Complementary and Alternative Medicine in Pediatric Rheumatology

A thesis
Submitted by

Caitlin M. Sgarlat, DO

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Adviser: Susan K. Parsons, MD, MRP

Abstract

Background: Complementary and alternative medicine (CAM) is defined as a group of diverse medical health care systems and practices, including natural products, mind-body medicine, manipulative body-based practices, practices of energy therapy, and whole medicinal systems. Studies suggest that CAM therapy in the adult population has increased in recent decades. Information about the extent of CAM usage among children and adolescents with chronic rheumatologic disorders, although anecdotally suspected, is not routinely collected. **Objective:** The purpose of this exploratory study was to solicit information on CAM usage from parents seeking care for their children in a pediatric rheumatology sub-specialty clinic. **Methods:** A previously field-tested survey of CAM usage was adapted for the pediatric rheumatology clinic population. The survey consisted of general demographic questions and specific questions on CAM use. Parents or caregivers of patients followed in the Pediatric Rheumatology Division at an academic medical center were invited to complete the survey during the recruiting period, which extended from June to October 2010. **Results:** 202 of 203 parents invited to participate in the survey completed it with the majority being mothers (88%) and Caucasian (91%) with a mean age of 42 years. Their children were predominantly female (67%) with a mean age 12.8 years. 63% of patients had juvenile idiopathic arthritis, although children with several other chronic conditions were also included. Overall, 50% of patients were CAM users. Of the CAM modalities, 69% of patients reported use of high-dose vitamin, mineral, or supplements. Of the CAM users, 42% had a parent or immediate family member with a history of CAM use, compared with 15% of non-CAM users. 80% of CAM users had a parent with some degree of college education, compared with 67% of non-users. Multivariate logistic regression revealed an adjusted OR of 3.8 (CI 1.8-8.1, p<0.001) for CAM use if a family member had used CAM. **Conclusions:** CAM use was common among patients followed in a pediatric rheumatology clinic (50%). Family use of CAM was strongly associated with patient CAM use. Very little is known about the benefits or potential harms of CAM despite its widespread use. It is important for physicians to understand factors that influence decisions to use CAM in children and what benefits parents seek with CAM use.

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Complementary and Alternative Medicine in Pediatric Rheumatology

Background

Pediatric Rheumatology comprises a broad range of chronic diseases, principally involving the musculoskeletal system. The nature of these diseases affects the emotional, physical, and social status of patients. Anecdotal clinical experience suggests that a substantial proportion of pediatric rheumatology patients use complementary and alternative therapies to treat their underlying diseases.

Complementary and alternative medicine (CAM) is defined by the National Center for Complementary and Alternative Medicine (NCCAM) as a group of diverse medical health care systems and practices that are not considered conventional modalities of medical treatment (1). CAM modalities are often grouped into five broad categories: natural products including high-dose vitamins, minerals and dietary supplementation; mind-body medicine, including yoga, tai chi and acupuncture; manipulative body-based practices, such as chiropractics; practices of various forms of energy therapy, including Reiki and magnet therapy; and whole medicinal systems, such as naturopathy and homeopathy (1).

Several studies have shown that up to one-third of the general healthy adult population use at least one CAM therapy (2, 3). The use of CAM modalities by adult patients has increased by 45% between 1990 and 1997, with further increases between 2002-07 (2, 3). Between 42 and 73% of adults with rheumatologic disorders have reported CAM use (4, 5), rates much higher than the general adult population.

As part of the 2007 National Health Interview Survey reported by NCCAM and the National Center for Health Statistics (NCHS), children were surveyed for CAM use

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with findings of 12% of children using some form of CAM (2). Other studies have shown that CAM use in the general pediatric population ranges between 20 and 40% (6, 7), while between 50-72% of children with chronic diseases (such as asthma and inflammatory bowel disease) use these remedies (8, 9). Only a limited number of studies have addressed CAM use in children with rheumatologic diseases, yielding strikingly different results. In an unpublished survey of CAM use in pediatric rheumatology conducted approximately a decade ago, approximately one quarter of children (22%) was found to be using CAM (Miller, personal communication). In contrast, a 2003 report described CAM use in a similar population at 66% (10). Most of these estimates were derived from parent-reported surveys.

CAM use is not routinely discussed in clinical practice. Clinicians may neglect to specifically inquire about these modalities. Parents and patients may forget to include this information when asked about medication use or may be reluctant to share this information, fearing that the clinicians may not approve. The specific reasons for non-disclosure of CAM use have been poorly studied (11-13).

Our understanding of the factors that influence the decisions to use CAM in chronic diseases is incomplete. Disease duration and side effects of conventional medications (14-19) have been cited as contributing reasons. CAM use in children with chronic conditions has been related to certain parental characteristics, including higher education levels and incomes (2, 20-23), as well as personal and familial use of these remedies (24-27). Details of these reasons have not been studied in a pediatric rheumatologic clinic population. It is important to understand what benefits parents are

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seeking with CAM use. Understanding these factors is important for parent-doctor communication as well as treatment decisions.

Similarly, despite the widespread use of CAM, very little is known about the benefits of the different therapies or the potential harms due to side effects, medication interactions, and altered medication adherence of other prescribed medications in this population (e.g., non-steroidal anti-inflammatory agents, immunosuppressive treatments, and biologic agents).

The increased use of CAM in the general population as well as among patients with chronic diseases raises the question as to whether this trend has also occurred among pediatric rheumatology patients. The characteristics of pediatric rheumatology CAM users and their caregivers are largely unknown, as are the types of CAM being used and factors that influence their use. Therefore, based on emerging evidence of increased use of CAM among patients with chronic diseases, we investigated CAM use in a tertiary pediatric rheumatology clinic (1) to characterize use patterns by CAM modality, (2) to assess factors associated with CAM use, and (3) to describe the prevalence of non-disclosure of CAM use to physicians.

Methods

Study Measure

The study consisted of an anonymous cross-sectional survey. A literature search was done to identify existing survey instruments on the subject of CAM. Several surveys that included CAM use in patients with rheumatologic conditions were identified that contained some of the desired elements such as, specific modalities, disease duration,

and demographics (2, 3, 6, 8, 10, 12, 13), although none of these captured all of the desired elements to address our research questions. Largely missing from other surveys were reasons for CAM use, disclosure to the physician, reasons for non-disclosure, and effect of the CAM therapies in a pediatric population followed in a pediatric rheumatology clinic.

