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Title: Preliminary Efficacy of a School-based Academic and Counseling Program for Older School-age Students, Staying Healthy-Asthma Responsible & Prepared

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Corresponding Author: Dr. Eileen Kae Kintner, Ph.D., R.N.

Corresponding Author's Institution: The University of Texas at Austin

First Author: Eileen Kae Kintner, Ph.D., R.N.

Order of Authors: Eileen Kae Kintner, Ph.D., R.N.; Alla Sikorskii, Ph.D

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Abstract: Background: Up to 17% of U.S. children have been diagnosed with asthma, with ages 9-14 years experiencing higher morbidity and mortality compared to other age groups. An academic and counseling program for older elementary students with asthma was developed in collaboration with school personnel, healthcare professionals, and community members: Staying Healthy-Asthma Responsible & Prepared (SHARP). The Lifespan Development perspective and Acceptance of Asthma Model guided development and implementation.
Objectives: To establish the preliminary efficacy of SHARP to improve cognitive, behavioral, psychosocial, and quality of life outcomes.
Method: A 2-group, longitudinal, prospective, cluster randomized clinical trial design was used. The sample of grade 4-6 students ($N = 66$) with asthma aged 9-12 years ($M = 10.5$, $SD = .9$) had 52% males, a diverse racial background (30% Black, 36% White, and 18% Bi-racial), and wide range of incomes. Three schools ($n = 38$ students) were randomized to receive SHARP, and 2 schools ($n = 28$ students) were assigned to usual care. Self-report instruments were used.
Results: Compared to the usual care group, statistically significant improvements in the SHARP group were found in student knowledge of asthma, reasoning about asthma, use of risk reduction behaviors, and participation in life activities, ($p < .01$, effect sizes > .7). Improvements in use of episode management behaviors and acceptance of asthma outcomes were clinically significant with medium effect sizes of .3-.5.
Discussion: The National Asthma Guidelines recommend expanding education beyond health clinics to school settings. Preliminary evidence of efficacy of a school-based intervention was obtained. Studies with larger and more diverse samples are needed to establish efficacy.

January 27, 2009

Molly Dougherty, Ph.D., R.N., F.A.A.N.
Professor and Editor
The University of North Carolina at Chapel Hill
School of Nursing
Carrington Hall, CB #7460
Chapel Hill, NC 27599-7460

Dear Dr. Dougherty,

Thank you for encouraging submission of this original research manuscript to *Nursing Research*.

1. Statement of Authorship: The authors certify that the manuscript represents valid work and that neither this manuscript nor one with substantially similar content under our authorship has been published or is being considered for publication elsewhere.

2. Notification of Conflicts of Interest: The authors declare that no conflicts of interest exist based on federal regulations.

3. Ethical Adherence: The protection of human subjects' approval was obtained through the University Institutional Review Board. The study was in compliance with the Helsinki Declaration and Health Insurance Portability and Accountability Act requirements.

If you have any questions, please do not hesitate to contact me through The University of Texas at Austin School of Nursing at 512-471-2847 or ekintner@mail.nur.utexas.edu . I shall be waiting to hear from you.

Sincerely,

Eileen Kae Kintner, Ph.D., R.N.
Associate Professor

***Title Page & Acknowledgements**

Preliminary Efficacy of a School-based Academic and Counseling Program

for Older School-age Students, *Staying Healthy-Asthma Responsible & Prepared*

Submitted by:

First Author is Corresponding Author:

Eileen K Kintner. Ph.D., R.N.
Associate Professor
The University of Texas at Austin School of Nursing
1700 Red River Street
NUR 4.132
Austin, Texas 78701-1499 USA
Office: 512-471-2847
FAX: 512-475-8755
Email: ekintner@mail.nur.utexas.edu

Alla Sikorskii, Ph.D.
Assistant Professor
Michigan State University Department of Statistics & Probability
East Lansing, MI 48824

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National Institutes of Health
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*Manuscript (Including Abstract, References and Figure Legends)

Abstract

Background: Up to 17% of U.S. children have been diagnosed with asthma, with ages 9-14 years experiencing higher morbidity and mortality compared to other age groups. An academic and counseling program for older elementary students with asthma was developed in collaboration with school personnel, healthcare professionals, and community members: Staying Healthy-Asthma Responsible & Prepared (SHARP). The Lifespan Development perspective and Acceptance of Asthma Model guided development and implementation.

Objectives: To establish the preliminary efficacy of SHARP to improve cognitive, behavioral, psychosocial, and quality of life outcomes.

Method: A 2-group, longitudinal, prospective, cluster randomized clinical trial design was used. The sample of grade 4-6 students ($N = 66$) with asthma aged 9-12 years ($M = 10.5$, $SD = .9$) had 52% males, a diverse racial background (30% Black, 36% White, and 18% Bi-racial), and wide range of incomes. Three schools ($n = 38$ students) were randomized to receive SHARP, and 2 schools ($n = 28$ students) were assigned to usual care. Self-report instruments were used.

