How to Review a Research Article

Bernice D. Mowery, PhD, PNP, RN
Pediatric Nursing Conference

Objectives:

- Identify the components of a research article
- Use a systematic approach to evaluate a nursing research article

What Do You Need to Review Research Articles?

- Fears?
  - Learn terminology
  - Get help with statistics
  - Evidence Based Practice (EBP)/Best Practice
  - How do you determine if a research article is applicable?
  - Is one article enough to support practice change?
- Plan
  - Learn components of a Research Study
  - Evaluate the quality of how it was done
  - Use a systematic format to evaluate studies

Evidence-Based Practice: Six Steps

1. Formulation of an answerable question to address a specific patient problem or situation
2. Systematic searching for the research evidence that could be used to answer the question
3. Appraisal of the validity, relevance and applicability of the research evidence
4. Integration of the research evidence with other information that might influence the management of the patient’s problems: clinical expertise, patient preferences, available resources
5. Implementation of the evidence-based practice decision
6. Evaluation of the outcome of the decision

http://ktlearninghouse.ca/cebmsyllabus/nursingintro

Tips for Review

- Use same approach each time
- Develop your own system
- Use a form to record your evaluation
- Write notes in margins as you read or use Track Changes
- May need to review several times before final evaluation
  - Review all articles on subject - then review again
  - Rank them for relevance and quality
  - Synthesize

Research Article Evaluation Form

Bernice D. Mowery, PhD, PNP, RN

Article Information: …
Critique of the Research Process

• Not just “yes” or “no” for each step
• Evaluate quality
• No such thing as “perfect” research
• Want the most strengths possible with limitations in areas of least importance for this study

Overview of the Article

• Author(s)
• Date of the research
• Title clear?
• Abstract helpful?
• What are clinical implications?
  • Priority area for nursing research
  • Focus of EBP (evidence based practice)
  • Is the approach quantitative or qualitative?

Purpose/Problem Statement

• Clarity of the problem
• Research aims/questions/hypotheses
• Builds on previous research
• Significance for nursing

Aims/Objectives/Research Questions

• Different words used to describe
  • Goals of the research
  • Are they logical & realistic
  • May include hypotheses
• Theoretical/Conceptual Framework/Model
  • Adequately described
  • Appropriate
  • Controversial if this is an absolute requirement

Background/Literature Review

• Review comprehensive
• Support for the current research questions
• Includes most current information
• Includes all pertinent variables
• Establishes significance

Methods:

• Type of study approach
  • Should match questions
  • Qualitative
  • Quantitative
  • Mixed methods
• IRB approval/human rights protection
• Procedures
  • Operational definitions for Measures & Outcomes
  • Participants
  • Plan for analysis
### Quantitative vs. Qualitative

- **Quantitative**
  - Study of phenomena that can be precisely measured and quantified
  - Statistical analyses

- **Qualitative**
  - Study of phenomena in an in-depth & holistic manner
  - Participant’s perspective of the phenomena (narrative data)

- **Mixed methods**
  - Combine Quantitative & Qualitative methods
  - Triangulation: research process along with data is analyzed from different directions – decreases bias & increases validity of results

### Study Design

- **Quantitative**
  - Experimental
    - Random Controlled Trial
  - Quasi-experimental Design
  - Non-experimental
    - Descriptive
    - Correlational
    - Blinding
    - Intervention (independent variable)

- **Qualitative**
  - Grounded theory
  - Phenomenology
  - Ethnography

### Quantitative Design

- Investigation of phenomena that allows precise measurement and quantification
- Usually involves rigorous and controlled design (Polit & Beck, 2012)
- Characterized by
  - Systematic collection and statistical analysis of numerical data
  - Relatively controlled conditions (Norwood, 2010)
  - Gathering and analyzing empirical evidence
  - Goal is generalizability (Polit & Beck, 2012)

### Qualitative Design

- Study of phenomena in an in-depth & holistic manner
- Participant’s perspective of the phenomena (narrative data)
- The “lived experience”

### Ethical Considerations

- Human rights protection
- All risks identified
- Participants fully informed
- Consent/Assent given
  - The National Commission for Protection of Human Subjects of Biomedical and Behavioral Research established age 7 as a reasonable minimum age for involving children in some kind of assent process
  - Younger may be able to assent
- Funding influences
- Investigator bias
Procedures

• Described adequately
  – To allow reviewer to evaluate
  – For duplication
• Operational definitions for
  – Interventions/Exposure/Treatment (Independent variable)
  – Outcomes (Dependent Variable)
• Realistic
  – Is it cost-effective?
  – Would this ever work in practice?