Although no standardized instruments are in widespread use, one survey was identified that captured the desired range of topics. This instrument, entitled the *Pediatric Complementary Therapy Survey,* was originally developed by Fernandez et al. (1998) and subsequently modified by Recklitis et al. (28, 29) for use in a pediatric oncology patient population. While the survey had been reviewed extensively prior to field testing by experts in survey design, patient and family education, and CAM, the psychometric properties of this survey have not been reported. The survey authors were contacted regarding further adaptation and use of the survey, and permission was obtained. This survey was then adapted for a population of patients followed in a pediatric rheumatology clinic to make it disease-specific with regard to diagnoses and specific medications.

The adapted survey consisted of 32 items in two sections (*Appendix i*). The first section consisted of questions on patient and family demographics, while the second section consisted of questions on CAM (sources of information, factors influencing use, benefits, and side effects). Although the survey contained separate items on race and ethnicity, the variables were combined to form a single variable for analytic purposes, using standard categories. CAM use was defined as the current or previous use of listed CAM therapies for the condition which the patient was being followed for in the pediatric

rheumatology clinic. Prior to study administration, the survey was pilot tested in a

pediatric rheumatology clinic population (n=7) to ensure relevance and clarity of the

survey items.

Survey Participants

Patient charts were reviewed one week prior to the scheduled clinic appointment

to determine preliminary eligibility. The inclusion criteria consisted of English-speaking

parents or caregivers of patients aged 3-19 years followed in the Pediatric Rheumatology

Division at the Floating Hospital for Children at Tufts Medical Center for a

rheumatologic disease or condition.

Eligible participants were approached for recruitment and enrolled in the clinic

setting at the time of their child's presentation to the clinic for a scheduled follow-up

appointment. Participants (parents and caregivers of patients) were enrolled in the study

only once, even if the child had more than one visit during the recruiting period, which

extended for a five-month time period from June through October 2010. Once the

surveys were completed by the participants, anonymity was maintained by instructing

participants to not include names or other identifiers on the survey and to return the

survey to the closed receptacle at the clinic desk. This study was approved by the Tufts

University Health Science Campus Investigation Review Board and was conducted in

compliance with HIPAA regulations.

Analysis

Descriptive statistics were performed to summarize demographics and clinical

factors. Distributions of continuous variables were examined to determine the

appropriateness of mean (standard deviation) versus median (25th to 75th percentile) to

summarize these variables. CAM use was calculated and its 95% confidence interval estimated. Prevalence of use by CAM modality was also described. In addition, reasons for CAM use and frequency of disclosure of this information to the physician were summarized. The correlation between age and disease duration was checked to investigate collinearity. Log transformation of duration of disease was used for analysis because of the large range and skewed distribution. Age, which was normally distributed, was considered as a dichotomous variable of younger (less than 10 years) vs. older (10 years and older) children because of nonlinearity with CAM use for the analysis (*Appendix ii*).

Univariate analyses were performed with CAM use as the outcome and the variables that were found to be statistically different between the two groups ($p \leq 0.10$). Demographic factors about the child and parent, as well as clinical factors about the child were compared using t-tests for the continuous variables and χ^2 tests for categorical variables. *A priori* determined clinically important factors, such as age, gender, and duration of disease, were also analyzed as we considered them candidate variables for inclusion in a multivariate model. A multivariate logistic regression model was then constructed with these variables to look at adjusted associations of significant factors with CAM use. The performance of our model was checked with an ROC curve and a calibration plot (*Appendix ii*).

Results

A sample of 202 parents of patients agreed to participate from among the 203 eligible consecutive parents or caregivers approached about the study. One parent declined invitation because of time constraints. Demographics are listed in Table 1. The

majority of the parents were mothers (88%), responding on behalf of their children. The children were predominantly female (66%) and Caucasian/Non-Hispanic (86%) with a mean age of 12.8 years. Interestingly, more than half (71%) of those parents who reported to be Hispanic or Latino also reported that the categories of race didn't fit them or they preferred not to state race. The predominant diagnosis of study patients was juvenile idiopathic arthritis (63%), although children with several other chronic conditions were also included. The median duration of illness was 29 months (25th to 75th percentile of 8-69 months). Ninety percent of study participants completed all survey items, and missing data were only identified in two variables. Specifically, family income was missing in 9% of the sample, and race/ethnicity was missing in <1% of the sample (see Table 1). Of note, there was no missing data regarding CAM use.

Overall, 50% of patients were CAM users. CAM users were found to be older, have shorter disease duration, and have parents who had completed a higher level of education and who more frequently used CAM therapies for themselves or immediate family members (See Table 2). There was a significant difference in CAM users versus non-users by level of parental education. When compared with parents of non-users, a higher percentage of parents of CAM users had completed some college or graduate school (80% vs. 67%, p=0.04). More CAM-users than non-CAM users had a parent or immediate family member with a history of CAM use (41% vs. 15%, p<0.001).

Unadjusted odds ratios describing the relationship of these variables with CAM use are presented in Table 3. Results of the multivariable model are shown in Table 4. Although the unadjusted odds ratios for age, disease duration, and gender were non-significant in the univariate analysis, they were retained in the model because of clinical

importance. After adjusting for age, disease duration, and gender, parental education was no longer significant, whereas familial CAM use remained significant with an adjusted odds ratio of 3.8 (CI,1.8-8.1; p<0.001).

CAM use was more prevalent among children ages 10 years and older compared to younger children with an unadjusted p-value of p=0.08. In the final model age was found to be significant with an adjusted odds ratio of 2.0 (CI, 1.0-3.9; p=0.05) of CAM use for older patients. Specifically, for children ages 10 years and older, the odds of CAM use versus non-CAM use was found to be 2 times higher compared with younger children.

The c statistic of our model was found to be 0.68 indicating our model was acceptable for our data and the calibration plot showed agreement of observed and predicted CAM use.

