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Journal of Pediatric Nursing

journal homepage: www.pediatricnursing.org

Association of parent demographic and psychophysical characteristics and pediatric hospital falls: A pilot and feasibility study

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ARTICLE INFO

Article history:

Received 3 August 2021

Revised 15 December 2021

Accepted 15 December 2021

Keywords:

Fall

Hospital

Inpatient

Parent

Fall risk

ABSTRACT

Purpose: This pilot project evaluated the feasibility of conducting a study describing parental characteristics associated with pediatric hospital falls.

Design and methods: This observational case-control study enrolled parent-child dyads of children who fell in the hospital and age-matched controls. Parents completed demographic, anxiety, depression, fatigue, sleep disturbance and stress questionnaires.

Results: Four of 14 (28.6%) eligible faller dyads were recruited. Stress scores were correlated with anxiety and depression scores. Power calculations indicated a need for 392 fallers for a future study to identify associations of parent characteristics and pediatric hospital falls.

Conclusions: Parents should be informed the ultimate goal of the research is to understand additional ways to prevent pediatric hospital falls. To decrease parental distraction during recruitment, researchers should engage volunteers or child life specialists to entertain younger children. Future studies should consider inclusion of non-English speaking subjects and children discharged within the post-fall eligibility time frame. To decrease multicollinearity concerns, the parent stress tool should be omitted. Due to the large number of fallers needed for an adequately powered sample, a multi-site study will be needed.

Practice implications: A parent is often present when their child falls in the hospital. Fall risk assessment focuses on patient characteristics, neglecting parental psychophysical characteristics which may be associated with risk of falling in the hospital. Associations of parent psychophysical characteristics and pediatric hospital falls needs to be studied further. This pilot study supports the feasibility of and provides recommendations for conducting a study to describe parent characteristics associated with pediatric hospital falls.

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Background

A fall is “an unintentional descent...that results in the patient coming to rest” at a lower position (National Database of Nursing Quality Indicators, 2016, p. 2). Falls account for about 42% of reported adverse events in hospitalized children (Alemdaroglu et al., 2017; Fujita et al., 2013; Lee et al., 2013). Parents are present for 60–83% of these falls (Bagnasco et al., 2010; Lee et al., 2013) and often witness the falls (Jamerson et al., 2014). In fact, children are more likely to be injured from a hospital fall when a parent is present (Jamerson et al., 2014; Schaffer et al., 2012). While we do not know why this association exists, some hypothesize that parent characteristics including demographic

(Almis et al., 2017) and other characteristics, such as anxiety, fatigue, and stress may contribute to the risk of children falling by causing parents to be distracted or less vigilant (Jamerson et al., 2014; Lee et al., 2013; Ryan-Wenger & Dufek, 2013). Associations of parent psychophysical characteristics with pediatric hospital falls has not been tested. Psychophysical characteristics have both psychological and physical components which may impact parents' responses. While researchers are beginning to investigate associations of parent demographic characteristics and pediatric hospital falls (Almis et al., 2017), further research about these associations in addition to psychophysical characteristics is needed.

Parent characteristics associated with pediatric injuries outside the hospital

Researchers have hypothesized the risk of pediatric hospital falls may be impacted by parent characteristics such as anxiety, stress, and

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fatigue causing them to be distracted or less vigilant at moments when other fall risk factors converge (Da Rin Della Mora et al., 2012; Jamerson et al., 2014; Ryan-Wenger & Dufek, 2013). Associations between parent psychophysical characteristics and hospital fall injuries have yet to be studied. However, outside of the hospital, decreased parent supervision activities have been found to be associated with injuries in young children (Morrongiello et al., 2009). It is unclear if parent supervision activities are impacted by parent psychophysical characteristics such as depression or stress. Some studies found weak to no association of moderate maternal depression with child injury risk (Rhodes & Iwashyna, 2007; Schwebel & Brezausk, 2008). However, a strong association between chronic maternal depression and child injury risk was found (Schwebel & Brezausk, 2008). Maternal depression has been shown to be associated with decreased social support and increased stress (Mulvaney & Kendrick, 2005). Decreased social support has been found to be associated with less safe home environments (Rhodes & Iwashyna, 2007). Parenting stress was not found to be different between injured and non-injured preschoolers (Bruce et al., 2004). However, the number of adverse family events was found to be associated with increased injuries in children outside of the hospital (McKinlay et al., 2010). In fact, four or more adverse events in the prior year was associated with almost three times the risk of traumatic brain injury in children (McKinlay et al., 2010).

Impact on parents of hospitalized children

Parental difficulties related to their child's hospitalization have been measured as anxiety, depression (Barnes et al., 2017; Stremler et al., 2017), stress (Hagstrom, 2017; Hasan Tehrani et al., 2012), fatigue (Stremler et al., 2014), and sleep alterations (McCann, 2008; Stremler et al., 2014). As expected, parent anxiety increased when their child was admitted to the intensive care unit (Al Maghaireh et al., 2016; Needle et al., 2009). For children hospitalized with an acute illness, parental stress increased as the length of stay (LOS) increased (Commodari, 2010; Hasan Tehrani et al., 2012). Interestingly for children with a chronic illness, a planned Pediatric Intensive Care Unit (PICU) admission was associated with a 4.6 times greater risk of parent depression compared to an unplanned admission (Fauman et al., 2011). This finding may be due to more time planning for the admission resulting in greater stress. Stress associated with an unplanned admission may be lower due to less time managing the illness or the parent not yet having time to process the situation's severity. It is clear that having a child hospitalized contributes to parental psychophysical challenges. However, we do not know how these challenges are associated with their child's safety in the hospital, specifically risk of falling.

