

## Self-Reported Quality of Life in Complementary and Alternative Medicine Treatment of Chronic Rhinosinusitis Among African Americans: A Preliminary, Open-Label Pilot Study

Yvonne G. Hipps, Ph.D.,<sup>1</sup> Yolanda E. Hacker, M.D.,<sup>2</sup> David L. Hoffmann, B.Sc., F.N.I.M.H.,<sup>3</sup>  
Josef A. Brinckmann,<sup>3</sup> Robin R. Socci, Ph.D.,<sup>4</sup> and Denine Rogers, R.D., L.D.<sup>5</sup>

### Abstract

**Objective:** The southern U.S. region has among the highest incidence of chronic rhinosinusitis (CRS). Historically, African Americans in this region have been a difficult to reach population for clinical research participation. This study's aim was to observe any association between herbal tea consumption and CRS symptoms among African Americans. We recount the volunteers self-reporting of measurements associated with self-treatment of CRS symptoms.

**Design:** The study design was a preliminary, open-label, pilot study.

**Settings:** Volunteers were drawn from Morehouse School of Medicine's outpatient clinics, community multi-purpose senior centers, and churches in Fulton and DeKalb Counties, GA.

**Subjects:** One hundred (100) African American volunteers were prescreened, of whom 55 with a clinical diagnosis of CRS met entrance criteria.

**Intervention:** Volunteers self-administered Breathe Easy<sup>®</sup> herbal tea for a duration of 6 weeks.

**Outcome measures:** The Chronic Sinusitis Survey (CSS) scale was administered to assess sinus health at baseline and term and overall quality of life was assessed using the Short Form-36 (SF-36) index.

**Results:** Of the 55 volunteers who met entrance criteria, 41 completed the study; groups were q.i.d. ( $n = 27$ ), t.i.d. ( $n = 4$ ), b.i.d. ( $n = 5$ ), and noncompliant ( $n = 5$ ). For the q.i.d. group ( $n = 27$ ), there was a significant increase in the CSS symptom score (difference in means 22.0 points;  $p = 0.020$ ) and CSS total score (11.1 points;  $p = 0.020$ ). Overall health status (SF-36) reported at baseline was 35% very good; 34% good; and 17% fair. After 6-weeks, the q.i.d. group showed a significant change to 44% good and 45% very good ( $p = 0.001$ ).

**Conclusions:** This preliminary pilot study suggests that q.i.d. self-administration of Breathe Easy was associated with improved volunteers' sinus health status (e.g., ability to fall sleep). Our results suggest that this herbal tea may contribute as a complementary therapy for management of CRS among African Americans. To further assess efficacy and applicability to other populations, randomized controlled trials in larger populations are warranted.

---

<sup>1</sup>Department of Pharmacology and Toxicology, Morehouse School of Medicine, Atlanta, GA.

<sup>2</sup>Department of Family Medicine, Morehouse School of Medicine, Atlanta, GA.

<sup>3</sup>Research and Development Department, Traditional Medicinals, Sebastopol, CA.

<sup>4</sup>Biostatistical Community Research Consultant, Morehouse School of Medicine, Atlanta, GA.

<sup>5</sup>Wellpoint Inc., Richmond, VA.

## Introduction

The southern region of the United States reports the highest incidence of rhinosinusitis, with higher prevalence among women than men, and higher incidences among African Americans compared to Hispanics.<sup>1</sup> Chronic rhinosinusitis (CRS) is one of the most common chronic diseases, affecting 14%–16% of all Americans,<sup>2,3</sup> resulting in 29.5 million individuals diagnosed each year.<sup>4</sup> Nearly 32 million cases of CRS are reported to the Centers for Disease Control and Prevention annually, with \$5.8 billion each year on related health care costs. Patients with CRS visit primary care clinicians twice as often as those without the disorder, and have five times as many prescriptions filled.<sup>5</sup> More than one in five antibiotics prescribed in adults are for sinusitis, making it the fifth most common diagnosis for which an antibiotic is prescribed.<sup>6</sup>

In an attempt to find relief, some chronic sinusitis sufferers are turning to complementary therapies. A survey of the use of complementary therapies amongst racial minorities found that 26% of African Americans had used a complementary modality for personal health care. With the exception of prayer, herbal medicines were the most commonly used therapy, and head colds were the second most frequently treated condition.<sup>7</sup> Based on our experience and knowledge, we find that African Americans in the southern United States have been a difficult-to-reach population for clinical research participation, particularly blinded studies. Health-related quality of life (HRQL) has optimum association with the health belief model of self-efficacy. Belief (attitude) influences behavior change over time.<sup>8</sup> This exploratory brief report observes study volunteers' self-reports of their sinus health beliefs reflected within the first Short Form-36 (SF-36) question. Our decision to design this preliminary study using a nonblinded, descriptive, and open-label methodology was related to our experience with the aforementioned target population of African Americans. The study site was located in the Atlanta, Georgia (GA) area, where African Americans comprise over 60% of the population. The primary aim of this pilot study was to observe the use of an herbal tea for self-care among African Americans with a diagnosis of CRS. We report on the volunteers' responses to quality-of-life measurements associated with their treatment of CRS symptoms by self-administration of an herbal tea containing botanicals traditionally used for sinusitis.

