

TOWSON UNIVERSITY
OFFICE OF GRADUATE STUDIES

COMPLIANCE IN CHILDREN WITH CONSTIPATION WITH AND WITHOUT
ENCOPRESIS: DOES FOLLOWING THE RULES IMPROVE THE CHILD'S
STOOLS?

by
Kristen A. Brock
A thesis
Presented to the faculty of
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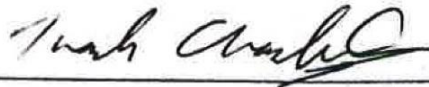
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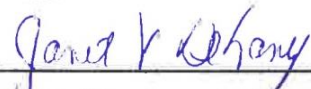
THESIS APPROVAL PAGE

This is to certify that the thesis prepared by Kristen A. Brock entitled Compliance in Children with Constipation with and without Encopresis: Does Following the Rules Improve the Child's Stools? has been approved by the thesis committee as satisfactorily completing the thesis requirements for the degree Master of Arts.

	<u>Mark Chachich</u>	<u>4/20/15</u>
Co-Chairperson, Thesis Committee Signature	Type Name	Date

	<u>Rick Parente</u>	<u>4/20/15</u>
Co-Chairperson, Thesis Committee Signature	Type Name	Date

	<u>Jessica Hankinson</u>	<u>4/20/15</u>
Committee Member Signature	Type Name	Date

	<u>Janet DeLany</u>	<u>4-21-15</u>
Dean of Graduate Studies	Type Name	Date

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Abstract

Compliance in Children with Constipation with and without Encopresis: Does Following the Rules Improve the Child's Stools?

Kristen A. Brock

Constipation is not an unusual problem for children. Painful defecation, the most frequently reported cause of constipation, leads to repeated withholding resulting in severe constipation and fecal soiling. Compliance is important for the success of treatment and the addition of behavioral interventions engaging positive reinforcement to medical treatment has shown increased rates of treatment compliance (Graves, Roberts, Rapoff, & Boyer, 2010). The purpose of this retrospective study was to broaden the literature and evaluate the relationship between compliance and clinical outcomes with the inclusion of a behavioral intervention. Patients seen in the Chronic Constipation Clinic at Johns Hopkins Children's Center completed the Pediatric Multidisciplinary Chronic Constipation Questionnaire during each clinic visit to assess compliance and clinical outcomes. Compliance, with medical and behavioral interventions, was found significantly related to the clinical outcomes selected for this study by way of a canonical correlation.

Keywords: constipation, encopresis, compliance, behavioral intervention, children

Table of Contents

List of Tables	vii
List of Figures	viii
Introduction	1
Compliance	3
Biobehavioral Approach	4
Rationale	9
The Present Study	12
Participants	13
Procedure	14
Materials	14
Compliance	14
Clinical Outcomes	15
Demographics	16
Results	16
Discussion	23
References	27
Appendix A	32
Appendix B	34
Appendix C	37
Appendix D	39
Curriculum Vitae	41

List of Tables

Table 1: Summary of Participant Demographics	14
Table 2: Compliance Variables	15
Table 3: Clinical Outcome Variables	16
Table 4: Significant Regression Models	17
Table 5: Significant Pearson Correlations	19
Table 6: Coefficients	22

List of Figures

Figure 1: Regression – BowelAccWk & RefuseSit	17
Figure 2: Regression – BowelAccYest & RefuseSit	18
Figure 3: Regression – SoilUnderwear & RefuseSit	18
Figure 4: Pearson Correlation – SoilUnderwear & RefuseSit	19
Figure 5: Pearson Correlation – BowelAccWk & RefuseSit	20
Figure 6: Pearson Correlation – BowelAccYest & RefuseSit	20
Figure 7: Pearson Correlation – BMtoiletYest & RefuseMeds	21
Figure 8: Regression – BMtoiletYest & NumbSitYest	22

Compliance in Children with Constipation with and without Encopresis: Does Following the Rules Improve the Child's Stools?

Constipation is not an unusual problem for children. It is estimated that nearly five percent of pediatric office visits and 25% of referrals for gastroenterology are for children suffering with constipation (Blackmer & Farrington, 2010). Johns Hopkins Children's Hospital developed a specialized clinic for children with constipation in response to the high demand of referrals to gastroenterology and in recognition of constipation's behavioral component ("Chronic constipation clinic," 2013). A recent meta-analysis suggests that pediatric patients had successful treatment outcomes, as defined by each study, and reduced soiling at a higher rate with the inclusion of behavioral interventions in comparison to medical treatment alone (Freeman, Riley, Duke, & Fu, 2014). This paper will define and further explain constipation, encopresis, and behavioral compliance, explore past research and the benefits of behavioral interventions on compliance and treatment of retentive encopresis and constipation in children, and discuss the present retrospective study of compliance and clinical outcomes in pediatric patients with constipation with and without encopresis in a multidisciplinary clinic.

The literature uses many different terms and definitions to identify constipation and encopresis making it challenging to analyze the literature properly for each condition. Many researchers (Di Lorenzo, 1994; Philichi, 2008; van Dijk, Benninga, Grootenhuis, Nieuwenhuizen, and Last, 2007) agree that constipation should be considered a symptom, not a disease, whereas Poenaru (1997) defines functional constipation as a condition not resulting from organic disease. Benninga, Voskuijl, and Taminiu (2004) characterize

constipation as a decrease in bowel movement frequency, or less than three bowel movements per week, and large stools associated with distress to the child. The most frequently reported cause of constipation is painful defecation (Borowitz et al., 2003). Repeated withholding is a consequence of the aversive reinforcement of painful defecation, which leads to severe constipation and fecal soiling (Partin, Hamill, Fischel, & Partin, 1992).

Encopresis, also known as fecal incontinence or soiling, refers to the repeated loss of feces in inappropriate places, or predominantly loose stool in the underwear, by a child older than 4 years developmentally (Benninga, Voskuijl, & Taminiu, 2004). Doleys (1983) characterizes children with retentive encopresis as having (a) chronic constipation, (b) infrequent bowel movements, (c) frequent soiling accidents (often more than two a day) in the form of small stains of liquid stool. Thus, retentive encopresis is also referred to as constipation with encopresis. Encopresis in this case is secondary to constipation; the child is having the leaking or soiling issue because they are so clogged with stool that it leaks out. McGrath, Mellon, and Murphy (2000) report that 85% of children with encopresis also have constipation. McGrath et al. (2000) very appropriately state that constipation and encopresis are overlapping medical problems that should be more clearly distinguished in the literature. Non-retentive encopresis is not included in the present study; it is not a product of constipation and is considered to be strictly behavioral as the child has normal daily bowel movements (Kuhn, Marcus & Pitner, 1999). The term encopresis will hereinafter assume presentation with constipation. The present study evaluated patients who have been diagnosed with constipation with and without encopresis in the Chronic Constipation Clinic at Johns Hopkins Children's Center.