Parent characteristics associated with pediatric hospital falls

Parent presence is not protective against pediatric hospital falls (Jamerson et al., 2014; Lee et al., 2013; Razmus et al., 2006). Some propose this may be due to parent distraction, fatigue, or stress (Fujita et al., 2013; Jamerson et al., 2014; Lee et al., 2013; Ryan-Wenger & Dufek, 2013). However, only one study that attempted to understand parent characteristics associated with pediatric hospital falls was found (Almis et al., 2017). This matched case-controlled observational study was conducted at a 600-bed teaching hospital in Turkey. Thirty-nine parent-child dyads of children who fell over approximately one year were matched based on parent and child age and gender with 78 non-faller dyads for a total of 117 dyads. Dyads were excluded if the parent or child had a chronic disease or were taking medications which could cause anxiety, sleep deprivation, restlessness or increase stress levels. Additionally, if the parent had a psychiatric disorder the dyad was excluded. Similar to other studies (Graf, 2005), Almisi et al. (2017) found a longer LOS was associated with increased odds of the child falling ($OR = 2.04$, 95% CI : 1.40, 2.95). Parent

characteristics associated with higher odds of the child falling were lower education level ($OR = 0.32$, 95% CI : 0.14, 0.69) and smoking ($OR = 5.80$, 95% CI : 1.19, 28.19).

While this study is novel in that it begins to identify parent characteristics associated with pediatric hospital falls, there were limitations. The only parent factors investigated were demographic characteristics omitting psychophysical characteristics such as anxiety, depression, fatigue, sleep deprivation, and stress hypothesized to be associated with hospital falls. Exclusion of patients or parents receiving/taking medications which could increase stress, anxiety, restlessness, or sleep deprivation limited the ability to describe associations of these characteristics with pediatric hospital falls. The authors attributed findings of increased odds of falling and longer LOS, to increased parent stress, anxiety, and distraction (Almis et al., 2017). However, they did not gather data related to these characteristics.

While there is evidence of associations of parent supervision activities and psychophysical characteristics with child injuries outside the hospital, this evidence does not exist for hospital injuries and falls. It is unclear if the hospital experience or environment contributes to changes in parent vigilance with supervision activities. Further research describing parent characteristics associated with pediatric hospital falls is needed, especially in relation to psychophysical characteristics such as anxiety, fatigue, stress, and depression which can be identified and mitigated during hospitalization. While the association of parental presence and pediatric hospital falls has been identified (Jamerson et al., 2014; Lee et al., 2013; Schaffer et al., 2012), there is a lack of understanding as to why this association exists and how to leverage parental presence to decrease these falls. Parents are often present during hospitalization. As such, it is key that the healthcare team partners with parents to promote optimal child safety during hospitalization.

While pediatric hospital falls are the most common type of adverse events reported for hospitalized children (Alemdaroglu et al., 2017; Fujita et al., 2013; Lee et al., 2013), they are relatively rare with a prevalence of 0.56 to 2.19 falls per 1000 patient days (Pauley et al., 2014). Since falls are unpredictable, pre-fall measurements of parent psychophysical characteristics are not practical. For research purposes, parent characteristic data must be collected within a relatively short time period after the fall to limit recall bias. The ability to recruit parents of children who have fallen in the hospital may be limited by at least two factors: 1) parents must be present for recruitment during the specified post-fall time frame, 2) parents may feel "blamed" for the fall and thus resistant to study participation. As a result, the time needed to recruit an adequate sample was unclear. Thus, a pilot study was undertaken to evaluate the feasibility of conducting a future study aimed at describing parent demographic and psychophysical characteristics, specifically anxiety; depression; fatigue; sleep disturbance; and stress, associated with pediatric hospital falls.

Objective

The aim of this pilot study was to evaluate the feasibility of conducting a future study to describe parent characteristics associated with pediatric hospital falls. Feasibility was addressed by evaluating recruitment, equipment needs, instrument acceptability, and descriptive data to inform power analysis for future research. This aim was addressed by:

1. Describing the fall population at a children's hospital over a 2.5-month period.
2. Identifying number of case subjects (faller parent-child dyads) that can be enrolled for a future study aimed at identifying parent characteristics associated with pediatric hospital falls.
3. Identifying sample size needed for an adequately powered study to describe parent characteristics associated with pediatric hospital falls.

Methods

Study design

An observational case-control study was undertaken to evaluate the feasibility of conducting a future study to recruit subjects and describe parent characteristics (demographic and psychophysical) associated with pediatric hospital falls.

Setting

This study was conducted at a children's hospital in the northwest United States, which provides inpatient and outpatient services across multiple specialties. It serves as a quaternary referral center for a four-state region. The hospital is licensed for 407 inpatient beds with an average daily census of 290 patients. The average nurse to patient ratio for acute care units is one nurse to three patients. In the year immediately preceding data collection, the fall rate across study units was 1.08 per 1000 patient days (January – December 2019). Parents were present for 78% of these falls.

Subjects

The population of interest was parent-child dyads of children who fell in the hospital and dyads of the child's age matched controls. Parent was defined as a person listed in the medical record as the child's guardian, legal custodian or was permitted to consent for care. Child was defined as a patient less than 18 years of age. Parent-child dyads of children admitted to a Medical, Surgical, Oncology, Rehabilitation, PICU, or Cardiac Intensive Care Unit (CICU) were eligible for recruitment. Subjects had to be able to understand and communicate (written and verbal) in English as all study materials were presented in English. Additionally, case subjects needed to have a fall risk assessment score documented in the Electronic Health Record (EHR) prior to the fall. The fall risk assessment tool is not completed for children less than 1 year of age therefore, these children were not eligible for recruitment. Parent child-dyads of children with suspected intentional falls were not eligible for recruitment.

Procedure

Following Institutional Review Board (IRB) approval, subjects were recruited over a 2.5-month period from January – mid March 2020. Potential case subjects were identified by review of the incident reporting system for a fall and were approached within 96 h after the child experienced a fall. Controls were parent-child dyads of children who did not experience a hospital fall prior to data collection and were identified by reviewing hospital census for matching characteristic of age within one year of case's age. Control subjects were approached after enrollment of the age matched case subject. Two controls were recruited for each case. To ensure independence of the data, only one parent was enrolled for each subject. If more than one parent was identified as interested during enrollment, the parents were asked to choose which one would participate.

