Parent educational intervention program for improving parental knowledge, self-efficacy and health related quality of life in children with sickle cell disease using smartphone technology: A randomized controlled trial

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Abstract

Purpose: Sickle cell disease (SCD) is a genetic blood disorder that increases the risk for recurrent painful episodes. Parents’ knowledge regarding SCD management is poor, leading to poor symptom management and lower Health Related Quality of Life (HRQOL) in children with SCD. The purpose of this study was to examine the effects of a parent educational intervention program (PEIP) on the parental knowledge, self-efficacy and perception of the HRQOL of their children with SCD.

Methods: Two groups of Omani parents of children with SCD were randomly assigned to either an experimental group (n=37) receiving PEIP accessed on a smartphone + weekly phone reinforcement for four weeks, or a control group (n=35) receiving Standard Educational Program (SEP) as part of standard of care.

Results: Parents’ knowledge and self-efficacy scores were significantly higher for the intervention group (PEIP) when compared to the SEP 4 weeks post intervention. Also, the total HRQOL scores were higher at 4 weeks compared to baseline, and were also higher in the PEIP compared to the SEP.

Conclusions: PEIP delivered by using a smartphone was effective in improving the parents’ knowledge, self-efficacy in symptom management, and parent and child perception of HRQOL. PEIP was innovative in that it targeted all dimensions of HRQOL in children with SCD. Finally, developing family-based interventions is the key factor for improving HRQOL in children with SCD. The study highlighted the effectiveness of smart phone technology for delivering a high quality educational intervention program for parents and their families.

Trial registration: Retrospectively registered.

Abbreviations: SCD: Sickle Cell Disease; HRQOL: Health-Related Quality of Life; PEIP: Parent Educational Intervention Program; SEP: Standard Educational Program; (SCD-PKQ): Sickle Cell Disease Parents Knowledge Questionnaire

Introduction

Sickle Cell Disease (SCD) is a chronic, inherited hematological disorder that is associated with life-threatening complications that affect all major systems [1-8]. It is characterized by crescent-shaped red blood cells that block the circulation of blood to tissues, resulting in tissue hypoxia [8-13]. The most common genotypes of SCD are hemoglobin SS (HgbSS), hemoglobin SC (HgbSC), hemoglobin S beta thalassemia (HgbSβ). Hemoglobin SS is the most severe (National Heart, Lung, and Blood Institute [14].

The SCD Association of America estimates that approximately 70,000 to 100,000 individuals in the United States have SCD and 3 million have sickle cell trait [15]. SCD commonly occurs among individuals of African American decent [14,16]. According to Centers for Disease Control and Prevention (CDC) statistics, approximately 1 of every 500 African Americans and 1 in 36,000 Hispanic Americans are born with sickle cell trait [17]. SCD in Oman is considered one of the most common genetic blood disorders, and contributes to increased mortality and morbidity rates in the country [18]. It was reported that 6% of Omanis have SCD in 1995 survey [19]. According to Oman Annual Health Statistics, the prevalence of SCD and other hematological disorders has increased from 86 to 141 cases per 10,000 Omanis from 1995 to 2005 due to high rate of consanguineous (first cousin) marriages [20]. This was the only available data in Oman. The birth prevalence of symptomatic hemoglobinopathies in Oman was 1 in 323, or 3.1 per 1000 live births; this rate included 2.7 per 1000 live births of HgbSS, with an estimate of 118 new cases per year [21]. SCD leads to high mortality and morbidity rates in children 5 five years of age [22]. Among the children with HgbSS, 1% die as a result of SCD-related complications during the first 3 years of life [17].

