

Title: Improving Therapeutic Patient Education for Atopic Dermatitis: Development and Evaluation of a Parent Handbook

Grant Number: 35610573

Abstract: The goal of our proposed project is the development and evaluation of an educational handbook to facilitate therapeutic education as a routine component of care for pediatric atopic dermatitis (AD). AD has a profound impact on patient and family quality of life. While effective treatments are available, poor adherence is a common cause of treatment failure. We are proposing the development of a parent handbook, focused on information and skills necessary to manage and cope with AD. The project will be conducted at Boston Children's Hospital and coordinated through the interdisciplinary Atopic Dermatitis Center. The primary audiences will include: 1) healthcare providers (physicians, nurses) at Boston Children's Hospital who care for pediatric patients with AD within specialty clinics (Atopic Dermatitis Center, Dermatology Program, Allergy Program) and Primary Care; and 2) parents of pediatric patients with AD treated at Boston Children's Hospital. We will conduct a randomized controlled trial to evaluate handbook effectiveness in improving AD symptoms, child and parent quality of life, and parent confidence in AD management. We will also assess parent satisfaction with the handbook. Following the trial, the handbook will be available for use by all Boston Children's Hospital healthcare providers as an educational tool for patients with AD. We will use online surveys to track healthcare provider use of and satisfaction with the handbook and utilize this data to address barriers to handbook use. The handbook will also be available publicly on the internet for dissemination beyond our institution as a free, accessible resource.

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REVIEWER COMMENTS

Review Panel Comments:

While all review panel members were interested by your program and look forward to reading your full proposal, there is a request for more information on the statistical plan and data collection.

Response to the Review Panel's Comments:

We appreciate the Review Panel's comments and have addressed them within our proposal. Specifically, we have detailed our plans for data collection within the Evaluation Design section of the proposal. Baseline data (parent surveys and healthcare provider ratings of skin severity using the Eczema Area and Severity Index [EASI]) will be collected in coordination with patient clinic visits at Boston Children's Hospital. Three-month follow-up data (parent surveys) will be collected electronically using REDCap (a secure web-based application designed to support electronic data capture for research studies) or by telephone as necessary. Although participants will not attend an in-person follow-up visit for the study, we will track study participants for whom the patient has a follow-up visit between two and four months after the baseline visit. For that subset of participants, the healthcare provider will administer the EASI to allow for evaluation of pre-post change in healthcare provider rated skin severity. This will be a secondary outcome measure; our primary clinical outcome will be parent report of AD symptoms.

The Evaluation Design section of the protocol also includes our statistical plan, as well as a power analysis for determination of the necessary sample size.

Of note, we have made some minor changes to the Protocol since initial submission of the letter of intent. We have increased our sample size based on the power analysis. The budget has also increased to reflect revised estimates of research coordinator/assistant time required for the randomized controlled trial data collection. We have based project timelines on previous research conducted by the Principal Investigator on a similar project (development and evaluation of a food allergy handbook) and previous research conducted by one of the Co-Investigators with parents of patients with AD in the Primary Care setting.

1. Overall Goals & Objectives

The goal our proposed project is the development and evaluation of an educational handbook to facilitate therapeutic patient education as a routine component of care for pediatric patients with atopic dermatitis (AD). Patient education is an important element of practice management guidelines for AD, particularly given complex treatment plans and high rates of non-adherence in this population. Recent consensus recommendations support the use of therapeutic patient education aimed at transferring knowledge and skills for managing and coping with the disease from the healthcare provider to the patient and parents. However, in clinical practice, healthcare providers may face barriers to routinely providing the comprehensive education needed to support optimal AD management.

We are proposing the development and evaluation of an accurate, easily accessible educational handbook for parents of pediatric patients with AD as a tool to supplement healthcare provider management of pediatric AD. Our objectives are:

- 1) To develop an educational handbook addressing knowledge and skills important for effective management of and coping with AD in the pediatric population
- 2) To evaluate the effectiveness of the handbook in improving clinical outcomes (AD symptoms, child and parent quality of life, parent confidence in AD management) and parent satisfaction with the handbook
- 3) To evaluate healthcare provider use of and satisfaction with the educational handbook

This project will be conducted at Boston Children's Hospital and coordinated through the interdisciplinary Atopic Dermatitis Center, with the intent of improving patient education for AD within our institution's specialty (Allergy, Dermatology) and Primary Care clinics. This project aligns with the Atopic Dermatitis Center mission to enhance care and quality of life for patients and their families through a collaborative approach to disease management. Development of this educational tool is also consistent with ongoing initiatives within our hospital to provide effective AD education and care plans across all clinical programs caring for patients with AD.