After written informed consent for participation, the parent was asked to complete the demographic questionnaire, the Pediatric Inventory for Parents (PIP) (Streisand et al., 2001), and Patient Reported Outcomes Measurement Information System (PROMIS) tools (Health Measures, 2018; National Institutes of Health, 2013) for anxiety, depression, fatigue, and sleep disturbance in the Research Electronic Data Capture (REDCap) system (Harris et al., 2009) (Fig. 1). Electronic devices (iPads) were used to decrease risk of transcriber error of entering responses into the database. Parents were informed the estimated time for tool completion was 20–30 min. After tool completion, the Principal Investigator (PI) or research assistant reviewed the child's EHR and obtained the fall risk score closest in proximity prior to the fall (cases) or

Study Instruments

Researcher developed demographic tool (parent and child)
PIP (parent)
PROMIS anxiety short form 7a (parent)
PROMIS depression short form 8a (parent)
PROMIS fatigue short form 7a (parent)
PROMIS sleep disturbance short form 8a (parent)
GRAF-PIF fall risk assessment tool (child)

Fig. 1. Study instruments.

the most recent score (controls) and other child data, such as age, sex, admission unit, diagnosis, and LOS. To ensure independence of the data, if a case experienced additional falls during the admission, this was recorded but data was not re-collected for the dyad.

Instruments

Parent tools were reviewed by 12 members of an organizational family advisory council to provide feedback on the appropriateness of concepts and tool organization. The family advisory council is a group of parents of current or past patients whose purpose is to represent and advocate for concerns of parents served by the hospital with the goal of improving care delivered. Members are recruited by other council members or referred by an employee of the organization or through publicity or outreach recruitment strategies and typically serve two-year terms. This council is often engaged to provide feedback and make suggestions on matters related to patient and family experiences at the organization. Based on their feedback, the order in which the PROMIS tools were administered was revised (i.e., moved anxiety and depression tools after fatigue and sleep disturbance tools). The council members also provided feedback on how to sensitively approach parents for study recruitment.

Demographic tool

An investigator developed, IRB-approved tool was used to gather parent and family demographic data. The tool consisted of multiple choice and short answer questions to elicit information about the parent such as age, gender, race, education level, and smoking status. The tool elicited family information such as number of adults and children in the household, working status of parent(s), and income.

Pediatric inventory for parents (PIP)

The PIP was used to measure parental stress related to caring for an ill child across four domains – Communication, Emotional Distress, Medical Care, and Role Function (Streisand et al., 2001). PIP is a self-report tool listing 42 medical related situations. Respondents use a 5-point Likert scale to rate the frequency (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = very often) and difficulty (1 = not at all, 2 = a little, 3 = somewhat, 4 = very much, 5 = extremely) related to each situation. Examples include learning upsetting news, feeling confused about medical information, and feeling helpless over child's condition. While initial psychometrics were conducted with parents of children with oncologic disorders, items are general enough to apply to other illnesses (Streisand et al., 2001). This tool has been used to assess parental stress associated with caring for children with other illnesses/conditions such as diabetes and sickle cell disease (Barakat et al., 2007; Streisand et al., 2005). Face validity was supported through input from parents of children on an oncology unit (Streisand et al., 2001). Construct validity is supported by significant correlation of total scores with a measure of state anxiety (State-Trait Anxiety Inventory) and a measure of general parenting stress (Parenting Stress Index-

Short Form) (Streisand et al., 2001). Internal consistency is supported with Cronbach alphas ranging from 0.77–0.96 across various chronic conditions (Gray et al., 2013; Streisand et al., 2001; Streisand et al., 2005).

PIP scores for each participant were calculated using the PIP scoring sheet (Streisand et al., 2001). PIP scores were obtained by summing frequency and difficulty items for each domain separately yielding eight scores (frequency and difficulty scores for each domain). Domain scores were then summed to yield a total frequency and total distress score resulting in two additional scores. Scores were measured on a continuum with total possible scores ranging from 42 to 210 points with more points indicating greater frequency or greater distress related to caring for an ill child. Responses were evaluated for missing data. If no more than one response per domain was missing, the missing data was imputed with the average of other scores in the same domain.

PROMIS tools

A battery of PROMIS tools was used to measure parent reported anxiety, depression, fatigue, and sleep-disturbance. PROMIS tools measure concepts of health and well-being across the lifespan with easy to complete questionnaires (Health Measures, 2018; National Institutes of Health, 2013). These tools were developed by a multi-centered group of clinicians, researchers, and measurement experts with support from the National Institutes of Health (Cella et al., 2007). Psychometric properties of PROMIS measures have been supported across large, clinically diverse populations. Construct validity of PROMIS item banks is supported by correlation of scores with other tools known to capture the concept of interest.

PROMIS tools use 5-point Likert scales. The anxiety (7-items), depression (8-items), and fatigue (7-items) tools measure self-reported frequency of events in the prior seven days (1 = never, 2 = rarely, 3 = sometimes, 4 = often, 5 = always). The sleep disturbance tool (8-items) measures perceptions of sleep depth and quality over the prior seven days (Cella et al., 2010; PROMIS Cooperative Group, 2018d). For each of the PROMIS tools, response values were summed to obtain a raw score (PROMIS Cooperative Group, 2018a, 2018b, 2018c, 2018d). Raw scores were converted to standardized t-scores (mean = 50, standard deviation = 10) using HealthMeasures scoring manuals. The web-based HealthMeasures scoring system was used to generate t-scores for PROMIS tools with missing data. Using t-scores allows for scores on various domains to be easily interpreted and compared to scores for other PROMIS domains (Health Measures, 2018). Higher scores indicated a greater amount of the concept, i.e., more anxiety, depression, fatigue, sleep disturbance.

Generalized risk assessment for pediatric inpatient falls (GRAF-PIF)

The GRAF-PIF tool is one of the first pediatric fall risk assessment tools developed. This tool is used to predict fall risk in children twelve months of age and older. The GRAF-PIF was developed based on a retrospective case control study of 200 patients (100 fallers and 100 non-fallers) (Graf, 2005, 2011). Five characteristics which place a child at greater risk of falling in the hospital were identified (LOS of five or more days, anti-seizure medications, musculoskeletal/orthopedic condition, physical/occupational therapy, and absence of an IV) (Graf, 2005, 2011). Each item is scored as zero or one point with the exception of LOS. Unlike other fall risk tools, GRAF-PIF uses LOS to aid in fall risk determination (LOS of 0–4 days = 0 points, 5–9 days = 1 point, 10+ days = 2 points). Scores of two or more points indicates high risk of falling during hospitalization. Additionally, a fall in the past month or during hospitalization places the child at risk for falling again and is scored as two points (Graf, 2011). Internal consistency of items is adequate (Cronbach α = 0.77) (Harvey et al., 2010). Sensitivity and specificity are 75% and 76% respectively (DiGerolamo & Davis, 2017; Ryan-Wenger et al., 2012).

