

BMJ Open Improving Asthma Care Together (IMPACT) mobile health intervention for school-age children with asthma and their parents: a pilot randomised controlled trial study protocol

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To cite: Sonney J, Ward T, Thompson HJ, *et al.* Improving Asthma Care Together (IMPACT) mobile health intervention for school-age children with asthma and their parents: a pilot randomised controlled trial study protocol. *BMJ Open* 2022;**12**:e059791. doi:10.1136/bmjopen-2021-059791

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2021-059791>).

Received 01 December 2021
Accepted 22 December 2021



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ABSTRACT

Introduction Asthma is an incurable, lifelong condition that places children at increased risk for exacerbation, hospitalisation and school absences. Most paediatric asthma interventions target parents alone and are overly prescriptive. Improving Asthma Care Together (IMPACT) is a novel shared management system comprised of a mobile health (mHealth) application, symptom watch and tailored health intervention that pairs parent and child together as an asthma management team. IMPACT helps families monitor asthma status, tailor asthma management strategies and facilitate intentional transition of asthma management to the child. The purpose of this study is to determine the feasibility, acceptability and preliminary efficacy of the IMPACT intervention.

Methods and analysis This pilot randomised controlled trial will recruit 60 children with asthma (7–11 years) and one parent. All parent–child dyads will complete data collection sessions at baseline, postintervention and follow-up. Dyads randomised to the intervention group (IMPACT) will complete the 8-week intervention comprised of weekly activities including symptom monitoring, goal setting and progress monitoring. Dyads randomised to the control group will receive usual care but then be provided access to IMPACT at the end of the study. Feasibility will be measured by the proportion of eligible dyads enrolled and retained. Acceptability of IMPACT will be assessed using the Acceptability of Intervention Measure, the System Usability Scale and a semistructured interview. Preliminary efficacy is determined based on change in primary outcomes, parent-reported and child-reported asthma responsibility and asthma self-efficacy scores, from baseline.

Ethics and dissemination This study has been approved by the University of Washington Institutional Review Board; study ID: STUDY00010461. Participants gave informed consent to participate in the study before taking part. Study results will be disseminated in peer-reviewed journals and scientific conferences. A lay summary will be provided to study participants.

Trial registration number NCT04908384 (ClinicalTrials.gov identifier).

Strengths and limitations of this study

- The Improving Asthma Care Together (IMPACT) mobile health intervention was iteratively codesigned by its intended end users, children with asthma and their parents.
- The dyadic study design pairs parents and children together to learn to share asthma management together.
- The study protocol includes remote study visit opportunities to broaden access to the IMPACT intervention.
- Given the pilot nature of this study, the IMPACT intervention is available only in English.
- The same size is small, which will limit generalisability of study findings.

INTRODUCTION

Asthma is most common chronic condition of childhood, affecting over six million US children.¹ Asthma is an incurable, lifelong condition that places children at increased risk for functional impairments, decreased quality of life, school absences, increased healthcare utilisation and irreversible structural airway remodelling.^{2–5} Asthma management requires symptom monitoring and response, trigger avoidance and timely and appropriate medication use.^{2 5 6} Unfortunately, fewer than 50% of children with asthma are adherent to management regimens, leading to increased disease morbidity and mortality and potentially irreversible airway damage.^{3 7} Improving paediatric asthma management represents a critical health need.

The school-age years (7–11) represent a natural transition in asthma management, as children assume increasing responsibility for asthma-related care while they progressively spend more time away from parents

at school and other extracurricular activities.⁸ Developmentally, school-age children are rule-driven, understand right and wrong and are able to problem solve, which supports their capability to be active participants in their own asthma management.^{9–15} Yet, the majority of existing interventions focus on parents alone and use prescriptive approaches, telling the parent what to ‘do’ to the child to manage their asthma.^{16–21} As a result, our current strategies are failing to provide children with asthma and their families the tools they need to manage asthma together within the realities of their daily lives.^{12 13} The answer to this problem lies in shared asthma management by the parent–child dyad,^{12 13} with the school-age years the ideal developmental period for children to begin sharing responsibility with their parents and establishing lifelong health behaviours.^{22–25}

Using a Human-Centred Design framework, we collaborated with parent–child dyads to codesign Improving Asthma Care Together (IMPACT), a tailored shared management mobile health (mHealth) application that pairs the parent and child together as a shared management team.^{26 27} IMPACT aims to help families tailor asthma management strategies to fit the realities of their social environments while facilitating intentional transition of asthma management to the child. We hypothesise that by giving children a voice in their own care, we will not only improve asthma management in the present but also support the successful future transition of asthma management to those individuals who will ultimately assume sole responsibility in managing their lifelong condition. The purpose of this pilot-randomised controlled trial is to determine the feasibility, acceptability and initial efficacy of IMPACT.

METHODS AND ANALYSIS

Study design and setting

This study protocol was developed in alignment with the Standard Protocol Items: Recommendations for Interventional Trials guidelines.²⁸ We will use a parallel group, randomised controlled pretest–posttest design to compare the 8-week IMPACT intervention with a usual care control. Data will be collected at baseline (T0), postintervention (T1) and 8-week follow-up (T2). See [figure 1](#) for the schedule of enrolment, intervention and assessment. The study will take place within participant homes, with data collection visits occurring either in person (if within the greater Seattle, Washington area) or remotely via Zoom videoconference (Zoom Video Communications, San Jose, California). Any trial modifications will be approved by the Institutional Review Board prior to implementation and will be reported to the trial registry.

