BRIEF REPORT

A PILOT STUDY OF MIND-BODY CHANGES IN ADULTS WITH ASTHMA WHO PRACTICE MENTAL IMAGERY

Gerald N. Epstein, MD, James P. Halper, MD, Elizabeth Ann Manhart Barrett, RN, PhD, FAAN, Carole Birdsall, RN, EdD, Monnie McGee, PhD, Kim P. Baron, MA, Stephen Lowenstein, MS, RRT

Gerald N. Epstein, MD, is assistant clinical professor of psychiatry, The Mount Sinai Medical Center, New York, NY, and director, The American Institute for Mental Imagery, New York, NY. **James P. Halper, MD,** is chief for research, Lenox Hill Hospital, New York, NY, and clinical associate professor of psychiatry New York University Medical School. **Elizabeth Ann Manhart Barrett, RN, PhD, FAAN,** is professor emerita at the School of Nursing, Hunter College, City University of New York and health patterning therapist, New York, NY. **Carole Birdsall, RN, EdD,** is professor at the School of Nursing, Hunter College, City University of New York. **Monnie McGee, PhD,** is assistant professor, Dept. of Mathematics and Statistics, Southern Methodist University. **Kim P. Baron, PhD,** is a clinical psychologist. **Stephen Lowenstein, MS, RRT,** is director, Pulmonary Laboratory and Sleep Diagnostic Center, Lenox Hill Hospital, New York, NY.

Context • *Despite the growing number of studies of imagery and the use of complementary and alternative modalities as treatments for asthma, research on mental imagery in adults with asthma is practically nonexistent. The purpose of this feasibility study was to lay groundwork for a larger follow-up clinical trial.*

Objective • *To determine whether pulmonary function, asthma symptoms, quality of life, depression, anxiety, and power differ over time in adults with asthma who do and do not practice mental imagery (MI). (Power is the ability to make aware choices with the intention of freely involving oneself in creating desired change.)*

Design • *Randomized controlled study using univariate repeated measures analysis of variance (ANOVA) and replacement through block design.*

Setting • *Lenox Hill Hospital, an affiliate of New York University Medical School, New York, NY.*

Subjects • *Sixty-eight adults with symptomatic asthma, after 4 weeks of baseline data collection and analysis, met requirements for this randomized controlled study. Thirty-three completed pulmonary function as well as self-report tests at 4 time points over 17 weeks. The 16 experimental participants also completed the 4-session imagery protocol.*

Intervention • *Individual imagery instruction (week 1) and follow-up (weeks 4, 9, 15). Participants were given 7 imagery exercises to select from and practice 3 times a day for a total of 15 minutes.*

Main Outcome Measures • *1) Spirometry (FEV_1); 2) medication use; 3) Asthma Quality of Life Questionnaire; 4) Beck Depression Inventory; 5) Spielberger Anxiety Scales (A-State and A-Trait); 6) Barrett Power as Knowing Participation in Change Tool, Version II; 7) Epstein Balloon Test of Ability to Image.*

Results • *There was little evidence of statistical change in this feasibility study; yet, valuable lessons were learned. Paired t-tests indicated there was a significant difference in the total power scores in the imagery group, and in the expected direction (two-tailed, t-statistic = –2.3, P = 0.035) and the choices sub-scale (two-tailed, t-statistic = –2.93, P = 0.01) of the power instrument from weeks one to 16 of the study. Eight of 17 (47%) participants in the MI group reduced or discontinued their medications. Three of 16 (19%) participants in the control group reduced their medications; none discontinued. Chi-square indicated differences between groups (X^2 = 4.66, P = 0.05). Persons who reduced or discontinued their medications showed neither an increase in pulmonary function prior to medication discontinuation, nor a fall in these parameters following discontinuation.*

Conclusions • *Findings related to major outcome measures must be viewed with caution due to the small sample size resulting from attrition related to labor intensiveness and, therefore, low statistical power. However, the study did provide significant data to plan a larger scale study of the use of mental imagery with adult asthmatics. The study also demonstrated that imagery is inexpensive, safe and, with training, can be used as an adjunct therapy by patients themselves. Its efficacy needs additional exploration. Further research for adults with asthma who practice imagery is important, as current treatments are not entirely efficacious. Lessons learned in this study may facilitate improvement in research designs. (Altern Ther Health Med. 2004;10(4):66-71.)*

Reprint requests: InnoVision Communications, 169 Saxony Road, Suite 103, Encinitas, CA 92024; phone, (866) 828-2962 or (760) 633-3910; e-mail, alternative.therapies@innerdoorway.com.

