

ORIGINAL RESEARCH

The Effects of a Blended Care Intervention in Partners of Patients With Acquired Brain Injury — Results of the CARE4Carer Randomized Controlled Trial



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Abstract

Objective: To assess effects of the CARE4Carer blended care intervention on caregiver mastery and psychosocial functioning compared with usual care in partners of patients with acquired brain injury (ABI).

Design: Multicenter randomized controlled trial.

Setting: Nine sites for rehabilitation medicine.

Participants: 120 partners of outpatients with ABI were randomly allocated to blended care (N=59) or usual care (N=61).

Intervention: The blended care intervention (20 weeks) was aimed at improving caregiving skills and consisted of 9 online sessions, combined with 2 face-to-face consultations with a social worker.

Main Outcome Measures: Mastery was assessed with the Caregiver Mastery Scale, secondary outcome measures were caregiver strain (Caregiver Strain Index), family functioning (Family Assessment Device), anxiety and depression (Hospital Anxiety and Depression Scale), burden (self-rated), and quality of life (CarerQol). Assessments were performed at baseline, 24, and 40 weeks.

Results: The adjusted mean difference in caregiver mastery between intervention and control group at week 24 was 1.31 (SD3.48, 95% confidence interval (CI) -0.12 to 2.74, $P=.072$) and at week 40 was 1.31 (SD3.69, 95% CI -0.26 to 2.88, $P=.100$). In the per protocol analysis, the adjusted mean difference in caregiver mastery at week 24 was 1.53 (SD3.38, 95% CI 0.10 to 2.96, $P=.036$) and at week 40 was 1.57 (SD3.63, 95% CI 0.01 to 3.14, $P=.049$). Regarding secondary outcomes, caregiver strain was lower in the intervention group in the per protocol analysis at week 40. Family functioning was higher in the intervention group in week 24, whereas anxiety was lower at both timepoints.

Conclusions: In the subset of participants who were able to complete the intervention, caregiver mastery and psychosocial functioning improved. Future work should focus on improving adherence as this will optimize beneficial effects of blended care.

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Spouses and domestic partners of patients with acquired brain injury (ABI) are often primary informal caregivers at home. While caregiving can be a positive experience,^{1,2} many partners also experience high burden³⁻⁶ and emotional problems such as anxiety and depression.^{5,7} They also experience restrictions in participation in society⁸ and decreased quality of life.⁹

Optimizing functioning at home is difficult for many patients and partners. Many caregivers feel ill-prepared for the situation at home after discharge from inpatient care and feel the need for continued rehabilitation input.¹⁰ To better support partners, programs aimed at the caregiving situation are necessary. Support programs ideally focus on psychoeducation, problem-solving skills, and successfully coping with stress.^{11,12} They should aim to increase levels of caregiver mastery. Caregiver mastery is one's belief to be able to control and influence the caregiving process and that one is competent and effective in managing it.¹³ Low caregiver mastery is associated with restricted participation and negative caregiving experiences^{1,8} and is also related to increased anxiety and depression.¹⁴

However, for partners of patients with ABI, taking part in a support program can be problematic. Caregiving tasks may already take up much time.¹⁵ Web-based interventions could provide a more easily accessible way of providing support, allowing partners to participate at a time and place of their own convenience. Web-based interventions have shown to positively affect chronic disease care and home care by improving caregivers' outcomes.¹⁶ However, Web-based interventions also have disadvantages such as low adherence, which is related to reduced effect of the intervention.¹⁷ Adherence can be improved by combining Web-based interventions with face-to-face consultations (blended care), creating opportunities to develop relatedness to a health care professional, and offer more personalized support.¹⁸ While blended care interventions are promising, there is little research on its effectiveness on psychosocial outcomes for partners of patients with ABI.

The CARE4Carer randomized controlled trial was designed to evaluate the effects of a blended care intervention for partners of patients with ABI in outpatient rehabilitation care. This intervention combines Web-based sessions with 2 face-to-face consultations with a social worker. It was designed to combine the elements of a successful support program (increasing caregiver mastery, psychoeducation, improving problem-solving skills) with the flexibility of a Web-based intervention and the improved adherence and personalized support of a face-to-face intervention.¹⁹

We examined if the CARE4Carer blended care intervention for partners of patients with ABI leads to higher caregiver mastery compared with usual care. We also determined the effects of the CARE4Carer intervention on caregiver strain, family functioning, anxiety, depression, caregiver burden, and caregiver quality of life. We expected the CARE4Carer intervention to improve psychosocial functioning compared with usual care.