Sample/Study Population

• Sample Size: Power Analysis or Saturation
• Gender
• Race
• Setting
• Age group
• Sampling method
• Same group as your interest

Measurements

• Multidimensional
  • Different tools to measure different dimensions of outcome
  • Different tools to measure same dimension of outcome
  • Mono-measurement is a threat to validity of the study
• Psychometric Characteristics
  • Reliability
  • Validity

Findings/Results

• Data and Analyses
  • Statistical analysis planned met assumptions
  • Do graphs and tables correlate with statistical report
• Significance
  • Statistical
  • Clinical
• Effect size
• Qualitative:
  • Themes & meaning elicited
  • Saturation reached

Statistical Tests

• Bivariate:
  • t-test
  • ANOVA
  • Chi-Square
  • Pearson’s r
• Multivariate
  • MANOVA
  • Multiple Regression
  • Logistical Regression

Rigor

• Striving for excellence in the research process
• Uses discipline
• Strict adherence to detail
• Extremely accurate
• Precision
  • Control over confounding/extraneous/intervening variables that could affect the dependent variable
• Effect size and Power
  • Effect size = the magnitude of difference the intervention makes on the outcome
  • Maximize differences made by the independent variable
  • Power is probability that a statistical test will detect a difference
Validity Threats

- Construct Validity
- Internal Validity
- External Validity
- Statistical Conclusion Validity Threat

Random Controlled Trial (RCT)

Three areas required:
1. Randomization
   - Random sample
   - Random assignment to control and experimental groups
   - Difficult to obtain random sample in clinical setting so most researchers use a convenience sample with random assignment
2. Comparison or control group
3. Controlled manipulation of the treatment/independent variable

Construct Validity

- Most often associated with measurements
- Key questions:
  - What is the instrument measuring?
  - Does it validly measure the abstract concept of interest?
- Use both logical and empirical procedures to evaluate
  - Use what is known to evaluate relationships in variables
  - Factor analysis – statistical method to identify clusters of related items on a scale

Internal Validity

- Did the experimental treatment(s), and not some extraneous variable, make the difference in this specific experimental instance?
- Common Threats:
  - Selection-Treatment interaction
  - History
  - Maturation
  - Mortality/Attrition
  - Fishing/Error rate

Selection-Treatment Interaction

- Bias from preexisting differences
- RCT helps control for this
- If not RCT, this is most significant threat to internal validity
- Also an issue if many elect not to receive the treatment

History

- Occurrence of events simultaneously with the intervention/independent variable
- Not sure which one is causing the effects
- Controlled by RTC – both groups (experimental & control) are affected by history
Maturation

- Time causes effects rather than intervention
- Lots of issues we study are affected by time
  - Coping
  - Wound healing
  - One-group before – after design is most vulnerable
  - Control: RCT – both groups affected

Mortality/Attrition

- Longitudinal studies may lose participants over time
- Those who drop out may be different from those that continue
- Attrition bias is same as selection bias
- Higher rates of attrition pose great validity threats
- Rates > 20% yield concerns about bias

Fishing/Error Rate

- If you keep evaluating enough variables, something will be significant when really it is not
- Analysis of variables without any theoretical or other support
- Outcomes report should match research aims/questions

Methodological Strengths

- Control of extraneous variables
- Sample large enough
- Does the experimental design control for competing influences = confounding variables
- Experimental rigor

External Validity

- Degree to which you can apply findings of this study to other settings and samples
- Consider the characteristics of the study participants
- Threats:
  - Reliability of treatment implementation
  - Statistical Regression
  - Best control for threats is RCT design

Reliability of Treatment Implementation

- Described thoroughly enough?
- Were treatments consistent?
  - Consistent person did all treatments
  - Workshop training for those providing treatments
  - Checks for consistency
- Were effects dependent on the person who provided the treatment?
Statistical Conclusion Validity

- Affected by
  - Sample size & Power
  - Strength of intervention (independent variable)
  - Strength of the outcomes (dependent variable)

Conflicts for validity

Tight study for internal validity may make the intervention not applicable to the real world

Discussion, Author’s Conclusions and General Recommendations

- Did author recognize threats and limitations of study?
- Recommendations for improvements to repeat study

Conclusions

- Drawn from the findings
- Logical
- Generalized to other groups
- Limitations affect generalizability

Generalizability

- Infers that findings can be generalized from the study sample to a broader group (i.e. population)
- Important when looking for support for evidence based practice to determine if the findings of a study are applicable to your interest group
- For example:
  - Would findings from a study evaluating an intervention for chronic pain be applicable for post-operative pain management?

