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Development and Pilot Testing of a Parent Education Intervention for T1DM: PETS-D (Parent Education Through Simulation-Diabetes)

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Abstract

Purpose—To conduct pilot work on the use of a pediatric human patient simulator (HPS) to teach parents diabetes management for their children newly diagnosed with type 1 diabetes (T1DM) referred to as PETS-D (Parent Education Thru Simulation-Diabetes).

Methods—A focus group study and two pilot (one group and a randomized 2-group) studies were used to develop and test a teaching intervention. Parents were recruited from the Pediatric Diabetes Clinic at UMMHC. A brainstorming group (N=6) discussed the simulator concept and what modifications would be necessary to enhance parent teaching; we also developed the initial hypoglycemia and hyperglycemia teaching vignettes. Two focus groups (N=13) discussed the acceptance of using a simulator, and the timing and content of the teaching sessions. Based on their recommendations we conducted a one-group pre-post test (N=10) pilot with parents receiving hypoglycemia education enhanced with the HPS; followed by a randomized 2-group (N=16) pilot study.

Findings—The focus group participants enthusiastically supported the use of the pediatric HPS after diagnosis and made recommendations for the timing and content of the teaching sessions. Major findings from the pilot work included: (1) successful recruitment of 16 subjects from only one site within 6 weeks, (2) instrument reliability demonstrated for all scales, and (3) mean change from baseline in the predicted direction for all measures.

Conclusion—HPS has the potential of providing parents an innovative means of learning diabetes management through visualization during the early months after diagnosis and warrants a powered study to determine its efficacy.

Keywords

HPS; T1D; parent education

Parent education is a critical part of diabetes management for children diagnosed with type 1 diabetes mellitus (T1D), the most common metabolic disorder in childhood (1.7 per 1000 children under the age of 20).[1] Mothers and fathers have reported feeling overwhelmed with the diagnosis, and with the expectations of having to learn how to provide and understand diabetes management in a short period of time (1–2 days due to shortened length of stay).[2] There is also a trend in some health care settings to treat the child and educate the parents in an outpatient environment when the child has mild to moderate symptoms.[3] Immediately after diagnosis(regardless whether the child is hospitalized or treated outpatient) parents must quickly learn how to apply complex disease-related knowledge (understanding and

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managing hypoglycemia and hyperglycemia, carbohydrate regulation, etc.) and to perform invasive technical skills (blood glucose monitoring and injections of insulin) in order to adequately manage their child's disorder. Parents have reported initially feeling technically incompetent, lacking confidence and feeling stressed and anxious in providing the disease-related care.[4]

With that in mind, we have been exploring innovative ways to help parents master the skills to manage their child's diabetes more readily. Human patient simulators (HPS) that are commonly used to educate nursing and medical students, were identified as one possible way to enhance the teaching-learning experiences for parents during the acute phase of post-diagnosis diabetes management.[5] A small randomized controlled trial using HPS with medical students rotating through the emergency department reported that with several simulation teaching sessions they found a small to moderate effect (Cohen's d, 0.36) change between groups with improvement in student knowledge, skills and learning satisfaction, with a 3.4% absolute difference in test scores, an important difference used to distinguish between letter grades.[5] Therefore, the purpose of this study was to explore through focus groups the concept of teaching parents with HPS; and to conduct pilot work using a pediatric HPS to teach parents management of children newly diagnosed with T1D. The aims were to 1). Explore qualitatively parents' receptivity to the use of HPS to teach diabetes education; 2).Test the feasibility of recruiting parents for diabetes management education using HPS to enhance the teaching experience;3). Measure preliminary differences between the experimental and control group on their diabetes knowledge, problem solving, self-efficacy, fear of hypoglycemia, and anxiety; and 4).Explore the use of a focused hypoglycemia teaching vignette with HPS to help parents visualize management per self-regulation theory.

