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Stay in treatment: Predicting dropout from pediatric weight management study protocol

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ABSTRACT

Introduction: Childhood obesity is a serious public health concern. Multidisciplinary pediatric weight management programs have been deemed effective. However, effectiveness of these programs is impacted by attrition, limiting health benefits to children, and inefficiently utilizing scarce resources.
Methods: We have developed a model (the Outcomes Forecasting System, OFS) that isolates variables associated with attrition from pediatric weight management, with the potential to forecast participant dropout. In Aim 1, we will increase the power and precision of the OFS and then validate the model through the consistent acquisition of key patient, family, and treatment data, from three different weight management sites. In Aim 2, external validity will be established through the application of the OFS at a fourth pediatric weight management program. Aim 3 will be a pilot clinical trial, incorporating an intervention built on the results of Aims 1 and 2 and utilizing the OFS to reduce attrition.
Discussion: A greater understanding of the patient, family, and disease-specific factors that predict dropout from pediatric weight management can be utilized to prevent attrition. The goal of the current study is to refine the OFS to a level of precision and efficiency to be a valuable tool to any weight management program. By identifying the most pertinent factors driving attrition across weight management sites, new avenues for treatment will be identified. This study will result in a valuable forecasting tool that will be applicable for diverse programs and populations, decrease program costs, and improve patient retention, adherence, and outcomes.
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1. Introduction

Despite the high prevalence of pediatric obesity, intensive treatment programs are scarce and typically concentrated within tertiary centers [1,2]. Such programs have been deemed effective by the United States (U.S.) Preventive Services Task Force, which has strongly advocated for increased access; however, such programs are typically intensive (26+ contact hours over 6–12 months) [3–5]. Unfortunately, their effectiveness has been hampered by attrition, which ranges from 27 to 73% [6]. Attrition from pediatric obesity treatment is a challenge, and results in significant financial losses for treatment programs and reduces the benefits children receive from these interventions [7–9].

Existing evidence of attrition is based on retrospective studies using varying definitions, variables, and outcomes [10,11]. These studies have typically focused on sociodemographic differences between patients who drop out of or complete treatment [10,11]. The heterogeneity between studies likely reflects the complex interplay between children, their families, and obesity as a disease, and the varying treatment

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modalities used to meet the needs of diverse families [7,12–16]. Several factors can account for attrition in a program. For instance, psychosocial concerns such as stress and dysfunction in the family, or a child's experience with bullying can increase the chances of drop out [12,13]. Higher levels of attrition have been reported in the presence of weight-related co-morbidities, who are often the children in greatest need of treatment [13]. Finally, studies on engagement and retention have noted challenges related to social determinants of health: lack of transportation, insurance coverage, and busy work schedules can lead to attrition, even when families indicate they are highly satisfied with the program [17–20].

To date, there is a paucity of interventions to prevent attrition from weight management [15,21]. Patient retention efforts often involve frequent electronic queries, monitoring clinic schedules, and phone calls from clinical staff, all of which are time- and resource-intensive [22–26]. Developing and implementing forecasting models to decrease attrition holds promise. By acquiring pertinent variables and prospectively following patients in different programs, settings, and locations, models can be developed, refined, and deployed to identify accurate profiles of those at the highest risk for attrition. From this, retention efforts can be focused on those most likely to cease attending treatment, and outcomes may be enhanced by addressing variables that contribute to attrition. As such, validation is key to the successful translation of tools and models into clinical practice. A comprehensive internal, external, and temporal validation process using diverse clinic populations is the next step to test and translate a forecasting model into clinical practice successfully [27].

Existing evidence is clear in demonstrating the problem of high attrition rates from treatment programs. Still, findings are inconsistent across studies, limiting the usefulness of the results [18,19,28]. We have developed a model that utilizes attrition-related variables to forecast participant dropout. We now seek to expand, refine, and validate this model to enable us to forecast with high precision the risk of a patient and family dropping out of pediatric obesity treatment.

