Published in final edited form as:

J Head Trauma Rehabil. 2015 ; 30(3): E33–E40. doi:10.1097/HTR.000000000000059.

Factors Influencing Attrition in a Multisite, Randomized, Clinical Trial Following Traumatic Brain Injury in Adolescence

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Abstract

Background—Attrition in longitudinal research negatively affects statistical power, disrupts statistical stability, and can produce unwanted bias.

Objective—To investigate factors associated with shorter length of study participation and lower rates of study completion (ie, attrition) in a large, multisite, longitudinal, randomized, clinical trial examining the efficacy of a Web-based family problem-solving treatment following traumatic brain injury (TBI) in adolescence.

Setting—Five major trauma centers in the central and western regions of the United States.

Participants—Children ($N = 132$) aged 12 to 17 years hospitalized for complicated mild to severe TBI within the previous 6 months.

Results—Completers had a higher primary caregiver education and higher family income than noncompleters, whereas ethnicity, latency to baseline assessment, and intervention group were not significantly associated with study completion.

Conclusion—This is the first study that has specifically examined factors of attrition in a pediatric TBI population. The results suggest that research on pediatric TBI populations may be biased toward higher-income families and highlights the importance of designing studies with increased awareness of the impact of participant demographic factors.

Keywords

adolescence; attrition; closed head injury; pediatrics; randomized clinical trial; retention; traumatic brain injury

To more fully understand the long-term outcomes of pediatric traumatic brain injury (TBI), it is essential to maintain research samples across time postinjury. Attrition negatively affects statistical power and can produce unwanted bias.^{1–3} Internal validity may be compromised by attrition due to the disruption of random composition of groups, whereas external validity is negatively affected by attrition because the data become biased and therefore less generalizable.^{3–7}

Attrition rates in longitudinal studies of TBI vary widely, although conservative estimates suggest that well over one-third of participants with TBI are lost to attrition during long-term outcome trials with adults.^{8,9} Attrition rates in prospective longitudinal pediatric TBI studies are comparable, with rates varying from 20% to more than 60%.^{10–12} Attrition and study length are positively correlated in pediatric TBI studies, with longer follow-up periods associated with higher attrition.^{13–16}

In a systematic review of attrition in randomized control trials for various pediatric chronic health conditions (eg, diabetes, asthma), Karlson and Rapoff⁵ found that personalized feedback, consistency of study procedures, and use of intensive tracking measures improved participant retention. Moreover, patient characteristics such as having private insurance, parental education level, parental age, parental and patient psychiatric symptoms, and severity of the child's medical condition have also been associated with attrition rates in pediatric healthcare studies.^{17–20}

In studies of pediatric TBI, higher rates of attrition have been reported among younger children and those with lower family income.^{8,13,15,21} Greater loss to follow-up has also been reported among adolescent boys than among adolescent girls,⁸ although other studies have failed to find such sex differences.²¹ Additional factors associated with higher attrition in pediatric TBI samples include lower parental education and minority ethnicity, which can lead to an underrepresentation of families with these characteristics.^{8,15,21} Wade et al¹⁵ also found higher attrition in children with more severe TBI, suggesting that dropout rates may vary with injury as well as background characteristics.

To our knowledge, no studies have examined study satisfaction and its relation with attrition in the pediatric TBI population. In fact, only a few studies of satisfaction and attrition exist in the broader literature.^{22–25} In these studies, participants who completed follow-up reported higher levels of satisfaction and personalized feedback and had a greater number of contacts with study personnel throughout follow-up than those who dropped out prior to study completion.^{22,23,25,26} Parents who participate in follow-up with their children rather than without them may also be more likely to complete studies.²³ Time spent actively engaged in a research study (eg, completing questionnaires, navigating Web sites, reading materials) has not been examined in relation to attrition in the pediatric TBI population. However, a study of children with asthma found that participants' compliance with initial study visits was the best predictor of future study involvement.²⁷

The primary goal of this study was to investigate factors associated with shorter length of study participation and lower rates of study completion (ie, attrition) in a large, multisite, longitudinal, randomized, clinical trial examining the efficacy of a Web-based family

problem-solving treatment following TBI in adolescence. We hoped that our findings would suggest strategies to promote participant retention in follow-up studies. Our first hypothesis was that the length of participation and rates of completion would be lower for families with lower median incomes, less parental education, minority status, and adolescents with more severe injuries. We also examined the possibility that less participation/completion would be associated with a longer time between injury and the baseline consent, referred to as a higher “latency” to enrollment. Our second hypothesis was that less participation/completion would be associated with lower self-reported caregiver and teen satisfaction and lower levels of engagement in the study, as measured by time spent online in research activities.

