided by problems reported by patients attending a dedicated ICU outpatient clinic (Whiston Hospital) in the preceding 5 yrs. The design and content of the manual were piloted on 20 patients before the study began to examine readability and ease of use. All patients in the pilot believed that the manual was easy to follow and that they had gained some benefit from the advice it contained; all had used the exercise program. In addition, 18 of 20 patients reported that their family had been very willing to become involved by encouraging them to exercise (12).

Outcome Measures

To assess physical and psychological recovery, evaluations took place at recruitment (while the majority of patients were still in hospital) and at 8 wks and 6 months post-ICU discharge. Trait anxiety was assessed at recruitment using the Spielberger's State-Trait Anxiety Inventory (13). The level of perceived social support the patient had was measured using the revised Norbeck Social Support Questionnaire (14). The Norbeck Social Support Questionnaire gives a number of scores that indicate the size of the respondent's social support network as well as its stability and availability. The functional properties of social support, that is, subcategories of social support, affect (support in the form of a sympathetic ear), affirmation (the provision of information and advice), and aid (physical support such as baby-sitting), and the different sources of support were listed. Anxiety and depression scores were recorded using the Hospital Anxiety and Depression Scale (HAD) at recruitment, 8 wks, and 6 months (15). The Impact of Events Scale (IES) was used at 8 wks and 6 months to assess PTSD-related symptoms (16). PTSD, as defined by the *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition Revised) (17), is characterized by a range of problems from three symptom groups, such as re-experiencing the event (flashbacks), avoidance of situations that remind one of the event, a numbed reaction, and symptoms of increased arousal. The IES assesses re-experiencing and avoidance.

Memory for the time in the ICU was assessed using the ICU Memory Tool in a cohort of patients (Whiston Hospital) (18). The Short-Form Health Survey (SF-36) physical function score was used to assess physical recovery at 8 wks and 6 months (19). Patients also completed the SF-36 at recruitment to the study and were asked to recall as best they could their premorbid health over the 6 months before admission to ICU. A separate researcher who was not aware of patient group assignment conducted the follow-up.

All patients had their illness severity assessed using an Acute Physiology and Chronic Health Evaluation II score calculated for the day of admission to ICU. Length of ICU stay, admission diagnosis, age, and gender were recorded. Use of antidepressants and benzodiazepines during the study period also was recorded.

Patients in the treatment group were introduced to the ICU rehabilitation manual by a research nurse using a printed training schedule, with a close relative or friend of their choosing present. Work with myocardial infarction patients has shown that including relatives in the provision of information increases patient compliance with advice (9). The rehabilitation manual introduction took place on the general wards the day after recruitment and was undertaken at the bedside if the ward was quiet or in a convenient office when the ward was very busy.

Statistics

The statistical analysis was performed using SPSS for Windows (version 9.0, SPSS, Chicago, IL). Questionnaire data were treated as ordinal and analyzed using nonparametric statistics (20). Parametric statistics were used with interval data, for example, age (21). However, parametric statistics were used with ordinal data if the variances across groups were approximately the same. The Levene statistic tested for equality of group variances. Clinical descriptors were used for comparison between control and intervention groups to ensure adequate randomization. A one-way analysis of variance (ANOVA) test was used to compare study groups. The Kruskal-Wallis one-way ANOVA test was adopted as the nonparametric equivalent. A repeated-measures ANOVA was employed to test for group effects over time. Variables hypothesized to influence recovery were tested as independent variables.

Assignment

Patients were approached to take part in the study once they had been on the general wards following ICU for $\geq$72 hrs. Patients were assigned to treatment or control groups using a closed envelope technique, randomized in blocks of 6. Intervention patients were not told that they were receiving anything extra.

