Abstract:

**Background:** Asthma is a chronic disease. It is usually controlled by the use of beta-agonists and corticosteroids. Recently, the Buteyko Method has gained some attention as it has been mentioned in the British Thoracic Society (BTS) 2008 guidelines and the Global Initiative for the Treatment of Asthma (GINA) 2011 guidelines as a possible complementary medical option for such patients. Trials on the Buteyko Method have shown effectiveness in improving asthma control, reducing symptoms, improving quality of life, reduction of Inhaled Corticosteroid and Beta-agonist use. However, the applicability of the method to Southeast Asian patients have not been demonstrated, as none of the trials have been done on this specific population.

**Objective:** To estimate the effectiveness of the Buteyko Breathing Technique as an adjunct treatment for patients with Asthma using Beta-Agonists and Corticosteroids as medications.

**Design:** A Randomized Controlled Trial of the Buteyko Method in a group of adults with asthma. The control group will be trained by a respiratory therapist in a generalized asthma education and relaxation technique.

**Main outcome measures:** Asthma control, defined by scores from the Shortened version of the Asthma Control Questionnaire (ACQ), Quality of Life based on the Mini Juniper Quality of Life Questionnaire, Average use of Corticosteroid and Beta-agonist use either inhaled or orally taken.
I. Introduction:

Asthma is a chronic disease. It is characterized by cough, difficulty of breathing, and wheezing. In the Philippines, it has been estimated to affect as much as 12% in children aged 13-14 years and 17-22% in older age groups.¹

Asthma can be controlled by the use of medications such as B-agonists and steroids. However, it is estimated that only a few patients have achieved a good control of their asthma. Among the reasons for a poor level of control include the fear or dislike of medications. In developing countries, this problem is compounded by the cost and availability of such medicines.²

Recently, a non-pharmaceutical intervention developed by Dr. Konstatin Buteyko, a Russian physician in the 1960’s has shown potential in reducing the need for such medications. This intervention, popularly known as the Buteyko Method has produced a following in countries such as Russia, England, and Australia. Proponents of the technique claim that the pathophysiology of asthma is triggered in part or in whole by the low CO₂ tension present in the patient’s bloodstream. Dr. Buteyko developed a technique involving breath holds and consciously controlled breathing which claim to increase the CO₂ tension, and thus, resolves the condition.²

It is said that 100,000 patients in Russia have completed the course and that 90% of them are no longer needing additional asthma medications. A similar success rate has been claimed in about 8,000 patients in Australia.³

Among medical practitioners, the acceptance of the Buteyko Method varies. The Soviet Health Ministry has approved its use for asthma patients in 1984. In 2008, the British Thoracic Society mentioned in their treatment guidelines on asthma that the Buteyko Method may be considered to help patients to control the symptoms of asthma. Similarly in 2011, the GINA guidelines concluded that the Buteyko Method may provide a useful supplement to conventional asthma management strategies, particularly in anxious patients or those habitually over-using rescue medications. Most recently, the evidence-based Agency for Healthcare Research and Quality in their Comparative Effectiveness Review concluded that Buteyko achieves medium to large improvements in Asthma symptoms and in reliever
medication use. Overall, the Buteyko Breathing Technique has not received widespread use among western doctors. ⁴,⁵,⁶

In the Philippines, the Buteyko Breathing Technique has generated interest through various media such as TV, print, radio, and internet. However, its applicability among Filipino patients has not been evaluated through a randomized controlled trial.

II. Research Question:

Using a Randomized Controlled Trial, is the Buteyko Method an effective, and safe complementary treatment for asthma patients taking Beta Agonists and Steroid controller medications?

III. Proponent:

Charles Edward Florendo, MD

IV. General Objectives:

To determine the effectiveness of the Buteyko Method as an adjunct treatment for Asthma patients taking Beta Agonists and Steroid controller medications.

V. Specific Objectives:

1. To teach and apply the Buteyko Method to Philippine-based subjects.
2. To present the effects of the Buteyko Method on symptoms and quality of life of asthma patients as compared to a respiratory therapy intervention.
3. To give an estimate on the overall effects of the Buteyko Method on the medication use of asthma patients on Beta agonists and steroid controller medication.
4. To present adverse effects of patients using the Buteyko method compared to a respiratory therapy intervention.