Theoretical Framework

The study was framed by Leventhal's[6] self-regulation theory as interpreted, tested and applied by Johnson.[7] This theoretical model has been well established and used over the past 35 years for pre-operative and pre-procedural teaching in that it provides individuals with concrete, written information about a procedure (visualization of equipment, descriptions of physical sensations, the surgical environment, causes of sensations, and temporal conditions such as timing of procedure). Thus, visual schemata of the experience are formed with a decrease in anxiety as well as decreased length of hospital stays.[8]

Since the turn of the 21st century, HPS has increasingly been used to teach nursing students the nuances of patient care[9–13] (such as psychomotor and decision-making skills) and has been reported to enhance the learning process. It is also a safe way (before working with patients) to learn and practice how to manage rare and infrequent events.[14, 15] Similarly, parents of newly diagnosed children with T1D must become proficient in these skills for effective day-to-day management. HPS provides a safe environment to learn health care tasks and responsibilities that mirror real world clinical situations. Internal consistency using HPS was reported in teaching medical students such psychomotor tasks as a difficult intubation, and managing critical events including anaphylactic reaction or postoperative hypotension.[14–16] We could find no studies or RCTs that have incorporated this type of technology into parent education for families of children with chronic conditions or illnesses.

Methods

Sample and Setting

All of the interrelated studies were conducted to inform the development and testing of an intervention. Figure 1 displays the sequence of studies with sample size. The majority of the

participants for the focus groups and pilot studies were recruited from the university based Pediatric Diabetes Clinic in Worcester MA. A few of the families in the focus groups had been involved with a multi-site parent support intervention conducted in the Northeast. Focus groups and pilot studies were conducted in the Graduate School of Nursing that is part of the health science center. This preliminary work was conducted over a period of two years. University IRB approval was secured for each study and all participants read and signed an informed consent prior to their involvement in the pilot work.

Preliminary study development

A pre-development group discussion included 2 parents, a diabetes educator, a pediatric clinical nurse specialist, a simulator specialist and the principal investigator (PI). We discussed the value of using a pediatric HPS with early parent teaching and what HPS adaptations might be beneficial in teaching diabetes management.

Focus groups

After the pre-development discussion we conducted two focus groups exclusively with parents of children with T1D and discussed their acceptance to the concept and general reaction to the simulator. We reviewed the content of the vignettes, timing of the teaching sessions, and use of the tremors simulating severe hypoglycemic reactions.

Pilot studies

We ran two pilot studies with the pediatric diabetes-adapted HPS: 1). a one-group, and 2). a 2-group with randomization, and used (for both pilots) a one-time hypoglycemia teaching vignette. In both pilot studies we recruited children who had been diagnosed within the last year because of the incidence and time restriction factors. In the one-group pilot we tested all procedures and questionnaires to refine study-related activities and sequencing of teaching, as well as to examine the subject burden and time needed to complete all activities. We developed a training manual for the diabetes educators and further developed the scenarios for teaching sessions. The child simulator is manufactured by Guamard Device Company Inc. and was adapted based on the preliminary study development, and now has the following capabilities pertinent to teaching parents with children with T1DM: It has a physical size of a 50th percentile five year old; it breathes, has eyes that open and close; it has fat pads on his arms, legs, and buttocks for injections; in addition, specific to diabetes purposes and recommended by parents and a diabetes educator, it has a tube with fluid running under the skin to simulate glucose monitoring checks; it can simulate subtle tremors to a mild seizure; it can talk with responses (informed by the focus groups and added to his repertoire of statements) such as `it hurts,' `I am thirsty', `I want candy', `I don't feel well.'

Pilot study I—The diabetes team members recruited English speaking mothers and fathers who had children diagnosed within one year. If they agreed to participate, the PI explained the study and had the parents complete the informed consents, demographic, and baseline data collection. We recruited and consented 10 parents within a one-month time period. They received standard hypoglycemia education using the vignette and pediatric (average 5-year old) HPS to illustrate the care. The teaching sessions lasted from 30–60 minutes long, and included review of glucose monitoring, daytime and nighttime hypoglycemia, drawing up and administering both insulin and glucagon, and observation and treatment of tremor/seizure activity. Subjects received a $25 incentive for their participation in the study.

Pilot study 2—Parents in the second pilot study were randomly assigned (using participant number-permutation assignment developed by the study statistician) to either a control or intervention group. Those in the control group received standard hypoglycemia diabetes

education (using the developed vignette) from one educator; the experimental group received the same education vignette with the same amount of teaching time from an `intervention only' diabetes educator who enhanced the teaching session with the HPS. All parents completed post-test questionnaires. Subjects in both study arms received a $25 incentive.

Outcome Measures: For both pilot studies general demographic data were collected from parents at the time of consent along with measures of diabetes knowledge, problem solving, self-efficacy, fear of hypoglycemia, and state-trait anxiety. For diabetes knowledge we used Diabetes Awareness and Reasoning Test-Parents (DART-P)[17] which is a 47-item multiple-choice (4 choices) questionnaire that measures diabetes knowledge and was developed for children and parents. We adapted the instrument (eliminating insulin-specific questions) reducing it to 38 items. The reported Cronbach's alpha by the developers was .92 and with the modified version it was .97.

Wysocki's Modified Problem-solving measure[18] (PSM) is a 5 item (4 choices) questionnaire that focuses on how to proactively prevent and treat hypoglycemia. Dr. Wysocki sent us one of his vignettes developed from the structured interview measure. Based on the examples of probes that are part of the interview, we constructed a 5-question multiple choice instrument to measure parental problem-solving abilities and knowledge synthesis. The Crohbach's alpha was between .80–.88.

The Self-Efficacy for Diabetes (SED) is a 22-item (Likert scale, 1=very sure I can't, to 5= very sure I can, with higher scores=more confidence) instrument that originally measured parents' confidence in managing adolescents care[19] and was adapted to measure parents' confidence in caring for children with T1DM[20]. Cronbach's alpha ranged from .83–.95.[20]

The Hypoglycemia Fear Survey-Parents (HFS-P) total score was used to measure parental fears and avoidance behaviors associated with hypoglycemia in their child.[21] There are 2 subscales that measure parental concerns of their child experiencing an episode of hypoglycemia, and behaviors they use to prevent these episodes from occurring. Reported internal consistencies have demonstrated good stability with 0.86 for the total scale and 0.89 for worry and 0.62 for parent behaviors. Streisand et al. reported internal consistency of 0.90 for total scores with parents of children with T1DM. The 27 item 5-point Likert scale had Cronbach's alpha of .85–.93.

Finally, State-Trait Anxiety (STAI) is a well established 40-item instrument (Likert scale, with 1=not at all, to 4= almost always) used to measure situational (state, how one feels at this moment) and stable (trait, how one feels in general) tendencies toward anxiety (reference). Higher scores signify more anxiety with reported Cronbach's alphas of 0.94 for state and 0.89 for trait[22] which were similar to our internal consistency.

Data management and analysis

Focus groups—We analyzed the focus group data using note-based technique.[23] This is a commonly used approach for analyzing focus group data that relies mainly on field notes the recorder has collected and clarified with participants and the recording tapes. We looked for consensus in topics throughout the two focus groups and used these findings to help frame the pilot studies' protocols & procedures (Table 1).

Pilot studies—Quantitative data were double-entered and analyzed with SPSS ®. Continuous variables (using mean and standard deviation) and discrete variables (using frequencies and percents) were summarized. Differences between groups were compared

using repeated measures for the continuous variables. The educators working with HPS briefly asked parents at the end of the teaching session about their learning experience and documented comments on a educator documentation form that we reviewed with each educator at the end of the teaching session.

Findings

The parents across all studies were English speaking, white, middle-aged with at least a high school education, and two-parent families. Table 2 displays Cronbach alphas and meaning direction of scores for the measurements used in the pilot studies.

Preliminary study development discussion

The findings from the preliminary discussion group included adapting the child simulator to include a computerized `bleeding finger' to practice and review blood glucose monitoring, the addition of fat pads on arms and legs to practice injections, and the ability to add voiceovers such as “my tummy hurts,”, “can I have some candy?”, and “I don't feel good.” During this discussion we also developed the shell of three teaching vignettes: hypoglycemia, hyperglycemia, and sick day management that would be further refined for the full randomized controlled trial (based on our pilot findings).

Focus group findings

The focus groups had parents whose children had a mean duration of illness of 45 months, compared to the second focus group with a mean duration of only 5 months. There was a difference in initial length of hospital stay, with the first group having spent a mean of 9 days (due to medical complications or other acute illnesses) and the second group only 3 days.

Regarding timing and content, both focus groups stressed limiting the amount of information shared with parents immediately after diagnosis. One father stated that learning diabetes management is a two-phase process: Phase 1). very mechanical (survival mode), and Phase 2). more complex and abstract (begin to think critically about what you are doing and its consequences) (See Table 1). Both groups recommended using the pediatric HPS to teach basic skills during the hospitalization or shortly after and having a second session one month after diagnosis to focus on more complex diabetes management concepts, followed by a 3 month teaching session where diabetes management information could be pulled together and reviewed. One father whose child was only 3 months post diagnosis, was unsure about the value of simulation teaching; but the majority thought it was a good idea with several stating they would have wanted to be shown everything up front. One mother stated it was a `detached introduction.' Both groups recommended offering the observation and practice of the tremors as an optional component initially. Offering 3 teaching sessions (baseline, 1 and 3 months) was well received and perceived as a way to build and strengthen knowledge and skills over the course of those stressful months after diagnosis.