METHODS

Procedure

The study was part of a larger, randomized, clinical trial comparing the efficacy of 2 Internet-based intervention groups: (1) a Counselor Assisted Problem Solving (CAPS) group that received a 6-month Web-based, family-centered intervention that focuses on problem solving, communication, and self-regulation; and (2) an Internet Resource Comparison (IRC) group. The parent project was conducted at 5 major trauma centers in the central and western regions of the United States. The study was approved by the institutional review board of each participating medical center.

The study trial period for participants was 18 months. Once enrolled, participants and their families were asked to complete questionnaires and interviews at each of 4 data collection points: baseline and 6-, 12-, and 18-month follow-ups. Participants and their families who completed all 4 interviews were considered to have successfully completed the study. All data were collected in the participants' homes.

To address potential disparities in Internet access and utilization, all participating families were provided with high-speed Internet access for the first 6 months, as well as a desktop computer. Families were also compensated for their time (\$10, \$50, and \$35 for the 6-, 12-, and 18-month follow-ups, respectively).

Participants

To be eligible for enrolment, children had to be 12 to 17 years of age, hospitalized for complicated mild to severe TBI as defined by a Glasgow Coma Scale (GCS)²⁸ score of less than 13 or evidence of TBI-related brain insult on neuroimaging, and seen within 6 months of injury.²⁹ Additional inclusionary criteria included English as the primary language in the home, the ability for the adolescent with TBI to participate in the intervention (ie, attend to the Web site modules and verbally participate in Skype sessions), and residence within 3-hour drive of the hospital. On the basis of these criteria, 308 families were identified as potentially eligible. The study was introduced to these families via face-to-face discussion when patients were still hospitalized or through telephone calls and postcards for patients who had been discharged. Of the 308 families eligible, 132 families agreed to participate. The sample included 86 adolescent boys and had a mean age of 14.47 years (SD = 1.72). All participants were enrolled from 2007 to 2011. The reasons for nonparticipation are detailed

in the CONSORT diagram presented in Figure 1. Non-participants did not differ from participants in age at injury but had less severe injuries and were more likely to be nonwhite. To ensure that both sex and race were balanced within each of the sites, randomization was carried out by stratifying on these 2 factors. The strata were nonwhite females, white females, nonwhite males, and white males within each site. A SAS program was created using permuted block sizes for each randomization.

The GCS scores were recorded in the medical records for 125 of the 132 participating adolescents. Fifty participants had severe TBI (GCS score= 3-8), 21 had moderate TBI (GCS score = 9-12), and 54 had complicated mild TBI (GCS = score 13-15, with evidence of trauma-related pathology on computed tomography or magnetic resonance imaging). Following previous research, we grouped individuals with the moderate and complicated mild injuries together into a single moderate group.³⁰ For the remaining 7 participants without a documented GCS score, a clinical neuropsychologist at each site reviewed the medical record and classified the injury as severe or not severe on the basis of length of coma, duration of impaired consciousness, and imaging findings. Missing GCS scores were replaced with the mean value for the corresponding injury severity group (severe = 5; moderate 13). The final groups included 51 participants with severe = TBI and 81 participants with moderate TBI.

Once enrolled, participants were randomly assigned to either of two 6-month long Internet-based interventions: CAPS, a family problem-solving intervention that included training in communications skills, self-regulation, and anger management; or the IRC group that received a self-guided, information-based program. Randomization was stratified by sex and race to ensure equivalent group composition on these factors, with 65 participants assigned to the CAPS group and 67 to the IRC group. Assessors were blinded to participants' group assignment.