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Research studies that assessed HRQOL found that Children with SCD have poor HRQOL that affects the physical, emotional, social and cognitive [11,16,23-25]. The corresponding interventions to address this problem are very limited [25-30]. There is a dearth of literature about the strategies that improve HRQOL of Children with SCD. Few studies conducted educational interventions to improve the physical health of children with SCD [31-35]. A quasi experimental study found that the caregiver’s knowledge about SCD and symptoms management were significantly increased after the intervention (M= 23, SD= 3.6, p = .001) in comparison to pre intervention (M=16, SD=4.4). The rate of re-admission was significantly decreased two months after the educational intervention (M= 2, SD= 2.1, p < .05) compared to pre intervention (M=4, SD=2.5). However, no control group was used, therefore, it was not clear whether the increase in knowledge was related to the intervention. There might be within group factors that led to the improvement in knowledge and may have produced biased results [35]. Another study found that the parents’ knowledge about the disease and ability to manage the symptoms at home were improved after a two-month period of using the written educational guide. More than (80%) of the caregivers answered the questions correctly, (96%) reported that the guide was easy to follow, and (96%) reported that the guide was helpful. However, parents’ knowledge was not measured at the baseline. Parents may have had a high knowledge before starting the intervention. Also, knowledge was assessed by asking the caregivers to respond to open-ended questions using paper and pen. The answers were analyzed subjectively by the researcher and this may suggest an intruding personal bias while interpreting the results [33].

Two studies utilized a strategy that consisted of educational sessions and standardized pain medication orders for 6 months period [36,37]. The intervention decreased the re-admission rate by (30%) compared to previous year records and improved treatment adherence. The investigators reported that of a total sample of 100 children, only 30 children were re-admitted few months after the intervention. The main reason for hospitalization was the pain crisis (83%). The other 70 children experienced different symptoms of SCD; however, they did not require admission [36]. Similarly, the other study compared the readmission rate between the intervention group and the control group after a health education program. They found significantly lower readmission rates in the intervention group compared to the control group after 6 months period (M= 2.1, M= 2.3, respectively, p = .003); however, the difference was not clinically meaningful, as the knowledge was not measured in this study and the primary outcome was the readmission [37].

Self-efficacy is one’s belief in the ability to execute behaviours necessary to attain specific performance. It reflects the individual’s confidence in the ability to exert control over one’s own motivation, and behaviour [38]. Research on parental self-efficacy and the association between parental self-efficacy and perception of children’s HRQOL in SCD are lacking. However, there are a few studies that evaluated self-efficacy on children with SCD, rather than parents. Self-efficacy in children was negatively associated with physical symptoms. The higher self-efficacy, the lower physical symptoms [39]. Another study evaluated a guided imagery intervention on pain management in children with SCD. Those who were assigned to the guided imagery intervention reported higher self-efficacy following the training (M= 36.6, SD= 3.9, p < .05) compared to pre-intervention (M= 26.4, SD = 8.3). No studies were found that evaluated the parents’ self-efficacy on their abilities to manage SCD and symptoms in children with SCD [40].

Parents reported lower perception of HRQOL of their children compared to the children’s own perception. Studies found that there was a significant difference between children’s self-report (M=88.69, SD=9.96) and parent-proxy reports (M = 85.51, SD = 9.45, p < .001) of HRQOL in children less than seven years old [41-43]. The parents’ level of education was a significant predictor of parent’s perception of HRQOL of children with SCD; parent’s with high level of education, had better perception of their children’s HRQOL [16,33,41,44].

Interventions to improve HRQOL are lacking in SCD. Little is known about the impact of poor disease and symptom management on physical, emotional, social and the cognitive aspects of HRQOL. There were no studies targeting parents as mediators to improve all aspects of HRQOL of children with SCD. Therefore, the purpose of the study was to examine the effects of a parent educational intervention program (PEIP) on the parents’ knowledge, self-efficacy to manage symptoms at home, and parents’ perception of the HRQOL of children with SCD in Oman.

Theoretical Framework

The Health Related Quality of Life (HRQOL) theoretical framework as proposed by Wilson and Clearly was used [45]. The HRQOL framework suggests that the individual and environmental characteristics are the broader factors that directly influence the four constructs (biological function, symptom status, functional status, general health perceptions) and the construct of HRQOL (Figure 1). Since parents are an important part of the social environment surrounding the child, targeting the environmental factor (parents) and designing an educational intervention targeted towards parents will influence the child’s overall HRQOL. The knowledge gained by parents from the Parent Educational Intervention Program is represented in the environment characteristics (Figure 1). The PEIP is designed to increase parental knowledge on 1) biological and physiological function, 2) symptom status, 3) functional status, and 4) general health perception of HRQOL. The improvement in the knowledge would increase parents’ self-efficacy. Self-efficacy is considered the mediator that will facilitate parental learning and applying the knowledge as they manage SCD symptoms at home [46].