Masking

All three hospitals in the study had well-established follow-up services for ICU patients, with ward visits before hospital discharge and a dedicated ICU follow-up clinic, and all patients followed a standardized follow-up protocol. The patients were not aware of which group they were in. Both controls and intervention patients received identical-looking folders with only the contents determining the program they followed. The control patients were told that the study was to find out how much help and advice patients need during their recovery and that to find this out some patients would follow the normal hospital discharge routine and others would receive some additional information.

At follow-up assessment in an outpatient clinic, neither the doctor nor the outcome assessor knew which group the patients were in. The patients' appointments were staggered so that study patients did not sit in the waiting room together. Data analysis was performed using coded data, and the code was broken only when the analysis was complete.

RESULTS

Participant Flow and Follow-Up

Recruitment consisted of 126 patients across the three study centers. Centre

Table 1. Demographic Details for Two Study Groups

Variable	Rehabilitation Group (n = 69) Mean (range, SD)	Control Group (n = 57) Mean (range, SD)	Significance Two-tailed *p*
At admission to ICU			
Age, yrs	57 (17–77, 17)	59 (17–84, 16)	.8
Male/female ratio	37:32	33:24	.7
SF-36 general health score (retrospectively assessed post-ICU discharge)	55 (20–100, 17)	55 (30–100, 16)	
SF-36 general health score (retrospectively assessed post-ICU)	55 (20–100, 17)	55 (30–100, 16)	.67
ICU stay, days	14 (2–114, 20)	13 (2–110, 18)	.13
Admission APACHE II score	17 (4–28, 5)	16 (4–34, 5)	.12
APACHE II risk of death prediction	0.17 (0–0.49, 0.13)	0.20 (0.07–0.80, 0.17)	.83
Admission TISS	36 (29–49, 5)	37 (20–48, 6)	.5
At recruitment to study (≈1 wk post-ICU discharge)			
HAD anxiety score	8 (0–20, 5)	8 (0–17, 4)	.38
HAD depression score	6 (0–17, 4)	6 (0–18, 6)	.94
Trait anxiety scores	42 (22–75, 12)	42 (23–61, 9)	.26
Ventilated, %	100	100	1.0
Cumulative TISS score	391 (73–1820)	367 (83–1000)	.15

ICU, intensive care unit; SF-36, Short-Form Health Survey; APACHE, Acute Physiology and Chronic Health Evaluation; TISS, Therapeutic Intervention Scoring System; HAD, Hospital Anxiety and Depression Scale.

Royal Berkshire Hospital only recruited seven patients (four intervention and three controls) due to staffing problems. The two remaining centers recruited similar numbers, 33 intervention and 30 control patients at Whiston Hospital and 32 intervention and 24 control patients at Manchester Royal Infirmary. One hundred four patients (58 intervention and 46 control patients) had close family members recruited to the study to help support them through their recovery. Patient characteristics were similar in the two study groups. No statistically significant differences were found (see Table 1).

At 8 wks, 63 of 69 (91%) intervention patients and 51 of 57 (89%) controls completed follow-up questionnaires. Three control and two intervention patients died before the 8-wk follow-up. At 6 months, those completing questionnaires had decreased to 58 of 69 (84%) intervention patients and 44 of 57 (77%) controls; those not completing the 6 months tended to be younger (Mann-Whitney U = 550, Z = −1.99, p = .046). Five patients died, three intervention patients and two controls, before the 6-month follow-up (see Fig. 1); they were older than the other study patients (Mann-Whitney U = 327, Z = −2.28, p = .022).