Statistical analysis

Data were analyzed using SAS/BASE software for Windows Version 9.4 (SAS Institute Inc, 2016). Continuous variables were assessed for normality using histograms and Q-Q plots. Since the data were not normally distributed, summaries were reported as medians and interquartile ranges. Categorical data were summarized as frequencies and percentages. PROMIS t-scores and PIP scores were plotted using a scatterplot to observe if a linear relationship existed. Pearson correlations among individual PROMIS t-scores and PIP scores were calculated. P-values of 0.05 or less were considered statistically significant indicating correlated scores measured similar concepts.

Power analysis calculations were conducted using PASS 14 Power Analysis and Sample Size Software (NCSS, 2015). Case sample sizes were calculated to achieve at least 80% power to detect a mean of paired differences (continuous variables) or odds ratios (categorical variables) pre-specified by the investigator. Standard deviations were estimated using the range from the pilot control population divided by 5. For categorical exposure variables, the probability of exposure among control patients was estimated using pilot control data. Since the correlation coefficient for exposure between matched case and control patients could not be estimated from the pilot data and was not known, a value of 0.2 was used. P-values of 0.05 were used for significance.

Results

During the 2.5-month data collection period, the average census was 274 patients per day and the fall rate was 1.33 per 1000 patient days across eligible units. Twenty-two fall reports were reviewed for case eligibility (Table 1). Ninety percent ($n = 18$) of fallers experienced one fall and 10% ($n = 2$) experienced two falls for a total of 20 fallers. Eighty percent of fallers ($n = 16$) were 1–17 years old and further screened for study eligibility. The majority of these fallers were female (62.5%, $n = 10$). The vast majority of falls resulted in no injury (93.75%, $n = 15$). Parents were present for 75% ($n = 12$) of falls.

Recruitment

The 22 fall reports reviewed for eligibility represented 14 case dyads (64% of fall reports) who met eligibility requirements. However, half ($n = 7$) of these case dyads were not present for recruitment in the 96-h post-fall time period. Four children were discharged prior to being approached for recruitment. Three parents were not present during multiple recruitment attempts. Thus, seven case dyads were eligible and available for recruitment (32% of fall reports, 50% of eligible fallers). Of the remaining eligible subjects ($n = 7$), three declined participation

Table 1
Fall population characteristics.

All faller ($N = 20$)		
Characteristics		n (%) or Median*
Age of fallers in years	0–<1	1 (5%)
	1–17	16 (80%)
	18+	3 (15%)
Reported falls in 0–17 year-olds ($N = 16$)		
Age in years		7.5 (4–12)
Gender	Female	10 (62.50%)
	Male	6 (37.50%)
Fall type	Accidental	8 (50.00%)
	Anticipated physiological	6 (37.50%)
	Unanticipated physiological	2 (12.50%)
Injury level	No injury	15 (93.75%)
	Minor injury	1 (6.25%)
Parent present at time of fall?	Yes	12 (75.00%)
	No	4 (25.00%)

* Median reported as median (25th %ile – 75th %ile) for continuous variables.

due to lack of interest or concerns about how study results would be used. The final sample included four case dyads (18% of fall reports, 28.6% of eligible fallers) and eight control dyads matched on the child's age for a total sample of 12 subjects (Fig. 2).

During recruitment several parents became distracted either from their child or the consent process. When asked if it was a convenient time to continue with recruitment, two parents asked if recruitment could be continued at a later time. This request was accommodated and both parents consented to study participation. After recruitment, 83.3% ($n = 10$) of parents completed the study tool within 24 h. However, 16.7% ($n = 2$) took two days to complete the tool. One parent lost the passcode to unlock the electronic device. No reason was given for the delay for the other parent.

Equipment needs

All parents completed data collection using the electronic device. No parents expressed contamination or infection prevention concerns related to using the electronic device. However, two subjects were in respiratory isolation, highlighting the need for equipment cleaning protocols.

Instrument acceptability

Instrument acceptability was measured by tool completion and missing data rates. All recruited parents completed the study tool and responded to at least 93.8% of items. Overall missing data rate was 1% (PROMIS tools: 0.6%, PIP: 1.1%). On the PIP tool, if a parent only had two missing items, the items were for frequency and difficulty for the same prompt. One parent, who reported being a stay-at-home parent did not respond to the prompt of "Being unable to go to work." One

parent had five missing difficulty ratings of items which they rated the frequency as "never".

Sample

The sample included an equal number of male and female children (Table 2). Median ages in faller and non-faller groups were similar at 10 years (120 and 126 months respectively). Fallers were admitted to only medical or rehabilitation units. Across both groups, half ($n = 6$) of the children had a neurologic diagnosis, and all the fallers ($n = 4$) had a neurologic diagnosis. The remaining diagnoses were relatively equal among oncology ($n = 2$), respiratory ($n = 1$), cardiac ($n = 1$), musculoskeletal ($n = 1$), and craniofacial disorders ($n = 1$) for non-fallers. LOS was longer among the faller group with a median of 11.5 days compared to non-fallers (5 days). LOS was not included for one outlier non-faller as at the close of data collection the patient remained hospitalized and had been admitted for more than 60 days. Across both groups, 75% ($n = 9$) were at risk of falling as determined by GRAF-PIF score of two or more points. Parents were present for half of the falls ($n = 2$).

Median parent age in the faller group was higher at 43 years compared to 35 years for the non-faller group. Across both groups the majority of parents were Caucasian (83.3%, $n = 10$), non-Hispanic (91.7%, $n = 11$), mothers (91.7%, $n = 11$). Most parents across both groups were married or partnered (91.7%, $n = 11$). No parents reported being smokers. In the faller group, the highest level of education was high school for half ($n = 2$) of the parents, whereas 75% ($n = 6$) of parents of non-fallers had a bachelor's degree ($n = 3$) or higher educational level ($n = 3$). All parents considered themselves to be employed or a stay-at-home parent. Seventy-five percent ($n = 3$) of faller parent subjects were stay-at-home parents, with 37.5% ($n = 3$) in the non-faller group.

