Transitioning Emergency Asthma Management to Primary Care (TEAM-PC)
IRB Protocol
~ Presented by Sona Chauhan ~

OUTLINE

A. Study Purpose & Rationale

The purpose of this study is to evaluate the effectiveness of an asthma control web based smartphone application in controlling patient's asthma symptoms, improving medication adherence, enhancing primary care provider (PCP) involvement and providing clinical decision support (CDS) for PCPs using the National Asthma Education and Prevention Program (NAEPP) guidelines.

Rationale for this study comes from literature regarding patient and provider cell phone use and guideline adherence. A 2014 systematic review and meta-analysis of using patient text-messaging reminders showed improved follow up rates for patients. [5]. As of January 2014 pew statistics, 90% of American adults have a cell phone and 55% of cell phone owners say they use their phones to go online — to browse the internet, exchange emails, or download applications. [4]. On the provider side, the use of the NAEPP guidelines by clinicians is unlikely to occur solely by publication and diffusion [1]. In a 2014 clinical trial using text pages to provide physicians with CDS, showed changed clinician behavior and shortened hospital length of stay [2]. A 2009 study by Kwok et al, showed the use of CDS in ED patients was associated with improvements in patient management discharge plans. [3]

B. Study Design & Statistical Analysis

The study will be a randomized controlled trial (RCT) comparing patients' symptom control as measured by the cACT/ACT using a smartphone application (PingMD) with reminders plus asthma education versus asthma education alone.

Randomization
Following consent, a research assistant will alert the Data Coordinating Center (DCC) via phone, and will input the patient age and ambulatory care network site of the patient. The patient will be randomized to either the intervention arm or the control arm. The randomization will be stratified by age group and clinic site.

All providers in the study will have a username/password set up with PingMD and get information from the application directly either by push notifications or via email notification to check the application for new survey results.

All patients in the study will provide baseline asthma information by interacting with a computer-based application. Asthma severity, asthma control, quality of life and health care utilization will be assessed using the following:
1) validated Asthma Control Test (ACT) or childhood Asthma Control Test (cACT).
2) validated Integrated Therapeutics Group Asthma Short Form (ITG-ASF) or Integrated Therapeutics Group Child Asthma Short Form (ITG-CASF)
3) self reported number of asthma-related ED visits in past 12 months
4) self reported controller medication currently being used

After completion of the initial surveys, the computer will generate an Asthma Action Plan (AAP) with National Asthma Education and Prevention Program (NAEPP) asthma guideline-based recommendations. The study team will ensure that the treating physician is aware of these recommendations. Next, the study team will have participants review a web based asthma educational module, which will provide information on the importance of controller medications, potential side effects, and common misconceptions. After completion of the module, the research assistant will help participants register with PingMD (web based application). After discharge, once every 2 months over a 12 month period, the PingMD application will prompt all participants to complete either ACT or cACT and compile a total score which the patients can view.

Intervention Arm (Group 1)
Participants in the intervention group will receive text message reminders via the Ping MD application to:
1) to take their medications daily for 1 week, then every other day for 1 month, then once every 2 weeks until the completion of the study
2) schedule follow-up visits with their PCPs once every 3 months.
The results of the bimonthly ACT or cACT surveys will be sent to their PCPs for immediate review.

Control Arm (Group 2)
Participants in the control group will NOT receive any text message reminders via the Ping MD application. The results of the bimonthly ACT or cACT surveys will be kept in a secure database not available to PCPs until completion of the study.

Study Outcomes
The primary outcome is asthma control as measured by the validated ACT or cACT over the one-year follow-up period. We will collect ACT/cACT score at baseline, 2, 4, 6, 8, 10, and 12 months. Baseline ACT/cACT score will be the average between the score at the time of enrollment and 2 month after enrollment to take into account varying level of asthma control between patients enrolled in the ED and those enrolled in the clinics. Outcome data will be the average of scores from month 10 and 12.

Secondary outcomes include healthcare utilization, adherence to controller medications, missed school/work days, asthma quality of life, and primary care provider communication.

Statistical Analysis
Power analysis (power of 0.80, alpha of 0.05) was performed for a chi-squared test. If final proportion of 0.3 (intervention group) and 0.6 (control group) showed poorly controlled asthma (ACT/cACT<19), then 48 subjects would be required in each treatment arm. Given a 15% drop out rate, this would require 57 subjects in each group.

