Attrition in Randomized Controlled Trials for Pediatric Chronic Conditions

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Objective To examine attrition variables in randomized controlled trials of cognitive behavioral interventions for children with chronic illnesses. Methods We examined attrition rates reported on 40 randomized cognitive behavioral interventions published in six pediatric research journals, during the years 2002–2007. Intervention focus was limited to children with a chronic medical condition, such as asthma, obesity, arthritis, diabetes, cancer, sickle cell disease, and cystic fibrosis. Results Mean rate of enrollment refusal was 37% (range 0–75%). Mean attrition rate was 20% (range 0–54%) for initial follow-up and 32% (range 0–59%) for extended follow-up. Of the reviewed articles, 40% included a CONSORT diagram. Conclusions Strategies that can be used to limit attrition include tailoring recruitment to the study population, providing personalized feedback, maintaining consistent study procedures, providing incentives, and using intensive tracking measures. There is a need for standardized definitions and reporting of attrition rates in randomized cognitive behavioral intervention studies.

Key words attrition; pediatric; chronic illness; cognitive behavioral intervention; randomized controlled trial.

Attrition or the loss of eligible participants is a significant threat to the internal, external, and statistical validity of intervention studies (Harris, 1998; Marcellus, 2004). Attrition may compromise internal validity by altering the random composition of groups and their equivalence (Kazdin, 1999). External validity may be compromised due to the potential for attrition to limit the generalizability of results to only those who are retained in a study. For instance, those participants retained in a study may be more persistent or more adherent, or have other characteristics that differ from those who drop-out. Attrition may also compromise statistical validity by reducing sample size and power or by systematically altering the variability within samples. Across various categories of intervention studies, reported attrition rates range from 5% to 70% and bias is thought to be a significant concern if the attrition rate exceeds 20% (Harris, 1998; Marcellus, 2004). An earlier review specific to behavioral medicine outpatient intervention studies for people with a chronic health condition found that attrition rates ranged from 10% to 59%, with a mean of 33% (Davis & Addis, 1999).

A major problem with understanding the potential threat of attrition is that it often goes unreported in studies. Sifers, Puddy, Warren, and Roberts (2002) reviewed 260 empirical studies published in 1997 in four major pediatric or child psychology journals (Journal of Pediatric Psychology, Journal of Clinical Child Psychology, Child Development, and Journal of Abnormal Child Psychology) and found that across these four journals only 19.6–36.2% of the articles (mean = 28%) reported information on attrition. With the adoption of the Consolidated Standards of Reporting Trials (CONSORT) statement by many journals (including this one in 2002), one might expect higher rates of reporting attrition and reasons for participant drop-out. Kane, Wang, and Garrard (2007) reviewed the quality of reporting in randomized controlled trials in the Journal of the American Medical Association (JAMA; which had adopted the CONSORT guidelines) and the New England Journal of Medicine (NEJM; which had not adopted the CONSORT guidelines) before and after the CONSORT guidelines were released. They found that JAMA showed more consistent improvements in all aspects of reporting on randomized trials.
(e.g., JAMA reports of the number completing a study rose from 36% pre-CONSORT to 88% post-CONSORT vs. 24–50% respectively for the NEJM). However, Kane et al. (2007) also noted that varying definitions of attrition were used and reasons for attrition were coded differently across the studies.

To foster consistency in the reporting of attrition rates, we have superimposed the different types of attrition defined in the literature onto the CONSORT diagram, which tracks the flow of participants throughout a study (Figure 1). *Enrollment refusal* occurs when participants who are otherwise eligible either refuse to participate or cannot complete study requirements. *Baseline attrition* occurs when participants sign an informed consent form but do not complete baseline data collection, and are therefore not randomized to a study arm. *Post-randomization attrition* occurs when participants do not receive the allocated intervention, prematurely discontinue the intervention, or do not complete follow-up measures after receiving the intervention (Zebracki et al., 2003). Note that in Figure 1 we have further delineated post-randomization attrition to *during intervention* and *during follow-up* in order to better categorize these different forms of attrition. *Attrition due to missing data* occurs when participants are missing sufficient amounts of data to be excluded from portions of analysis.