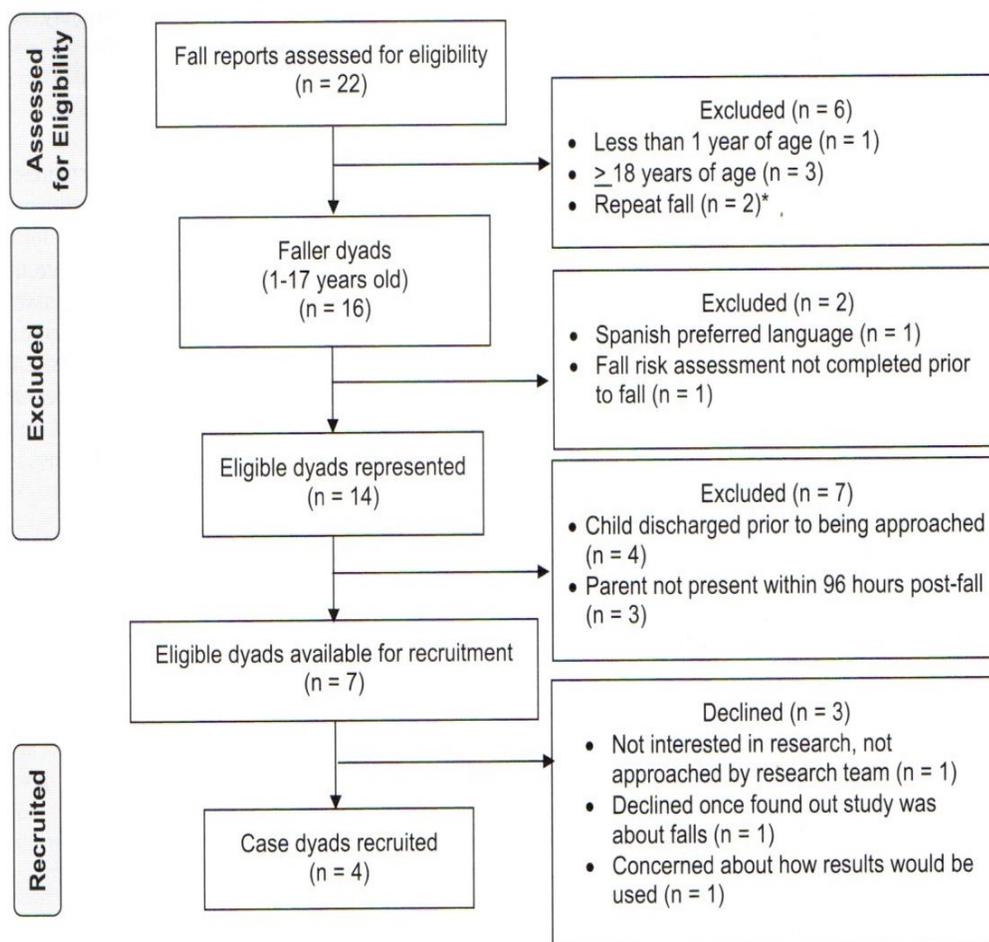


Fig. 2. Flow diagram for case sample recruitment.

*To ensure independence of the data, for patients with repeat falls only data from the first fall were utilized.

Table 2
 Recruited subjects' characteristics.

		n	Non -Fallers (n = 8) n (%) or Median*	Fallers (n = 4) n (%) or Median*	All subjects (n = 12) n (%) or Median*
Child characteristics					
Sex	Male	12	4 (50.0)	2 (50.0)	6 (50.0)
	Female		4 (50.0)	2 (50.0)	6 (50.0)
Age (months)	Months	12	126 (72–156)	120 (78–150)	120 (78–156)
Unit	Surgical	12	3 (37.5)	0 (0.0)	3 (25.0)
	Medical		2 (25.0)	2 (50.0)	4 (33.3)
	Oncology		2 (25.0)	0 (0.0)	2 (16.7)
	Rehabilitation		1 (12.5)	2 (50.0)	3 (25.0)
Diagnosis	Hematology/Oncology	12	2 (25.0)	0 (0.0)	2 (16.7)
	Respiratory/Pulmonary		1 (12.5)	0 (0.0)	1 (8.3)
	Neurologic/Nervous System		2 (25.0)	4 (100.0)	6 (50.0)
	Cardiac		1 (12.5)	0 (0.0)	1 (8.3)
	Skin/Musculoskeletal/Orthopedic		1 (12.5)	0 (0.0)	1 (8.3)
EENT/Craniofacial			1 (12.5)	0 (0.0)	1 (8.3)
		11	5 (4–18)	11.5 (5–43.5)	8 (4–18)
Total LOS (days)					
Total GRAF – PIF Score	Number of Points	12	2 (1.5–2.5)	2.5 (1–3.5)	2 (1.5–3)
Fall Risk (GRAF – PIF ≥ 2)	No	12	2 (25.0)	1 (25.0)	3 (25.0)
	Yes		6 (75.0)	3 (75.0)	9 (75.0)
Parent present for fall?	No	4		2 (50)	
	Yes			2 (50)	
Parent/family characteristics					
Parent Age	Years	10	35.0 (32.0–46.0)	43.0 (37.0–50.0)	40 (32–46)
Parent Ethnicity	Hispanic or Latino	12	1 (12.5)	0 (0.0)	1 (8.3)
	NOT Hispanic or Latino		7 (87.5)	4 (100.0)	11 (91.7)
Parent Race	Asian	12	0 (0.0)	1 (25.0)	1 (8.3)
	Caucasian/White		7 (87.5)	3 (75.0)	10 (83.3)
	Unknown/Not reported		1 (12.5)	0 (0.0)	1 (8.3)
Parent Gender	Male	12	1 (12.5)	0 (0.0)	1 (8.3)
	Female		7 (87.5)	4 (100.0)	11 (91.7)
Marital Status	Partnered	12	1 (12.5)	0 (0.0)	1 (8.3)
	Married		7 (87.5)	3 (75.0)	10 (83.3)
	Divorced		0 (0.0)	1 (25.0)	1 (8.3)
Smoker?	No	12	8 (100)	4 (100)	12 (100)
Parent Education Level	High School	12	1 (12.5)	2 (50.0)	3 (25.0)
	Associate degree		1 (12.5)	0 (0.0)	1 (8.3)
	Bachelor's Degree		3 (37.5)	1 (25.0)	4 (33.3)
	Graduate Degree		3 (37.5)	1 (25.0)	4 (33.3)
Employment Status	Stay at home parent	12	3 (37.5)	3 (75.0)	6 (50.0)
	Employed outside the home		5 (62.5)	1 (25.0)	6 (50.0)
Relation to Child	Father	12	1 (12.5)	0 (0.0)	1 (8.3)
	Mother		7 (87.5)	3 (75.0)	10 (83.3)
	Grandparent		0 (0.0)	1 (25.0)	1 (8.3)
Others in household besides parent and child	No	12	1 (12.5)	1 (25.0)	2 (16.7)
	Yes		7 (87.5)	3 (75.0)	10 (83.3)
Roles living in house	Father	12	4 (50.0)	2 (50.0)	6 (50.0)
	Stepfather		2 (25.0)	0 (0.0)	2 (16.7)
	Mother		1 (12.5)	1 (25.0)	2 (16.7)
	Stepmother		1 (12.5)	0 (0.0)	1 (8.3)
	Grandparent		0 (0.0)	1 (25.0)	1 (8.3)
	Brothers and sisters		4 (50.0)	2 (50.0)	6 (50.0)
Number children living in the home			3 (2–3.25)	2 (1–3)	3 (1.75–3)
Parent work	Two parents in home, both parents work outside home	12	3 (37.5)	0 (0.0)	3 (25.0)
	Two parents in home, one parent works outside the home, one parent works at home		1 (12.5)	1 (25.0)	2 (16.7)
	Two parents in home, one parent works outside home, one parent unemployed		4 (50.0)	2 (50.0)	6 (50.0)
Income	Single parent, works outside the home		0 (0.0)	1 (25.0)	1 (25.0)
	Less than \$25,000	12	1 (12.5)	2 (50.0)	3 (25.0)
	\$25,000–\$49,999		1 (12.5)	0 (0.0)	1 (8.3)
	\$50,000–\$74,999		1 (12.5)	1 (25.0)	2 (16.7)
	\$75,000–\$99,999		1 (12.5)	0 (0.0)	1 (8.3)
\$100,000 or more		4 (50.0)	1 (25.0)	5 (41.7)	