Upon completion of the project the handbook will also be available publicly on the internet for dissemination beyond our institution as a free resource for healthcare providers and parents/caregivers.

2. Current Assessment of Need in Target Area

AD is the most prevalent skin disorder in the pediatric population, affecting 10 to 20% of children.¹⁻² The disease has a profound impact on patient and caregiver quality of life, including intense pruritus, risk for skin infection, sleep impairment with implications for daytime behavior and attention, social stigma and bullying, and mental health comorbidities.³⁻¹⁰ While effective treatments for AD are available, poor adherence is a common cause of treatment failure.¹¹⁻¹² Families must assess the condition of the skin at home and tailor treatments for acute

exacerbations and maintenance. AD management can be complex and time consuming. Gaps in patient and parent knowledge about AD pathophysiology, disease chronicity, and management goals, as well errors in application of topical treatments, concerns about medication side effects, and challenges with child cooperation may all limit consistent skincare and appropriate use of therapeutic agents.¹²⁻¹⁶ Moreover, families commonly lack strategies to break the itch-scratch cycle or cope with the impact of AD on quality of life.³⁻⁴

Comprehensive patient and parent education is essential to improving clinical outcomes in this population. Recent consensus recommendations published by an international group of multi-specialty healthcare providers have highlighted the need for therapeutic education to transfer the information and skills necessary for manage and cope with AD from the provider to the patient and family.¹⁷⁻¹⁸ Existing approaches for the delivery of therapeutic patient/parent education for AD include specialty clinics with interdisciplinary treatment teams, nurse-led teaching sessions, and structured educational groups (“eczema schools”).¹⁹⁻²⁰ While there is evidence to support the effectiveness of such programs in improving outcomes such as AD severity and quality of life,²¹⁻²⁶ there are also barriers to their widespread implementation. A recent survey of institutions providing therapeutic education for AD indicates that programs are typically provided through major medical centers and targeted towards patients with moderate to severe disease.¹⁹ Availability is limited by cost (limitations in insurance reimbursement and funding) and professional resources required, as well as patient proximity to services.¹⁹ Time allotted for most visits with healthcare providers may not be sufficient for adequate patient and parent education.

The Atopic Dermatitis Center at Boston Children’s Hospital is an interdisciplinary outpatient program for patients with refractory AD. Patients are frequently referred by dermatologists, allergists, and primary care physicians from within and outside of our institution. The foundation of our program is comprehensive patient and family education, provided by a pediatric allergist, pediatric nurse practitioner, psychologist, and dietitian. The initial visit to our program typically lasts 3-4 hours, with significant education focused on patient and family understanding of the disease and medical management, as well as about behavioral techniques to enhance treatment adherence and improve coping skills. A recent chart review of 150 patients with an initial visit in the Atopic Dermatitis Center between January 2013 and December 2016 indicated that the greatest improvement in skin severity as measured by nurse practitioner or physician administered Eczema Area and Severity Index (EASI) score²⁷ occurred between the initial visit and the first follow-up visit (mean change = 8.9, SD = 9.0, $p < .001$; mean duration between visits = 2.1 months), with smaller reductions in AD severity at subsequent follow-up visits (significant change maintained from baseline). This highlights the benefits of comprehensive education as key component of care. Additionally, published data from our program demonstrate that improvement in parent difficulty following the treatment routine is associated with improvement in skin severity, supporting the need for therapeutic education to facilitate adherence to care plans.²⁸

In other clinical settings within our institution (Allergy, Dermatology, Primary Care clinics), time allocated for new and follow-up appointments with patients with AD is more limited, with typical clinic visits for patients with AD ranging from 15-45 minutes for new patients and 10 to

30 minutes for return patients. Eczema care plans and skincare handouts are utilized for patient education, but there is no comprehensive or interdisciplinary educational resource for families. Our proposed project, the development and evaluation of an educational handbook for parents of pediatric patients with AD, would serve as a cost-effective and evidence-based resource to supplement healthcare provider management of pediatric AD across our institution.

3. Target Audience

The primary audiences for this project include: 1) healthcare providers (physicians, nurses) at Boston Children's Hospital who care for pediatric patients with AD within specialty clinics (Atopic Dermatitis Center, Dermatology Program, Allergy Program) and Primary Care; and 2) parents of pediatric patients with AD followed at Boston Children's Hospital.

A recent report of research gaps related to the burden of AD on patients and families found that the majority of research studies involved only participants with moderate to severe AD, and recommended that more studies are needed in populations with varying disease severity and in primary care settings.²⁹ Our co-Investigators on this project include healthcare providers from the Allergy Program, Dermatology Program and Primary Care, to ensure that the handbook will meet the needs of all clinical programs ultimately utilizing this resource and is an appropriate resource for patients with varied levels of disease severity.

As described in Section 5 below (Evaluation Design), we plan to recruit 240 parents of patients with AD for a randomized controlled trial of the handbook. Following the trial, the handbook will be available for use by all Boston Children's Hospital healthcare providers as an educational tool for their patients with AD (>1800 patients seen annually). Although the randomized controlled trial will only evaluate an English language version of the handbook, we will also translate the completed handbook into Spanish, in order to increase the reach of this resource to a larger target audience.

Upon project completion the handbook will be available publicly on the internet for dissemination beyond our institution as a free, easily accessible resource for healthcare providers and parents/caregivers of pediatric patients with AD.

4. Project Design and Methods

***Objective 1:** To develop an educational tool addressing knowledge and skills important for effective management of and coping with AD in the pediatric population.*

We have reviewed the literature relevant to our proposed project for published reports/clinical trials of available patient/parent education tools for AD management. We identified one report of online video education and written pamphlets for adults with AD, and one German report of

video-aided education for parents of children with AD.³⁰⁻³¹ While there are studies of written care plans for atopic dermatitis,³²⁻³³ we did not identify more comprehensive educational resources readily available for our clinical population at BCH. Additionally, as further described below, we believe that our handbook will offer unique educational elements, such as behavioral strategies to improve quality of life (itching and scratching, sleep disruption, social-emotional issues) and enhance cooperation with treatment in pediatric populations.

The educational handbook will be developed by an interdisciplinary team of healthcare providers in the Atopic Dermatitis Center at Boston Children's Hospital (Jennifer LeBovidge, PhD, Lynda Schneider, MD, Karol Timmons, RN, MS, CPNP, Wendy Elverson, RD, LDN), with involvement from study Co-Investigators in Dermatology (Marilyn Liang, MD) and Primary Care (Corinna Rea, MD, MPH). Content will be based on practice guidelines for AD management,³⁴⁻³⁷ consensus recommendations for therapeutic patient education for AD,¹⁷⁻¹⁸ and clinical experience of our project team (see Organizational Detail for further elaboration). Development of the handbook will expand on work previously conducted by our project team. This includes clinical experience providing therapeutic education for patients with AD in the clinic setting and through group-based education for patients/parents of children with AD. Members of our team have also completed projects including a quality improvement study examining the impact of written eczema action plans on parent comfort with eczema treatment³⁸ and a randomized controlled trial evaluating the impact of eczema care plans in the primary care setting on outcomes including parent treatment comfort level, disease severity, and quality of life.³⁹ Additionally, our project team has authored publications on topics relevant to the development of handbook content, including practice parameters for AD management, therapeutic patient education for AD, and interdisciplinary approaches to AD care.^{26, 34-35, 40-41} The Principal Investigator has previous experience developing and evaluating a handbook for parents of children with food allergy.⁴² This study also aligns with current interdepartmental collaboration (Allergy, Dermatology, Primary Care) to develop evidence-based guidelines for eczema management. Please see the Organizational Detail and staff biosketches for further details on these projects and publications.

Handbook content will include topics central to effective AD management, such as pathophysiology/course, elements of multi-step management plans and basic information about how these elements work to improve AD, specific skincare techniques, and trigger avoidance. We will also address issues central to quality of life, such as breaking the itch-scratch cycle, improving sleep, coping with social-emotional issues (e.g., promoting self-esteem, handling questions and bullying, stress management, when to seek support), and managing AD in other settings, such as school. For each topic, there will be suggestions for teaching children and adolescents about AD management.

To support Boston Children's Hospital's goal of being a health literate organization (defined by the Institute of Medicine as an organization that "makes it easier for people to navigate, understand and use information and services to take care of their health"), we will obtain support from our hospital's Clinical Education and Informatics' Patient and Family Education Program in the development of the handbook. The Patient and Family Education Program is

comprised of a project manager/certified health education specialist, graphic designer and part-time medical writer who have expertise in health literacy, plain language writing, and health communication. We plan to utilize plain language at the sixth grade level or lower, with visual presentation of information whenever possible.

We will obtain feedback on the handbook from a sample of healthcare providers (approximately 5-10 physicians and nurses) caring for patients with AD at BCH through the Dermatology Program, Allergy Program, and Primary Care, as well as pilot the handbook with a group of parents (approximately 10 parents) from these programs and the Atopic Dermatitis Center. Healthcare provider reviewers will be provided with a draft of the handbook (hard and electronic copies) and will be asked to provide feedback on each section of the handbook, including comments on elements such as clarity of information and usefulness for parents/families. Reviewers will also be asked for feedback on the organization and visual appeal of the handbook, as well as recommendations for sections to edit, remove, or add to the handbook. Reviewer ratings and comments will be collected via electronic surveys.

Parents will be identified and invited to review the handbook by the study team/Co-Investigators. Parents will be provided with a hard copy of the handbook (mailed or provided during a clinic visit) and/or emailed (with their permission) an electronic copy. Parents will be asked to provide feedback on elements such as clarity and usefulness of the information. Parents will also be asked for feedback on the organization and visual appeal of the handbook, as well as recommendations for additional content that would be helpful to include in the handbook. Parent feedback will be collected via mail, electronic surveys, or phone, based on parent preference. Parents involved in this initial review of the handbook will not be recruited to participate in the randomized controlled trial of the handbook described below. The Patient and Family Education Program will also provide support in the initial review of the handbook. This program works closely with families, including those on the hospital-wide Family Advisory Council, to vet the understandability of written resources.

Healthcare provider and parent reviewer feedback will be incorporated into a revised version of the handbook prior to conducting the randomized controlled trial. The handbook will also be translated into Spanish through the Patient and Family Education Program, but the Spanish version of the handbook will not be evaluated in the proposed clinical trial. As noted previously, upon completion of the project, the handbook will be available free of cost for use by Boston Children's Hospital healthcare providers and patients/parents. It will also be available publicly on the internet as a free resource available for dissemination beyond our institution.

***Objective 2:** To evaluate the effectiveness of the handbook in improving clinical outcomes (AD symptoms, child and parent quality of life, parent confidence in AD management) and parent satisfaction with the handbook.*

We hypothesize that use of the educational handbook as an adjunct to standard healthcare provider management of AD will improve AD symptoms, child and parent quality of life, and

parent confidence in AD management more than standard management alone. We also hypothesize that the handbook will demonstrate promise on measures of satisfaction, as defined by at least 80% of parents reporting use of the handbook between the baseline and follow-up visit and positive ratings of the usefulness of content.

We will conduct a randomized controlled trial to evaluate the effectiveness of the educational handbook in improving clinical outcomes for pediatric patients with AD and their parents. Participants will include parents of children (ages 0-16 years) with AD who are followed in the Atopic Dermatitis Center, Allergy Program, Dermatology Program, or Primary Care at Boston Children's Hospital, including both new and return patients. The two arms of the study will include: 1) the handbook arm (handbook provided as an adjunct to standard AD management with a healthcare provider at BCH); and 2) the control arm (standard management alone). Participants will complete study measures at baseline (immediately prior to a clinic appointment for AD care) and at a 3-month follow-up conducted via an online survey or by phone. Data will be analyzed for change on primary study outcomes, which include parent-report measures of AD symptoms, child and parent/family quality of life, and parent confidence in AD management. Secondary study outcomes will include parent satisfaction with AD care and satisfaction with the handbook (for parents in the handbook arm only). For a subset of patients who have a follow-up clinic visit scheduled 2-4 months after their baseline study visit, we will evaluate change on a healthcare provider-assessed measure of AD skin severity. We will also examine differences in the effectiveness of the handbook based on patient AD severity at the baseline visit. A detailed description of the evaluation design is provided below.

Objective 3: To evaluate healthcare provider use of and satisfaction with the educational handbook.