![Figure 1. Definitions of attrition.](image-url)
data occurs when participants are excluded from study analyses due to incomplete, inaccurate, or missing data (Ahern & Le Brocque, 2005). Because most studies do not report on attrition due to missing data (possibly because participants who do not complete follow-up measures overlap with those missing data), we will focus on baseline and post-randomization attrition.

In addition to having standard definitions of attrition and use of the CONSORT flowchart to track participants throughout a study, it is also important to understand why potential participants refuse to participate or drop-out at various phases of a study. Determining reasons for or predictors of attrition is usually done by asking participants why they refused or dropped out and/or by using available data (such as demographic or disease-related information) to compare those who consent and complete a study versus those who refuse to enroll or drop-out. Standardized reporting methods are essential for comparing attrition rates across intervention studies and determining predictors of attrition. Thus, the primary purpose of this paper is to examine attrition rates reported in randomized cognitive behavioral treatment (CBT) studies for children and adolescents with chronic medical conditions in six pediatric or health psychology journals. Predictors of attrition and recommendations for minimizing attrition are also discussed.

Methods
Database
We examined attrition rates reported for randomized cognitive behavioral interventions, published during the years 2002–2007, in six pediatric or health psychology journals: Pediatrics (n = 9), Journal of Pediatrics (n = 5), Children’s Health Care (n = 6), Journal of Pediatric Psychology (n = 15), Health Psychology (n = 4), and Journal of Clinical Psychology in Medical Settings (n = 1). Each journal issue printed between January 2002 and November 2007 was reviewed by hand for eligible articles. In addition to hand-review, an electronic search was performed within each of the six journals using the following key terms: randomly assigned; cognitive behavioral therapy; cognitive behavioral intervention; randomized and behavior; intervention and behavior; chronic and intervention.

Articles were included in analyses if the following criteria were met: (a) a randomized controlled trial, (b) it utilized a cognitive and/or behavioral intervention (e.g., education, exercise, cognitive behavioral therapy), and (c) the target population was children or adolescents with a chronic medical condition, such as asthma, obesity, arthritis, diabetes, cancer, sickle cell disease, and cystic fibrosis. Studies conducted with children with mental health disorders or developmental disabilities, such as depression, autism, or ADHD, were excluded. Published abstracts were also excluded.

Coding Procedures
Eligible articles were coded by the first author using a 10-point worksheet. In order to determine accuracy of coding, 25% of the 40 eligible articles (10 articles, at least one from each journal) were randomly selected using a SPSS 15.0 random number generator and independently coded by the second author. Agreements arose when coders identified the same number of participants or information in an article, or judged it to be absent. Percent agreement is provided for each of the 10 coded variables. Fleiss and Cohen (1973) suggest that intraclass correlation coefficient (ICC) is the mathematical equivalent of the weighted Kappa for ordinal data. Thus the intraclass correlation coefficients (Model 2, individual agreement; Shrout & Fleiss, 1979) and raw agreement were calculated for ordinal variables one through six: (1) number of eligible participants (ICC = 1.0; 80%), (2) number of participants enrolled (ICC = .97; 80%), (3) number of participants who completed the baseline assessment (ICC = 1.0; 90%), (4) number of participants who were randomized (ICC = 1.0; 90%), (5) number of participants who completed the intervention (ICC = 1.0; 80%), and (6) number of participants who completed follow-up assessments at each follow-up (ICC = .97; 85%). Cohen’s (1960) kappa statistic and raw agreement were calculated for the categorical variables (seven through ten), coded as yes or no: (7) whether a CONSORT diagram or comparable flow-chart was provided (kappa = 1.0; 100%), (8) whether differences between completers and noncompleters were reported (kappa = 1.0; 100%), (9) whether reasons for refusal or drop-out were provided (kappa = .80; 90%), and (10) whether incentives for participation were discussed (kappa = .29; 70%). Overall ICC (n = 63 discrete data points) was .76 for this study. Overall kappa (n = 40 discrete data points) was .78. Overall percent agreement was 87% determined by dividing the total number of matches (n = 90) by the potential number of matches (n = 103) across the 10 coded variables. Discrepancies were resolved through consensus.