Modalities of CAM use were diverse (Table 5). The most reported used CAM modalities were natural products (69% of CAM users). Other frequently used therapies included mind-body medicines, such as yoga, acupuncture and tai chi (55%), and manipulative body-based practices, such as chiropractic therapy (40%).

Reasons for CAM use varied (Table 6). The most commonly endorsed reasons were to do everything possible to fight the child's disease (39%), to make the child healthier in order to fight the disease process (35%), and to boost the child's immune system (25%). Many parents endorsed more than one response.

Many CAM users (49%) agreed with the statement that CAM therapies improved their child's disease state, with the proportion of positive response varying by modality (Table 7). Of note, 66% of CAM users reported non-disclosure of CAM use specifically

to their child's pediatric rheumatologist, although 43% of CAM users reported disclosing CAM use to other providers including pediatricians, pediatric nurses, social workers, psychologists, and complementary medicine providers. Of those parents who did discuss CAM use with a provider, 60% reported that they felt that their provider approved of CAM use, while 28% thought the provider had no opinion and 12% felt they disapproved of CAM use. Among those who brought up CAM use with a provider, 82% of these parents felt comfortable with disclosing this information to the provider, while the remaining 18% felt uncomfortable disclosing CAM use. Many parents (78%) of CAM users also reported discussing their child's CAM use with family, friends, and other parents.

Discussion

We found that CAM use was extensive (50%) by patients with pediatric rheumatologic diseases, followed in a subspecialty clinic. This rate is comparable to reported rates of CAM use by pediatric patients with other chronic diseases, such as asthma and inflammatory bowel disease (8, 9). The extent of CAM use among children with chronic disease is striking, particularly given the paucity of information about the benefits or potential harms (e.g., side effects, medication interactions, and adherence of prescribed medications) of these practices.

The significant association between familial CAM use and patient CAM use highlights how parents and parental beliefs in CAM therapies influence patient care. We also found that older children and adolescents were more likely to be CAM users, although this was not explained by increased disease duration. Thus, it remains unclear if

the association of increased CAM use in older children is a function of parental choice or greater request by the older children and adolescents themselves.

Overall our findings are comparable to the NCCAM and NCHS 2007 National Health Interview Survey, which included a nationwide sample of more than 9,000 children. While the national survey reported a lower rate of overall CAM use (12%) across all children than we found in our study, three of the top four reported reasons for CAM use were found in children with back pain, musculoskeletal problems, and joint pain, all of which could be problems of patients followed in a rheumatologic clinic.

The NCHS survey also found a higher rate of CAM use among children whose parents used CAM (23.9%), among children whose parents had a higher level of education (14.7% in children with parents having completed some education after high school), and among adolescents compared with children (16.4%), all of which trend with our findings odds of increased CAM use in children with familial CAM use, higher education, and older age (2). Also, the reported modalities of CAM use in the NCHS survey are similar to our findings. Specifically, they, too, found that most used products were natural products including dietary supplements (2). This is of concern because the safety and efficacy of such remedies remain unproven. These therapies have not been widely studied and remain uncontrolled by the FDA. Many risks of such treatments remain unstudied, with potential for adverse side effects and/or interactions with conventional treatments. Moreover, the use of manipulative body-based practices, including chiropractic treatment, which were reported in our survey, may be undesirable in patients with underlying joint and musculoskeletal diseases, though there have been

reports of benefits with certain body-based practices such as tai chi in adult patients with rheumatologic diseases (30, 31).

Unlike our survey, the national survey did not address all other factors including disease duration, disclosure of CAM use to health care providers, and reasons for non-disclosure. In this regard, our survey yielded interesting findings. In particular, the finding that 66% of parents did not disclose CAM use to the pediatric rheumatologist revealed an unexpected gap in communication between parents and physician. Interestingly, 50% of parents who gave their children CAM use because of problems with conventional therapies did not disclose this practice to the pediatric rheumatologist. Our findings of 12% of parents who did discuss CAM use with a provider felt the provider disapproved, as well as 18% of parents feeling uncomfortable discussing CAM use also signals uninvestigated parent-doctor communication problems, and suggests the need for additional research on this topic. Alternatively, parents may be reluctant to offer information about CAM use when the provider does not directly inquire about this. Reasons for non-disclosure were not collected in our survey, a deficiency that should be addressed in future studies.

In general, CAM users were happy with the results of these treatments, with nearly half (49%) attributing improvements in their child's condition to these remedies. It is unclear if this perceived improvement translates to clinical improvements, but parental perception of clinical progress may even translate to better outcomes. This relationship warrants further investigation.

We acknowledge the limitations of our study. This was a cross-sectional study, thus longitudinal data on CAM use was not collected. Anonymity of the survey

prevented follow up or clarification, for example to evaluate in more detail if clinical improvement or deterioration related to CAM treatment. Non-English speaking parents were excluded from our survey; it is not known if the findings from our study would be applicable across other linguistic and cultural groups. The use of this survey in other populations, which may vary with respect to parental education and racial/ethnic mix, may require further evaluation with formal cognitive testing. Finally, while our model successfully identify some factors associated with CAM use, future studies are needed to identify other potential factors influencing CAM use in this population, as indicated by the precision of our model.

From the reasons given by the parents surveyed for using CAM in their children (e.g., "to do everything possible", "to make the child healthier to fight disease", "to boost immunity") we can conclude that these parents are highly motivated to help their children. Future studies and programs within this population should consider how to best channel this heightened parental motivation to further benefit the children. Other studies in adult with rheumatologic disease have demonstrated that specific modalities of CAM appear to benefit this population, such as mind-body medicine, resulting in positive outcomes (30, 31).

This is the first study investigating CAM use in a pediatric rheumatology clinic that includes information about reasons for CAM use and parental disclosure to the health providers. Future research could address parental beliefs about the benefits and adverse effects of CAM therapies, reasons for use in their children, and rationale for non-disclosure to pediatric rheumatologists.