Asthma continues to increase at an alarming rate in the United States for all age, sex, and racial groups.[1] More than 17 million people in the U.S. have asthma.[2] Despite recent advances, treatment is not entirely effective; innovative, evidence-based strategies are needed.[3] The use of complementary and alternative medicine (CAM) is also rapidly ris-

ing, partly because people want to be more powerful partners in their care.[4] Mental imagery (MI) is a CAM modality whereby people use the natural language of the mind to create images that affect the body.[5-8] The purpose of this study was to examine the efficacy of MI to empower people to more effectively manage asthma symptoms and improve the quality of their lives.

Research Questions

The study team asked the following questions:

1. Do volume of air forced out of the lungs in one second (FEV_1) and Peak Expiratory Flow Rate (PEFR) differ over time in adults with asthma who do and do not practice mental imagery?
2. Do depression, anxiety, quality of life, and power differ over time in adults with asthma who do and do not practice mental imagery?
3. Do symptoms and "events" (relapses, major flares) differ over time in adults with asthma who do and do not use mental imagery?

METHODS

Design

This was a randomized controlled study using univariate repeated-measures analysis of variance (ANOVA). Random assignment to the imagery or no imagery group considered factors of sex, race, age, atopy, severity, treatment regimen, and smoking; a block design was used.

Inclusion and Exclusion Criteria

Inclusion criteria included: 1) one diagnosis of asthma confirmed by pulmonary function testing; 2) ages 25-55; 3) ability to read, speak, and understand English.

Exclusion criteria included: 1) unstable medical conditions and/or conditions being treated with agents directly affecting the nervous system; 2) psychotropic drugs for prior 6 months; 3) psychiatric hospitalizations in last 2 years; 4) axis I psychiatric disorder; 5) asthma related hospitalizations in prior 6 months; 6) $FEV_1 < 50\%$; 7) significant irreversible airway obstruction; 8) upper respiratory infections within prior 6 weeks; 9) innovative anti-inflammatory agents such as methotrexate; 10) not at baseline and requiring immediate treatment alteration; and, 11) negative results on the Epstein Balloon Screening Test for Imagery Ability.[6]

Instruments

Instruments included: 1) demographic information form; 2) measurement of symptom intensity using patient diaries; 3) measurement of airflow impairment including: a) peak expiratory flow rate using peak flow meters and recorded in diaries; b) spirometry as measured by FEV_1 at baseline and weeks 4, 10, and 16 in the hospital pulmonary laboratory; 4) medication use as determined by quantitative change as well as changes in the nature of the regimen (addition or subtraction) and recorded in diaries; 5) Asthma Quality of Life Questionnaire (AQLQ);[9,10] 6) Beck Depression Inventory (BDI);[11] 7) Spielberger Anxiety Scales (A-State; A-Trait);[12] 8) qualitative measurement of imagery ability using The Epstein Balloon Test[6]; and, 9) Barrett Power as Knowing Participation in Change Tool, Version II (PKPCT).[13,14] Internal consistency reliability of the AQLQ, BDI, PKPCT, A-State, and A-Trait were computed for week 1 and week 16 using Cronbach's alpha and ranged from 0.89 to 0.99 for the various instruments.

Imagery Treatment Protocol

Following Institutional Review Board approval, participants who were randomized, after completion of pre-testing and the baseline period, to the imagery group were seen by a therapist trained in imagery therapy at weeks 1, 4, 9, and 15 for imagery instruction and follow-up. Each participant was given 7 imagery exercises to select from and practice three times a day for a total of 15 minutes. Spirometry and paper-pencil testing occurred one week after each of the 3 imagery follow-up visits. An example of one of the 7 standard imagery exercises is presented in Box 1. The control group received no intervention.