Results: Compared to the usual care group, statistically significant improvements in the SHARP group were found in student knowledge of asthma, reasoning about asthma, use of risk reduction behaviors, and participation in life activities, ($p < .01$, effect sizes $> .7$). Improvements in use of episode management behaviors and acceptance of asthma outcomes were clinically significant with medium effect sizes of .3-.5.

Discussion: The National Asthma Guidelines recommend expanding education beyond health clinics to school settings. Preliminary evidence of efficacy of a school-based intervention was obtained. Studies with larger and more diverse samples are needed to establish efficacy.

Nine million (12%) U.S. children less than age 18 years have been diagnosed with asthma at some point in their lives, and approximately 4.5 million (6%) children have had an asthma episode in the last 12 months (L. Akinbami, 2006; L. J. Akinbami, 2007; American Lung Association, 2004; Dey, 2004; Mannino, 2002; Michigan Department of Community Health, 2004). Children with asthma are admitted to hospitals in life-threatening situations (L. J. Akinbami, 2007; Mannino, 2002), restricted from participating in normal life activities (Hallstrand, Curtis, Aitken, & Sullivan, 2003; Janson & Reed, 2000; Riccioni et al., 2003; Strunk, Sternberg, Bacharier, & Szefler, 2002), and absent from school more than their peers (American Academy of Allergy, 2004). Children ages 9-14 years experience increased morbidity and mortality compared to all other age groups (L. J. Akinbami, 2007; Mannino, 2002). While some healthcare professionals commonly assume that older school-age children are unable or unwilling to accept responsibility for managing their asthma, most healthcare providers realize that asthma is multi-factorial and that there are patient, family, healthcare system, and biological factors that affect how well asthma is controlled. The National Asthma Education and Prevention Guidelines specify that part of a successful management program includes educating children with asthma and their caregivers about the condition. The updated Guidelines released August 2007 (National Institutes of Health, 2007) recommend expanding education beyond health offices and clinics to schools and community settings. Yet, schools are reluctant to adopt programs that are not academically-focused in the era of “No Child Left Behind” (U.S. Department of Education, 2002)

School-based programs are needed that address the multiple factors affecting outcomes for older school-age children with asthma, hereafter referred to as students, in ways that are

developmentally appropriate for this age group and that integrate into schools in such a way that they are likely to be embraced by schools pressured to demonstrate academic outcomes. “Staying Healthy–Asthma Responsible & Prepared” (SHARP) was designed to address this gap. SHARP was developed in collaboration with school personnel and members of a community asthma coalition to foster acceptance of asthma by addressing cognitive, behavioral, and psychosocial aspects of asthma management that impact quality of life outcomes.

The purpose of this study was to evaluate the preliminary efficacy of SHARP. Compared to the usual care control group, students who received SHARP were projected to demonstrate increased knowledge of asthma (cognitive), logical reasoning abilities for managing acute episodes of symptom exacerbation (cognitive), use of effective episode management and risk reduction asthma health behaviors (behavior), acceptance of asthma as a chronic condition (psychosocial), and participation in life activities (quality of life). The theory-driven and evidenced-guided SHARP was designed from a lifespan development perspective as a developmentally-appropriate academic and counseling program for students on growth trajectories for shifting away from parental to more personal responsibility for managing their condition as they move from elementary to middle or junior high school.

SHARP has two components: a Student Component and a Community Component. For the Student Component, students with asthma met for 50-minute sessions once a week for 10 weeks during school hours. Caregivers, family members, friends, neighbors, schoolteachers, and club/sports leaders were invited by students to participate in one of three programs of the Community Component that occurred during the early weekday hours or on the weekend.

Theoretical Framework

A lifespan development perspective (Baltes, Reese, & Lipsitt, 1980; Hultsch & Deutsch, 1981; Lerner, 1986; Reigel, 1976; Sugarman, 1986; Werner & Kaplan, 1956) guided this study and served as the framework for development of the Acceptance of Asthma Model (Kintner, 1996, 1997, 2004, 2007). Cognitive, behavioral, and psychosocial needs of students with asthma are addressed to foster acceptance of asthma by increasing long-term responsibility for maintaining and promoting health, and preventing complications.

Lifespan development is an orientation, providing conceptual and methodological framing for the study of human behavioral development and change processes. Influenced by a wide range of factors both inside and outside the person (Lerner, 1986), development is viewed as a lifelong process, embedded within a historical and cultural context that can take multiple directions (Baltes et al., 1980). Change is believed to proceed toward increasing complexity, differentiation, and specialization while increasing in hierarchical integration and organization (Werner & Kaplan, 1956). Interactions between individual, environment, and hereditary factors influence the process (Reigel, 1976). Conflicts between the factors provide energy for change and are subject to interventions aimed at enhancing, promoting, and facilitating healthy development (Sugarman, 1986). Anticipatory guidance is viewed as the key to effective intervention. Interventions are selected from an array of possibilities including education programs, counseling sessions, and use of supportive networks (Sugarman, 1986).