Participants

Sixty children and one parent (or caregiver) dyad will be recruited for this study. Child eligibility criteria include: (1) age 7–11 years, (2) diagnosed with persistent asthma

(defined as a prescription for daily asthma medication) and (3) speak English. Parent eligibility criteria include: (1) child’s primary caregiver residing with the child 50% or more, (2) 18 years or older, (3) speak and read English, (4) have a smartphone with data plan and (5) have a parent-reported asthma responsibility mean score of ≤ 2.5 (indicating parent assumes majority of asthma management responsibility). The study catchment area is the USA. Participants who reside in the greater Seattle area in Washington State will have the option for in person visits, whereas those who reside outside of the greater Seattle area will be eligible for remote visits only. Children will be excluded if they have parent-reported conditions that may impair the child’s ability to learn shared management, including developmental delay (language < 5 year level), comorbid condition (cancer, diabetes, autism spectrum disorder) or current asthma exacerbation at the time of recruitment (defined as a prescription for oral corticosteroids), as this is a serious health threat and not an opportune time for learning shared management. There are no parental exclusion criteria.

Recruitment, screening and consent

Numerous strategies will be used to recruit the study sample, including social media posts, elementary school flyers and recruitment flyers posted in community-based paediatric clinics and other community locations (eg, libraries). Prospective participants will also be identified through an electronic medical record screening within UW Medicine, a large hospital system and network of neighbourhood clinics in Washington State, and receive a study flyer via mail or email. All recruitment materials will contain the study screening weblink and quick response (QR) code as well as the Principal Investigator (PI) contact information.

REDCap, a secure, encrypted online data management system,²⁹ will be used for all study-related data collection and management, including study screening. The IMPACT weblink and QR codes will direct users to the IMPACT REDCap webpage and prompt them to complete the eligibility screening. The screening will be automatically scored and indicate whether participants appear to meet eligibility criteria or not. Those who are not eligible will be thanked for their time. Those who are eligible will be asked to provide their contact information in order for the study team to contact them. They will then access the e-consent form (online supplemental file 1), with electronic signature enabled as well as a video assent form for children. The study team will contact all eligible participants to answer any questions, discuss consent and assent (including offer of paper forms if preferred) and to schedule a baseline data collection session.

Data collection

Data collection sessions will occur either in person or remote via Zoom videoconference. Participants who live within the greater Seattle, Washington area will be given the choice between remote or in person visits.

	STUDY PERIOD				
	Enrollment	Allocation	Post-Allocation	Closeout	
Timepoint		T0	8 Weeks	T1	T2
ENROLLMENT:					
Eligibility Screening	X				
Informed consent (P)	X				
Assent (C)	X				
Allocation		X			
INTERVENTION:					
IMPACT		◆————◆			
Control group		◆————◆			
ASSESSMENTS:					
Demographics (P)		X			
Asthma responsibility (P,C)		X		X	X
Asthma self-efficacy (P, C)		X		X	X
Asthma control test (P,C)		X		X	X
Lung functioning/Spirometry (C)		X		X	X
Medication adherence (P, C)		X		X	X
Asthma QOL (P,C)		X		X	X
Family functioning (P)		X		X	X
Medication beliefs (P,C)		X		X	X
Illness perception (P,C)		X		X	X
Feasibility of intervention (P,C)				I	
Acceptability of intervention (P,C)				I	
System usability (P,C)				I	
Semi-structured interview (P,C)				I	

Figure 1 SPIRIT Schedule of enrolment, interventions and assessment. C, child; I, intervention group only; P, parent; QOL, quality of life; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trial; X, all participants.

Participants outside of the greater Seattle area will only be offered remote visits. Data collection will occur via REDCap. Participants who withdraw during the study will be encouraged to complete data collection sessions and reasons for withdrawal will be documented.

Baseline (T0)

In person procedures

The study team will perform direct child measures (height and weight). Next, the study team will assist the parent with pairing the spirometer with their mobile device. Note, spirometers use a reference database to evaluate lung functioning. As such, the spirometer requires patient details including age, gender, height and weight. The study team will instruct the parent to input the study identification number (ID) instead of the child's name and year of birth (not date) to avoid unnecessary personal health information disclosure. The study team will coach the child through spirometry and upload

a screenshot of the results to the REDCap database. Note, every effort will be made to perform spirometry outside (weather permitting) and remain socially distanced while wearing masks, given that spirometry is considered an aerosolising procedure.

Next, individual data collection will commence. The parent participants will be provided an iPad with the electronic REDCap instruments preloaded. Parents will be instructed to complete the instruments to the best of their ability and to ask questions as needed. At the same time, the study team will work 1:1 with the child to assist with instrument completion using a separate iPad (reading items if requested). Should the parent finish their instruments prior to the child, the parent will be asked to refrain from providing input on the child's answers. The estimated time burden for data collection is less than 1 hour. Following data collection, the study team will randomise parent–child dyads into intervention

or control groups (described below). For those assigned to the intervention group, the study personnel will assist intervention dyads with downloading the IMPACT app, pairing the symptom watch and reader with app and reviewing written instructions for use. Dyads assigned to the control arm will receive an information sheet about upcoming data collection sessions and be advised keep the spirometer for future study sessions. Participant dyads will be emailed a US\$50 digital gift card following the T0 visit.

Remote procedures

To facilitate a remote baseline visit, the study team will mail the study supplies to participants prior to the video-conference study visit. During the remote visit, the study team will assist the parent with pairing the spirometer with their mobile device and coach the child through performing spirometry. Parents will be asked to email the spirometry report to the study team. Next, the study team will send the parent a personalised weblink to complete their study instruments via REDCap (either using a different device or after the visit). The study team will screenshare the child's REDCap study instruments and assist with completion, specifically asking that the parent not interfere with the child's answers. Children may choose to verbalise their answers or use Zoom 'mouse control' to self-select their responses. Randomisation and instructions, based on group assignment, and compensation will follow the procedure described above.

Postintervention (T1)

All parent-child dyads will complete a T1 postintervention (8 weeks) study visit, either in person or remote. Survey completion procedures will mirror the T0 protocol. Additionally, families assigned to the intervention group will complete a brief semistructured interview to assess the acceptability of the intervention. Participant dyads will be emailed a US\$100 digital gift card following the T1 visit.