VI. Conceptual Framework

Patients diagnosed with Asthma
VII. Review of Literature

The Buteyko Method, also called the Buteyko Breathing Technique, has been studied in several clinical trials in Russia since the 1960’s. However, none of these trials qualified as Randomized Controlled Trials. In 1998 Bowler, et al., conducted the first western trial of the Buteyko Breathing Technique. Their results claimed that subjects using the Buteyko Breathing Technique had improvements in asthma control, and reduction of B2-agonist and inhaled corticosteroid use. In 2000, Opat, et al., conducted a trial on the Buteyko Method using a video to teach it to patients. He concluded that it had no significant improvement against placebo. However, he agreed that patients using the Buteyko Breathing Technique had gained significant reduction in their use of Inhaled Corticosteroids.

In 2003, Cooper, et al., did a 3-way trial on the Buteyko Breathing Technique comparing it side-by-side with a placebo control arm and a pranayama yoga treatment arm. Contrary to Opat’s findings, it concluded that the Buteyko Method produced significantly better asthma control, with no difference in its ability to reduce inhaled corticosteroid use. In the same year, Mchugh, et al. Did a trial which improved the protocol of Bowler and had similar conclusions to that of Bowler.

In 2006, Quality of Life Scores were introduced into trials by Slader, et al., who compared the Buteyko Breathing Technique with that of unspecified upper body exercises. He concluded that the Buteyko Breathing Technique did not significantly improve the Quality of Life scores, nor did it reduce corticosteroid use of patients as compared to the unspecified upper body exercises he used in his trial.
In 2007, Cowie, et al. Concluded a trial on the Buteyko Breathing Technique vs. a respiratory therapy intervention which concluded that the Buteyko Breathing Technique did not offer any significant change in asthma control nor quality of life scores as compared to a respiratory therapy intervention, but it was able to reduce beta agonist and corticosteroid use significantly.\(^2\)

In 2011, Prem, et al. Completed a trial where the Buteyko Breathing Technique group showed better trends of improvement in quality of life and asthma control than a group performing pranayama breathing exercises and a control group.

In a recent Cochrane review, breathing retraining interventions were found to be effective in reducing the dependency of patients on inhaled corticosteroids. However, this review tested included the results of different types of breathing retraining regimes including the Buteyko Breathing Technique. Other published metanalysis and systematic reviews, had also lumped the Buteyko Breathing Technique with other breathing retraining exercises such as yoga, relaxation exercises, papsworth method, etc. Thus, the effects noted by these studies were not specific to the Buteyko Breathing Technique. The Buteyko Breathing Technique has a different proposed mechanism and a different set of exercises and goals compared to yoga and other breathing retraining programs. Furthermore, the availability of the Buteyko Breathing Technique is different from those of other breathing retraining programs.\(^{10}\)

A systematic review by the Agency for Healthcare Research and Quality in 2012 concluded that the Buteyko method achieves medium to large improvements in Asthma symptoms and reliever medication use. However, the same study noted that there were no trials done in the US setting, citing it as a limitation on its applicability on US settings.

VIII. Methods

A. Study Participants

A1. Inclusion Criteria

Subjects of the trial will be screened from the triage section of the University of Santo Tomas Hospital Out Patient Department. Subjects for the study will be male and female participants aged between 18 and 50 years of age who reside within Metro Manila, Philippines, and must be easily contacted by phone. They must be literate in either Filipino or English and must have a minimum educational attainment of elementary grade 1. Subjects must present a valid Philippine Government issued identification card or other legal document which can state their citizenship.

They must have had asthma as confirmed by a physician’s diagnosis and current use of asthma medications. They must be using inhaled corticosteroids as well as B\(_2\)-agonists, either
inhaled or orally taken, of any type for their treatment. Their dose of inhaled corticosteroids should have been stable for at least 4 weeks prior to entry to the study. Smokers and non-smokers may be included in the trial. Subjects with a diagnosis of non-respiratory diseases may be included provided that their non-respiratory diagnosis is stable and that they do not meet the exclusion criteria. Patients receiving medications not meant for asthma or cough such as anti-hypertensive, vitamins, proton-pump inhibitors, and pain relievers are eligible. Although medications meant for allergy and allergic rhinitis such as anti-histamines may resolve certain types of cough, patients on this type of medication will be allowed to join the study.

Eligible subjects must agree to be randomized to either the Buteyko group or to the respiratory therapy group. They must sign a consent form and waiver form prior to being randomized and must agree to be followed-up at the University of Santo Tomas Hospital Department of Family Medicine Out-Patient Department and/or a specified physician when needed. Likewise, study participants must receive clearance from a pulmonologist who will be part of the trial.