List of abbreviations:

ABI	acquired brain injury
CarerQol-7D	Carer Quality of life – 7 dimensions
CarerQol-VAS	Carer Quality of life – visual analog scale
CMS	caregiver mastery scale
CSI	caregiver strain index
FAD	McMaster family assessment device
HADS	Hospital Anxiety and Depression Scale
SRB	self-rated burden

Methods

The protocol for the CARE4Carer study includes the procedures in more detail.¹⁹

Participants

Patients with ABI with an acute onset, such as stroke, subarachnoid hemorrhage, traumatic brain injury, and their partners were recruited as dyads from 6 rehabilitation centers and 3 outpatient rehabilitation hospital departments in The Netherlands. Recruitment took place between September 2016 and January 2020.

All participants gave informed consent. Patients were enrolled in a multidisciplinary outpatient rehabilitation program at the start of the study. Partners were their primary caregivers.

Exclusion criteria for patients were neurodegenerative or progressive ABI. Exclusion criteria for partners were insufficient computer skills or no internet access.

The Medical Research Ethics Committee of the University Medical Center Utrecht confirmed the Dutch Medical Research Involving Human Subjects Act (WMO) does not apply to this study. All participating rehabilitation centers approved the study protocol.

Design

The CARE4Carer study was a randomized controlled trial. Participants were blinded during baseline measurements. Further blinding was not possible because of the nature of the intervention. Participants were randomized using an online randomization tool. They were stratified by rehabilitation site, and block randomization with 2 block sizes (2 and 4) was used to balance across groups. To detect a standardized mean difference of 0.5SD in the primary outcome measure, with an alpha of 0.05 and 80% power, a total of 100 partners were needed, 50 per group. Assuming a drop-out rate of 20%, a total of 120 dyads were included.

Procedure

Participants gained access to an online environment in which questionnaires became available at baseline, at 24 weeks (T1), and at 40 weeks (T2). Additionally, partners who were randomized to the intervention group gained access to the Web-based care program after submitting the questionnaire at baseline. The intervention consisted of 9 online sessions and 2 face-to-face consultations with a social worker. The online sessions were designed using principles of cognitive behavior therapy and solution-focused therapy. Expert input from social workers, psychologists and caregivers was also used. These sessions focused on how to take care of your partner, which care choices to make, burden and resilience, how to get a grip on feelings and thoughts, communication, how to take care of yourself and asking for support. Information was provided by written text and short video clips. There were fill-in assignments focusing on skill building. Each session took a few hours to complete. Partners were asked to complete all online sessions by 20 weeks after the baseline measurement. Partners in the control group received usual care according to the national guidelines of the Netherlands Society of Neurology. They were offered education and counseling tailored to individual needs. This could consist of individual consultation(s) with a social worker or psychologist when necessary, or could involve a peer support group. Participants in the intervention group could also

take part in usual care. All participants in both groups were allowed to receive additional care as needed.

Independent variables

At baseline, data on age, sex, education level, and employment were collected. ABI characteristics were retrospectively obtained from the rehabilitation facility.

Outcome measures

The primary outcome measure was caregiver mastery as measured by the Caregiver Mastery Scale (CMS). It consists of 7 statements regarding caregiver mastery, such as "In general, you are able to handle most problems in the care of your partner". Partners can indicate their (dis)agreement to the statements. Total scores range from 7 to 35 with higher scores indicating higher levels of caregiver mastery. The CMS has been validated in partners of patients with ABI.¹⁴

Secondary outcomes measures were Caregiver Strain Index (CSI), the McMaster Family Assessment Device (FAD), the Hospital Anxiety and Depression Scale (HADS), Self-Rated Burden (SRB), and the Carer Quality of life (CarerQoL).