Follow-up (T2)

All parent-child dyads will complete a T2 follow-up study visit 8 weeks after T1, either in person or remote. Survey completion will follow the previously described protocol. For control group families that are interested, the study team will assist with accessing the IMPACT app and orient the dyad to app use. Participant dyads will be emailed a \$150 digital gift card following the T2 visit.

Randomisation

A statistician independent from the study team will generate a block randomisation allocation sequence, stratified by child gender. The order of the blocks will be random. This sequence will be uploaded to the REDCap IMPACT data management system. Following the T0 data collection, the REDCap randomisation module will automatically assign parent-child dyads to the intervention or control group. The study statistician will be blinded to participant allocation.

Sample size

Power estimates are based on projected sample of 30 per arm, assuming 15% attrition. A sample of 60 will provide 80% power to detect an effect as small as $d=0.28$ in a paired *t* test (eg, child spirometry) or a parent-child correlation as small as $r=0.22$. Statistical power of dyadic analyses based on the Actor-Partner Inter-dependence Model,³⁰ appropriate for variables such as self-efficacy and quality of life, was estimated with the APIMPowerRdis³¹ routine in R, assuming modest actor effects with a partial $r=0.35$, partner effects with a partial $r=0.20$ and correlation of the parent-child T0 variables and error terms of $r=0.35$. Such a model would have power=0.98 to detect the actor effects and 0.67 to detect the partner effects. With 30 cases in each group, mixed model analyses of covariance (ANCOVAs) that compare the groups at two time points, assuming an average correlation of $r=0.60$ between measures, would have power=0.80 to detect group difference effects as small as $f=0.28$ ($\eta^2=0.05$), and power=0.80 to detect the within groups pre-/postdifference as small as $f=0.17$ ($\eta^2=0.02$) and a Group \times Time interaction (the most critical of the three effects) as small as $f=0.37$ ($\eta^2=0.07$).

Measures

Participant characteristics

Parents will complete an investigator-developed survey, including demographic information about the parent and child. Parent characteristics include gender identity, education, employment status, race and ethnicity. Child characteristics include age, gender identity, sex at birth (necessary for spirometry algorithm), grade in school, race, ethnicity and insurance coverage. The survey also includes a brief asthma history, including age at asthma diagnosis, number of asthma attacks (exacerbations) in past year, steroid prescriptions in past year and history of asthma emergency department visits, hospitalisation and/or intensive care admission.

Primary outcome measures

Asthma responsibility

The Asthma Responsibility Questionnaire (ARQ) is comprised of 10 items using a 5-point scale to report asthma management task responsibility, with higher scores indicating higher management responsibility for the child.³² The ARQ has established reliability and validity.³²

Asthma self-efficacy

Asthma Management Self-Efficacy scale (13-items for parent, 12-items for child) uses a 5-point scale to assess asthma self-efficacy, with higher scores indicating higher self-efficacy.³³ The Asthma Management Self-Efficacy scale has established reliability and validity.³³

Secondary outcome measures

Asthma control

Asthma control will be evaluated using a self-report scale, the Childhood Asthma Control Test (C-ACT).³⁴

The C-ACT is a clinically validated 7-item scale, with three items for parents (6-point scale) and four for children (4-point scale), to assess asthma control. Scores are summed, with higher scores indicating better asthma control. Clinically established cut points will be used to classify asthma status, with scores ≤ 12 , indicating poorly controlled asthma, 13–19, not well-controlled asthma, and ≥ 20 well controlled asthma.^{34 35}

Lung functioning

Spirometry, an objective measure of lung functioning, is a standard clinical tool to assess lung functioning. The Spirobank Smart is a single-patient reusable handheld spirometer that complies with the American Thoracic Society and European Respiratory Society standards for spirometry as outlined in the International Organization for Standardization (MIR Medical International Research, Rome, Italy). The Spirobank Smart pairs via Bluetooth to the companion Spirobank health app provides instructional prompts, visual incentives and generates spirometry performance reports based on the Global Lung Initiative reference population. Using the Spirobank Smart and companion app, all child subjects will perform spirometry following coaching from the study team. Asthma control will be assessed based on two spirometry values calculated by the device: the forced expiratory volume in 1 s (FEV1) and FEV1/Forced Vital Capacity (FVC) ratio. Asthma control classification as well controlled, not well controlled or very poorly controlled will be based on the NHLBI clinical asthma guideline control cut points FEV1 and FEV1/FVC.³⁶ There is potential disagreement between C-ACT and spirometry values; should this occur, the study team will prioritise the objective measure (spirometry) over the C-ACT score.

Medication adherence

The Medication Adherence Report Scale for Asthma (MARS-A) is comprised of 10 items using a 5-point scale to assess reported asthma controller medication adherence.³⁷ A mean score of ≥ 4.5 indicates adherence. While the MARS-A has established reliability and validity in adults;³⁷ to our knowledge, it has been used, though not validated, in previous studies with children and adolescents.^{38–40}

Asthma-related quality of life

The Mini Asthma Quality of Life Questionnaire (child)⁴¹ and Pediatric Asthma Caregiver Quality of Life Questionnaire (parent)⁴² are designed to measure the physical, social and emotional impact of asthma on one's life. Both scales are comprised of 13 items using a 7-point scale, with higher scores indicating higher quality of life. Both scales have established reliability and validity.^{41 42}

Exploratory outcome measures

Family functioning

The McMaster Family Assessment Device (FAD) is a 60-item parent-report instrument that uses a 4-point scale to evaluate family functioning.⁴³ Higher scores indicate

worsened levels of family functioning. The FAD has established reliability and validity in families with school-age children.⁴⁴

Illness perception

The Brief Illness Perception Questionnaire (BIPQ) is an 8-item scale that uses a 10-point scale to assess individual beliefs about a health condition.⁴⁵ Higher scores indicate more burdensome perception. The BIPQ has established reliability and validity in adults⁴⁵ and children.⁴⁶