Following completion of the randomized controlled trial, we will make the handbook available within our clinics where patients with AD are treated (Atopic Dermatitis Center, Allergy Program, Dermatology Program, Primary Care), including bound printed copies and links on the Boston Children's Hospital Family Education e-library for providers to download and distribute. We will also make the handbook available for families to download directly from the Boston Children's Hospital website (within Patient Educational Materials section for each clinical program).

We will use online surveys to track how frequently healthcare providers within Boston Children's Hospital distribute the handbook, their satisfaction with the handbook, and barriers to its use/distribution to families. We will also work with the Information Services Department and the Patient and Family Education Program at Boston Children's Hospital to track downloads of the handbook from the hospital internal and external websites. We will utilize information collected to identify and address any barriers to use of the handbook.

5. Evaluation Design

Randomized Controlled Trial

Participant Selection Criteria

Parents (or primary caregivers) of children ages 0-16 years who are scheduled for a clinic visit for evaluation/management of atopic dermatitis in the Atopic Dermatitis Center, Allergy Program, Dermatology Program, or Primary Care Program will be eligible for participation in the study. Additionally, participating parents must be comfortable speaking English and take care of the child with atopic dermatitis most days of the week.

Recruitment Methods

We will use an electronic medical record (EMR) query system to identify potentially eligible patients with upcoming new patient visits, follow-up visits, or well-child visits (Primary Care only). An AD diagnosis will be identified for patients having a billing code or problem list notation for AD (ICD-10 L20.81, L20.82, L20.83, L20.89, L20.9, L23.81) during the previous 12 months, or for new patients AD will be noted as the reason for the visit. The research coordinator will also review Atopic Dermatitis Center, Allergy Program, and Dermatology Program provider schedules for upcoming patient visits for AD. Letters will be mailed to introduce the study to potential participants with an addressed, stamped opt-out postcard if parents do not wish to be contacted further about the study. The letter will provide contact information for interested families to contact the research team. A member of the research team will also place follow-up telephone calls to parents who do not return the opt-out postcard within several weeks of the recruitment letter being sent. Parents interested in participating will undergo a verbal screen over the telephone and/or in person in clinic to ensure eligibility criteria. Parents will be asked to arrive for their clinic appointment approximately 45 minutes before the appointment to allow time to obtain informed consent and complete the study survey. Parents who do not mail back the opt-out postcard may also be approached in clinic about the study.

Data Collection Methods

Prior to the child's appointment with the healthcare provider, the research coordinator/assistant will obtain informed consent and introduce the study survey. The research coordinator will also collect participant contact information and preferred method of contact for the follow-up study. Parents in both study arms will complete the survey prior to the clinic visit, either in the waiting area or in the exam room. It is anticipated that the baseline survey will take approximately 30 minutes to complete.

During the clinic visit, the healthcare provider or a trained research coordinator will complete a measure of skin severity to enable classification of child AD at baseline. Participants in the handbook arm of the study will be given a copy of the handbook at the conclusion of their visit with the healthcare provider and encouraged to read it as a tool to help manage the child's AD. Participants in the control condition will be given a 2-page education sheet about AD that is standardly used in the hospital to act as a "placebo" to separate the effect of distributing any informational material from the specific effect of the educational handbook.

Approximately three months after the clinic visit, the research coordinator/assistant will contact participants via email. Participants will be sent a unique link to complete the follow-up survey via the internet, using REDCap, a secure web-based application designed to support electronic data capture for research studies. For participants who indicated at the baseline visit that they do not have internet access or prefer to complete the follow-up survey by telephone, the research coordinator/assistant will contact those individuals by telephone to administer the follow-up survey. The follow-up survey will be identical to the baseline survey with the exception of the addition of questions about satisfaction with their AD care and feedback questions about the handbook (for participants in the handbook arm). It is anticipated that the follow-up survey will take approximately 25 minutes to complete for parents in the control group, and 30-40 minutes for parents in the handbook group (longer due to questions about handbook satisfaction). Following completion of both study surveys, participants will be compensated for their time with a Target gift card.

Although participants will not attend an in-person follow-up visit for the study, the research assistant/coordinator will utilize the EMR to track study participants for whom the child/patient has a follow-up visit between 2-4 months after the baseline visit. For these participants, the healthcare provider will complete an assessment of skin severity, to allow for evaluation of pre-post change for this subset of patients.