Fifth-grade students, ages 9-12 years, are entering puberty and transitioning from elementary to middle or junior high schools in the grades 6-7. Developmental goals for the age group include progression toward acceptance of one's body, achievement of formal operational thought, formation of a sense of identity, independence, attainment of a workable belief system, and establishment of mutually giving relationships (Erikson, 1963; Jolley & Mitchell, 1996;

Montemayor, Adams, & Gullotta, 1990; Piaget, 1952). As individual responsibilities become more apparent (Jolley & Mitchell, 1996; Montemayor et al., 1990) asthma management is affected. Following students as they transition from elementary to middle school is a central feature of this program of research.

The Acceptance of Asthma Model was developed within the lifespan development perspective through a series of qualitative and quantitative studies. The model depicts the multi-dimensional process of how students develop to accept asthma as a chronic condition (Kintner, 1996, 1997, 2004, 2007). Acceptance is a process that is iterative for each developmental phase. The process begins with initial awareness of symptoms and interaction with healthcare professionals that leads to symptom acknowledgment through a diagnosis and prescription for treatment. Students seek information about the diagnosis from a variety of sources including caregivers to gain asthma knowledge. As students develop decision-making and reasoning abilities, they begin to explore options and choices, as well as cause and effect relationships. Reasoning about asthma leads to drawing conclusions about the condition that resolves their inner turmoil of negative emotions, along with the formation of beliefs about asthma for coming to terms with their condition. Two components of acceptance are the focus of this study: Taking control and Vigilance. Acceptance of asthma and use of effective asthma risk reduction, and episode management behaviors effect one’s participation in life activities. Individual, condition, and environmental factors influence students as they move though the process. Table 1 contains constructs, concepts, definitions, their components, and instruments used to operationalize them.

Method

A two-group, longitudinal, prospective, cluster randomized clinical trial was used to evaluate preliminary efficacy of the SHARP program. The protection of human subjects'

approval was obtained through the University Institutional Review Board. The study was in compliance with the Helsinki Declaration and Health Insurance Portability and Accountability Act requirements.

Eligibility Inclusion Criteria

Student eligibility criteria included (a) a diagnosis of asthma, (b) availability to participate in scheduled classes or make-up sessions, and (c) verbal and written assent to participate. Student exclusion criteria included student's expressed unwillingness to participate or lack of consent from parent/legal guardian. Family caregiver eligibility criteria included (a) being a designated caregiver of a student with asthma, (b) ability to understand English, and (c) expressed availability to attend and participate in the community component. Exclusion criteria included expressed unwillingness to participate or lack of consent.

Accrual

Notification letters and recruitment brochures prepared by the research team were mailed from the school district to family caregivers of all 4-5th grade students enrolled in a south-central Michigan school district alerting all families in the spring of the SHARP program to become available in the fall. Recruitment letters with colorful brochures, response forms, and postage prepaid envelopes were mailed to caregivers of all 4-6th grade students in September inviting participation. Families interested in learning about the study were directed to contact the project director. The racially and economically diverse county ranked third in the state for highest incidence of asthma with estimates of 10-16% of the students diagnosed.

Two weeks after the recruitment letters were mailed in the fall, school nurses serving as trained recruiters, with their time reimbursed through grant funds, began making follow-up telephone calls to caregivers of students known to the school to be diagnosed with asthma

1 inviting participation. In compliance with protection of human subjects' and HIPAA regulations,
2 the research team did not have access to students' health or school records. However, as required
3 by the State Inhaler Law (Michigan, 2004), school nurses did have information about students
4 approved to carry emergency medication. Only information of families that were eligible,
5 expressed interest, and agreed to be contacted were provided to the research team.
6 With family contact information, the project director established relationships and
7 scheduled appointments for enrollment and data collection at a time and location convenient for
8 the student and parent dyads and evaluator pairs. Informed written consent was obtained from a
9 parent or legal guardian and assent from the student by pairs of trained evaluators prior to data
10 collection. Period of recruitment including pre-intervention data collection extended from
11 September through December 2006 and follow-up extended from April through June 2007.
12 *Randomization*
13 Because there is much interaction between students within a given school, subjects were
14 randomized by school (rather than each student or each classroom) to avoid contamination
15 within a particular school. Recruiters and evaluators were blinded to randomization status during
16 pre-intervention (Time 1) data collection. Randomization was computer generated following
17 Time 1 data collection. Three elementary schools were randomly allocated to the treatment
18 group, and two elementary-schools were assigned to the control group. Students assigned to the
19 treatment group received the 10-week Student Component and their caregivers were delivered
20 the Community Component. Students assigned to the control group received usual health care.
21 Interveners and participants were not blinded to randomization after schools were
22 designated to treatment and control groups. Evaluators were instructed not to assume or ask
23 randomization status of participants. Participants were requested not to disclose randomization

status to evaluators. School of choice offered additional blinding of evaluators in that evaluators could not assume randomization based on the participants' home street addresses.