*Median reported as median (25th %ile – 75th %ile) for continuous variables.

Conceptual clarity

Parent scores for all PROMIS measures were similar across both groups (Table 3). Likewise, PIP scores were similar across both groups for communication frequency, medical care difficulty, role function frequency, and role function difficulty scores. Parents of fallers had lower scores for other PIP scores. PROMIS anxiety t-scores were significantly correlated with all PIP scores. Similarly, PROMIS depression t-scores were correlated with all PIP scores except communication difficulty (Table 4).

Sample size calculations

Case sample sizes needed for a future adequately powered case:control (1:3) study are presented in Table 5. If child's LOS is used to detect a mean difference of one day, 5471 cases would be needed. However, if mean difference is expanded to 5 days, which corresponds to LOS range in the GRAF-PIF tool, the number of cases needed drops to 221. After LOS to detect a mean difference of one day, the variable with the next highest case sample size is parent gender. To detect an odds ratio of 1.5 of the association of parent gender and pediatric hospital falls, 392 cases would be needed for an adequately powered study.

Discussion

Recruitment strategies

Less than one-third of eligible case dyads were recruited. For half of these dyads, the parent was unavailable for recruitment either due to the child being discharged or parent not staying with the child constantly during admission. The study setting is a referral center for a four-state region. Parents who live a distance from the hospital may not be able to be with their child due to work or family obligations. It is unknown if parent-child dyads of these patients would have agreed to participation. For a future study, recruitment strategies for parents who are not present in the hospital and/or children who are recently discharged should be considered. Virtual or telephone recruitment strategies and electronic consent signatures should be considered.

Eligibility criteria should be revised to include those who communicate in non-English languages and those who do not have a fall risk score documented. PROMIS tools are translated into several languages. Prior to a full-scale study, common language preferences of patients at the study site need to be investigated. The consent form and study tools should be translated into the most common non-English languages. Interpreter services should be engaged for recruitment. The

pool of eligible case subjects can be increased by not requiring a fall risk score to be documented. Since the focus of the study would be understanding parent characteristics associated with pediatric hospital falls, the risk score requirement could be eliminated without impacting study results.

Approaching parents for study recruitment while the child was hospitalized posed concerns about distracting the parent from attending to the child. Parents were asked if it was a convenient time for recruitment procedures. The researcher must be sensitive to the child's care needs to decrease risk of the child falling as a result of parent distraction during recruitment. Additionally, the parent may be distracted by the child's care needs during recruitment and may not fully understand the study's purposes and requirements. In a future study, it may be helpful to engage volunteer services or child life specialists to interact with the child to decrease parent distraction and potential fall risk during recruitment.

Prior to recruiting subjects for the pilot study, the PI conducted a focus group discussion with an organizational family advisory council. Council members provided guidance on non-blaming wording which was used in recruitment attempts. Recommendations included acknowledging falls are part of normal growth and development and occur in the normal course of life. Council members suggested reminding parents that hospital falls can be more dangerous than those outside the hospital. Efforts were taken during recruitment to reinforce the purpose was to understand associations of parent characteristics with hospital falls in hopes of learning how to assess for these characteristics and provide support to parents. However, some parents may have been concerned a hidden goal was to blame the parent for falls or that results may be used for reporting to child protective services. Parents need to be re-assured the goal is to provide support and identify ways the healthcare team can partner with them to improve the child's safety in the hospital.