Sample Screening and Selection

Participants were recruited through the hospital asthma clinic, newspaper advertisements, posted flyers, and word of mouth. A sample size of 60 was proposed; 68 began and 33 finished. Therefore, the power to detect a moderate treatment effect at a 0.05 level of significance decreased from 0.8 to 0.35. During screening, ability to image was assessed using the qualitative Epstein Balloon Test. Participants were asked to close their eyes and imagine seeing a box of colored balloons on a table and to take one out and blow it up.[6] If unable to visualize in this imagery exercise, they were excluded. Persons with asthma were given pulmonary function tests (FEV_1) in the hospital laboratory to confirm a diagnosis of asthma in the moderate or moderately severe categories defined by the National Asthma Expert Panel.[1] A reduced FEV_1, the volume of air forced out of the lungs in one second, indicates increased airflow obstruction as seen with asthma. Scores are reported as percent of normal predicted for persons in a particular category of asthma severity. While 329 were initially screened by phone, only 68

Box 1 Example of Imagery Exercise

"Taking a Weight Off Your Chest"[6]

Close your eyes and breathe out three times slowly. See and sense a weight on and in your chest. Feel and sense the constriction it gives you. Breathe out one time slowly and remove this weight. See and sense your lungs expanding and filling with white light as you find your breathing becoming easy and flowing. Then, open your eyes.

(NOTE: In addition to its scheduled use, this exercise was to be done at any time chest constriction was sensed.)