Conclusions, Implications and Recommendations

- Rigorous
- Practice/EBP
- Research
PRACTICE, PRACTICE, PRACTICE
Adherence in Single-Parent Households In a Long-Term Asthma Clinical Trial

Mary Spicher, Nancy Bollers, Tamara Chinn, Anita Hall, Anne Plunkett, Denise Rodgers, D.A. Sundström, Laura Wilson, The Childhood Asthma Management Program (CAMP) Research Group

Adherence of participants in a long-term clinical trial is necessary to assure validity of findings. This article examines adherence differences between single-parent and two-parent families in the Childhood Asthma Management Program (CAMP). Adherence was defined as the percentage of completed daily diary cards and scheduled study visits during the course of the trial. Logistic regression and ordinal logistic regression analyses were used. Children from single-parent families had a lower percentage of completed diary cards (72% vs. 84%) than two-parent families. Single-parent families were also more likely to reschedule visits (62% vs. 45%) and miss more clinic visits (23% vs. 17%) than two-parent families. Suggestions are given for study coordinators to assist participants in completing a long-term clinical trial. Many suggestions may be adapted for nurses in inpatient or outpatient settings for assisting parents of patients with chronic diseases.

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The Childhood Asthma Management Program (CAMP) Research Group. Please see credit roster at the end of this article.

Adherence is the extent to which a patient follows a reasonable treatment that has been prescribed for him or her by a qualified caregiver (Bender, Milgrom, & Rand, 1997). Non-adherence is of widespread concern in the medical community. Bender et al. (1997) found that patients’ symptoms and the need to use the medical care system for acute care could all be reduced by improved adherence. Additional consequences of non-adherence for many patients and parents can be missed work or school days (Bender et al., 1997). Quality of life has been found to improve if persons are adherent to their prescribed medications (Mannheimer et al., 2005). The World Health Organization defines adherence as the extent to which a person’s behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with the instructions given by health care providers (Sabeté et al., 2003). In addition, lack of adherence to clinical research protocols, which includes the recording of outcomes, attending scheduled visits for measurements, and taking of medication, can threaten the validity of the findings of a study. Determining factors that have a significant impact on adherence in a clinical trial can improve the selection process as well as identify patients with chronic diseases that might benefit from added attention and instruction.

The purpose of this study was to determine if adherence in a long-term clinical trial of asthma therapy is decreased in single-parent families. Single-parent households make up 25% of households in the United States. Specifically, the researchers wanted to test the hypothesis that single-parent families would be less adherent than two-parent families during a long-term asthma clinical trial. The researchers analyzed data from children and families enrolled in the Childhood Asthma Management Program (CAMP), a 4- to 6-year clinical trial comparing two anti-inflammatory medications with placebo in children with persistent asthma. All children received inhaled albuterol as needed for symptoms (CAMP Research Group, 1999).

Methods

The design and methods of the CAMP trial as well as the main outcomes have been detailed elsewhere (CAMP Research Group, 1999, 2000). Pertinent to this ancillary study were the following: 1) 1041 children 5 to 12 years of age were enrolled across eight clinical centers, and 2) clinical research coordinators were initially trained and certified centrally to establish standardization across all eight centers for visitation schedule and the measuring and recording of outcomes that were then submitted to a central data coordinating center (CAMP Research Group, 1999). In addition, a centralized asthma educational group was formed to develop and disseminate ongoing standardized asthma education across the centers to improve and maintain adherence to the study protocol (CAMP Research Group, 1998). Approval for all study procedures was obtained from the Institutional Review Board at each institution. Parents and children signed consent and assent forms respectively.
### Table 1. Characteristics of the CAMP Participants at Baseline