Medication beliefs

The Beliefs about Medicines Questionnaire (BMQ) uses a 5-point scale to assess perceived medication necessity (5 items) and concerns (5 items).⁴⁷ The perceived necessity-concern differential is calculated by subtracting the sum of the concern item scores from the sum of the necessity item scores. A positive necessity-concern differential indicates perceived medication necessity outweighs concerns, whereas a negative differential indicates that perceived medication concerns outweigh perceived necessity. The BMQ has established validity and reliability in adults⁴⁷ as well as parents and children.⁴⁸

Impact feasibility and acceptability

Feasibility

The feasibility of IMPACT will be determined by study eligibility, enrolment, retention and use of the IMPACT intervention. We will also use the Feasibility of Intervention measure, a 4-item scale that uses a 5-point scale, with higher scores indicating higher intervention feasibility.⁴⁹

Acceptability (intervention group only)

Acceptability of IMPACT will be assessed using the Acceptability of Intervention Measure (AIM), System Usability Scale (SUS) and semistructured interview.^{49 50} The AIM is comprised of 4 items and uses a 5-point scale, with higher scores indicating higher acceptability. The SUS is a 10-item scale that uses a 5-point scale to report the perceived usability of a system, with higher scores indicating higher usability. Both scales have established reliability and validity.^{49 50} A brief, investigator-developed 12-question semistructured interview will be used to elicit parent and child feedback on the IMPACT intervention.

Impact intervention

The IMPACT system was designed to facilitate parent-child asthma monitoring as well as improved shared management of asthma responsibility. The IMPACT system is comprised of a wearable 'symptom watch', spirometer and mHealth IMPACT app. The symptom watch is worn by the child and functions as an event marker to allow children to report asthma symptoms as they occur. These symptom events are synced with the IMPACT app and tracked graphically within the IMPACT dashboard. The dashboard also tracks weekly asthma control scores (C-ACT) as well as child spirometry values (FEV1).



The IMPACT intervention is imbedded within the IMPACT app. Parent–child dyads will be prompted by push notification to complete weekly study activities throughout the 8-week intervention. Each week, dyads will be prompted to complete the C-ACT and child spirometry. Next, dyads will be prompted to select a weekly evidence-based asthma shared management goal, such as conducting asthma check-ins together to discuss symptoms and medication use or remembering to take daily asthma medication doses. After selecting goals, participants will be prompted to anticipate barriers and problem solve those barriers together. Each subsequent week, participants will also be prompted to evaluate their progress together.

Control group

Dyads assigned to the control group will receive usual asthma care from their healthcare provider(s). Additionally, the principal investigator will conduct an asthma control assessment, based on the C-ACT and spirometry, and provide an asthma resource list. This report may be shared with the child's healthcare provider(s), if desired.

Statistical analyses

Feasibility

Eligibility, enrolment and retention (number who complete the study) data will be summarised in a study flowchart. A priori feasibility benchmarks include $\geq 60\%$ recruitment (eligible dyads who enrol) and $\geq 80\%$ retention. Study withdrawal reasons will also be reported.

Acceptability

Participants will report on IMPACT acceptability via the AIM and SUS scales as well as by semistructured interview. The a priori acceptability benchmark will be $\geq 60\%$ of participants rating IMPACT as acceptable (4 or 5 on AIM, 7–10 on SYS). Semistructured interview data will undergo thematic analysis to identify, analyse and report patterns within the data. Preliminary codes will be generated, then the study team will work together to code the data with existing, refined or newly created codes and then identify themes. After this, the team will define and name each theme.

Primary outcomes (asthma responsibility score, self-efficacy)

Descriptive summaries of deidentified data will be transferred into SPSS V.24 (IBM, Armonk, New York) for analyses. Distributions of interval and ratio level variables will be checked for normality and transformed as necessary. We will compare characteristics of those who completed the study to those who did not to inform the generalisability of findings. We expect an increase in asthma management responsibility scores and increased dyadic interdependence (ie, non-independence of scores between dyads)³⁰ between parent and child-reported outcomes over time in the intervention group, suggesting true shared management.

Secondary outcomes

Secondary outcome analyses will use mixed model ANCOVAs to assess whether the primary outcome variable means, adjusted for baseline scores, differ between intervention

and control groups. We predict a Group \times Time interaction such that shared management and health outcome variables (asthma responsibility score, self-efficacy, medication adherence, asthma control, quality of life (QOL)) will increase to a greater extent in the intervention group. The dyadic effect of the intervention will be tested with the Actor-Partner Interdependence Model^{30 51} using structural equation modelling with full information maximum likelihood (FIML) estimation. First, the pattern of missing data will be tested to determine whether it is missing at random. The FIML method is superior to listwise deletion of missing data points in terms of producing less biased estimates. Next, intraclass correlations will be examined for parent and child asthma responsibility, self-efficacy, and general health scores. The APIM produces estimates of actor effects (Person A's pretest \rightarrow Person A's post-test) and partner effects (Person A's pretest \rightarrow Person B's post-test). Actor effects are estimated while controlling for partner effects, and vice versa. In these analyses, dyadic interdependence is indicated by statistically significant partner effects (eg, parent pretest \rightarrow child post-test, controlling for child pretest). Intervention condition will be entered into the model as a dummy-coded variable. For each measure taken from both parent and child (ie, self-efficacy, asthma responsibility), two APIMs will be compared; one in which all of the paths from child variables are constrained equal to their respective paths from the parent variables, and one in which all paths are unconstrained and, thus, free to vary. Comparison of the fit of these two models indicates whether the effects emanating from the parent are significantly different from those emanating from the child. Parent–child dyads in IMPACT are expected to show stronger partner effects than those in the comparison group.