Methods

Design

The study was a randomized controlled trial (RCT) with two groups of parents of children with SCD (Figure 2). One group was randomly assigned to the PEIP group, and the other was the control
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The Parent Educational Intervention Program (PEIP) consisted of two video clips; the first video addressed the physical aspects -- basic information about SCD (7 minutes). The second video (6 minutes) addressed 1) emotional aspects -- fear, anxiety, worry, sleep disruptions; 2) social -- relationship with peers, siblings, ability to enjoy leisurely activities; and 3) cognitive aspects -- the child’s ability to do well in school, ability to communicate, solve problems, make decisions, resolve conflicts. The PEIP was delivered via smartphone with reinforcement phone conversation facilitated once per week, over a 4-week period. Measurement of outcomes (parents’ knowledge, parents’ self-efficacy, and parent’s perceptions of HRQOL as well as the children’s perception of their HRQOL were done at baseline, and four weeks post intervention. The control group received the standard education program (SEP) that was given by the staff nurses in the clinic. The SEP consisted of verbal information about the follow up appointments. For the study, a booklet containing questions and answers related to typical questions and answers that parents receive about SCD were distributed to the control group.

Sample
A convenience sampling approach was used. First, parents were eligible if the age of their child with SCD is between 8 to 12 years. Second, the parents were eligible if they were Omani citizens because the PEIP was specifically designed, so that it was culturally appropriate for Omanis. Parents were also excluded if they: 1) were not available for consenting procedures; 2) were not willing to participate; and 3) had physical, cognitive, and/or neurological impairments. The nurse screened the eligible participants for any neurological impairment using the Decision-Making Capacity Assessment tool. The participants were given an information sheet to read. They were informed that the information would be kept confidential and they had the right to withdraw anytime from the study. Parents received a $30 “Lulu” shopping voucher for their participation at the end of the study. Parents willing to participate were then asked to sign the consent form and the children were given an assent form to sign.

Sample Size determination
The total number of parents that were enrolled were 74 (37 in each group). Using G-power, the sample size of 37 in each group was able to detect a 0.71 effect size increase in knowledge [35] 0.59 increase in parent’s self-efficacy [47] and 0.5 increase in HRQOL [19] compared to control groups.

CONSORT Flow Diagram

Enrollment
Assessed for eligibility (n= 83)
Excluded (n= 9)
- Not meeting inclusion criteria (n= 4)
- Declined to participate (n= 5)

Randomized (n=74)

Allocation
Allocated to intervention (n=37)
- Received Parent Educational Intervention Program [PEIP]
(n=37)
Allocated to Control (n=37)
- Received Standardized Educational Program [SEP]
(n=37)

Follow-Up
Discontinued intervention (n= 0)
Discontinued (n= 2), the participants were unable to travel to the capital were the study was conducted due to long distance.

Analysis
Analysed (n=37)
- Excluded from analysis (n= 0)
Analysed (n=35)
- Excluded from analysis (n=2), posttest results were missing.

Figure 2. Consort Flow Diagram for PEIP & SEP

Setting
The parents (either father or mother) of children with SCD were recruited from the Royal Hospital (RH) and Sultan Qaboos University Hospital (SQUH), both tertiary hospitals in the Sultanate of Oman.
Randomization Procedures: To minimize the risk of contamination, a cluster randomization approach was used, with enrollment occurring on two separate days for the intervention (PEIP) and the control groups (SEP). To minimize potential temporal bias, a coin flipping was used every week to decide on the days for the cluster placement to the PEIP or the SEP group.

Data Collection Tools: All parents, were asked to complete the following tools: 1) Parents Knowledge Questionnaire, 25 items (PKQ); 2) PedsQL Generic, 23 items; 3) PedsQL SCD module, 43 items; 4) Self-Efficacy Scale, 9 items (SES); 5) Demographics Questionnaire (2 minutes). The children were asked to complete the following age appropriate PedsQL: 1) PedsQL Generic; 2) PedsQL SCD module. The internal consistency reliability for all tools showed Cronbach’s coefficient alpha > 0.70, which was considered very good reliability.