Results
Table 1 presents attrition data for each of the 40 reviewed articles. Enrollment refusal rate is presented as the number of participants who signed an informed consent form
<table>
<thead>
<tr>
<th>Research study</th>
<th>No. enrolled/ No. eligible [Refusal (%)]</th>
<th>No. baseline/ No. enrolled [Attrition (%)]</th>
<th>No. intervention/ No. randomized [Attrition (%)]</th>
<th>No. follow-up/ No. randomized [Attrition (%)]</th>
<th>CONSORT diagram</th>
<th>Noncompleter differences</th>
<th>Reasons for refusal or drop-out</th>
<th>Incentives reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Krishna et al. (2003)</td>
<td>246/249 (1)</td>
<td>228/246 (7)</td>
<td>228/246 (7)</td>
<td>3 month 163/246 (16)</td>
<td>No</td>
<td>Not analyzed</td>
<td>Too busy, not interested, too much hassle</td>
<td>No</td>
</tr>
<tr>
<td>Powers et al. (2005)</td>
<td>10/14 (29)</td>
<td>10/10 (0)</td>
<td>9/10 (10)</td>
<td>3 month 9/10 (10)</td>
<td>Yes</td>
<td>Not analyzed</td>
<td>Time constraints</td>
<td>No</td>
</tr>
<tr>
<td>Cabana et al. (2006)</td>
<td>971/2270 (57)</td>
<td>964/971 (1)</td>
<td>101/101 (0)</td>
<td>12 month 101/101 (10)</td>
<td>Yes</td>
<td>Not analyzed</td>
<td>None reported</td>
<td>Yes: CME and $50/year</td>
</tr>
<tr>
<td>Daley, Copeland, Wright, Roaf, and Wales (2006)</td>
<td>81/132 (39)</td>
<td>81/81 (0)</td>
<td>81/81 (0)</td>
<td>8 week 75/81 (7)</td>
<td>Yes</td>
<td>Not analyzed</td>
<td>Not interested</td>
<td>Yes: £37.50</td>
</tr>
<tr>
<td>Gorelick et al. (2006)</td>
<td>352/618 (43)</td>
<td>352/352 (0)</td>
<td>352/352 (0)</td>
<td>6 month 273/352 (22)</td>
<td>Yes</td>
<td>Public insurance, ethnic minority</td>
<td>None reported</td>
<td>No</td>
</tr>
<tr>
<td>McPherson, Glazebrook, Forster, James, and Smyth (2006)</td>
<td>101/163 (38)</td>
<td>101/101 (0)</td>
<td>99/101 (2)</td>
<td>1 month 99/101 (2)</td>
<td>Yes</td>
<td>No differences found</td>
<td>Family concerns</td>
<td>No</td>
</tr>
<tr>
<td>Sockrider et al. (2006)</td>
<td>464</td>
<td>464/464 (0)</td>
<td>464/464 (0)</td>
<td>14 day 214/464 (54)</td>
<td>No</td>
<td>Not analyzed</td>
<td>None reported</td>
<td>No</td>
</tr>
<tr>
<td>Chan et al. (2007)</td>
<td>120/126 (5)</td>
<td>120/120 (0)</td>
<td>120/120 (0)</td>
<td>54 week 102/120 (14)</td>
<td>Yes</td>
<td>Not analyzed</td>
<td>Unanticipated move</td>
<td>No</td>
</tr>
<tr>
<td>Golley, Magarey, Baur, Steinbeck, and Daniels (2007)</td>
<td>115/193 (40)</td>
<td>111/115 (3)</td>
<td>68/75 (9)</td>
<td>6 month 57/75 (24)</td>
<td>Yes</td>
<td>Older, higher BMI</td>
<td>None reported</td>
<td>No</td>
</tr>
<tr>
<td>Lee et al. (2002)</td>
<td>28</td>
<td>28/28 (0)</td>
<td>25/28 (11)</td>
<td>10 week 25/28 (11)</td>
<td>No</td>
<td>Not analyzed</td>
<td>Pain; medical complication</td>
<td>No</td>
</tr>
<tr>
<td>Kelly et al. (2004)</td>
<td>25</td>
<td>25/25 (0)</td>
<td>20/20 (0)</td>
<td>8 week 20/20 (0)</td>
<td>No</td>
<td>Not analyzed</td>
<td>None reported</td>
<td>No</td>
</tr>
<tr>
<td>Watts et al. (2004)</td>
<td>21</td>
<td>21/21 (0)</td>
<td>14/14 (0)</td>
<td>8 week 14/14 (0)</td>
<td>No</td>
<td>Not analyzed</td>
<td>None reported</td>
<td>Yes: volunteer payment</td>
</tr>
<tr>
<td>Balagopal et al. (2005)</td>
<td>21</td>
<td>21/21 (0)</td>
<td>15/15 (0)</td>
<td>3 month 15/15 (0)</td>
<td>No</td>
<td>Not analyzed</td>
<td>None reported</td>
<td>Yes: payment</td>
</tr>
<tr>
<td>Stark et al. (2006)</td>
<td>65/194 (66)</td>
<td>58/65 (11)</td>
<td>52/65 (20)</td>
<td>6 month 49/65 (25)</td>
<td>No</td>
<td>Older, low, and high medication use</td>
<td>Too busy, too far, too many appointments, not interested, intervention not necessary</td>
<td>No</td>
</tr>
</tbody>
</table>

(continued)
<table>
<thead>
<tr>
<th>Research study</th>
<th>No. enrolled/No. eligible [Refusal (%)]</th>
<th>No. baseline/No. enrolled [Attrition (%)]</th>
<th>No. intervention/No. randomized [Attrition (%)]</th>
<th>No. follow-up/No. randomized [Attrition (%)]</th>
<th>CONSORT diagram</th>
<th>Noncompleter differences</th>
<th>Reasons for refusal or drop-out</th>
<th>Incentives reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applegate et al. (2003)</td>
<td>124/124 (0)</td>
<td>124/124 (0)</td>
<td>123/124 (1)</td>
<td>0 day 122/124 (2)</td>
<td>No</td>
<td>Not analyzed</td>
<td>Patient death, hospitalization</td>
<td>No</td>
</tr>
<tr>
<td>Powers et al., 2003</td>
<td>12/13 (8)</td>
<td>12/12 (0)</td>
<td>9/12 (25)</td>
<td>1 year 8/12 (33)</td>
<td>No</td>
<td>No differences found</td>
<td>Work demands, change in family situation, child illness, new baby</td>
<td>No</td>
</tr>
<tr>
<td>Herrera, Johnson, and Steele (2004)</td>
<td>75/79 (5)</td>
<td>75/75 (0)</td>
<td>46/50 (8)</td>
<td>10 week 46/50 (8)</td>
<td>No</td>
<td>Not analyzed</td>
<td>None reported</td>
<td>No</td>
</tr>
<tr>
<td>Krishna, Balas, Francisco, and Kong (2006)</td>
<td>246/1000 (75)</td>
<td>235/246 (4)</td>
<td>235/246 (4)</td>
<td>3/12 month 228/246 (7)</td>
<td>No</td>
<td>Milder disease, male, young</td>
<td>Too busy, too far, follow-up time too great, medical and technical problems</td>
<td>No</td>
</tr>
<tr>
<td>Abram et al. (2007)</td>
<td>81/105 (23)</td>
<td>81/81 (0)</td>
<td>81/81 (0)</td>
<td>3 month 50/81 (38) 6 month 66/81 (19)</td>
<td>Yes</td>
<td>Not analyzed</td>
<td>None reported</td>
<td>No</td>
</tr>
<tr>
<td>Schwartz, Radcliffe, and Banakat (2007)</td>
<td>58/102 (43)</td>
<td>49/58 (16)</td>
<td>41/49 (16)</td>
<td>2 month 41/49 (16)</td>
<td>No</td>
<td>Not analyzed</td>
<td>Too busy, not interested, started new treatment</td>
<td>No</td>
</tr>
<tr>
<td>Journal of Pediatric Psychology Brown et al. (2002)</td>
<td>111/144 (23)</td>
<td>101/111 (9)</td>
<td>95/101 (6)</td>
<td>3 month 91/101 (10) 12 month 93/101 (8)</td>
<td>No</td>
<td>Male</td>
<td>None reported</td>
<td>Yes: $75</td>
</tr>
<tr>
<td>Madsen, Roisman, and Collins (2002)</td>
<td>224</td>
<td>224/224 (0)</td>
<td>224/224 (0)</td>
<td>Not reported</td>
<td>No</td>
<td>Not analyzed</td>
<td>None reported</td>
<td>Yes: volunteer</td>
</tr>
<tr>
<td>Davis, Quittner, Stack, and Yang (2004)</td>
<td>47/48 (2)</td>
<td>47/47 (0)</td>
<td>47/47 (0)</td>
<td>3 month 47/47 (0) 6 month 22/22 (0)</td>
<td>No</td>
<td>Not analyzed</td>
<td>Lack of access to computer</td>
<td>Yes: $15</td>
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<tr>
<td>Klosky et al. (2004)</td>
<td>79/79 (0)</td>
<td>79/79 (0)</td>
<td>79/79 (0)</td>
<td>0 day 79/79 (0)</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>No</td>
</tr>
<tr>
<td>Koontz, Short, Kalmyak, and Noll (2004)</td>
<td>24/26 (8)</td>
<td>24/24 (0)</td>
<td>24/24 (0)</td>
<td>24/24 (0)</td>
<td>No</td>
<td>N/A</td>
<td>None reported</td>
<td>No</td>
</tr>
<tr>
<td>Ellis et al. (2005)</td>
<td>38/47 (19)</td>
<td>31/38 (18)</td>
<td>26/31 (16)</td>
<td>9 month 23/31 (26)</td>
<td>Yes</td>
<td>Not analyzed</td>
<td>Disagreement regarding direction of therapy; low engagement in therapy</td>
<td>No</td>
</tr>
<tr>
<td>Kazak et al. (2005)</td>
<td>19/47 (60)</td>
<td>19/19 (0)</td>
<td>16/19 (16)</td>
<td>2 month 17/19 (11)</td>
<td>Yes</td>
<td>No differences found</td>
<td>Not interested, unwilling to leave child, scheduling conflict, overwhelmed</td>
<td>No</td>
</tr>
<tr>
<td>Robins, Smith, Glutting, and Bishop (2005)</td>
<td>86/103 (17)</td>
<td>86/86 (0)</td>
<td>77/86 (10)</td>
<td>3 month 70/86 (19) 6-12 month 69/86 (20)</td>
<td>Yes</td>
<td>Not analyzed</td>
<td>Too busy, too far, wanted to be in treatment arm, started additional therapy</td>
<td>Yes: $25</td>
</tr>
<tr>
<td>Stark et al. (2005)</td>
<td>65/194 (66)</td>
<td>57/65 (12)</td>
<td>52/65 (20)</td>
<td>8 weeks 49/65 (2.5)</td>
<td>Yes</td>
<td>Older, low, and high medication use</td>
<td>Too busy, could not provide food diary</td>
<td>No</td>
</tr>
<tr>
<td>Research study</td>