CRS can be defined as a symptomatic inflammation of the paranasal sinuses and nasal cavity lasting more than 12 weeks, with or without acute exacerbations.<sup>9</sup> Symptoms vary in both severity and prevalence. Nasal obstruction is most common (81%–95%), followed by facial congestion with pressure and fullness (70%–85%), discolored nasal discharge (51%–83%), and hyposmia (61%–69%).<sup>10</sup> Causation is multifactorial, making treatment problematic.<sup>11</sup>

Medically resistant chronic sinusitis may be more debilitating than angina, congestive heart failure, chronic obstructive pulmonary disease, and chronic back pain or sciatica.<sup>12</sup> This common condition not only causes significant physical symptoms but also results in substantial functional and emotional impairment.<sup>13</sup> Mood, body pain, energy level, physical functioning, and social functioning are all affected in addition to local symptoms. A range of predisposing factors, such as allergic rhinitis, cystic fibrosis, an immuno-

compromised state, ciliary dyskinesia, and anatomic variation, might contribute to the persistence and/or recurrence of CRS.<sup>9</sup> Thus, CRS impacts both patients and the health care system, requiring repeated physician office visits, prescription medications, over-the-counter medications, and surgical therapy.

Making herbal tea, which is the aqueous extraction of medicinal herbs by decoction, infusion, or maceration, is an ancient tradition shared by most cultures. Extraction is the process by which the soluble herb constituents are separated from inert, fibrous matter, thus making them bioavailable. In addition to any therapeutic value, the drinking of herb tea is a relatively low-cost therapy that is readily available in local grocery stores, is culturally and personally familiar, as well as conceptually nonchallenging. Although increasing research focuses on the herbal *materia medica* and its potential therapeutic contribution, little research is published on the methods and formulations of traditional herbalism. Thus, the local use of medicinal herbal teas for self-care of common conditions raises some important, largely unaddressed questions, particularly among minority populations.

Breathe Easy<sup>®</sup> tea (Traditional Medicinals<sup>®</sup>, Sebastopol, CA) contains as its primary active component a concentrated dry aqueous extract of a Traditional Chinese Medicine formula, *biyan pian* (nose inflammation tablets), in combination with herbs with expectorant action that are traditionally used in medicinal herbal teas for catarrhs of the respiratory tract. *biyan pian* is thought to be based on a formula first described in *Formulas to Aid the Living*, a text by Yan Yonghe from 1253 CE. *Biyan pian* is an official preparation of the Pharmacopoeia of the People's Republic of China (PPRC),<sup>14</sup> indicated for treatment of acute or chronic rhinitis with manifestations of stuffy and running nose. It is used for treating a range of upper respiratory tract (URT) symptoms including sneezing, itchy eyes, facial congestion, and sinus pain.

It should be noted that different versions of the *biyan pian* formulation are commercially available and that some have been found to contain undeclared and/or restricted components subjecting them to regulatory alerts. It is precisely for this reason that the manufacturer of the investigational product has it specially manufactured according to the formulation described in the official monograph published in the PPRC 1997.

## Materials and Methods

### Study design

This study was designed as a preliminary, open-label pilot study administering two quantitative self-report questionnaires, the Chronic Sinusitis Survey (CSS) and Short Form-36 (SF-36) that explored the participants' use of a Complementary and Alternative Medicine (CAM) Breathe Easy herbal tea for CRS; and elicited demographic information, including age, marital status, gender, education level, and ethnicity.

### Participants

One hundred (100) volunteers were drawn from Morehouse School of Medicine's outpatient clinics, community multipurpose senior centers, and churches in Fulton and DeKalb Counties, GA. Participants were recruited using

brochures and flyers at these locations. Of the 100 volunteers, 55 were eligible for enrollment. The main study site was Quality Living Service (Atlanta, GA). Other sites included Providence Missionary Baptist Church, Morehouse School of Medicine Internal Medicine Clinic, Positive Passtime, Inc., Rainbow Women's International Inc., Green Forest Baptist Church, and Green Pastures Church. The study was approved by Morehouse School of Medicine Institutional Review Board (IRB). Volunteers provided written consent prior to participation and were not compensated. This study was conducted in accordance with IRB regulations, good clinical practice and the Declaration of Helsinki.

#### Inclusion and exclusion criteria

Evaluated for enrollment were African Americans ages 35–75 years of age with residence in Fulton and DeKalb Counties, GA, volunteers with CRS, and a 1-year minimum diagnosis prior to the study intake interval. Volunteers' physician and our study physician verified the CRS diagnosis with medical record documentation and physical examinations.