Scoring & Interpretation: For PKQ, each correct response scored 1 point, then the total correct scores was obtained. The HRQOL-Generic and HRQOL-SCD Module were scored from 0-4 scale, 0 was “never a problem” and 4 was “almost always a problem”, and were converted to the 0 to 100 scores for standardized interpretation. For Self-efficacy scale, response choices for each item were 0= “Not at all sure” and 4= “Very sure”. The total scores were obtained by summing responses for all nine items; the range of scores were 0 to 36, with higher scores indicating greater self-efficacy.

Data Analyses
The data were analyzed using SPSS (version 24). Frequencies, means, and standard deviations were calculated to describe the characteristics of the parent and child sample. Scores were calculated for primary outcomes. Repeated measures ANOVA were used to test differences between the PEIP and SEP groups at baseline and 4 weeks. A p-value (p≤ 0.05) was considered significant.

Results
Parents’ Demographics
A total of 72 parent and child participants were enrolled (Table 1). Parental age ranged between 28 and 55 years. There were more mothers in the PEIP (n=25; 68%) and compared to the SEP (n=11; 31.4%). All parents (100%) in the SEP were married, compared to 95% of the parents in the PEIP. Parent educational level was equivalent in both groups with the majority completing a high school degree (64% PEIP; 75% SEP), and fewer with Associate, Bachelor or Master degrees (Table 1). About half (52%) of the participants were residing in the northern region in Oman, mostly from Batinah (27%) and Muscat (25%). About one third (31%) were from the west (Al Dhahiriya; 28%) and central (Al-Dahira; 3%). Few were residing in the east (17%), mostly from Sharqiyya. Two participants withdrew from the study.

Children’s Demographics
Children’s age ranged from 8 to 12 years. The sex distribution in the children’s group was equivalent with 19 (51%) males in the PEIP and 15 (43%) males in the SEP. Less than half (41% PEIP; 49% SEP) of the children were receiving hydroxyurea drug.

Parental Knowledge outcome
Results indicated a significant group-by-time interaction (F(1,66)= 363.7, p <.001) in knowledge scores (Figure 1). The findings elicited a significant difference in change for the PEIP from baseline to 4 weeks posttest (F(1,32)= 23.14, partial η2 = .4 , p < .001). Knowledge scores were significantly higher at 4 weeks (21.8 ± 1.3) for the PEIP compared to baseline (11.00 ± 2.5). In addition, the differential change across groups produced a significant difference in knowledge scores at 4 weeks [F(1,66)= 477.9, p< .001, partial η2 = .87]. The PEIP group had significantly higher knowledge scores (21.8 ± 1.3) at week 4, compared to the control group at 4 weeks (11.7 ± 2.3).

Self-Efficacy outcome
There was a significant group-by-time interaction in the self-efficacy scores [F(1, 66)= 790.02, p = .001] (Figure 3). The findings revealed a significant difference in change for the PEIP from baseline to 4 weeks posttest (F(1,32)= 12.4, partial η2 = .3, p < .001). The PEIP had significantly higher self-efficacy scores (30.2 ± 2.3) at 4 weeks, compared to baseline (13.7 ± 2.5). In addition, the differential change across groups produced a significant difference in knowledge scores at 4 weeks [F(1,66)= 666.2, partial η2 = .91, p < .001]. The PEIP had significantly higher self-efficacy scores (30.2 ± 2.3), compared to SEP group at 4 weeks (15.1 ± 2.2).

HRQOL-Generic outcome
There was a significant group-by-time interaction in the health related quality of life (HRQOL-Generic) scores [F(2,69)= 187.9, p = .001] (Figure 4). The findings revealed a significant difference in change for the PEIP from baseline to 4 weeks post intervention. The PEIP had significantly higher HRQOL-Generic scores (76.2 ± 6.15) at 4 weeks, compared to baseline (53.2 ± 7.5), [F(1,32)= 10.91, p = .002, partial η2 = .3]. The differential change across groups also produced a significant difference in HRQOL-Generic scores at 4 weeks F(1,66)= 148.92, p = .001, partial η2 = .70. The PEIP had significantly higher HRQOL-Generic scores (76.2 ± 6.2) at 4 weeks, compared to the SEP group (57.6 ± 8.3) at 4 weeks.