<td>No. enrolled/No. eligible [Refusal (%)]</td>
<td>No. baseline/No. enrolled [Attrition (%)]</td>
<td>No. intervention/No. randomized [Attrition (%)]</td>
<td>No. follow-up/No. randomized [Attrition (%)]</td>
<td>CONSORT diagram</td>
<td>Noncompleter differences</td>
<td>Reasons for refusal or drop-out</td>
<td>Incentives reported</td>
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<tr>
<td>Connelly, Rapoff, Thompson, and Connelly (2006)</td>
<td>41/50 (26)</td>
<td>37/41 (10)</td>
<td>36/37 (3)</td>
<td>3 month 31/37 (16)</td>
<td>Yes</td>
<td>Not analyzed</td>
<td>Too busy, technology difficulties</td>
<td>Yes: $50</td>
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<tr>
<td>Hicks, Baeyer, and McGrath (2006)</td>
<td>72/83 (13)</td>
<td>47/72 (35)</td>
<td>42/47 (11)</td>
<td>1 month 37/47 (21)</td>
<td>Yes</td>
<td>No differences found</td>
<td>None reported</td>
<td>No</td>
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<tr>
<td>Warner et al. (2006)</td>
<td>61/180 (66)</td>
<td>Not reported</td>
<td>55/61 (10)</td>
<td>1 month 50/61 (18)</td>
<td>No</td>
<td>No differences found</td>
<td>None reported</td>
<td>Yes: $15 or $45</td>
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<tr>
<td>Wysocki et al. (2006)</td>
<td>104/388 (73)</td>
<td>104/104 (0)</td>
<td>104/104 (0)</td>
<td>6 month 92/104 (12)</td>
<td>Yes</td>
<td>Lower SES, living with single parent</td>
<td>None reported</td>
<td>Yes: $100 or $200</td>
</tr>
<tr>
<td>Ellis et al. (2007)</td>
<td>144/182 (21)</td>
<td>127/144 (12)</td>
<td>111/127 (13)</td>
<td>7 month 110/127 (13)</td>
<td>No</td>
<td>Not analyzed</td>
<td>Too busy, parental disinterest; did not think intervention helpful</td>
<td>No</td>
</tr>
<tr>
<td>Goldfield et al. (2007)</td>
<td>30/30 (0)</td>
<td>30/30 (0)</td>
<td>30/30 (0)</td>
<td>8 week 30/30 (0)</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>Yes: Park and transport</td>
</tr>
<tr>
<td>Health Psychology</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Dahlquist, Pendly, Landthrip, Jones, and Steuber (2002)</td>
<td>31/44 (30)</td>
<td>31/31 (0)</td>
<td>29/29 (0)</td>
<td>8 week 29/29 (0)</td>
<td>No</td>
<td>Not analyzed</td>
<td>Intervention not necessary</td>
<td>Yes: Prizes</td>
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<tr>
<td>Rapoff et al. (2002)</td>
<td>54/90 (40)</td>
<td>54/54 (0)</td>
<td>54/54 (0)</td>
<td>52 week 34/54 (37)</td>
<td>No</td>
<td>Less disease activity</td>
<td>Taken off medications</td>
<td>No</td>
</tr>
<tr>
<td>Epstein, Palach, Kilanowski, and Baynor (2004)</td>
<td>72/72 (0)</td>
<td>63/72 (12)</td>
<td>61/63 (3)</td>
<td>6 month 61/63 (3)</td>
<td>Yes</td>
<td>Not analyzed</td>
<td>None reported</td>
<td>No</td>
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<tr>
<td>Liossi, White, and Hatira (2006)</td>
<td>45/49 (8)</td>
<td>45/45 (0)</td>
<td>45/45 (0)</td>
<td>1 month 45/45 (0)</td>
<td>Yes</td>
<td>Not analyzed</td>
<td>Families too distressed, felt intervention not necessary</td>
<td>No</td>
</tr>
<tr>
<td>Journal of Clinical Psychology in Medical Settings</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Ellis et al. (2004)</td>
<td>38/47 (19)</td>
<td>31/38 (18)</td>
<td>27/31 (13)</td>
<td>6 month 25/31 (19)</td>
<td>No</td>
<td>No differences found</td>
<td>None reported</td>
<td>No</td>
</tr>
</tbody>
</table>
(i.e., enrolled) over the number of participants who were eligible to participate in the study, along with percent enrollment refusal. Baseline attrition is presented as the number of participants who completed the baseline assessment over the number of participants who enrolled in the study, along with percent attrition. Post-randomization attrition during intervention is presented as the number of participants who remained in the study during the intervention period over the number of participants who were randomized to a study arm, along with percent attrition. Post-randomization attrition during follow-up is presented as the number of participants who completed the follow-up assessment over the number of participants who were randomized, along with percent attrition.