Exclusion criteria specific to the investigational product were volunteers with hypokalemia, inflammatory disorders of the gastrointestinal tract and biliary ducts, impaired kidney function, high blood pressure or heart disease; those who are pregnant or breastfeeding; those who are allergic to plants of the Asteraceae (daisy) family; and volunteers taking any hormonal therapies, diuretics, potassium-depleting agents, or monoamine oxidase inhibitors. Other exclusion criteria specified by the investigators relative to this target population were acute sinusitis, diabetes and metabolic syndrome, bronchiectasis, or allergic rhinosinusitis; with inflammation beyond 3 months; who are unable to ingest or digest the research herbal therapies; prescribed with blood thinner medications such as warfarin, heparin, aspirin; who are using antibiotics, nasal sprays, or any other sinus medications; with a clinical diagnosis of having had or needing CRS surgery; and African Americans residing in assisted living, or nursing homes.

#### Intervention

Over a 6-week period at baseline and at follow-up 2-week intervals, study volunteers were provided a sealed box containing two plastic bags each containing 32 individual envelopes of Breathe Easy herbal tea, a 16 day supply prescribed q.i.d. The volunteers were also presented with a standard cup, lid, and written instructions to prepare and drink the tea as follows: Pour 8 oz of freshly boiled water over one tea bag in the heat-resistant porcelain cup. Cover the cup and steep for 10–15 minutes. Then gently squeeze the tea bag over the cup in order to release any remaining extractive from the herbal mixture. Do not add sugar.

The study principal investigator (PI) observed participants signing for their box of tea; opening their box; and counting the envelopes at baseline and at each 2-week dissemination of the investigational product. Participants were instructed by the PI individually and in a group at baseline and at 2-week intervals in tea preparation; in safety measures; in study adherence; in reviewing the narrative on the outside of the box and on each plastic bag in the box; in consuming the tea without sweetener or other condiment; and in al-

lowing *only* themselves to consume any of the herbal product. Volunteers were instructed to return their boxes at each 2-week interval of the study protocol and to bring back any unused sealed tea bag envelopes. The remaining tea bags were adherence indicators monitoring levels of consumption at two, three, or four times a day, reviewed by the PI for study compliance. The study physician at baseline verbally presented CRS information to the volunteers. The PI presented a toolkit with general CRS lifestyle and medical recommendations to all volunteers at the study term interval. The study physician was on call for the volunteers regarding any health questions or issues with the tea consumption. Additionally, CRS health examinations were completed by the study physician at baseline and study term.

Breathe Easy (lot #JUN 08 9543) was supplied by the product manufacturer as a homogeneous mixture of dried botanicals and dried aqueous extract packaged in an unbleached double-pouch filter tea bag, individually sealed in a tamper-evident envelope. Production of the investigational product was carried out according to good manufacturing practice and the quality standards of the botanical raw materials are documented in their written specifications according to current pharmacopoeial standards. Breathe Easy contains, per single dose, 1500 mg of a homogeneous blend of 300 mg licorice root PhEur (*Glycyrrhiza glabra* L.), 285 mg eucalyptus leaf PhEur (*Eucalyptus globulus* Labill.), 255 mg bitter fennel fruit PhEur (*Foeniculum vulgare* Mill. ssp. *vulgare* var. *vulgare*), 60 mg pleurisy root BHP (*Asclepias tuberosa* L.), and 120 mg *biyan pian* PPRC dry aqueous extract 8:1 (w/w). *Biyan pian* contains the extract obtained from a traditional decoction of the following botanicals in order of predominance: xanthium fruit (*Xanthium sibiricum* Patr. ex Widder), magnolia flower (*Magnolia officinalis* Rehder & E.H. Wilson), siler root (*Saposhnikovia divaricata* (Turcz.) Schischk.), forsythia fruit (*Forsythia suspensa* (Thunb.) Vahl), wild chrysanthemum flower (*Chrysanthemum indicum* L.), schisandra fruit (*Schisandra chinensis* (Turcz.) Baill.), platycodon root (*Platycodon grandiflorum* (Jacq.) A. DC.), fragrant angelica root (*Angelica dahurica* (Fisch. ex Hoffm.) Benth. & Hook. f. ex Franch. & Sav.), anemarrhena rhizome (*Anemarrhena asphodeloides* Bunge), schizonepeta herb (*Nepeta tenuifolia* Benth.), and Chinese licorice root (*Glycyrrhiza uralensis* Fisch. Ex DC). Other components contained in the investigation product are peppermint leaf PhEur (*Mentha × piperita* L.), calendula flower PhEur (*Calendula officinalis* L.), and ginger rhizome PhEur (*Zingiber officinale* Roscoe).

#### Outcome measurements

At baseline and at the 6-week termination of the study, volunteers completed two surveys, the Chronic Sinusitis Survey (CSS) and the Short Form-36 (SF-36). Through the CSS, volunteers self-reported their symptoms (sinus congestion, sinus drip, headache, or facial pain) and severity of symptoms. Study candidates and/or their physicians indicating administration of prescribed or over-the-counter sinus medications were excluded from the study. The SF-36 assessed their general HRQL.