HRQOL-SCD outcome
Similarly, the findings elicited a significant group-by-time interaction in the health related quality of life (HRQOL-SCD) scores [F(2,69)= 349.74, p = .001] (Figure 5). The PEIP had significantly higher HRQOL-SCD scores (78.2 ± 5.47) at 4 weeks, compared to baseline (46.9 ± 10.50), [F(1,32)= 13.16, p = .001, partial η2 = .3]. In addition, the differential change across groups produced a significant difference in HRQOL-SCD scores at 4 weeks [F(1,66)= 317.26, p
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**Correlation Between Parent & Child HRQOL Scores**

The parent and child HRQOL-SCD scores were moderately correlated ($r = .44$) at baseline. The parent and child HRQOL-GENERIC scores were also moderately correlated (overall $r= .38$, $p=0.001$) at baseline. The correlations were higher at 4 weeks for both HRQOL-SCD ($r = .91$) and HRQOL-GENERIC (overall $r= .95$, $p=0.001$).

**Discussion**

We compared the effects of two educational intervention programs, PEIP and SEP on parents’ knowledge, self-efficacy, and perception of the child’s HRQOL. There was significant improvement in the parents’ knowledge after the PEIP, and their knowledge scores were significantly higher at week 4 when compared to the SEP at week 4. The findings are consistent with other reports indicating significant improvements in knowledge after educational intervention programs [29].

It is important to note that 75% of the parents had low educational status; yet, they were able to learn about the disease and symptom management from the PEIP, and applied their knowledge. Previous studies indicated that low educational status of parents was associated with adverse health outcomes in children [35]. The PEIP was culturally-sensitive and used a simple language that could be understood by caregivers with low literacy level [35]. Omani parents with low literacy status were able to understand the content.

A unique feature of the PEIP was that it may be viewed by using a smartphone; which was powerful and congruent with the increasing availability and use of technology in relatively remote areas. Participants from the study represented several regions in the east, west, and northern Oman. Having the PEIP in the smartphones facilitated retention and having the ability to refer and access information about SCD as needed. Our study is the first to use this innovative educational approach in using smart phones, for delivering important health information that is comprehensive, more engaging than the traditional educational methods, and may be readily accessible multiple times at home [48].

Similar to previous studies, another unique feature of PEIP is that it facilitated communication with parents every week for 4 weeks to discuss the material, address questions and concerns about SCD, and discuss how the content may be individually applied as they provide care for their children with SCD [34]. It is possible that the individual attention provided during the 4 week study period, may have empowered them, thereby increasing their self-efficacy.

Our data showed that parent self-efficacy in PEIP was higher at 4 weeks compared to baseline, and was also higher compared to the SEP at four weeks. Findings from the study support the association between self-efficacy and individual capabilities. It is possible that with improvement in parents’ knowledge through the PEIP, self-efficacy increased, which consequently lead to improvement in their ability to manage pain and symptoms for their child with SCD, as previously reported [48,49]. Our study was the first to evaluate parents’ self-efficacy of children with SCD.

Findings from the study indicated improvement in the physical dimension of HRQOL. One of the main content that was emphasized in the PEIP was the physical dimension, such as avoiding exposure to hot and cold weather, dehydration, performing excessive exercises, experiencing stress, and being exposed to infectious agents, and how to prevent them. The PEIP also described the role of hydroxyurea in reducing the frequency of the pain episodes, and encouraged adherence to hydroxyurea [50]. The PEIP allowed parents to learn more about hydroxyurea, and allowed them to express thoughts and concerns, and ask questions during the phone call, thereby promoting adherence to its administration.
In Oman, the lack of parents’ knowledge to manage symptoms of SCD at home, led to increase in healthcare utilization (clinic, ED visits) and hospitalization. Omani families typically manage pain using traditional practices such as herbs and oil massage. Providing medicine to alleviate pain is given late after trying non-pharmacological interventions. PEIP not only provided information to parents about hydroxyurea, but also specific instructions on how to assess child’s level of pain, manage pain at home based on severity, minimize delay in pain treatments, and when to proceed to the emergency room to minimize serious complications. Therefore, the ability of the parents to recognize the triggers, assess and manage pain at home, and most importantly their prompt responses to the child’s pain, most likely affected their children’ physical health [51-55].