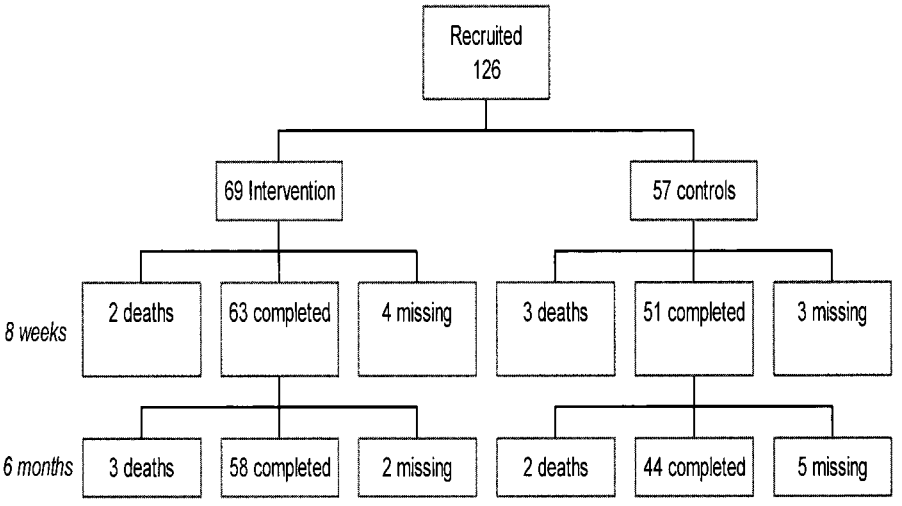

Figure 1. Trial profile.

Analysis

Intervention patients showed closer to normal SF-36 physical function scores at 8 wks and 6 months than control patients. A repeated-measures ANOVA (group by time interaction effect) of the SF-36 physical function scores at the three time points (premorbid, 8 wks, and 6 months), when controlled for length of ICU stay, was significant (F = 3.7, df = 4, p = .006; Fig. 2).

A smaller percentage of intervention patients, compared with controls, were above the cutoff of 11 on the HAD scale for depression at 8 wks, 8 (12%) vs. 13 (25%). However, this did not quite reach statistical significance (Fisher's exact test, chi-square = 3.1, p = .066). There was no difference in the level of social support measured by the Norbeck Social Support Questionnaire between the intervention patients and the controls. Thirteen intervention patients (22%) and eight (18%) controls were prescribed antidepressants before the 8-wk follow-up. When only those patients who had received an antidepressant were examined, those in the intervention group reported a significantly lower level of depression at 8 wks than the controls (one-way ANOVA, F = 10.47, df = 1, p = .004). At 6 months, the rate of depression in the two study groups was very similar, 10% in the intervention group and 12% in control patients. This is consistent the fact that in both patient groups, their general physical recovery was improving. The intervention was designed to speed up recovery, and the controls took some months to catch up.

There was no statistical difference in the percentage of patients in the two

study groups above the cutoff of 11 on the HAD anxiety scale at 8 wks or 6 months, 19 (32.7%) of intervention patients vs. 15 (34%) of controls at 6 months. Thirteen (21%) intervention patients and eight (15.7%) controls were taking benzodiazepines. Removing these patients from the analysis did not change the levels of anxiety between the two groups (one-way ANOVA, $F = 0.14$, $df = 1$, $p = .71$).

IES scores were lower in the intervention patients at 8 wks, indicating lower levels of intrusion and avoidance of reminders of their illness, and this was statistically significant (one-way ANOVA, $F = 5.24$, $df = 1$, $p = .026$). When patients who received benzodiazepines were removed from the analysis, IES scores were much lower in the intervention patients at 8 wks (one-way ANOVA, $F = 6.32$, $df = 1$, $p = .014$). This difference in those receiving or not receiving benzodiazepines was not repeated at 6 months, as the intervention patients' scores deteriorated.

There was a significant difference in the prescription of both benzodiazepines and antidepressants between the study sites. Forty-five percent of patients at one site were prescribed benzodiazepines post-ICU discharge, with only 6% and 0% at the other two sites. Similarly, 48% of patients at the same site were prescribed antidepressants post-ICU discharge vs. 13% and 25% at the other two sites. Retrospective analysis showed that the only association between benzodiazepine and antidepressant prescription post-ICU discharge was the type of sedative drug used in ICU. The site with the high prescription of these drugs post-ICU was the one that used predominantly midazolam as a sedative in the ICU compared with propofol in the other sites.

Effect of Delusional Memories

In a cohort of patients (at Whiston Hospital), information on the presence of delusional memories from ICU was available (intervention n = 28, controls n = 24). Patients with delusional memories, in both study groups, had higher HAD anxiety scores at 6 months than those without delusional memories (one-way ANOVA, $F = 4.28$, $df = 1$, $p = .044$). Similarly, IES scores were higher for those patients with delusional memories at 6 months than those without delusional memories (one-way ANOVA, $F = 4.38$, $df = 3$, $p = .008$, Fig. 3).

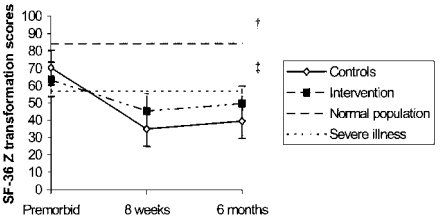

Figure 2. Short-Form Health Survey (*SF-36*) physical function Z transformation scores (mean and SD) over time by study group. †Mean for normal population (n = 2474); ‡mean for population with severe illness (n = 256).

When we used the upper cutoff point of >19 of PTSD-related symptoms (IES) that are considered a cause for concern (22), 52 (51%) of the 102 study patients scored above this level at 6 months post-ICU. This proportion was divided equally between the study groups, 21 of 44 (48%) controls and 31 of 58 (53%) intervention patients (Fisher's exact test, chi-square = 0.32, $df = 1$, $p = .57$). When a subgroup analysis was performed using those patients with data on recall of delusional memories on ICU, 21 of 35 (60%) patients with delusional memories scored >19 and five of 18 (28%) were without such memories at 6 months post-ICU (Fisher's exact test, chi-square = 4.8, $df = 1$, $p = .028$). This study center had a low rate of prescription of benzodiazepines and antidepressants in the period post-ICU discharge.

DISCUSSION

The study had a number of limitations, the main one being the lack of true baseline data for physical function. It was impossible to get information before the ICU admission because these were emergency admissions; hence, patients were asked to recall how their health had been over the 6 months leading up to that admission. There is an obvious possibility that this recall may be colored by subsequent events. Similarly, patients were asked if they had a history of psychological distress and may not have been completely open. We made efforts to circumvent this possibility by double verification with the family and medical notes. The possibility of cross-group contamination, however, was reduced as far as possible by scheduling study patients to staggered outpatient appointments so that they did not meet in the waiting room. But it may have been possible for contamination to take place on the general wards before

A self-help rehabilitation manual is effective in aiding physical recovery and reducing depression.

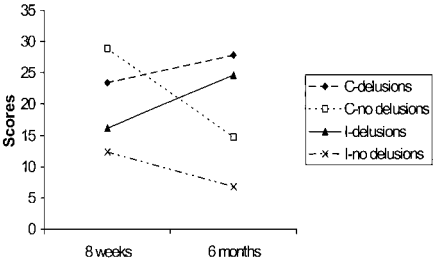

Figure 3. Mean Impact of Events Scale scores by study group and delusional memories. *C*, control group; *I*, intervention group.

hospital admission where two study patients were on the same ward at the same time. In reality, two study patients being on the same ward at the same time only happened twice in the duration of the study.

The study design of blinded follow-up enabled us to test the rehabilitation package in a mixed population of general emergency ICU patients. The diary kept by the intervention patients showed that the majority of the patients were well motivated and adhered to the program. The rehabilitation package proved to be successful in aiding the recovery of physical function in those patients completing the study. The deaths and dropouts from the study were equivalent in both groups. The patients who died before the 6-month follow-up (three interventions, two controls) did so from pneumonia. The accelerated physical recovery is similar to the improvement seen with myocardial infarction patients following a rehabilitation program (6). The rehabilitation package was designed to be patient-centered and self-directed, returning the control of their physical recovery to the patient. Although the package only covered a 6-wk period, patients were allowed to keep the manual, and many continued to use the exercises and information on issues such as nutrition and quitting smoking afterward. Very little physical rehabilitation is given to patients in the United King once they leave ICU and particularly when they leave the

hospital due to the acute shortage of physiotherapists in the National Health Service. Recruiting relatives to help patients adhere to the package may have removed some of the conflict between patients and their relatives that can happen when the family is overprotective.