Chronic Sinusitis Survey (CSS). The CSS screen is a six-item, duration-based monitor of sinusitis-specific outcomes that has demonstrated statistical reliability and validity (see

Appendix).<sup>12</sup> It examines duration of specific sinusitis symptoms and duration of medication use (in this case to detect noncompliant medication use). In addition, we included an extra question set about the severity of the symptoms from the severity-based CSS. All questions were scored from 1 to 4 or 5 for the Likert-type scale. Then, the duration-based questions were rescored and organized into symptom and medication subscales as well as a total score each calculated on a scale from 0 (worst) to 100 (best).<sup>12</sup> The CSS is an efficient and responsive instrument that has been validated in many populations.<sup>12,15,16,17,18</sup>

**Short Form-36 (SF-36).** The SF-36 was used to characterize HRQL measures among the study population. The SF-36 has been widely used and tested to determine the relative burden of different disease conditions and populations including ethnic minorities and the elderly.<sup>19–22</sup>

This SF-36 questionnaire represents HRQL measures and can be self-administered, typically taking less than 10 minutes to complete (see Appendix). It is divided into two component scores: the physical component score (PCS) and the mental component score (MCS). The PCS consists of four health domains: (1) physical functioning; (2) role functioning–physical; (3) bodily pain; and (4) general health. The MCS comprises four mental health domains: (1) vitality; (2) social functioning; (3) role functioning–emotional; and (4) mental health. SF-36 items and scales are constructed on a Likert method of summated ratings. The subscores and the PCS and MCS scores were normalized to a scale ranging from 0 (worst) to 100 (best) according to published algorithms.<sup>23</sup>

**Statistical analysis.** The scores from the measurement screens SF-36 and CSS collected at baseline and at the 6-week termination of the study were analyzed using Student's *t* test and comparisons of association. In addition, several individual questions from the two surveys were assessed separately to highlight aspects of the volunteers' general quality of life and the duration and severity of some symptoms. The internal consistency of the CSS and SF-36 surveys was evaluated using Cronbach's  $\alpha$  correlation coefficients. Statistical significance was set to 0.05. We used SPSS for Windows software (Statistical Package for Social Sciences, SPSS Inc., Chicago, IL), version 13.0, for these analyses.

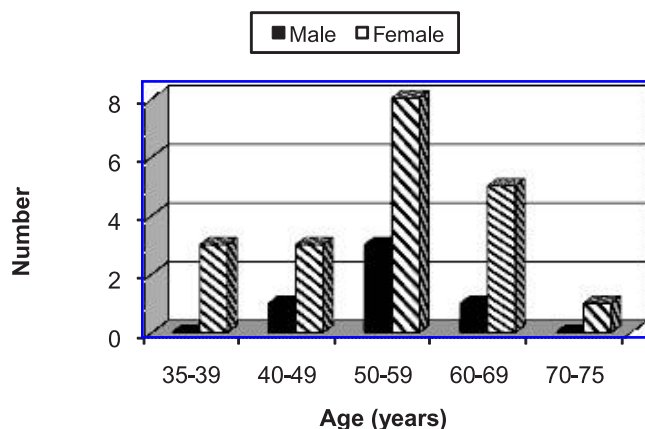


FIG. 1. Distribution of age by gender of tea q.i.d. group participants.

TABLE 1. AGE AND GENDER DISTRIBUTION OF PARTICIPANTS IN TEA Q.I.D. GROUP

	Number	%
<b>A. Gender</b>		
Female	21	78
Male	6	22
Total	27	100
<b>B. Age (37–75)</b>		
	Number	%
35–39	3	11
40–49	4	15
50–59	11	39
60–69	6	23
70–75	1	4
Missing	2	8
Total	27	100
Average = 53 ± 9.59 years (Mean ± SD)		

SD, standard deviation.

**Compliance.** At each 2-week study interval, the tea dosage compliance was confirmed by the PI, who monitored the number of returned unopened tea bags and volunteer's consumption report in their Daily Diary schedule. Tea dosage measurements were analyzed by the biostatistician at b.i.d., t.i.d., and q.i.d.

## Results

Of the 100 candidates who applied for enrollment, 55 met the entrance criteria for participation. Of these, 41 volunteers completed the study; 27 complied with the q.i.d. study dosage schedule. Over one third of the recruited candidates interested in the study had attendance challenges or did not meet the inclusion criteria. Fourteen (14) study volunteers had self-selected out due to lack of transportation or family supports. Recruitment and retention interruptions were due to winter holidays for the volunteers, agencies, and clinics that supported this study. African Americans reportedly have a disproportionate number of health challenges such as some or all of the metabolic syndrome, hypertension, type 2 diabetes, and hyperlipidemia. Hypertension was a significant exclusion factor for tea consumption among 33 candidates. The ages of the volunteers in the q.i.d. group ranged from 35 to 75 years, average = 53 ± 9.59 years (mean ± standard error of the mean), of whom 78% were female (Fig. 1; Tables 1A and 1B).