Equipment needs

In the pre-study focus group discussion, council members indicated they had been approached for research studies in the past which used electronic devices for data capture. They indicated if they been expected to complete the tool immediately at the time of enrollment, they may not have participated. As a result, the researcher left electronic devices with parents for tool completion at their convenience. Most subjects completed the tool prior to the end of the day; however, two subjects completed the tool within 24–48 h after recruitment. This practice resulted in the need for additional electronic devices to facilitate enrollment of multiple subjects at a time.

Table 3
Parent PROMIS and PIP scores (N = 12).

	Non-Fallers (n = 8) Median*	Fallers (n = 4) Median*	All subjects (n = 12) Median*
PROMIS T-scores			
Fatigue	53.0(50.5–55.8)	55.1(53.0–61.5)	54.4(51.3–55.8)
Sleep Disturbance	52.8(49.6–57.9)	51.2(49.6–52.2)	51.7(49.6–54.3)
Anxiety	55.8(46.0–61.6)	53.9(44.5–55.7)	53.9(46.0–59.7)
Depression	48.4(41.5–55.5)	49.4(43.8–56.2)	49.4(41.5–55.5)
PIP scores			
Communication Frequency	26(20–32.5)	25(18–28)	26(19–30.5)
Communication Difficulty	20(11.5–22)	14(12–18.5)	18(12–21)
Medical Care Frequency	31(20.5–32)	26.5(18.5–30.5)	30(20–32)
Medical Care Difficulty	19.5(16–22.5)	18.5(15–19)	19(16–21)
Emotional Distress Frequency	47.5(33.5–56.5)	44.5(36.5–45.5)	44.5(33.5–52)
Emotional Distress Difficulty	45(36.5–51.5)	41.5(32–46)	43.5(35.5–49.5)
Role Function Frequency	28.5(22.5–36)	27.5(21–29)	27.5(22.5–33.5)
Role Function Difficulty	25(22.5–30.5)	25(20–25.5)	25(22.5–26.5)
Total Frequency	131(95–157)	124.5(97.5–129.5)	124.5(95–150.5)
Total Difficulty	117.5(85–121)	100(81.5–106.5)	106.5(85–118.5)

* Median reported as median (25th %ile – 75th %ile).

Table 4
Correlations of PROMIS T – scores and PIP scores (N = 12).

	Fatigue	Sleep	Anxiety	Depression	Communication Frequency	Communication Difficulty	Medical Care Frequency	Medical Care Difficulty	Emotional Distress Frequency	Emotional Distress Difficulty	Role Function Frequency	Role Function Difficulty	Total Frequency	Total Difficulty
PROMIS Fatigue	1.00													
PROMIS Sleep	0.41	1.00												
Disturbance														
PROMIS Anxiety	0.23	-0.08	1.00											
PROMIS Depression	0.64	0.01	0.87	1.00										
PIP Communication Frequency	0.36	0.49	0.71	0.65	1.00									
PIP Communication Difficulty	-0.01	0.10	0.76	0.56	0.78	1.00								
PIP Medical Care Frequency	0.56	0.60	0.63	0.69	0.89	0.52	1.00							
PIP Medical Care Difficulty	0.10	-0.10	0.91	0.75	0.67	0.83	0.60	1.00						
PIP Emotional Distress Frequency	0.27	0.18	0.90	0.78	0.78	0.86	0.67	0.89	1.00					
PIP Emotional Distress Difficulty	0.23	-0.06	0.80	0.71	0.49	0.74	0.38	0.81	0.83	1.00				
PIP Role Function Frequency	0.33	0.40	0.81	0.70	0.89	0.79	0.84	0.79	0.88	0.59	1.00			
PIP Role Function Difficulty	0.32	0.41	0.67	0.58	0.85	0.74	0.73	0.65	0.73	0.52	0.90	1.00		
PIP Total Frequency	0.39	0.42	0.84	0.77	0.94	0.81	0.89	0.82	0.92	0.65	0.97	0.85	1.00	
PIP Total Difficulty	0.20	0.07	0.88	0.74	0.74	0.91	0.58	0.91	0.92	0.65	0.82	0.78	0.85	1.00

PROMIS scores are T-scores.

* $p \leq 0.05$.

** $p \leq 0.01$.

safety of the hospitalized child. This would represent risk factors amenable to change during hospitalization whereas, many patient-level factors included in fall risk tools are not amenable to change during hospitalization.

Limitations

This was a pilot study to understand the feasibility of conducting a future adequately powered study to test associations of parent characteristics and pediatric hospital falls. As such the current study was not a hypothesis-testing study but does provide recommendations for conducting a hypothesis-testing study. Limitations of this study include that it was conducted at a single hospital with few cases and recommendations may not be generalizable to other organizations. Another significant limitation was that data collection had to be halted prematurely due to world-wide pandemic conditions (COVID-19). While the number of falls during the data collection period was similar to the prior twelve quarters, it is unclear if infection prevention practices impacted discharge timing of patients who were discharged less than 48 h after falling.

Data was collected from case parents after the fall had occurred, therefore responses to anxiety, depression, fatigue, sleep deprivation, and stress items may not be reflective of those concepts at the time of the fall. To help limit this recall bias, case subjects were enrolled within 96 h of falling. Parent data was obtained by self-report after consent for participation. We did not have the opportunity to gather data from parents who declined participation. We do not know if parents who chose to participate were different from those who declined participation in relation to the measured variables.

Conclusions

While researchers have identified an association of parental presence and pediatric falls, they merely hypothesized this association may be related to parental anxiety, distraction, fatigue, sleep disturbance, stress, etc. Researchers have not tested this hypothesis. This pilot study provides recommendations for conducting a full-scale study to validate findings of a prior study describing associations of parent demographic characteristics (Almis et al., 2017) while extending findings by adding stress related measures of anxiety, depression, fatigue, and sleep disturbance.

Pediatric hospital fall risks are multifactorial and necessitate a multi-pronged approach to prevention. The current approach to preventing these falls focuses on use of standardized fall risk assessment tools which identify risk level based solely on patient characteristics. Current fall risk assessment tools are not sufficient to predict pediatric hospital fall risk. Nurses must consider factors outside of the child, including parent psychophysical characteristics which may increase the child's fall risk. Parents are often present when children fall in the hospital. When parent risk factors are identified, nurses and the healthcare team can identify interventions and support to mitigate these factors to engage parents in preventing pediatric hospital falls.