2. Methods

Stay in Treatment (SIT): Predicting Dropout from Pediatric Weight Management is funded by the National Institute of Nursing Research (R01NR017639, originally titled War of Attrition) is registered on clinicaltrials.gov (Identifier: NCT04364282). The Wake Forest University Health Sciences Institutional Review Board reviewed and approved all the study protocol and procedures as the single IRB of record in January 2020, and all other institutions entered into a reliance agreement. The full study protocol, informed consent document, and study results will be published on clinicaltrials.gov upon study completion.

2.1. Study purpose and hypotheses

The overall goals of this study are to increase the precision and power of our attrition prediction model by testing it in additional multidisciplinary pediatric weight management programs and to demonstrate its internal, external, and temporal validity. Aim 1 is to install an Outcomes Forecasting System (OFS) in three pediatric weight management programs, calibrate it, and build its precision using a conceptual model of adherence. Through this model and preliminary work, we have identified several plausible variables (described in section 2.4.1) that will be used to refine and validate the OFS. We hypothesize that the attrition forecasting model will accurately predict patient and family dropout from treatment, with an area under the curve (AUC) greater than 0.70 and with similar accuracy in predicting weight outcomes. We further hypothesize that an attrition forecasting model built across three different but similarly structured weight management programs will have both internal and temporal validity. Aim 2 is to install and externally validate the accuracy of an omnibus OFS in an additional weight management program. The OFS will be applied to a fourth pediatric weight management program not involved in the original data collection and calibration. We hypothesize that an omnibus OFS will be similarly accurate in predicting dropout and weight outcomes in a fourth site, as it was in the three that built its precision and calibration. Via a randomized pilot trial, Aim 3 will establish the feasibility and utility of an intervention using the OFS in three multidisciplinary pediatric weight management programs to identify patients and families at the highest risk of dropping out. We hypothesize the OFS will improve effectiveness of pediatric weight management by reducing attrition in high-risk patients and families.

By identifying the most pertinent factors driving attrition across weight management sites, we can intervene to prevent families from dropping out and increase their exposure to necessary treatment. Our rigorous and reproducible tool will be made available for broad dissemination to improve adherence, decrease costs, and improve outcomes. Results will be designed for rapid uptake and could change practice through meaningfully addressing the critical need for more tailored pediatric weight management programs. We also have included weight- and behavior-related outcomes in the prediction model, adding richness to our findings.

2.2. Sites and partners

All involved sites house tertiary care multidisciplinary obesity treatment programs. The Brenner FIT® (Families in Training) program is located in Winston-Salem, North Carolina, and has 12 years of experience in clinical treatment and research. The Optimal Wellness for Life (OWL) program is located at Boston Children's Hospital in Boston, Massachusetts, and has over 20 years of experience in clinical treatment and research. The Promoting Health in Teens and Kids (PHIT Kids) program is located at Children's Mercy Kansas City, Missouri, and has 13 years of experience in clinical treatment and research. The fourth site, which will be used for external validation, is the Center for Healthy Weight and Nutrition at the Nationwide Children's Hospital at The Ohio State University, and also has extensive experience in clinical treatment and research (Table 1).

2.3. Conceptual model

Rapoff's Model of Adherence to Pediatric Medical Regimens is the conceptual model for the study [29]. The Principal Investigator (JS) previously adapted the model for obesity treatment, which guided his preliminary research on attrition from weight management programs (Fig. 1) [6]. First, the model considers the child and their family in relation to sociodemographic factors, family function and structure, stress, and physical and mental health-all factors believed to play a role in attrition. Second, it focuses on obesity as a disease process and focuses on symptoms, weight severity, perceived severity, and comorbidities. Third, it takes into account the treatment program, including the cost, side-effects, efficacy, patient satisfaction, and approach.

2.4. Study design

In the initial phase (Aim 1), we will obtain key data consistently across three treatment sites to refine our model of attrition prediction. The second phase will establish temporal validation through continued use of the OFS within the three original sites (second part of Aim 1), and external validation, installing the OFS in a fourth weight management program (Aim 2).