The CSI measures strain experienced by the caregiver. Higher scores indicate higher strain, with scores of 7 or higher indicating substantial strain. The CSI is clinically validated²⁰ and used in caregivers of stroke patients.²¹

The FAD is used to assess family functioning. The General Functioning subscale was used. A mean score of 2.0 or higher indicates problematic family functioning. The FAD has good psychometric properties.²²

The HADS consists of 2 subscales with 7 items measuring anxiety (HADS-A) and 7 items measuring depression (HADS-D). Scores above 7 are indicative of anxiety or depression. The HADS has good psychometric properties.²³

To assess burden, partners indicate how burdensome caring for the patient is for them on a 0 ("not hard at all") to 100 ("much too hard") visual analog scale. The SRB has been validated in caregivers of patients with stroke.²⁰

The CarerQoL is used to assess caregiving related quality of life. It consists of CarerQoL-7Dimensions (CarerQoL-7D) and CarerQoL-Visual Analog Scale (CarerQoL-VAS). The CarerQoL-7D consists of 7 items measuring subjective burden using 5 negative and 2 positive domains of informal caregiving. The CarerQoL-VAS uses a visual analog scale to assess caregivers well-being on a 0-10 scale. Higher scores on the CarerQoL-7D and CarerQoL-VAS indicated better functioning. The CarerQoL has good construct and clinical validity.^{24,25}

At T1, partners in both groups self-reported their care consumption (number of consultations) with different health care providers (social worker, psychologist, primary care physician, general practice nurse or aftercare nurse, or participation in peer support groups) during the study period up until T1.

Statistical analysis

Descriptive statistics and care consumption data were examined via *t* test for parametric and Chi-square tests or Mann-Whitney *U* tests for non-parametric data.

CMS was analyzed at baseline, T1 and T2 using a linear mixed model according to the intention-to-treat principle, including all partners randomized irrespective of whether they completed the

intervention, with at least 1 post-baseline efficacy measurement (modified intention to treat). The linear mixed model consisted of a fixed effect for treatment (intervention or control), baseline CMS, time (T1 or T2) and the interaction between treatment and time. Time was assessed as a categorical variable. The random part consisted of a random effect for time and intercept per individual. Two additional sensitivity analyses were performed, one in which participants without a post-baseline efficacy measurement were imputed by means of baseline observation carried forward, the second by pooling together outcomes at T1 and T2 into 1 post-intervention outcome. In addition, we conducted a per protocol analysis using partners in the intervention group who had completed at least 5 out of 9 sessions and had at least 1 consultation with a social worker. Additionally, all partners, including those in the control arm, had completed at least 1 questionnaire at either T1 or T2.

The analysis for the secondary outcome measures was similar. IBM SPSS statistics version 28 was used for all analyses. *P* values below .05 were considered significant.

Results

Partner characteristics

A total of 120 couples were included in the study. 59 partners were randomized to the intervention group, 61 partners to the control group. See [figure 1](#) for a flow chart of the study. Nine participants (5 in the intervention group, 4 in the control group) were randomized but did not complete the baseline questionnaire. At week 40, 64% of those randomized to the intervention group were still participating in the study compared with 79% of those randomized to the control group.

Baseline characteristics of patients and partners are shown in [table 1](#), stratified by randomized allocation. Overall, the groups were well-balanced in key baseline variables. When comparing characteristics of participants who stopped prematurely (*n*=11) to those who completed follow-up (*n*=43) in the intervention group, the baseline score on the CarerQoL-7D was statistically different (mean difference 9.14, 95% confidence interval (CI) 0.49 to 17.79; *P*=.039), in favor of the completers.

Effect of the CARE4Carer intervention on caregiver mastery

The means and standard deviations of the outcome measures are shown in [table 1](#) (baseline) and [table 2](#) (T1 and T2). Results of the linear mixed models are shown in [table 2](#) (intention to treat) and [table 3](#) (per protocol). See [Supplementary table](#) (available online only at <http://www.archives-pmr.org/>) for full model output.

There was no statistically significant difference in CMS scores between the groups at T1 (mean difference 1.31, 95% CI -0.12 to 2.74; *P*=.072) or T2 (mean difference 1.31, 95% CI -0.26 to 2.88; *P*=.100) in the intention to treat analysis. Sensitivity analysis by imputing missing values showed a mean difference in CMS at T1 of 0.66 (95% CI -0.56 to 1.87; *P*=.29) and at T2 of 0.69 (95% CI -0.69 to 2.04; *P*=.31).