C. Study Procedure

Two bilingual (English/Spanish) research assistants will be dedicated to conducting study procedures on a full time basis. They will assist in the recruitment of participants visiting the ED for acute asthma care, randomization of subjects, communicating with PingMD service to ensure usage of the application by both patients and providers.

D. Study Drugs

No experimental drugs will be used in this study.

E. Medical Device.

No experimental medical devices will be used in this study.

F. Study Questionnaires

Both the Asthma Control Test (ACT) and the childhood Asthma Control Test (cACT) are surveys for assessing asthma control. The ACT is a five item questionnaire for patients aged 12 and older with a score range from 5 to 25 while the cACT is a seven item questionnaire for patients aged 4 to 11 with score range from 0 to 27. Both tools use a score of 19 of less to indicate poorly controlled asthma.

G. Study Subjects

Patients will be recruited from the pediatric emergency department and the ambulatory care sites, according to the inclusion and exclusion criteria detailed in Section H. Children 4 to 18 years old will be enrolled in this study. It is important to include children in this study as they have a disproportionately high prevalence of asthma as compared with adults. Research assistants will explain the study to both them and their legal guardians. Either written or verbal assent will be obtained from children aged 7 years or older, depending on their literacy level. Parental consent will be obtained from at least one parent prior to enrollment of children into the study.

H. Recruitment of Subjects

Primary Care providers will be recruited from the four (4) ambulatory care network sites at the Children's Hospital of New York (CHONY).

Patients will be recruited from the pediatric emergency department or the pediatric ambulatory care network sites at the Children's Hospital of New York (CHONY), according to the following criteria.

Inclusion Criteria: Subjects (or their caregivers as appropriate) must be
1) aged 4 -18 years old
2) patient of the ACN clinic
3) have history of clinician diagnosed asthma
4) be able to speak and read either English or Spanish
5) be able and willing to use smartphone capable of downloading a web based application (iPhone, android)

Exclusion Criteria: Subjects must not be
1) diagnosed with a co-morbid respiratory condition (Ex: Cystic Fibrosis, Chronic Obstructive Pulmonary Disease, etc.)
2) too ill for participation, as per the treating physician
3) cognitively impaired
4) a foster child or a ward of the state

An MD or research coordinator will approach caregivers and their asthmatic children, explain the study, and obtain consent and assent for the study as appropriate.

I. Confidentiality of Study Data

All information entered by patients will by initially sent to PingMD, which is a HIPAA compliant server. Follow-up data will be collected via the PingMD app, which uses secure log in, server processes, and data encryption to ensure full HIPAA compliance. Prior to statistical analysis, all data will be de-identified.

J. Potential Conflict of Interest

The authors of this study have no potential conflicts of interest to disclose.

K. Location of the Study

Recruitment for the study will take place entirely within the Pediatric Emergency Department and Ambulatory Care Network sites at the Children's Hospital of New York.

L. Potential Risks

There is a potential risk of loss of confidentiality, which will be minimized by restricting access of any personal information to the study team and keeping any personal information in a secure location. There is also potential risk for patients to believe that all their questionnaire data is being sent directly to their PCP and expecting immediate feedback, this will be minimized by using the consent form to explicitly detail that providers may or may not be receiving the data that patients are putting into Ping MD. There is also risk of patients/care takers

misunderstanding the utilization of the application causing a delay in seeking treatment via the ED or their PCP.

M. Potential Benefits

Participating caretakers of children with persistent asthma will be better equipped to manage their children's asthma and participants can immediately implement the knowledge, resources and tools gained from the study to better care for asthma. Furthermore, they will receive direct help in acquiring proper care for their child's asthma. The children will also benefit in that they will be able to better manage their asthma on their own.

N. Alternative Therapies

Patients and their families who visit the ED may choose not to participate in the study and continue with their asthma management. Patients and their families may also drop out of the study at any time.

O. Compensation to Subjects

To compensate for the time the participants offer for the study, each participant will have a $10 gift certificate mailed to them each time they complete the bimonthly survey. All participants will receive an additional $25 gift certificate for each time they complete the 6-month and 12-month follow-up telephone surveys. We do not believe this will change their intended behaviors as compensation is given based on completion of questionnaires, not on behavioral changes. We feel that compensation is needed especially for the control group in order to minimize loss to follow-up.

P. Costs to Subjects

We do not anticipate subjects incurring any additional costs as a result of their participation in this study.

References:

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