Power

Because of the exploratory nature of the study, the sample size was not based on pre-determined effect sizes since no estimates of the effect size were available prior to the preliminary testing of this innovative intervention program. The sample size was determined based on feasibility considerations, i.e. the number of schools within a school district where SHARP program can be implemented within the study time frame.

Procedures

Students enrolled in elementary schools assigned to SHARP received the Student Component, and their caregivers participated in the Community Component.

Student School Component. At the elementary level, content is taught using integrated modules. SHARP integrated into the schools a teaching module. Students met for 50-minute sessions delivered once a week for 10 weeks from January through March. Students worked though the 100-page SHARP Workbook, that was designed to be colorful, entertaining, educational, and developmentally appropriate, as well as gender, racially, and culturally diverse. The program incorporated its components into the existing curriculum as an elective course by including spelling words, math problems, reading and writing assignments, discussions and demonstrations, and hands-on learning activities from biology, psychology, and sociology. Students were offered a personal choice to accept responsibility for management of their asthma early in the program, and were then provided guidance to reach their goals.

Caregiver Community Component. To support SHARP students; caregivers and others participated in a 3-hour information sharing program. Students offered personalized invitations

to close friends, neighbors, schoolteachers, and club/sport leaders who defined their social networks. Display tables with asthma-related handouts, pamphlets, and products, staffed by asthma coalition members placed in a location designated by the area coalition in the hospital auditorium were arranged similar to an asthma health fair. As families arrived, attendance was recorded and participants were encouraged to visit the displays.

The intervener and a coalition representative presented content interspersed with discussion, and question and answer sessions directed toward increasing asthma knowledge, logical reasoning abilities for managing acute episodes, use of effective asthma health behaviors, and acceptance of asthma, as well as providing an overview of coalition activities. Presentation time was limited to 90 minutes. Handouts of the content were provided.

Measures

Self-report measures were used. Age-appropriateness, reliability, validity, and readability were considered in the selection of instruments. Instruments, item numbers, sample size, standardized alpha reliability for internal consistency, potential and actual score ranges with means and standard deviation scores for this sample at baseline are presented in Table 2.

Knowledge of Asthma Survey. Students and caregivers complete this 18-item matching/ multiple-choice quiz measuring level of asthma knowledge (Kintner, 1996). Items contain information reflective of 6 objectives related to the naming the respiratory system, describing pathology, distinguishing symptoms, discussing stimuli, contrasting medications, and assessing use of management techniques. The first matching item requests anatomical parts to be named. A composite score was computed for the matching section by dividing the correct number of identified body parts by 3. Items 2-18 are multiple-choice. The composite matching score and multiple-choice score were summed. Concurrent validity was supported when scores yielded

1 significant and strong correlations between (a) caregiver and student scores, (b) students' scores
2 and reasoning abilities, and (c) students' scores and participation in education programs.
3 *Reasoning about Asthma Scenarios*. Completed by students, this is a 4-scenario, process-
4 learning instrument measuring how students use knowledge and experience to make decisions,
5 solve problems, and draw conclusions related to management of their condition (Kintner, 2007).
6 The instrument contains 7 items for each scenario addressing: symptom recognition, severity
7 classification, stimuli identification, helper selection, medication consideration, management
8 technique usage, and summary of experiential learning. Mean scores were computed for each
9 item and scenario on a 3-point scale ranging from 0 (less logical reasoning) to 1 (more) and 2
10 (most) before computing a grand mean for overall reasoning ability. With appropriate factor
11 loadings, the items accounted for 62% of the variance explained.
12 *Asthma Health Behaviors Survey.* Completed by caregivers as an objective measure of
13 use of asthma health behaviors, this is a 30-item, 5-point Likert-type instrument (Kintner, 2007).
14 Two subscales were used: Use of episode management (6 items) and risk reduction (6 items)
15 behaviors. With appropriate factor loadings the items accounted for 52% and 69% of the
16 variance explained, respectively. Mean scores were computed.
17 *Acceptance of Asthma Questionnaire*. Completed by students, this is a two-part, 5-point
18 Likert-type questionnaire measuring aspects of an individual's level of acceptance of asthma
19 (Kintner, 2007). Two scales were used: taking control (6 items) and vigilance (6 items). With
20 clean factor loadings the items accounted for 51% and 48% of the variance explained,
21 respectively. Mean scores were computed for both.
22 *Participation in Life Activities*. Completed by students, this questionnaire contains 15
23 yes/no questions that are summarized into three items designed to measure planning for,