Table 1: Demographics (N=202 Participants)

	All Patients N (%)	
Patient Characteristics		
Mean Age (s.d.)	12.8 yrs (4.6)	
Sex, female	136	(67)
Race/Ethnicity		
White	174	(86)
Hispanic or Latino	14	(7)
Asian	6	(3)
African American	4	(2)
Categories don't fit/Prefer not to state	16	(8)
Missing	2	(<1)
Diagnosis		
Established:		
Juvenile Idiopathic Arthritis	128	(63)
Systemic Lupus Erythematosus	6	(3)
Mixed Connective Tissue Disease	3	(1)
Other rheumatologic diseases[a]	11	(5)
Pain syndrome	10	(5)
Other/Diagnosis not yet established	44	(22)
Median Duration of Illness	29 months	
(25th-75th percentile)	8 -69 months	
Child CAM use	101	(50)
Family/Parent Characteristics		
Annual Household Income ($)		
<20,000	13	(7)
20-40,000	22	(12)
40-60,000	32	(17)
60-80,000	25	(13)
>80,000	92	(49)
Missing	18	(9)
Parental Education		
Completed Grade School	6	(3)
Completed High School	47	(23)
College/Graduate School	149	(74)
Familial CAM use	58	(29)

[a]Diagnoses include the following: Uveitis, Behcet's, Henoch-Shonlein purpura, Post-Streptococcal Arthritis, Lyme Arthritis, Celiac Disease, Ehlers Danlos Syndrome, Raynaud 's phenomenon, Eosinophilic Esophagitis, Antiphospholipid Antibodies, Lymphedema

Table 2: Characteristics of CAM User vs. Non-user

	CAM user N (%)		CAM nonuser N(%)		P-value
Mean Age (s.d.)	13.3 yrs (4.1)		12.4 yrs (4.9)		0.16
Sex, female	73	(72)	63	(62)	0.13
Parental Education College or Graduate School	81	(80)	68	(67)	0.04
Median Duration of Illness 25th-75th percentiles	29 months 7-69 months		26.5 months 8-73 months		0.70
Familial CAM use	42	(42)	15	(15)	<0.001

Table 3: Results of Unadjusted Logistic Regression Models for Associations with CAM Use

Factors	β Coefficient	P	OR	CI
Age (≥10yrs)	0.53	0.08	1.7	0.9-3.1
Sex (f)	0.45	0.13	1.6	0.9-2.8
Disease duration[a]	-0.023	0.85	1.0	0.8-1.2
Education ≥college	0.68	0.04	2.0	1.03-3.7
Parental CAM use	1.4	<0.001	4.1	2.1-8.0

[a]Log duration of months of illness used

Table 4: Multivariate Associations with CAM Use (N=202 Participants)

Factors	β Coefficient	P	Adjusted OR	CI
Age (≥10 yrs)	0.69	0.05	2.0	1.0-3.9
Sex (f)	0.44	0.20	1.6	0.8-3.1
Disease duration[a]	-0.01	0.92	1.0	0.8-1.3
Education ≥college	0.46	0.23	1.6	0.7-3.4
Parental CAM use	1.3	<0.001	3.8	1.8-8.1

[a]Log duration of months of illness used

Table 5: CAM Modalities[a]

CAM Modalities	Percentage of 101 CAM Users Reporting use of Modality (%)
Natural products	
High dose vits/minerals	44
Dietary Supplements	37
Specific diets	24
Fish oil	24
Glucosamine chondroitin	11
Herbal supplements	9
Enzyme supplements	6
Essiac Tea	5
Chinese supplements	4
Lactobacillus	3
Subtotal	69
Mind/body medicine	
Spiritual healing/prayer	22
Yoga	21
Meditation	13
Relaxation techniques/guided imagery	13
Acupuncture	11
Acupressure	7
Biofeedback therapy	6
Hypnosis	5
Tai chi	5
Subtotal	55
Manipulative body-based practices	
Chiropractic therapy	25
Massage therapy techniques	23
Subtotal	40
Practices of energy therapy	
Therapeutic touch	10
Healer/healing touch	7
Aromatherapy	7
Magnetic therapy	3
Ozone therapy	3
Subtotal	24
Whole medicinal systems	
Homeopathy	7
Subtotal	7

[a]Participants could endorse more than one modality within or across categories. The subtotal for each category represents users of one or more modality within the category.

Table 6: Reasons for CAM Use[a]

Reasons for CAM Use	%[a]
To do everything possible	39
To make child healthier to fight disease	35
To boost immunity	29
Conventional medicine not working	19
To use a more holistic approach	19
To make child's body healthier in general	18
To cure rheumatologic disease	16
To decrease conventional medicine side effects	15
To use psychological forces	8

[a] Results based on n=101 CAM users. Of note, all CAM users reported at least one reason for use.

Table 7: Proportion of CAM Users Reporting Positive Benefit [a]

CAM Response	Total	Positive Response N	Positive Response (%)
Natural Products	70	37	53
Mind/body medicine	55	26	47
Manipulative body-based practices	40	26	53
Practices of Energy Therapy	24	15	63
Whole medicinal systems	7	5	71

[a]Participants could endorse more than one modality within or across categories. The subtotal for each category represents users of one or more modality within the category.

Appendix i: Survey

This survey explores the use of complementary and alternative therapies in rheumatologic disorders. The first section of the survey contains questions about your family and your child. The second section asks about complementary and alternative therapies. Please do the best you can to answer all of the questions.

Section I

A. About My Child

1. My child's diagnosis is:

    □ Juvenile Idiopathic Arthritis   □ Chronic pain/
       (formerly called JRA)   pain amplification
    □ Lupus (SLE)   □ Patellofemoral syndrome
    □ Juvenile Dermatomyositis   □ Uveitis
    □ Mixed Connective Tissue Disease   □ Reflex Sympathetic Dystrophy
    □ Other

2. My child's current year of birth is:_ __

3. My child's gender is: □male   □female

4. My child was diagnosed on (mm/yy): __ __/__ __

B. <u>About My Child's Diagnosis and Treatment</u>

 5. Please check all of the <u>current</u> medications prescribed for this condition:

    □ Anti-inflammatories
       Including ibuprofen (Motrin or Advil), naproxen (Naprosyn), tometin (Tolectin),
       indomethacin (Indocin), celecoxib (Celebrex), meloxicam (Mobic)
    □ Methotrexate (pills or injection)
    □ Prednisone
    □ Hydroxychloroquine (Plaquenil)
    □ Cyclophosphamide (Cytoxan)
    □ Etanercept (Enbrel) or Adalimumab (Humira)
    □ Other (please list) _____