Sensitivity analysis by pooling together the CMS scores at T1 and T2 showed an overall mean of CMS of 24.42 in the intervention group and 23.10 in the control group (mean difference 1.32, 95% CI 0.01 to 2.63; *P*=.048).

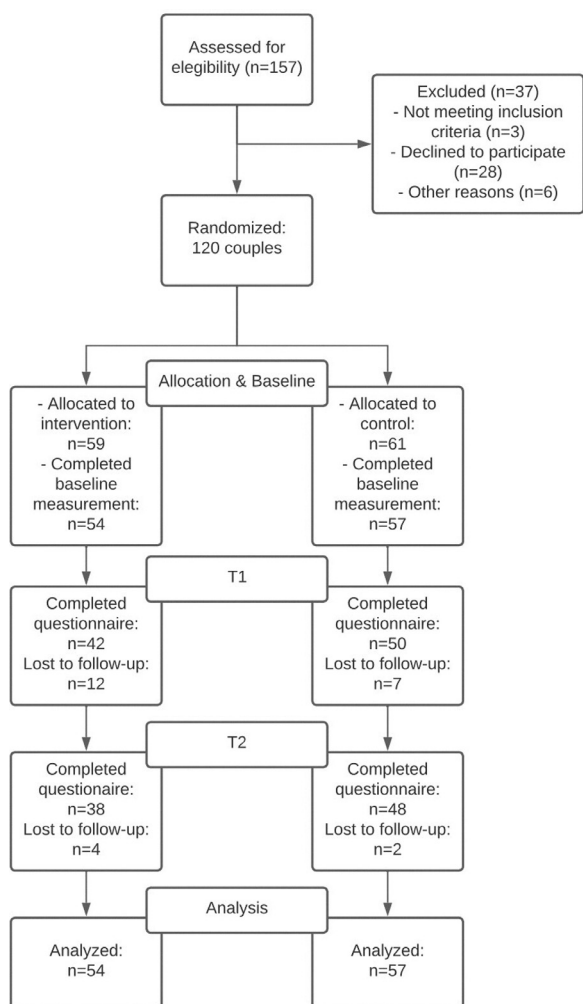


Fig 1 Flow chart of the Care4Carer study

In the per protocol analysis, there were 88 partners included at T1 (38 from the intervention group, 50 from the control group) and 84 at T2 (36 from the intervention group, 48 from the control group). The per protocol analysis showed a significant estimated mean difference in CMS between the 2 groups at T1 of 1.53 (95% CI 0.10 to 2.96, $P=.036$) and at T2 of 1.57 (95% CI 0.01 to 3.14; $P=.049$), in favor of the intervention.

Effect of the CARE4Carer intervention on secondary outcome measures

Intention to treat analysis of secondary outcome measures revealed a decreasing FAD at T1 (mean difference -0.21; 95% CI -0.36 to -0.06; $P=.008$) and decreasing HADS-anxiety at both T1 (mean difference -1.76; 95% CI -3.20 to -0.32; $P=.017$) and T2 (mean difference -1.54; 95% CI -2.94 to -0.15; $P=.030$), in favor of the intervention.

Other secondary outcome measures (CSI, HADS-depression, SRB, CarerQol) showed no statistically significant differences between intervention and controls in the intention to treat analysis (see table 2).

The per protocol analyses of secondary outcome measures showed decreasing CSI at T2 (mean difference -1.24; 95% CI -2.25 to -0.23; $P=.017$), decreasing FAD at T1 (mean difference

