COVER PAGE

Study Title: Evaluation of adherence and outcomes in children with functional constipation after implementing a constipation action plan

NCT: *pending*

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Study Protocol Title
Evaluation of adherence and outcomes in children with functional constipation after implementing a constipation action plan

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Study Title
Evaluation of adherence and outcomes in children with functional constipation after implementing a constipation action plan

Study Population
Children are eligible to participate in the study if they are otherwise healthy children whose primary language is English with no conditions that would predispose them to develop constipation, between the ages of 3 and 8 years of age and meet the ROME IV criteria for functional constipation.

Study Agent and Intervention Description
Implementation of a Constipation action plan tool: a document describing step by step what needs to be done in response to the patient's daily symptomatology of constipation.

Primary Objective
1. To assess compliance in pediatric patients with functional constipation that have been provided a constipation action plan plus educational information.
    Outcome measures: compliance
    Sticker reward chart review at 3 month visit in addition to constipation/adherence questionnaire at initial visit, 1 month telephone encounter and 3 month follow up visit.

Secondary Objectives
1. To assess improvement of constipation symptoms in pediatric patients with functional constipation that have been provided a constipation action plan and educational information
    Outcome measures: symptoms
    Assess constipation symptoms by using the constipation/adherence questionnaire involving ROME IV Criteria at enrollment (with demographics), 1 month telephone encounter and 3 month follow up visit.

2. To assess the perceived effectiveness of the constipation action plan from the viewpoint of the family
    Outcome measures: perceived effectiveness of the constipation action plan
    Assess the perceived effectiveness by an anonymous survey

Study design/methodology
This is a randomized controlled single blind study to measure compliance and outcomes in pediatric patients diagnosed with functional constipation. Participants will be recruited from the Division of Pediatric Gastroenterology and Nutrition at Nemours/A.I. duPont Hospital for Children who are being seen with a complaint of constipation. Children are eligible to participate in the study if they are otherwise healthy children whose primary language is English with no conditions that would predispose them to develop constipation, between the ages of 3 and 8 years old and meet the ROME IV criteria for functional constipation. We will obtain parental permission and assent from children older than 7 years of age from all participants. Each family will receive a randomized packet containing educational information (i.e. definitions, water and fiber intake, toilet sitting and medication information), rewards charts and stickers and half of the families will receive an additional constipation action plan tool. The treatment plan for each participant will be determined based on recommendations from the clinical guidelines for the Evaluation and Treatment of Functional Constipation Infants and Children as published by the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. The packets containing the additional constipation action plan tool will not be known to the investigator prior to assigning the packet to a family. At the first visit, the families will complete an initial paper questionnaire regarding symptomatology, adherence to the treatment plan and demographics. The questionnaires will not contain any patient identifiers and will be stored securely at Nemours. At 1 month, the co-investigator will call each family and administer a phone survey through REDcap regarding symptomatology and adherence to the treatment plan in the past month. At 3 months, the families will return for a follow up visit with their 3 month reward charts and complete a final paper survey regarding the child's symptomatology and adherence to the treatment plan. The CO-I will upload the questionnaire responses onto REDcap based on the identification number. The families who were randomized into the group that received the constipation action plan tool will be mailed a survey regarding the utility of the constipation action plan and whether or not it was helpful in improving adherence to treatment and outcomes. Once received, the feedback survey will also be uploaded onto REDcap based on the identification number.

Study Schedule
Children will be recruited from November 2016 - October of 2017. Participants will remain in the study for a total of 3 months, or until the '3-month follow up appointment' is completed, but no later than February 2018.

Adverse Event Reporting
All adverse events and serious adverse events in association with this study will be reported immediately to the IRB. An adverse event is defined as any unfavorable medical occurrence in a human subject, including any abnormal sign (abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. The AE or SAE will be documented in the online secure database and the participant will have the opportunity to withdraw from the study if warranted, further follow up and monitoring with be scheduled as indicated based on the adverse event.