6. Has a doctor ever told you that your child has had:

		Yes	No
a.	Diabetes	□	□
b.	Asthma	□	□
c.	Overweight or excessive Weight gain	□	□
d.	An eating disorder-anorexia Or bulimia	□	□

e. Attention Disorder such as
   ADD or ADHD   □   □

f. Depression or other emotional
   Problems   □   □

g. Autism, mental retardation, or
   Other developmental problems   □   □

h. Epilepsy or seizure disorder   □   □

i. Cystic fibrosis   □   □

j. Birth defect (including spina
   bifida and congenital heart disease)   □   □

k. Other chronic (long term)
   health condition (please specify)   □   □

   _____

C. About You and Your Family

7. What is your relationship to this child?

   □ 1. Mother
   □ 2. Father
   □ 3. Grandmother
   □ 4. Grandfather
   □ 5. Other Guardian
   □ 6. Other (please describe) _____

8. What is your current age? _____

9. Are you Hispanic or Latino?

   Yes…………......1

   No……………..2

10. How would you describe your race? (Please circle response.)

    American Indian or Alsaka Native ………………………….1

    Asian………………………………………………………2

    Black or African American………………………………..3

    Native Hawaiian or other Pacific Islander………………..…4

    White……………………………………………………....5

Prefer not to state……………………………………….....6

These categories don't fit for me………………………….7

11.   Please indicate the highest grade that you have completed in school:

        (Please circle one number.)

K….1….2….3….4….5….6….7….8   9….10….11….12/GED   13….14….15….16   17+
        Grade School   High School   College/Graduate/
                                                                                  Professional
                                                                                  School

12.   What kind of health insurance do you have for your child?

        (Please circle one.)

        Private (e.g. Prudential, Blue Cross/Blue Shield, HMO)…….1

        Public (e.g. Medicaid, Medicare, CHAMPUS)……………...2

        No Insurance………………………………………………….3

13.   At the time that your child was diagnosed with his or her rheumatologic disease, what was the

        annual income of the household where the child lived?

        □ 1. less than $10,000
        □ 2. $10,000 - $20,000
        □ 3. $20,001 - $40,000
        □ 4. $40,001 - $60,000
        □ 5. $60,001 - $80,000
        □ 6. $80,001 - $90,000
        □ 7. more than $90,000

Section II.

Complementary Therapies

Complementary therapies are sometimes called holistic or alternative therapies, and refer to many therapies that are not traditionally prescribed by a doctor. Complementary therapies can include such things as massage, acupuncture, homeopathy, Tai Chi, herbs, vitamins, and enzymes (A longer list of complementary therapies is given on pages 5 and 6.) We are interested in learning more about what types of complementary therapies, if any, that your child and your family have used or thought about using.

Please answer the following questions about complementary therapies. The list of complementary therapies we provide is not complete, so it is important that you write in any other complementary therapies you have used in the spaces provided.

We invite you to add any feedback, questions or information on the back of the questionnaire.

14. <u>Before your child was diagnosed with a rheumatologic disease</u>, did anyone in your

immediate family use complementary therapies?

    □ 1. Yes
    □ 2. No

15. <u>Before your child was diagnosed with a rheumatologic disease</u>, what did you think
about complementary therapies?

□ 1.	□ 2.	□ 3.	□ 4.	□ 5.
Very helpful	A little helpful	Neither helpful nor harmful	A little harmful	Very harmful

16. Your child's medical care includes a primary care doctor or nurse practitioner, a primary care nurse, a pediatric rheumatologist, and a pediatric rheumatology clinic nurse. Please indicate who, if anyone, has asked you about use of complementary therapies or your interest in using them.

1. Primary doctor/nurse practitioner   □ Yes   □ No
2. Primary outpatient clinic nurse   □ Yes   □ No
3. Pediatric rheumatologist   □ Yes   □ No
4. Pediatric rheumatology clinic nurse   □ Yes   □ No

17. When did you <u>first use</u> complementary therapies for your child's rheumatologic disease?
    □ 1. My child did not receive complementary therapies
    □ 2. When my child was diagnosed with his or her rheumatologic disease
    □ 3. When my child began having symptoms of his/her disease
    □ 4. When conventional medicine seemed to have failed or was failing
    □ 5. During my child's treatment as additional treatment
    □ 6. After conventional treatment was finished
    □ 7. Other

18. How did you learn about complementary therapies?

(Please check all that apply.)

□ 1. I didn't learn about them	□ 8. Media (i.e. magazines, TV, radio)
□ 2. Doctor	□ 9. Naturopath/Homeopath
□ 3. Nurse	□ 10. Parents of children with chronic diseases
□ 4. Friend	□ 11. Internet
□ 5. Family	□ 12. Don't remember
□ 6. Pharmacist	□ 13. Other_____
□ 7. Health food store	

19a. With whom did you talk about using complementary therapies?

□ 1. No one	□ 6. Family
□ 2. Pediatric rheumatologist	□ 7. Friends
□ 3. Primary doctor	□ 8. Complementary healthcare provider

□ 4.   Nurse   □ 9.   Other parents
□ 5.   Social worker/psychologist   □ 10.   Other_____

19b. If you brought up the topic of complementary therapies with your pediatric rheumatologist, how comfortable did you feel?

□ 1.	□ 2.	□ 3.	□ 4.
Very Comfortable	Comfortable	A Little Uncomfortable	Very Uncomfortable

□ 5. I never brought it up (skip next question)

19c. If you brought up the topic of complementary therapies with your pediatric rheumatologist, how do you think that he or she felt about it?

□ 1.	□ 2.	□ 3.	□ 4.	□ 5.
Approved	Approved somewhat	Had no opinion	Disapproved somewhat	Disapproved strongly

20. Please let us know which of the following treatments you have used <u>for your child.</u> If you have never used one of these treatments, mark the first box and continue to the next item. If you <u>have</u> given your child this treatment, mark the boxes that show when you used it – before diagnosis of rheumatologic disease, after diagnosis, or both (check both boxes). Please list specific types of therapies in space provided.