To prevent subjects from getting materials on either the Buteyko or the respiratory therapy group from outside sources, subjects must also agree to be blinded to the names of both treatment arms.

A2. Exclusion Criteria

Subjects who cannot communicate in either English or Filipino are excluded. Likewise, subjects with a diagnosis of other respiratory diseases including COPD within 4 weeks prior to the start of the trial are not eligible to join. Subjects who are suspected to have psychiatric disorders, mentally challenged, or confirmed or suspected to be pregnant are likewise excluded. Patients with disabilities such as blindness, hearing impairment, inability to use either arms, have difficulty in ambulating or balance, muscular dystrophy, or any other condition which may restrict their participation in either treatment arms are also excluded. Patients who are not medically stable or those suspected or confirmed to be afflicted with communicable or life threatening diseases including Tuberculosis, AIDS, or meningitis at the time of the start of the study are excluded. Subjects may be disqualified by the trial organizers, their physicians or by physicians of the trial due to compelling reasons which may not be listed here.

Subjects who have been taught, trained, or have received prior instructions through self-help materials such as books, DVD’s or internet sources to interventions involving breathing exercises including the Buteyko Method, Papsworth method, yoga, transcendent meditation,
and respiratory rehabilitation will also be excluded from the trial. Subjects receiving additional medications for asthma at the time of study other than inhaled corticosteroids or $\beta_2$-agonists such as but not limited to leukotriene modifiers, theophylline, cromones, systemic steroids, mast cell inhibitors, Anti-IgE, and herbal preparations meant to relieve cough or asthma will also be disqualified. Subject participants who cannot commit to the trial’s schedules are likewise excluded. Since subject pairing will be done in this study, subjects who cannot be paired because there is a lack of a similar participant will be excluded from the study as well.

B. Subject Pairing

To ensure that participants in each treatment arm will receive the same number and duration of contact of treatment with their instructors, all subjects will be paired to another subject of the other treatment arm based on the severity of their asthma as determined by a pulmonologist.

C. Randomization

Participants will be randomly assigned a computer generated number. These numbers shall be placed in sealed envelopes which participants will pick out from a stack. They will write the value of the computer generated number on their patient information sheets. After pairing has been done, subjects with the computer generated number of lesser value as compared to their paired participant will be assigned to the first group. The subjects with the computer generated number of higher value will be assigned to the second group. The groups’ designations as treatment or control shall be determined by flipping a 1-peso coin. If the coin reveals a head, then the first group’s designation shall become the treatment arm while the second group becomes control. The reverse is true if the coin flip reveals a tail.

D. Sample Size Determination

Sample size calculation will be based around the observed differences in the Brisbane study. This indicated a requirement for approximately 20 participants in each group to demonstrate a statistically significant reduction in medication usage, at a 95% confidence interval (CI) and 80% power to demonstrate such a difference. 

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E. Instruments

D.1. Questionnaires as described by the data collection section

D.2. Statistical Software

F. Setting

The study will be administered to patients of a single university hospital in Manila, Philippines. After taking up tuition in either the Buteyko Method or a Respiratory Therapy intervention, patients shall be followed up for 6 weeks for the results of the intervention.

G. Procedure

F.1. Before administering the instruments, necessary permits will be obtained for the use of the instruments, and from the Department of Family Medicine of the University of Santo Tomas Hospital, the Institutional Review Board of the University of Santo Tomas Hospital, as well as other related institutions whose permits are necessary for the study to proceed.

F.2. All subjects must have volunteered for the study and must sign a consent form after reading the Patient Information Table. Patients will then be seen by the trial’s pulmonologist who will ask them to answer the Asthma Control Questionnaire as well as give them clearance for the trial.

F.3. All participants will be paired and randomized as described in the randomization procedure. Participants will be given a letter which explains the trial procedure which they can present to their physicians in the event that they will need hospitalization or emergency room consult during the course of the trial.

F.4. Participants of both groups shall be asked to attend classes on their respective treatment arms, which will consist of five 2-hour sessions with the first 3 sessions scheduled 1-2 days apart, and the last 2 sessions, 3-4 days apart from their previous sessions.

F.5. Participants shall be asked to fill up the questionnaires before the start of their classes. They will be asked to fill up the questionnaires again 2 weeks after the last day of their classes, 4 weeks after the last day of their classes, as well as 6 weeks after the last day of their classes. Participants shall also be contacted by phone by a blinded research assistant to ask
them on their medication usage as measured by their ug and/or mg daily usage. Trial participants whose paired subject drops out of the trial will still be followed up until the end of the trial in the same fashion as other subjects.