<table>
<thead>
<tr>
<th></th>
<th>Single-Parent Family (n = 177)</th>
<th>Two-Parent Family (n = 854)</th>
<th>Total (N = 1031)</th>
<th>p-Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age – Year (Mean ± SD)</strong></td>
<td>9.0 ± 2.1</td>
<td>8.9 ± 2.1</td>
<td>8.9 ± 2.1</td>
<td>0.68</td>
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<tr>
<td>Range</td>
<td>5 to 13</td>
<td>5 to 13</td>
<td>5 to 13</td>
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<tr>
<td><strong>Race or Ethnic Group – %</strong></td>
<td></td>
<td></td>
<td>&lt; 0.0001</td>
<td></td>
</tr>
<tr>
<td>Minority</td>
<td>55.9%</td>
<td>26.4%</td>
<td>31.4%</td>
<td></td>
</tr>
<tr>
<td>Non-minority</td>
<td>44.1%</td>
<td>73.7%</td>
<td>68.6%</td>
<td></td>
</tr>
<tr>
<td><strong>Sex – %</strong></td>
<td></td>
<td></td>
<td>0.26</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>44.1%</td>
<td>39.5%</td>
<td>40.3%</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>55.9%</td>
<td>60.5%</td>
<td>59.7%</td>
<td></td>
</tr>
<tr>
<td><strong>Severity of Asthma – %</strong></td>
<td></td>
<td></td>
<td>0.70</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>49.2%</td>
<td>47.5%</td>
<td>47.8%</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>50.9%</td>
<td>52.5%</td>
<td>52.2%</td>
<td></td>
</tr>
<tr>
<td><strong>Annual Income – %</strong></td>
<td></td>
<td></td>
<td>&lt; 0.0001</td>
<td></td>
</tr>
<tr>
<td>Less than $15,000</td>
<td>21.1%</td>
<td>3.8%</td>
<td>6.8%</td>
<td></td>
</tr>
<tr>
<td>$15,000 to $29,999</td>
<td>33.3%</td>
<td>14.2%</td>
<td>17.5%</td>
<td></td>
</tr>
<tr>
<td>$30,000 to $49,999</td>
<td>36.8%</td>
<td>32.7%</td>
<td>33.4%</td>
<td></td>
</tr>
<tr>
<td>$50,000 or more</td>
<td>8.8%</td>
<td>49.3%</td>
<td>42.3%</td>
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</tr>
<tr>
<td><strong>Annual Income Among Caucasians – %</strong></td>
<td></td>
<td></td>
<td>&lt; 0.0001</td>
<td></td>
</tr>
<tr>
<td>Less than $15,000</td>
<td>21.1%</td>
<td>3.3%</td>
<td>5.3%</td>
<td></td>
</tr>
<tr>
<td>$15,000 to $29,999</td>
<td>35.5%</td>
<td>13.0%</td>
<td>15.5%</td>
<td></td>
</tr>
<tr>
<td>$30,000 to $49,999</td>
<td>34.2%</td>
<td>30.5%</td>
<td>30.9%</td>
<td></td>
</tr>
<tr>
<td>$50,000 or more</td>
<td>9.2%</td>
<td>53.1 %</td>
<td>48.2%</td>
<td></td>
</tr>
<tr>
<td><strong>Annual Income Among Minorities – %</strong></td>
<td></td>
<td></td>
<td>&lt; 0.0001</td>
<td></td>
</tr>
<tr>
<td>Less than $15,000</td>
<td>21.1%</td>
<td>5.2%</td>
<td>10.1%</td>
<td></td>
</tr>
<tr>
<td>$15,000 to $29,999</td>
<td>31.6%</td>
<td>17.4%</td>
<td>21.8%</td>
<td></td>
</tr>
<tr>
<td>$30,000 to $49,999</td>
<td>39.0%</td>
<td>39.0%</td>
<td>39.0%</td>
<td></td>
</tr>
<tr>
<td>$50,000 or more</td>
<td>8.4%</td>
<td>38.5%</td>
<td>29.2%</td>
<td></td>
</tr>
<tr>
<td><strong>Education Level – %</strong>†</td>
<td></td>
<td></td>
<td>&lt; 0.0001</td>
<td></td>
</tr>
<tr>
<td>High school education or less</td>
<td>19.8%</td>
<td>10.0%</td>
<td>11.7%</td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>47.5%</td>
<td>35.1%</td>
<td>37.3%</td>
<td></td>
</tr>
<tr>
<td>Completed college</td>
<td>32.8%</td>
<td>54.9%</td>
<td>51.1%</td>
<td></td>
</tr>
<tr>
<td><strong>Education Level Among Caucasians – %</strong>†</td>
<td></td>
<td></td>
<td>&lt; 0.0001</td>
<td></td>
</tr>
<tr>
<td>High school education or less</td>
<td>21.8%</td>
<td>8.8%</td>
<td>10.2%</td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>51.3%</td>
<td>33.3%</td>
<td>35.3%</td>
<td></td>
</tr>
<tr>
<td>Completed college</td>
<td>26.9%</td>
<td>58.0%</td>
<td>54.5%</td>
<td></td>
</tr>
<tr>
<td><strong>Education Level Among Minorities – %</strong>†</td>
<td></td>
<td></td>
<td>0.27</td>
<td></td>
</tr>
<tr>
<td>High school education or less</td>
<td>18.2%</td>
<td>13.3%</td>
<td>14.8%</td>
<td></td>
</tr>
<tr>
<td>Some college</td>
<td>44.4%</td>
<td>40.4%</td>
<td>41.7%</td>
<td></td>
</tr>
<tr>
<td>Completed college</td>
<td>37.4%</td>
<td>46.2%</td>
<td>43.5%</td>
<td></td>
</tr>
<tr>
<td><strong>Impact on Family Scale (IFS) Score‡</strong></td>
<td></td>
<td></td>
<td>&lt; 0.0001</td>
<td></td>
</tr>
<tr>
<td>Mean ± standard deviation</td>
<td>35.9 ± 11.4</td>
<td>32.2 ± 10.2</td>
<td>32.8 ± 10.5</td>
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</tr>
<tr>
<td>Range</td>
<td>19 to 73</td>
<td>19 to 73</td>
<td>19 to 73</td>
<td></td>
</tr>
</tbody>
</table>