interference with, and prevention from participation in chosen life activities (Kintner, 2008; Kintner & Sikorskii, 2008). Subjects are asked to list 5 of their favorite activities then answer 3 questions about each. Three measurement items, summarizing five favorite activities, seek information on whether or not a) subjects need to think about their asthma when planning for activities, b) asthma interferes with participating in the activity, and c) asthma prevents them from participating in the activity. Items reflect the level of restriction believed to motivate behavioral changes in management. Scoring is summative across 3 items. Higher scores are reflective of increased participation. With appropriate factor loadings, the items accounted for 66% of the variance explained.

General Health History Survey including the *Nam-Powers SES Index Scores* (Nam & Powers, 1983). Completed by caregivers, this is a 36-item survey developed for collecting demographic data (sex, age, grade in school, race/ethnicity, family structure, and SES) and asthma-related information (age at onset of symptoms and diagnosis, and prescribed medications) (Kintner, 1996). Nam-Powers Socioeconomic Index Scores (Nam & Powers, 1983) use 3 items to average parents' occupation and education, and family income scores. The SEIS has demonstrated high degrees of stability with correlation coefficients of .97 over 10 years and .91 over 20 years (Miller, 1991).

Severity of Illness Rating Scheme. Completed by caregivers, this is a 4-item instrument measuring asthma severity (Kieckhefer, 1987) that taps both pathophysiological aspects and responses to the condition. Concurrent validity was supported when scores yielded significant correlations with parents' perceptions of their children's health status, school attendance records, and numbers of acute visits and hospitalizations.

Data Collection

The FileMaker Pro® database system was used to enter and manage the data. Audio-linked, self-report surveys were loaded on password-protected laptop computers for data entry. The system included quality control methods that restricted field ranges and values, provided internal consistency checks, prevented entry of erroneous data, and tracked missing data. Following informed written consent and assent, pre-program (Time 1) data were collected by pairs of trained evaluators in the home from students with asthma and their family caregivers using data entry systems loaded on laptop computers. Time 2 data were collected immediately post-intervention. Data were encrypted and electronically transferred to a password and firewall protected, secure computer at the primary site by project director as soon as possible after each data collection session. Raw data were downloaded into SAS (SAS, 2002-2003) for processing and analysis.

The majority of caregivers (75%) completed surveys in less than 65 minutes (range 25-120 min.), and students (75%) completed surveys in less than 90 minutes (range 40-150 min. with a break). Virtually no missing data were present in completed surveys. Students and caregivers were each offered monetary awards of $15 at each data collection point for their time. Students and caregivers who participated in both collection points were awarded a total of $30 each or $60 per dyad.

Data Analysis

SAS 9.1 (SAS, 2002-2003) was used for systematic analysis of the data to establish preliminary efficacy of SHARP. Descriptive statistics were computed for all variables to ensure data quality and to evaluate the assumptions of statistical tests. Psychometric properties of all instruments for each cohort were evaluated beginning immediately following pre-program (Time 1) data collection. Specifically, internal consistency reliability was assessed using Cronbach's

alpha or Kuder-Richardson-20. Frequencies, means, and standard deviations were computed for demographic and asthma-specific variables.

Intent to treat approach was adopted for analysis: all participants were analyzed as randomized regardless of their adherence to the intervention protocol. Following randomization, differences between treatment and control groups' demographic characteristics at baseline were examined. Characteristics of those who dropped out of the study between time 1 and time 2 were compared to those who completed the study. Since there were no drop-outs in the control group, and only 4 drop-outs in the experimental group, attrition analysis by study group was not performed. Analysis of the effect of the intervention was performed using a statistical model that included the outcome at baseline as a covariate, and the study group variable. School was included as a random effect to account for student clustering. Inclusion of the outcome at baseline as a covariate controlled for the differences between groups at baseline, and increased power compared to unadjusted analysis since outcomes at baseline and post-intervention were correlated. Adjusted means and their standard errors were calculated by study group and differences between them were tested. Since the study was exploratory, in addition to formal tests of significance, estimates of the effect sizes (ES), using adjusted means and baseline standard deviation of the outcomes were also calculated.

*Threats to Validity***.** Model assumptions were also tested to assure validity including assessment of reliability and validity of all instruments for this sample. No adverse events were identified for participants randomized to the intervention or control groups.

Results

The convenience sample consisted of students ($N = 66$), ages 9 to 12 years ($M = 10.5$, $SD = .92$), and their family caregivers. Flows of student and caregiver participants through each

stage of the study are reported in Figures 1 and 2, respectively. Of the 66 students enrolled, 38 students were allocated to the treatment intervention and 28 to usual care control groups. Regardless of adherence to the intervention protocol, all students and caregivers allocated to the treatment group received copies of the Student Component Workbook and Community Component Handout. Baseline demographic and asthma-specific characteristics of each group are presented in Table 3.