The OFS was originally developed on existing data from a clinical database of the Brenner FIT program (Wake Forest School of Medicine IRB#00007733), then applied to another existing data set from PHIT Kids program in Kansas City (University of Missouri Kansas City IRB#12070346). The OFS allows the development of an on-going dynamic model that is tailored to each site. Attrition predictors, based on our previous work and that of others, plus conceptual model, have been specified via the study measures and questionnaires.

Table 1
Participating pediatric weight management programs.

	Brenner FIT Winston-Salem, NC	OWL Boston, MA	PHIT Kids Kansas City, MO	CHWN Columbus, Ohio
Clinicians	Nurses Pediatricians Dietitians Behavioral Counselors Exercise Specialist *Available- Physical Therapist, Social Worker*	Pediatricians, Nurse practitioners Nurse educator Dietitians Psychologists Exercise Specialist Resource Specialist *Available- Physical Therapist, Social Work*	Pediatricians, Nurse Practitioners Dietitians Social Workers *Available- Psychologist, Physical Therapist*	Nurses Pediatricians, Nurse Practitioners Dietitians Psychologists Physical Therapist, Social Worker Athletic trainer
Behavioral approach	Motivational interviewing (MI), Cognitive Behavioral Therapy (CBT), Parenting, Family Counseling	MI, Family counseling *As needed- CBT*	MI, Parenting *As needed- CBT,* Family counseling	MI, CBT *Family counseling*
Dietary approach	General recommendations (GR)[a]	GR[a] Low-glycemic index	GR[a]	GR[a] Low glycemic index, Protein-sparing diet
Activity/ Exercise	Increased time spent in moderate-vigorous physical activity (MVPA) Family-based activity	Decreased sedentary activity Increased time spent in MVPA	Decreased sedentary activity Increased time spent in MVPA	Decreased sedentary activity Increased time spent in MVPA
Duration	6 months with optional longterm follow-up	No set duration; minimum of 6 months	6–12 months	No set duration; minimum of 3–6 months
Frequency of visits	Once-monthly clinic Once-monthly class	Twice-monthly clinic recommended	Once every 4–6 weeks	Every 4–6 weekly
Other	Group orientation, Parent-only class, Family-based activity programs, cooking classes (optional)	Physical activity Classes	Optional group programming	Linkages to community programs (e.g. cooking classes, grocery store tours)
Volume	~200 new patients/year	~500 new patients/year	~500 new patients/year	~750 new patients/year

[a] Decrease sugar-sweetened beverages, increased fruits and vegetables, lean proteins, family meals, decrease foods away from home, meal schedule and structure, decreased snacking, balanced plate model.

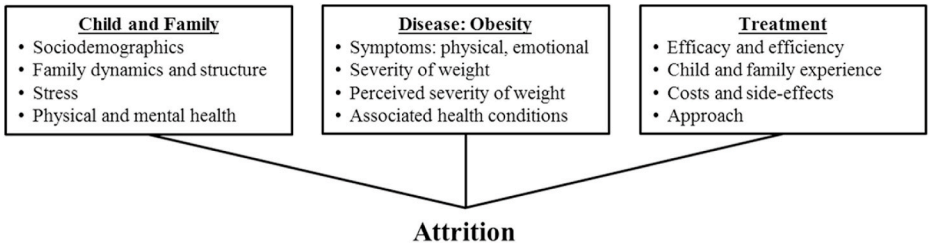

Fig. 1. Conceptual model of attrition (adapted from Rapoff [29]).

2.4.1. Study design for Aim 1

Aim 1 is a prospective, longitudinal observational study to collect comprehensive data on child and family, obesity, and treatment-related variables. All of these programs are similar enough to support the data elements collected but unique enough to add variability and strength to the model.