**Source:** United States Census Bureau, 2003.

*Unadjusted p-value for homogeneity among groups.
†If two-parent household, parent with highest education level was used.
‡Impact on Family Scale, which is completed by the parent, is a measure of family quality of life related to the child’s illness. The total score ranges from 19 to 76, where higher scores indicate a greater impact on the families.
Data were obtained from forms completed by the participants, their parents, and from study coordinators involved in the study. Income and educational data were obtained by self-report from the parents at the start of the trial. The Impact on Family Scale (IFS), a measure of family quality of life related to the child’s illness, was administered to a parent just prior to randomization and completed annually. Most measurements obtained in the study were of the child, but parents also had a role in the study by completing forms, providing insight about the child, and taking care of logistics, such as assisting with diary card completion, mailing, and transportation to clinic visits.

Participants attended three clinic visits per year to monitor their asthma, obtain lung function measurements, and complete interim reviews. They were instructed to contact their center study coordinator between clinic visits if there were any difficulties with their asthma. Participants and parents helping younger children were also asked to complete daily diary cards that recorded daily morning and evening peak flows, awakening at night by asthma symptoms, use of study and rescue medications, absence from school due to asthma, contacting the physician for asthma symptoms, and severity of symptoms. Participants and their parents were given stamped return envelopes to use for mailing diaries to the clinics between visits.

Coordinators provided information regarding family status (single-parent or two-parent) at the beginning of the study and at the conclusion of CAMP. The study coordinators characterized the frequency with which patients had rescheduled their visits, categorizing each patient as someone who frequently or chronically rescheduled visits (5 to 7 times), occasionally rescheduled visits (3 to 5 times), or rarely/never rescheduled visits (0 to 2 times). If no visits were missed, participants should have completed a minimum of 14 and a maximum of 18 clinic visits depending on date of randomization into the study. The coordinators would typically schedule a visit early in the allotted visit time window to allow as much time as possible for the visit to be completed in case of rescheduling. A visit was considered missed if none of the study data for that visit were completed. Adherence was defined as percentage of daily diary cards filled out and the number of missed or rescheduled clinic visits in the CAMP study. Diary card non-adherence was defined as less than 75% of diary days not completed. If at least one item for the day was filled out, the diary was considered completed for that day.

Statistical Methods

Logistic regression and ordinal logistic regression analyses were used to evaluate the association between family status and the three measures of non-adherence: 1) percent of diary cards with any data, 2) missed clinic visits (at least 1 missed versus none), and 3) a tendency to reschedule clinic visits – frequently, occasionally, or rarely/never. These models were used to calculate the adjusted relative odds (RO) of non-adherence for single-versus two-parent families. All models were adjusted for age at randomization, gender, race, income at randomization, asthma severity at randomization, IFS score at baseline, treatment group, and clinic.

Due to the small number of children missing more than one visit, missed clinic visits were dichotomized into zero missed visits versus one or more missed visits. All analyses were performed with SAS software version 8 (SAS Institute, Inc., Cary, NC).

Results

CAMP study participants ranged in age from 5 to 12 years at the beginning of the study and participated in the study an average of 4.3 years. There were 1041 participants randomized into the study. The study coordinators were unable to characterize the family status for 10 participants, so data from 1031 participants were analyzed. The mean ± standard deviation age of the participants in the study was 8.9 years ± 2.1, with 59.7% males, 68.6% Caucasian, and 31.4% minorities. The breakdown of minorities is 13% African American, 9.5% Hispanic, and 8.9% other. The other category of minorities consisted of Asian, Native American, Native Alaskan, and Native Hawaiian or other Pacific Islander populations. The proportions of participants from single-parent families were more likely to be minority race/ethnicity than participants from two-parent families (p < 0.0001) (see Table 1). Asthma severity was evenly distributed between mild and moderate within the single- and two-parent families. Annual income was categorized as less than $15,000, $15,000 to $29,999, $30,000 to $49,999, and $50,000 or more. As expected by national data, incomes of single-parent families were lower than those of two-parent families (see Table 1) (U.S. Census Bureau, 2003).

On average, 82.1% of diary cards distributed during the course of the trial were completed (see Table 2), and 76.9% of participants were categorized as being adherent with diary card completion. Eighty-two percent of participants did not miss any clinic visits during the trial. Fifty-two percent never or rarely rescheduled, so slightly less than half sometimes or frequently rescheduled visits (see Table 2).

Children from single-parent families had a lower diary card completion rate (72.4% vs. 84.1%, p < 0.0001) and had a greater number of missed visits (0.9 vs. 0.6, p = 0.03). In addition to missed visits, single-parent families were more likely to reschedule visits: 31.6% were categorized as frequently rescheduling visits vs. 20.1% for two-parent families (p = 0.0001) (see Table 2).