Demographic characteristics of the students and caregivers assigned to the intervention group that did not participate in the treatment, did not significantly differ from those who participated. Baseline characteristics of those who dropped out from the intervention group did not differ from those who completed post-intervention assessment. However, due to the small number of schools ($N = 5$) that were randomized to the intervention and control groups, treatment and usual care groups were not equivalent at baseline on socioeconomic status and baseline assessment of outcome measures. See Tables 3 and 4. This baseline group imbalance was addressed by adjusting for baseline values of outcomes in the analyses. Over and above baseline values of the outcomes, socio-demographic characteristics had no significant effect on the outcomes post-intervention, and were not included in the final statistical models. Estimates of adjusted means and effect sizes for treatment and control groups' post-intervention outcomes are provided in Table 4.

Where effect sizes are large (ES > .7) (Cohen, 1988) for asthma knowledge, reasoning about asthma, risk reduction behaviors, and participation in life activities, results were statistically significant. The outcomes of episode management behaviors, taking control, and vigilance were better in the treatment group compared to control with the effect sizes ranging from 0.32 to 0.47. Since the goals of this exploratory study were to establish feasibility and

1 obtain preliminary evidence of efficacy, the study was not powered to detect these effect sizes as
2 statistically significant. The ES above .3 or improvements above 30% are considered clinically
3 significant (Guyatt, 2002; McQuay, 2003).

4 ## Discussion

5 Evaluation of SHARP Student and Community Components confirms preliminary
6 efficacy with large effect sizes for statistically significant asthma knowledge, reasoning about
7 asthma, use of risk reduction behaviors, and participation in life activities; and medium effect
8 sizes for clinically significant use of episode management behaviors, and acceptance of asthma
9 in taking control and vigilance. A larger sample size than was used in this pilot study is needed
10 to reach statistical significance where observed effect sizes were medium. Clinical significance
11 in scores with improvements above 30% warrants further testing with larger sample sizes.

12 The theory-guided and evidence-based SHARP program offers education to improve
13 student and caregiver asthma knowledge, reasoning about management of acute episodes, and
14 use of effective health behaviors; and provides health counseling to improve acceptance of
15 asthma in taking control and vigilance to ultimately impact overall quality of life reflected in
16 unrestricted participation in life activities. More research is needed to assess the impact of
17 SHARP on lessening condition severity, use of healthcare services, and school or work
18 absenteeism due to asthma symptoms.

19 We acknowledge that all outcomes were derived from self-report of individuals
20 participating in the intervention. Self-report measures have been found to contain inherent
21 limitations including distortion in recall, lack of objectivity, and social desirability. However,
22 self-report measures capture personal dynamics, convey perceptions of experiences, have value,
23 and are of interest to health researchers. Additionally, by definition, symptoms and quality of life

ratings come from person's perspective thus making self-report the only appropriate way to measure these outcomes. In completion of instruments, participants were assured responses are not right or wrong.

We caution generalizing findings from this situation to larger populations due to a limited sample drawn from one moderate size Midwest community. Larger sample sizes drawn from more diverse communities are needed to fully evaluate the efficacy and effect of the program. To reach Hispanic or Latino populations, SHARP and measures used to evaluate the program should be translated into colloquial Spanish.

Once efficacy is demonstrated, community members and school personnel working together to support the developmental needs of older school-age students and their caregivers as the students transition from elementary into middle or junior high school will have a program that is not currently available. Innovative features of the Student Component support rapid adoption by school systems and key features of the Community Component support adoption by coalitions that are searching for best methods to increase public awareness and knowledge in order to address prevalence and decrease morbidity and mortality.

In summary, the National Asthma Education and Prevention Guidelines (National Institutes of Health, 2007) recommend expanding education and counseling programs beyond health offices and clinics to schools and community settings. SHARP was designed to address cognitive, behavioral, and psychosocial aspects of asthma management affecting quality of life outcomes for older school-age students with asthma in ways that are developmentally appropriate for this age group and that integrate into schools in such a way that it will more likely to be embraced by schools pressured to demonstrate academic outcomes. SHARP Student and Community Components demonstrate preliminary efficacy for improving asthma

1 knowledge, reasoning about asthma, use of episode management and risk reduction behaviors,

2 acceptance of asthma in taking control and vigilance, and participation in life activities.

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Figure Caption

Figure 1. The CONSORT E-Flowchart for student participants.

Figure Caption

Figure 2. The CONSORT E-Flowchart for caregiver participants.

Table 1

Table 1

The constructs, concepts, definitions, their components, and instruments used to operationalize them.