**CSS.** The CSS duration scores are shown in Table 2 for the q.i.d. tea group. Symptom scores reflected a significant increase post tea consumption (difference in mean 22.0 points;  $p = 0.020$ ) as does the total score (11.1 points;  $p = 0.020$ ). The medication score was 100 and did not change ( $p > 0.05$ ) relative to volunteers reporting no self-administration of prescribed or over-the-counter sinus medications from baseline to term. Tea consumption reports q.i.d. were

TABLE 2. CHRONIC SINUSITIS SURVEY (CSS) AND SHORT FORM-36 (SF-36) OUTCOMES

	Mean ± SD (n = 27)		Difference in means	p-value
	Baseline	6-week termination		
CSS symptom	58.9 ± 24.7	80.9 ± 23.4	22.0	0.020
CSS medication	100 ± 0.00	100 ± 0.00	0.00	p > 0.05
CSS total	79.4 ± 12.3	90.5 ± 11.7	11.1	0.020
CSS severity	66.4 ± 25.4	88.4 ± 24.8	22.0	0.005
SF-36 PF	86.5 ± 22.5	87.1 ± 17.0	0.60	p > 0.05
SF-36 RP	60.4 ± 38.4	69.2 ± 38.5	8.80	p > 0.05
SF-36 BP	69.7 ± 21.9	79.8 ± 20.5	10.1	p > 0.05
SF-36 GH	76.4 ± 17.7	80.5 ± 11.9	4.10	p > 0.05
SF-36 SF	85.3 ± 17.1	87.5 ± 19.1	2.20	p > 0.05
SF-36 VT	70.8 ± 20.8	75.6 ± 21.4	4.80	p > 0.05
SF-36 RE	66.7 ± 39.8	76.6 ± 34.7	9.90	p > 0.05
SF-36 MH	88.1 ± 17.7	91.1 ± 16.0	3.00	p > 0.05
SF-36 PCS	48.0 ± 8.52	51.1 ± 6.90	3.10	p > 0.05
SF-36 MCS	51.4 ± 9.36	53.6 ± 7.49	2.20	p > 0.05

p-value significance (p < 0.05); SD, standard deviation; PF, physical functioning; RP, role functioning-physical; BP, bodily pain; GH, general health; SF, social functioning; VT, vitality; RE, role functioning—emotional; MH, mental health; PCS, physical component score; MCS, mental component score.

consistent with sinus relief in reducing symptoms over the course of the study. According to a review of clinical outcomes in chronic sinusitis,<sup>22</sup> an 8-point change in score requires a 50% reduction in the duration of symptoms or medication usage. The Severity score for symptoms showed a significant change over the course of the study (difference of 22 points; p = 0.005; Table 2).

Question 1 queries for reduction in the duration of headache/facial pain showed significance (p = 0.004) as well as for nasal congestion (p = 0.035). There was no evidence of reduction in the duration of nasal drainage/postnasal drip (p > 0.05) (Table 3A). Question

3, querying sinusitis severity symptoms, found significant reduction of headache/facial pain (p = 0.035) and nasal congestion (p = 0.024), but not for nasal drainage/postnasal drip or their ability to smell (p > 0.05) (Table 3B). Additionally, volunteers reported improved ability to fall/remain asleep (p = 0.032).

Cronbach’s α correlation coefficients for internal consistency were calculated as 0.267 for symptoms, 0.257 for medications, and 0.390 for total score. The severity score had a Cronbach’s α of 0.285. This level of internal consistency was similar to that of a Norwegian study, where the low α’s were attributed to the small number of survey items.<sup>16</sup>

TABLE 3. TEA Q.I.D. VOLUNTEERS’ HEALTH STATUS—CHRONIC SINUSITIS SURVEY

A. Question #1: During the past week, how many days have you had \_\_\_\_\_ ?  
(Scale: 1 = 0 days; 2 = 1–2 days; 3 = 3–4 days; 4 = 5–6 days; 5 = 7 days)

Question #1 duration	Mean ± SD (n = 27)		p-value
	Baseline	6-week termination	
Headache/facial pain	2.55 ± 1.19	1.74 ± 0.86	p = 0.004
Nasal drainage/postnasal drip	2.70 ± 1.48	2.25 ± 1.33	p > 0.05
Nasal congestion	2.86 ± 1.52	1.90 ± 1.06	p = 0.035

SD, standard deviation.

B. Question #3: During the past week, how much have the following symptoms bothered you?  
(Scale: 1 = Not at all; 2 = A little; 3 = A moderate amount; 4 = A lot)

Question #3 severity	Mean ± SD (n = 27)		p-value
	Baseline	6-week termination	
Headache/facial pain	2.43 ± 1.14	1.90 ± 0.85	p = 0.035
Nasal drainage/postnasal drip	2.42 ± 1.29	2.05 ± 1.02	p > 0.05
Nasal congestion	2.75 ± 1.04	1.95 ± 0.94	p = 0.024
Ability to smell	1.95 ± 1.02	1.54 ± 0.89	p > 0.05
Difficulty falling asleep	2.45 ± 1.29	1.45 ± 0.88	p = 0.032

SD, standard deviation.