Enrollment refusal rates were available for 34 of the 40 articles. Overall, 37% (median = 22%; range 0–75%) of those participants who were eligible for a study, and were offered the opportunity to participate, refused to participate. Baseline attrition rates were available for 38 of the 40 reviewed articles. On average, 4% (median = 0%; range 0–35%) of participants who agreed to participate and signed an informed consent form did not complete study baseline measures.

Post-randomization attrition during intervention rates were available for 39 of 40 articles, with 16 of the 40 articles (40%) providing a CONSORT diagram, or similar participant flow chart. On average, 6% (median = 2%; range 0–23%) of participants randomized to a study arm dropped out during the study treatment period or did not receive the allocated treatment. Initial follow-up or immediate post-treatment attrition rates were reported in 39 of 40 articles. Overall, 20% (median = 12%; range 0–54%) of participants did not complete initial follow-up assessments. Of the 16 studies that collected extended follow-up data, the overall attrition rate increased to 32% (median = 12%; range 0–59%) at extended follow-up. Correlational analyses revealed that as the initial follow-up interval increased so did the rate of attrition at that follow-up ($r = .34, p = .04$). Interestingly, overall, attrition rates did not differ significantly between treatment, comparison, or control groups at any assessment period, $F$’s ranged from $1.6$ to $.73$, $p$’s ranged from $.49$ to $.86$. However, 12 individual studies experienced differential attrition rates of 10% or more between treatment and control or comparison groups.