We will recruit all eligible children ages 7–18 years who are referred for obesity treatment, and a parent or legal guardian. The inclusion criteria will be as follows: children must have obesity (body mass index [BMI] $\geq$ 95th percentile for age and sex), assent to participate, have at least one parent/legal guardian (hereafter called "parent") consent to participate and consent to the child's participation, and speak either English or Spanish. The parent has to be the primary parent accompanying the child to treatment, and the child's primary residence must be with that parent. Children will be excluded if they cannot complete measures and study activities, or the parent or child refuses to participate, does not want to complete six months of treatment, or anticipates being unable to participate in follow-up data collection. Patients referred for weight management explicitly for the treatment of type 2 diabetes will be excluded. Patients diagnosed with diabetes at the initial evaluation will remain eligible. Patients with chronic health conditions impacting weight or genetic conditions associated with weight gain will be excluded from participation.

Measures will be administered electronically by touch screen tablets or virtually with real-time verification by research staff. Paper questionnaires will be available. We will use the Research Electronic Data Capture (REDCap) system for secure, web-based data entry and management. Data collectors will verify complete data entry and data will undergo verification bi-weekly. All sites have access to and familiarity with REDCap.

Children and parents will be recruited from three weight management sites initially. Data collectors will meet the children and parents at the clinic, research center, or virtually and obtain consent and assent, collect measures, and complete measurements within two weeks before or after starting the weight management program. As patients and families participate longitudinally, the data collector will collect appointment attendance, subsequent anthropometric data, and duration of treatment.

Follow-up data will be collected on children and parents after six months. Those children and parents with delays in completing the measures within six months but still actively engaged in treatment will receive an extra month to complete follow-up data collection.

Measures and variables are captured by our Conceptual Model (Fig. 1). Nearly all measures of complex psychosocial, behavioral, and

family variables have established validity and reliability, with some adapted from existing measures. The domains and supporting evidence of our conceptual model are child and family variables, disease (obesity) variables, and treatment variables as follows.

2.5. Child and family variables

2.5.1. Sociodemographics

Age, race, ethnicity, sex, and socioeconomic status will be captured, including any food insecurity by the 2-item Hunger Vital Sign [30], and parent employment and education level. Child and parent weight and child height will be measured by direct measure using established protocols; we have developed protocols for home measurement, observed remotely by research staff, based on CDC guidelines [31].

2.5.2. Family factors

The *Family Nutrition and Physical Activity Screening Tool* will be used to assess eating, activity, and other habits within the family and home environment [32]. It is a measure for capturing family health habits, including family meal patterns and eating habits, meal and beverage quality, media and electronic entertainment use, family activity, child activity, and sleep. The measure has established construct validity and internal consistency ($\alpha = 0.84$). While primarily used as a screening tool, it has been used in longitudinal studies of childhood obesity [33], and its brief nature makes it a practical tool for clinical use. The *Family Assessment Device (FAD)* will be used to assess family functioning [34,35]. The FAD is a seven scale measure, and the General Functioning Subscale (12-item) is an acceptable proxy for an overall picture of family function with minimal burden. This scale has been used previously in obesity research with excellent reliability ($\alpha = 0.92$) [34]. Parenting type will be determined by the *Child Report of Parent Behavior Inventory*, a valid and reliable self-report measure on parent behavior across three dimensions: psychological control vs autonomy, acceptance vs rejection, and firm vs lax control [36]. We will determine the structure of the family using a self-report questionnaire to determine if it is a blended family and the number of adults and children living in the household. The *Confusion, Hubbub, and Order Scale (CHAOS)* will assess home environment organization, confusion, and hurriedness and is a distinct variable from the socioeconomic status of the home and family [37]. The scale is reliable and consistent, having been validated against direct observation of household behaviors [37]. Child perception of the family will be assessed by the *PROMIS Pediatric Family Relationships* measure, short-form (8 questions) [38].

2.5.3. Stress

The *Parent-Perceived Stress Scale* will be used to measure stress perception over the previous month; it has established validity (0.52–0.76) and reliability ($\alpha = 0.84$–0.86) [39]. The *Child-PROMIS Psychological Stress Experience Short Form 4a* will be used to capture psychological stress reactions, feeling overwhelmed, perceived lack of control of one's life, and cognitive-perceptual disruption [38].

