Multi-Site, Multi-Country Randomized Clinical Trial of an Acute Traumatic Brain Injury Caregiver Transition Assistance Program in Latin America

Paul B. Perrin^{1,2}, Yaneth Rodriguez-Agudelo³, Silvia Leonor Olivera Plaza⁴, Maria Cristina

Quijano-Martinez⁵, Michael A. Trujillo⁶, Erin R. Smith⁷, Annahir N. Cariello⁷, & Juan Carlos

Arango-Lasprilla⁷

¹University of Virginia, Charlottesville, USA

²Central Virginia Veterans Affairs Health Care System, Richmond, USA

²Neuropsychology Department, National Institute of Neurology and Neurosurgery, Mexico City,

Mexico

⁴Universidad Surcolombiana, Neiva, Colombia

⁵Departartment of Social Sciences, Pontificia Universidad Javeriana, Cali, Colombia

⁶Carnegie Mellon University, Philadelphia, USA

⁷Virginia Commonwealth University, Richmond, USA

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Corresponding author: Paul B. Perrin, Ph.D. School of Data Science and Department of Psychology University of Virginia Email: perrin@virginia.edu

Abstract

BACKGROUND: Individuals with traumatic brain injury (TBI) in Latin America experience high levels of disability and extremely poor functional outcomes, and their informal caregivers play a key role in their rehabilitation and care.

OBJECTIVE: To improve TBI rehabilitation through stronger informal caregiving, this study developed and evaluated an evidence-based and culturally appropriate Transition Assistance Program (TAP) for informal caregivers of individuals with TBI in Latin America, specifically targeting the time period before and after the transition from hospital to home.

METHODS: A sample of 89 people with a new TBI and their primary informal caregiver (n = 178) was recruited from two hospitals in Mexico City, Mexico, and in Cali, Colombia. Caregivers were randomly assigned to either the TAP group or to a control group receiving the standard care provided by the hospital. Caregivers completed measures of depression and burden, and individuals with TBI completed measures of depression and self-perceived burden

on caregivers before hospital discharge and at 2- and 4-month follow ups.

RESULTS: Caregivers in the TAP group reported significantly lower burden than those in the control group and marginally lower depression. Individuals with TBI whose caregivers had been in the TAP group reported significantly lower depression than those whose caregivers had been in the control group and non-significant but lower self-perceived burden on their caregivers. CONCLUSIONS: The results suggest that the TAP has strong potential to benefit both TBI caregivers and individuals with TBI during the transition from acute TBI hospitalization to home in Latin America, generally showing small- or medium-sized effects on key outcomes. Keywords: Traumatic brain injury; caregiver; acute rehabilitation; Latin America; intervention; randomized clinical trial.

Multi-Site, Multi-Country Randomized Clinical Trial of an Acute Traumatic Brain Injury

Caregiver Transition Assistance Program in Latin America

Traumatic brain injury (TBI) has been called a "silent epidemic" in that it is one of the largest contributors to death and disability around the world (Vaishnavi, Rao, & Fann, 2009). The highest incidences of TBI due to violence and road traffic injuries occur in Latin America (Hyder et al., 2007; Puvanachandra & Hyder, 2008). Recent estimates from literature reviews and national registries suggest that there are approximately 909 new TBI cases per 100,000 people in the region (Dewan et al., 2018). In Colombia, TBI prevalence is approximately 6.4 per 1,000 people, due heavily to intentional injuries resulting from hostile guerillas and landmine explosions (Pradilla, Vesga, León-Sarmiento, & Grupo GENECO, 2003). Similarly, in Mexico, TBI is the third leading cause of death, and injuries are caused predominantly by motor vehicle accidents (Julio César, et al., 2008). As compared to 56.8 per 100,000 inhabitants in the United States, overall TBI mortality rates in Latin America are estimated to be 75.5 per 100,000 (Charry, 2017; Peterson, Xu, Daugherty, & Breiding, 2014). TBI burden disproportionally affects low- and middle-income countries due to a higher prevalence of risk factors coupled with less developed health and rehabilitation systems to deal with associated health outcomes. According to the World Health Organization, low- and middle-income countries, including those in Latin America, more than 90% of deaths caused by TBI are due to risk factors such as living below the poverty line, residing in a conflict zone, a lack of prevention measures, and underresourced health systems (MRC CRASH Trial Collaborators, 2008; Gosselin et al., 2009). In Latin America, the effects of TBI are especially severe due to limited medical and rehabilitation resources (Arango-Lasprilla et al., 2010).