Table 1 Baseline characteristics

Characteristic	Intervention Group (n=59)	Control Group (n=61)
Demographic factors partners		
Age at randomization, mean ± SD	59.8 (9.2)*	58.8 (10.3)†
Men, n (%)	14 (23.7)*	17 (27.9)†
Higher educational level, n (%)	18 (33.4)‡	17 (29.9)§
Paid work, fulltime or parttime, n (%)	33 (61.1)‡	38 (66.7)§
Demographic factors patients		
Age, mean ± SD	61.8 (9.1)*	59.9 (10.0)†
Men, n (%)	45 (76.3)*	43 (70.5)†
ABI-related factors		
Ischemic stroke, n (%)	34 (57.6)*	39 (63.9)*
Hemorrhage, n (%)	19 (32.2)*	15 (24.6)*
Traumatic brain injury, n (%)	6 (10.2)*	5 (8.3)*
Other, n (%)	0 (0.0)*	2 (3.3)*
Barthel Index, median (IQR)	15.5 (11.0)¶	18.0 (10.0)¶
MoCA, median (IQR)	24.0 (7.0)**	25.0 (8.0)††
Baseline measurements partners		
CMS, mean ± SD	23.3 (4.5)‡	22.7 (4.6)§
CSI, mean ± SD	8.1 (2.6)‡	7.6 (3.0)§
FAD, mean ± SD	1.9 (0.5)‡	1.9 (0.5)§
HADS-anxiety, mean ± SD	8.0 (4.1)‡	7.9 (3.9)§
HADS-depression, mean ± SD	7.0 (3.6)‡	6.6 (3.6)§
SRB, mean ± SD	47.4 (23.1)‡	50.3 (24.9)§
CarerQol-7D, mean ± SD	75.9 (15.4)‡	75.3 (16.3)§
CarerQol-VAS, mean ± SD	6.4 (1.4)‡	6.6 (1.3)§

Abbreviation: IQR, interquartile range.

- * n=59
- † n=61
- ‡ n=54
- § n=57
- ¶ n=38
- ¶ n=39
- ** n=33
- †† n=35

-0.20; 95% CI -0.36 to -0.05; $P=.011$) and decreasing HADS-A at T1 (mean difference -2.04; 95% CI -3.50 to -0.57; $P=.007$) and T2 (mean difference -1.77; 95% CI -3.15 to -0.40; $P=.012$) in favor of the intervention. Other effects (HADS-D, SRB, CarerQol) were not significant (see table 3).

At T1, the intervention group reported more consultations with a social worker compared with the control group (mean 2.21 vs 1.00; $P<.001$) as was expected because of the study design. Regarding additional care, the intervention group reported less consultations with the aftercare nurse (mean 0.08 vs 0.37; $P=.037$). Number of consultations with other health care providers was not statistically different.

Discussion

The CARE4Carer blended care intervention aimed to provide partners of patients with ABI support through eHealth in combination with consultations with social workers. This blended care intervention did not lead to a statistically significant increase in caregiver mastery compared with usual care. However, when only including participants who completed most intervention elements, a statistically significant effect was reached on caregiver mastery, compared with care as usual.

Blended care is a relatively novel form of health care which may not be suitable to all individuals. When including partners who completed most of the therapy elements (ie, per protocol analysis), the effects seem more positive. Because of the nature of the intervention, it is highly unlikely that drop-out is caused by (serious) adverse

Table 2 Estimated effects of Care4Carer invention on outcome measures at T1 and T2

Outcome Measure	Time point	Intervention (T1: n=42 T2: n=38)	Control (T1: n=50 T2: n=48)	Mean Difference	SD	95% CI	P Value
Caregiver Mastery Scale	T0	23.28	22.68				
	T1	24.54	23.23	1.31	3.49	-0.12 to 2.74	.072
	T2	24.24	22.92	1.31	3.69	-0.26 to 2.88	.100
Caregiver Strain Index	T0	8.06	7.63				
	T1	6.72	7.30	-0.58	2.44	-1.57 to 0.44	.26
	T2	6.89	7.84	-0.95	2.41	-1.97 to 0.08	.069
Family Assessment Device	T0	1.92	1.88				
	T1	1.89	2.10	-0.21	0.37	-0.36 to -0.06	.008
	T2	2.01	2.11	-0.10	0.39	-0.27 to 0.06	.22
HADS-Anxiety	T0	7.98	7.88				
	T1	6.79	8.56	-1.76	3.51	-3.20 to -0.32	.017
	T2	6.66	8.20	-1.54	3.27	-2.94 to -0.15	.030
HADS-Depression	T0	7.00	6.61				
	T1	6.40	7.25	-0.85	3.33	-2.21 to 0.52	.22
	T2	6.47	7.52	-1.05	3.37	-2.48 to 0.40	.151
Self-Rated Burden	T0	47.37	50.32				
	T1	42.03	47.52	-5.49	23.80	-15.25 to 4.27	.27
	T2	43.78	49.08	-5.29	23.63	-15.35 to 4.76	.30
CarerQoL-7D	T0	75.90	75.30				
	T1	80.26	76.75	3.51	11.84	-1.35 to 8.37	.155
	T2	78.75	74.56	4.20	12.87	-1.28 to 9.68	.131
CarerQoL-VAS	T0	6.39	6.58				
	T1	6.68	6.66	0.30	1.10	-0.15 to 0.75	.190
	T2	6.38	6.38	0.29	1.34	-0.28 to 0.85	.32