Randomization

In order to adjust for possible differences in treatment regimens at different clinic recruitment sites (Atopic Dermatitis Center, Allergy Program, Dermatology Program, Primary Care), the study team will perform a stratified randomization to the handbook arm and control arm with each clinic treated as a separate randomization block.

Measures

Demographic Information.

At baseline only, parents will complete questions about: child gender, child age, parent gender, parent race, parent ethnicity, and parent education level.

AD History.

At baseline only, parents will report on the child's age at AD diagnosis, history of other atopic conditions (e.g., asthma, allergic rhinitis, food allergy), and use of other AD educational resources. We will also review the EMR as necessary for AD history.

AD Symptoms.

Parents will complete the Patient-Oriented Eczema Measure (POEM).⁴³⁻⁴⁴ The POEM is a validated self-assessment tool used to measure eczema symptoms. The POEM consists of seven questions about the child's symptoms during the previous week. The POEM score ranges from 0 (clear, no eczema) to 28 (very severe eczema). The POEM has been recommended as the preferred measure of AD symptoms in clinical trials with AD patients, to ensure cross-trial comparisons.⁴⁵

Healthcare Provider Assessment of AD Severity.

Healthcare providers (physicians, nurse practitioners) will complete the Eczema Area and Severity Index (EASI) during the patient's clinic visit.²⁷ For patients who complete a follow-up clinic visit within 2 to 4 months of the baseline study visit, healthcare providers will be asked to complete the EASI at the time of that visit. The EASI is a validated objective measure of AD severity and extent. In an international consensus study, the EASI was identified as the preferred core instrument to measure clinical signs of AD in clinical trials, to enable better evidence-based decision making.⁴⁶

Dr. Lynda Schneider, project collaborator and Director of the Atopic Dermatitis Center and Allergy Program, will coordinate the training of healthcare providers in use of the EASI. The research coordinator will also be trained in administration of the EASI and will perform 3 assessments under the supervision of Dr. Schneider. Once trained, the research coordinator will be available to complete this assessment if necessary.

Disease-Specific Quality of Life (Child).

Parents will complete either the Infant's Dermatitis Quality of Life Index (IDQOL)⁴⁷⁻⁴⁸ for children aged less than 4 years of age or the Children's Dermatology Life Quality Index (CDLQI)⁴⁹ for children aged 4 to 16 years. Both instruments are validated and include 10 questions about various aspects of the child's life such as sleep, mood, school, bathing and problems with treatment. Scores range from 0 (quality of life not affected at all) to 30 (quality of life severely affected). If a child turns 4 years old between the two study time points, the IDQOL will be utilized for the follow-up survey as well.

Disease-Specific Quality of Life (Parent).

Parents will complete the Dermatology Family Impact Questionnaire (DFI).⁵⁰⁻⁵¹ The DFI is a validated disease-specific measure to assess the impact of atopic eczema on the quality of life of the parents and family members of affected children. The DFI includes 10 questions about aspects of family life such as caregivers' sleep, family leisure activities, emotional stress, and treatment burden. Scores range from 0 (no impact on family life) to 30 (maximum effect on family life).

Confidence in AD Management.

Parents will complete 12 questions adapted from two validated measures, the Parental Self-Efficacy with Eczema Care Index (PASECHI)⁵² and the Parents' Eczema Management Scale (PEMS).⁵³ The PASECHI was developed to measure parental confidence in managing childhood eczema as a pre- and post-intervention tool in the evaluation of a structured eczema education program. The PEMS was developed from the PASECI, to expand on domains of eczema management. Specific questions were chosen for this study for their relevance to the handbook content (e.g., make the right choice of treatment option if skin becomes worse, successfully apply moisturizer, manage scratching behavior, reduce sleep disturbance, help child to get involved in eczema management). Parents rate items on an 11-point Likert scale

response format (0 = never confident, 10 = always confident), for a total scores in this study of 0 to 120.

Satisfaction with AD Care.

At follow-up, participants will answer questions about their level of satisfaction with their AD care. We will utilize standard questions from the patient satisfaction survey used by our institution.

Handbook Satisfaction.

