



Published in final edited form as:

*Arch Phys Med Rehabil.* 2018 November ; 99(11): 2342–2354. doi:10.1016/j.apmr.2018.04.016.

## Systematic Review of Caregiver and Dyad Interventions After Adult Traumatic Brain Injury

Natalie Kreitzer, MD<sup>a,b</sup>, Brad G. Kurowski, MD, MS<sup>c</sup>, Tamilyn Bakas, PhD, RN<sup>d</sup>

<sup>a</sup>Department of Emergency Medicine, College of Medicine, University of Cincinnati, Cincinnati, Ohio

<sup>b</sup>Division of Neurocritical Care, College of Medicine, University of Cincinnati, Cincinnati, Ohio

<sup>c</sup>Department of Pediatrics, Neurology and Rehabilitation Medicine

<sup>d</sup>College of Nursing, University of Cincinnati, Cincinnati, Ohio, United States

### Abstract

**Objective:** To describe and synthesize the literature on adult traumatic brain injury (TBI) family caregiver and dyad intervention. TBI is a common injury that has a significant long-term impact, and is sometimes even characterized as a chronic condition. Informal (ie, unpaid) family caregivers of adults with TBI experience high rates of burnout, depression, fatigue, anxiety, lower subjective well-being, and poorer levels of physical health compared to noncaregivers. This study addresses the critical gap in the understanding of interventions designed to address the impact of TBI on adult patients and their family caregivers.

**Data Sources:** PubMed and MEDLINE.

**Study Selection:** Studies selected for review had to be written in English and be quasi-experimental or experimental in design, report on TBI caregivers, survivors with heavy involvement of caregivers, or caregiver dyads, involve moderate and severe TBI, and describe an intervention implemented during some portion of the TBI care continuum.

**Data Extraction:** The search identified 2171 articles, of which 14 met our criteria for inclusion. Of the identified studies, 10 were randomized clinical trials and 4 were nonrandomized quasi-experimental studies. A secondary search to describe studies that included individuals with other forms of acquired brain injury in addition to TBI resulted in 852 additional titles, of which 5 met our inclusion criteria.

**Data Synthesis:** Interventions that targeted the caregiver primarily were more likely to provide benefit than those that targeted caregiver/survivor dyad or the survivor only. Many of the studies were limited by poor fidelity, low sample sizes, and high risk for bias based on randomization techniques.

**Conclusions:** Future studies of TBI caregivers should enroll a more generalizable number of participants and ensure adequate fidelity to properly compare interventions.

## Keywords

Brain injuries; traumatic; Caregivers; Rehabilitation

---

In the United States, 2.5 million people each year sustain traumatic brain injuries (TBI), and more than 5.3 million people with TBI live with long-term physical, cognitive, and psychological disabilities.<sup>1-3</sup> Due to its long-term impact, TBI is considered a chronic condition.<sup>4</sup> After moderate and severe TBI, individuals are unable to make their own decisions. Families of adults with TBI are generally not prepared for their new complex role as a caregiver. Unlike many chronic diseases, TBI affects people of all ages, with many young patients requiring decades, and potentially a lifetime, of specialized, highly involved care. In a large national dataset from Canada, adults with TBI were among the youngest in home care, nursing home care, and complex continued care settings when compared to both other neurological and non-neurological conditions.<sup>5</sup> Much research has focused on factors that might influence outcomes from moderate and severe TBI; fewer studies have investigated the role of caregivers and families in outcomes after moderate and severe TBI in adults.

With TBI, disabilities persist for months or years post injury.<sup>6,7</sup> On returning home from inpatient care, individuals with TBI often must rely on informal and untrained caregivers for support and advocacy. These caregivers include spouses, children, other family members, or friends, and not trained caregivers. Patients with TBI may find it difficult to find and access the resources that support their choice to live at home rather than in an institution.

Compared to patient-oriented interventions, fewer interventions have targeted untrained caregivers of adults with TBI. Caregivers of adults with chronic medical conditions suffer from depression, fatigue, burden, burnout, anxiety, lower subjective well-being, and poorer levels of physical health compared to non-caregivers.<sup>8-17</sup> Family caregivers of such chronic conditions are typically unpaid, and caregiver satisfaction with life worsens over time, especially when caring for individuals with severe TBI.<sup>18</sup> Caregiver impaired health status and burden correlated with global disability after severe TBI.<sup>17</sup> Thus, interventions that reduce strain are important both for patients and caregivers. At this time, no guidelines or recommendations from official governing are available to clinicians who wish to offer guidance to caregivers of adults with TBI. The purpose of this systematic review was to describe and synthesize the existing literature of published adult TBI family caregiver and dyad intervention studies.

## Methods

We conducted a critical analysis of studies of adult TBI family caregiver and dyad intervention. Studies had to meet the following inclusion criteria: (1) be written in English; (2) use a quasi-experimental or experimental design with a comparison group and intervention group; (3) describe an intervention in TBI caregivers, TBI survivors with heavy involvement of caregivers, or TBI caregiver dyads; (4) involve moderate or severe TBIs; (5) include an intervention that was implemented during some portion of the care continuum; (6) enroll adult patients as participants. We excluded studies that (1) involved

patients with only mild TBI; (2) included patients with other forms of acquired brain injury (ie, stroke); (3) did not involve caregivers in the study or did not report outcomes of caregivers in the study; (4) enrolled pediatric patients as participants. We later conducted a post-hoc search to describe and reference additional interventions that enrolled individuals with other forms of acquired brain injury. We defined moderate and severe TBI by using the Glasgow Coma Scale, or, if the scale was not reported, by using consensus from authors of the respective studies.<sup>19</sup> We excluded from our review dissertations, books, abstracts, ongoing unpublished studies, and conference proceedings. We searched PubMed and MEDLINE for the following keywords: *traumatic brain injury and family; traumatic brain injury caregiver; traumatic brain injury caregiver interventions; traumatic brain injury and caregiver experimental studies; traumatic brain injury caregiver quasi-experimental studies*. We included articles published before the date of the search (October 22, 2017). We tracked the search process with a Preferred Reporting Items for Systematic Reviews and Meta-Analysis flow diagram (fig 1). In table 1, we provide summaries of the articles meeting our inclusion criteria, and we describe their interventions in table 2 and their outcomes in table 3. All authors reached consensus was reached on article inclusion. For each study, 1 team member completed the data extraction using a pre-developed electronic form. Table 4 includes information extracted from each study. A second team member verified all extracted data, and disagreements were resolved through discussion or third party consultation when consensus could not be reached. Two authors (N.K., T.B.) categorized the interventions, and a third author (B.G.K.) adjudicated any disagreements in categorization of the interventions.

To critique the studies, we followed a practice like that followed by Bakas and colleagues<sup>20,21</sup> in their reviews of stroke caregiver and dyad interventions. We used criteria from the Consolidated Standards of Reporting Trials (CONSORT) and Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statements and assessing the reports for threats to bias and validity.<sup>22–25</sup> We described the samples, interventions, and outcomes, and highlighted the best designed studies highlighted for further discussion. We extracted details of the interventions by the Template for Intervention Description and Replication checklist.<sup>26</sup> Inter-study heterogeneity, including severity of TBI, time since TBI, types of interventions, outcome measures, and duration of treatment, was high, precluding a meta-analysis, and, therefore, we used a narrative synthesis of all the included studies.

### Post-Hoc Literature Search

We conducted a secondary search of studies that additionally enrolled caregivers of individuals with other forms of acquired brain injury, because some of these interventions targeted components of brain injury recovery that also may be beneficial for caregivers of individuals with TBI. In the rehabilitation period, for instance, similar techniques for caregivers may be applicable across different disease spectrums. Therefore, we also separately reviewed literature that included subjects with other neurological disease processes in addition to TBI to determine best strategies for caregivers. Our original literature search excluded 3 studies that enrolled non-TBI subjects into the study, and a second literature search of articles with the additional keywords *brain injury caregiver* resulted in 2 more studies, giving us 5 more studies to analyze.