SF-36. From the SF-36, among the 27 volunteers in the q.i.d. group at baseline, overall general health (question 1) was reported by 10 as “very good,” 9 as “good,” and 5 as “fair” (Table 4A). At the 6-week term, the q.i.d. group increased their reported general health to 12 as “very good” and 12 as “good” ( $p = 0.001$ ) (Table 4B).

In contrast, when the overall general health subscores and physical and mental component scores of the SF-36 were examined, there were no significant changes after tea administration ( $p > 0.05$ ) (Table 2). In our study, the internal consistency of the SF-36 was good, with Cronbach’s  $\alpha$  correlation coefficients calculated as 0.673 for the PCS and 0.671 for the MCS. It should be noted that, for some diseases, disease-specific health measures are more sensitive to change than are the scores of the SF-36.<sup>12</sup>

In consideration of both surveys, volunteers’ reports of q.i.d. consumption indicated a reduction in the duration and severity of symptoms over the course of the study (nasal drainage/postnasal drip; nasal congestion; and headache/facial pain, Table 3). Responses to the severity of symptoms were significant for headache/facial pain ( $p = 0.004$ ) and nasal congestion ( $p = 0.035$ ). Volunteer’s reports indicated that q.i.d. tea consumption has significance in managing their CRS (e.g., sleep).

## Discussion

This preliminary pilot study reflects sinus and health quality of life status changes in African American volunteers associated with the self-administration of an herbal tea, Breathe Easy. Although this study’s sample size was less than anticipated, it appears that these preliminary findings are significant for this hard to outreach and retain minority population. Additionally, we have compiled valuable indicators for further CAM respiratory health research among African Americans in the southeast, the highest region of CRS prevalence in the United States.<sup>1</sup>

The CSS variables explored over time (between baseline and study term) indicate that the sinus disease health belief within the behaviors changed. We postulate that HRQL has determinants for health and wellness, in particular, sinus

health. George et al. (2003) proposed that the beliefs and attitudes of African American patients influence clinical treatment and explain, in part, low adherence to medical therapy and the consequent high burden of morbidity from asthma among low-income urban minorities.<sup>24</sup>

This study does appear to fit into the goals identified in The National Center for Complementary and Alternative Medicine Strategic Plan 2005–2009.<sup>25</sup> The research was conducted by a multidisciplinary team of mainstream practitioners and researchers, with phytotherapists and the herb industry. This partnership was undertaken to do the following:

- Study the efficacy of Breathe Easy tea among a minority population in the maintenance of URT health, an area of great public health importance
- Augment understanding of the social and cultural factors and beliefs relating to self-care of CRS with an herbal preparation among minority populations
- Investigate whether the utilization of Breathe Easy herbal tea improved the quality of life among a population of African Americans with CRS.

The authors recognize some limitations in this preliminary pilot study, including the small sample size and the fact that the study was not designed as a randomized, controlled trial. The prescreening recruitment interval outreached 100 interested candidates with self-reports of CRS. Study exclusion criteria such as candidates’ contraindications to the investigational product, no substantiation of a CRS diagnosis from their physician, and out-of-home placements decreased the numbers for enrollment at the intake interval.

Additional study limitations included the absence of a control group, which would have supported additional findings for a study of this magnitude. Age and gender may be factors among this hard-to-outreach ethnic group. A future study to alter limitations might include criteria for a clinic-based site, African American women 40–60 years of age, with limited morbidity contraindications to the tea, and an education intervention with cause-and-effect parameters.

TABLE 4. TEA Q.I.D. VOLUNTEERS’ HEALTH STATUS—SHORT FORM-36

A. Question #1: In general, would you say your health is:					
	Percentage of study volunteers—%				
Overall health (question #1)	Excellent	Very good	Good	Fair	Poor
Baseline	14	35	34	17	0
Study term	11	45	44	0	0

B. Question #1: In general, would you say your health is: (Scale: 1 = Excellent; 2 = Very good; 3 = Good; 4 = Fair; 5 = Poor)	
Overall health (question #1)	Mean $\pm$ SD
Baseline	2.67 $\pm$ 0.95
6-week termination	2.33 $\pm$ 0.68
N	27
t value	8.57
p value	0.001

SD, standard deviation.

## Conclusions

This preliminary pilot study suggests that q.i.d. self-administration of Breathe Easy was associated with a beneficial health influence in the management of CRS. Subjective reports from volunteers indicate health enhancements with noted significance to sleep (Table 3). Our results suggest that positive sleep change in the management of CRS may be a factor to further examine among this ethnic population and other groups with this disease. To further assess efficacy and applicability to other populations, randomized controlled trials in larger populations are warranted.

## Acknowledgments

We wish to thank Katie Huggins, VP of Quality Control, Traditional Medicinals, for her role in the manufacture and quality control of the investigational product. We would also like to acknowledge Marvin L. Crawford, M.D., Brenda Hayes, D.S.W., M.P.H., Andrew Reed, Littron Cole, RW & Associates, Quality Living Services, Providence Missionary Baptist Church, Positive Passtime, Inc., Rainbow Women's International Inc., Green Forest Baptist Church, and Green Pastures Church. This study was funded, in part, by Traditional Medicinals, the manufacturer of the investigational product.