At follow-up, parents in the handbook arm of the study will complete questions about their use of and satisfaction with the handbook. Structured questions will assess: use of the handbook (frequency), usefulness of specific sections of the handbook (not at all to extremely useful), and to what extent parents felt that the handbook improved their ability to manage their child's AD. Open-ended questions will ask about the most useful information in the handbook, any information that was confusing, reasons why parents did not use the handbook, and suggestions of additional information to add to the handbook.

Additional AD Care.

For descriptive purposes, we will utilize the EMR to collect information on additional AD care since the baseline visit (clinic visits, emergency department visits, inpatient admissions).

Statistical Analysis Plan

We will summarize demographic characteristics and baseline clinical severity with counts and percentages for categorical variables and medians with interquartile ranges for continuous variables. Univariate statistical tests (i.e., chi square and Wilcoxon rank-sum tests for categorical and continuous variables, respectively) will be used to compare the intervention and control groups on baseline factors to verify the balancing effect of randomization.

We will summarize the satisfaction measures of handbook use frequency, handbook section usefulness, and AD management improvement in the handbook arm with counts and percentages for each response at follow-up.

The primary clinical outcome measure of AD symptoms, patients' POEM score, will be modeled as a dependent variable in a linear regression using the Generalized Estimating Equation (GEE) framework with time (follow-up over baseline), treatment arm (handbook over control), and an interaction term of time and treatment arm as the independent variables. The null hypothesis will be that the interaction term is zero, indicating no difference in change over time between the control and intervention groups. A significant interaction term will indicate statistical evidence for a decrease in the POEM score in the intervention group, beyond the change in the control group. Quality of life and confidence outcomes will be analyzed with similar methods.

We expect that the randomization procedure will control for the effect of baseline skin severity on the POEM score at follow-up when estimating the intervention effect. As a secondary

analysis, we will model follow-up POEM score in a linear regression on initial severity, treatment arm, and an interaction term between initial severity and treatment arm, to estimate, within the handbook arm, the effect of initial severity on follow-up severity.

Power analysis

For the determination of sample size, we assume an attrition rate of 10%, based on a previous, similar study conducted by the Principal Investigator to evaluate a food allergy handbook (89.5% follow-up at 2 months) and an RCT of an eczema care plan conducted by the Co-Investigator which had a 94% completion rate.

The following table displays sample size estimates for 80% and 90% power across a range of intervention effects as measured by a mean difference in the POEM between the intervention and control groups, assuming a baseline mean of 15, standard deviation of 7, and an alpha level of 0.05:

Intervention effect	Power = 90%	Power = 80%
2.5 points	530	396
3.4 points	288	216
4 points	208	156
5 points	134	102

A delta of 3.4 has been determined as the minimal clinically important difference for the POEM.⁵⁴ Assuming an attrition rate of 10%, an initial recruitment sample of **240 patients**, with 216 patients retained at follow-up and 24 lost to follow-up, will give the study 80% power to detect a difference of 3.4 points on the POEM scale.

Survey of Provider Experience with the Handbook

Following the randomized clinical trial, healthcare providers in the Atopic Dermatitis Center Allergy Program, Dermatology Program, and Primary Care clinic will be encouraged to provide the handbook to their patients with AD. Information about the handbook will be communicated through means such as staff meetings, newsletters, and emails. Two months after the handbook has been available for use in clinics, providers will be asked to complete a brief electronic survey about the feasibility of using the handbook during clinic visits. Providers will complete ratings of their overall impression of the usefulness of the handbook, how often they provide the handbook to families, the format used (hard copy, website link provided), whether they use the handbook as a teaching tool in clinic, and barriers to use of the handbook. Open-ended questions will be used to elicit additional comments about provider experience using the handbook or suggestions to facilitate improved use/availability of the handbook.

We will also work with the Information Services Department and the Patient and Family Education Program at Boston Children’s Hospital to track downloads of the handbook from the

hospital internal website (Family Education e-library for use by healthcare providers) and the external website (patient education materials).

We will compile data from the provider surveys for each program/clinic and use this information to address any barriers to use of this educational tool, with findings/plans communicated through means such as staff meetings, newsletters, and emails.

Dissemination of Findings

We plan to disseminate project outcomes through national patient and professional organizations for Pediatrics, Allergy, Dermatology, Nursing, and Psychology. This will include presentations at national conferences, publications in peer-reviewed scientific journals, as well as through professional and patient organization websites. We will focus on reaching a broad audience of healthcare professionals caring for patients with AD.