Despite these relatively high rates of death in certain global regions, TBI is increasingly

being seen as a chronic health condition (Corrigan & Hammond, 2013). People with TBI experience chronic neurocognitive impairments that increase vulnerability to adverse health outcomes and produce long-term symptoms across cognitive (poor concentration, memory problems, executive function difficulties), somatic (headache, nausea), affective (depression, restlessness, irritability), behavioral (aggressiveness), and motor domains (Corrigan & Hammond, 2013). Recovery time is extremely variable, and many major symptoms remain even after five years, especially with more severe injuries (Huang, Ho, & Yang, 2010). In part because of these symptoms, only 40% of people with TBI return to work within two years post-injury (Van Velzen, Van Bennekom, Edelaar, Sluiter, & Frings-Dresen, 2009), and more severe symptoms are associated with reduced employment (Andelic et al., 2012).

The responsibility for TBI symptom management often falls on family members who become informal caregivers, and a large proportion of family caregivers devote over 40-50 hours a week to TBI symptom management (Kreutzer, Serio, & Bergquist, 1994). Family members are often unprepared and inexperienced in caregiving and symptom management, and families affected by TBI in Latin America experience myriad unmet emotional, instrumental, and professional support needs regarding symptom management (Arango-Lasprilla, et al., 2010). Though these needs have been similarly rated as important by United States TBI caregivers, they are more likely to be unmet for caregivers in Colombia (Arango-Lasprilla, et al., 2010). Physical symptoms in individuals with TBI in Latin America are associated with greater family household needs, and emotional symptoms with greater family informational needs (Sung et al., 2013). Research in Latin America has shown these high rates of unmet needs are very closely associated with mental health problems in family caregivers (Doyle et al., 2013). Family caregivers of individuals with TBI in Mexico report poorer health-related quality of life than do healthy controls across various domains of mental and general health (Arango-Lasprilla et al., 2011). In Colombia, the majority of family caregivers studied reported some level of depression, and about half reported being overwhelmed by their caretaking responsibilities (Stevens et al., 2012).

It is not surprising then, that this transition to becoming a caregiver, coupled with a lack of rehabilitation services or family-based coping strategies, can lead to increased stress on caregivers (Turner et al., 2007). The current paradigm in TBI intervention research both in Latin America and globally lacks a theoretical foundation for providing services to the primary caregiver at hospital discharge to aid as the TBI patient transitions home, and nearly all TBI caregiver interventions occur during the chronic phase, many months or years after injury (Wise et al., 2012; Brown et al., 1999). These chronic-phase caregiver interventions tend to provide psychoeducation (Brown et al., 1999), stress management strategies (Albert et al., 2002), techniques to manage cognitive or behavioral symptoms in the individual with TBI (Carnevale, Anselmi, Busichio, & Millis, 2002), and problem-solving skills (Rivera, Elliott, Berry, & Grant, 2008). Some use a combination of these approaches (Kreutzer et al., 2009). In general, these interventions have been shown to increase caregiver problem-solving skills (Rivera, Elliott, Berry, & Grant, 2008), reduce burden (Albert et al., 2002), and decrease anxiety (Brown et al., 1999) and depression (Rivera, Elliott, Berry, & Grant, 2008). Psychoeducational programs are less effective for improving caregiver outcomes (Carnevale, Anselmi, Busichio, & Millis, 2002).

Critical needs exist for research on the development of rehabilitation interventions for TBI caregivers in Latin America. The incidence of TBI is extremely high in this region, but caregiving resources such as nursing homes, adult day-care, health care facilities, education, and support groups are scarce (Arango-Lasprilla et al., 2011). Unfortunately, very few studies (e.g., Doyle et al., 2013), have examined the psychosocial impact of caregiving for an individual with TBI in Latin America. Latin America is comprised of many low to middle income countries, and about 36% of the region's population lives in poverty (Leipziger, 2001). Treatment interventions that include family caregivers may maximize the strengths of Latino families, such as a strong sense of familism (Lehan, Arango-Lasprilla, de los Reyes, & Quijano, 2012). Further, the majority of TBI patients in this global region are discharged directly home, and family members shoulder the burden of care (Arango-Lasprilla et al., 2011). To date, no interventions exist in Spanish for TBI caregivers, none have been systematically tested or implemented in Latin America, and no TBI caregiver interventions even outside of Latin America focus on supporting caregivers as the person with TBI transitions from hospital to home immediately after injury. This is a particularly glaring gap in rehabilitation services as many healthcare professionals working with TBI caregivers are unsure how to intervene most effectively to aid in transitioning home post-injury (Stejskal, 2012). As a result, to improve TBI rehabilitation through stronger informal caregiving, the purpose of this study was to develop and evaluate an evidence-based and culturally appropriate Transition Assistance Program (TAP) for informal caregivers of individuals with TBI in Latin America during the transition from hospital to home.

Method

Transparency and Openness

All statistical analyses and hypotheses were pre-registered on clinicaltrials.gov. All anonymized data, research materials, and code for statistical analyses are available upon request from the corresponding author. Analyses were conducted using SPSS Version 27.

Participants

Originally, a sample of 109 people with a new TBI and their primary informal caregiver (total n = 218) was recruited from three hospitals in Mexico City, Mexico (n = 68 dyads), and in

Cali (n = 21 dyads) and Neiva (n = 20 dyads), Colombia. Due to a systematic error in the randomization of caregivers to intervention and control conditions in Neiva, these 20 dyads were excluded from the current analyses, leaving an analytic sample of 89 people with TBI and their caregiver (n = 178). Patient inclusion criteria included: (a) have a diagnosis of TBI, (b) be discharged home, (c) be over the age of 18 at enrollment, (d) be able to communicate orally in Spanish, (e) give permission for their caregiver to participate, and (f) sign an informed consent giving permission to obtain demographic and health information. Caregiver inclusion criteria included: (a) be the primary caregiver for the person with TBI, (b) be between 18-85 years of age, (c) be able to communicate orally in Spanish, (d) sign an informed consent, and (e) score at least a 13 on a health literacy screening tool (Huan, 2007) (f) or be able to identify a family member or friend to review TAP guidebook with the caregiver (if no one was identified, the TAP clinician reviewed the materials with the caregiver). Participants' demographic information appears in Table 1.

Procedure

Informed consent, questionnaires, and all other study materials were approved by the Virginia Commonwealth University Institutional Review Board, in addition to approval from each site in Latin America. Patient and caregiver eligibility for the study was determined through a pre-screening. If potential participants appeared to meet preliminary eligibility, a detailed review of the patient's medical records was conducted to assess whether full inclusion criteria were met. The first data collection occurred in person in the hospital as close to hospital discharge from the new TBI as possible, and the second and third data collections occurred in the homes of participants at 2 months and 4 months after discharge. All data collections were conducted by professional psychologists or highly trained research assistants. Participants each

received the local equivalent of US \$10 cash per data collection. An important feature of the informed consent process was that the research team clearly stated that they were required by law to report to the authorities or a medical team any incidents where a patient or caregiver reported current abuse or indicated that they intended to harm themselves or others. If participant reported moderate or severe psychological distress or suicidality, study staff provided an appropriate referral (e.g., to a psychologist) if it was deemed clinically necessary. TBI caregivers were randomly assigned to either the intervention group or to a control group receiving the standard care provided by the hospital. A visual model of the randomized clinical trial (RCT) design is presented in Figure 1.

Transition Assistance Program (TAP)

The TAP is based on an intervention originally developed for caregivers of individuals with stroke (Perrin et al., 2010) begins before discharge and extends across 6 weeks. It addresses three domains to improve caregiver mental health and informal care: (a) skill development, (b) education, and (c) supportive problem solving. It includes a culturally tailored, Spanish TBI caregiving guidebook that is provided in a 1-hour face-to-face intervention session by a TBI clinician before the patient's hospital discharge, and four 1-hour in-home visits at 1, 2, 4, and 6 weeks after discharge by the same TBI clinician.