Pilot study I findings

There were 8 female and 2 male caregivers whose median age was 41 years, with a range of 12–14 years of education. There were 6 girls and 4 boys who ranged in age from 7 to 13 years with the majority (n=7) having been recently diagnosed (under 2 months) and the other three within the past year. The parents interviewed (n=5) stated the tremors and seizures were good to see (not scary) but could have been stronger since some of the parents had heard sometimes children will thrash with seizure activity. Several parents shared that the teaching sessions would be helpful for their older child as well. The parents shared that the questionnaires were easy to access and complete (on average, 40 minutes). The diabetes

educator reported that the vignette interactions with the parents were more focused; and the HPS was a nice way to illustrate tremors.

Pilot Study II Findings

Over a 6 week time span we recruited/consented 16 participants. All subjects had children who were newly diagnosed with T1D. The sample included 13 female and 3 male caregivers, 15 White and 1 Latina; mean age was 42 years old, with 15.4 years of education. The children's mean age was 8 years. Only one mother in the experimental group stated she did not like the simulator (because she has a fear of clowns). All other participants reported it was helpful to practice how to treat hypoglycemia with the pediatric HPS. We were able to easily recruit 16 subjects from only one site within 6 weeks. The opportunity for additional diabetes education was seen as advantageous by the parents.

We were able to demonstrate strong reliability with all of the instruments (See Table 2). Most important, there was a mean change from baseline in the predicted direction for all measures. This change also occurred with the trait portion of the STAII, which is supposed to remain stable over time. The diabetes educators reported similar parent positive teaching experiences when using HPS. One father reported to the educator that he didn't like to read so this was helpful.

Another important finding from the pilot was the need for close coordination between the parents schedules and the teaching session times (for both experimental and control arms). We have adapted the procedure manual to accommodate this finding.

Discussion

We used the data collected from the parents in the focus groups to build the intervention, especially addressing their teaching timeline suggestions to maximize the best `teachable moments.' Their firsthand experiences also helped us determine what would be the best key ingredients for optimizing the intervention effect.[24]

The formation of visual schemata, as purported in the self-regulation framework, may be an important way of boosting parent skill level and confidence in the early weeks after diagnosis. To our knowledge these preliminary studies were the first to explore the use of pediatric HPS to teach parents diabetes management. Because the findings were promising, a larger intervention study is being conducted to determine efficacy of such an approach in affecting parental technical skill competence, confidence, fear, and stress levels in the first few months after diagnosis. It is possible that parents who have the opportunity to learn their children's care through the formation of visual schemata/cues early in the learning process will have a better understanding and perform care more readily.[7] This is especially important if parents have limited health literacy in disease management, which can lead to many medical complications, missed school days, and for the parents, missed work days.[25]

In addition, we have added to the procedure manual (based on the pilot study findings) post teaching session phone call follow-up schedule and documentation by both the health care providers and the parents to track how families are doing with the diabetes management in between teaching sessions. This added information will help determine the efficacy of the teaching sessions.

Based on our pilot work we see education potential with the pediatric HPS for better addressing the learning needs of other caregivers such as school nurses, EMTs, grandparents, and babysitters. Based on the positive anecdotal comments from the children who observed the pediatric HPS after their parents' education session, we are also

developing another study for school-aged and young adolescents to facilitate a gradual transition to self-management. Ultimately, this enhanced teaching strategy may also have potential for educating parents of children newly diagnosed with other chronic conditions such as asthma or seizure disorders, as well as those with high technology needs.

Limitations

This study was restricted to parents in New England with limited cultural diversity. Although the pilot was not powered for significant differences, the small sample size contributed to large standard errors. Another limitation was having only a one-time teaching session. The powered RCT has three 1-hour teaching sessions over the course of 3 months (as recommended by the focus group data).