There was a suggestion that the rate of depression was reduced by half at 8 wks with the rehabilitation package, although this did not reach statistical significance. However, once the prescription of antidepressants was taken into account, this became significant. The control patients on antidepressants were more likely to remain depressed at the 8-wk follow-up.

Anxiety rates did not follow the pattern found using a self-directed rehabilitation package with myocardial infarction patients (6). High anxiety scores were seen in patients recalling delusional memories regardless of study group. A similar pattern was seen with IES scores. Fifth-one percent of all the patients completing the study scored above the cause for concern cutoff at 6 months. This very high incidence of PTSD-related symptoms was a major concern. In common with the HAD anxiety scores, the patients who had the highest IES scores were those patients recalling delusional memories from ICU in both study groups, which confirmed our previous observation (10). This finding is also in line with recent work with psychiatric patients followed up after their first psychotic episode, which showed that recall of delusions was distressing and associated with the later development of PTSD (23).

The center where memories for ICU were recorded was a low prescriber of benzodiazepines in the follow-up period post-ICU discharge. This is not to say that benzodiazepines should be prescribed to help patients cope with such memories, as the incidence of PTSD-related symptoms was not any different between the sites. The consensus guidelines on treatment of PTSD recommend avoiding benzodiazepines where possible because of potential problems with addiction (24). Psychotropic medication per se is not seen as a first-line treatment, and psychotherapy, such as anxiety management and normalization of symptoms, is the first-line, evidence-based treatment (25).

It could be argued that patients who receive benzodiazepines in ICU should not recall delusional memories because of the amnesic properties of the drugs. However, acute withdrawal from benzodiazepines, such as midazolam, can produce delirium and hallucinations (25), which may be recalled subsequently. In one study, 32% of ICU patients developed acute withdrawal symptoms from opiate or benzodiazepine infusions, with those receiving unusually high mean daily and peak doses most at risk (26). One interesting small study found an association between the use of sedatives in ICU and PTSD symptoms at 6–41 months post-ICU in patients recovering from adult respiratory distress syndrome (27).

The fact that >30% of all the patients in the study scored as having anxiety on the HAD would suggest that this is a significant problem and needs to be addressed during the rehabilitation period. This is despite the rehabilitation package containing information on coping strategies that have been shown to interrupt the worry/anxiety cycle, such as recognition of symptoms to aid self-awareness, relaxation, and challenging those thoughts that causes anxiety (28, 29).

The psychological problems the patients exhibited in this study, which may be exacerbated by the presence of delusional memories of ICU, strongly indicate urgent further investigation in rehabilitation research. The ICU rehabilitation manual clearly was not addressing all the worries and concerns of those patients who have delusional memories precipitated by ICU attendance. Although some mention was made in the ICU rehabilitation manual of nightmares, hallucinations, and delusions and how frightening and realistic these phenomena could be, no specific information was given to normalize the possible experience of PTSD-related symptoms etc. This would be a worthwhile addition to the program. However, with such a high rate of PTSD-related symptoms, an educational intervention of this nature may have only a moderate impact. A more extensive intervention such as counseling or the introduction of a specific psychological intervention is worthy of consideration but requires formal testing.

The study suggests that a rehabilitation package is a useful initial intervention to aid physical and psychological recovery after critical illness. The study population was drawn from three intensive care units and added to their existing follow-up programs. Rehabilitation would have to be combined with screening for delusional memories, as it is likely that these patients would need not only further psychological support but also, in some cases, professional intervention. Since the study, the rehabilitation package has been incorporated into the follow-up routine with the addition of screening for memory of ICU and PTSD symptoms.

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