Co-morbidity of enuresis or urinary incontinence is common in children with constipation and retentive encopresis (Loening-Baucke, 1997). Loening-Baucke (1997) found that 29% and 34% of 234 children with functional constipation and encopresis complained of daytime urinary incontinence and nighttime urinary incontinence respectively. Levine (1975) reported similar results; approximately 31% of the 102 encopretic children that they studied reported enuresis as well. Loening-Baucke (1997) suggests that these urologic issues are so greatly affected by constipation and encopresis that simply treating and eliminating the gastrological issues can cure the enuresis.

Compliance

Owen, Slep, and Heyman (2012) define compliance as “acting in accordance with a directive to engage in or to stop engaging in a behavior” (p. 364). In the present study, compliance refers to taking the prescribed medications as directed by the physician and adhering to the sit schedule as laid out by the psychologist. Compliance, behavioral compliance, and adherence are used interchangeably in the literature when referring to how children follow or obey their prescribed treatment, whether medical and / or behavioral. Noncompliance to treatment is not a new phenomenon in the chronically ill population; directly affecting the quality of life for pediatric patients and their families (Steiner et al., 2014). Steiner et al. (2014) suggest that including the patient and their families in some of the treatment related decisions could contribute to better compliance. The present study does incorporate parental guidance and involvement in the reinforcement process, which should lead to increased rates of compliance to treatment. Compliance to treatment is of great importance not only to the patient’s health, but also their quality of life, and overall financial costs. The addition of behavioral interventions

engaging positive reinforcement to medical treatment has shown increased rates of treatment compliance (Graves, Roberts, Rapoff, & Boyer, 2010).

An integral part of behavioral intervention for constipation is the use of a sit schedule. “Bowel sits” refer to time spent sitting on the toilet, regardless of the urge to have a bowel movement. Most children who suffer from chronic constipation have lost the ability to feel the urge to go to the toilet to expel a bowel movement (van Dijk, Benninga, Grootenhuis, Nieuwenhuizen, & Last, 2007). There are also many children who fear having a bowel movement on the toilet and thus need to spend time sitting on the toilet regardless of the intent to expel stool (McGrath, Mellon, & Murphy, 2000). The number of times a patient sits and for how long is determined by their diagnosis, age and motivation. Though not a measure collected for the present study, many patients use a sticker chart at home to keep track of their sit schedule. Sticker chart programs are patient specific and vary throughout treatment. For example, some children will earn a sticker for simply complying and sitting when scheduled, whereas other children will have to produce stool to earn a sticker. Luersen et al. (2012) found that children with chronic diseases have increased compliance and improved clinical outcomes with the use of sticker charts.

Biobehavioral Approach

As pediatric psychology is a fairly new field, there is limited research in this area of constipation and retentive encopresis with a focus on behavioral compliance. However, extensive research has established the need for behavioral interventions in addition to medical treatment. Levine and Bakow (1976) are thought to be among the

first to propose combining medical and behavioral interventions in the treatment of children with chronic encopresis (Borowitz, Cox, Sutphen, & Kovatchev, 2002).

Reimers (1996) looked at two separate cases of children with encopresis and found that medical treatment alone was not satisfactory in curing their encopresis thus, supporting the idea of a biobehavioral approach: Use of both medical and behavioral interventions simultaneously. For behavioral interventions to be successful, the use of a stool softener is likely necessary and adequate compliance is critical. The use of positive and negative reinforcement, token system or praise for appropriate voiding and assisting with clean up after soiling, were required to show significant improvement.

Stark et al. (1997) found comparable results in their replication of Stark, Owens-Stively, Spirito, Lewis and Guevermont (1990), which utilized a group therapy intervention protocol: “85% reduction in soiling pre- to posttreatment across the sample...and 86.5% of the children participating in the present study had fewer than 1 soiling episode per week by the end of treatment” (p. 630). The results of the initial study, and its replication, suggest that behavioral group treatments are highly effective for children with retentive encopresis (Stark et al., 1997). However, treatment success might be affected by certain child and family characteristics. Since Stark et al. (1997) found positive results with the inclusion of children as young as 2 years 8 months in their study, their results support the idea that behavioral interventions may be beneficial for the younger populations. With the exception of Stark et al.’s study, the literature lacks evidence of these interventions being used on children age 4 years and younger with constipation.

Borowitz, Cox, Sutphen and Kovatchev (2002) hypothesized that children who received the most treatment, three modalities versus only one or two, would have the best clinical outcomes. Therefore, they used an additive model of treatment modalities; two of the three modalities included behavioral interventions. Eighty-seven children with chronic encopresis were randomly assigned to one of the following three treatment groups: Intensive medical therapy (IMT group), intensive medical therapy with a behavior management program (enhanced toilet training, ETT group), or intensive medical therapy with enhanced toilet training and external anal sphincter-electromyographic biofeedback therapy (BF group). Though all three treatment groups had comparable decreases in soiling frequency, the medical and behavioral intervention group achieved this effect while taking fewer laxatives and attended fewer treatment sessions. Interestingly, Borowitz et al. (2002) found that if 2 weeks of treatment has been ineffective, continuing that treatment is not likely to yield positive results.

Based on the success demonstrated with Borowitz et al.'s (2002) ETT group, Ritterband et al. (2003) developed an internet based intervention, UCanPoopToo, that utilizes the ETT model of a behavioral intervention in addition to treatments provided by the treating physician. Initial results supported their hypotheses of reduced inappropriate soiling and increased bowel movements in the toilet of school-age children (6 to 12 yo) with encopresis. Ritterband et al. (2013) created a revised version of UCanPoopToo to investigate the success rate of the intervention with treatment as usual (TAU) with a larger sample with 1-year post intervention data. Participants who received UCanPoopToo and TAU reported significantly fewer soiling episodes than children who did not receive the internet intervention. While those children did experience clinical

outcome improvements, it took much longer. These results strengthen the evidence that behavioral interventions are critical for successful treatment of encopresis in children.