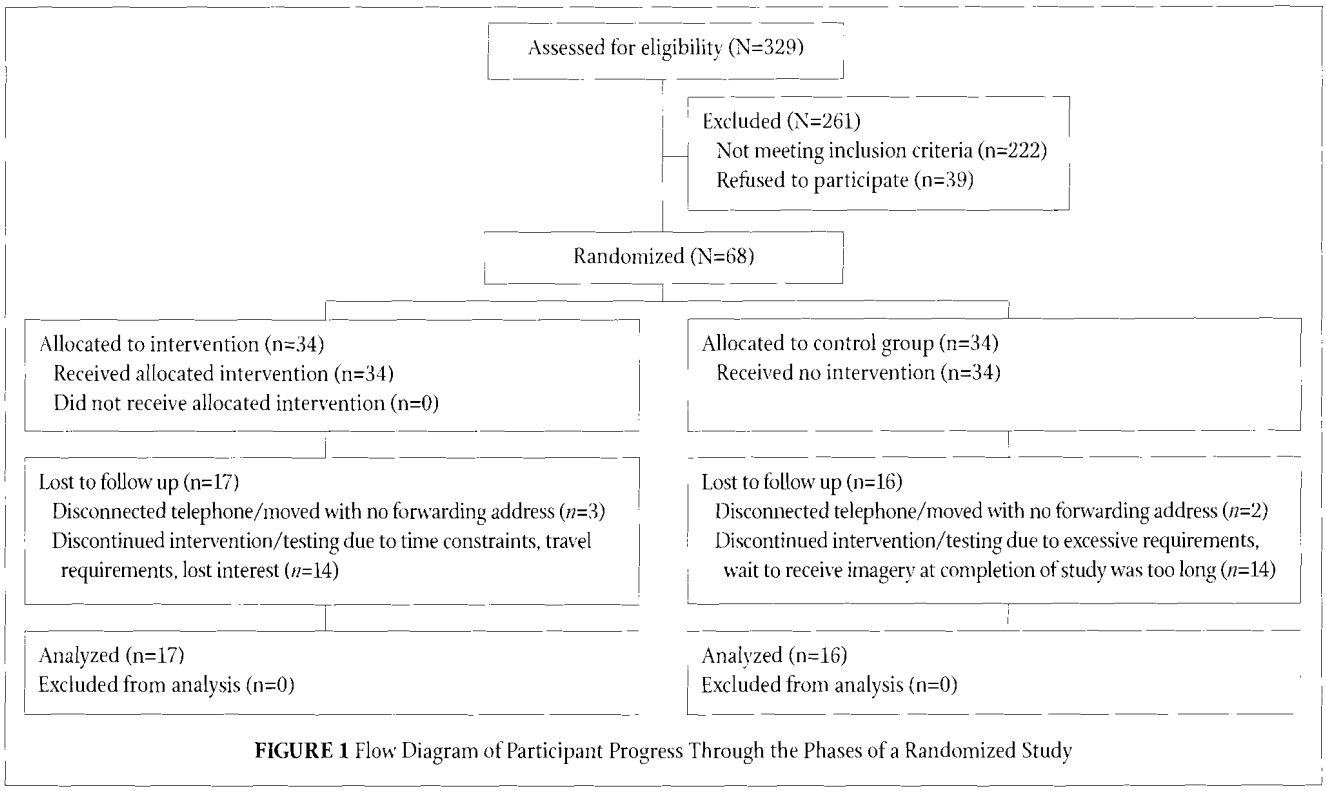

FIGURE 1 Flow Diagram of Participant Progress Through the Phases of a Randomized Study

met requirements after completing 4 weeks of baseline data collection and pre-testing.

Data Collection

Following randomization, 17 participants completed 4 imagery sessions over 16 weeks and 16 participants were in the control group. The consort diagram, in Figure 1, tracks the participants as they progressed through the study. Both groups continued usual care with their physicians and completed paper-pencil and laboratory tests at weeks 1, 4, 10, and 16. Using a block design for participant replacement, randomization remained intact. Table 1 presents demographics, indicators of asthma severity, and screening test scores. The control group was offered imagery sessions at the completion of the study.

After 4 weeks of baseline data collection, participants were scheduled for spirometry (FEV_1) at week 1, 4, 10, and 16. During these visits the AQLQ, BDI, A-Trait and the PKPCT were administered. Participants were provided with diaries to record symptoms, medication usage (including regimen changes), objective measures (PEFR morning and evening), A-State and BDI self reports, and frequency of practicing imagery exercises.

RESULTS

Initial baseline levels of all outcome variables were controlled for in the analysis. The first research question asked, "Do FEV_1 and PEFR differ over time in adults with asthma who do and do not practice mental imagery?" Repeated-measures-ANOVA tests with FEV_1 as the dependent variable, weeks of study as the repeated factor, and group membership as the between-groups factor show that differences between imagery and control groups are not statistically significant ($P = 0.35$). The change in mean FEV_1 value for the imagery group from week 1 to week 16 is not clinically significant. Excessive missing data prevented conducting analyses for differences in PEFR.

The second research question asked, "Do depression, anxiety, quality of life, and power differ over time in adults with asthma who do and do not practice mental imagery?" Using univariate-repeated measures-ANOVA, there were no statistically significant differences between groups for BDI, A-State, A-Trait, and AQLQ. The paired sample t-test that compared quality of life in week 1 with week 16 revealed a trend toward improvement in only the mental imagery group for the activity sub-scale (mean difference = 0.72; $P = 0.06$). Figure 2 presents a graph that lists the mean raw total power scores for four time periods and both treatment groups. Paired t tests for the imagery group comparing week 1 with week 16 showed statistically significant findings in the expected direction. The scores for total power (awareness, choices, freedom to act intentionally, and involvement in creating change) in the mental imagery group were higher at the end of the study than at the beginning (mean difference = –11.7; SD = 20.97; t-statistic = –2.3, P = 0.035). The control group scores were not statistically significant (mean difference = 7.19, SD = 53.35, t-statistic = 0.539, P = 0.538). The choices sub-scale scores of the PKPCT also increased when a paired sample t-test compared differences between week 1 and week 16 (mean difference = –4.65, SD =

TABLE 1 Demographic and other Characteristics (n=33)