Investigated differences between those participants who withdrew from the study and those who completed the study (i.e., noncompleters and completers) were reported in 14 of the 37 articles (38%) with post-randomization attrition. Authors of these 14 articles used analysis of variance (ANOVA) tests to determine if demographic variables differed significantly between completers and non-completers. These studies found that non-completers were significantly more likely to have mild or severe disease ($n = 3$ studies), be younger or older ($n = 3$ studies), be male ($n = 2$ studies), be an ethnic minority ($n = 1$ study), have government issued insurance (i.e., Medicare or Medicaid; $n = 1$ study), be of lower socioeconomic status ($n = 1$ study), and have single parents ($n = 1$ study). No differences were found between completers and non-completers in 6 of the 14 studies.

Reported reasons for families refusing to participate or for withdrawing from a study early were provided in 21 of 38 articles (55%) that had enrollment refusal or attrition. The most commonly cited reasons for enrollment refusal or study drop-out, along with the percent cited, were: being too busy (mean = 19%, median = 4%), not being interested in the research project (mean = 18%, median = 0 for this and all subsequent reasons), research project was too much hassle (mean = 8%), technical complications with study procedures (e.g., did not have two caregivers available or lack of computer access; mean = 7%), intervention was not necessary (mean = 5%), travel distance was too far (mean = 4%), and too many doctor appointments (mean = .5%). The most common reasons given for withdrawing from a study early, along with percent cited, were: not wanting to continue with treatment or wanting to start a different treatment (mean = 14%), medical complications (mean = 9%) being too busy (mean = 8%), family concerns (mean = 7%), and unanticipated move (mean = 2%).

Whether or not participants were offered incentives for participation in the study were reported in 14 of the 40 articles (35%). Eleven articles provided some form of compensation or incentive, whereas three articles reported that participants were volunteers. Surprisingly, there were no differences in enrollment refusal or attrition rates among studies that provided incentives compared to studies that did not report incentives being provided, $F$’s ranged from $.43$ to $2.57$, $p$’s ranged from $.12$ to $.51$.

Lastly, 35 articles (88%) reported significant positive outcomes in at least half of their measured variables. Regarding missing data, one study reported using outcome means to impute missing data; 11 studies used some form of intent-to-treat (ITT) analysis; and 19 studies used only complete data sets. Nine studies experienced no attrition. Of the 11 studies that used ITT analysis, one study coded missing data as adverse outcomes, one study used baseline scores with no change, two studies carried the last observation forward, and the rest reported no specific ITT
method (four studies) or only that they controlled for baseline (two studies). In this review, there was no significant difference in outcomes for those studies that used ITT analysis compared to those that did not, \( F(1, 38) = 2.18, p = .15 \). It should be noted that the use of ITT analysis is important in reducing biases that may result from differential or non-random study attrition (Gross & Fogg, 2004; Nich & Carroll, 2002). Thus, researchers may have more confidence in results that arise from ITT analysis, as this type of analysis provides conservative estimates of negative or null results for participants who do not complete a study.

Discussion

Attrition rates obtained from this review are similar to those of earlier reviews (e.g., Davis & Addis, 1999). On average, approximately 37% of eligible families of children with chronic medical conditions refused to participate in cognitive behavioral intervention studies. Approximately 20% of those who enrolled withdrew before completing the first follow-up assessment, and 32% did not complete the extended follow-up assessment. A longer initial follow-up interval was significantly correlated with higher attrition rates at follow-up.

In general, results of this review suggest a wide variability in reporting of and attention to attrition rates across journals and articles. Only 40% of the reviewed articles included a CONSORT diagram or comparable flow chart, only 38% reported any type of comparison between study completers and noncompleters, and only 28% used ITT analyses. Although no differential rates of attrition were found between treatment and control groups overall, 12 individual studies experienced differential attrition rates of 10% or more, while only four of these studies used ITT analysis. This current level of methodological attention leaves room for improvement. Rigorous adoption of the CONSORT statement across pediatric and health psychology journals, use of standardized definitions of attrition, and use of ITT statistical analyses will guide authors in reporting study variables that are critical to the internal, external, and statistical integrity of research studies.