6. Detailed Workplan and Deliverables Schedule

We anticipate that 3 years will be necessary to complete the study. See Figure 1 (Deliverables Schedule) for a timetable for completion of the workplan.

Year 1 of the study will include:

- Drafting of the handbook (to be completed primarily by the Principal Investigator and Co-Investigators from the Atopic Dermatitis Center team, with support of other Co-Investigators, health literacy consultation and graphic design support from the Patient and Family Education Program)
- Piloting the handbook with families (Principal Investigator, Co-Investigators, Patient and Family Education Program, Research Coordinator)
- Gathering healthcare provider feedback on the handbook (Principal Investigator, Co-Investigators, Research Coordinator)
- Revisions of the handbook based on feedback and final graphic design (Principal Investigator, Co-Investigators, Patient and Family Education Program)
- Handbook printing (Creative Services Department)
- Finalization of surveys for the randomized controlled trial (Principal Investigator, Research Coordinator, Statistician guidance as needed)
- Development of the electronic study database in REDCap (Research Coordinator, Principal Investigator, Statisticians)
- IRB submission (Principal Investigator, Research Coordinator)

Year 2 of the study will include:

- EASI training for healthcare providers and the Research Coordinator (Lynda Schneider, MD, Co-Investigator)
- Randomized controlled trial recruitment (Research Coordinator and Primary Care Research Assistant with support from the Principal Investigator and Co-Investigators)

- Randomized controlled trial enrollment and completion of baseline surveys (Research Coordinator and Primary Care Research Assistant with support from the Principal Investigator and Co-Investigators)
- Randomized controlled trial completion of follow-up surveys (Research Coordinator and Primary Care Research Assistant with support from the Principal Investigator and Co-Investigators)

Year 3 of the study will include:

- Implementation of handbook use in the Atopic Dermatitis Center, Allergy Program, Dermatology Program, and Primary Care (Principal Investigator and Co-Investigators)
- Finalization of the online healthcare provider handbook use/satisfaction survey (Principal Investigator with support from Co-Investigators)
- Collection of healthcare provider handbook use/satisfaction surveys (Principal Investigator, with support from Co-Investigators)
- Tracking of handbook downloads from the internal and external hospital website (Principal Investigator with support from the Information Services Department)
- Statistical analysis for the randomized controlled trial and healthcare provider surveys (Statisticians and Principal Investigator)
- Professional conference abstract submissions and presentations (Principal Investigator, Co-Investigators, Statisticians, Research Coordinator)
- Manuscript preparation/submission/revisions (Principal Investigator, Co-Investigators, Statisticians, Research Coordinator)
- Identification of barriers to handbook use by healthcare providers/plans made to address barriers (Principal Investigator in coordination with Co-Investigators from each relevant clinical program)

FIGURE 1. Deliverables Schedule

YEAR 1

Study Month	1	2	3	4	5	6	7	8	9	10	11	12
Handbook –draft completed with health literacy review	X	X	X	X								
Handbook – feedback obtained (families, providers)					X	X	X					
Handbook – final product completed with graphic design								X	X	X		
Handbook – printed											X	X
RCT* surveys developed/finalized			X	X								
Electronic database completed					X	X	X					
IRB submission completed								X	X	X		

YEAR 2

Study Month	13	14	15	16	17	18	19	20	21	22	23	24
EASI* training completed	X	X										
RTC recruitment completed	X	X	X	X	X	X	X	X	X			
RTC enrollment/baseline survey completed			X	X	X	X	X	X	X			
RTC follow-up survey completed						X	X	X	X	X	X	X

YEAR 3

Study Month	25	26	27	28	29	30	31	32	33	34	35	36
Handbooks incorporated into clinics	X	X										
Provider satisfaction surveys developed/finalized	X	X										
Healthcare providers satisfaction surveys completed			X	X	X							
Handbook download tracking	X	X	X	X	X							
Statistical analysis completed (RTC and provider surveys)			X	X	X	X	X					
Conference presentation submissions completed						X	X	X	X			
Manuscript preparation/submission/revision completed							X	X	X	X	X	X
Handbook use barriers identified/addressed in clinics						X	X	X				

*RCT = randomized controlled trial; **EASI = Eczema Severity and Area Index

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