	Never used	Used before diagnosis	Used after diagnosis
1. Acupressure	□	□	□
2. Acupuncture	□	□	□
3. Aromatherapy	□	□	□
4. Biofeedback	□	□	□
5. Chinese Medicines (please list)_____	□	□	□
6. Chiropractic	□	□	□
7. Specific diets (macrobiotics, vegan, etc.) please list)_____	□	□	□
8. Dietary supplements (i.e. wheat grass, kelp, fish oil) please list_____	□	□	□
9. High dose vitamins or minerals (not regular multivitamin but vitamin C, zinc, supplements) please list_____	□	□	□
10. Glucosamine chondroitin	□	□	□
11. Fish oil	□	□	□
12. Enzymes (please list) (please list)_____	□	□	□

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	Never used	Used before diagnosis	Used after diagnosis
13. Essiac tea	□	□	□
14. Healer/Healing touch	□	□	□
15. Herbal treatments	□	□	□
(ginseng, echinachea, etc.)			
please list)_____			
_____			
16. Homeopathic Medicine	□	□	□
17. Hypnosis	□	□	□
18. Lactobacillus	□	□	□
19. Magnets	□	□	□
20. Massage/Bodywork/Shiatsu	□	□	□
21. Meditation	□	□	□
22. Ozone therapy	□	□	□
23. Prayer or Spiritual healing	□	□	□
24. Qi gong or Tai Chi	□	□	□
25. Relaxation techniques or	□	□	□
Guided Imagery			
26. Shaman	□	□	□
27. Shark cartilage	□	□	□
28. Therapeutic Touch/Reiki	□	□	□
Polarity Therapy			
29. Yoga	□	□	□
Other complementary therapies			
30. _____	□	□	□
31. _____	□	□	□
32. _____	□	□	□
33. _____	□	□	□

21. If u answered yes to any other condition listed that your child may have in question #6, did you use CAM for your child for that condition?
□Yes   □No

22.   We are interested in knowing if anyone in <u>your immediate family</u> used any complimentary

therapies before your child was diagnosed with his or her rheumatologic disease, or since then.

	Never used	Used before diagnosis	Used after diagnosis
1. Acupressure	□	□	□
2. Acupuncture	□	□	□
3. Aromatherapy	□	□	□
4. Biofeedback	□	□	□
5. Chinese Medicines (please list)_____ _____	□	□	□
6. Chiropractic	□	□	□
7. Specific diets (macrobiotics, vegan, etc.) please list)_____ _____	□	□	□
8. Dietary supplements (i.e. wheat grass, kelp, fish oil) please list_____ _____	□	□	□
9. High dose vitamins or minerals (not regular multivitamin but vitamin C, zinc, supplements) please list_____ _____ _____	□ □	□ □	□ □
10. Glucosamine chondroitin	□	□	□
11. Fish oil	□	□	□
12. Enzymes (please list) (please list)_____ _____	□	□	□
13. Essiac tea	□	□	□
14. Healer/Healing touch	□	□	□
15. Herbal treatments (ginseng, echinachea, etc.) please list_____	□	□	□
16. Homeopathic Medicine	□	□	□
17. Hypnosis	□	□	□
18. Lactobacillus	□	□	□
19. Magnets	□	□	□
20. Massage/Bodywork/Shiatsu	□	□	□
21. Meditation	□	□	□
22. Ozone therapy	□	□	□
23. Prayer or Spiritual healing	□	□	□
24. Qi gong or Tai Chi	□	□	□
25. Relaxation techniques or Guided Imagery	□	□	□
26. Shaman	□	□	□
27. Shark cartilage	□	□	□
28. Therapeutic Touch/Reiki	□	□	□

	Never used	Used before diagnosis	Used after diagnosis
29. Yoga	□	□	□
Other complementary therapies			
30. _____	□	□	□
31. _____	□	□	□
32. _____	□	□	□
33. _____	□	□	□

If your child is NOT receiving any complementary therapies, please go to the last page of the survey.

23.   Have you ever chosen to use complementary therapies for your child **instead of** the conventional medical treatment your pediatric rheumatologist recommended?

        □ 1. Yes - please describe_____

        □ 2. No

        □ 3. Prefer not to answer

24.   For what reasons did you decide to try complementary therapies for your child?
      (Please check all that apply.)

1.	To cure the rheumatologic disease	□Yes	□ No
2.	To boost the immune system	□ Yes	□ No
3.	To do everything possible	□ Yes	□ No
4.	To decrease the side effects of medical treatments	□ Yes	□ No
5.	Because conventional medicine was not working	□ Yes	□ No
6.	To use psychological forces	□ Yes	□ No
7.	To use a more holistic approach	□ Yes	□ No
8.	Because of poor communication with my pediatric rheumatologist	□ Yes	□ No
9.	Because of pressure from family or friends	□ Yes	□ No
10.	To make my child's body healthier to fight the rheumatologic disease	□ Yes	□ No
11.	To be more involved in the care of my child	□ Yes	□ No
12.	Don't know	□ Yes	□ No
13.	Other_____	□ Yes	□ No
14.	Other_____	□ Yes	□ No
15.	Other_____	□ Yes	□ No

25.   Please put a star beside the reason from above which was the most important to you.

26.   How do you feel that using complementary therapies has affected your child's health and well-being?

□ 1.	□ 2.	□ 3.	□ 4.	□ 5.
Very improved	Improved	No change	Worse	Much worse

27.   If complementary therapies helped your child, how did they do so?
      (Please check all that apply.)

        □ 1.   Cured the rheumatologic disease

□ 2. Helped conventional treatments to cure the rheumatologic disease
□ 3. Helped decrease the side effects from the conventional medicine
□ 4. Helped decrease the symptoms of the disease
□ 5. Made my child better because he/she knew we were doing everything possible
□ 6. Strengthened the immune system
□ 7. Made my child healthier
□ 8. Made my child psychologically stronger
□ 9. Don't know
□ 10.   Other_____

28.   Were there unwanted effects of the complementary therapies? Is so, please indicate all the

unwanted effects.