Constructs/Concepts	Definitions	Components	Instruments
Cognitive Student Asthma Knowledge	Information pertinent to the chronic condition gained either through study or experience (Kintner, 1996, 1997, 2004, 2007).	Anatomy, Pathophysiology, Symptoms, Stimuli, Treatments & Management	Knowledge of Asthma Survey
Cognitive Student Reasoning about Asthma	Process of reflective, introspective thinking through which situations are examined and options are considered (Kintner, 1996, 1997, 2004, 2007).	Simple, Complex, Familiar & Unfamiliar Reasoning	Reasoning About Asthma Scenarios
Psychosocial Acceptance of Asthma	Desiring to take possession of one's chronic condition versus resignation or expressed reluctance to take possession (Kintner, 1996, 1997, 2004, 2007).	Vigilance & Taking Control	Acceptance of Asthma Questionnaire
Behavior Asthma Health Behaviors	Risk reducing, episode managing, and health promoting activities influential in effectively controlling one's chronic condition (Kintner, 2007).	Risk Reduction Behaviors & Episode Management Behaviors	Asthma Health Behavior Survey
Quality of Life Participation in Life Activities	Unrestricted involvement in chosen pursuits, such as sports, clubs, interests, and hobbies (Kintner, 1996, 1997, 2004, 2007).	Planning for, Interference with & Restriction from participation	Participation in Life Activities Scale (Kintner, 2008; Kintner & Sikorskii, 2008)

Table 2

Table 2

Summaries of the instruments including number of items, standardized alphas, potential score ranges, and actual score ranges with means and standard deviations for this sample (N=65) [a] *at baseline.*

Instruments/Subscales	Completed by	No. of Items	Alpha (*n*)	Potential Score Range	Actual Score Range	*M*(*SD*)
Knowledge of Asthma	Student	18	.70 (*65*)	0-20	2.90-12.8	7.63 (2.27)
Reasoning about Asthma	Student	4	.74 (*61*)	0-2	0.61-1.71	1.19 (0.22)
Asthma Health Behaviors -						
Episode Management	Caregiver	6	.77 (*66*)	0-4	0.00-3.67	1.29 (0.70)
Risk Reduction	Caregiver	6	.74 (*66*)	0-4	0.00-4.00	1.69 (.91)
Acceptance of Asthma-						
Taking Control	Student	6	.61 (*65*)	1-5	1.00-5.00	3.57 (.65)
Vigilance	Student	6	.69 (65)	1-5	1.82-4.91	3.54 (.61)
Participation in Life Activities	Student	3	.74 (*63*)	0-3	0-3	1.83(.77)

[a]Student with cognitive processing challenges omitted

Table 3

Table 3

Demographic and clinical characteristics of control and treatment groups at baseline.

Demographic Characteristic	Usual Care Control Group (N = 27)[a]		SHARP Intervention Group (N = 38)	
	n	%	*n*	(%)
Sex/Gender				
Male	11	40.7	22	57.9
Female	16	59.3	16	42.1
Grade				
4th grade	5	18.5	11	28.9
5th grade	12	44.4	11	28.9
6th grade	10	37.0	16	42.1
Race/Ethnic Grouping				
Black/African American	13	48.1	8	21.1
White/Caucasian American	10	37.0	15	39.5
Hispanic/Latino/Mexican American	0	0	2	5.3
Bi-racial (Black and White)	3	11.1	7	18.4
Other [b]	1	3.7	6	15.8
	Range	*M (SD)*	Range	*M (SD)*
Age	9-12	10.6 (0.89)	9-12	10.5 (0.95)
Nam-Powers Socioeconomic Scores*	19-95	64.0 (26.1)	16-93	48.5 (16.4)
Severity of Illness Rating Scheme	4-10	5.93 (1.54)	4-10	5.84 (1.88)

[a]Student with cognitive processing challenges omitted
[b]Native American (n = 1), Pacific Islander (n = 1), listed Other (n = 2), not reported (n = 2)
*t-test = 2.73, p = .009 for NP-SES (equal variances were not assumed)

Table 4

Table 4

Unadjusted and adjusted means of outcome variables by group.