Table 3 Estimated effects of Care4Carer invention on outcome measures at T1 and T2, per protocol analysis

Outcome Measure	Time point	Intervention (T1: n=38 T2: n=36)	Control (T1: n=50 T2: n=48)	Mean Difference	SD	95% CI	P Value
Caregiver Mastery Scale	T0	23.28	22.68				
	T1	24.75	23.22	1.53	3.38	0.103 to 2.958	.036
	T2	24.48	22.90	1.57	3.63	0.005 to 3.142	.049
Caregiver Strain Index	T0	8.06	7.63				
	T1	6.36	7.28	-0.92	2.38	-1.92 to 0.09	.072
	T2	6.59	7.83	-1.24	2.34	-2.25 to -0.23	.017
Family Assessment Device	T0	1.92	1.88				
	T1	1.89	2.10	-0.20	0.37	-0.36 to -0.05	.011
	T2	1.99	2.11	-0.11	0.39	-0.28 to 0.06	.184
HADS-Anxiety	T0	7.98	7.88				
	T1	6.46	8.49	-2.04	3.47	-3.50 to -0.57	.007
	T2	6.36	8.13	-1.78	3.18	-3.15 to -0.40	.012
HADS-Depression	T0	7.00	6.61				
	T1	6.13	7.12	-0.98	3.22	-2.34 to 0.38	.154
	T2	6.25	7.38	-1.13	3.27	-2.54 to 0.29	.117
Self-Rated Burden	T0	47.37	50.32				
	T1	40.09	47.29	-7.20	22.56	-16.72 to 2.31	.136
	T2	42.51	48.93	-6.41	23.62	-16.62 to 3.80	.22
CarerQoL-7D	T0	75.90	76.30				
	T1	80.92	77.07	3.84	11.07	-0.83 to 8.51	.106
	T2	79.51	74.86	4.65	12.46	-0.74 to 10.03	.090
CarerQoL-VAS	T0	6.39	6.58				
	T1	6.76	6.40	0.36	1.00	-0.06 to 0.78	.094
	T2	6.75	6.39	0.36	1.30	-0.20 to 0.92	.20

events. Therefore, this blended care intervention could be a valuable treatment tool for support for partners of patients with ABI, when they can be stimulated to complete the intervention.

However, dropout could have introduced a selection bias in the results. Completers and non-completers only differed in their baseline score on the CarerQol-7D, with completers scoring higher on this measurement of caregiver related quality of life. Compared with other outcome measures, the CarerQol-7D more explicitly measures positive aspects of caregiving. This may indicate that partners who had a more positive outlook on caregiving at baseline were more likely to complete the intervention.

Known causes for low adherence to (mostly) online support programs that might have played a role in the current study are time issues, little or no interest of the participants, the perception that treatment is not necessary or not effective, other priorities in daily life and technical problems.²⁶ In comparison with the control group, there was more dropout in the intervention group. Participants who had invested more time in the intervention or with more negative views of the intervention may have been less willing to complete the questionnaires, compared with control group participants. Because of the COVID-19 pandemic in 2020, a minority of partners were not able to have face-to-face appointments with their social workers. In these cases, appointments were over the phone or through video-calls. This may have had a negative effect on efficacy and adherence.

The relatively high dropout rate, although comparable with other blended care intervention for partners,^{27,28} suggests that blended care interventions need further improvement besides simply being blended. Personalized content is a predictor of high adherence.²⁹ Careful selection of partners with a preference for Web-based/from-home care, or with needs that are specifically addressed in the eHealth program, could also increase adherence. A process evaluation of the CARE4Carer program, including participants' likes and dislikes, will be conducted, to hopefully offer further insights into increasing adherence.