Measures

Length of participation was measured as a continuous variable (0-3) that was reverse-coded to represent the latest assessment completed, with 0 indicating full participation in all baseline and follow-up assessments (ie, study completion); 1 indicating completion through 12-month follow-up; 2 indicating completion through 6-month follow-up; and 3 indicating completion of only the baseline assessment. One family was unavailable at the 12-month follow-up but completed the others; another family missed the 6-month assessment but completed the others. Both were coded as 0, indicating participation through the 18-month follow-up.

A background questionnaire was completed at the baseline assessment, which included information regarding injury severity that was verified through hospital records. Sociodemographic information, including census tract information on the median income for the family zip code, and family-reported race, ethnicity, and primary caregiver educational attainment were also collected.

At the 6-month follow-up, caregivers and teens in both groups completed a Satisfaction Survey Scale,¹⁵ as well as a companion questionnaire, the Web Rating Scale (WRS). Both

measures assessed ease of use and helpfulness of specific aspects of the Web sites visited and, for participants assigned to CAPS, components of the CAPS intervention. The Satisfaction Survey Scale contains 23 questions assessing program-specific goals (eg, the program met my expectations) and is rated either on a 4-point scale (SD = strongly disagree; D = disagree; A = agree; SA = strongly agree) or on a 1 to 10 = scale (1 = not at all to 10 completely/extremely). The WRS contains 32 questions = assessing the ease of use of the TBI Web site visited most frequently (eg, logging on, navigating), ease of use and helpfulness of the videoconferences (if applicable), and the helpfulness of specific Web site content. The WRS also provided information on the amount of time families spent engaging in independent Web-based activities (ie, engagement). Most questions in the WRS are rated on a 5-point Likert scale (1 = not at all; 2 = a little; 3 = moderately; 4 = very; 5 = extremely).

Analyses

Analyses were conducted using SPSS 18.0. Length of participation, income, percent poverty level, GCS score, age at injury, and days between injury and study baseline (ie latency) were treated as continuous. Primary caregiver education was treated as ordinal, and dichotomous variables included study completion (completers vs noncompleters), nonwhite, study group, and severe versus moderate injury. All data were initially inspected for outliers and normal distributions prior to analysis. Variables with outliers included primary caregiver engagement, child engagement, and zip code median income; these outliers were Winsorized (ie, elimination of most extreme values) to 3 SDs from the mean. Variable distributions were normal, with skew and kurtosis values within an acceptable range. Comparisons of completers to noncompleters were conducted using *t* tests for continuous variables and χ^2 tests for ordinal and dichotomous variables. Pearson product moment correlation was used to examine associations of continuous variables, Spearman ρ for associations between continuous and ordinal measures, and point-biserial correlation for associations between dichotomous variables.

RESULTS

Attrition was 6% at the 6-month follow-up, 16% at the 12-month follow-up, and 25% at the 18-month follow-up, yielding a completion rate of 75%. The average number of assessments completed (out of 4) was 3.58 (SD = 0.84). Preliminary analysis failed to reveal significant associations between most predictor variables, the only exception being associations of higher primary caregiver education with both higher zip code median income ($r = 0.37$, $P < .001$) and Caucasian ethnicity ($\chi^2_5 = 25.12$, $P < .001$).

Hypothesis 1

Completers had a higher primary caregiver education and higher family income than noncompleters, whereas ethnicity, latency to baseline assessment, and intervention group (ie, CAPS and IRC) were not significantly associated with study completion (see Table 1). A shorter length of study participation was associated with a lower zip code median income ($r = -0.33$, $P < .001$) and fewer years of parental education ($r = -0.24$, $P < .01$) but not with injury severity, latency to baseline assessment, or minority status (see Table 2). When we modeled these predictors simultaneously in a linear regression, only zip code median income

remained significant ($\beta = .27, P = .004$), indicating that primary caregiver education was not contributing unique variance to the outcome ($\beta = .13, P = .15$).

Hypothesis 2

Because satisfaction and engagement were measured only at the 6-month follow-up, only participants who completed at least the first 2 assessments were included in these analyses ($n = 125$). Study completion for this subset of the sample was not significantly related to satisfaction reported by either the adolescent or the primary caregiver ($r = -0.02, P = .80$; $r = 0.05, P = .57$), nor was it associated with the amount of time engaged in the study intervention for either the adolescent ($r = 0.10, P = .28$) or the primary caregiver ($r = 0.07, P = .48$) (see Table 3).