In contrast to much of the other literature, Rolider and van Houten (1985) used a reversal design that included a negative reinforcement procedure, avoidance of prolonged bowel sits (20, 40 or 90 minutes), to treat a 12-year-old girl suffering from retentive encopresis. Prolonged bowel sits occurred three times each day during that phase of treatment. The first sit was immediately after waking up for 20 minutes or until the girl produced a satisfactory amount of stool. If she failed to defecate during that sit, she was required to sit for forty minutes beginning at 1:30pm. Again, if she defecated before the end of the forty minutes then her time was up. If the girl had not defecated by 7:30pm, she would begin her third sit for the day that lasted ninety minutes unless she defecated before the time was finished. It is important to note that the girl was not allowed to read or occupy herself in any other manner during these sits; thus, there was no incentive to want to withhold a bowel movement longer. Measures included hourly checks of the girl's underwear by her mother to detect if the girl had soiled herself. In addition, all bowel movements, whether prompted or unprompted, were checked by the girl's mother or father to determine scoring. On average, 28% of initial baseline checks revealed soiled underwear; upon negative reinforcement introduction, the girl's underwear was soiled on only 1.6% of checks. A return to baseline resulted in an increase of soiling to 16%; once negative reinforcement was reintroduced, soiling was completely suppressed. The positive results of this simple negative reinforcement procedure provide evidence that using this technique is merited. However, further research on this negative reinforcement model was not found.

Another behavioral intervention that has been studied in children with encopresis is biofeedback. Biofeedback treatment has been shown to produce better short-term results in children with chronic constipation, encopresis and abnormal defecation dynamics compared to conventional treatment alone (Loening-Baucke, 1995). However, in follow-up evaluations Loening-Baucke (1995) found that long-term recovery was superior using conventional treatment (62%) over biofeedback training (50%). Improvement was seen in most patients with chronic constipation and encopresis, yet recovery was achieved in more patients who only received conventional treatment, which included medication and a sit schedule. Moreover, Borowitz et al. (2002) found the addition of biofeedback did not make a significant difference in clinical outcomes.

Cox, Morris, Borowitz, and Sutphen (2002) further investigated a biopsychobehavioral model of encopresis (cited in Cox et al., 2002) by evaluating children being treated for encopresis, siblings of the children with encopresis, and children without bowel disorders. Behavior and family environment assessments were completed by the maternal caretaker, the child's teacher completed a questionnaire, and the child completed an achievement assessment and a self-concept assessment. The two comparison groups, sibling and nonsibling, were combined for evaluation; they did not significantly differ on any of the subscales. Their results suggest that only 25% of children with encopresis might benefit from an intervention that extends past the typical symptom-focused behavioral intervention. Taitz, Wales, Urwin, and Molnar (1986) support these results with their observation that adding psychodynamic psychotherapy routinely to behavioral interventions is generally not beneficial. Cox et al. (2002) evaluated behavioral issues that may need to be addressed in a psychotherapy setting

compared to the present study that looks at behavioral compliance during behavioral interventions. It is important to distinguish between behavioral issues, such as anxiety/depression, disruptive behaviors, and attentional difficulties, and behavioral compliance. Although the aforementioned behavioral issues could affect behavioral compliance, that is not the focus of the present research.

Rationale

The present study enlists a positive reinforcement tactic, a sticker chart, as part of the at-home-application of a behavioral intervention in the treatment of constipation and encopresis in children. Though not directly measured in the present study, positive reinforcement is thought to have an effect on compliance. In the present study, the desired behavior is following the specified sit schedule; the positive event is receiving a sticker or token which will result in a prize or privilege determined by the child's parents and / or psychologist. A meta-analysis by Graves, Roberts, Rapoff, and Boyer (2010) provided evidence that positive reinforcement improved adherence to clinical protocols by children with chronic diseases. Furthermore, improved compliance has been shown to be somewhat effective in improving clinical outcomes (Graves et al., 2010). Since adherence to medical treatments is so important in the clinical outcome of the patient, research on compliance and its implications on clinical outcomes is critical.

As mentioned previously, Borowitz et al. (2002) credit Levine and Bakow (1976) as among the first to propose combining medical and behavioral interventions in the treatment of children with chronic encopresis. They investigated the treatment outcome of 127 children aged 4 to 16 years who were considered to have encopresis. Of the 110 children whose parents provided one-year outcome data via questionnaire, 51% were

considered in remission, 27% showed marked improvement, 14% showed some improvement and 8% were essentially unchanged. An integral part of their treatment included the use of a sit schedule, which was positively reinforced using a sticker chart for children under 8 years. After one-year, each case was assigned a compliance rating which was determined by various factors, including resistance to training or taking medications as reported by the child's parents. Compliance with the training regime was shown to be a major determinant of success after one year of treatment. Lack of compliance resulted in the failure of the intervention. Levine and Bakow (1976) demonstrate the importance of compliance in treating constipation and retentive encopresis and the need for additional research regarding compliance in patients being treated using a medical and behavioral approach.

Stark et al. (1997) found comparable results in their replication of Stark et al. (1990), suggesting that behavioral group treatments are highly effective for children with retentive encopresis. Since they found positive results with the inclusion of children as young as 2 years 8 months in their study, their results support the idea that behavioral interventions may be beneficial for the younger populations. Borowitz et al. (2002) and Loening-Baucke (1995) hypothesized that children who received biofeedback in addition to conventional medical treatment would have better outcome results than children who had only received conventional medical treatment, but their results did not support this claim. Loening-Baucke (1995) found that although children with chronic constipation, encopresis and abnormal defecation dynamics who received at least one biofeedback treatment did have better short-term outcomes, they did not have significantly better long-term outcomes than those children who only received conventional medical

treatment, which included a sit schedule. Borowitz et al. (2002) and Ritterband et al. (2003, 2013) found that medical treatment combined with a behavioral intervention had the greatest effect on children with encopresis.

In contrast to much of the other research, Rolider and van Houten (1985) completely suppressed the soiling of a 12-year-old girl suffering from retentive encopresis using a negative reinforcement procedure, which included avoidance of prolonged bowel sits. Additional research was merited to determine if similar results would occur with additional children, however, no further research enlisting a negative reinforcement model alone was found. Cox et al. (2002) provides an example of research evaluating behavioral issues, such as anxiety/depression, disruptive behaviors, and attentional difficulties, that may need to be addressed in a psychotherapy setting whereas the proposed study will look at behavioral compliance during treatment involving behavioral interventions. Stark et al.'s (1997) findings supporting behavioral group treatments "contributes to the broader field of pediatric psychology by demonstrating that behavioral treatment can enhance the outcome of medical management and by providing a model for an interdisciplinary approach to complex medical problems requiring extensive and ongoing life-style changes on the part of the child and family" (p. 632). Moreover, Levine and Bakow (1976) demonstrated the importance of compliance in treating constipation and retentive encopresis and the need for additional research measuring compliance in patients being treated using a medical and behavioral approach.

Due to the private nature of bowel movements, reliability data is difficult to collect and we are left to rely on parent- or self-report data (Stark et al., 1997).