## Results

Our primary search identified 2148 journal articles. From other sources, we identified another 23 articles, which gave us 2171 articles. After we removed duplicates, we had 2167 articles, and, from these articles, we excluded 2139 based on relevance of titles or abstracts. As a result, we now had 28 papers from 27 unique studies that merited review of the full text articles. Based on our inclusion and exclusion criteria, we identified 14 of these 28 studies that met our criteria for inclusion (see fig 1).

Our secondary literature search, on February 15, 2018, resulted in 852 additional unique titles for review. The interventions of these 5 studies that enrolled individuals with TBI in addition to other types of acquired brain injuries are summarized in table 5.

## Designs

Of the 14 studies identified for inclusion in our study, 10 were randomized clinical trials (RCTs) of interventions and 4 were nonrandomized quasi-experimental studies. We used CONSORT statement criteria to determine quality and validity of the RCT studies. Randomization was poor in some studies, in which there was no block randomization or attempt to equalize the groups.<sup>27,28</sup> Some studies provided little information about how subjects were randomized.<sup>28–30</sup> Only 2 studies provided detail about the study design's randomization methods: Powell et al<sup>31</sup> used block randomization based on hospital disposition, and Bell et al<sup>32</sup> used stratified randomization based on discharge FIM, location, and block randomization. Neither the RCTs nor the nonrandomized quasi-experimental studies could blind the intervention to the survivor or the caregiver. Nonrandomized quasi-experimental studies had a higher risk of bias.<sup>33,34</sup>

## Samples

Most of the studies provided their sample demographics in tables.<sup>27,29,31–33,35–39</sup> Sample sizes ranged from 34 to 514 participants. Depending on the particular study enrollments, the sample size may have reflected the number of caregivers or survivors, or both. Country locations of the studies were the United States (8 studies),<sup>27,29,31,32,35–37,39</sup> the United Kingdom (2 studies),<sup>34,38</sup> Scotland (2 studies),<sup>30,40</sup> Canada (1 study),<sup>28</sup> and Australia (1 study).<sup>33</sup> Sample sizes for 3 of the studies were <50 caregivers enrolled in the study.<sup>28,33,40</sup> In studies reporting age, the mean age of caregivers was 48.25 years. Several studies reported age ranges of survivors and caregivers. Most caregivers in studies that reported sex were female (n=621/751, 83%), and most survivors were male (n=399/1140, 35%), data consistent with that reported in literature on both TBI and caregiving.<sup>41,42</sup> Most caregivers were spouses or parents.

Five studies evaluated an intervention specifically for the caregiver,<sup>27,29,31,38,40</sup> 5 studies for the caregiver dyad,<sup>30,33,35,36,43</sup> and 4 studies included heavy involvement of the caregiver, but ultimately the studies were conducted with interventions designed primarily for the TBI survivor.<sup>28,32,34,39</sup> In general, studies with interventions for the survivor, but heavily involved the caregiver, did not measure caregiver outcomes at all,<sup>32,39</sup> and only 1 such study had significant caregiver outcomes.<sup>34</sup> Of the 5 studies that involved the caregiver only, 3

had positive significant findings in the caregivers.<sup>27,29,40</sup> Of the 5 dyad studies, 3 showed positive findings in both the survivor and caregiver.<sup>30,33,36</sup>

## Interventions

Like interventions found for poststroke caregivers,<sup>20,21</sup> the TBI caregiver and dyad interventions were of 3 main types: (1) support; (2) skill-building; (3) a combination of these 2 types. Skill-building interventions involve strategies that focus on processes that facilitate problem solving, goal setting, and communicating with healthcare professionals; stress management; hands-on training in such skills as lifting and mobility techniques and assistance with activities of daily living; and communication tailored to the needs of the individual with TBI.<sup>20</sup> Support interventions are defined as engaging in interactions with peers for support and advice (eg, support groups, online discussion forums).<sup>20</sup> Twelve studies were classified as skill building. Skill building encompassed all modalities of delivery, including the Web, in-person, written education, and phone. Another study combined skill building and support.<sup>37</sup> Only 1 study involving an intervention that specifically provided support to caregivers as a primary intervention was included, even though several studies listed *support* as a secondary feature of their study intervention. This study was designed to teach curriculum-based or self-directed advocacy training.<sup>37</sup> Unlike the stroke literature, there were no interventions that were primarily psychoeducational (provision of information only).<sup>20,21</sup>

## Modes of Delivery

In the studies we reviewed, study content was delivered to participants in person, by telephone, online, via written information, or through a combination of these methods (see table 1). Interventions that required face-to-face meetings were evaluated in 8 studies,<sup>27,28,30,33–35,38,43</sup> most of these studies were conducted in the home setting, but other studies required participants to travel to centralized locations.<sup>33,43</sup> Two additional studies required face-to-face meetings to complete multidisciplinary team-based interventions<sup>34,38</sup>; the 2 interventions discussed in these studies incorporated the skills of therapists, counselors, social workers, psychologists, and nurses.

Four studies<sup>31,32,36,39</sup> about interventions delivered by telephone exclusively met criteria for our review (see table 1). Three of these 4 studies<sup>31,32,39</sup> were among the strongest methodologically of all studies we reviewed. Two additional studies<sup>27,35</sup> used telephone interventions as a component of the study, with additional in-person sessions; the telephone interventions covered several matters, including coping strategies, education, caregiver-specific needs, and rehabilitation advice.

Only 1 study<sup>29</sup> described a web-based intervention. This study recruited participants via a website, thereby ensuring participation by individuals likely to use the Web to begin with.<sup>29</sup> The fidelity of this study was difficult to determine, because participants were encouraged but not required to access the Web program, and participants' time spent on the website was not explicitly recorded.

A written intervention was described by only 1 study,<sup>40</sup> wherein the researchers provided caregivers with an educational pamphlet. Qualitative evidence indicated that participants

thought the pamphlet was helpful, but there were no statistically significant outcomes. However, there was a trend that approached significance for anxiety reduction in caregivers who received the booklet earlier in the course of illness (<9mo) compared to caregivers who received the booklet later in the course of illness (>1y).<sup>40</sup>

Across the studies we reviewed, the number of intervention sessions varied from 2 to 18, with generally a higher number of sessions if participants were close geographically to the study site, or if sessions were not in person (see table 1). Of all the interventions, 57% (n=8/14) were tailored for the specific caregiver or caregiver dyad and 43% (n=6/14) were not specifically tailored (see table 1).

## Outcomes

Outcomes of interest varied across the studies. For individuals with TBI, outcomes included global functioning, physiologic measures, communication abilities, balance, conversation skills, and personal relationships (see table 3). For caregivers, outcomes included measures of fatigue, depressive symptoms, anxiety, caregiver strain, and overall health outcomes specific to caregivers of adults with TBI. The most common outcome tested in both caregivers and survivors was depressive symptoms. Several validated instruments were used, including the Brief Symptom Inventory 18,<sup>31,36</sup> the Center for Epidemiological Studies Depression Scale,<sup>27,35</sup> the Wimbledon self-reported scale,<sup>38</sup> and the Hospital Anxiety and Depression Scale.<sup>30</sup> Many had been described previously in caregivers and adults with TBI, such as Satisfaction With Life Scale in caregivers, FIM in survivors, and the Brief Symptom Inventory 18 in both caregivers and survivors. Although many of the measures have known evidence of reliability and validity, their use for TBI likely has limitations (see table 3).

