

## **Pilot Study Summary**

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**The following summary is based on a self-reporting, preliminary study of the Formula that makes up Resprin. The below-described study was Not a clinical study. Accordingly, the results may not receive wide-acceptance by the relevant scientific community. Although the below-described study was conducted on asthma patients, this summary is not intended to imply that our product cures or treats any disease, including, without limitation asthma or other breathing conditions. Our product is not intended to diagnose, treat, cure or prevent any disease.**

The study was an open-label, pilot trial done in 2003 by an independent, well-respected research center. Open-label means that the researchers and subjects knew the type of product or “intervention” being administered. A pilot study refers to a preliminary study, which frequency occurs before the main study. This study was non-randomized. In other words, the treatment was not assigned at random to the study participants. The study did not include a placebo arm, which means that all participants received the treatment, as compared to one group taking a placebo. The study was conducted at an independent research facility. The study was assessed by a board-certified pulmonologist, who was impressed with the preliminary results. (Also see letter of Dr. Blum attached, in which he calls this study very promising.)

The purpose of the study was to observe the efficacy and short-term safety of Jiang Jing’s Amazin: An Herbal Blend Designed to Reduce Asthma Symptoms. Our product has the same formula as the Jiang Jing’s Amazin product. The Jiang Jing’s Amazin product includes a proprietary blend of 23 herbs used in traditional Chinese medicine. The blend is formulated to alleviate various lung conditions, or other types of congestion or inflammation. The dose of the Jiang Jing’s Amazin product is three grams, which was delivered in six capsules. This is the same as the serving size recommended in the Directions for Use on our label.

The study included three phases. Phase one of the study lasted for two weeks and involved a single dose of the Jiang Jing’s Amazin product on day one. Phase two lasted for two weeks and involved daily doses of the Jiang Jing’s Amazin product for the first week. Phase three lasted for one month. The researchers took blood from subjects at two, four and eight weeks. A registered nurse or the principal investigator saw all subjects at each visit to the research facility. The subjects in phase three were instructed to take the Jiang Jing’s Amazin product for a month.

The subjects of the study originated from the Bangor, Maine area. Subjects with alcohol abuse and major health issues were excluded from the study. Thirty-two subjects enrolled in the study, but only twenty-five started and completed phase one. One subject stopped after completing phase one of the study. Study subjects received \$100 after phase two was completed and \$25 after phase three was completed. The subjects included men and women, and ranged in age from 18 to 70 years of age. The subjects reported diagnosed or under-controlled asthma.

For purposes of this study, under-controlled asthma means those individuals requiring rescue inhalation at least two times a month.

The study tracked peak flow spirometry, frequency and the amount of asthma related medications, gross pulmonary functional status, amount of daily energy, P53, general health status and nursing assessment. Peak flow refers to a person's maximum speed of expiration. Spirometry generally refers to measuring breath through a pulmonary function test. P53 means a blood test used to detect a marker for lung disease. In addition to the primary outcomes listed above, the study also tracked blood pressure, pulse, respirations and overall well being. Peak flow was measured using two forms of analysis. Subjects were given questions to answer at each visit. One of the questions concerned the ability to climb two flights of stairs without experiencing any shortness of breath. The researchers tried to measure percent improvement as reported by the subject answers.

There were no serious adverse events reported in this study. The average peak flow for the subjects rose at each phase of the study. The nursing assessment, which involved a discussion between the nurse and each subject at each visit, demonstrated a linear pattern of improvement consistent with a dose-response relationship. The subjects did not show significant improvement with respect to the number and frequency of medications. Subject energy levels were more ambiguous with increases in reported energy and activity, and a slight drop at the end of phase three. There were no clinical differences for blood pressure, pulse and respirations. The study revealed no safety concerns with the Jiang Jing's Amazin product. **Approximately half of the subjects reported the highest level of improvement, and only one reported no improvement.** The study supports the efficacy of the herbal blend in the Jiang Jing's Amazin product because asthma symptoms were reduced, thus showing that respiratory function improved. The researchers observed that the product reduced chronic asthma symptoms, and allowed the subjects to recover their functional abilities of everyday activities.

Nu Century Herbs later engaged two scientists to review all the scientific literature as to the herbal ingredients in the product, and this Pilot Study, and to conduct in vitro testing of lung tissue. The overall conclusion of these scientists was as follows: "Similarly, both the experiments and the scientific literature above suggest that (or indicate that) the herbal product Resprin helps to promote proper immune function and normal inflammatory response in healthy adults." Please see their Report, also in this Ask the Experts Section.