## Disclosure Statement

Two of the study co-authors, David Hoffmann and Josef Brinckmann, are researchers employed by Traditional Medicinals. While they participated along with the lead investigators in the development of the study protocol, Traditional Medicinals had no involvement in, or control over, the conduct of the study, nor in the collection, analysis, or interpretation of the data. The other authors have no conflicts.

## References

- Anand VK. Epidemiology and economic impact of rhinosinusitis. *Ann Otol Rhinol Laryngol* 2004;193:3–5.
- Cherry DK, Woodwell DA. National Ambulatory Medical Care Survey: 2000 Summary. Hyattsville, MD: National Center for Health Statistics, 2000.
- National Centre for Health Statistics. Fast Stats A to Z: Chronic Sinusitis. Hyattsville, MD: National Center for Health Statistics. Online document at: [www.cdc.gov/nchs/fastats/sinuses.htm](http://www.cdc.gov/nchs/fastats/sinuses.htm) Accessed November 29, 2007.
- National Institute of Allergy and Infectious Diseases. Sinus Infection (Sinusitis). Bethesda, MD: National Institute of Allergy and Infectious Diseases. Online document at: [www.niaid.nih.gov/healthscience/healthtopics/sinus/overview.htm](http://www.niaid.nih.gov/healthscience/healthtopics/sinus/overview.htm) Accessed November 29, 2007.
- Ray NF, Baraniuk JN, Thamer M, Rinehart CS, et al. Healthcare expenditures for sinusitis in 1996: Contributions of asthma, rhinitis, and other airway disorders. *J Allergy Clin Immunol* 1999;103(3 Pt 1):408–414.
- Sinus and Allergy Health Partnership. Antimicrobial treatment guidelines for acute bacterial rhinosinusitis. *Otolaryngol Head Neck Surg* 2004;130(1 suppl):1–45.
- Graham RE, Ahn AC, Davis RB, et al. Use of complementary and alternative medical therapies among racial and ethnic minority adults: Results from the 2002 National Health Interview Survey. *J Natl Med Assoc* 2005;97:535–545.
- Becker MH. The health belief model and personal health behavior. *Health Educ Monogr* 1974;2:324–473.
- Rosenfeld RM, Andes D, Bhattacharyya N, et al. Clinical practice guideline: Adult sinusitis. *Otolaryngol Head Neck Surg* 2007;137(3 suppl):S1–S31.
- Bhattacharyya N. The economic burden and symptom manifestations of chronic rhinosinusitis. *Am J Rhinol* 2003;17:27–32.
- Ressel G. Practice guidelines, sinus and allergy health partnership releases report on adult chronic rhinosinusitis. *Am Family Physician* 2004;69:2248–2249.
- Gliklich RE, Metson R. The health impact of chronic sinusitis in patients seeking otolaryngologic care. *Otolaryngol Head Neck Surg* 1995;113:104–109.
- Senior B, Glaze C, Benninger M. Use of the rhinosinusitis disability index in rhinologic disease. *Am J Rhinol* 2001;15:15–20.
- Pharmacopoeia Commission of PRC. Pharmacopoeia of the Peoples Republic of China, English edition (1997). Beijing: Chemical Industry Press, 1997:251.
- Linder JA, Singer DE, Ancker M, Atlas SJ. Measures of health-related quality of life for adults with acute sinusitis: A systematic review. *J Gen Intern Med* 2003;18:390–401.
- Stavem K, Rossberg E, Larsson PG. Reliability, validity and responsiveness of a Norwegian version of the Chronic Sinusitis Survey. *BMC Ear Nose Throat Disord* 2006;6:9.
- Wang PC, Tai CJ, Chu CC, Liang SC. Translation and validation assessment of the Chinese version of the chronic sinusitis survey. *Chang Gung Med J* 2002;25:9–15.
- Metson RB, Gliklich RE. Clinical outcomes in patients with chronic sinusitis. *Laryngoscope* 2000;110(3 Pt 3):24–28.
- Staniszewska S, Ahmed L, Jenkinson C. The conceptual validity and appropriateness of using health-related quality of life measures with minority ethnic groups. *Ethn Health* 1999;4:51–63.
- Bennett JA, Riegel B. United States Spanish short-form-36 health survey: Scaling assumptions and reliability in elderly community-dwelling Mexican Americans. *Nurs Res* 2003;52:262–269.
- Peek MK, Ray L, Patel K, et al. Reliability and validity of the SF-36 among older Mexican Americans. *Gerontologist* 2004;44:418–425.
- Lyons RA, Perry HM, Littlepage BN. Evidence for the validity of the Short-form 36 Questionnaire (SF-36) in an elderly population. *Age Ageing* 1994;23:182–184.
- International Resource Center for Health Care Assessment. How to Score the Medical Outcomes Study (MOS) 36-Item Short-Form Health Survey (SF-36). Boston: MOS Trust, 1991.
- George M, Freedman TG, Norfleet AL, et al. Qualitative research-enhanced understanding of patients' beliefs: Results of focus groups with low-income, urban, African American adults with asthma. *J Allergy Clin Immunol* 2003;111:967–973.
- National Center for Complementary and Alternative Medicine (NCCAM). Expanding Horizons of Health Care: Strategic Plan 2005–2009. 2005. Online document at: <http://nccam.nih.gov/about/plans/2005/strategicplan.pdf> Accessed November 29, 2007.