Conclusions

In summary, diabetes care relies extensively upon the parent assuming the day-to-day care which is critical to achieving optimal diabetes control. With new goals of tighter control and improved technology for care, parents must master complex skills and tools in a shorter period of time. Their ability to understand diabetes management has a huge impact on their child's future well-being and glycemic control. We speculate that this novel teaching approach will facilitate their educational process. T1D affects everyone in the family, thus finding ways to enhance the early teaching sessions for parents of children newly diagnosed with T1DM may have a far-reaching impact.

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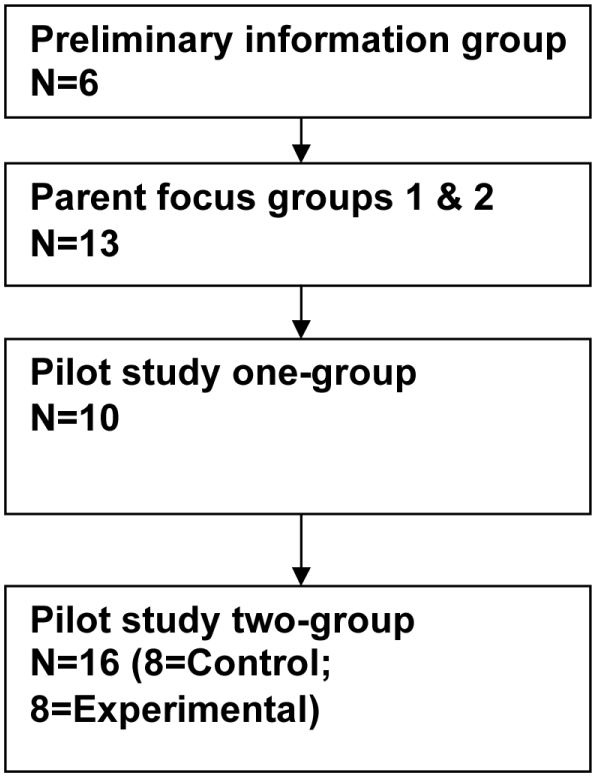

Figure 1.
Sequence & Sample Size for each PETS-D Development Study

Table 1

Information Topics Emerging from Focus Groups

Topic	Illustrations
HPS in General	Dress in fun clothes, gender-specific for child newly diagnosed; eventually culturally specific
Vignettes	Include hypoglycemia treatment with glucagon injections; cleaning hands before rechecking glucose with monitor
Timing and teaching during early months	Learning a process with 2 phases: **1).** Mechanical and survival skills **2).** Start thinking more complex and abstractly (“if he does this, I have to factor that into his diabetes management”)
Seizures	Individualize, depending on parents' needs may want to offer in first session or one of the other 2 sessions; need to practice to be prepared

Table 2

Pilot Study II Outcome Variable Results

Variables	Time	Experimental group (n=8) Mean (SD)	Control group (n=8) Mean (SD)	F	P	Pilot Reliability estimates N=16
DART-P	*Baseline*	*62 (30)*	*67 (31)*	*3.15*	*.94*	*.97*
(higher scores=more knowledge)	*Time 2*	*78 (11)*	*51 (44)*			*.98*
	Time 2 minus baseline	***+16***	***− 16***			
PSM	*Baseline*	*55 (26)*	*33 (28)*	*.00*	*1*	*.80*
(higher scores=improved problem solving)	*Time 2*	*63 (39)*	*40 (35)*			*.88*
	Time 2 minus baseline	***+8***	***+7***			
STAII State	*Baseline*	*37 (10)*	*30 (6)*	*.19*	*.67*	*.91*
(lower scores=less state anxiety)	*Time 2*	*32 (12)*	*27 (5)*			*.95*
	Time 2 minus baseline	***− 5***	***− 3***			
STAII Trait	*Baseline*	*38 (5)*	*30 (6)*	*1.9*	*.18*	*.87*
(lower scores=less trait anxiety)	*Time 2*	*35 (7)*	*30 (8)*			*.84*
	Time 2 minus baseline	***− 3***	***0***			
SED-P	*Baseline*	*90 (11)*	*95 (4)*	*.17*	*.68*	*.95*
(higher scores=more confidence in diabetes care)	*Time 2*	*98 (4)*	*101 (4)*			*.83*
	Time 2 minus baseline	**+8**	**+6**			
HFS	*Baseline*	*42 (10)*	*42 (13)*	*.03*	*.87*	*.85*
(lower scores=less fear)	*Time 2*	*37 (4)*	*35 (19)*			*.93*
	Time 2 minus baseline	***− 5***	***− 7***			