2.5.4. Physical and mental health

The *PROMIS Pediatric/Parent Proxy Profile 25 - Short Forms* for children assesses anxiety, depression, fatigue, pain, physical function/mobility, and peer relationships [38]. We will use both the child self-report and the Parent Proxy Report. The *PROMIS-29 Profile 2.0 – Short Forms* will be used to examine parent general and psychosocial health; it assesses anxiety, depression, fatigue, pain, physical function, sleep, and ability to participate in social activities [38]. The *Importance, Confidence, and Readiness Measure* will be used to measure motivation and self-efficacy in weight management with parents and children and has established reliability ($\alpha = 0.8$) [40].

2.5.5. Health literacy

The *Newest Vital Sign* will be used to measure health literacy, capturing the parent's ability to understand words, numbers, and forms [41]. This brief measure is reliable and valid in English and Spanish and only takes 3 min to administer. Given the age range of our study population and the significant role of parents and family in pediatric weight management, only the parent's health literacy will be assessed.

2.6. Disease and obesity variables

2.6.1. Physical and emotional symptoms

The nature and extent of weight-based victimization (teasing and bullying because of weight) will be assessed with a questionnaire adapted from Puhl et al., the *Weight-based Victimization Questionnaire* [42]. Child and parent are provided with a detailed definition of bullying, followed by the questions determining duration and nature of weight-based victimization. Physical symptoms will be captured by the *PROMIS Pediatric/Parent Proxy Profile 25 - Short Forms,* as detailed earlier, which includes items on fatigue, pain, physical function, and ability to participate in social activities [38].

2.6.2. Weight severity

Children's weight will be by direct measure using established protocols. Body mass index (BMI) will be calculated, and given the anticipated weight status ranges, percent of the 95th percentile will be calculated and used as the primary determinant of obesity severity [43].

2.6.3. Perceived weight severity

Perceived severity of weight will be assessed using a single self-reported item with adaptation for the parent as has been used in previous obesity research [44,45].

2.6.4. Comorbidities

The presence of major and minor weight-related comorbidities, using a framework established by Skelton et al. [13], will be captured through the electronic health record (her), as will any weight-related laboratory studies commonly obtained by referring providers or within the programs (liver function tests, glucose, hemoglobin A1c, lipid profile). Also, it will be noted if the patient is receiving treatment for any weight-related comorbidities: anti-hypertension agents, lipid-lowering agents, diabetes medications, or treatment for sleep apnea (CPAP, BiPAP).

2.7. Treatment program and approach

2.7.1. Costs

The cost of the program for the patient and its perceived impact on the family will be assessed. First, parents will be asked to self-report out-of-pocket clinic visit expenses (e.g., copays) at initial and follow-up visits to estimate per-visit cost. Impact of the cost of treatment will be evaluated through a measure of financial toxicity resulting from treatment. This will be captured using a measure developed by de Souza et al. [46]. with established validity and reliability, which has been minimally modified for use in pediatric weight management programs.

2.7.2. Effectiveness and satisfaction

We will use short items of overall satisfaction with treatment and an overall question of quality of care used in previous research. Also, we will use a measure adapted from the RAND Patient Satisfaction Questionnaire Short form (PSQ-18) [47], with additional questions to cover domains of satisfaction outlined by Skelton et al. [48]. Effectiveness of the OFS on treatment outcomes will be assessed using BMI measurement at subsequent visits.

2.7.3. Approach

We will account for different treatment program sites in the analytic plan and include visit frequency and total visit number, and specialized treatment tracks (stated interest in future bariatric surgery,

telemedicine, weight-loss medications). These will be included in the analysis of differential attrition rates between sites.

2.7.4. Distance to treatment

Given the current COVID-19 pandemic, all programs have incorporated or expanded telemedicine capabilities. The number or proportion of telemedicine visits will be captured. For in-person appointments, distance from home to treatment will be determined in two ways: by parent report of time in minutes spent driving to the visit, and miles from home zip code to clinic location, as determined by Google Maps.