Additionally, Stark et al. (1997) were not able to distinguish the unique contributions or

vitality of any one treatment component. Due to the extensive nature of Borowitz et al.'s (2002) enhanced toilet training program, which included modeling of appropriate defecation straining, and practical time limitations, ETT is an unrealistic treatment option for the typical pediatric or gastroenterology practice. As of publishing, they were investigating the effectiveness of presenting the training in the format of an interactive, child-oriented compact disc. McGrath et al. (2000) mentions the need for clarifying operational definitions in the research, the need for evaluating the efficacy of the varying treatment interventions across the distinct groups of symptoms, and the need for research on adherence of interventions. McGrath et al. (2000) report that "although encopresis has been researched for decades, no studies have included an adherence check with the intervention by the child and parents, although it has been hypothesized as a major contributor to treatment failures (Rappaport, Landman, Fenton, & Levine, 1986; Stark et al., 1990)" (p. 239). The present study focuses on the relationship between compliance and clinical outcomes in the treatment of constipation with and without encopresis in children with the inclusion of a behavioral intervention.

The Present Study

The purpose of the present study is to examine the relationship between compliance of children with constipation with and without encopresis and their clinical outcomes. Specifically, the present study will examine whether the children being seen in the Chronic Constipation Clinic are complying with the current treatment, taking medications and use of a sit schedule, and if their compliance is directly or indirectly related to successful bowel movements in the toilet, bowel accidents, inappropriate soiling, painful defecation, reports of constipation, and the ability to control the urge to

defecate. This is a retrospective quasi-experimental study. Compliance in the present study is shown when refused bowel sittings decrease over time and when refused medications decrease over time. Clinical outcomes are representative of the patient improvement. If compliance increases, then successful bowel movements in the toilet, and the ability to control the urge to defecate will increase; bowel accidents, inappropriate soiling, painful defecation, and reports of constipation will decrease.

Method

Participants

Two-hundred and thirty-two patients completed the Pediatric Multidisciplinary Chronic Constipation Clinic Questionnaire during at least one visit to the Chronic Constipation Clinic at Johns Hopkins Children's Center. The present study only includes patients who completed their first Pediatric Multidisciplinary Chronic Constipation Clinic Questionnaire on their initial visit to the clinic to control for previous treatment experience. Thus, reducing the participant pool to 172 patients. Since our hypotheses include change over time, patients must have completed two or more questionnaires to be included in data analysis. Fifty-nine patients' medical records were used for data analysis. Participants were seen in the Chronic Constipation Clinic at Johns Hopkins Children's Center with a diagnosis of constipation with and without encopresis. Demographic data is presented in Table 1.

Table 1

Summary of Participant Demographics

Gender	Frequency	Percent	Age	Frequency	Percent
Male	29	49.2%	1 - 4 yo	27	45.7%
Female	30	50.8%	5 - 10 yo	25	42.5%
			11 - 15 yo	7	11.9%

Note. yo = years old.

Number of Visits	Frequency	Percent
2	33	55.93%
3	14	23.73%
4	5	8.47%
5	3	5.08%
6	2	3.39%
7	1	1.70%
8	1	1.70%

Procedure

Participants or their parent(s) completed the Pediatric Multidisciplinary Chronic Constipation Clinic Questionnaire during each visit to the clinic. Generally, participants visited the clinic every three months. This questionnaire has been part of the patient's medical record for clinical outcome tracking purposes since July 1, 2013; data collected between July 1, 2013 and March 2, 2015 was evaluated for the present study.

Materials

Compliance. The present study used the Pediatric Multidisciplinary Chronic Constipation Clinic Questionnaire (see Appendix A) to assess compliance. The two-sided, 27 item questionnaire is comprised of the Pediatric Incontinence/Constipation Score (Fichtner-Fiegl, Sailer, Höcht & Thiede, 2003), which is a validated medical questionnaire, and non-validated compliance questions designed by the clinic's nurse

practitioner and psychologist. Specifically, the present study examined six items to assess compliance (see Table 2). The participant or parent(s) reported the frequency numerically.

Table 2

Compliance Variables

Variable Name	Variable Description/Questionnaire Item
MissedMedsWk	“Number of missed doses [of medication] in past week,”
MissedMedsYest	“Number of missed doses [of medication] yesterday,”
RefuseMeds	“Frequency of times in past week when [patient] refused to take medication on schedule,”
AvgSitDay	“Average number of [bowel] sits per day,”
NumbSitYest	“Number of [bowel] sits yesterday,”
RefuseSit	“Frequency of times in past week when [patient] refused to follow [bowel] sit schedule”

Clinical Outcomes. The present study also used the Pediatric Multidisciplinary Chronic Constipation Clinic Questionnaire to assess clinical outcomes. The two-sided, 27 item questionnaire is comprised of the Pediatric Incontinence/Constipation Score (Fichtner-Fiegl, Sailer, Höcht & Thiede, 2003), which is a validated medical questionnaire, and non-validated compliance questions designed by the clinic’s nurse practitioner and psychologist. The questionnaire was edited in September 2014 (see Appendix B), which included the addition of two items that will be assessed for the current study. Specifically, the present study examined eight items to assess clinical outcomes (see Table 3). The participant or parent(s) reported the frequency numerically or according to a 3-point Likert scale (Yes always, sometimes, no/never) where applicable.

Table 3

Clinical Outcome Variables

Variable Name	Variable Description/Questionnaire Item
BMtoiletWk	“Number of bowel movements in the toilet in the past week,”
BMtoiletYest	“Number of bowel movements in the toilet yesterday,”
BowelAccWk	“Number of [bowel] accidents in past week,”
BowelAccYest	“Number of [bowel] accidents yesterday,”
SoilUnderwear	“Does your child regularly soil its underclothes by involuntarily passing small amounts of stool?,”
PainWhenBM	“Does your child feel pain when opening its bowels?,”
Constipation	“Does your child suffer from constipation?,”
ControlUrge	“Can your child control the urge to open its bowels?”

Demographics. Four items including patient’s name, age, medical record number (MRN), and date of clinic visit were collected on the questionnaire, while date of birth (DOB) and gender were collected from the medical record. However, the present study only recorded the MRN, [patient’s] age, date of clinic visit, DOB, and gender. MRN was only used to identify each participant’s case for data recording purposes and was removed prior to analysis.

Results

The average of each variable was calculated for each patient. These averages were used for data analysis unless otherwise noted. Canonical correlation was used to test the hypothesis that compliance is globally correlated with clinical outcomes, as listed in Tables 1 and 2. Overall, the relationship between compliance and clinical outcomes was statistically significant; Roy’s Greatest Root = 25.08, $F(8) = 25.08$, $p < .001$. This

emerges as a very strong relationship, adjusted canonical correlation = 0.966463.