Family and public involvement

The IMPACT system and intervention were iteratively codeigned by children with asthma and their parents. Generative research determined parent–child dyad needs and priorities with respect to asthma management.²⁷ Next, dyads worked alongside the study team to select the type of intervention (mobile health app and wearable) and refine the features to ensure they address dyad-identified priorities.^{26 27} Finally, dyads participated in extensive usability testing and refinement to ensure IMPACT emerged as an engaging, useful and functional system to support shared asthma management.²⁶ Parent–child dyads will not be involved in participant recruitment for this pilot RCT, but study results will be disseminated to all families that contributed to the development of IMPACT.

ETHICS AND DISSEMINATION

Data management

All appropriate steps will be taken to maintain security of participant data. All participants will be assigned a unique study identifier. Electronic study records will be stored within the REDCap database, a secure cloud-based data management system that is compliant with the Health Insurance Portability and Accountability Act. IMPACT

intervention use data will be stored in an encrypted cloud database. Only the study team members will have access to the final study data set. Data quality will be ensured by having survey completions verified within REDCap. Ongoing quality control procedures will be implemented, to include an audit of selected cases (10%) to ensure adherence with IRB requirements and study protocols.

Participant safety

Given that this study was deemed ‘minimal risk’, we do not anticipate any serious adverse events. However, to ensure participant safety, we will send a monthly report of all unanticipated problems, adverse events and protocol deviations to a Scientific Monitoring Committee (SMC), comprised of a paediatric pulmonologist and senior nurse scientist. Potential adverse events will be graded by the PI and SMC following standard procedures for the University of Washington Adverse Event Reporting Policy. Any potential serious adverse events, such as those resulting in medical problems or breach of confidentiality, will be reviewed by PI and SMC, graded and reported to the Institutional Review Board.

Ethics approval and consent to participate

The University of Washington Institutional Review Board approved this protocol and deemed the study minimal risk. We will submit any protocol modifications to the Institutional Review Board for approval; once approved, the ClinicalTrials.gov registry will be subsequently updated. Study participants will complete consent (parent) and assent (child) procedures, as described above.

Dissemination

Aggregated study findings will be disseminated via publication and presentation to paediatric clinical, scientific and clinical informatics audiences. In addition, we will provide study results to our community of interest, specifically parent–child dyads that assisted with IMPACT development and testing. Authorship eligibility will follow the International Committee of Medical Journal Editors recommendations.⁵² Findings from this study will inform future refinements of the IMPACT system and, if the preliminary evidence is promising, a full-scale clinical trial with broader participant representation. We also anticipate that our study may serve as a pragmatic example of designing behavioural interventions to promote parent–child shared management of chronic health conditions.

Study status

Screening and recruitment commenced on 1 October 2021. This study is ongoing until July 2022 (estimated).

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Funding This work was supported by the National Institutes of Health/National Institute of Nursing Research grant number R21NR019328 and the National Institutes of Health/National Center for Advancing Translational Sciences KL2TR002317. JS also receives support from the US Health Resources Services Administration grant number T72MC00007. The content is solely the responsibility of the authors and does not necessarily reflect the official views of the funding source, nor will the funding source have any role in the design, execution, analysis, interpretation or dissemination of the study.

Competing interests None declared.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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REFERENCES

- Centers for Disease Control and Prevention. *Most recent national asthma data Atlanta*. GA: US Department of Health and Human Services, 2019. https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm
- National asthma education prevention program (NAEPP). Expert panel report 3 (EPR-3): guidelines for the diagnosis and management of Asthma—Summary report 2007. *J Allergy Clin Immunol* 2007;120:S94–138.
- Celano MP, Linzer JF, Demi A, *et al*. Treatment adherence among low-income, African American children with persistent asthma. *J Asthma* 2010;47:317–22.
- Grainge CL, Lau LCK, Ward JA, *et al*. Effect of bronchoconstriction on airway remodeling in asthma. *N Engl J Med* 2011;364:2006–15.
- Brand PLP, Mäkelä MJ, Szefer SJ, *et al*. Monitoring asthma in childhood: symptoms, exacerbations and quality of life. *Eur Respir Rev* 2015;24:187–93.
- McQuaid EL, Kopel SJ, Klein RB, *et al*. Medication adherence in pediatric asthma: reasoning, responsibility, and behavior. *J Pediatr Psychol* 2003;28:323–33.
- Elkout H, Helms PJ, Simpson CR, *et al*. Adequate levels of adherence with controller medication is associated with increased use of rescue medication in asthmatic children. *PLoS One* 2012;7:e39130–6.
- Buford TA. School-Age children with asthma and their parents: relationships with health care providers. *Issues Compr Pediatr Nurs* 2005;28:153–62.
- Olson LM, Radecki L, Frintner MP, *et al*. At what age can children report dependably on their asthma health status? *Pediatrics* 2007;119:e93–102.
- Rebok G, Riley A, Forrest C, *et al*. Elementary school-aged children's reports of their health: a cognitive interviewing study. *Qual Life Res* 2001;10:59–70.