Other outcomes had little to no external reliability or validity, and 4 outcomes were endpoints designed specifically for a particular study.<sup>33,34,36,37</sup> Some studies tested participants' knowledge of the intervention, in addition to, or instead of, pre-validated outcome measures.<sup>28,29</sup> Such endpoints may emphasize statistical significance of findings, with little attention to effect sizes or clinical significance.

The reliability and validity of outcome measures in TBI survivors and caregivers either were not described or were incomplete for 6 studies.<sup>28,29,33,36–38</sup> For example, studies commonly did not describe whether the survivor or the caregiver completed the survivors' data collection forms. For studies in which data were collected from survivors, studies did not report the cognitive and language skills as well as the ability to respond to questionnaires.<sup>28,36,37</sup> Many studies used bivariate statistics rather than multivariate analyses to report findings, and only 1 study reported an intention-to-treat analysis.<sup>36</sup> Some studies used well validated, appropriate outcomes.<sup>27,31,35</sup> Three studies used a composite outcome derived from numerous previously well-validated outcome measures on the basis of a couple of rationales: for one, the numerous separate endpoints could lead to false positive results, and, for another, the needs of the patient population after TBI are heterogeneous.<sup>31,32,39</sup>

In determining the outcome of the intervention, most studies did not follow their participants longer than a year.<sup>27–29,31–33,35,37–40</sup> Three studies enrolled participants for 2 years.<sup>32,34,36</sup>

Without data on long-term outcomes, it is difficult to know whether the interventions might have had enduring benefits for caregivers or for individuals with TBI.

### Summary and Best Designed Studies

Based on our critique, 3 studies demonstrated positive significant results, and were likely to have limited risk of bias. The study by Powell<sup>31</sup> was a high fidelity RCT with outcomes that were well validated. The study evaluated a telehealth-based mentored problem solving intervention and demonstrated that caregivers in the intervention group had an improved composite score consisting of a combination of coping, wellbeing as a caregiver, depressive symptoms, community participation, and caregiving mastery.<sup>31</sup>

The study by Moriarty et al<sup>35</sup> was also a high fidelity RCT of an in-home and phone intervention designed to improve family knowledge and support, while assuring that modifiable in-home environmental factors were improved. The study concluded that caregivers in the intervention group had significantly lower depressive symptoms and caregiving burden.<sup>35</sup> However, both Powell<sup>31</sup> and Moriarty<sup>35</sup> each used the same occupational therapist throughout the study, and, therefore, the conclusion may not be generalizable to other institutions.

Bell<sup>32</sup> conducted a high fidelity RCT evaluating a telephone intervention, using a composite score in a heterogeneous group of patients.<sup>39</sup> When the study was expanded later to a multicenter trial, the results were not statistically significant, perhaps because the cumulative endpoint was obtained in survivors rather than in the caregivers who participated heavily in the program.<sup>32</sup>

### Secondary Findings

In table 5, we describe a summary of additional interventions that enrolled subjects with other forms of acquired brain injury (such as strokes or brain tumors). Of these studies, 4 were high fidelity RCTs that focused on caregiver coping strategies, behavioral management, education, and support.<sup>44-47</sup> The fifth study was a large pre- and post-intervention study that evaluated an advisory program for individuals with acquired brain injury and their caregivers.<sup>48</sup> There were 4 dyad studies.<sup>44-47</sup> Grill et al<sup>48</sup> did not enroll caregivers but included heavy involvement of the caregiver. In the 4 dyad studies, all interventions took place in person, and 1 study added telephone mode of delivery.<sup>48</sup> Interventions described in the studies ranged from 5 to 16 sessions, and a wide range of 38 to 1534 subjects were enrolled in the interventions. All interventions focused on skill building, and 1 study included support and psychoeducation in the intervention.<sup>44</sup> Backhaus et al<sup>44</sup> and Kreutzer et al<sup>47</sup> demonstrated significant benefit to caregivers (see table 5). Grill,<sup>44</sup> Backhaus,<sup>46</sup> and Carnavale<sup>48</sup> and colleagues discussed the significant benefit of the interventions to survivors (see table 5).

### Discussion

We critiqued and described the 14 studies selected for review based on basic features of each study as well as common elements described in the TREND and CONSORT statements. These include descriptions of study design, study samples, intervention fidelity

and precision, types of intervention, method of delivery, tailoring vs one-size-fits-all approach, time spent in intervention, outcome assessment, and generalizability. Because the field of interventions for caregivers of adult TBI is nascent in comparison to that of stroke or pediatric TBI, we compared and contrasted these 2 similar fields in certain instances. Our recommendations are presented in table 6.

### Study Designs

We reviewed 4 nonrandomized comparison studies,<sup>33,34,38,40</sup> using the TREND statement criteria for our evaluation. The nonrandomized nature of these studies increases risk for study bias. Nonrandomized studies based the groupings on geography, convenience, or time since injury. For example, Bowen et al<sup>38</sup> and Morris et al<sup>40</sup> based the early vs late intervention on the time since TBI. Other groups were formed by convenience based on geographical proximity or willingness to participate in the intervention.<sup>33,34</sup> This presents difficulty in making further clinical recommendations based on conclusions from these nonrandomized studies. Future studies evaluating interventions for caregivers of individuals with TBI should randomize participants to decrease the risk for bias.

### Samples

An important criterion in CONSORT and TREND guidelines is assessing for baseline differences on key demographics (eg, caregiver sex, relationship, social class) and other characteristics, but 3 studies<sup>28,34,40</sup> provided none of this information or minimal information to this effect. Inclusion criteria for survivors differed among the studies for time since TBI and severity of TBI. These differences make recommending improvements to interventions difficult, particularly for the optimal timing and caregiver selection criteria, for a couple of reasons: for one, the needs of caregivers after critical illness are known to change over time, and, for another, the adaptive and coping skills learned by caregivers in the inpatient environment may not translate to the home setting.<sup>49</sup> In general, studies did not describe modifying the intervention to accommodate for potential cognitive impairments. Future studies of caregivers of individuals with TBI should enroll participants at the same time frame and standardize outcomes to account for TBI severity or cognitive impairments of the individual with TBI.

### Intervention Fidelity and Precision

The CONSORT and TREND statements advocate for details about the interventions and how they are delivered. Treatment fidelity consists of 5 components: (1) treatment design; (2) training; (3) delivery of treatment; (4) receipt of treatment; and (5) enactment.<sup>50</sup> Treatment fidelity was well described in only 6 of the 14 studies.<sup>27,31,32,35,37,39</sup> Treatment design includes the theoretical background of the intervention and information about the dosage for both the treatment and control groups (length, number, content, and duration of contacts). Training for the interveners should be described, as well as how the intervention is delivered and evaluated (eg, evaluation checklists). Only 5 studies described the intervention well enough to be considered high fidelity.<sup>27,32,35,37,39</sup> Further, imprecision of the intervention was high in many studies, which presents a challenge when trying to make clinical recommendations based on study outcomes.<sup>34,38</sup> Future interventions should



strive to have high treatment intervention fidelity built into study designs by maintaining the number, length, and frequency of intervention sessions.<sup>50</sup>

### Types of Interventions

Most studies that met criteria for this review were classified as skill building. Because only 1 study discussed an intervention specifically for caregivers, we cannot make definitive clinical recommendations about the utility of support groups as opposed to skill building interventions for caregivers of individuals with TBI. Many stroke-related aftercare interventions highlight the importance of psychoeducational interventions,<sup>51–57</sup> but, in our study sample, we found no reported interventions that were psychoeducational only. While psychoeducational intervention alone is not recommended for stroke,<sup>20,21</sup> studies have reported that combining psychoeducational strategies with skill building interventions can reduce anxiety depressive symptoms among caregivers and lead to improved quality of life for both caregivers and TBI survivors.<sup>20,21</sup> Future studies involving caregivers of individuals with TBI should explore the role of the combination of psychoeducational and skill building interventions.