Multiple regressions were conducted to determine which factors of compliance predict clinical outcomes. Significant regression models are presented in Table 4 and Figures 1, 2, and 3.

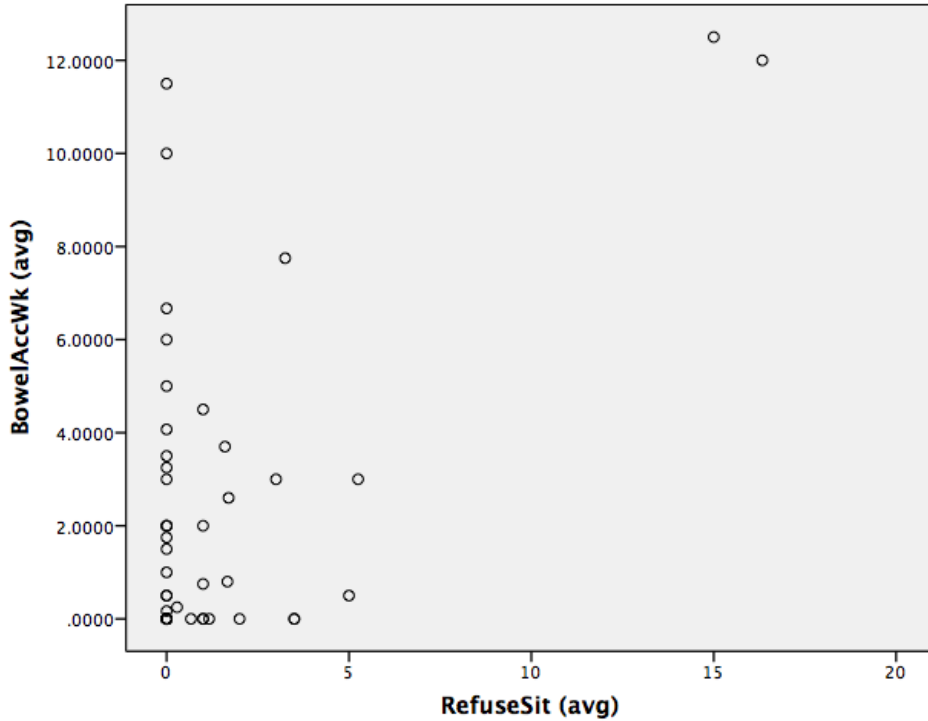
Table 4

Significant Regression Models

Outcome	Predictor	R-Square	Significance Level of Model	Significance Level of Predictor
BowelAccWk	RefuseSit	0.3963	0.0014	<.0001
BowelAccYest	RefuseSit	0.4128	0.0009	<.0001
SoilUnderwear	RefuseSit	0.3281	0.0077	0.0010

*p < .05

Figure 1: Regression - BowelAccWk & RefuseSit



*p < .05

Parametric correlations were computed on all variables to determine the relationships among compliance and clinical outcomes. Significant correlations among compliance and clinical symptoms are presented in Table 5 and Figures 4, 5, 6, and 7.

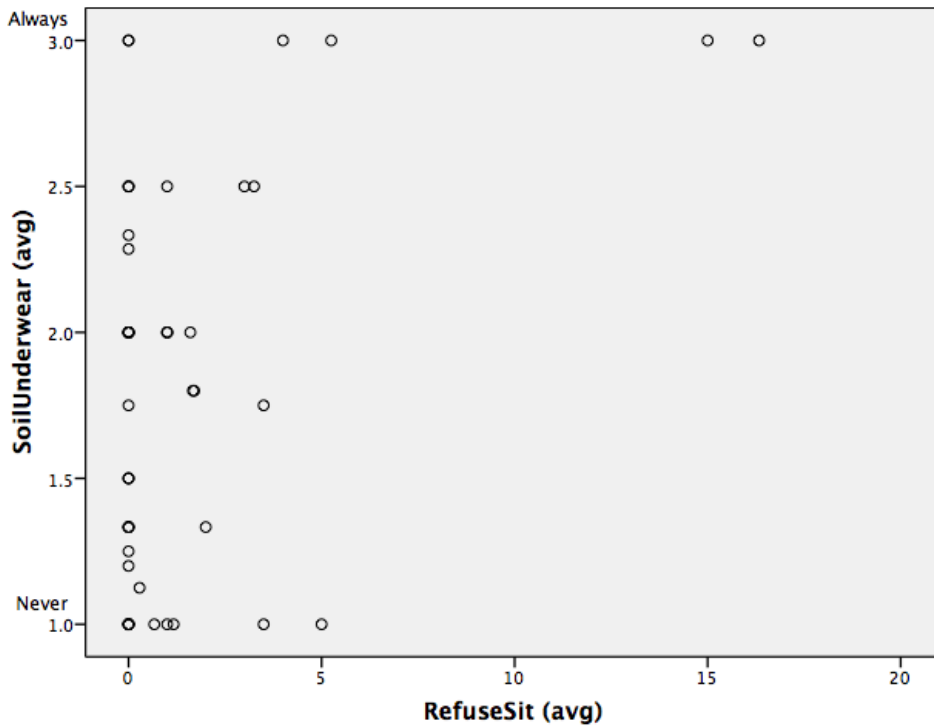
Table 5

Significant Pearson Correlations

Compliance	Clinical Outcome	r	Significance Value	n
RefuseSit	SoilUnderwear	0.40910	0.0032	50
RefuseSit	BowelAccWk	0.54768	<.001	49
RefuseSit	BowelAccYest	0.60385	<.0001	49
RefuseMeds	BMtoiletYest	-0.44879	0.0472	20

*p < .05

Figure 4: Pearson Correlation – SoilUnderwear & RefuseSit



*p < .05



*p < .05

Additionally, reports of pain during bowel movements were directly correlated ($r = 0.47469$, $p < .01$) with reports of constipation. Not surprisingly, reports of soiling were indirectly correlated ($r = -0.54009$, $p < .01$) with reports of the child's ability to control the urge to open their bowels.

Change scores were created to demonstrate change over time for each variable. Using these change scores, the number of bowel sits completed yesterday predicted bowel movements in the toilet yesterday, $p < .05$ (see Table 6).