- 11 Riley AW. Evidence that school-age children can self-report on their health. *Ambul Pediatr* 2004;4:371–6.
- 12 Kieckhefer GM, Trahms CM. Supporting development of children with chronic conditions: from compliance toward shared management. *Pediatr Nurs* 2000;26:354–63.
- 13 Sonney JT, Insel KC. Reformulating the common sense model of self-regulation: toward parent-child shared regulation. *Nurs Sci Q* 2016;29:154–9.
- 14 Malerstein AJ, Ahern MM. Piaget's stages of cognitive development and adult character structure. *Am J Psychother* 1979;33:107–18.
- 15 Newton JT, Harrison V. The cognitive and social development of the child. *Dent Update* 2005;32:33–8.
- 16 Marcano Belisario JS, Huckvale K, Greenfield G, et al. Smartphone and tablet self management apps for asthma. *Cochrane Database Syst Rev* 2013;11:CD010013.
- 17 Bender BG, Cvietusa PJ, Goodrich GK, et al. Pragmatic trial of health care technologies to improve adherence to pediatric asthma treatment: a randomized clinical trial. *JAMA Pediatr* 2015;169:317–23.
- 18 Vasbinder EC, Janssens HM, Rutten-van Mölken MPMH, et al. e-Monitoring of asthma therapy to improve compliance in children using a real-time medication monitoring system (RTMM): the e-MATIC study protocol. *BMC Med Inform Decis Mak* 2013;13:38.
- 19 Welsh EJ, Hasan M, Li P. Home-based educational interventions for children with asthma. *Cochrane Database Syst Rev* 2011;10:CD008469.
- 20 Shegog R, Bartholomew LK, Parcel GS, et al. Impact of a computer-assisted education program on factors related to asthma self-management behavior. *J Am Med Inform Assoc* 2001;8:49–61.
- 21 Chiang L-C, Huang J-L, Yeh K-W, et al. Effects of a self-management asthma educational program in Taiwan based on PRECEDE-PROCEED model for parents with asthmatic children. *J Asthma* 2004;41:205–15.
- 22 Ekim A, Ocakci AF. Perceptions of parents and children regarding asthma management responsibilities. *J Spec Pediatr Nurs* 2013;18:289–96.
- 23 Sonney JT, Gerald LB, Insel KC. Parent and child asthma illness representations: a systematic review. *J Asthma* 2016;53:510–6.
- 24 Butz AM, Walker JM, Pulsifer M, et al. Shared decision making in school age children with asthma. *Pediatr Nurs* 2007;33:111–6.
- 25 Brown N, Gallagher R, Fowler C, et al. The role of parents in managing asthma in middle childhood: an important consideration in chronic care. *Collegian* 2010;17:71–6.
- 26 Sonney J, Cho Emily (Enubi), Zheng Q, et al. Refinement of a parent-child shared asthma management mHealth APP: human centered design study (Preprint). *JMIR Pediatr Parent* 2021.
- 27 Sonney J, Duffy M, Hoogerheyde LX, et al. Applying Human-Centered design to the development of an asthma essentials kit for school-aged children and their parents. *J Pediatr Health Care* 2019;33:169–77.
- 28 Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2013;158:200–7.
- 29 Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
- 30 Kenny DA, Kashy DA, Cook WL. *Dyadic data analysis*. New York, NY: The Guildford Press, 2006.
- 31 Ackerman RA, Kenny DA. APIMPowerR: An interactive tool for Actor-Partner Interdependence Model power analysis [computer software], 2016. Available: <https://robert-a-ackerman.shinyapps.io/APIMPowerRdis/> [Accessed 25 Apr 2017].
- 32 McQuaid EL, Penza-Clyve SM, Nassau JH, et al. The asthma responsibility questionnaire: patterns of family responsibility for asthma management. *Children's Health Care* 2001;30:183–99.
- 33 Bursch B, Schwankovsky L, Gilbert J, et al. Construction and validation of four childhood asthma self-management scales: parent barriers, child and parent self-efficacy, and parent belief in treatment efficacy. *Journal of Asthma* 1999;36:115–28.
- 34 Liu AH, Zeiger R, Sorkness C, et al. Development and cross-sectional validation of the childhood asthma control test. *J Allergy Clin Immunol* 2007;119:817–25.
- 35 Liu AH, Zeiger RS, Sorkness CA, et al. The childhood asthma control test: retrospective determination and clinical validation of a cut point to identify children with very poorly controlled asthma. *J Allergy Clin Immunol* 2010;126:e1:267–73.
- 36 Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. *J Allergy Clin Immunol* 2020;146:1217–70.
- 37 Cohen JL, Mann DM, Wisnivesky JP, et al. Assessing the validity of self-reported medication adherence among inner-city asthmatic adults: the medication adherence report scale for asthma. *Ann Allergy Asthma Immunol* 2009;103:325–31.
- 38 Sonney J, Insel KC, Segrin C, et al. Association of asthma illness representations and reported controller medication adherence among school-aged children and their parents. *J Pediatr Health Care* 2017;31:703–12.
- 39 Kosse RC, Koster ES, Kaptein AA, et al. Asthma control and quality of life in adolescents: the role of illness perceptions, medication beliefs, and adherence. *J Asthma* 2020;57:1145–54.
- 40 Tiggelman D, van de Ven MOM, van Schayck OCP, et al. Longitudinal associations between asthma control, medication adherence, and quality of life among adolescents: results from a cross-lagged analysis. *Qual Life Res* 2015;24:2067–74.
- 41 Juniper EF, Guyatt GH, Feeny DH, et al. Measuring quality of life in children with asthma. *Qual Life Res* 1996;5:35–46.
- 42 Juniper EF, Guyatt GH, Feeny DH, et al. Measuring quality of life in the parents of children with asthma. *Qual Life Res* 1996;5:27–34.
- 43 Epstein NB, Baldwin LM, Bishop DS. The McMaster family assessment DEVICE*. *J Marital Fam Ther* 1983;9:171–80.
- 44 Bihun JT, Wamboldt MZ, Gavin LA, et al. Can the family assessment device (FAD) be used with school aged children? *Fam Process* 2002;41:723–31.
- 45 Broadbent E, Petrie KJ, Main J, et al. The brief illness perception questionnaire. *J Psychosom Res* 2006;60:631–7.
- 46 Valero-Moreno S, Lacomba-Trejo L, Casaña-Granell S, et al. Psychometric properties of the questionnaire on threat perception of chronic illnesses in pediatric patients. *Rev Lat Am Enfermagem* 2020;28:e3242.
- 47 Horne R, Weinman J, Hankins M. The beliefs about medicines questionnaire: the development and evaluation of a new method for assessing the cognitive representation of medication. *Psychol Health* 1999;14:1–24.
- 48 Yilmaz O, Eroglu N, Ozalp D, et al. Beliefs about medications in asthmatic children presenting to emergency department and their parents. *J Asthma* 2012;49:282–7.
- 49 Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. *Implement Sci* 2017;12:108.
- 50 Brooke J. System usability scale usability.gov: improving the user experience: US. Department of Health & Human Services, 2018. Available: <https://www.usability.gov/how-to-and-tools/methods/system-usability-scale.html> [Accessed 17 Jun 2018].
- 51 Kenny DA, Cook W. Partner effects in relationship research: conceptual issues, analytic difficulties, and illustrations. *Pers Relatsh* 1999;6:433–48.
- 52 International Committee of Medical Journal Editors. Defining the role of authors and contributors, 2021. Available: <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html> [Accessed 20 Dec 2021].