Address reprint requests to:

Josef A. Brinckmann  
Research and Development Department  
Traditional Medicinals  
4515 Ross Road  
Sebastopol, CA 95472

E-mail: [jbrinckmann@tradmed.com](mailto:jbrinckmann@tradmed.com)

APPENDIX

1) Short Form-36 Health Survey

2) Chronic Sinusitis Survey

Study Volunteer ID Number \_\_\_\_\_  
 (First initial of last name and last 4 digits of phone number)

Date \_\_\_\_\_

*Short Form-36 Health Survey: Your Health and Well-Being—Recall*

This survey asks for your views about your health, how well you feel, and how well you are able to do your usual activities. Thank you for completing this survey!

For each of the following questions, please mark an “X” in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor

2. Compared to 1 year ago, how would you rate your health in general now?

Much better than 1 year ago	Somewhat better now than 1 year ago	About the same as 1 year ago	Somewhat worse than 1 year ago	Much worse now than 1 year ago

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	Not limited at all
<u>Vigorous activities</u> , such as running, lifting heavy objects, participating in strenuous sports			
<u>Moderate activities</u> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf			
Lifting or carrying groceries			
Climbing <u>several</u> flights of stairs			
Climbing <u>one</u> flight of stairs			
Bending, kneeling, or stooping			
Walking <u>more than a mile</u>			
Walking <u>several blocks</u>			
Walking <u>one block</u>			
Bathing or dressing yourself			

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
Cut down on the amount of time you spent on work or other activities		
<u>Accomplished less</u> than you would like		
Were limited to the <u>kind</u> of work or other activities		
Had <u>difficulty</u> performing the work or other activities (for example, it took extra effort)		

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
Cut down on the <u>amount of time</u> you spent on work or other activities <u>Accomplished less</u> than you would like		
Did work or other activities less carefully <u>than usual</u>		

6. During the past 4 weeks, to what extent have your physical health or emotional problems interfered with your normal modal activities with family, friends, neighbors, or groups?

Not at all	Slightly	Moderately	Quite a bit	Extremely

7. How much bodily pain have you had during the last 4 weeks?

None	Very mild	Mild	Moderate	Severe	Very Severe

8. During the next 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Did you feel full of pep?						
Have you been a very nervous person?						
Have you felt so down in the dumps that nothing could cheer you up?						
Have you felt so calm and peaceful?						
Did you have a lot of energy?						
Have you felt downhearted and blue?						

9. (Continued) These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
Did you feel worn out?						
Have you been a happy person?						
Did you feel tired?						

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time

11. How TRUE or FALSE is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
I seem to get sick a little easier than other people					
I am as healthy as anybody I know					
I expect my health to get worse					
My health is excellent					

Male	Female

Age

*Thank you for completing these questions!*

Study Volunteer ID Number \_\_\_\_\_ Date \_\_\_\_\_  
 (First initial of last name and last 4 digits of phone number)

*Chronic Sinusitis Survey – Weekly Recall*

This survey asks for your view about your sinus symptoms and treatment.  
 Answer every question by circling the appropriate number.  
 If you are unsure about how to answer a question, please give the best answer you can.

1. During the past week, how many days have you had: (Mark the box in each row with an “X”)

Sinus headaches, facial pain, or pressure	0 days	1–2 days	3–4 days	5–6 days	7 days
Nasal drainage or postnasal drip	0 days	1–2 days	3–4 days	5–6 days	7 days
Nasal congestion or difficulty breathing through your nose	0 days	1–2 days	3–4 days	5–6 days	7 days

2. During the past week, how many days have you taken: (Mark the box in each row with an “X”)

Antibiotics	0 days	1–2 days	3–4 days	5–6 days	7 days
Nasal sprays prescribed by your doctor	0 days	1–2 days	3–4 days	5–6 days	7 days
Sinus medications in pill form (such as antihistamines, decongestants)	0 days	1–2 days	3–4 days	5–6 days	7 days

3. During the past week, how much have the following symptoms bothered you? (Mark the box in each row with an “X”)

Sinus headaches, facial pain, or pressure	Not at all	A little	A moderate amount	A lot
Nasal drainage or postnasal drip	Not at all	A little	A moderate amount	A lot
Nasal congestion or difficulty breathing through your nose	Not at all	A little	A moderate amount	A lot
A reduced ability to smell things	Not at all	A little	A moderate amount	A lot
Difficulty falling asleep or disturbed sleep	Not at all	A little	A moderate amount	A lot

4. Who completed this form? (Mark the box with an “X”)

I filled it out myself	Someone asked me the questions	By telephone
------------------------	--------------------------------	--------------

Male	Female
------	--------

Age
-----

*Thank you for completing these questions!*