Characteristic	Imagery (n=17)	Control (n=16)
Sex	Female: 73% Male: 27%	Female: 57% Male: 43%
Race	Caucasian: 76% African American: 24% Hispanic: 0	Caucasian: 69% African American: 20% Hispanic: 11%
Smokers	Yes: 31% No: 69%	Yes: 41% No: 59%
Allergies: Environmental Grasses, Animals, and/or Dust	Yes: 88% No: 12%	Yes: 80% No: 20%
Allergies: Food	Yes: 36% No: 64%	Yes: 29% No: 71%
Allergies: Medication	Yes: 46% No: 54%	Yes: 34% No: 66%
History of Upper Respiratory Infections	Yes: 76% No: 24%	Yes: 77% No: 23%
Exacerbation from Exercise	Yes: 52% No: 48%	Yes: 54% No: 46%
Five or Fewer Emergency Department Visits in Lifetime	Yes: 99% No: 1%	Yes: 88% No: 12%
Chronic Oral Steroid Use (Counts, Not Percents)	Week 1: 2 Week 16: 0	Week 1: 3 Week 16: 2
FEV_1 at Screening	67.29 % (SD 17.35%)	69.86 % (SD 13.57%)
AQLQ at Screening	X = 134.96 (SD 32.20)	130.33 (SD 34.5)
State Anxiety at Screening	X = 40.90 (SD 14.42)	39.86 (SD 13.28)
Trait Anxiety at Screening	X = 42.06 (SD 10.03)	41.48 (SD 13.56)
Depression at Screening	X = 9.67 (SD 9.12)	8.24 (SD 7.18)

6.54, t-statistic = – 2.931, P = 0.01). Again, the control group scores were not statistically significant (mean difference = 1.31, SD = 11.89, t-statistic = 0.442, P = 0.665).

The third research question asked: "Do symptoms and "events" (relapses, major flares) differ over time in adults with asthma who are and are not trained in mental imagery?" No significant values were found for differences between groups for coughing, wheezing, activity, sleep or adverse events, such as visits to an emergency department.

ADDITIONAL ANALYSES

Discontinuing or Decreasing Medications

Eight of the 17 (47%) MI participants reduced (n=4) or discontinued (n=4) their medications. Three of the 16 (19%) control participants reduced their medications, but none discontinued. Of the total group, 11 participants had a medication change and 22 had no medication change. A *chi-square* test of independence between treatment group and medication change was performed and indicated the 2 groups were statistically different (X^2 = 4.66, P = 0.05). Fisher's exact-test indicated that there might be an association between treatment group and medication change (P = 0.087). Despite the small cell sizes in the *chi-square* analysis, it is clinically significant that 4 participants using imagery discontinued their medications. Participants who did discontinue or decrease medications showed neither an improvement in pulmonary function prior to medication discontinuation nor a fall in these parameters following discontinuation. It is important to note that 5 participants were taking oral steroids at the beginning of the study and 2 were taking oral steroids at the end of the study. Of these, 2 were in the imagery group and both discontinued oral steroids; 3 were in the control group and 1 discontinued oral steroids.

Completers versus Noncompleters

Mann Whitney tests revealed no statistically significant differences between completers versus non-completers for scores on the BDI, PKPCT, and A-State or A-Trait Scales. For AQLQ total score and activity and emotional functioning subscale scores, those scoring higher at screening or week 1 were more likely to complete the study (each with P = 0.02).

DISCUSSION

Inclusion of objective measures of health status in the current study was designed to ensure patient safety in the event that change in participants' perception of symptoms led to undetected disease progression and/or inappropriate neglect of somatic treatment. In addition, participants remained in treatment with the primary care and/or specialist physicians of their choice during the study.

One possible explanation for not seeing an overall improvement in pulmonary function tests for the mental imagery group is that 8 of the 17 participants reduced or discontinued their asthma medication. On the other hand, it is possible that imagery is only effective as an addition to medication treatment, even though those who changed their medication had more positive scores on several of the psychosocial measures. It should be noted that the imagery participants did not experience a significant decrease in FEV_1. The sample was too small to compare FEV_1 of those who decreased or discontinued medications with imagers who did not; this requires further examination in future studies as does the long-term effects of discontinuing steroids. Despite these caveats, 47% of the imagers did decrease or discontinue medications and pul-