Table 6

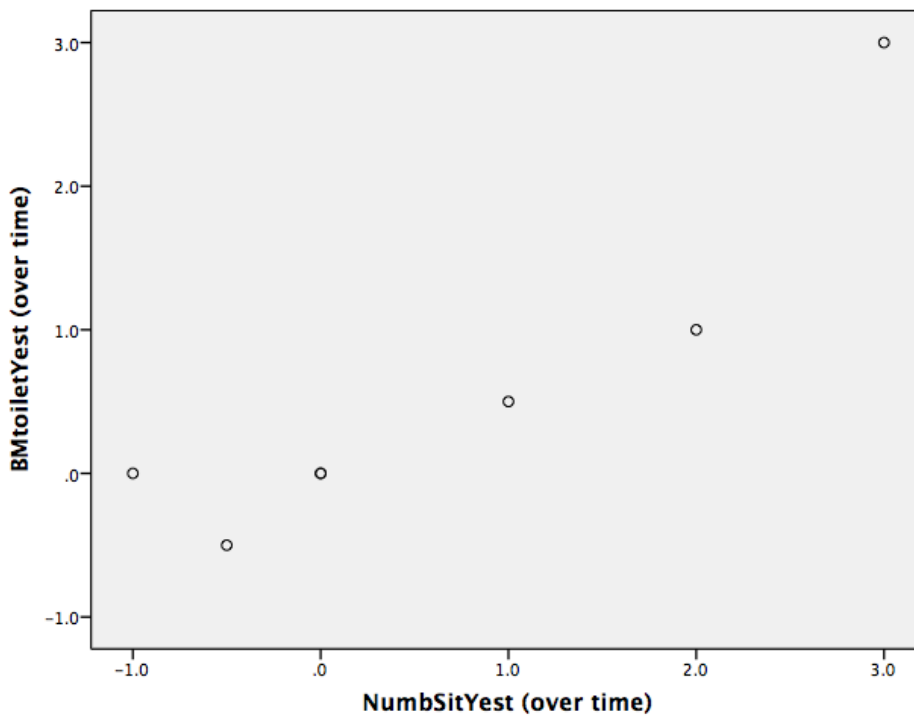
Coefficients^a

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	.114	.272		.419	.697
NSYC	.737	.171	.907	4.314	.013

a. Dependent Variable: BMTYC

Number of bowel sits completed yesterday also explained a significant proportion of variance in bowel movements in the toilet yesterday, $R^2 = .823$, $F(1, 5) = 18.608$, $p < .05$. Figure 8 illustrates this regression.

Figure 8: Regression – BMtoiletYest & NumbSitYest



*p < .05

Discussion

This retrospective study of compliance and clinical outcomes in pediatric patients with constipation with and without encopresis in a multidisciplinary clinic has extended the literature supporting the inclusion of behavioral interventions (Freeman et al., 2014; Levine & Bakow, 1976; Ritterband et al., 2013; Rolider & van Houten, 1985) and the importance of compliance (Graves et al., 2010; Luerson et al., 2012; Steiner et al., 2014) in improving clinical outcomes. Compliance, with medical and behavioral interventions, was found significantly related to the clinical outcomes selected for this study by way of a canonical correlation. While this relationship was very strong across all variables, we were unable to determine any relationships with the effect of time.

Multiple regressions deduced that not complying with treatment, specifically a behavioral intervention, by refusing to perform bowel sits in the past week, significantly predicts bowel accidents (in the past week and yesterday) and regular soiling of the child's underwear. It is assumed that compliance to treatment would improve these clinical outcomes. Thus, these results indirectly support our hypothesis that compliance with treatment that includes a behavioral intervention would lead to improved clinical outcomes.

These regression models were further supported by moderate to strong direct correlations of refused bowel sits in the past week and bowel accidents in the past week, yesterday, and regular soiling of the child's underwear. Bowel sits help to retrain the child to have a bowel movement (BM) in the toilet. Refusing to engage in this aspect of treatment reduces the likelihood of having appropriate BMs, thus maintaining constipation and resulting in leakage of stool in the child's underwear. While research on

this sensitive topic is often complicated due to gaining reliable data, it is encouraging to see that multiple reports of a similar item produced consistent results. That is, reports of regular soiling in the child's underwear using a scale (yes always, sometimes, no/never) corresponded with numerical reports of bowel accidents in the past week and yesterday; suggesting that this subset of the data was reliable.

Furthermore, a moderate indirect correlation was found with the number of times the child refused to take their medicine in the past week and the number of BMs they had in the toilet yesterday. These children are generally prescribed one dose of Miralax each day. Miralax, an osmotic laxative, has generally better rates of compliance compared to polyethylene glycol solutions that contain electrolytes (PEG-EL; Savino et al., 2012). PEG-only solutions, like Miralax, are less prone to cause nausea, bloating, and bad taste (Savino et al., 2012). Compliance with taking their medicine as prescribed would result in an increased number of BMs in the toilet yesterday. The child's refusal to take their medicine would make producing stool in the toilet more difficult for severely constipated children.

In agreement with much of the literature on constipation with and without encopresis, reports of pain when opening its bowels were moderately correlated directly with reports of constipation. Generally, children with constipation experience pain when opening their bowels as a result of the large amount of stool often impacted in their bowels (Borowitz et al., 2003). Also, regular soiling of the child's underwear was moderately correlated indirectly with reports of the child's ability to control the urge to open their bowels. Children that are unable to control the urge to open their bowels are

likely to have higher incidences of soiling their underwear (Doleys, 1983; van Dijk et al., 2007).

An evaluation of change scores created to show change over time for each variable was carried out. Regression analysis found that bowel sits completed yesterday significantly predicted bowel movements in the toilet yesterday. This suggests that complying with bowel sits over time leads to having BMs in the toilet over time. However, this may also be a false prediction stemming from a misunderstanding between what a bowel sit consists of and a BM on the toilet. The number of bowel sits completed yesterday should exceed the number of BMs in the toilet yesterday. Yet, Figure 8 suggests that patients completed equally as many bowel sits as BMs in the toilet. Clarification on what constitutes a bowel sit versus a BM in the toilet would provide the prospect for more discrete conclusions. Nevertheless, based on these analyses, compliance with behavioral interventions improved clinical outcomes in children with constipation with and without encopresis.

Limitations for the present study include: (a) the notion that this is a sensitive topic to discuss, thus, collecting reliable data via self and parent reports is difficult (Stark et al., 1997); (b) some items on the questionnaire may need clarification to ensure accurate reporting of bowel sits versus BMs on the toilet; and (c) most children are reliant on their parents to help them comply with their bowel sit schedule and to take their medicine as prescribed, consequently, if the parent forgot to give the child their medicine or to abide by their sit schedule the child's clinical outcomes will not improve. In this particular sample, gender was evenly balanced; therefore it should have no impact in the present study. Nearly half of the sample was younger than 5 years old, which suggests

that young children do benefit from the implementation of behavioral interventions (Stark et al., 1997).