Outcome Variables	Usual Care Control (n=27)		SHARP Intervention (n=34)		Adjusted Means (SE)		*P-*	*Effect*
	Pre	Post	Pre	Post	Control	SHARP	*value*	*size*
	Mean (SD)	*Mean(SD)*	*Mean (SD)*	*Mean (SD)*	Mean (SE)	Mean (SE)		
Student Asthma Knowledge	7.94(2.19)	8.05(2.60)	7.39(2.34)	10.0(3.03)	7.96(0.47)	10.18(.43)	<.01	0.91
Reasoning About Asthma	1.28(0.20)	1.29(0.23)	1.14(0.19)	1.38(0.21)	1.24(0.03)	1.42(0.03)	<.01	1.19
Behaviors: Risk Reduction	1.65(0.75)	1.71(0.64)	1.49(0.87)	2.08(0.76)	1.66(0.09)	2.13(0.08)	<.01	0.98
Behaviors: Episode Mgmt	0.87(0.79)	1.01(0.81)	1.04(0.76)	1.41(0.96)	1.09(0.15)	1.34(0.13)	0.20	0.33
Acceptance: Taking Control	3.76(0.66)	3.71(0.63)	3.43(0.61)	3.85(0.62)	3.61(0.17)	3.88(0.15)	0.26	0.47
Acceptance: Vigilance	3.63 (0.57)	3.69(0.61)	3.45(0.63)	3.76(0.50)	3.61(0.15)	3.77(0.13)	0.42	0.32
Participation in Activities	1.90 (0.77)	1.72(0.71)	1.78(0.77)	2.12(0.65)	1.70(0.11)	2.13(0.10)	<.01	0.72

Figure 1

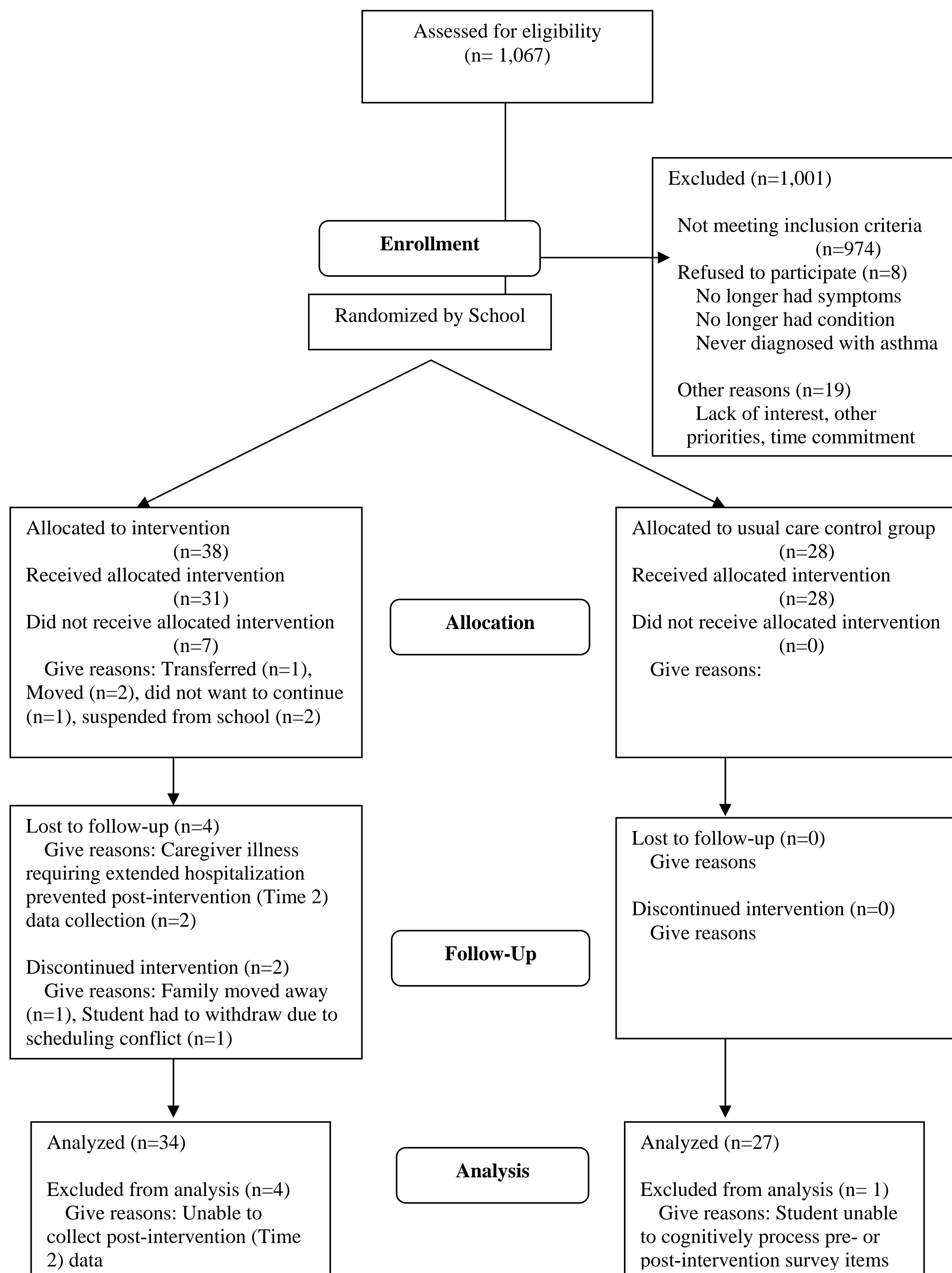

Figure 2