Guidebook Development. A guidebook was developed entitled "A Guidebook for TBI Caregivers" based heavily research examining the needs of TBI caregivers in Latin America, as well as on other published studies on TBI. This guidebook was created to target common unmet needs directly and therefore included chapters addressing (a) basic medical information about TBI, (b) common caregiver experiences, (c) TBI recovery issues such as disability, disruption in sense of self, social isolation, and depression, and (e) resources to assist TBI caregivers. An extensive formative evaluation of the guidebook included focus groups with TBI clinicians at the hospitals in Mexico and Colombia, as well as with TBI clinicians and researchers in the United States. The guidebook was translated into Spanish and piloted with TBI clinicians and caregivers at the sites in Colombia and Mexico who provided qualitative feedback, which was then integrated, on the guidebook's appropriateness for TBI caregivers in the region.

Session 1. In preparation for Session 1 with the caregiver, a rehabilitation clinician (in this case, psychologists) delivering the TAP meets with the facility's medical team to identify the primary difficulties anticipated for the TBI patient after discharge. The clinician takes notes on the particular needs of the patient and bring these notes to Session 1 with the caregiver. Before discharge, the clinician implements Session 1, a 1-hour meeting with the caregiver. The primary focus of Session 1 is to orient the caregiver to the TAP and prepare the caregiver for discharge home. The clinician provides the caregiver a guidebook and orientation to it, encouraging the caregiver to use it as a resource.

The clinician also administers the health literacy screening tool (Huan, 2007), and with caregivers who score below a 13, the clinician helps identify a family member or friend to review the guidebook with the caregiver (or the clinician if no family member or friend can be identified). The clinician then asks what concerns the caregiver has about taking care of the TBI patient after discharge, taking notes on the caregiver's responses. The clinician also shares with the caregiver the primary difficulties that the medical team has anticipated the TBI patient experiencing after discharge. The clinician provides support and helps the caregiver problem-solve caregiving related to these issues.

Sessions 2-5. The clinician makes four 1-hour in-home visits to the TBI caregiver at 1, 2, 4, and 6 weeks after hospital discharge. The TBI patient may or may not be present during these

visits, depending on the needs and wishes of the caregiver. These visits involve the same general format. The clinician brings his or her notes from the previous sessions and from the medical team's input. The clinician reviews the content of these notes with the caregiver, checking in to see whether the problems are still present and to what extent. The clinician engages in supportive problem-solving and refers the caregiver to the guidebook sections relevant to the issues, walking the caregiver through those sections.

Because of this format, the TAP is specifically designed for clinicians to tailor its use not only according to possible regional differences in what may be necessary for the intervention, but also for differences in caregiver care responsibilities and needs within a specific clinic. The entire structure of the TAP is centered around the caregiver's most pressing needs. The clinician takes notes on the continued problems and the strategies for resolving them.

Measures

Data were collected from caregivers and individuals with TBI at baseline in the hospital immediately before discharge and at 2 and 4 months after discharge. A research assistant read items aloud from an assessment packet to the individual with TBI and caregiver, circling participants' responses, in order to account for possible literacy issues.

Patient Health Questionnaire-9 (PHQ-9; caregiver and patient). The Spanish PHQ-9 is a depression module based on the 9-item DSM-IV criteria (Arrieta et al., 2017; Muñoz-Navarro et al., 2017). The PHQ-9 was designed for use in clinical practice and research. The depression module scores each of the 9-item DSM-IV criteria as "0" (not at all) to "3" (nearly every day). Scoring used the mean of all items such that higher mean scores indicate higher levels of depression. The PHQ-9 has good internal reliability with a Cronbach's alpha = .89,

good test-retest reliability, sensitivity of 88% and specificity of 80% (Arrieta et al., 2017; Muñoz-Navarro et al., 2017).