Future research should evaluate whether there are any differences based on socioeconomic status and education level of parent(s). The role of the parent(s) in this treatment plan is very important to the child's successful improvement of clinical outcomes. Accordingly, children whose parent(s) work during the day may not be able to follow through with treatment at the same level as a stay-at-home parent who can monitor bowel sits on schedule. A larger sample of patients that have been seen in the multidisciplinary clinic more than two times would improve the analysis of impact on compliance and clinical outcomes over time. The majority of patients in the present study were only seen in the clinic twice, as a result, analysis of change over time among compliance and clinical outcomes was limited. While there is room for improvement, the present study added to the literature regarding the benefits of behavioral interventions and compliance with these treatments to improve clinical outcomes in children with constipation with and without encopresis.

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Appendix A
Pediatric Multidisciplinary Chronic Constipation Clinic Questionnaire



Date:
 Patient Name:
 Age:
 MRN:

Medication

Number of missed doses in past week:

Number of missed doses yesterday:

Frequency of times in past week when **refused** to take medication on schedule:

“Bowel Sits”

Average number of sits per day:

Number of sits yesterday:

Frequency of times in past week when **refused** to follow sit schedule:

Bowel Accidents

Number of accidents in past week:

Number of accidents yesterday:

Urine Accidents

Number of **daytime accidents** in past week:

Number of **daytime accidents** yesterday:

Number of **nighttime accidents** in past week:

Number of **nighttime accidents** yesterday:

Bowel Cleanses (if applicable since last clinic visit)

Successful (end result of clear broth-like stools) **Yes** or **No** or **N/A**

If inpatient admission, length of stay:

(Over)

How often does your child open its bowels?

Several times a day

Once daily

Less often

What does the stool usually look like?

Watery

Variable

Thick

Can your child tell the difference between stool and air in the bowels?

Yes always

Sometimes

No

Does your child regularly soil its underclothes by involuntarily passing small amounts of stool?

Yes always

Sometimes

No

Does your child have trouble opening its bowels completely (incomplete emptying)?

Yes always

Sometimes

No

Does your child feel pain when opening its bowels?

Yes always

Sometimes

No

Does your child have to press hard to empty its bowels?

Yes

Normal

No

Does your child have a lot of wind?

Yes always

Sometimes

Never

Does your child suffer from constipation?

Yes always

Sometimes

Never

Does your child have pains in the tummy?

Yes always

Sometimes

Never

Does your child wear diapers during the day?

Always

Sometimes

No

Does your child wear diapers during the night?

Always

Sometimes

No

Can your child control the urge to open its bowels?

Yes always

Sometimes

No

Appendix B
Pediatric Multidisciplinary Chronic Constipation Clinic Questionnaire

Date:
Patient Name:
Age:
MRN:



Number of bowel movements in the toilet in the past week:

Number of bowel movements in the toilet yesterday:

Medication

Number of missed doses in past week:

Number of missed doses yesterday:

Frequency of times in past week when **refused** to take medication on schedule:

“Bowel Sits”

Average number of sits per day:

Number of sits yesterday:

Frequency of times in past week when **refused** to follow sit schedule:

Bowel Accidents

If yes, what type of accidents is your child having?

Number of accidents in past week:

Full bowel movement

Number of accidents yesterday:

Streak/smear

Both

Urine Accidents

Number of **daytime accidents** in past week:

Number of **daytime accidents** yesterday:

Number of **nighttime accidents** in past week:

Number of **nighttime accidents** yesterday:

Bowel Cleanses (if applicable since last clinic visit)

Successful (end result of clear broth-like stools) **Yes** or **No** or **N/A**

If inpatient admission, length of stay:

How often does your child open its bowels? Does your child have a lot of wind (i.e. "gas")?

Several times a day

Yes always

Once daily

Sometimes

Less often

Never

Does your child regularly soil its underclothes by involuntarily passing small amounts of stool?

Does your child suffer from constipation?

Yes always

Yes always

Sometimes

Sometimes

No

Never

Does your child have pains in the tummy?

Does your child have trouble with incomplete emptying (i.e. feels like more stool needs to come out)?

Yes always

Yes always

Sometimes

Sometimes

Never

No

Does your child wear diapers during the day?

Does your child feel pain when opening its bowels?

Always

Yes always

Sometimes

Sometimes

No

Does your child wear diapers during the night?

No

Always

Does your child have to press hard (i.e. "strain") to empty its bowels?

Sometimes

Yes

No

Normal

Can your child control the urge to open its bowels?

No

Yes always








Sometimes

No

Using the Bristol Stool Chart below, on average, what type of stools is your child having?

_____ (1-7)

Bristol Stool Chart

Type 1		Separate hard lumps, like nuts (hard to pass)
Type 2		Sausage-shaped but lumpy
Type 3		Like a sausage but with cracks on its surface
Type 4		Like a sausage or snake, smooth and soft
Type 5		Soft blobs with clear-cut edges (passed easily)
Type 6		Fluffy pieces with ragged edges, a mushy stool
Type 7		Watery, no solid pieces. Entirely Liquid

How effective or helpful was the treatment you received through the Constipation Clinic at Johns Hopkins?

1=None or Not Effective

2

3=Some

4

5= A lot

Appendix C**APPROVAL NUMBER: 14-A092**

To: Kristen Brock
8000 York Road
Towson MD 21252

From: Institutional Review Board for the Protection of Human
Subjects Beth Merryman, Member

Date: Tuesday, June 03, 2014

RE: Application for Approval of Research Involving the Use of
Human Participants



Office of Sponsored Programs
& Research
Towson University
8000 York Road
Towson, MD 21252-0001
t. 410 704-2236
f. 410 704-4494
www.towson.edu/ospr

Thank you for submitting an Application for Approval of Research Involving the Use of Human Participants to the Institutional Review Board for the Protection of Human Participants (IRB) at Towson University. The IRB hereby approves your proposal titled:

Assessment of Medical and Behavioral Outcomes in Children With Chronic Constipation

If you should encounter any new risks, reactions, or injuries while conducting your research, please notify the IRB. Should your research extend beyond one year in duration, or should there be substantive changes in your research protocol, you will need to submit another application for approval at that time.

We wish you every success in your research project. If you have any questions, please call me at (410) 704-2236.

CC: M. Chachich
File



Date: Tuesday, June 03, 2014

NOTICE OF APPROVAL

TO: Kristen Brock **DEPT:** PSYC

PROJECT TITLE: *Assessment of Medical and Behavioral Outcomes in Children With Chronic Constipation*

SPONSORING AGENCY:

APPROVAL NUMBER: 14-A092

The Institutional Review Board for the Protection of Human Participants has approved the project described above. Approval was based on the descriptive material and procedures you submitted for review. Should any changes be made in your procedures, or if you should encounter any new risks, reactions, injuries, or deaths of persons as participants, you must notify the Board.