Author statement

The primary author was involved in the development, design, and conduct of the research study and the resultant manuscript. The second author had significant involvement in conducting this research study by providing biostatistical expertise and assisting with the analysis and interpretation of the data and review of the manuscript. The third author provided guidance and input on the development and design of the research study, critical evaluation, and approval of the manuscript for submission.

This study was made possible by funding from a Nursing Research Grant at the organization where the study was conducted and a

university dissertation scholarship. The funders had no role in the design and conduct of the study.

Conflicts of interest

The authors report no actual or potential conflicts of interests.

Acknowledgment

This work was funded by a University of Washington Hester McLaws Nursing Dissertation Scholarship and a Seattle Children's Hospital Nursing Research grant. None of the funders had roles in determining the study protocol, data collection, data interpretation or reporting of findings.

The authors thank Sydnee Dismuke, Seattle Children's Research Institute for data collection assistance. The authors thank Elaine Walsh, PhD, RN, PMHCNS-BC, FAAN, Seattle Children's and University of Washington, for her manuscript review.

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Table 5
Sample size calculations for future adequately powered study.

Predictor Variable	Effect Size Type	Effect Size	Number of Cases* (Assuming 3 matched controls)
Child LOS	Mean Difference	1 day	5471
Child LOS	Mean Difference	5 days	221
Parent Age	Mean Difference	2 years	23
Number of children in the house	Mean Difference	1 child	10
PROMIS Anxiety	Mean Difference	10 points	6
PROMIS Depression	Mean Difference	10 points	4
PROMIS Fatigue	Mean Difference	10 points	3
PROMIS Sleep Disturbance	Mean Difference	10 points	4
Parent Education Level	Odds Ratio	0.32	131
Parent Smoking Status	Odds Ratio	3.0	63
Parent Gender	Odds Ratio	1.5	392
Parent Employment Type	Odds Ratio	1.5	299

* case sample sizes calculated to needed to achieve at least 80% power to detect a mean of paired differences (continuous variables) or odds ratio (categorical variables).

An additional consideration for multiple use electronic devices is infection prevention. Proper protection equipment (masks, gloves, etc.) must be used as appropriate. Containment (sealable plastic container) and cleaning strategies must be developed for when electronic devices are used in isolation rooms. Omitting the use of a cover on the device will make cleaning easier.

Instrument acceptability

All recruited parents completed the study tool on the electronic device. Furthermore, the percentage of missing data was low. The high completion rate and low missing data rate may be due to the use of multiple-choice responses throughout the tool which allowed for quicker responses and less cognitive burden to think of possible answers. Multiple choice responses also streamlined data analysis as the researcher did not have to categorize responses. Electronic devices allowed subjects to directly enter responses into the database without concern for transcriber error associated with pen and paper tools. Overall, the instrument content and format were acceptable to subjects.

Conceptual clarity

Pilot studies are intended to evaluate the feasibility of future larger scale studies and are not hypothesis testing studies (Leon et al., 2011). Thus, inferential statistical tests are generally not indicated (Leon et al., 2011). For this reason, testing of associations of parent characteristics with pediatric falls was not conducted in the current study. However, correlations of PROMIS measures t-scores with PIP scores were evaluated to determine if the tool could be streamlined. Since PROMIS anxiety and depression measures were correlated with all PIP scores, the PIP tool can be omitted in a future study without impacting the ability to test associations of parent psychophysical characteristics. PROMIS tools are preferred over the PIP tool for several reasons:

1. PROMIS tools are shorter, limiting respondent burden and tool completion time.
2. PROMIS tools have a standardized approach for dealing with missing data using the HealthMeasures scoring system.
3. PROMIS tools have standardized scores with established standard deviations allowing for scores on various domains to be easily interpreted and compared to other PROMIS domains (Health Measures, 2018). Whereas PIP scores are measured on a continuum without established cut points for various levels of stress.

Concerns of multicollinearity among predictor variables can be decreased by eliminating two variables (relationship to child and parent employment status). Parent relationship to child (mother, father, stepmother, stepfather etc.) is related to parent gender and can be omitted.

Parent employment status is the employment status of the person completing the tool, whereas the parent employment type variable is the employment status of the household parental unit. Since parent employment type provides information on number of parents in the house and employment status of the parental unit, this variable should replace the variable relating solely to employment status of person completing the tool.

Sample size calculation

Power analysis results support modification of the LOS variable. Recruitment of a case sample size sufficient to detect the effect of a one day mean difference in LOS at a single study site with less than 100 falls per year and an estimated 28.6% successful case recruitment rate would take several years. Thus, for a future study, the effect size should be expanded to detect a mean difference of 5 days, as this drops the case sample size significantly. The number of cases needed for an adequately powered study to describe parent characteristics associated with pediatric hospital falls is based on the largest number calculated for any single variable. The parent gender variable would require 392 cases to detect a 1.5 odds ratio. Increasing the match to three controls per case slightly increases power which decreases number of cases needed. With a 1:3 match and 392 cases for an adequately powered study, a total sample of 1568 subjects would be needed. Recruitment of a sufficient sample at a single research site would likely take several years. Thus, a multi-site study should be undertaken to understand associations of parent characteristics with pediatric hospital falls. A multi-site study would contribute not only to swifter recruitment of subjects but generalizability of findings.

Practice implications

The current approach to fall prevention uses risk assessment tools based on patient characteristics, such as age, sex, LOS, and cognitive/physical capabilities to aid in fall likelihood prediction (Graf, 2005; Hill-Rodriguez et al., 2009). These tools neglect parental demographic and/or psychophysical characteristics, which may be associated with risk of their child falling in the hospital. As a result, pediatric hospital fall prevention strategies focus on patient-level risk characteristics without consideration of parent and caregiver-level risk characteristics (Fujita et al., 2013; Lee et al., 2013). This study provides recommendations for conducting a study to test the hypothesis of associations of parent stress, sleep disturbance, fatigue, anxiety, and depression with pediatric hospital falls. It is important to test and describe associations with pediatric hospital falls because a parent is often present with a child during hospitalization. If parent characteristics are found to be associated with pediatric hospital fall risk, the healthcare team can partner with parents to identify and develop mitigation strategies to improve

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