Zarit Burden Interview (ZBI; caregiver). The ZBI (Zarit, Reever, & Bach-Peterson, 1980) is one of the most widely used scales measuring subjective caregiver burden. It is a 22item, self-report questionnaire with items referring to the caregiver/patient relationship and evaluating the caregiver's health condition, psychological well-being, finances, and social life. Responses can range from 'never' to 'nearly always,' and higher scores indicate greater levels of caregiver distress (Karlikaya et al., 2005). The Spanish version of the ZBI has good internal reliability (Martín et al., 1996).

Self-Perceived Burden Scale (SPBS; patient). The SPBS (Cousineau et al., 2003) assesses care recipients' feelings of dependence and guilt over responsibility for their caregiver's difficulties.41 The SPBS contains 10 items which respondents rate with a 5-point Likert scale (1 = none of the time and 5 = all of the time), with higher scores indicating higher self-perception of a being a burden.

Data Analyses

In order to determine whether the TAP was effective in improving caregiver depression and burden, as well as patient depression and self-perceived burden, four repeated-measures analyses of covariance (ANCOVAs) were conducted with group (TAP vs. control), time (2month and 4-month follow up), and the group*time interaction as independent variables. In each analysis, the dependent variable at baseline was included as a covariate, and respective estimated marginal means with 95% confidence intervals (CIs) were calculated by group in order to graph potential statistical effects. One dyad was lost to follow-up at the 2-month follow up and three additional dyads at the 4-month follow up. The expectation maximization algorithm was used to impute missing values for these participants in order to retain the full sample.

Results

Caregiver Depression

In the repeated-measures ANCOVA with caregiver depression as the dependent variable, there was a marginally significant main effect of group, F(1,82) = 3.79, p = .055, $\eta_p^2 = .044$, a small-sized effect. Caregivers in the TAP group had marginally lower depression scores across the two follow-up time points than those in the control group. There was not a significant group*time effect, F(1,82) = .38, p = .540, $\eta_p^2 = .005$, suggesting no differential change over time as a function of group. The depression estimated marginal means (and standard errors) across the two time points for caregivers in the control group were 5.78 (.53) and 5.43 (.53), while those in the TAP group were 4.26 (.53) and 4.19 (.52), respectively (Figure 2).

Caregiver Burden

In the repeated-measures ANCOVA with caregiver burden as the dependent variable, there was a statistically significant main effect of group, F(1,82) = 4.15, p = .045, $\eta_p^2 = .048$, a small-sized effect. Caregivers in the TAP group had significantly lower burden scores across the two follow-up time points than those in the control group. There was not a significant group*time effect, F(1,82) = .72, p = .399, $\eta_p^2 = .009$, suggesting no differential change over time as a function of group. The burden estimated marginal means (and standard errors) across the two time points for caregivers in the control group were 31.15 (1.97) and 26.16 (2.15), while those in the TAP group were 24.74 (1.95) and 21.80 (2.13), respectively (Figure 3).

Patient Depression

In the repeated-measures ANCOVA with patient depression as the dependent variable, there was a statistically significant main effect of group, F(1,82) = 4.76, p = .032, $\eta_p^2 = .055$, a medium-sized effect. Patients in the TAP group had significantly lower depression scores across the two follow-up time points than those in the control group. There was not a significant group*time effect, F(1,82) = .49, p = .487, $\eta_p^2 = .006$, suggesting no differential change over time as a function of group. The depression estimated marginal means (and standard errors) across the two time points for patients in the control group were 6.56 (.63) and 6.41 (.66), while those in the TAP group were 5.01 (.63) and 4.33 (.65), respectively (Figure 4).

Patient Self-Perceived Burden

In the repeated-measures ANCOVA with patient self-perceived burden as the dependent variable, there was no statistically significant main effect of group, F(1,82) = 1.70, p = .196, $\eta_p^2 = .020$, a small-sized but non-significant effect. Patients in the TAP group visually had lower self-perceived burden scores across the two follow-up time points than those in the control group. There was not a significant group*time effect, F(1,82) = .04, p = .850, $\eta_p^2 = .000$, suggesting no differential change over time as a function of group. The self-perceived burden estimated marginal means (and standard errors) across the two time points for patients in the control group were 28.55 (1.08) and 27.32 (1.15), while those in the TAP group were 26.86 (1.07) and 25.36 (1.14), respectively (Figure 5).