□ No unwanted effects	
□ 1. Pain	□ 6. Headaches
□ 2. Nausea/vomiting	□ 7. Moodiness
□ 3. Diarrhea	□ 8. Irritability
□ 4. Poor appetite	□ 9. Fear/upset feelings
□ 5. Skin rashes	□ 10. Other _____

29.   How did your child accept the complementary therapies?

□ 1.	□ 2.	□ 3.	□ 4.
Easily -	Some difficulty	Moderate	Serious problems
no problems	or resistance	difficulty or resistance	accepting the therapies

□ 5.   My child refused the complementary therapies
Please describe_____

30. Did you have to stop using complementary therapies before you wanted to?

If so, please indicate why.

(Please check all that apply.)

□ 1. I did not have to stop using complementary therapies before I wanted to
□ 2. Side effects of treatment
□ 3. Incompatibility with medical treatment
□ 4.Cost
□ 5. Too far to go for treatment
□ 6. Too difficult to give treatment
□ 7. Refusal of child
□ 7. Advised to stop by medical professional
□ 8. Other_____

31.   Would you recommend the complementary therapies you used to other parents of children with

rheumatologic diseases?

□ 1. Yes   □ 2. No   □ 3. Don't know

If yes, what would you recommend and why?_____

If no, why not? _____

32.   About how much did the complementary therapies cost per year?

□ 1. $0 - $100   □ 5. $1,001 - $2,000
□ 2 $101-150   □ 6. $2,001 - $3,000
□ 3. $251 - $500   □ 7. $3,001 or more
□ 4. $501 - $1,000

33.   How often have these costs been covered by insurance?
        □ 1. Never
        □ 2. Sometimes
        □ 3. Usually
        □ 4. Always
        □ 5.Don't know

Please restart here if your child did NOT receive complementary therapies.
If your child did receive complementary therapies please stop here.

34.   If your child <u>DID NOT</u> receive complementary therapies, what were the reasons?

1.	I did not know about them	□ Yes	□ No
2.	Afraid of the unknown	□ Yes	□ No
3.	It was not "scientific"	□ Yes	□ No
4.	It cost too much	□ Yes	□ No
5.	It would interfere with conventional medical treatment	□ Yes	□ No
6.	It would be uncomfortable to child	□ Yes	□ No
7.	My child did not want to use it	□ Yes	□ No
8.	I did not believe they would work	□ Yes	□ No
9.	My pediatric rheumatologist did not approve or recommend it	□ Yes	□ No
10.	My family or friends told me not to	□ Yes	□ No
11.	Not needed - my child's prognosis was good	□ Yes	□ No
12.	No time to think about it	□Yes	□ No
13.	Not needed - My child had few problems or side effects from treatment	□Yes	□ No
14.	Other _____		
15.	Other _____		

Please put a star next to the reason above which was most important to you.

Appendix ii: **Analysis**

Power Calculation

Our goal of 200 survey participants was obtained from a rough power calculation. From our estimation that we would find 50% prevalence of CAM use, we calculated a power of 81% using a detection rate of 20% difference between variable proportions between CAM users vs. non-users. Therefore, with a sample of 200 survey participants with 100 CAM users vs. 100 non-CAM users, a difference in a variable such as parental CAM use of 60% compared with 40% could be detected with 81% power.

Age

In the univariate analysis as well as in the multivariate analysis age was not used as a continuous linear variable, but as a dichotomous variable of younger aged children (age less than 10 years) and older children and adolescents (age 10 years and older). We initially investigated age for linearity by dividing age into 3 year intervals and looking at associations with CAM use. Without adjusting for any other variables we found age not to be linear, with % CAM use lowest at younger ages with a peak around age 10 to 12 and then slightly lowering in adolescents. We also found this non-linear relationship after adjusting for the other variables included in our multivariate model. In order to include the most appropriate from of age for our model, we looked at different models using age as (1) a continuous (linear) variable, (2) a continuous variable with both age and age^2 in the model to allow for a quadratic relationship, and (3) age as a dichotomous variable with the cut-off of 10 years derived from the initial investigation of whether fitting age as a linear term was best capturing the relationship of age and CAM use. After comparing the χ^2 values of each model accounting for degrees of freedom, the best

model, based on the likelihood ratio chi-square statistic and AIC was with age included as a dichotomous variable.

Model

Distributions of all variables of interest were checked for normality. Disease duration was also transformed into log of duration for the univariate and multivariate analysis because of the extensive range and skewed distribution of this measure. The correlation between the disease duration and age was also investigated before putting both variables into the multivariable model out of concern of possible collinearity of these two variables, which we did not find.

Univariate analyses were done using t-tests for the continuous variables age, disease duration, and χ^2 tests were used for categorical variables gender, parental education completion, and familial CAM use. The Wilcoxon rank-sum test was used to test for disease duration as disease duration. Age, after investigated for linearity, was used as a dichotomous variable ($\leq$ vs. >10) because of an observed non-linear relationship with CAM use, and also for ease of interpretation of the odds ratios in the logistic regression models.

A multivariate logistic regression model was then constructed to look at adjusted associations of significant factors with CAM use. 202 patients were included in our final model. All factors found to be significantly different for users vs. nonusers at an unadjusted p-value of < 0.10, as well as the *a priori* identified important clinical factors of age, gender, and disease duration, were included into the multivariate logistic regression model. We included these factors, though we found them to be not significant, because of reported significance in other studies of CAM use, as well as the possibility

that these clinical factors may be significant in other populations.   Some interactions were checked, as this analysis was exploratory in nature, including two-factor interactions between age and gender, age and disease duration, gender and disease duration, and parental education with parental CAM use, although none of these interactions were found to be significant and thus were not included in our final model. These interactions were checked by adding them each individually as a sixth variable along with the five variables included in the final model (age, gender, disease duration, parental education, and parental CAM use).

We checked our model fit with the Hosmer and Lemeshow goodness-of-fit test and found our model statistic to be 3.54 with a non-significant p-value. Thus, this measure supported our model's adequacy for these data. We also checked the overall fit of our model with Pearson and deviance χ^2 residuals, and used index plots to identify any large residuals indicating outliers, and to access for patterns of variation, though none of these were found.

We checked the performance of our model with an ROC curve and computing the corresponding area under the curve and also creating a calibration chart to see how well our model's predicted CAM use, based on the variables we used for our multivariate model, compared to the observed CAM use and also to check where our model fit best. The c statistic, or area under the ROC curve, of our model was found to be 0.68. We divided our predicted probabilities are divided into quintiles for our calibration chart and calculated mean observed and predicted probabilities, which show agreement, though it can be graphically seen that at the lowest as well as highest predicted probabilities, our model is slightly under-predicting CAM use.