**UNIVERSITY OF WASHINGTON
CONSENT & PARENTAL PERMISSION FORM**

Improving Asthma Care Together (IMPACT): A Pilot Study

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Researchers' statement

We are asking you and your child to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether you and your child will join the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you both to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you and your child want to be in the study or not. This process is called "informed consent." We will email you a copy of this form for your records.

KEY INFORMATION ABOUT THIS STUDY

- Participation in research is voluntary and will not affect your child's healthcare or any services you or your child receive through the UW or elsewhere.
- The purpose of this study is to test a new childhood asthma management app (IMPACT) designed for children and their parents to use together.
- All parent-child teams will participate in 3 data collection sessions – 1) at the start of the study, 2) at the end of the 8-week study, and 3) 2 months later. During these sessions, parents and children will answer questions about themselves, the child's asthma, their family, and ways they manage the child's asthma.
- Approximately half of the parent-child teams in this study will test the IMPACT app (intervention group) and the other half will not (control group).
- Parent-child teams that are testing the IMPACT app will complete weekly study activities, including monitoring the child's asthma status and learning strategies for managing asthma together. These activities should take 30 minutes or less per week.
- Parent-child teams that are not assigned to test the IMPACT app will complete data collection sessions only. At the end of the study, they will be given access to the IMPACT app if desired.
- You and your child may not benefit from this study. Some children may experience improved asthma status and management.
- The main risk involved with the study is fatigue from answering study questions.
- This study and its activities do not replace the care that you and your child receive from your health care professional. Participation in this study does not entail any change to your asthma medications or management plan.

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PURPOSE OF THE STUDY

The purpose of this study is to test a new health app, IMPACT, which was co-designed with children and parents. IMPACT aims to help children and their parent manage asthma better. We think about 60 children with asthma and their parent/caregiver will participate in this study.

STUDY PROCEDURES

If you and your child join the study, we ask that you participate for 8 weeks plus a follow-up visit 2 months later. Half of the parent-child teams will be assigned to try IMPACT while the other half will not (this is called a control group). After the follow-up visit, control group participants will be offered access to IMPACT if they are interested.

RESEARCH PROCEDURES

This study involves three data collection sessions for all participants. There are additional activities for those assigned to the intervention or control groups.

Data collection sessions

Unless not allowed due to COVID-19 restrictions, data collection will occur in person either at participant homes or a convenient location, such as a community library. Sessions will last 1-1.5 hours with the majority of data collected using iPads. Study team members will assist the child with the iPads, as needed.

You and/or your child may refuse to answer or participate in any of the study activities and may leave the study at any time. This study involves three in-person data collection sessions. These may be held at your home or a convenient location, such as a community library.

	Activities
Visit 1 Begin study Approx 1-1.5 hours	Review parent consent and child assent, obtain signatures <u>Child:</u> <ul style="list-style-type: none"> • Height, weight, and child breathing test • Answer questions about asthma control and asthma beliefs. • OPTIONAL: Play remembering and attention games using an iPad. <u>Parent:</u> <ul style="list-style-type: none"> • Answer questions about themselves, sleep, their family, quality of life, and asthma beliefs. • Answer questions about their child and child's asthma. <u>Group assignment</u> <ul style="list-style-type: none"> • After the questions, parent-child teams will be randomly assigned by computer to intervention or control groups. • Groups are described below
Visit 2 8 weeks Approx 1-1.5 hours	<u>Child:</u> <ul style="list-style-type: none"> • Breathing test & answer questions from visit 1 <u>Parent:</u> <ul style="list-style-type: none"> • Answer questions from visit 1 <u>Intervention group only:</u> <ul style="list-style-type: none"> • Answer questions about IMPACT and provide feedback about IMPACT
Visit 3 16 weeks Approx 1-1.5 hours	<u>Child:</u> <ul style="list-style-type: none"> • Breathing test & answer questions from visit 1 <u>Parent:</u> <ul style="list-style-type: none"> • Answer questions from visit 1 <u>Control group only:</u> <ul style="list-style-type: none"> • Indicate whether interested in getting access to IMPACT app.

Breathing test (called Spirometry)

This is a common test used to see how lungs are working by measuring how much air you exhale and how quickly you exhale. Typically, 2-3 exhalations are needed to complete the test. It does not cause discomfort, though participants may feel tired after exhaling as long and as fast as they can.

Optional Memory and Attention testing

Using an iPad, children will play a series of games and exercises that measures their attention, short-term memory (working memory), and processing speed. These tests take about 30 minutes.

IMPACT Intervention Group

The IMPACT intervention is delivered via a mobile app that will include tracking asthma symptoms and status, setting goals, thinking about barriers, and problem solving. Children will receive a "symptom watch" that allows them to report asthma symptoms when they occur. These reports will sync with the IMPACT app so families may track them over time. Children and parents will be asked to log on to the app once per week for 8 weeks and complete study activities, designed to take 30 minutes or less each week. These activities include setting

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asthma management goals, completing spirometry and an asthma control questionnaire. Families may choose to receive text reminders to complete study procedures through app settings. **Total treatment duration is estimated to be approximately 4 hours each for both parent and child.**

Control Group

The control group will not have any study-specific activities other than the 3 study visits described above. All control group families will receive a spirometer to use during study visits and to keep after the study is over. At the end of the follow-up visit (16 weeks), control group families will be offered access to IMPACT.