Discussion

To improve TBI rehabilitation through stronger informal caregiving, this study evaluated the Transition Assistance Program (TAP) for informal caregivers of individuals with TBI in Latin America, specifically targeting the time period before and after the transition from hospital to home. A sample of people with a new TBI and their primary informal caregiver was recruited from two hospitals in Mexico City, Mexico, and in Cali, Colombia. Caregivers were randomly assigned to either the TAP group or to a control group receiving the standard care provided by the hospital. Caregivers completed measures of depression and burden, and individuals with TBI completed measures of depression and self-perceived burden on caregivers before hospital discharge and at 2- and 4-month follow ups. Caregivers in the TAP group reported significantly lower burden than those in the control group and marginally lower depression. Individuals with TBI whose caregivers had been in the TAP group reported significantly lower depression than those whose caregivers had been in the control group and non-significant but lower self-perceived burden on their caregivers.

Interpretation of Findings

Caregivers. The findings that the TAP produced a small-sized improvement in caregiver burden and a marginal but small-sized improvement in caregiver depression show that it is likely very helpful in targeting key psychological adjustment outcomes for new TBI caregivers, particularly during the extremely stressful time period before and immediately after hospital discharge (Turner et al., 2007) when they are learning to be TBI caregivers for the very first time. These positive effects for the TAP are in line with other previous studies documenting the effects of TBI caregiver interventions on burden (Albert et al., 2002) and depression (Rivera, Elliott, Berry, & Grant, 2008) many months or years after the initial TBI. Likely one of the primary reasons that the TAP was helpful to new TBI caregivers in this study is because it included a combination of a guidebook concretely teaching caregivers some of the basics about TBI itself and the caregiving process. Additionally, the supportive problem-solving approach was meant in a culturally responsive way to help caregivers with the caregiving issues that they deemed most pressing that week and to teach them a problem-solving skill set that would generalize to other caregiving challenges. Additionally, the in-home nature of sessions 2-5 likely overcame transportation and other logistical challenges commonly faced by TBI caregivers generally and especially those in Latin America.

Patients. The findings that the TAP produced a medium-sized improvement in patient depression and a non-significant but small-sized improvement in self-perceived burden show that it is not only helpful for caregivers but that its effects can actually extend to individuals with TBI themselves during the extremely challenging transition from hospital to home. This is one of the first times in the scientific literature that a caregiver-only intervention produced generalized positive effects extending to individuals with TBI. While the precise mechanisms of this generalized effect are unknown, likely possibilities include improvement in the quality of care provided, improved relationship satisfaction, and simply better caregiver mental health that could presumably create similarly good mental health in the other member of that important caregiving relationship. Previous research has found that teaching techniques to manage cognitive or behavioral symptoms in the individual with TBI can be very helpful for caregivers (Carnevale, Anselmi, Busichio, & Millis, 2002), and some of the approaches addressed in the TAP guidebook and problem-solving training indeed deal with managing these symptoms in patients, also possibly accounting for the patient-level effects.

Clinical Implications

The TAP is the first known evidence-based intervention to help support family members in becoming TBI caregivers for the first time during the extremely difficult hospital-to-home transition period. Particularly as applied to Latin America, caregiver interventions like this are critical. TBI rehabilitation in Latin America focuses exclusively on the individual with TBI and rarely includes caregivers, a rehabilitation approach that taps perhaps only half the effectiveness it potentially could. In addition to being unique in its focus on the transition period, to date, no intervention for TBI caregivers has been systematically developed or tested in Latin America this was the first TBI caregiver RCT in the entire global region. In Latin America, treatment interventions like the TAP that include family caregivers may maximize the strengths of Latino families, such as a strong sense of familism (Lehan et al., 2012). Other than the TAP, no evidence-based interventions exist in Spanish targeting the primary caregiver of individuals with TBI, and none have been systematically tested or implemented in Latin America.