Over time, children from both single- and two-parent families became less adherent with completing diary cards, but children from single-parent families had a greater decrease than children from two-parent families (see Table 3). When comparing diary card completion in the first six months of the study to the last six months of study participation, diary card completion rate dropped by 25% among single-parent families vs. 13% among two-parent families. During the last six months of study participation, children from single-parent families completed only 66.4% of diary cards, while children from two-parent families completed 82.4% (p < 0.0001). Ninety-one percent of children from single-parent families had no missed visits in the first six months vs. 90% in the last six months of participation, compared to 95% in the first six months and 91% in the last six months for two-parent families.

Although adherence decreased slightly over the duration of the trial, children from both single- and two-parent families showed a decrease in IFS score, indicating the impact of the children’s asthma was lessening over time (Bender et al., 2000). This was reflected in asthma severity assessed
Table 2. Adherence over Course of Trial

<table>
<thead>
<tr>
<th>Adherence Measure</th>
<th>Single-Parent Family (n = 177)</th>
<th>Two-Parent Family (n = 854)</th>
<th>Total (N = 1031)</th>
<th>p-Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percent of days with diary cards completed†, mean ± SD (range)</td>
<td>72.4 ± 27.3 (1.2 to 99.0)</td>
<td>84.1 ± 22.6 (0.2 to 99.9)</td>
<td>82.1 ± 23.9 (0.2 to 99.9)</td>
<td>&lt; 0.0001</td>
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<tr>
<td>Number of missed visits, mean ± SD (range)</td>
<td>0.9 ± 2.3 (0 to 14)</td>
<td>0.6 ± 2.1 (0 to 14)</td>
<td>0.7 ± 2.1 (0 to 14)</td>
<td>0.03</td>
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<td>Patients with no missed visits – %</td>
<td>76.8%</td>
<td>83.5%</td>
<td>82.4%</td>
<td>0.03</td>
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<td>Tendency to reschedule visits – %</td>
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<td>Frequently rescheduled</td>
<td>31.6%</td>
<td>20.1%</td>
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<td>Sometimes rescheduled</td>
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<td>Rarely/never rescheduled</td>
<td>38.4%</td>
<td>55.1%</td>
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*Unadjusted p-value for homogeneity among groups.
†For diary day to be counted as complete, at least one item on the diary card must have been completed each day.

Table 3. Change in CAMP Participants Over Study Follow-Up Time

<table>
<thead>
<tr>
<th>Change in asthma severity**</th>
<th>Single-Parent Family (n = 177)</th>
<th>Two-Parent Family (n = 854)</th>
<th>p-Value*</th>
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<tbody>
<tr>
<td>Asthma less severe or in remission, compared to baseline</td>
<td>37.3%</td>
<td>39.0%</td>
<td>0.86</td>
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<tr>
<td>Asthma more severe, compared to baseline</td>
<td>11.1%</td>
<td>9.9%</td>
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<tr>
<td>No change in asthma severity</td>
<td>51.6%</td>
<td>51.2%</td>
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<tr>
<td>Change from baseline in IFS score – Mean ± SD***</td>
<td>-5.6 ± 11.7</td>
<td>-4.1 ± 10.6</td>
<td>0.10</td>
</tr>
<tr>
<td>Percent of days with diary cards completed in the first 6 months of CAMP – Mean ± SD</td>
<td>88.7 ± 19.0</td>
<td>94.2 ± 12.7</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Percent of days with diary cards completed in the last 6 months of CAMP – Mean ± SD</td>
<td>66.4 ± 37.3</td>
<td>82.4 ± 27.4</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Percent of patients with no missed visits in the first 6 months of CAMP</td>
<td>91.0%</td>
<td>94.9%</td>
<td>0.04</td>
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<tr>
<td>Percent of patients with no missed visits in the last 6 months of CAMP</td>
<td>89.8%</td>
<td>90.5%</td>
<td>0.78</td>
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</tbody>
</table>

*Unadjusted p-value for homogeneity among groups.
**N = 923 because of missing data or because asthma severity may have been categorized as “other.”
***Impact on Family Scale, which is completed by the parent, is a measure of family quality of life related to the child’s illness. The total score ranges from 19 to 76, where higher scores indicate a greater impact on the family.

during the first six months and last six months of the trial (see Table 3). The results were comparable between single- and two-parent families (p = 0.86). There was no change in asthma severity in 51% of the participants overall. Asthma was less severe or in remission in 37% of single-parent families and 39% in two-parent families. Participants whose asthma became more severe were 11% in single-parent families and almost 10% in two-parent families.

