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# Association of step count with PROMIS<sup>®</sup> pediatric health-related quality of life measures in children and adolescents with persistent asthma

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# Keywords

Asthma; Patient-Reported Outcomes; PROMIS; Health Related Quality of Life; Children; Adolescents; mHealth; pedometry

Asthma is a common chronic condition that affects approximately 4.7 million U.S. children (1). Poor asthma control accounts for the majority of total asthma-related health care costs (2, 3). Differing patient-provider viewpoints of what constitutes asthma control likely contribute to challenges in disease management. For example, clinicians typically use spirometry and frequency of rescue medication use while adolescents perceive physical activity limitations as important indicators of asthma control (4). Collecting data that provides insight into how a patient's life is impacted by asthma outside the clinic setting is essential to develop sustainable interventions to improve asthma control.

Prior research has found that increased physical activity reflects better health-related quality of life (HRQOL) in a general population of children and adolescents (5), but it is unknown if

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the same relationship exists for children whose asthma is not well-controlled. We designed a study to test the hypothesis that physical activity, assessed via pedometry, could serve as a marker of HRQOL in children and adolescents with partly controlled or uncontrolled asthma.

We recruited children ages 8–17 with asthma that was uncontrolled or partly controlled from the North Carolina Children's Hospital, Chapel Hill, NC and Boston Children's Hospital, Boston, MA. Children were recruited to have approximately equal representation within two age groups: 8–11 years and 12–17 years. Uncontrolled or partly controlled asthma was defined by meeting any one of the following three criteria: a) FEV<sub>1</sub> (Forced expiratory volume in 1 second) less than 80% of predicted; b) one or more exacerbations requiring systemic corticosteroids in the last year; or c) parent/child report of partly controlled or uncontrolled asthma, using the GINA guidelines (6). Baseline asthma severity, assessed by study physicians, was approximated by National Asthma Education and Prevention Program treatment step (7). The study was approved by Duke University (coordinating center), UNC-Chapel Hill and Boston Children's Hospital Institutional Review Boards and listed on ClinicalTrials.gov (NCT03933540).

Study involvement lasted four weeks and comprised two in-person visits and four weekly surveys. Web-based surveys included Patient-Reported Outcomes Measurement Information System<sup>®</sup> (PROMIS<sup>®</sup>) Pediatric measures (8) of Asthma Impact, Depressive Symptoms, Anxiety, Peer Relationships, Fatigue and Physical Functioning – Mobility. Higher PROMIS symptom scores reflect worse symptoms, and higher mobility and peer relationship scores reflect better functioning. At the baseline visit, participants were instructed to wear the Garmin Vivofit3 activity monitor at all times for the next 28 days. Participants completed their first survey after wearing the activity monitor for 7 full days (study day 7, week 1), and every subsequent week (Study days 14, 21, and 28; weeks 2, 3, and 4 respectively).

Bivariate analyses examined the association between a child's activity (measured as average daily step count per week) with demographic characteristics using t-tests or ANOVA and Pearson's correlation coefficients, separately for each week. A linear mixed regression model (including age, sex, race, ethnicity, BMI, parent's education level, and timepoint as fixed effects) examined the association between a child's step count and each PROMIS domain as the model outcome over the 4-week period, while accounting for baseline asthma severity. We used a 2-tailed significance level of  $\alpha$ =0.05 for all assessments. The data was generated using SAS software (Cary, NC).

Ninety-one of 105 participants (86.7%) had at least partial pedometry data (Table 1). Of those with at least partial pedometry data, participants were excluded from analyses if they did not wear the device at least 4 of the 7 days within a given week. Each of the 4+ days required at least 10 hours of wear time. Mild attrition was noted over the four-week study period (top of Table 2).

Lower average daily step count was significantly associated with worse Asthma Impact, Depressive Symptoms, and Mobility scores for Week 1 (Table 2). By the end of week 2, there remained a significant negative correlation between average daily steps and Asthma

Impact and Mobility scores. There were no significant associations between pedometry and any PROMIS Measures in weeks 3 and 4. After controlling for baseline asthma severity, age, sex and time, the regression model showed that both Asthma Impact and Mobility were significantly associated with average daily step count over the 4-week period. A one-point increase in Asthma Impact score was associated with 28.4 (standard error 13.2) fewer average daily steps-per-week and a one-point increase in Mobility was associated with 48.5 (standard error 19.4) additional average daily steps-per-week.

In children and adolescents with asthma, increased average daily steps were modestly associated with improved HRQOL, and these relationships for Asthma Impact and Mobility are maintained after adjusting for age and baseline asthma severity. However, the significance of these associations was reduced during the second half of the study period, when less pedometry data was available due to participants losing the pedometer or wearing it infrequently.