### Method of Delivery

We categorized the interventions performed in the 14 selected studies into 5 broad categories for method of delivery: (1) face to face; (2) written; (3) telephone delivery; (4) Web; (5) a combination of these methods (see table 1). Studies describing face-to-face delivery<sup>27,28,30,34</sup> reported favorable outcomes for caregivers in the realms of depressive symptoms, functional problem solving, health complaints, and distress levels. The favorable outcomes must be weighed against the cost and resources needed for in-person meetings, especially in rural settings or when studies involve a multidisciplinary team intervention.<sup>34,38</sup> Face-to-face meetings seem an appropriate modality of delivery in teaching specific skills (eg, balance training, conversational tools),<sup>28,33</sup> but may be less beneficial for teaching skills of advocacy.<sup>38</sup>

Telephone and Web interventions offer certain conveniences. Caregivers may access Web interventions from their home or work at any time during the day. Caregivers may also connect with others who are at a distance. A disadvantage of telephone and Web interventions is that caregivers and TBI individuals may not have access to a telephone, computer, or high-speed Internet service, or may lack the appropriate skills for using these methods. Even so, RCTs in pediatric TBI literature report benefit from Web-based caregiver interventions, especially in poorer populations, thus supporting the notion that Web-based interventions may be generalizable to participants of all socioeconomic statuses.<sup>58–60</sup> At the same time, the pediatric TBI caregiver literature discusses the need for individualized computer skills training to fully benefit from computer and Web-based intervention.<sup>61</sup>

Web access can be inconsistent, especially in rural areas, and may not be accessible to all caregivers. Our review included 1 Web-based study, but fidelity can be inconsistent. If Web-based interventions are developed, we recommend that time spent in various portions are able to be tracked, and that participants are engaged in the intervention. This review did not describe interventions delivered by teleconferencing. An upcoming teleconferencing

intervention for caregivers of children with TBI may give us an opportunity to study how this delivery method could work for adults.<sup>62</sup>

### **Tailoring Vs One Size Fits All**

Many of the studies used a tailored approach rather than a one-size-fits-all approach.<sup>27,31,36,38</sup> Tailored approaches are difficult to generalize outside of the study. For instance, in Bowen et al,<sup>38</sup> the treatment team determined when and whether the caregiver or patient required interventions. In studies with a one-size-fits-all approach, an outline of the treatment intervention is beneficial if the study is to be replicated. Moriarty<sup>35</sup> provides a table listing the goals for both caregiver and patient at each session, such that the intervention could be reproduced. Nonetheless, tailored studies seem to offer the most benefit for caregivers of individuals with TBI when compared to a one-size-fits-all approach, particularly for depressive symptoms.

### **Time Spent and Number of Sessions in Interventions**

We could not determine from this review whether the amount of time spent in an intervention was proportional to positive results. Therefore, we cannot make clinical recommendations cannot about the time necessary to spend in the intervention. Future studies should consider that caregivers generally do not have ample free time, and time spent in interventions should be efficient in order to maximize benefits.

### **Outcomes**

Despite the heavy burden placed on caregivers of TBI, no outcome specifically measures caregiving burden in families with a TBI survivor. Therefore, we used caregiving outcomes that have been validated in other disease processes, including stroke, including the Composite of Bakas Caregiving Outcomes Scale,<sup>31</sup> the Caregiving Appraisal Scale,<sup>35</sup> and the Caregiver Burden Scale.<sup>27,35</sup> Many of the caregiving outcome measures have been used across several different types of medical populations, but it may be worthwhile to consider testing these existing measures in the TBI population.

The stroke caregiver literature shows that interventions are preferred for best caregiver outcomes and that dyad interventions are preferred for survivor outcomes.<sup>20</sup> We did not find a similar relation in the TBI studies reviewed. Indeed, 4 of 5 of the dyad studies<sup>30,33,35,36</sup> reported positive findings among the caregivers. Of the 4 studies that provided an intervention to the survivor that required heavy involvement of the caregiver, only 1 study reported positive results in the caregiver; the study required intense multidisciplinary rehabilitation using a family-focused team approach.<sup>34</sup> Although clinical implications cannot be made at this time, future studies involving caregivers should target caregivers and provide outcomes specific to needs of caregivers only when caregivers are heavily involved in the intervention.

### **Generalizability**

Many studies had limited generalizability, thus making it challenging to provide clinical recommendations based on this review. Studies that enrolled only spouse caregivers may not generalize to adult children or other unpaid caregivers. Because we reviewed only

studies written in English, generalizability is limited to countries with drastically different healthcare systems and cultural norms around illness recovery and caregiving.

### **Critique of Studies Included in Secondary Analysis**

Five studies in our secondary analysis enrolled individuals with other forms of acquired brain injury in addition to TBI. We critiqued these interventions using the CONSORT and TREND statements. Overall, these 5 studies described high fidelity interventions. The 4 RCT studies in the secondary analysis described the randomization process appropriately.<sup>44-47</sup> Like the studies enrolling individuals with only TBI, the 4 RCT studies included no obvious correlation between outcome and number of sessions. Two of the RCT studies required the survivor to have passed cognitive testing prior to consenting for the study to determine whether survivors could respond to outcome measures, thus improving the validity of outcomes.<sup>44,45</sup> Three of these studies enrolled <50 subjects,<sup>44-46</sup> and all studies except Carnevale et al<sup>46</sup> recruited subjects from the same institution, making these samples less generalizable to a broader population. However, the interventions were likely broadly generalizable to a wider group of brain injured individuals themselves, because they used tailored approaches (eg, cognitive behavioral therapy) or targeted specific behaviors (eg, aggression). Grill<sup>48</sup> had the largest participant sample of all studies we analyzed in both our primary and secondary reviews; it was also the only study to demonstrate survival benefit in its intervention group. This particular study described an extensive 2-year post-discharge rehabilitation program. Four of the 5 studies used well validated outcome measures.<sup>44,45,47,48</sup>

If interventions are developed to target specific rehabilitative outcomes (eg, behavioral impairments, caregiver coping, specific skillsets), further research should consider TBI interventions that also enroll individuals with other acquired brain injuries. However, for interventions targeting TBI specific concerns (eg, injury prevention, TBI related education, TBI support), we recommend referencing studies that enroll TBI individuals only.

### **Study Limitations**

To minimize publication bias, we conducted an extensive search of multiple databases, but we may have missed papers beyond the scope of the databases we searched. We searched solely English language publications. The overall quality of the studies was heterogeneous, with studies of varying quality and bias based on the CONSORT and TREND guidelines.

Our systematic review is limited by our exclusion of studies in the primary search that enrolled individuals with other types of brain injury. Because individuals who have sustained a TBI may be younger than those with other neurologic disorders, their caregivers also may be younger. However, depending on the specific need addressed by an intervention, it is likely that data can be extrapolated from studies that enrolled subjects with other disease processes (see table 5). Of the 4 published RCTs that included subjects with other acquired brain injuries overall, none were powered to detect whether the intervention worked better specifically in individuals and their caregivers after TBI when compared to other acquired brain injuries (see table 5).<sup>44-46,48</sup>

We could not conduct a meta-analysis of the data reviewed for several reasons. The measured outcomes of studies, even for similar interventions, were in multiple broad categories, resulting in significant heterogeneity. The intervention types, targets, modes of delivery, and number of sessions also differed considerably.