2.8. Data collection and outcomes

2.8.1. Data collection

Baseline data collection will take approximately 45 min for the parents and 30 min for the children. The six-month follow-up data collection will take 30 min for each parent and child. At both data collection visits, the child and parent will each receive a $25 gift certificate.

Data collectors will track children's and parents' program participation within the EHR system. Participation will be tracked by visit as missed appointments or attended appointments, and program completion as completed six months of treatment or dropped out.

2.8.2. Outcomes

Attrition from treatment will be the primary outcome, captured in three distinct ways: total appointments attended, overall proportion of the appointments attended, and the dichotomous treatment completion versus dropout. These will be defined as:

- Total appointments attended: the number of clinic visits attended by participants in six month time period;
- Proportion of appointments attended: total number of clinic visits attended/total number of clinic visits offered to participants;
- Treatment completion versus dropout: participants still active in treatment after six months; inactive defined as a missed appointment with no rescheduled appointment by participants despite two telephone calls and a letter over a one month time period, or no clinic attendance in six weeks without a future scheduled appointment.

The secondary outcomes will include a change in percent of the 95th percentile BMI, change in parent weight, and change in measures of health and health behaviors such as children's general and/or psychosocial health and family health habits. The OFS will also be formulated to build power and precision to predict the change in percent of the 95th percentile BMI. To address potential selection bias, missing BMI data will be multiply imputed using information from the prediction model (i.e., the predicted probability of attrition) and other demographic predictors with prognostic value for weight (e.g., baseline BMI, age, sex, height).

Process measures will include a brief exit interview to determine the reasons for dropping out, factors that kept patients enrolled, general satisfaction or dissatisfaction, and overall experience. To not unduly influence the primary outcome of attrition, if, upon contact, dropouts elect to re-enroll or begin treatment again, they will still be considered dropped out and have data collected, but they can re-engage in treatment if they desire. Their decision to re-enroll will be noted in the data, and the family will be assisted in scheduling an appointment.

2.8.3. Statistical analyses

The development and refinement of the OFS, and the statistical methods involved will be finalized in a separate statistical analysis plan (SAP). This plan will conform to the recommendations provided in the Transparent Reporting of a Multivariable Prediction Model (TRIPOD) guidelines [49]. In short, attrition prediction in this study will utilize Bayesian methods. Bayesian predictive modeling is similar to typical approaches, such as multivariable logistic regression, where predictors are incorporated into a model, and their associations (e.g., odds ratios) are estimated along with the uncertainty of those associations. In Bayesian modeling, prior probabilities can be considered as a 'best guess' to what the odds ratios will be. This will accommodate differences across sites, and allow the prediction model to be applied to future sites by using estimated associations from all of the other sites as the prior probability distribution of the new sites. This will allow the model to be flexible concerning site heterogeneity. This approach was developed by Houle et al. in the study of headaches [50]. The OFS is coded in the R language using several different publicly available packages. The sample size considerations related to the model discrimination methods are reported below.

2.8.4. Statistical power

For Aim 1, each site will enroll n = 100 dyads over two years (N = 300 dyads). This sample size will allow us to evaluate the hypothesis that the predictive accuracy of the forecasting model is AUC $\geq$0.70. Assuming a 50% attrition rate (i.e., event rate), N = 300 provides power = .80 to reject a one-sided null hypothesis test, assuming that the overall performance of the model is AUC$\geq$ 0.772. Furthermore, this sample size will allow the evaluation of individual parameters and parameter blocks within the model. For example, this sample size provides power = .80 to detect an OR$\geq$ 1.5 for any single predictor of attrition, assuming that this predictor is moderately correlated with the other predictors in the model ($R^2 = 0.40$) and ignoring across-site heterogeneity in the estimates.