A consent form: is is not required of each participant

Assent: is is not required of each participant

This protocol was first approved on: 2014-06-03

This research will be reviewed every year from the date of first approval.


Beth Merryman, Member
Towson University Institutional Review Board

Appendix D**Office of Human Subjects Research*****Institutional Review Boards***

1620 McElderry Street, Reed Hall, Suite B-130 Baltimore, Maryland
21205-1911 410-955-3008 410-955-4367 Fax

e-mail: jhmirb@jhmi.edu



Date: May 12, 2014

APPLICATION APPROVAL

Review Type: Expedited

PI Name: Jessica Hankinson

Study #: NA_00091839

Study Name: Assessment of medical and behavioral outcomes in children with chronic constipation

Committee Chair: Susan Bassett

Committee: IRB-X

Date of approval: May 1, 2014

Date of expiration: April 30, 2015

The JHM IRB approved the above-referenced Application.

IRB review included the following:

45 CFR 46.116: A waiver of consent was granted based on the following criteria: 1) the research involves no more than minimal risk to subjects; 2) the waiver will not adversely affect the rights and welfare of the subjects; 3) the research could not be practicably carried out without the waiver; and 4) the IRB will advise you if it is appropriate for participants to be provided with additional pertinent information after participation.

45CFR46.404 and/or 21 CFR 50.51: This study has been approved for the inclusion of children as 'research not involving greater than minimal risk'. The permission of parents/guardians is waived.

Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

Date of Approval and Expiration Date: The approval and expiration date for this research are listed above. If the approval lapses, the research must stop and you must submit a request to the IRB to determine whether it is in the best interests of individual participants to continue with protocol-related procedures.

Changes in Research: All proposed changes to the research must be submitted using a Change in Research application. The changes must be approved by the JHM IRB prior to implementation, with the following exception: changes made to eliminate apparent immediate hazards to participants may be made immediately, and promptly reported to the JHM IRB.

Continuing Review: Continuing Review Applications should be submitted at least 6 weeks prior to the study expiration date. Failure to allow sufficient time for review may result in a lapse of approval. If the Continuing Review Application is not submitted prior to the expiration date, your study will be terminated and a New Application must be submitted to reinitiate the research.

Unanticipated Problems: All unanticipated problems must be submitted using a Protocol Event Report.

If this research has a commercial sponsor, the research may not start until the sponsor and JHU have signed a contract.

Study documents:

HIPAA Form 4:

FINAL_Hankinson_NA_00091839_HIPPAform4 for JHU IRB v5_05012014.docx

Additional Supplemental Study Documents:

Constipation Clinic Variables.xlsx

Study Team Members:

Lisa Santo Domingo, Kristen Brock, Maria Oliva-Hemker, Rick Ostrander

The Johns Hopkins Institutions operates under multiple Federal-Wide Assurances: The Johns Hopkins University School of Medicine - FWA00005752, The Johns Hopkins University School of Nursing - FWA00006088, The Johns Hopkins Hospital and Johns Hopkins Health Systems - FWA00006087, Johns Hopkins Bayview Medical Center - FWA00006089, Howard County General Hospital - FWA00005743, Hugo W. Moser Research Institute at Kennedy Krieger, Inc. - FWA00005719, Johns Hopkins Community Physicians - FWA00002251, Suburban Hospital and Health System - FWA00005924

KRISTEN A. BROCK**EDUCATION:**

Towson University, Towson, MD

Master of Arts in Experimental Psychology, 2015 (Expected), GPA: 3.742

Bachelor of Science in Psychology, 2013, GPA: 3.941

Harford Community College, Bel Air, MD

Associate of Sciences in Chemistry, 2011, High Honors, GPA: 3.83

ACADEMIC EXPERIENCE:

Towson University, Towson, MD, Department of Psychology

Graduate Teaching Assistant

- Psychology of Aging, May – June 2014
- Cross-Cultural Psychology, August 2013 – May 2014

Undergraduate Proctor

- Physiological Psychology, January – May 2013
- Behavioral Statistics, August – December 2012

PROFESSIONAL RESEARCH EXPERIENCE:

Johns Hopkins University – School of Medicine, Child & Adolescent Psychiatry

Research Assistant (June 2012 – present)

Update Excel & SPSS databases, score Behavior Assessment System for Children (BASC) forms, and observe psychology consults of patients diagnosed with urological and gastroenterological disease.

ACADEMIC HONORS:

2012 – Psi Chi International Honor Society

2012 – Golden Key International Honour Society

2012 – Omicron Delta Kappa National Leadership Honor Society

2012 – Tau Sigma National Honor Society

2012 – Delta Alpha Pi International Honor Society

2010 – All-Maryland Academic Team

2010 – Phi Theta Kappa Honor Society

2009 – Alfred C. O'Connell Honors Scholarship, Harford Community College

RESEARCH INTERESTS:

Chronic illness

- Depression and anxiety
- Peer relationships and self-confidence
- Stress

Biopsychology

SERVICE TO EDUCATIONAL INSTITUTIONS:

President, Towson University Chapter, Golden Key International Honour Society
(May 2012 – May 2013)

Member, Fundraising Committee, Delta Alpha Pi International Honor Society
(February 2012 – May 2013)

Representative, Higher Education and Conference Center, Tau Sigma National Honor Society (February 2012 – May 2013)

President, Rho Beta Chapter, Phi Theta Kappa Honor Society, Harford Community College
(December 2010 – May 2011)

Secretary of Scholarship, Rho Beta Chapter, Phi Theta Kappa Honor Society, Harford Community College (May – December 2010)

PRESENTATIONS:

Brock, K. A., Hankinson, J., & Chachich, M. (April, 2015). Compliance in Children with Constipation with and without Encopresis: Does Following the Rules Improve the Child's Stools? Poster presented at the Undergraduate and Graduate Research and Performance Expo at Towson University, Towson, MD.

Kalodner, C., & Brock, K. A. (April, 2014). Cross-Cultural Psychology Collaboration with English Language Center. Poster presented at the Service Learning Faculty Fellows Showcase at Towson University, Towson, MD.

OTHER WORK EXPERIENCE:

Childcare Provider, Mountain Christian Church – The EPICENTER at Edgewood, Edgewood, MD, (August 2013 – December 2014)

LET'S GO STEM Program Assistant, Boys and Girls Club of Harford County, Aberdeen, MD, (March 2011 – May 2011)

COMMUNITY INVOLVEMENT:

Lifetime Girl Scout

Mentor and Bible Study Co-Leader for Tenth-Grade girls (Fall 2009 – present)