## Conclusions

Deficiencies in the literature make it difficult to develop definitive clinical recommendations for caregiver guidance. Future research should include more rigorous study design; pay particular attention to fidelity of interventional delivery, sustainability of outcome, dosage of interventions, and feasibility of the interventions; and consider timing of the study relative to injury as well as feasibility and accessibility of interventions. It may be difficult to generalize findings from tailored studies that are patient- or caregiver-centered, because of the many different measures and outcomes discussed in these studies; however, using outcome measures with stronger evidence of reliability and validity would allow for better comparisons of these studies. Caregiver interventions within practice settings could improve outcomes not only for caregivers (eg, mental and physical health, quality of life) but also for patients (eg, reduced readmission rates, less chance of institutionalization, reduced disability, improved quality of life).

## List of abbreviations:

<b>CONSORT</b>	Consolidated Standards of Reporting Trials
<b>RCT</b>	randomized controlled trial
<b>TBI</b>	traumatic brain injury
<b>TREND</b>	Transparent Reporting of Evaluations with Nonrandomized Designs

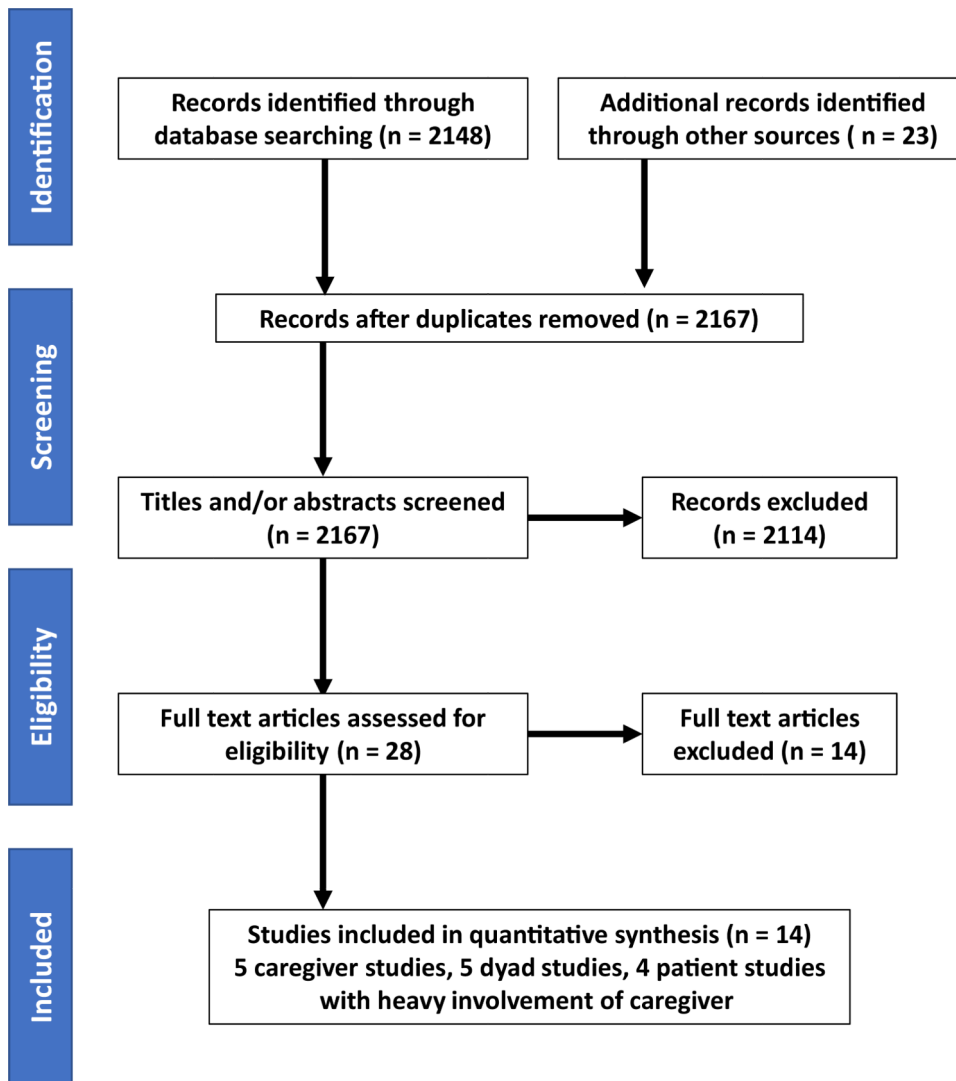
## References

1. Zaloshnja E, Miller T, Langlois JA, Selassie AW. Prevalence of long-term disability from traumatic brain injury in the civilian population of the United States, 2005. *J Head Trauma Rehabil* 2008;23:394–400.
2. Thurman DJ, Alverson C, Dunn KA, Guerrero J, Sniezek JE. Traumatic brain injury in the United States: A public health perspective. *J Head Trauma Rehabil* 1999;14:602–15. [PubMed: 10671706]
3. Taylor CA. Traumatic brain injury—related emergency department visits, hospitalizations, and deaths—United States, 2007 and 2013. *MMWR Surveillance Summaries* 2017;66:1–16.
4. Masel BE, DeWitt DS. Traumatic brain injury: a disease process, not an event. *J Neurotrauma* 2010;27:1529–40. [PubMed: 20504161]
5. Colantonio A, Hsueh J, Petgrave J, Hirdes JP, Berg K. A profile of patients with traumatic brain injury within home care, long-term care, complex continuing care, and institutional mental health settings in a publicly insured population. *J Head Trauma Rehabil* 2015; 30:E18–29. [PubMed: 25699620]
6. Bazarian JJ, Cernak I, Noble-Haeusslein L, Potolicchio S, Ternkin N. Long-term neurologic outcomes after traumatic brain injury. *J Head Trauma Rehabil* 2009;24:439–51. [PubMed: 19940677]
7. Jourdan C, Bayen E, Pradat-Diehl P, et al. A comprehensive picture of 4-year outcome of severe brain injuries. Results from the Paris-TBI study. *Ann Phys Rehabil Med* 2016;59:100–6. [PubMed: 26704071]