Participants who completed the study showed a trend toward higher child satisfaction ratings ($\chi^2_{27,117} = 39.66, P = .05$), although primary caregiver satisfaction was not associated with completion ($\chi^2_{24,119} = 23.29, P = .50$). Neither child nor primary caregiver engagement (ie, the amount of time engaged in the study intervention, such as searching the Internet or talking with the counselor) was significantly associated with completion: $\chi^2_{7,132} = 7.13, P = .41$, and $\chi^2_{5,132} = 2.77, P = .73$, respectively. In contrast, more primary caregiver satisfaction was associated with participant demographics, including lower education level for the primary caregiver and designation in the CAPS study group. Adolescent satisfaction was not significantly correlated with any participant characteristics. Higher primary caregiver engagement was associated with lower GCS scores. More engagement by the adolescent was associated with lower primary caregiver education and a longer time span between the injury and baseline assessment (see Table 3).

DISCUSSION

Only 2 participant characteristics—family income and parental education—were associated with markers of attrition in this multisite, randomized, clinical trial of a family intervention for adolescent TBI. Consistent with findings from previous TBI and other healthcare intervention studies, lower median family income was the strongest predictor of shorter study participation and study noncompletion. The other marker of greater attrition—fewer years of parental education—also com-ports with earlier findings. In contrast to previous findings, minorities were not more likely to drop out of the current study than whites, which may be partially attributable to low power from a relatively small minority representation ($n = 30$). Contrary to our expectations, attrition was not associated with the interval between injury and study enrollment, injury severity, time spent engaged in research-related activities, or satisfaction with the research study.

The study findings have several important implications. First, lower median income participants were underrepresented throughout the course of the study, lending support to the idea that healthcare research may be biased toward higher-income families and inadequately represent the true needs and outcomes of families from lower socioeconomic backgrounds. Second, the lack of association of attrition with engagement and satisfaction in the study underscores the importance of focusing on participant demographic factors in increasing

retention, rather than focusing exclusively on study design factors. The absence of an association of attrition with time to enrollment after injury also argues against the need for narrow recruitment windows, at least as a means to increase study completion.

Given that neither family income nor parental education is a variable that can be influenced directly by investigators, researchers should begin to empirically investigate malleable factors that might promote long-term study participation. Such future efforts may include strategies such as sliding scale incentivized programs for participants from varying income levels, reimbursements that more directly target the individual family's needs (eg, payment of electrical bill), or more frequent check-ins with families (eg, telephone call) between follow-ups. Institutional review boards are typically wary of reimbursement strategies that could be interpreted as coercive or unjust. However, ethical and scientifically sound approaches to research also imply inclusion of a representative sample. Thus, the benefits of obtaining results that can be said to apply to both higher- and lower-income families may outweigh the risk of coercion in some cases. Although primary caregiver education was not found to be an independent predictor of attrition when zip code median income was included in the model, the 2 variables are only moderately correlated ($r = 0.37$). Consequently, to the degree that lower income and lower education do not overlap, one approach to minimizing attrition in less-educated families might be to include a brief tutorial during the consent process regarding the importance of research, as well as its relation to cost and quality of personal healthcare.

Future investigations might also focus on other modifiable factors of attrition, such as the impact that research personnel turnover has on attrition during a longitudinal study, and an examination of attrition rates between studies with home visit follow-ups and those that require in-hospital follow-ups. Because participant recruitment and retention rates in randomized control trials are often not reported,³¹ future efforts may be warranted to develop guidelines for defining and reporting attrition, with journals adopting clear expectations in this regard.³² In the meantime, individual investigative groups need to take responsibility for clearly reporting retention rates and factors influencing participant bias in all studies.

One limitation of this study is that severity of injury was restricted to adolescents with more severe injuries. Attrition may have been more variable or related to other child and family characteristics had the sample included younger children or a broader spectrum of injury severity. Predictors of attrition may also have differed if the sample had included a greater proportion of ethnic minorities or had we been able to enroll non-English-speaking families.

Despite these limitations, this study remains the first study that has specifically examined factors of attrition in a pediatric TBI population. The results suggest that pediatric TBI research may be biased toward higher-income families and highlight the need for researchers to clearly report attrition factors when disseminating their results and to design future studies with an increased awareness of demographic factors that may decrease participant bias.