F.6. The answers of participants in their questionnaires will then be compiled and statistically analyzed by a qualified statistician.

H. Data Collection

H1. Asthma Control Questionnaire (ACQ)

The Asthma Control Questionnaire is a 7-item questionnaire developed to measure the adequacy of asthma control both in clinical research studies and in clinical practice. It has been designed to measure the full range of clinical impairment from “totally controlled”, where in patients have no limitations to “extremely poorly controlled”, which is life-threatening.

It has been shown in large studies that omission of the 7th question which regards to FEV1 measurements does not affect the questionnaire’s validity, thus, participants of this study will only be asked to answer the first 6 questions. The ACQ is available and validated in both an English and Filipino version for the Philippines. It has a recall period of one week.

H2. Mini Asthma Quality of Life Questionnaire (MiniAQLQ)

The Mini Asthma Quality of Life Questionnaire (MiniAQLQ) and its variants were developed by Dr. Elizabeth Juniper and is copyrighted by QOL Technologies Ltd. The MiniAQLQ is a variant with only 15 questions. It can by self administered or administered by an interviewer. It measures 4 domains: Symptoms, Activity Limitation, Emotional Function, and Environmental Stimuli. It has strong measurement properties and has been fully validated for use in both clinical practice and clinical trials. It has good discriminative properties (reliability and cross-sectional validity), strong evaluative properties (responsiveness and longitudinal validity). The MiniAQLQ has been used extensively with a recall period of one week specially when used with the ACQ, although strong evidence suggests that it is still accurate with a recall of 2 weeks.

IX. Intervention
Participants will be paired on the basis of the severity of their asthma scores. A member of each pair will then be randomized to receive either the Buteyko Method or the Respiratory Intervention treatment. Investigators will be blinded as to the treatment assignment.

Trial participants will undergo training in 2 separate groups. Teaching will occur over 5 days spread over 2 weeks with each session lasting 60-120 minutes. Patients will be informed that the trial will involve 2 different forms of asthma education which are both thought to be useful in reducing reliance on medication and improving asthma control.

A senior Buteyko Practitioner of the International Association of Buteyko Practitioners (IAOBP) will teach the Buteyko Method. The Buteyko Method will consist of a series of exercises promoting the reduction of hyperventilation, as well as lifestyle modifications. The Respiratory Training group will consist of a general asthma education and relaxation techniques currently used by the University of Santo Tomas Hospital.

Their tutors will be free to contact participants in both groups one week after conclusion of the final teaching session. Participants will be instructed to contact their tutor thereafter whenever they wished. If contact occurs, the matched participant in the other treatment group will be contacted by their tutor to control for frequency of contact in the same manner.

X. Ethical Considerations

A. The Licensed use of copyrighted materials in the research.

Permission for the use of the Asthma Control Questionnaire (ACQ), and the Juniper Mini Asthma Quality of Life Questionnaire have been granted by the author and copyright holder of the questionnaires. In the meantime, The Buteyko Method was covered by a Russian Patent which has already expired. Heirs of Dr. Konstantin Buteyko, have already acknowledged that the technique can be used without prior authorization from his estate.

B. Securing Permits to undergo the study at required institutions.

Permission from the University of Santo Tomas Department of Family Medicine as well as the hospital's Institutional Review Board must be met before undergoing the trial.

C. Disclosure of research objectives to all participants.

Participants will be informed of the research objectives both verbally and in writing before they are allowed to sign their consent form.

D. Confidentiality of the answers of the research participants.

To improve communications, names of research participants will be revealed to the tutors of their respective treatment arm. For safety concerns and ease of follow-up, their names may
also be revealed to the study’s physicians and research assistant. However, their names and identities will not be revealed to the statistician, and to persons not related to the study.

E. Confidentiality as the type of treatment being given

As subjects may unintentionally reveal their treatment assignment to the blinded research assistant, subjects will not be informed as to what treatment they are receiving. They will only be informed that they will receive asthma education and “breathing exercises”.

E. Voluntariness and consent of all participants to partake in the study.

Participants must sign consent forms voluntarily to partake in the study. Participants are free to discontinue their participation in the trial at anytime during the trial.

XI. Conflict of Interest Statement

The principal investigator is certified as a Buteyko Practitioner by the Buteyko Breathing Association, England; Asthmahilfe Foundation, Austria; and by the Buteyko Clinic, Ireland. He is a co-founder and consultant of the Controlled Breathing Association, Cameroon.

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