Additional analyses will extend these models with the inclusion of covariates such as age and age group (7–12, 13–18 years), sex/gender, race/ethnicity, primary language spoken, etc. Combined with variables of race, ethnicity, and geography, a proxy variable of culture will be created. This is an important consideration given the family-based variables important to the conceptual model.

2.8.5. Temporal validation

We will conduct a temporal validation to examine if the performance of the system changes over time. Considering the issue of changing attrition over time strengthens the overall study design, findings, and potential clinical application, which involves evaluating the prediction model on subsequent patients from the same centers on which the prediction model was built. The same study design and processes will be used in the temporal validation, recruiting from the three weight management sites, enrolling patients, and prospectively following them in treatment. The model will be refined over years 1 and 2. Temporal validation will take place during year 3, in which each of the three sites is enrolling an additional 50 child-parent dyads (150 total). Multiple metrics, including predictive accuracy (sensitivity, specificity) and AUC, will be considered.

2.8.6. Study design for Aim 2

For Aim 2, we will install and externally validate the accuracy of a powerful omnibus OFS in an additional weight management program. The OFS will be applied to a fourth pediatric weight management program not involved in the original data collection to build external validity.

The study design will mirror that in Aim 1, prospectively enrolling all eligible children ages 7–18 years of age and a parent or guardian in a longitudinal observational study. Processes and procedures will be the same as in Aim 1. All variables included in Aim 1 will also be collected at the fourth site using the same processes for recruitment, enrollment, and tracking. External validation will occur at the Center for Healthy Weight and Nutrition at Nationwide Children's Hospital. As in Aim 1, we will recruit 100 child-parent dyads over two years. Eligibility, data management, study procedures, participant tracking, retention, and study measures will be the same as Aim 1.

2.8.6.1. Statistical Power. This hypothesis will be tested using a one-sided non-inferiority test comparing the AUC from Aim 1 to that obtained from a novel site. A sample size of n = 200 in Aim 2 pooled with n = 300 from Aim1 provides 80% power to examine this hypothesis for a non-inferiority region of 0.037 in the AUC. Thus, assuming that the model performance in Aim 1 is AUC = 0.775, the lower bound of model performance in Aim 2 must be > 0.738 to be considered non-inferior. Differences of this magnitude or smaller are not clinically meaningful and support the global utility of the model.

2.8.7. Study design for Aim 3

In Aim 3, we will operationalize the OFS to identify patients and families at the highest risk of dropping out of treatment, and institute an attrition-reduction intervention. Data collected in Aims 1 and 2 will inform the final design, with operations mirroring those of the first two aims. We will use a stepped-wedge cluster randomized trial, a pragmatic study design well suited for service delivery research [51]. We will conduct the intervention at the three original sites.

2.8.7.1. Stepped wedge cluster randomization. This will be a naturalistic study, assessing influence of knowing dropout risk on treatment course. While not as powerful as a randomized controlled trial, a naturalistic design is appropriate for a complex disease (obesity) in a complex setting (multidisciplinary treatment programs) with diverse participants (children and families) [53]. We will use the same Study Procedures as Aim 1, with three arms to study attrition reduction through use of the OFS: Control, Passive, and Active. Site activity will alternate every 3 months with the stepwise addition of passive and active interventions at sites:

Control arm: the data collection activities conducted in Aims 1 and 2 will occur, but individual risk of patient attrition using the OFS will not provided to the clinical team.

Passive: the same data will be collected as in the previous observational phases and Control arm, with the OFS generating an individual risk profile after beginning the weight management program and completing study measures. Study staff will provide the risk profile to clinical teams only on a monthly basis. For communicating probability/risk of dropout, a single-page print out will be provided to clinicians shortly after their first visit to the weight management clinic. The purpose of a passive arm is to assess if clinician knowledge/awareness of dropout risk would modify behaviors and clinical interactions to an extent that participant attrition is influenced.