We found that at baseline, children reported lower scores on the physical aspects of HRQOL when compared with the parents’ ratings, suggesting that parents’ may not be aware of the child’s pain experiences prior to the PEIP intervention. It is interesting that the correlation between the parents’ and the children on the physical aspects of HRQOL was stronger at the end of 4 weeks. This finding suggests that parents were able to assess pain accurately and respond to pain more readily at 4 weeks. Children on hydroxyurea had higher HRQOL scores when compared to children not on hydroxyurea. It is possible that the PEIP increased adherence to hydroxyurea thereby decreasing frequency and improvement in parent management of the acute pain episodes. The findings are consistent with other reports suggesting improvement in the HRQOL of children with SCD using hydroxyurea drug [28,51,52,53]. We also found that the total HRQOL scores were higher at 4 weeks compared to baseline, and were also higher in the PEIP compared to the SEP. The inclusions of strategies for improving the physical, emotional, social and cognitive status may have led to improvement in the overall HRQOL in children with SCD. Knowledge gained through the PEIP affected the parents’ self-efficacy; which consequently improved the parents’ perception of the child’s HRQOL, as our findings indicated that knowledge and self-efficacy were significant predictors for improving HRQOL [56-60].

Limitations & Recommendations

There are several limitations that need to be considered when interpreting the findings in our study. First, the sample size was small and was conducted only in Oman; therefore, it is not possible to make generalizations to other settings. Second, we only included parents and children 8 to 12 years old, and therefore would not be generalizable to parents and children younger than 8 years, or older than 12 years. We were not able to examine the effects of PEIP on health care utilization (clinic, ER visits) and frequency and duration hospitalization during the 4 months before and 4 months after intervention. We also did not evaluate parents’ satisfaction with the PEIP, and other features that they found most useful, not so useful, and potential barriers to future use. Finally, the duration of the intervention was only for 4 weeks, and its effects over a longer period of time were not evaluated. Future studies are therefore, recommended to evaluate the impact of PEIP on health care use, assess the features that were most and least useful, barriers to future implementation, determine whether the effects may be sustained beyond 4 weeks, and whether additional reinforcements may be required over a longer period of time. Cultural adaptation of the PEIP to other languages, cultures, regions, and settings are also recommended.

Conclusions

PEIP delivered by using a smartphone is effective in improving the parents’ knowledge, self-efficacy in symptom management, and parent and child perception of HRQOL. PEIP was innovative in that it targeted all dimensions (physical, emotional, social and cognitive) of HRQOL in children with SCD. The study highlighted the feasibility of using smartphone technology for delivering effective high quality educational interventions. Finally, the family played an important role in the process of care and therefore, developing family-based interventions is the key factor for improving HRQOL in children with SCD. Findings supported the use of PEIP using smartphone technology for improving parental knowledge and parental self-efficacy that led to improvement in the HRQOL in children with SCD. The study also highlighted the effectiveness of smartphone technology for delivering a high quality educational intervention program for parents and their families.

Declarations

Ethical Approval

Ethics approval was obtained from the UCLA Institutional Review Board, the Ministry of Health, the Royal Hospital (RH), and the Sultan Qaboos University Hospital (SQUH). Parents who were interested to participate were provided with a consent form to sign.

Consent to Participate

all children whose parents agreed to participate, agreed to take part of the study and were asked to sign a child assent form. The participants were informed that being part of the research would not affect the care the child receives, and the information would be kept confidential. Moreover, the parents were informed that the participation was voluntary and they had the right to withdraw anytime from the study.

Consent for Publication

The manuscript does not contain identified individuals, videos or images. Children in this study were asked to sign a consent form after their parents’ approval.

Availability of Data and Material: All data generated or analyzed during this study are included in the published article.

Competing interests

There is no competing interest to disclose.

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Conflict of interest

No conflicts of interest to disclose.
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