Acknowledgments

This work was supported in part by (1) NIH grant R01-MH073764 from the National Institute of Mental Health, (2) a grant from the Colorado Traumatic Brain Injury Trust Fund Research Program, Colorado Department of Human Services, Division of Vocational Rehabilitation, Traumatic Brain Injury Program, and (3) a grant from the Department of Education, NIDRR grant number H133B090010-01 (the contents do not necessarily represent the policy of the Department of Education, and endorsement by the Federal Government cannot be assumed).

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Figure 1.
CONSORT flowchart. CAPS indicates Counselor-Assisted Problem Solving; IRC, Internet Resource Comparison.

TABLE 1

Comparison of demographic and study design factors between study completers and noncompleters

	Completers (<i>n</i> = 101)	Noncompleters (<i>n</i> = 31)	Total (<i>N</i> = 132)	<i>P</i>
Primary caregiver education in years, ^a mean (SD)	4.97 (1.1)	4.26 (1.0)	4.8 (1.1)	<.05 ^b
Percent poverty level, ^c mean (SD)	109.7 (41.0)	83.7 (29.4)	103.6 (40.1)	<.01 ^b
Zip code median income, mean (SD)	\$73 973 (28 082)	\$50 954 (18 491)	\$68 567 (27 861)	<.001 ^b
Glasgow Coma Scale, mean (SD)	9.73 (4.7)	11.45 (3.7)	10.13 (4.5)	<.05 ^b
% Nonwhite	19	36	23	
% Severe injury	43	26	39	
Latency, mean (SD), d	105.1 (53.1)	119.4 (53.8)	108.4 (53.4)	
% CAPS study group	48	55	49	

Abbreviation: CAPS, Counselor-Assisted Problem Solving.

^aSeven-point scale (1 = less than 7 years school; 2 = less than 2 years high school; 3 = at least 2 years high school; 4 = high school degree/GED; 5 = at least 2 years of college; 6 = bachelor's degree; 7 = graduate degree).

^bSignificant group differences.

^cPercent poverty level reflects family income relative to the national poverty threshold, with more than 100 reflecting a higher income.

TABLE 2Correlations between degree of attrition and participant factors^a

	Correlation
Primary caregiver education ^b	−0.24 ^c
Zip code median income ^d	−0.33 ^e
Glasgow Coma Scale ^d	0.15
Nonwhite ^f	0.10
Age at injury ^d	0.07
Latency to baseline ^d	0.07
CAPS study group ^f	0.09

Abbreviation: CAPS, Counselor-Assisted Problem Solving.

^aDegree of attrition ranges from 0 to 3, with 0 = completed all assessments, 3 = dropped after baseline.^bSpearman ρ correlation coefficient.^c $P < .01$.^dTwo-tailed Pearson correlation coefficient.^e $P < .001$.^fPoint-biserial correlation coefficient.

TABLE 3Correlations between satisfaction, engagement, and participant factors^a

	Adolescent satisfaction	Primary caregiver satisfaction	Adolescent engagement	Primary caregiver engagement
Primary caregiver education ^b	- 0.09	- 0.28 ^c	- 0.18 ^d	- 0.15
Zip code median income ^e	- 0.01	- 0.14	- 0.14	- 0.13
Glasgow Coma Scale ^e	- 0.10	- 0.04	- 0.04	- 0.29 ^c
Nonwhite ^f	- 0.17	0.07	0.01	0.08
Age at injury ^e	0.04	- 0.06	0.05	- 0.11
Latency to baseline ^e	0.02	0.01	0.20 ^d	0.15
CAPS study group ^f	- 0.11	0.35 ^{gh}	0.05	- 0.14
Attrition ^e	- 0.02	0.05	0.10	0.07

Abbreviations: CAPS, Counselor-Assisted Problem Solving; IRC, Internet Resource Comparison.

^aCorrelations only include participants who completed at least 2 assessments ($n = 125$).^bSpearman ρ correlation coefficient.^c $P < .01$.^d $P = .05$.^eTwo-tailed Pearson correlation coefficient.^fPoint-biserial correlation coefficient.^g $P < .001$.^hCaregivers in the CAPS group were more satisfied than those in the IRC group.