Previous studies have evaluated the effects of blended care for caregivers. In a study evaluating a blended care intervention for partners of amyotrophic lateral sclerosis and progressive muscular atrophy patients, no effects were reported on psychosocial outcomes.²⁷ This may indicate that blended care might be more effective in partners of patients with ABI, who are not confronted with swift progressive disease.

In a blended-care program for caregivers of patients with mild dementia, large effect sizes were found in favor of the intervention improving caregiver mastery. In this study, the participants could choose online modules most applicable to their situation. During the program, there was email feedback.²⁸ This personalized approach could explain the larger effect on caregiver mastery.

In this study, the CMS was used as primary outcome measure. Caregiver mastery is a psychological construct that correlates with other constructs such as burden, anxiety, depression, and well-being.¹⁴ We hypothesized that caregiver mastery is an overarching construct, and while individual sessions of the intervention may focus more heavily on other constructs (such as family functioning or anxiety), the overall effect would be to increase caregiver mastery. However, interdependence between these constructs is not yet clear and warrants further experimentation. This could aid selection of primary and secondary outcome measures.

Study limitations

As mentioned and discussed, the study was limited by a lower than expected adherence, leading to a higher drop-out rate and possibly selection bias.

Our primary outcome measure, the CMS, is not routinely used in clinical care or research and its interpretation is difficult. As the minimal clinically importance difference of this scale is not known or agreed upon, we do not know if the confidence interval includes clinically relevant effect sizes.

Our study was conducted in participants whose partners with ABI needed multidisciplinary rehabilitation care but were able to live at home. This limits the generalizability to a more general ABI population.

Conclusion

The Care4Carer intervention did not statistically increase feelings of caregiver mastery in partners of patients with ABI compared with usual care. When including only those partners who had completed at least most intervention elements, caregiver mastery did significantly increase compared with usual care. Concerning secondary outcome measures, the CARE4Carer intervention increased family functioning temporarily, decreased feelings of anxiety and, in the per protocol analysis, decreased caregiver strain at the end of the follow-up period. Therefore, this intervention can be seen as a potential treatment option, especially when fitting the partner's needs and preferences.

Keywords

Brain injury; Caregiver; Randomized controlled trial; Rehabilitation; Telehealth

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References

1. Cameron JJ, Stewart DE, Streiner DL, Coyte PC, Cheung AM. What makes family caregivers happy during the first 2 years post stroke? *Stroke* 2014;45:1084–9.
2. Mackenzie A, Greenwood N. Positive experiences of caregiving in stroke: a systematic review. *Disabil Rehabil* 2012;34:1413–22.
3. Pont W, Groeneveld I, Arwert H, et al. Caregiver burden after stroke: changes over time? *Disabil Rehabil* 2020;42:360–7.
4. Achilike S, Beauchamp J, Cron S, et al. Caregiver burden and associated factors among informal caregivers of stroke survivors. *J Neurosci Nurs* 2020;52:277–83.
5. Smeets S, van Heugten C, Geboers J, Visser-Meily J, Schepers V. Respite care after acquired brain injury: the well-being of caregivers and patients. *Arch Phys Med Rehabil* 2012;93:834–41.