8. Gillen R, Tennen H, Affleck G, Steinpreis R. Distress, depressive symptoms, and depressive disorder among caregivers of patients with brain injury. *J Head Trauma Rehabil* 1998;13:31–43. [PubMed: 9582177]
9. Marsh NV, Kersel DA, Havill JA, Sleigh JW. Caregiver burden during the year following severe traumatic brain injury. *J Clin Exp Neuropsych* 2002;24:434–47.
10. Saban KL, Griffin JM, Urban A, Janusek MA, Pape TL, Collins E. Perceived health, caregiver burden, and quality of life in women partners providing care to veterans with traumatic brain injury. *J Rehabil Res Dev* 2016;53:681–92. [PubMed: 27997670]
11. Mellick D, Gerhart KA, Whiteneck GG. Understanding outcomes based on the post-acute hospitalization pathways followed by persons with traumatic brain injury. *Brain Injury* 2003;17:55–71. [PubMed: 12519648]
12. Schmotz C, Richinger C, Lorenzl S. High burden and depression among late-stage idiopathic Parkinson disease and progressive supranuclear palsy caregivers. *J Geriatr Psychiatry Neurol* 2017;30: 267–72. [PubMed: 28747135]
13. Takai M, Takahashi M, Iwamitsu Y, et al. The experience of burnout among home caregivers of patients with dementia: relations to depression and quality of life. *Arch Gerontol Geriatr* 2009;49:e1–5. [PubMed: 18703239]
14. Johansen S, Cvancarova M, Ruland C. The effect of cancer patients' and their family caregivers' physical and emotional symptoms on caregiver burden. *Cancer Nurs* 2017;4:91–9.
15. Leibach GG, Trapp SK, Perrin PB, et al. Family needs and TBI caregiver mental health in Guadalajara, Mexico. *NeuroRehabilitation* 2014;34:167–75. [PubMed: 24284459]
16. Pinquart M, Sorensen S. Differences between caregivers and non-caregivers in psychological health and physical health: a meta-analysis. *Psychol Aging* 2003;18:250–67. [PubMed: 12825775]
17. Bayen E, Pradat-Diehl P, Jourdan C, et al. Predictors of informal care burden 1 year after a severe traumatic brain injury: results from the PariS-TBI study. *J Head Trauma Rehabil* 2013;28:408–18. [PubMed: 22691963]
18. Manskow US, Friborg O, Roe C, Braine M, Damsgard E, Anke A. Patterns of change and stability in caregiver burden and life satisfaction from 1 to 2 years after severe traumatic brain injury: a Norwegian longitudinal study. *NeuroRehabilitation* 2017;40:211–22. [PubMed: 27935561]
19. Teasdale G, Jennett B. Assessment of coma and impaired consciousness. A practical scale. *Lancet* 1974;2:81–4. [PubMed: 4136544]
20. 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. [PubMed: 25034718]
21. Bakas T, McCarthy M, Miller ET. Update on the state of the evidence for stroke family caregiver and dyad interventions. *Stroke* 2017;48:e122–5. [PubMed: 28351961]
22. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS* 2009;6:e1000097.
23. Boutron I, Moher D, Altman DG, Schulz KF, Ravaud P. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med* 2008;148: 295–309. [PubMed: 18283207]
24. Des Jarlais DC, Lyles C, Crepaz N. Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND statement. *Am J Public Health* 2004;94:361–6. [PubMed: 14998794]
25. Shadish WR, Cook TD, Campbell DT. *Experimental and quasi-experimental designs for generalized causal inference*. Boston: Wadsworth Cengage Learning; 2002.
26. Hoffmann TC, Glasziou PP, Boutron I, et al. [Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide] [German]. *Gesundheitswesen* 2016;78:175–88. [PubMed: 26824401]
27. Rivera PA, Elliott TR, Berry JW, Grant JS. Problem-solving training for family caregivers of persons with traumatic brain injuries: a randomized controlled trial. *Arch Phys Med Rehabil* 2008;89:931–41. [PubMed: 18452743]

28. Thornton M, Marshall S, McComas J, Finestone H, McCormick A, Sveistrup H. Benefits of activity and virtual reality based balance exercise programmes for adults with traumatic brain injury: perceptions of participants and their caregivers. *Brain Injury* 2005;19: 989–1000. [PubMed: 16263641]
29. McLaughlin KA, Glang A, Beaver SV, Gau JM, Keen S. Web-based training in family advocacy. *J Head Trauma Rehabil* 2013;28:341–8. [PubMed: 22688211]
30. Sinnakaruppan I, Downey B, Morrison S. Head injury and family carers: a pilot study to investigate an innovative community-based educational programme for family carers and patients. *Brain Injury* 2005;19:283–308. [PubMed: 15832874]
31. Powell JM, Fraser R, Brockway JA, Temkin N, Bell KR. A telehealth approach to caregiver self-management following traumatic brain injury: a randomized controlled trial. *J Head Trauma Rehabil* 2016; 31:180–90. [PubMed: 26394294]
32. Bell KR, Brockway JA, Hart T, et al. Scheduled telephone intervention for traumatic brain injury: a multicenter randomized controlled trial. *Arch Phys Med Rehabil* 2011;92:1552–60. [PubMed: 21963122]
33. Togher L, McDonald S, Tate R, Power E, Rietdijk R. Training communication partners of people with severe traumatic brain injury improves everyday conversations: a multicenter single blind clinical trial. *J Rehabil Med* 2013;45:637–45. [PubMed: 23803687]
34. Semlyen JK, Summers SJ, Barnes MP. Traumatic brain injury: efficacy of multidisciplinary rehabilitation. *Arch Phys Med Rehabil* 1998;79:678–83. [PubMed: 9630149]
35. Moriarty H, Winter L, Robinson K, et al. A randomized controlled trial to evaluate the veterans' in-home program for military veterans with traumatic brain injury and their families: report on impact for family members. *PM R* 2016;8:495–509. [PubMed: 26514790]
36. Hanks RA, Rapport LJ, Wertheimer J, Koviak C. Randomized controlled trial of peer mentoring for individuals with traumatic brain injury and their significant others. *Arch Phys Med Rehabil* 2012;93: 1297–304. [PubMed: 22840826]
37. Brown AW, Moessner AM, Bergquist TF, Kendall KS, Diehl NN, Mandrekar J. A randomized practical behavioural trial of curriculum-based advocacy training for individuals with traumatic brain injury and their families. *Brain Injury* 2015;29:1530–8. [PubMed: 26488141]
38. Bowen A, Tennant A, Neumann V, Chamberlain MA. Neuropsychological rehabilitation for traumatic brain injury: do carers benefit? *Brain Injury* 2001;15:29–38. [PubMed: 11201312]
39. Bell KR, Temkin NR, Esselman PC, et al. The effect of a scheduled telephone intervention on outcome after moderate to severe traumatic brain injury: a randomized trial. *Arch Phys Med Rehabil* 2005;86: 851–6. [PubMed: 15895327]
40. Morris KC. Psychological distress in carers of head injured individuals: the provision of written information. *Brain Injury* 2001;15: 239–54. [PubMed: 11260772]
41. U.S. Department of Health and Human Service: Centers for Disease Control and Prevention. Report to Congress: traumatic brain injury in the United States. Washington (DC): U.S. Government Printing Office; 1999.
42. Stone R, Cafferata GL, Sangl J. Caregivers of the frail elderly: a national profile. *Gerontologist* 1987;27:616–26. [PubMed: 2960595]
43. Brown R, Pain K, Berwald C, Hirschi P, Delehanty R, Miller H. Distance education and caregiver support groups: comparison of traditional and telephone groups. *J Head Trauma Rehabil* 1999;14: 257–68. [PubMed: 10381978]
44. Backhaus SL, Ibarra SL, Klyce D, Trexler LE, Malec JF. Brain injury coping skills group: a preventative intervention for patients with brain injury and their caregivers. *Arch Phys Med Rehabil* 2010;91: 840–8. [PubMed: 20510972]
45. Backhaus S, Ibarra S, Parrott D, Malec J. Comparison of a cognitive-behavioral coping skills group to a peer support group in a brain injury population. *Arch Phys Med Rehabil* 2016;97:281–91. [PubMed: 26551230]
46. Carnevale GJ, Anselmi V, Johnston MV, Busichio K, Walsh V. A natural setting behavior management program for persons with acquired brain injury: a randomized controlled trial. *Arch Phys Med Rehabil* 2006;87:1289–97. [PubMed: 17023236]