Active: a risk profile for all enrolled patients will be provided to clinical teams as in the Passive intervention. Patients and families in the highest risk category (High Risk-defined as top quartile of dropout risk estimates) will be targeted for intervention. The Active intervention is based on evidence-based approaches [22–25,52–54]:

- Monitoring: Monthly query [22] of high-risk patients and families to determine if active (visit to or scheduled appointment with program in upcoming 4 weeks) or potentially inactive (no appointment in past 4 weeks and no appointment presently scheduled). Queries will be prepared by study staff and provided to the clinical team. Goal is to provide additional active monitoring of High Risk group, with subsequent contact made by study staff and/or clinical team of patients and families without a recent clinic appointment.
- Awareness: Weekly notification of High Risk patients and families with upcoming clinic visit. Personalized contact [25] if patient cancels or does not arrive for appointment; brief phone call made during the scheduled clinic visit time, allowing patient/family to reschedule or discuss reasons for missed appointment [24].
- Personalized mobile phone message (text, SMS): made by study staff the day before appointment [24,52,54]. Since this method may incur costs for some patients and families, it will be optional ("opt-in").
- Establishing relationship: single follow-up phone call by clinic staff after initial visit to facilitate relationship building with family, show to improve continuity and follow-up visit adherence [23,55].

The above will be done only for High Risk patients/families due to the added effort, which would be burdensome for all patients. Existing appointment reminder systems in place (similar between sites: automated reminder phone calls, mailed letters) will continue unchanged.

We will use the same recruitment strategies as in Aims 1 and 2. We will recruit 50 child-parent dyads at each site (150 total dyads) over 2 years, with the same eligibility criteria. Primary and secondary outcomes will also be the same as Aim 1 (Primary: attrition, number of total visits, percentage of visits attended; Secondary: change in child weight status, change in parent weight, change in measures of health behaviors). Most importantly, we will compare intervention (passive and active) versus control attrition.

2.8.7.2. Statistical design. Exploratory analyses will be run which extend these models through the inclusion of covariates such as age, sex, race/ethnicity, etc. Pair-wise interactions with study arm will be included in the models to determine if the effect of the intervention differs depending on the level of the covariate (e.g., differential effects for males and females). These interactions will be removed if not significant. The covariate main effects will be retained in the models to determine if they are associated with changes in the outcomes (e.g., sex might be related to the change in percent of 95th percentile, but the intervention could be equally effective for both sexes) and to assess the intervention effect after adjustment for the participant covariates.

2.8.7.3. Statistical Power. Participants will be followed for 6 months, to determine differences between active and passive interventions and control cohorts. A formal sample size will not be calculated, as this is an exploratory aim, designed to allow estimation of effect size to power a future, more definitive study.

3. Discussion

This manuscript provides a summary of the study design and methods of the Stay in Treatment (SIT) Study: Predicting Dropout from Pediatric Weight Management. Aim 1 is to install an Outcomes Forecasting System (OFS) in three pediatric weight management programs, calibrate it, and build its precision using a conceptual model of adherence. Aim 2 is to install and externally validate the accuracy of an omnibus OFS in an additional weight management program. The outputs from this study will then be used to develop a pilot intervention study to implement the OFS in pediatric weight management programs to decrease participant and family dropout.

The outcomes of this study will identify the most pertinent factors driving attrition from pediatric weight management, which may lead to new avenues for treatment as well as improved adherence and program engagement. The OFS will be made available to pediatric weight management programs to improve adherence and potentially patient outcomes. With improvement in electronic health records' (EHR) ability to incorporate prediction models, the OFS could potentially improve existing EHR models, making it even more practical and feasible to use. Machine learning tools are increasingly utilized in healthcare; this study will guide its use in pediatric weight management through the use of theoretical models of adherence and extensive validation.

4. Conclusion

The goal of this study is to validate the OFS so it can be quickly disseminated to pediatric weight management clinics. If successful, it will be instrumental in forecasting attrition and improving the care of obesity in pediatrics.

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Declaration of competing interest

Dr. Rhodes is the Site Principal Investigator for a clinical trial sponsored by Astra Zeneca.

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Dr. Sweeney is a member of Paediatric Obesity Global Advisory Board for Novo Norkisk.

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