Results from a logistic regression analysis showed that family status was found to be associated with non-adherence, adjusted for age, gender, race, income, asthma severity, IFS score, treatment group, and clinic (see Table 4). Children from single-parent families were more likely to be non-adherent with diary card completion. The adjusted relative odds for diary card non-adherence among children from single-parent families versus those from two-parent families were 1.85 (95% confidence interval, 1.24 to 2.76, p = 0.003). There was no difference in the adjusted relative odds of having a missed visit (p = 0.34), but single-parent families were more likely to reschedule clinic visits than two-parent families. The adjusted relative odds of frequently rescheduling versus occasionally or rarely/never rescheduling were 1.57 for single-parent families compared to two-parent families (95% confidence interval, 1.10 to 2.23, p = 0.01).

Discussion

Adherence in the CAMP trial was very high regardless of family status. Overall, there was 82% compliance in diary cards, and 82% of participants did not miss a visit during the five-year trial. Fifty-two percent of participants infrequently rescheduled a visit.
The percentage of non-adherence among single-parent families was much less than originally hypothesized. The hypothesis formed prior to the data analysis was that there would be a much greater percentage of non-adherence among single-parent families. The U.S. Census Bureau (2003) stated that single-parent families account for 23% of the nation’s families. Because single-parent families are only slightly less adherent than two-parent families as shown by this clinical trial, these families should continue to be included as participants in research studies because they represent approximately one-fourth of families in society.

This diminished adherence of single-parent families could be due to the difficulty of single parents with transportation issues or work situations. Several single parents reported the following reasons they had difficulty attending the scheduled clinic visits: 1) inability to take time off work, 2) babysitting problems for the other children in the home, and 3) time constraints. In general, single-parent families have lower incomes than two-parent families.

During each study visit, participants and families received standardized education regarding their disease, treatment for their disease, and any difficulties participants might have living with their disease. Some participants incorporated their asthma education into science fair projects for school. Education improves the ability to manage the disease and can prevent emergency room visits and hospitalizations (Lara et al., 2002; Wallace, Scott, Klinnert, & Anderson, 2004). Participants often have difficulty understanding the reasons for asthma treatment (Bender, 2002); therefore, educating the participant regarding his or her disease leads to self-management of the disease (Conboy-Ellis, 2006). The CAMP standardized ongoing education program was likely a contributor to overall good adherence in the study (Bender et al., 2003).

A major determinant of adherence is the trust developed between the participant and the health professional (Bender et al., 2003; DiMatteo, 2004). A participant is more willing to complete treatment if he or she believes there is a commitment from the health professional (Jonsson, Lindberg, Oscarson, & Ohn, 2006), feels listened to by the clinician (Bender et al., 2003; Bender, 2005), and receives consistent reinforcement with positive feedback (Strunk et al., 2002). Health care workers must make special efforts to be supportive of their clients (Coleman, Hall-Barrow, Coon, & Stewart, 2003).

Table 4. Association of Parental Status with Noncompliance of Child*

<table>
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<tr>
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<th>Odds Ratio</th>
<th>95% CI</th>
<th>p-Value</th>
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<tr>
<td>Diary Card Non-Compliance**</td>
<td>1.85</td>
<td>1.24 to 2.76</td>
<td>0.003</td>
</tr>
<tr>
<td>Missed visits***</td>
<td>1.25</td>
<td>0.79 to 1.99</td>
<td>0.340</td>
</tr>
<tr>
<td>Rescheduled visits****</td>
<td>1.57</td>
<td>1.10 to 2.23</td>
<td>0.010</td>
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</tbody>
</table>

*Odds ratios, 95% confidence intervals (CIs), and p-values from logistic regression model of noncompliance measures (diary card noncompliance, missed visits, and rescheduled visits on family status at baseline). All models were adjusted for age at randomization, gender, race, income at randomization, asthma severity at randomization, IFS score at randomization, treatment group, and clinic.

**Diary card noncompliance is defined as less than 75% of diary cards not completed.

***Missed visits were categorized as missing one or more visits versus missing zero visits due to the small number of children missing more than one visit.

****Families were categorized as frequently rescheduled visits, occasionally rescheduled, or never/seldom rescheduled. Ordinal logistic regression was used to model the tendency of the family to reschedule clinic visits on family status at baseline.

Implications of Nursing Practice

During the CAMP trial, attempts were made to reduce difficulties families might have in continuing in a long-term trial. These measures were for all families but appeared to be especially valuable for the single-parent families.

The percentage of non-adherence among single-parent families was much less than originally hypothesized. The hypothesis formed prior to the data analysis was that there would be a much greater percentage of non-adherence among single-parent families. The U.S. Census Bureau (2003) stated that single-parent families account for 23% of the nation’s families. Because single-parent families are only slightly less adherent than two-parent families as shown by this clinical trial, these families should continue to be included as participants in research studies because they represent approximately one-fourth of families in society.