47. Kreutzer JS, Marwitz JH, Sima AP, Godwin EE. Efficacy of the brain injury family intervention: impact on family members. *J Head Trauma Rehabil* 2015;30:249–60. [PubMed: 26147315]
48. Grill E, Ewert T, Lipp B, Mansmann U, Stucki G. Effectiveness of a community-based 3-year advisory program after acquired brain injury. *Eur J Neurol* 2007;14:1256–65. [PubMed: 17956446]
49. Adams D, Dahdah M. Coping and adaptive strategies of traumatic brain injury survivors and primary caregivers. *NeuroRehabilitation* 2016;39:223–37. [PubMed: 27372358]
50. Borrelli B, Sepinwall D, Ernst D, et al. A new tool to assess treatment fidelity and evaluation of treatment fidelity across 10 years of health behavior research. *J Consult Clin Psychol* 2005;73:852–60. [PubMed: 16287385]
51. Clark MS, Rubenach S, Winsor A. A randomized controlled trial of an education and counselling intervention for families after stroke. *Clin Rehabil* 2003;17:703–12. [PubMed: 14606735]
52. Burton C, Gibbon B. Expanding the role of the stroke nurse: a pragmatic clinical trial. *J Adv Nurs* 2005;52:640–50. [PubMed: 16313377]
53. Dennis M, O'Rourke S, Slattery J, Staniforth T, Warlow C. Evaluation of a stroke family care worker: results of a randomised controlled trial. *BMJ (Clinical research ed)* 1997;314:1071–6 [discussion: 1076–7].
54. Tilling K, Coshall C, McKeivitt C, Daneski K, Wolfe C. A family support organiser for stroke patients and their carers: a randomised controlled trial. *Cerebrovasc Dis* 2005;20:85–91. [PubMed: 15976500]
55. Forster A, Dickerson J, Young J, et al. A structured training programme for caregivers of inpatients after stroke (TRACS): a cluster randomised controlled trial and cost-effectiveness analysis. *Lancet* 2013;382:2069–76. [PubMed: 24054816]
56. Lincoln NB, Francis VM, Lilley SA, Sharma JC, Summerfield M. Evaluation of a stroke family support organiser: a randomized controlled trial. *Stroke* 2003;34:116–21. [PubMed: 12511761]
57. Braithwaite V, McGown A. Caregivers' emotional well-being and their capacity to learn about stroke. *J Adv Nurs* 1993;18:195–202. [PubMed: 8436710]
58. Antonini TN, Raj SP, Oberjohn KS, et al. A pilot randomized trial of an online parenting skills program for pediatric traumatic brain injury: improvements in parenting and child behavior. *Behav Ther* 2014;45:455–68. [PubMed: 24912459]
59. Petranovich CL, Wade SL, Taylor HG, et al. Long-term caregiver mental health outcomes following a predominately online intervention for adolescents with complicated mild to severe traumatic brain injury. *J Pediatr Psychol* 2015;40:680–8. [PubMed: 25682211]
60. Wade SL, Kurowski BG, Kirkwood MW, et al. Online problem-solving therapy after traumatic brain injury: a randomized controlled trial. *Pediatrics* 2015;135:e487–95. [PubMed: 25583911]
61. Carey JC, Wade SL, Wolfe CR. Lessons learned: the effect of prior technology use on Web-based interventions. *Cyberpsychol Behav* 2008;11:188–95. [PubMed: 18422412]
62. Taylor K, Catroppa C, Godfrey C, et al. Managing challenging behaviour in preschool children post-traumatic brain injury with online clinician support: protocol for a pilot study. *Pilot Feasibility Stud* 2017;3:30. [PubMed: 28580165]



\*A secondary search was conducted to additionally review studies that enrolled individuals with other types of acquired brain injuries. 852 additional titles were identified, and 5 additional studies reviewed in a post hoc analysis.

**Fig 1.** We excluded 14 articles from our systematic review of literature on interventions for individuals with TBI and their caregivers. We found that 8 studies were not quasi-experimental or experimental in design; 1 study include nonfamily caregivers who were paid and preselected; and 5 studies included patients with other forms of acquired brain injury (eg, stroke, aneurysm).



Summary description of studies in systematic review for literature on interventions for individuals with TBI and their caregivers

Table 1

Study	Study Size	Time From TBI to Enrollment	Enrolled	Intervention Target	Intervention Type	Tailored vs OSFA	Mode of Delivery	Sessions (No.)
1 Rivera <sup>27</sup>	67	NA	CG	CG	SB	Tailored	IP	12
2 Moriarty <sup>35</sup>	162	11.17 y	Dyad	Dyad	SB	OSFA	IP & phone	8
3 Powell <sup>31</sup>	153	NA	CG	Dyad	SB	Tailored	Phone	10
4 Hanks <sup>36</sup>	158	NA	Dyad	CG	Support	Tailored	Phone	5.4
5 Brown <sup>37</sup>	514	>1 y	Dyad	Dyad	SB & support	OSFA	IP	4
6 McLaughlin <sup>29</sup>	201	20% >1 y	CG	CG	SB	OSFA	Web	10
7 Morris <sup>40</sup>	34	66% >1 y	CG	CG	SB	OSFA	Written	2
8 Semlyen <sup>34</sup>	112	<4 wk	Dyad	Survivor	SB	Tailored	IP	Variable
9 Thornton <sup>28</sup>	54	>6 mo	Dyad	Survivor	SB	OSFA	IP	18
10 Bell <sup>39</sup>	171	<1 y	S	Survivor	SB	Tailored	Phone	7
11 Bell <sup>32</sup>	433	<1 y	S	Survivor	SB	Tailored	Phone	11
12 Toghiani <sup>33</sup>	88	>9 mo	Dyad	Dyad	SB	Tailored	IP	10
13 Bowen <sup>38</sup>	96	Variable	CG	CG	SB	Tailored	IP	Variable
14 Simmakuruppan <sup>30</sup>	99	3 y	Dyad	Dyad	SB	OSFA	IP	8

NOTE: Study size indicates number enrolled in each study. Enrolled column indicates if survivors, caregivers, or both (dyads) were included in this number. Abbreviations: CG, caregiver; IP, in person; NA, not applicable; OSFA, one-size-fits-all method; S, survivor; SB, skill building.

Table 2

Brief description of interventions and specific outcome measures found in review of literature on TBI individuals and their caregivers

Author	Intervention	Design	Survivor Outcomes ( $P < .05$ )	Caregiver Outcomes ( $P < .05$ )
Rivera <sup>27</sup>	Problem-solving vs written materials	RCT	None significant	Depressive symptoms (favored I) Dysfunctional problem solving (favored I) Caregiver health complaints (favored I group)
Moriarty <sup>35</sup>	Cognitive, behavioral, interpersonal, and home environment strategies	RCT	NA	Depressive symptoms: favored I Burden: favored I
Thomton <sup>28</sup>	Balance retraining: conventional vs virtual reality	Quasi RCT	No significant difference	Qualitative outcome only: virtual reality group had more enjoyment and confidence
Togher <sup>33</sup>	Conversation skills: dyad vs patient only training vs control	RCT	I group: improved conversation	Caregiver ability to acknowledge and reveal competence of survivor most improved in dyad group
Powell <sup>31</sup>	Education and mentored problem-solving & written materials vs usual care	RCT	None significant	Composite and BSI favored I group
Hanks <sup>36</sup>	Mentor vs no mentor	RCT	I group with better behavioral control, less chaos in the living environment, lower alcohol use, less emotion-focused and avoidance coping, and good physical quality of life compared to control group.	I group had greater community integration
Brown <sup>37</sup>	Curriculum-based or self-directed advocacy training group (via ABRs)	RCT	Pre- and post-improvement in ABRs.	None
Bell <sup>39</sup>	Telephone call vs usual care after discharge	RCT	Primary composite in favor of I group.	None measured
Bell <sup>32</sup>	Telephone call vs usual care after discharge	RCT	None	None
Morris <sup>40</sup>	Informational booklet for caregivers	Longitudinal, mixed variable, within- and between-subject design.	None	The book was readable, useful, and they read the entire book.
McLaughlin <sup>29</sup>	Web site focused on advocacy, communication skills, and resources for families.	RCT	None tested	Skill application, intentions, knowledge better in I group.
Bowen <sup>38</sup>	Multidisciplinary team approach compared 3 groups of patients: (1) early, (2) late and (3) control	Non-blinded trial	None obtained	No differences
Semlyen <sup>34</sup>	Multidisciplinary service compared to single discipline.	Quasi-experimental design	Multidisciplinary group experienced improvement in all measures as time went on	Lowered level of distress favoring multidisciplinary group
Sinnakaruppan <sup>30</sup>	Community-based educational program	RCT; within and between subject comparison	I group had improved depressive symptoms, anxiety, somatic symptoms, social dysfunction, and self-esteem within group. COPE-I (acceptance), COPE-J (focus on and venting emotion), COPE-N (alcohol or drug use) were significant improvement in the between group comparison. The caregivers rating of the FIM scores of the patients was statistically significant different in the experimental group compared to control.	Lower depressive symptoms, improved coping using social support