6. Kreitzer N, Kurowski BG, Bakas T. Systematic review of caregiver and dyad interventions after adult traumatic brain injury. *Arch Phys Med Rehabil* 2018;99:2342–54.
7. Kruithof W, Post M, van Mierlo M, van den Bos G, de Man - van Ginkel J, Visser-Meily J. Caregiver burden and emotional problems in partners of stroke patients at two months and one year post-stroke: determinants and prediction. *Patient Educ Couns* 2016;99:1632–940.
8. Grigorovich A, Forde S, Levinson D, Bastawrous M, Cheung AM, Cameron JJ. Restricted participation in stroke caregivers: who is at risk? *Arch Phys Med Rehabil* 2015;96:1284–90.
9. Visser-Meily A, Post M, Schepers V, Lindeman E. Spouses' quality of life 1 year after stroke: prediction at the start of clinical rehabilitation. *Cerebrovasc Dis* 2005;20:443–8.
10. Murray J, Young J, Forster A, Ashworth R. Developing a primary care-based stroke model: the prevalence of longer-term problems experienced by patients and carers. *Br J Gen Pract* 2003;53:803–7.
11. Cheng HY, Chair SY, Chau JP-C. The effectiveness of psychosocial interventions for stroke family caregivers and stroke survivors: a systematic review and meta-analysis. *Patient Educ Couns* 2014;95:30–44.
12. Bakas T, Clark PC, Kelly - Hayes M, King RB, Lutz BJ, Miller EL. Evidence for stroke family caregiver and dyad interventions: a statement for healthcare professionals from the American Heart Association and American Stroke Association. *Stroke* 2014;45:2836–52.
13. Lawton MP, Kleban MH, Moss M, Rovine M, Glicksman A. Measuring caregiving appraisal. *J Gerontol* 1989;44:P61–71.
14. Cox VCM, Schepers VPM, Ketelaar M, Kruithof WJ, van Heugten CM, Visser-Meily JMA. A validation study of the Caregiver Mastery Scale for partners of patients with acquired brain injury. *Clin Rehabil* 2018;32:493–500.
15. Tooth L, McKenna K, Barnett A, Prescott C, Murphy S. Caregiver burden, time spent caring and health status in the first 12 months following stroke. *Brain Inj* 2005;19:963–74.
16. Chi N-C, Demiris G. A systematic review of telehealth tools and interventions to support family caregivers. *J Telemed Telecare* 2015;21:37–44.
17. Ryan C, Bergin M, Wells JS. Theoretical perspectives of adherence to Web-based interventions: a scoping review. *Int J Behav Med* 2018;25:17–29.
18. Wilhelmsen M, Lillevoll K, Risør MB, et al. Motivation to persist with internet-based cognitive behavioural treatment using blended care: a qualitative study. *BMC Psychiatry* 2013;13:296.
19. Cox VC, Schepers VP, Ketelaar M, van Heugten CM, Visser-Meily JM. Evaluating the CARE4Carer blended care intervention for partners of patients with acquired brain injury: protocol for a randomized controlled trial. *JMIR Res Protoc* 2018;7:e60.
20. van Exel NJA, Scholte op Reimer WJM, Brouwer WBF, van den Berg B, Koopmanschap MA, van den Bos GAM. Instruments for assessing the burden of informal caregiving for stroke patients in clinical practice: a comparison of CSI, CRA, SCQ and self-rated burden. *Clin Rehabil* 2004;18:203–14.
21. Visser-Meily JMA, Post MWM, Riphagen II, Lindeman E. Measures used to assess burden among caregivers of stroke patients: a review. *Clin Rehabil* 2004;18:601–23.
22. Hamilton E, Carr A. Systematic review of self-report family assessment measures. *Fam Process* 2016;55:16–30.
23. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *J Psychosom Res* 2002;52:69–77.
24. Hoefman RJ, van Exel J, Brouwer WBF. Measuring the impact of caregiving on informal carers: a construct validation study of the Care-rQol instrument. *Health Qual Life Outcomes* 2013;11:173.
25. Hoefman RJ, van Exel NJA, Foets M, Brouwer WBF. Sustained informal care: the feasibility, construct validity and test-retest reliability of the CarerQol-instrument to measure the impact of informal care in long-term care. *Aging Ment Health* 2011;15:1018–27.
26. Brown M, O'Neill N, van Woerden H, Eslambolchilar P, Jones M, John A. Gamification and adherence to Web-based mental health interventions: a systematic review. *JMIR Ment Health* 2016;3:e39.
27. De Wit J, Beelen A, Drossaert CHC, et al. Blended psychosocial support for partners of patients with ALS and PMA: results of a randomized controlled trial. *Amyotroph Lateral Scler Frontotemporal Degener* 2020;21:344–54.
28. Boots LM, de Vugt ME, Kempen GI, Verhey FR. Effectiveness of a blended care self-management program for caregivers of people with early-stage dementia (partner in balance): randomized controlled trial. *J Med Internet Res* 2018;20:e10017.
29. Beatty L, Binnion C. A systematic review of predictors of, and reasons for, adherence to online psychological interventions. *Int J Behav Med* 2016;23:776–94.