Although we found an association between PROMIS Asthma Impact and daily step count, an eight-week study of 22 adolescents with persistent asthma found no association between Asthma Impact and physical activity measured by Fitbit<sup>TM</sup> (9). This may be explained by other factors beyond the smaller sample size: participants were not selected based on asthma control status, Fitbit active minutes (instead of average daily steps) were analyzed, and only adolescents (ages 14–17) were included. Our study found that older adolescents (ages 12–17) took fewer steps overall than younger children during 3 of 4 study weeks (p<0.05 weeks 1, 3, and 4), which may present challenges in relating changes in pedometry with HRQOL in adolescents.

Our study has several limitations. A step count alone provides a narrow view of a specific type of physical activity and does not indicate the intensity of physical activity. Reduced adherence to pedometer use during the last two study weeks reduced our ability to detect fuller relationships between activity and HRQOL and highlight the need to develop strategies that promote consistent use of these devices for monitoring of chronic conditions.

In conclusion, patient-generated activity data shows promise as an objective and complementary measure of HRQOL in children and adolescents with poor asthma control, providing clinicians with additional insight into the true impact of asthma on pediatric patients.

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## **CLINICAL IMPLICATIONS:**

Tracking measures of physical activity may help us gauge HRQOL in children and adolescents with asthma. Clinicians may incorporate this objective data as they tailor therapeutic approaches to improve asthma control in populations with partly-controlled or uncontrolled asthma.

### Table 1.

Demographic and Clinical Characteristics of Study Participants

(N=105)	No. (%)							
Age (mean, SD) in years	11.45, 2.58							
Female sex	49 (47%)							
Race								
White	35 (33%)							
Black	47 (45%)							
Asian	2 (2%)							
Mixed Race	15 (14%)							
Other	6 (6%)							
Ethnicity - Hispanic	17 (16%)							
BMI								
Normal (5-85% tile)	50 (48%)							
Overweight (>85–94% tile)	18 (17%)							
Obese (>95% tile)	37 (35%)							
Baselin	ne PROMIS Scores							
PROMIS Domain	(mean, SD)							
Asthma Impact	45.0, 10.8							
Anxiety	42.3, 10.3							
Depressive Symptoms	42.5, 10.1							
Fatigue	42.0, 10.6							
Mobility	48.9, 8.1							
Peer Relationships	50.2, 9.8							
Asthma Sta	tus of Study Participa	ants						
	Ages 8-11 (N=56)	Ages 12–17 (N=49)						
Asthma Severity								
Mild Intermittent	5 2							
Mild Persistent	16 7							
Moderate Persistent	21 19							
Severe Persistent	14	21						

#### Table 2.

#### Relationship between Average Daily Steps and PROMIS HRQOL Domains

Average Daily Steps By Week													
	Week 1		Week 2		Week 3			Week 4					
All Participants Mean (SD)	N=82 8523 (2773)		N=84 8640 (2803)			N=78 8045 (2872)			N=74 7506 (2758)				
Ages 8–11	N=44 9134 (2472)			N=46 8915 (2631)			N=45 8644 (2687)			N=42 8070 (2705)			
Ages 12–17	N=38 7816 (2962)*			N=38 8307 (2999)			N=33 7228 (2955) *			N=32 6766 (2690)*			
Pearson's Correlation Coefficients (r) of Average Daily Steps with PROMIS Scores													
	Week 1			Week 2			Week 3			Week 4			
PROMIS Pediatric Domain	Ν	r	р	Ν	r	р	Ν	r	р	N	r	р	
Asthma Impact	79	-0.30	0.01	76	-0.28	0.01	73	-0.05	0.69	67	-0.17	0.17	
Anxiety	79	-0.18	0.11	76	-0.15	0.21	73	-0.12	0.33	67	-0.08	0.52	
Depressive Symptoms	79	-0.24	0.03	76	-0.08	0.51	73	-0.07	0.56	67	-0.09	0.45	
Fatigue	79	-0.22	0.05	76	-0.19	0.09	73	0.05	0.66	67	-0.12	0.35	
Mobility	78	0.30	0.01	76	0.35	0.002	73	0.17	0.15	67	0.15	0.23	
Peer Relationships	78	0.12	0.28	76	0.18	0.11	73	-0.07	0.54	67	-0.06	0.64	

For comparisons between 8–11 and 12–17 year old groups:

\* p<0.05

Pearson correlation coefficients that were p<0.05 are denoted in bold.