RISKS, STRESS, OR DISCOMFORT

There are potential harms or risks if you and your child take part in this study, these are described below. These risks include potential loss of confidentiality, invasion of privacy, anxiety related to survey questions, fatigue related to lung function testing (child), and subject burden.

Loss of Confidentiality and/or Privacy

Privacy for you and your child is very important to us. If you and your child join the study, we will use safety measures to protect your information. However, we cannot guarantee that you/your child would never be identified if you share your information with us. We think this is unlikely but want to make sure you are aware of the risk.

Surveys/Questionnaires

The surveys/questionnaires during might ask questions or for information that makes you or your child feel uncomfortable. You and your child should skip questions that you do not want to answer. You or your child might feel tired or fatigued after answering study surveys/questionnaires as well. Should you and/or your child experience fatigue, you will be offered breaks as needed.

Spirometry

Your child might feel tired while completing the lung function testing (spirometry). Should they feel tired, breaks will be offered. They may also choose not to complete the spirometry.

Symptom Watch (Intervention Group Only)

The symptom watch may cause minor skin irritation. If this occurs, the child should remove the device and the parent should call or email the Principal Investigator (Dr. Sonney). An alternative watch band may be offered. It also might be burdensome to remember to use the symptom button.

Asthma Attack or Exacerbation

Your child may experience an asthma attack (exacerbation) during the study. The IMPACT intervention does not replace the advice of a health care professional. If your child has an attack, please contact your health care provider or seek emergent care.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you and your child choose not to be in this study, you could find information about improving your child's asthma through books or on the internet.

BENEFITS OF THE STUDY

Potential Benefits for You

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There may be no direct benefits to participants in the study; however, being in this study might benefit you and your child. A possible benefit is that you and your child may learn more about helpful strategies to involve your child in his/her asthma management.

Potential Benefits for Others

We hope to use information we get from this study to benefit others who have asthma. This information will help us understand management of asthma at home and whether our IMPACT solution is easy to use and makes sense to children with asthma and their parents.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the National Center for Advancing Translational Sciences and the National Institute of Nursing Research. A description of this clinical trial will be available on <https://www.clinicaltrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY OF RESEARCH INFORMATION

If you participate in this study, the information that you and your child provide is important. A unique study code number will identify your child. This code number will be attached to you and your child's confidential data. We will not put your/your child's name on any research data. The master list that links a person to their study number is stored in a password protected, secure and encrypted server at the UW School of Nursing separate from the other research files. Identifying information will be destroyed after the UW's required retention period has passed.

However, de-identified data from this study will be used for research purposes and will be kept in a locked cabinet and secure computer files indefinitely. No names or other identifying information will be used in any publications or presentations that may result from this study.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- Washington State authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

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The Certificate expires when the funding for this study ends. Currently this is 7/31/2022. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

USE OF INFORMATION

Commercial Profit

The information we collect as part of this research may be used for future commercial profit. There is no plan to share this profit with you.

Returning Results to You

The study team will send you results of asthma control assessments completed at each study visit. These results may indicate poor lung functioning, which is associated with a higher risk of asthma attack (exacerbation). These results may be shared with your health care provider, if you choose to do so.

Using Your Data in Future Research

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

OTHER INFORMATION

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form. If you take part in this study, there will be no cost to you and no cost to your insurance company for these research activities.

Each family will receive up to \$375 in digital gift cards to compensate them for the time and effort involved in participating in the study. Gift cards will be emailed to the parent following the session.

- Data collection session 1: \$50 digital gift card following completion of session
- Data collection session 2: \$100 digital gift card following completion of session (includes following completion of IMPACT intervention for intervention group)
- Data collection session 3: \$150 digital gift card following completion of session.
- OPTIONAL Cognitive battery (attention and memory games): \$25 digital gift card after each session.

A copy of the consent form will be emailed to you at an email address that you provide. It will be a "PDF" document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn't already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher listed on page 1 of this consent form.

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RESEARCH-RELATED INJURY

If you think you/your child have been harmed from being in this research, contact Dr. Sonney at 206-685-2161 right away. She will refer you/your child for treatment.

OPTIONAL FUTURE CONTACT

Would you like to know about future research studies? We would like to contact you in the future to tell you about other research studies you might want to take part in. Research is always a choice. We are only asking you if you would like to hear about other studies.

What happens if I check “YES”?

If you check the “YES” box, you are allowing us to contact you if a study that you could take part in comes up. This means we will store your contact information in a secure electronic file. You can decide to stop allowing us to contact you at any time. You would need to let Dr. Sonney know if you did not want to be contacted in the future.

What happens if I check “NO”?

Deciding not to take part will NOT affect your care. There will be no penalty or loss of benefits to you for deciding that you do not want to be contacted in the future. You can still participate in this SKIP study if you check “NO”.

Your contact information will not be shared with anyone outside this research team or others as required by law.

- YES, it is okay for you to contact me about future research studies.

Please tell us what would be the best way to contact you:

- Phone: _____
- Email: _____
- Mailing Address: _____

- NO, please do not contact me about future research studies.

OPTIONAL COGNITIVE ASSESSMENT

Would you like to opt-in to the optional cognitive evaluation for your child? This involves attention and memory games on an iPad. These will be completed at each data collection session and last about 30 minutes.

- YES, I agree to have my child complete the cognitive assessment.
- NO, I do not agree to have my child complete the cognitive assessment.

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Subject's statement

This study has been explained to me. I volunteer for **myself and my child** to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive an emailed copy of this consent form.

Parent/Caregiver Participant:

 Printed name of **subject**
(parent/caregiver)

Signature of subject

Date

Child participant (subject is a minor):

 Printed name of **child** participant

 Printed name of person authorized to
consent for child participant
Signature of person authorized to
consent for child participant

Date

 Relationship to the subject

 Copies to: Researcher
 Subject

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