Abbreviations: ABRS, Advocacy Behavioral Rating Scale; C, Control group; I, Intervention group.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Table 3

Summary table of instruments used to measure outcomes in caregiver and dyad TBI intervention studies

Outcome (Global or Broad)	Studies That Tested These Outcomes	Instruments Used
Caregiver life changes and appraisal	Powell, <sup>31</sup> Moriarty <sup>35</sup>	Composite of Bakas Caregiving Outcomes Scale, <sup>31</sup> Caregiving Appraisal Scale <sup>35</sup>
Depressive symptoms	Powell, <sup>31</sup> Rivera, <sup>27</sup> Moriarty, <sup>35</sup> Hanks, <sup>36</sup> Bowen, <sup>38</sup> Sinnakaruppan <sup>30</sup>	Brief Symptom Inventory 18, <sup>31,36</sup> Center for Epidemiological Studies Depression Scale, <sup>27,35</sup> Wimbeldon self-reported scale, <sup>38</sup> HADS <sup>30</sup>
Coping	Powell, <sup>31</sup> Hanks, <sup>36</sup> Sinnakaruppan <sup>30</sup>	Brief COPE, <sup>31</sup> coping inventory, <sup>36</sup> COPE scale <sup>30</sup>
Well-being	Rivera, <sup>27</sup> McLaughlin <sup>29</sup>	Satisfaction with Life Scale <sup>27,29</sup>
Caregiver burden	Rivera <sup>27,35</sup>	Caregiver Burden Scale <sup>27,35</sup>
Social problem-solving abilities	Rivera <sup>27</sup>	Social problem solving scale <sup>27</sup>
Community integration	Hanks <sup>36</sup>	Community integration measure <sup>36</sup>
Family assessment	Hanks <sup>36</sup>	Family assessment device <sup>36</sup>
Health-related quality of life	Hanks <sup>36</sup>	SF-12 <sup>36</sup>
Alcohol use	Hanks <sup>36</sup>	Short Michigan alcoholism screening test <sup>36</sup>
Advocacy	Brown <sup>37</sup>	Advocacy Behavioral Rating Scale <sup>37</sup>
Skill application, intentions, knowledge about TBI	McLaughlin <sup>29</sup>	Skills pertaining to web training <sup>29</sup>
Level of informed	Bowen <sup>38</sup>	Survey of being informed <sup>38</sup>
Anxiety (or other common psychiatric symptoms)	Morris, <sup>40</sup> Semlyen, <sup>34</sup> Sinnakaruppan <sup>30</sup>	HADS anxiety scale, <sup>41</sup> GHQ-28 <sup>30,34,40</sup>
Functional status after TBI	Semlyen, <sup>34</sup> Sinnakaruppan <sup>30</sup>	Barthel Index, <sup>34</sup> FIM, <sup>30,34</sup> Newcastle Independence Assessment Form <sup>35</sup>
Balance	Thornton <sup>28</sup>	ABC, <sup>28</sup> LEFS <sup>28</sup>
Composite outcome	Bell <sup>32,39</sup>	Composite outcome that included numerous previously described outcomes, <sup>32,39</sup>
Conversational skills	Togher <sup>33</sup>	Adapted measure of participation in conversation <sup>33</sup>
Self-esteem	Sinnakaruppan <sup>30</sup>	Rosenburg self-esteem scale <sup>30</sup>

Abbreviations: ABC, Activities-specific Balance Confidence Scale; COPES, COPE scale; GHQ-28, General Health Questionnaire; HADS, Hospital Anxiety and Depression Scale; LEFS, Lower Extremity Functional Scale; SF-12, Medical Outcomes Study 12-Item Short-Form Health Survey.

**Table 4**

Information extracted from each study

Methodology	Demographics	Intervention
Title	Sample size	Type of interventions
Study design	Age of participants	Materials and procedures used
Caregiver and survivor outcomes	Gender of participants	Training of interventionist
Instruments used in the study	Study inclusion and exclusion criteria	Mode of delivery
Process of study randomization	If demographics table was provided	Location and infrastructure needed
Concerns about generalization of study	Study attrition	Total time in session
Clinical significance of findings	Target patient population	Number of sessions
Bivariate or multivariate analyses	Country of study	Schedule of sessions
Methodological strength of study	NA	If intervention was tailored or not
Methodological strength of study	NA	If intervention was changed during study period
Methodological strength of study	NA	If fidelity and precision was adhered to
Methodological strength of study	NA	If intervention delivery as planned

Abbreviations: ABC, Activities-specific Balance Confidence Scale; COPES, COPE scale; GHQ-28, General Health Questionnaire; LEFS, Lower Extremity Functional Scale; NA, not applicable; SF-12, Medical Outcomes Study 12-Item Short-Form Health Survey.

**Table 5**  
 Brief description of interventions that enrolled individuals with TBI in addition to other types of acquired brain injuries

Study (Author and Year of Publication)	Intervention	Design	Number of Survivors With TBI of Total	Survivor Outcome (P<.05)	CG Outcome (P<.05)
Backhaus 2010 <sup>44</sup>	Training in coping strategies. Participants were randomized to 12 in person sessions compared to usual care	RCT	9/20	Less emotional distress, improved perceived self-efficacy	Less emotional distress, improved perceived self-efficacy
Backhaus 2016 <sup>45</sup>	Brain injury coping skills program—manualized cognitive behavioral treatment compared to support group.	RCT	6/19	None	None
Camevale 2006 <sup>46</sup>	Natural behavioral setting management (education & individual behavior) vs education vs control group, targeted to participants with behavioral impairment.	3 arm RCT	24/37	Decreased frequency targeted behavioral problems	NA
Grill 2007 <sup>48</sup>	3-y advisory program after acquired brain injury	Nonrandomized prospective before and after study	426/1534	FIM and survival	none
Kreitzer 2015 <sup>47</sup>	Brain injury family intervention that entailed curriculum-based education, skill building, and support	Prospective controlled repeat measures design	116/137	None	Improvement in met needs, satisfaction with services, reduced burden

Abbreviation: CG, caregiver.

**Table 6**

**Recommendations for interventions for TBI individuals and their caregivers based on a systematic review of the literature**

Component	Recommendation
Caregiver vs dyad vs heavily involved caregiver in a survivor intervention	Interventions that are specifically designed to help the survivor, but require heavy input of the caregiver are unlikely to be of benefit for the caregiver.
Interventions	As most interventions are skill building, it is unknown if other kinds of interventions, such as psychosocial or support based, are as beneficial. Future studies are needed. If interventions are skill building in nature, they should be tailored to the individual's disability or functional status
Tailored vs one size fits all	Interventions that are tailored are better for both survivor and caregiver.
Mode of delivery	Face to face delivery methods are more likely to confer benefit, and are preferred. Telephone interventions may provide help to caregivers, but are less likely to have significant benefits for survivors. At this time, there is not enough information to determine if web based studies will provide benefit.
Number of sessions	5 to 9 sessions likely confer the most benefit to survivors and caregivers