Predictors of Attrition

The pediatric literature, outside the scope of randomized controlled trials, has begun examining predictor variables of early study drop-out. In these outside studies, the most commonly cited predictors are age, ethnicity and socioeconomic status (e.g., Spoth, Goldenberg & Redmond, 1999). These demographic variables were also found to be related to study drop-out in this review. Other characteristics common to noncompleters, found in both outside literature and this review, are greater and milder disease activity, less response to treatment (van den Akker et al., 2007) and lack of insurance coverage (Barlow & Ohlemeyer, 2006; Cote et al., 2004). In addition, several studies have found that the presence of mental illness, emotional disturbance, or behavioral concerns predict early drop-out ( Cotter, Burke, Loebere & Mutchke, 2005; Dierker, Nargiso, Wiseman & Hoff, 2001). For instance, in one long-term asthma treatment program, children with lower cognitive, academic, and social skills and greater family conflict were significantly more likely to withdraw before study completion (Bender et al., 2003).

Attrition Recommendations

This and previous reviews of cognitive behavioral intervention studies indicate that some attrition is likely to occur in most studies. Thus, in intervention planning and preparation, it would be advantageous for researchers to anticipate a 30% attrition rate and enroll 30% more participants than deemed necessary in a priori power analyses (Mitchell & Abernethy, 2005). Although internal and external validity can be threatened at this level of attrition, statistical validity can be maintained in this manner through the preservation of adequate power and the use of ITT analyses.

Recommendations for minimizing attrition from the outset include emphasizing benefits of research, giving control to participants, minimizing participant burden, providing problem-solving support, being persistent, being flexible, enlisting outside social support, providing incentives or tokens of appreciation, and maintaining a good tracking system (Coday et al., 2005). In particular, minimizing participant burden by using short questionnaire forms, incorporating data collection into regular clinic visits, and offering high monetary incentives appear to be useful in reducing attrition (Capaldi & Patterson, 1987). Other strategies reported to be useful in maximizing enrollment and reducing attrition include (a) tailoring recruitment to the population being studied (e.g., conducting focus groups, implementing culturally sensitive interventions) (Boys et al., 2003); (b) having repeated contact with participants that is positive in nature (Prinz et al., 2001); (c) staying in touch between assessments and maintaining continuity of personnel and procedures; (d) beginning studies with detailed orientation sessions (Germann, Kirschenbaum, & Rich, 2006) or motivational counseling sessions (Pierce & Stoltenberg, 1990); and (e) obtaining extensive background information and conducting extensive phone number searches (Morrison et al., 1997;
Pirie et al., 1989). Additionally, given the reported problems with insurance coverage for some treatment programs, assisting families to obtain insurance coverage or offsetting the cost of treatment may be helpful in decreasing attrition (Cote et al., 2004; Warren et al., 2007).

**Future Directions**

The full effect of attrition on randomized clinical trial outcomes in pediatric intervention studies is unclear at this time. To date, there has been a dearth of research in the area of attrition in pediatric intervention studies. It may be the case that the above strategies for reducing attrition have minimal effects, while carrying the potential for compromising internal study validity. Additionally, it may be the case that the use of conservative ITT analysis substantially reduces the effect size of a study; thereby underestimating the efficacy of an intervention. Despite characteristic attrition rates and limited attention to potential attrition biases, 88% of the articles in this review reported positive results in measured outcomes. Thus, it seems clear that systematic research is needed to further assess the impact of attrition and usefulness of retention strategies in pediatric intervention studies.

**Conclusions**

Standardized definitions of attrition and increased reporting of attrition rates are needed to determine the internal, external, and statistical validity of randomized controlled trials (Betan, Roberts & McCluskey-Fawcett, 1995; Sifers et al., 2002). Although the recent increased use of the CONSORT diagram is a significant improvement in methodological reporting, additional information, such as differences between completers and noncompleters, reasons for refusal and drop-out, and whether participant incentives were provided should be routinely reported in randomized pediatric intervention studies.

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**References**