ROC Curve for Model
Area Under the Curve = 0.6822

Model Calibration Chart
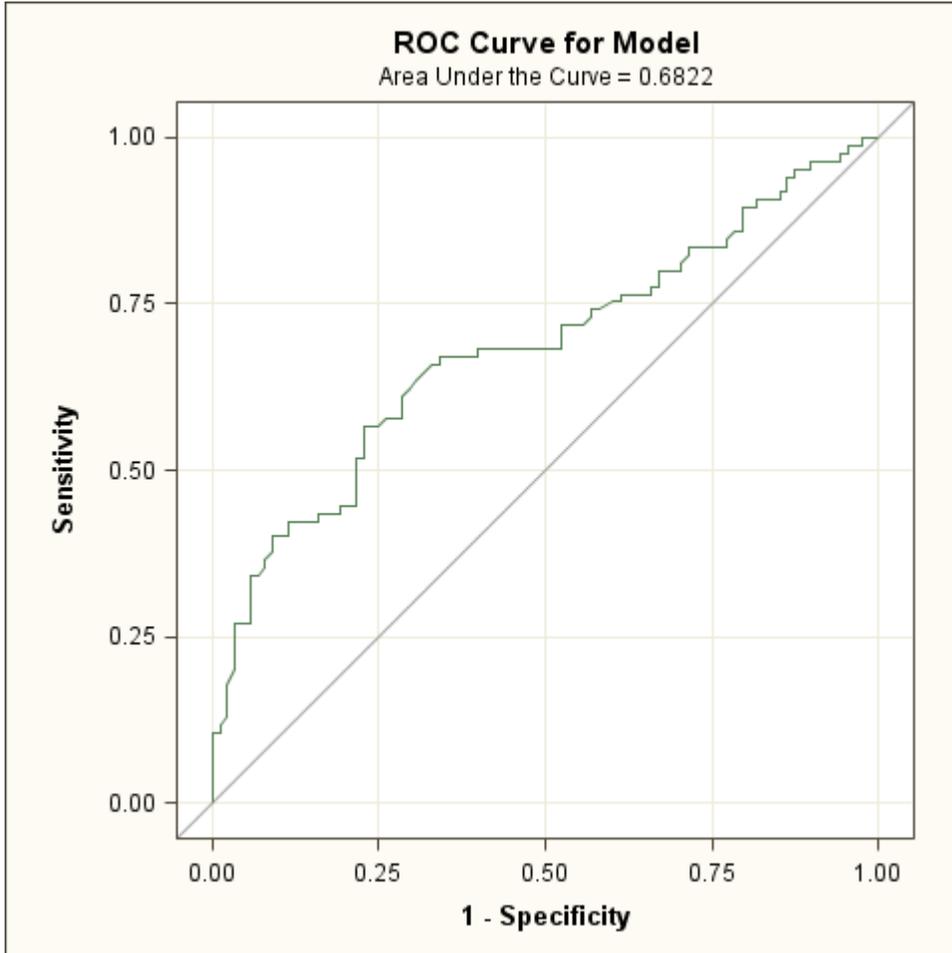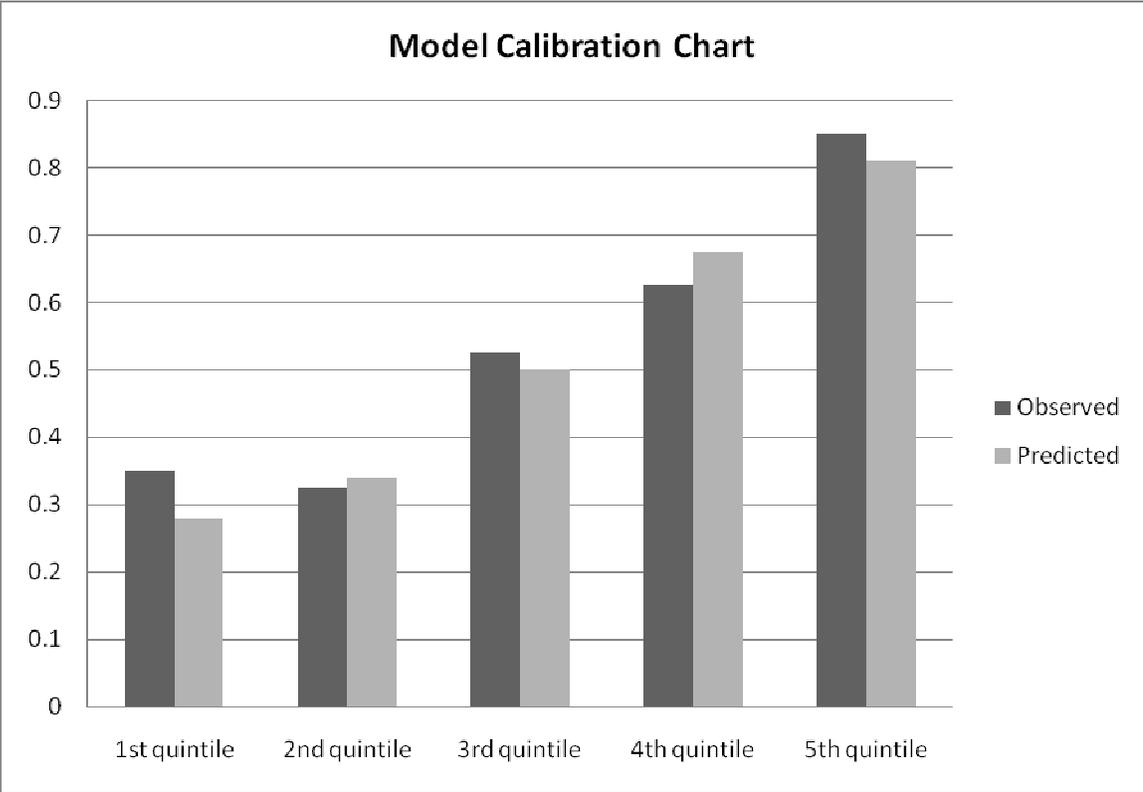
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