Study Protocol Plan

Title: Smartphone App for Asthma Self-care: Assessment of Outcomes (Asthma Progression and Cost)

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Methods

Study population

This trial will be conducted at the pediatric outpatient clinics of Taipei Hospital, Ministry of Health and Welfare from January 1, 2021, to June 30, 2021. The inclusion criteria are children: (i) aged between 3 and 18 years; (ii) who have access to the smartphone app; (iii) with asthma treatment steps 2–4, requiring regular treatment with controller medication (for at least 6 months over the past year) according to the GINA guidelines; and (iv) who have at least two clinic or emergency department visits related to asthma in the previous year. Children who have comorbidities, or other major medical problems, and who do not have a smartphone or whose caregivers did not have a smartphone were excluded from the study.

Protocol

The study enrolls 210 children to detect a 50% reduction in ACT scores, with 80% power and a 20% attrition rate. They will be randomly assigned to an intervention group and a control group The intervention group download the asthma smartphone app, and follow up monthly via phone calls and clinic visits, while the control group receives reminder calls. At baseline, pediatric allergists examine participants using the International Study of Asthma and Allergies of Childhood (ISAAC) questionnaire. At 3 and 6 months, ACT scores, Mini Pediatric Asthma Quality of Life Questionnaire (MiniPAQLQ), Pediatric Asthma Severity Scores (PASS), Pediatric Asthma Caregiver

Quality of Life Questionnaire (PACQLQ), and peak expiratory flow (PEF) are determined by written informed consent will be obtained from the patients or their guardians. Study protocol approved by the hospital's Institutional Review Board

Smartphone app

Smartphone self-care app for childhood asthma, based on GINA guidelines, offers personalized support through alerts, information inquiries, data entry, and self-test record reports. Alerts included self-assessment of asthma control, individualized coaching, and air quality information updates. The ACT was used for self-assessments, focusing on shortness of breath, nocturnal symptoms, rescue inhaler use, and daily activities over the last month [16]. Patients were categorized based on ACT scores into green (score > 25), yellow (score 20-24), or red (score<20). Patients with poor control received education on managing symptoms, trigger avoidance, medication adherence, inhaler technique, peak flow meter usage, and acute symptoms management. The app offers personalized suggestions, advises patients to seek care if control is poor, and assesses situations based on app records.

Outcome measures

The physician diagnoses asthma at Taipei Hospital; National Health Insurance Program retracted sociodemographic data. A retrospective chart review is used to assess the use of prescribed systemic corticosteroids (prednisolone), maintenance inhaler treatment (salmeterol/fluticasone [Seretide™, GSK Group of Companies], and anti-leukotriene treatment (montelukast). Six months before and after using the app, direct (unscheduled visits to the emergency department and hospitalization costs) and indirect costs (days off work by parents to care for their children and transportation costs) are measured, and transportation costs were estimated using a national website.

Statistical analysis

The study is used an independent t-test to compare baseline demographic data and outcome variables between intervention and control groups. The paired t-test is used to compare

intragroup scores, prescribed treatment courses, PEF changes, and medical costs 6 months before and after the intervention.

The difference-in-difference method is used to assess costs before and at 6 months between intervention and control groups. Significance is set at a two-tailed α value of .05, and all analyses were conducted using SAS software version 9.1 (SAS Institute, Cary, NC, USA).