Limitations and Future Directions

The current findings should be considered in the context of several limitations, which also present directions for future research. First, although this was a multi-country RCT, participants were only from two sites in two countries, Mexico and Colombia. Therefore, caution should be exercised in generalizing the effectiveness of the TAP to other countries in Central and South America. Future studies should investigate the TAP in other countries as well as in non-Spanish speaking countries when translated into the appropriate languages and piloted with TBI caregivers in those countries. Second, this study had a relatively limited follow-up time period, with outcome variables assessed at 2 and 4 months. Psychological adjustment of caregivers and individuals with TBI is extremely likely to continue beyond this initial period, so future studies should collect data at 6 months, 1 year, and beyond in order to determine the duration of treatment effects. Third, unfortunately a systematic randomization error precluded the findings from one of the original sites (Neiva, Colombia) from being included in the current study. While running federally-funded caregiver RCTs in Latin America across multiple sites and countries is extremely challenging, future related research would benefit from making sure all study staff are extremely well trained and fully on board with randomization schedules and the tightly

controlled environment needed for an experimental RCT. Fourth, there is no standard way that injury severity is assessed across these different sites/countries, and they do not or variably use common measures such as Glasgow Coma Scale or length of posttraumatic amnesia. Future research would benefit from collecting a standard assessment of injury severity. Doing so would allow, for example, comparisons across sites/countries, as well as between subsamples in different intervention arms. Finally, additional follow-up variables should be collected in future studies that might shed light on mechanisms of action for caregiver intervention effects, such as objective measures of quality of caregiving, caregiving dyad relational dynamics, caregiver selfefficacy, caregiver coping styles, and general health-related quality of life.

Conclusion

Despite these limitations, the results of this study suggest that the TAP has strong potential to benefit both TBI caregivers and individuals with TBI during the transition from acute TBI hospitalization to home in Latin America, generally showing small- or medium-sized effects on key outcomes. The TAP for TBI caregivers should be tested in larger-scale trials in additional countries and regions of Latin America and globally. If shown to have consistent treatment effects, the TAP could be exported across other rehabilitation facilities in Latin America or other global regions and become part of the standard of care for regions with extremely high rates of TBI and little standardized support for caregivers.

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Table 1. Participant demographics

Caregiver Demographics		(<i>n</i> = 89)
Age, $M(SD)$		41.91 (14.10)
Education, years, $M(SD)$		10.39 (5.23)
Sex, <i>n</i> (%)	Male	17 (19.1)
	Female	72 (80.9)
Relationship to patient, n (%)	Parent	22 (24.7)
	Spouse	25 (28.1)
	Sibling	11 (12.4)
	Child	21 (23.6)
	Aunt/Uncle	2 (2.2)
	Other	8 (9.0)
Pre-injury Employment Status, n (%)	Employed Full-time	32 (36.0)
	Employed Part-time	18 (20.2)
	Homemaker	29 (32.6)
	Unemployed	5 (5.6)
	Student	4 (4.5)
	Retired/Pension	1 (1.1)
Patient Demographics		(<i>n</i> = 89)
Age, $M(SD)$		37.20 (14.64)
Days in the hospital, $M(SD)$		23.15 (31.34)
Sex, <i>n</i> (%)	Male	71 (79.8)
	Female	18 (20.2)
Cause of Injury, <i>n</i> (%)	Automobile Accident	12 (13.5)
	Motorcycle Accident	27 (30.3)
	Bicycle Accident	1 (1.1)
	Pedestrian Accident	6 (6.7)
	Firearm	2 (2.2)
	Act of Violence	17 (19.1)
	Sports Accident	1 (1.1)
	Fall	20 (22.5)
	Other	3 (3.4)
Pre-injury Employment Status, n (%)	Employed Full-time	48 (53.9)
	Employed Part-time	16 (18.0)
	Home/Family Care	8 (9.0)
	Unemployed	7 (7.9)
	Student	8 (9.0)
	Retired/Pension	2 (2.2)









Figure 3. Caregiver follow-up burden estimated marginal means (and 95% CIs) controlling for baseline burden



Figure 4. Patient follow-up depression estimated marginal means (and 95% CIs) controlling for baseline depression

Figure 5. Patient follow-up self-perceived burden estimated marginal means (and 95% CIs) controlling for baseline self-perceived burden