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Limitations to this study include the lack of randomization of single-parent and two-parent families. Race/ethnicity, income, education, and Impact on Family scores were different between the family groups. These factors could have contributed to the differences in adherence observed in single-parent vs. two-parent families. Thus, factors that demonstrated statistically significant differences were controlled for in the regression analysis. Further, the study was not designed to determine whether the level of adherence affected patient outcomes; researchers were primarily interested in whether single-parent families should be recruited into clinical trials.
Adherence in Single-Parent Households in a Long-Term Asthma Clinical Trial

children. Participants would be asked periodically what type of items they would like to see in the store. As the study participants matured, the “CAMP store” added gift certificates to stores along with the items available for exchange.

The coordinators at the various centers made an effort to make the CAMP visit a positive experience for participants and their families. They developed a trusting relationship with these families while monitoring participants’ asthma for the length of the trial. This encouraged continued participation from all families.

Many methods used in the clinical trial could be adapted for use in nursing practice. Education was a vital component in the study as it must be for all patients whether seen in hospitals, outpatient clinics, or in research studies. Nursing staff must be supportive of patients, develop a sense of trust, and be willing to answer their questions. Another approach to ensure patient adherence is to follow up with those who have missed appointments and/or rescheduled appointments, and accommodate their needs when possible. These suggestions add minutes to an overloaded schedule but can have an enormous impact on the quality of the patient care.

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Members of the CAMP Research Group Clinical Centers

ASTHMA, Inc, Seattle, WA: Paul Williams, MD (Principal Investigator); Mary V. Lasley, MD (Co-Director); Tamara Chinn, MSN, ARNP (Coordinator). Michele Hinatsu, MSN, ARNP; Clifton T. Furukawa, MD; Leonard C. Altman, MD; Frank S. Virant, MD; Michael S. Kennedy, MD; Jonathan W. Becker, MD; Stephen Tilles, MD; Miranda MacLaren, C. Warren Bierman, MD (1992-1997); Dan Crawford, RN (1996-2002); Thomas DuHamel (1991-2004); Heather Eliassen, BA (1996-1999); Babi Hammond (1996-1999); Dominick A. Minotti, MD (1992-2003); Chris Reagan (1992-2003); Gail Shapiro (1996-2001, Principal Investigator); Marian Sharpe, RN (1992-1994); Ashley Tatum, MD (2004-2007); Grace White (1991-2007); Timothy G. Wighton, PhD (1994-1998).


CAMP Credit Roster (April 2009)

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National Jewish Health, Denver, CO: Stanley Szefler, MD (Director); Harold S. Nelson, MD (Co-Director); Bruce Bender, PhD (Co-Investigator); Ronina Covar, MD (Co-Investigator); Andrew Liu, MD (Co-Investigator); Joseph Spahn, MD (Co-Investigator); D Sundström (Coordinator); Melanie Phillips; Michael P. White; Melanie Gleason, PA-C; Marzena Krawiec, MD; Gary Larsen, MD; Gayle Spears, PA-C. Kristin Breidolf (1997-1999); Jessyca Bridges (1995-1997); Jody Ciacco (1993-1996); Michael Eltz (1994-1995); Jeryl Feeley, MA (Coordinator, 1992-1995); Michael Flynn (1995-1996); Tara Junk-Blanchard (1997-2000); Joseph Hassell (1992-1998); Marcia Hefner (1992-1994); Caroline Hendrickson, RN (1995-1998; Coordinator, 1995-1997); Daniel Hettleman, MA (1995-1996); Charles G. Irvin, PhD (1992-1998); Alan Kamada, PharmD (1994-1997); Sai Nimmagadda, MD (1993-1996); Kendra Sandoval (1995-1997); Jessica Sheridan (1994-1995); Trena Washington (1993-1997); Eric Willcutt, MA (1996-1997). We also thank the pediatric allergy/immunology and pulmonory fellows for their participation (Ivan Cardona, MD; Kirstin Carel, MD; Jayna Doshi, MD; Rich Hendershot, MD; Jeffrey Jacobs, MD; Neal Jain, MD; June-ku Brian Kang, MD; Tracy Kruzik, MD; Harvey Leo, MD; Beth Macomber, MD; Jonathan Malka, MD; Chris Mjaanes, MD; John Prpich, MD; Lora Stewart, MD; Ben Song, MD; Grace Tamesis, MD).

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References
Bender, B. (2002). Overcoming barriers to non-adherence in asthma treatment. Journal of Allergy and Clinical Immunology, 109(6, Suppl.), S554-S559.

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Additional Readings


### Research Article Review Form
Bernice D. Mowery, PhD, PNP, RN

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