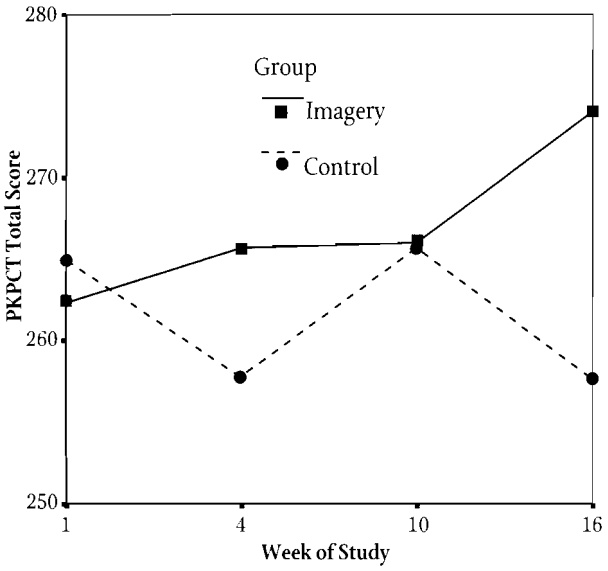

FIGURE 2 Power as Knowing Participation in Change Tool (PKPCT) Scores by Week of Study and Treatment Groups

monary function neither increased nor decreased prior to or following medication changes. This is an important finding as it might indicate that mental imagery did enable the participants to maintain their health status and simultaneously decrease or discontinue medications. The necessity of adequate imagery training with sufficient follow-up along with diligent adherence to imagery practice seems critical. With asthma, the effect of imagery is often experienced in the immediate relief of symptoms when using imagery during an attack or impending attack. This reinforces both the power of imagery as well as the power of the person to use the imagery process effectively.

Some of the most positive findings were differences in the 2 groups related to power. Imagery appears to be a means to enhance power in persons with asthma. Outcomes from the qualitative arm of the study, reported elsewhere, provided stronger evidence that power was enhanced in experimental participants.[15] For example, participants reported that the daily imagery regimen opened up possibilities for active participation in their treatment by often preventing or aborting dangerous asthma attacks, allowing them to feel safe, secure, and powerful.[15]

IMPLICATIONS FOR FUTURE RESEARCH

Considering that 8 participants in the mental imagery group decreased or went off their medications compared with only 3 in the control group who decreased medications, the lack of differences in FEV_1 between the 2 groups takes on new meaning and warrants future investigation. The data suggest that further exploration of the power variable be considered in future research since total power scores ($P = 0.04$) and the choices sub-scale scores ($P = 0.01$) increased from week 1 to week 16. There seemed to be an interaction between time and mean total PKPCT scores between the two groups. For both groups, the major change was between week 10 and 16, but in opposite directions. Both the importance of quality of life for persons with asthma and the findings from this study suggest further exploration of the relationship of imagery and quality of life, as well as the potential for the AQLQ to predict study completion. In future research, control for effect of additional time spent with experimental participants must be instituted along with long-term follow-up.

LESSONS LEARNED

The design for this study was too complex for the budget of $30,000. There were insufficient funds for advertising. Recruitment of participants was much more difficult than originally anticipated. This was likely due to excessively restrictive inclusion-exclusion criteria. Resources allowing for adequate staff time for follow up phone calls to both groups is also essential. The labor intensiveness of the study, along with lack of monetary remuneration, undoubtedly contributed to the 51% attrition; many participants who dropped out verbalized this. In addition, data kept in diaries, such as measurements from peak flow meters, was often missing and therefore not available for analysis. We learned that it is necessary to solicit only critical information, preferably by phone calls from study personnel to both groups, and that it is not necessary for participants to have such frequent pulmonary function tests. Paper-and-pencil tests could be completed at home and sent in by mail, thereby, requiring fewer in-person visits. Although all instruments were reliable, the depression and anxiety scales did not seem to add meaningful information and could be eliminated to relieve participant burden. Imagery could be reinforced by use of an audiotape, thus decreasing the number of in-person sessions. Findings from this study are being used to design a larger randomized controlled study.

CONCLUSIONS

The fact that there was little evidence of statistical change in this study may be attributable to the lack of statistical power to detect differences in the data because of the small sample size. These preliminary data can facilitate power and sample size calculations for a larger study. Future study designs can be enhanced using the lessons learned from this study, particularly with regard to facilitating sample recruitment and participant retention.

It was demonstrated that adults with asthma can learn to use mental imagery, sometimes with immediate relief of symptoms, and that mental imagery is safe, cost-effective, always available, and it requires little time to use. Some of these very preliminary findings suggest that imagery may make a positive difference in lives of asthmatics. Since current treatments are not completely efficacious, investigators are invited to further research the effectiveness of mental imagery in the treatment of adults with asthma.

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