Pediatric Dermatology Research Alliance

Helping Children with Skin Diseases through Collaborative Research

Stigma, anxiety and depression in children and adolescents with skin disorders: The "BIG" study

BACKGROUND

- Having a highly visible, chronic skin disease is thought to impact the psychosocial development of children
- Stigmatization, defined as the process by which negative and often false ideas are attached to an individual, is thought to contribute to this impact, and ultimately may lead to anxiety or depression.
- Stigmatization can have a strong impact on a child's quality of life.
- Research on the stigma related to skin and other conditions that negatively affect a child's physical appearance has been limited

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AIMS

- We propose to examine the ability of validated series of instruments to assess the severity and type of stigma experienced in various potentially stigmatizing skin conditions including:
- **Modified Neuro-QoL (stigma scale)** for either widespread or skin-specific use to asses stigma
- **PROMIS tools** to assess pediatric anxiety, depression, and social functioning
- We also propose to examine the ability of the **Skindex-Teen**, quality of life instruments to assess stigma and psychiatric issues related to skin disease.
- With these tools, we expect to generate data which can be used to measure the value of disease intervention and to measure the burden of stigma to support the development of new therapeutics

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OBJECTIVES

Primary endpoint:

Measure the stigma experienced by children as a function of the child's perceived skin lesion visibility

Secondary endpoints:

- Correlate stigma experienced by children with disease severity
- Correlate stigma experienced by children with parenteral assessment of stigma
- Correlate stigma experienced by children with the occurrence of anxiety
- Correlate stigma experienced by children with the occurrence of depression
- Correlate stigma experienced by children with social functioning score
- Correlate stigma experienced by children with lesional localization
- Assess the ability of Skindex-Teen* to correlate with measures of stigma, anxiety and depression

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INCLUSION CRITERIA

- We will recruit up to 2,500 parent/child dyads across all sites
- To be a site, must commit to recruiting at least 50 parent/child dyads at each site
  - Subjects must be aged 8-17 years of age
  - Subject must be diagnosed with a chronic skin disease deemed to be severe enough and/or visible enough to cause stigma as determined by the study doctor
  - Subject and parent must both be English speaking with at least one parent/guardian who will complete the questionnaires
  - Parent/Guardian must be able to complete the relevant questionnaires

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PLANNED ASSESSMENTS

Physician clinical evaluation:

- Skin disease diagnosis of stigmatizing disease
- PGA of Disease Severity (mild, moderate or severe)
- PGA of Disease Visibility (mild , moderate or severe)

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PLANNED ASSESSMENTS

Child/adolescent cognitive interviews:

- Skin disease diagnosis of stigmatizing disease
- Disease Severity (mild, moderate or severe)
- Disease Visibility (mild , moderate or severe)
- Recent environmental stresses

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PLANNED ASSESSMENTS

Parent Cognitive Interviews:

- Demographics
- Diagnosis; If more than one skin disease, what else – and which is the one felt to be stigmatizing?
- Duration of the disease
- Severity (mild, moderate or severe)
- Visibility (mild, moderate or severe)

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PLANNED ASSESSMENTS

Parent Cognitive Interviews:

- Map of sites of involvement
- Co-morbid conditions
- Family history of psychiatric disease or potential stigmatizing condition (if in parent completing questionnaires, info re diagnosis, severity, visibility)
- Recent environmental stresses

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PLANNED ASSESSMENTS

Children/adolescents questionnaires (67 items)

- The stigma scale (22 items)
- Depression scale short form (8 items)
- Anxiety scale short form (8 items)
- Social functioning scale short form (8 items)
- Skindex-Teen (21 questions)*

Parent proxy questionnaires (43 items)

- The parent proxy stigma scale (22 items)
- Parent proxy depression scale short form (6 items)
- Parent proxy anxiety scale short form (8 items)
- Parent proxy social functioning scale short form (7 items)

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IRB & REGULATORY

- Using the Smart IRB mechanism with Lurie Children's Hospital IRB as the IRB of record (https://smartirb.org/)
- Template ICFs will be sent to participating sites for site specific edits. They will be incorporated into our LCH IRB submission as a new site. Depending on your local IRB requirements, you may still need to submit to your local IRB following approval of your site with the LCH IRB
- https://smartirb.org/participating-institutions/

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SCHEDULE OF EVENTS

- We anticipate starting this study within the next 4-5 months
- We will establish a relatively short deadline (3 months or less) once the protocol and instructions are sent to an institution to obtain IRB approval
- 6 month window for enrollment
- 4 months for data sorting, cleanup, first statistical analysis
- We anticipate having our initial data for presentation and drafting of a manuscript within the next 16 months

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FINANCIAL/CONTRACTING

- This is an investigator-initiated study
- Sponsor: PeDRA (currently trying to raise funds)
- Participating sites will be sent a sub-contract from Northwestern University that includes their per subject site budget (includes personnel costs, subject compensation, start-up/regulatory costs)
- Invoicing to PeDRA for costs

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ORGANIZING COMMITTEE

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- Gabriella Andrade
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- Kristi Holland
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- Steve Humphrey
- Irene Lara-Corrales
- Margaret Lee
- Dawn Siegel
- Karina Vivar
- Dennis West

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This is the PeDRA "BIG" study

Please get involved…

If you would like to participate in this study, please sign up …… Sheets passing around

Or reach out to me (apaller@northwestern.edu) or to
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