Statistical Analysis Plan

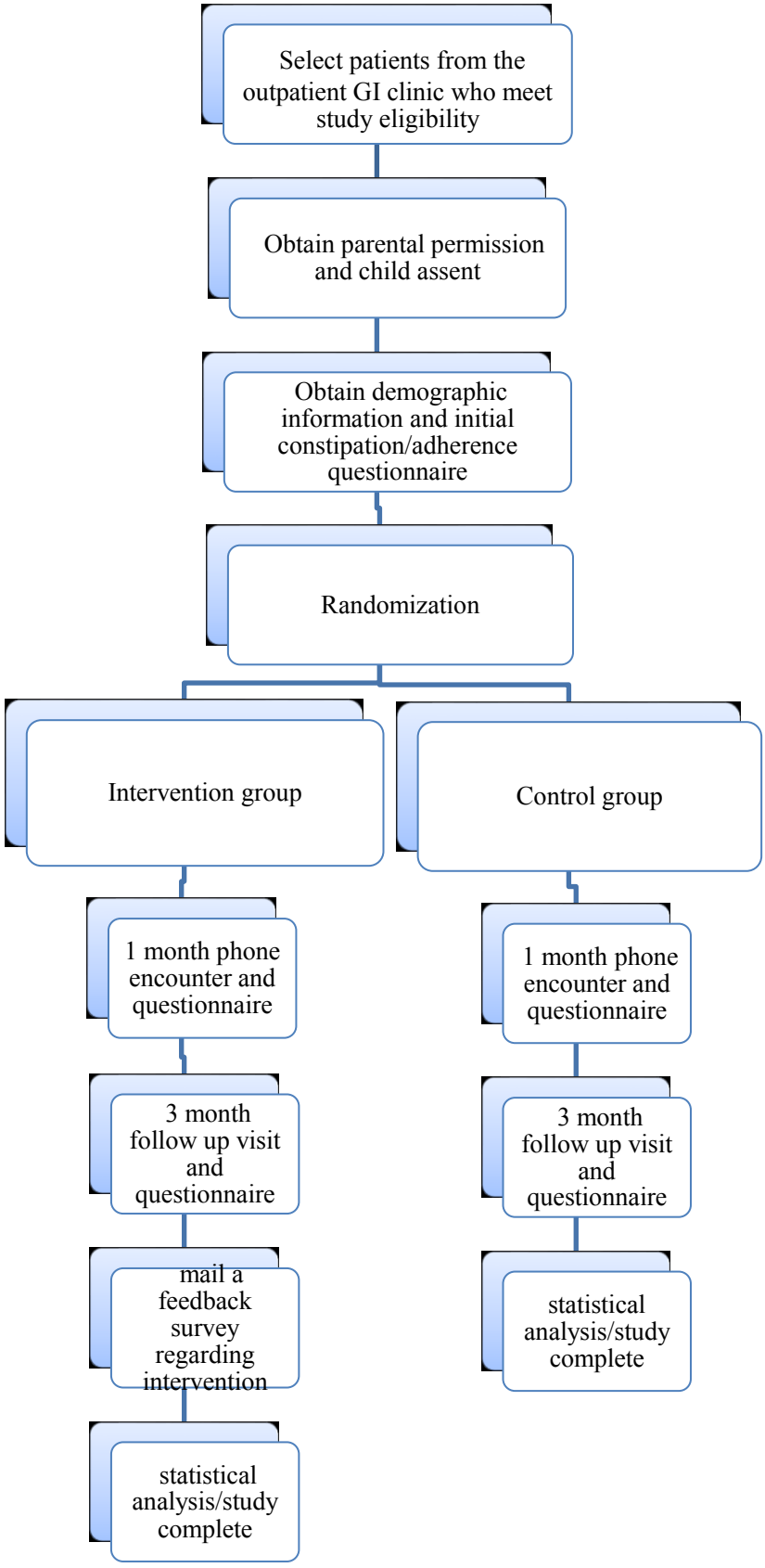
Descriptive statistics will be used to determine the distribution of key outcome and predictor variables. Means and standard deviations will be calculated to describe the distributions of continuous variables. Counts and proportions will be calculated to describe the distributions of categorical variables. The effectiveness of the constipation action plan tool will be assessed by comparing the parent/survey-responder's reported adherence of the child to the constipation treatment in the intervention and control groups, at each follow-up survey, using multivariable logistic regression model. The change in effectiveness of the constipation action plan tool will be assessed by comparing the intervention and control groups across waves of the follow-up surveys, using multivariable mix-effects logistic regression model. Differences in demographic characteristics between the groups will be adjusted for during analysis. The association between compliance and constipation outcomes will be examined likewise.

Informed Consent Process

Informed consent will be taken after the patient is seen in the outpatient setting and has agreed to participate in the study. The CO-I will discuss the project details with the family and allow them to return on a subsequent visit to sign the consent and fill out the forms if they feel they require more time to think about participation. The families will be allowed to ask questions regarding the project and all questions will be answered prior to signing the consent form. The families will meet with the CO-I; all information will be provided to the families including a detailed description of the study and an explanation of how this will contribute to the scientific community. Assent will be obtained from all children 7 years of age and above. We will follow the families at 1 month and at 3 months to complete questionnaires and discuss their continued participation in the study. If the families decide they no longer wish to participate in the study they will be withdrawn. Translations will be submitted to the IRB for review and approval before enrolling non-English speaking participants.

Privacy and confidentiality

Each family will be seen in a private room for the visit encounters. In addition, the follow up surveys are completed via private telephone encounters and follow up interviews in private rooms. The CO-I will organize the list of participants and subsequent study identification numbers (as indicated on each packet they will receive) on password protected computer files (excel spreadsheet) on the Nemours server. The excel spreadsheet will be the only document containing PHI. All printed questionnaires are void of PHI and will contain only a participant (ID) number. The CO-I will upload the questionnaires to a secure website (REDcap) using the appropriate participant ID.


Select patients from the outpatient GI clinic who meet study eligibility
Obtain parental permission and child assent
Obtain demographic information and initial constipation/adherence questionnaire
Randomization
Intervention group
Control group
1 month phone encounter and questionnaire
3 month follow up visit and questionnaire
mail a feedback survey regarding intervention
statistical analysis/study complete
1 month phone encounter and questionnaire
3 month follow up visit and questionnaire
statistical analysis/study complete

For questions or problems, call:

Name:_____

Phone:_____

Constipation Action Plan

To be completed by your child's doctor or nurse so that you know how best to manage your child's constipation

Doing Well: **Stools every 1-2 days** No straining or pain Stool is soft	Daily Medicine Name: Dose: How Often: **Continue stool softeners, high fiber diet, increased fluid intake, exercise and scheduled toilet breaks everyday.	Notes:
Constipation worsening: **No stool in 2-3 days** some pain, or hard stools	**In addition to your Green Zone medicine, you can:** - **Increase your:** - **If your symptoms do not return to the GREEN zone after 3 days of treatment then add:**	Notes:
Pay attention: **More than 3 stools each day**	Does child seem to have GI illness (fever, vomiting, watery stools, diarrhea)? Stop constipation medicines for 3 days or until diarrhea resolves •Call doctor for: Refusing liquids, dark urine, loose stools for ___ days No fever, vomiting or signs of illness? Change daily medicine: Dose How often:	Notes:
Alert! **no stool in 5 or more days** Stomach pain, vomiting,.	- First, Take: - Second, call your doctor now for help	Notes: