Title

Parent Educational Intervention Program (PEIP) for improving Parental Knowledge, Self-Efficacy, & Parent Perception of Health Related Quality of Life in Children with Sickle Cell Disease Using Smartphone Technology

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Parent Educational Intervention Program (PEIP) for improving Parental Knowledge, Self-Efficacy, & Parent Perception of Health Related Quality of Life in Children with Sickle Cell Disease Using Smartphone Technology

A dissertation submitted in partial satisfaction of the requirements for the degree

Doctor of Philosophy in Nursing

by

Yusra Sulaiman Mohamed Al Nasiri

2018

ABSTRACT OF THE DISSERTATION

Parent Educational Intervention Program (PEIP) for improving Parental Knowledge, Self-Efficacy, & Parent Perception of Health Related Quality of Life in Children with Sickle Cell Disease Using Smartphone Technology

By

Yusra Sulaiman Mohamed Al Nasiri

Doctor of Philosophy in Nursing

University of California, Los Angeles, 2018

Professor Eunice Eunkyung Lee, Chair

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.

Theoretical Framework. The HRQOL theoretical framework as proposed by Wilson and Clearly (1995) was used to guide the study. Social-Cognitive Learning Theory (Bandura, 1986) was used to explain the relationship between knowledge, self-efficacy and perceived HRQOL.

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. Outcome measures (Knowledge Questionnair, Self-Efficacy Scale, and HRQOL-SCD + HRQOL-GENERIC were administered twice (at enrollment, and 4 weeks after enrollment). Statistical Pakage for Social Science, version 24 was used for data analyses.

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*. Parents' knowledge, self-efficacy, use of hydroxyurea, child's age and gender, were significant predictors of HRQOL in children with SCD.

Conclusion. *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, 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.

Implications. The study highlighted the effectiveness of smart phone technology for delivering a high quality educational intervention program for parents and their families.

The dissertation of Yusra Sulaiman Mohamed Al Nasiri is approved.

Mary-Lynn Brecht

Wendie A Robbins

Adey Nyamathi

Eunice Eunkyung Lee, Committee Chair

University of California Los Angeles

2018

DEDICATION

I dedicate the accomplishment of this work to Dr. Eufemia Jacob, my previous Dissertation Chair and mentor, what can I say that would adequately define your worth to me? I can never fully express my gratitude to you with mere words. You have encouraged and supported me every time. Without your guidance and support, I would not have been able to come up with this outstanding dissertation. Your expertise in sickle cell disease and research methodology is admirable! Above all of this, you are really a great mentor. I learned a lot from you.

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TABLE OF CONTENTS

LIST OF FIGURES AND TABLES

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VITA/BIOGRAPHICAL SKETCH

I am a lecturer at Oman College of Nursing and Health Sciences in Oman since 2006. I was the head of Child and Maternal Health department at Oman College of Nursing. I had BSN from Villanova University, USA in 2003 and master degree in advanced practice nursing education from Cardiff University, UK in 2009. I was a high achiever student at both universities and got distinction in my masters' thesis from Cardiff University, 2009. I was awarded a scholarship from the Ministry of Health, Oman for BSN and doctoral study. I was also awarded a scholarship for masters' degree from Cardiff University, 2008. In 2004, I was awarded a certicficate of apprection from Oman Embassy, USA for excellent study achievement. This year (2018), I am the recipient of Ph.D dissertation award from the University of Califonia Los Angeles (UCLA). I have a total of 10 publications in different journals. During Ph.D study, I published 5 manuscripts, four of which I was the primary author. I served in different committees in Oman 1) The research committee; 2) The curriculum development committee; 3) The staff professional development committee. I am a member in Oman Herdiatery Genetic Blood Association and Oman Cancer Association.

CHAPTER 1 – INTRODUCTION

BACKGROUND & SIGNIFICANCE

Sickle Cell Disease (SCD) is a chronic, inherited hematological disorder that is associated with life- threatening complications that affect all major systems (Stuart & Nagel, 2004). It is characterized by crescent-shaped red blood cells that block the circulation of blood to tissues, resulting in tissue hypoxia (Brousse, Panepinto, Nimmer, 2014; Forrester,Barton-Gooden, Pitter, Lindo, 2015; Wrotriak, Schall, Brault, Balmer, Stallings, 2012). The most common two 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 [NHLBI], 2015).

SCD affects million of individuals worldwide, and 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 (Sickle Cell Disease Association of America [SCDAA], 2015). SCD commonly occurs among individuals of African American decent (Terrie, 2014). 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 SCD each year, and 1 in 13 African-Americans are born with sickle cell trait (CDC, 2016). SCD in Oman is considered one of the most common genetic blood disorders, and contributes to increased mortality and morbidity rates in the country (Ministry of Health, 2013). It was reported that 6% of Omanis have SCD in 1995 survey (Oman, 2014). According to Oman Annual Health Statistics (2011), 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 marriage) marriages (Al-Riyami & Ebrahim, 2003; El-Hazmi; Al-Hazmi; Warsy, 2001). 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 (Rajab, Patton & Modell, 2000).

SCD leads to high mortality and morbidity rates in children 5 five years of age (World Health Organization [WHO], 2010). Among the children with HgbSS, 1% die as a result of SCD-related complications during the first 3 years of life (CDC, 2016). In California and Illinois, the cumulative mortality rate was 1.5 per 100 African American children with SCD. The equivalent cumulative mortality rate for all African American infants born in California and Illinois was 2.0 per 100 African American newborns (CDC, 2016).

Complications in Sickle Cell Disease

Children with SCD are at a greater risk for developing life-threatening complications due to disease complexity. Similar to other countries, severe pain crisis, ischemia, infections and organ failure are considered the leading cause for frequent admissions in the Sultanate of Oman (Ministry of Health [MOH], 2011, Wali, Beshlaw, Fawaz, Al Khavat, Zalabany, Al-Kindy, Al-Rawas, Klein, 2012). Despite advances in disease management over the past five years in Oman, HRQOL is significantly low in Children with SCD (MOH, 2013). The frequent hospitalizations for pain crisis and other SCD complications affect the children's physical, emotional, social and mental health. Effective strategies for improving HRQOL of children with SCD in Oman are needed.

Vaso-Occlusive Pain Events. The recurrent acute pain is the hallmark characteristic of SCD and is the main reason for frequent hospitalization among children with SCD (Terrie, 2014; WHO, 2010; Wrotriak Schall, Brault, Balmer, & Stallings, 2012). The acute pain in SCD was described as severe, sharp and intense (Jacob, Miaskowski, Savedra, Beyer, Treadwell, Styles, 2003). The frequency and intensity vary from patient to patient. Pain duration may range from hours to days (Terrie, 2014), with the mean duration (2-9 days). In the longitudinal study in hospitalized children with sickle cell disease who were admitted for acute pain episode, Jacob and colleagues (2003) found that the onset of pain occurs on average 4.5 days prior to admissions. The health care providers were contacted on average 2.6 days prior to admission. Almost half (48.1%) had a visit to the emergency department due to pain crisis with a mean of

2.9 emergency visits during the previous 12 months (Jacob et al. 2003).

The frequent pain episodes (also known as vaso-occlusive crisis or VOC) can lead to various complications and severe organ damage (NHLBI, 2015). Frequent hospitalizations for VOC places a burden on the children and their families, as well as on the economy of the country (WHO, 2010). An average of 75,000 hospitalizations due to SCD occurs in the United States, costing approximately $475 million (CDC, 2012). The medical expenditures for children with SCD averaged $11,702 for children with Medicaid coverage and $14,772 for children with employer-sponsored insurance. About 40% of both groups had at least one hospital stay per year (CDC, 2016), with mean length of stay is 5.9 days (Jacob et al., 2003).

Acute Chest Syndrome. Several complications occur as a consequence of having SCD-related vaso-occlusion. Acute chest syndrome (ACS) is among the most serious complication that results from blockage of blood vessels in the lungs, leading to oxygen deprivation. Injury to blood vessels in the lungs can increase the pressure in the lung blood vessels, leading to pulmonary hypertension (NHLBI, 2015). ACS is common in children less than five years and gradually declines in older age groups. ACS is the second most common cause of hospitalization, and the leading cause of death among children with SCD, contributing to almost (25%) of SCD related mortality (Sylvester, Patey, Milligan, Rafferty, Broughton, Rees, 2006).

Recurrent episodes of ACS negatively impact long-term lung function resulting in chronic lung disease (Nansseu; Yanda; Chelo, Tatah; Awa; Seungue ; Koki, 2015). Recurrent vaso-occlusive episodes may also contribute to osteonecrosis and sudden death. This complication occurs with an incidence of 10, 500 to100,000 child per year. Nansseu and colleagues (2015) found that within six months of hospitalization, 21 cases of children with SCD were admitted because of ACS (*Mean* age = 5.5, *SD*=3.4). ACS accounted for (6.2%) of hospital admissions with almost 2.1 child presenting with ACS per month (Nansseu, et al., 2015). The most common causes of ACS are pneumonia or systemic infection, fat embolism, and direct pulmonary infarction from HbS-containing erythrocytes (Miller & Gladwin, 2012). ACS

management includes hospitalization, hydration, analgesics, broad-spectrum antibiotics, bronchodilators, incentive spirometry, supplemental oxygen, and blood transfusions (Bernard & Yasin, 2007; Bernard & Yasin 2008; Miller, 2011). ACS can be prevented by teaching patients and parents to recognize the early signs and symptoms, and immediately seek care (Nansseu et al., 2015).

Stroke & Neurologic Events. Another common complication is stroke as a result of vaso-occlusion to vessels in the brain. Stroke occurs in 17 to 24 percent of children with SCD, between the ages of 3 and 10 years (The Internet Stroke Center, 2016). Ischemic strokes most often occur in children under the age of 15 and adults over the age of 30, while hemorrhagic strokes most often occur in young adults between the ages of 20 and 30 (The Internet Stroke Center, 2016). An estimate of 17 percent of children with SCD under the age of 14 have silent strokes and the rate increases to 23 percent by the age of 18 (The Internet Stroke Center, 2016). Silent strokes often occur in frontal areas of the brain, the areas responsible for executive abilities and mostly having to do with academic achievement and memory. Stroke events can impair intellectual ability, academic ability, attention, visual-spatial skills, language, and long-term memory. Early detection through screening and brain imaging is the most important, since imaging can help prevent recurrences. (The Internet Stroke Center, 2016).

Acute care management of stroke includes immediate evaluation by taking an image of the brain, initial laboratory evaluation, and oxygen therapy. An increase rate of additional strokes after initial stroke may be expected, and therefore, long-term management to prevent future strokes is needed. Regular blood transfusion therapy, exchange blood transfusion (simple and exchange transfusion), hydroxyurea therapy, and hematopoietic stem cell transplant are different options (Kassim, Galadanci, Pruthi, DeBaun, 2016). Periodic cognitive testing is recommended for children to assess cognitive strengths and weaknesses such as memory, attention, intellectual functioning. The assessment of cognitive impairments should lead to the development of an individualized education program (Nansseu and colleagues

(2015) along with family support to help children with cognitive impairments meet academic standards (Kassim et al., 2016).

Frequent blood transfusions for stroke prevention, however, causes iron excess in the blood that may damage the heart and other organs. Blood transfusions are used to treat severe anemia, to decrease the risk of stroke (Kassim et al., 2016), and to manage acute illnesses such as splenic sequestration, aplastic crisis and ACS (Dogra &Sidhu, 2016). The frequent blood transfusion leads to iron overload and toxicity (DeBaun & Vichninsky, 2016). As red cells are destroyed, the majority of the released iron cannot be excreted and accumulates in the reticuloendothelial system, liver, heart, spleen, and endocrine organs causing tissue damage that leads to heart failure, liver failure, diabetes and hypothyroidism (Sahu, Hemlata &Verma, 2014). Iron overload is managed by infusing iron chelation therapy to minimize accumulation of excess in the body (NHLBI, 2015).

Retinopathy. SCD can injure blood vessels in the eye and cause damage to the retina. Retinal detachment can occur which may cause visual impairment and vision loss (NHLBI,2015). Traore and colleagues (2006) found that 27 patients out of 38 presented with retinal neovascularization. Retinal damage was more prevalent in patients with HgbSS than other sickle cell types. The treatment of retinopathy is directed to prevent ischemia, infarction and the dread complication of neovascularization. Examples of treatment include hydroxycarbamide to prevent sickle cell retinopathy, exchange transfusion, and hyperbaric oxygen therapy to improve visual acuity (Sambhara & Shah, 2016). Early screening and management programs for patient with SCD are important to reduce ocular complications and optimize visual efficiency (Traore et al., 2006).

Liver Complications. The life span of red blood cells in SCD is less than 120 days, which causes red cells to hemolyze, releasing haemoglobin that breaks down into bilirubin. Bilirubin can form stones that may be trapped in the gallbladder. The liver may be blocked by sickled red cells preventing oxygen from reaching liver tissue, causing a condition called sickle

cell hepatopathy (Banerjee & DeBaun, 2016). The liver may be affected not only by the sickling process but also by treatments. In addition to the vascular complications from the sickling process, patients with SCD have often received multiple transfusions, placing them at risk for viral hepatitis, iron overload, and the development of pigment gallstones, all of which may contribute to the development of liver disease (Banerjee & DeBaun, 2016). The effective management for sickle cell hepatopathy is exchange transfusion; which could be very effective for initial episodes (Ahn & Wang, 2005). Ahn & Wang (2005) established a guideline for managing hepatopathy of SCD. The mortality rate was (64%) in the patients with SCD who did not have the exchange transfusion compared to the patients who was on exchange transfusions regularly (Ahn & Wang, 2005).

Splenic Sequestration. Another serious complication of SCD is splenic sequestration, which occurs with blood pooling into the spleen, trapping of red blood cells in the spleen, spleen enlargement and potentially hypovolemic shock. Acute splenic sequestration crisis (ASSC) is a life-threatening complication seen mainly in children with HgbSS. Mortality rate from ASSC has been estimated as 15% (Wang-Gillam, Lee & Brotman , 2004). Brousse and colleagues (2012) found that 67% of patients with SCD had ACCS episodes and required spleenectomy. Since ASSC is a life-threatening complication, spleenectomy is considered the treatment of choice (Wang-Gillam et al., 2004). Removing the spleen can lead to the risk for serious bacterial infections that can be life-threatening (Wang-Gillam et al., 2004).

Sickle Cell Nephropathy. Sickling of red blood cells affects the kidneys causing a condition called Sickle Cell Nephropathy (SCN). In this condition, kidney function is impaired and may result in chronic kidney disease (Sharp & Thein, 2014). The incidence of renal failure in SCD ranges from 5-18% (McPherson , Jabbar, Osunkwo, 2011). In a prospective, case-control study by Powers, and colleagues (1991), 31 (4.2%) patients with SCD had by renal failure. The median age at the time of renal failure was 23.1 years. Survival time was four years with a median age of death of 27 years after the diagnosis of end-stage renal disease (ESRD) in

spite of dialysis treatment. Treatment is directed toward the prevention of vaso-occlusive crises and control of infections that can worsen renal function, as well as toward adequate identification and management of renal complications (McPherson et al., 2011).

Musculo-Skeletal Complications. Joint complications are very common in SCD due to decrease oxygen flow to the bones and joints, leading to a condition called aseptic necrosis or osteonecrosis (NHLBI, 2015). One of the long-term consequences of vasocclusive pain episodes in the musculoskeletal system is avascular necrosis of the femoral heads and collapsed vertebral bodies, which may lead to chronic pain in addition to the more acute painful episodes (George & DeBaun, 2016). Moreover, sickle cells can cause leg sores or ulcers that may or may not heal (NHLBI, 2015). In addition, dactylitis (known as hand-foot syndrome) is another serious complication affecting children under five years that is characterized by pain and edema on the dorsum of the hands or feet or both simultaneously (Junior, Daher, Rocha, 2012; Almeida & Roberts, 2005).

The incidence of dactylitis in children with SCD is (12%); it is the first manifestation in children with SCD (Junior et al., 2012). Babela and colleagues (2005) found that hand and foot syndrome was more predominant in African children with SCD (77.8%). The treatment depends on the type of musculoskeletal complication present. Generally the treatment may be conservative medical treatment such as reducing weight overload on the joints, administration of analgesics and non-steroidal anti-inflammatory drugs and hydrotherapy. Physical therapy may also help to strengthen the muscles of the hip and thighs or surgery (Junior et al., 2012). The preventive measures for bone complications include chronic blood transfusions, hydroxyurea, and bone marrow transplantation (Wang, 2001). Another complication is aplastic anemia, which results when the bone marrow stops producing new red blood cells (NHLBI, 2015).

In summary, SCD is complex and the complications associated with it are significantly affecting children's overall health related quality of life (Frei-Jones, Field, DeBaun, 2009). Health related quality of life (HRQOL) is a subjective perception of the individuals' health, personal thoughts,

feelings and the meaning of one's life. It is a multi-dimensional concept that represents the individuals' perception of their physical, psychological, social and cognitive health (Ameringer, Elswick, & Smith 2014; Beverung, Varni, Panepinto, 2014; CDC, 2012; Dale, Cochran, Lmswap, Buchanan, 2011; Fisak, Belkin, Lehe , Bansal, 2010; Hijmans, Fijnvandraat, Oosterlaan, 2010; Jackson, Lemanek , Clough-Paabo, Rhodes, 2014; Lowry & Pakenham, 2008; Limbers & Skipper, 2014; Muszalik & Kędziora-Kornatowska, 2009; Panipento, O'Mahar, DeBaun, 2005; Palermo, Valenzuela, Stork, 2002; Sawyer, Reynolds, Couper, French, Kennedy, Martin, Baghurst, 2005; Strine, Chapman, Balluz, Moriarty, & Mokdad, 2008; Schlenz, Schatz, McClellan, Roberts, 2012).

Health Related Quality of Life in Sickle Cell Disease

HRQOL is an important outcome and a focus in many research studies because it focuses on specific domains of health including physical, psychological, mental, and social functioning (Palermo et al., 2004; Panipento, et al., 2005). Children with SCD have generally poor HRQOL compared to the healthy children their age due to frequent pain crisis that consequently affects their physical, mental, and psychosocial health (Beverung et al., 2014; Dale et al., 2011; WHO, 2010). The studies that evaluated QOL in children with SCD suggest that, pain is the most important indicator for having worse quality of life among children with SCD (Beverung et al., 2014; Constantinou, Payne, Inusa, 2015; Smith, Patterson, Szabo, Barakat, 2013, Wrotniak et al., 2012; Panepinto, Torres, Varni, 2012, Dale et al., 2011; Fisak et al., 2010; Hijmans et al., 2010; Panepinto,Pajewski , Foerster, 2008; Panepinto et al., 2005; Palermo et al., 2004). Findings by Wrotniak and colleagues (2012) showed that the physical and psychological health were the significant predictors for HRQOL. Physical health was significantly low (Beta= 7.1, p = 0.02) in children who had been hospitalized at least once in the previous year. Also, the psychological health was significantly low (Beta= 8.4, p = .003) in children who had SCD and other comorbidities. Due to hospitalization, cognitive health of children with SCD revealed significantly low scores (Beta= 8.5, p = .009), suggesting cognitive

impairment.

Physical Aspects of HRQOL. Palermo and colleagues (2004) found that the physical and the psychosocial functioning were significant predicators for HRQOL [$F(7.31=4.57, p < .01$]; the lower physical and psychosocial functioning, the poorer the HRQOL. Beverung and colleagues (2014) also found that children with severe disease (having history of stroke, acute chest syndrome, and hospitalizations more than 3 times the previous 3 years) had lower scores in the physical function of HRQOL *(M*= 46.53, *SD*= 12.89 on 0 to 100 scale) than children with mild/moderate disease (*M*= 89.28, *SD*= 9.40). Pain was the primary indicator of low physical functioning in the children with severe disease. Similar results were found by Hijmans and colleagues (2010) who reported that children with SCD with frequent pain crisis had significantly lower scores (*M*= 49, *SD*= 8.7 on 0 to 100 scale) in the physical aspect of HRQOL, when compared to the healthy children (*M*= 54, *SD*= 11.4, $p < .05$).

Cognitive Aspects of HRQOL Some studies reported that there were deteriorations in school competence for children with SCD, compared to healthy peers (Smith et al., 2013). This also contributed to low quality of life perception reported by children with SCD (Smith et al., 2013; Trzepacz, Vannatta, Gerhardt, Ramey, Noll, 2004). Smith and colleagues (2013) found that children with SCD had low HRQOL total scores (*M*= 70.49, *SD*= 15.21 on 0 to 100 scale). Pain frequency, and stroke were significant predictors for the cognitive functioning of children with SCD [$R^2 = .52$, $F(5, 77) = 16.37$, $p < .01$]. Children, who experienced frequent painful crisis and stroke due to blockage of flow in the brain, had poor memory and attention in the class (Smith et al., 2013).

Emotional Aspects of HRQOL Children with SCD may also experience emotional problems such as anxiety, mood changes and depression that might impact their physical functioning. The literature reported that negative mood is associated with decreased functional status of children with SCD (Zempsky, Palermo, Corsi, Lewandowski, Zhou, & Casella, 2013; Hoff, Palermo, Schluchter, Drotar, 2006). Positive affect over time was significantly associated

with the adolescents' physical function scores (*B*=0.24, 95% CI 0.12 to 0.35). In contrast, negative affect was positively associated with pain and inversely associated with physical function scores (*B*= 1.58, 95% CI 0.23 to 2.93).

Social Aspects of HRQOL. The functional status affects the children's social life. In SCD, pain crisis can interrupt children's social activities and may result in social withdrawal (Anie, 2005). Also, patients with low physical function and low vitality, have low social function (Ahmed, Alaskar, Al-Suliaman, Jazieh, McClish, Al Salamah, Ali, Malhan, Mendoza, Gorashi, El-toum, 2015). Ahmed and colleagues (2015) found that patients who experience worse pain and had a history of blood transfusion had poor physical function (*B*= 6.7, *p* = .04), emotional role function (*B*= 12.9, *p* = .02) and social function scores (*B*= 7.4, *p* = .02).

SCD remains a global concern that requires multilevel strategies to reduce the worldwide mortality (WHO, 2010), and to improve HRQOL in children affected by SCD. Management of SCD is a challenge for the hematologists and for the affected children and their parents (Reagan, DeBaun, Frei-Jones, 2011). Although SCD treatment has advanced over the past 10 years (hydroxyurea, opioids, bone marrow transplant, chronic transfusion), HRQOL of children with SCD remains poor (Kaslow, Collins, Rashid, Baskin, Griffith, Hollins, & Eckman, 2000; McClellan, Schatz, Sanchez, Stancil, 2009; Shahine, Kurdahi, Karam, Abboud, 2015; Wrotniak et al., 2012). Therefore, improving HRQOL is deemed a priority (WHO, 2013).

Educational Interventions & HRQOL

Research studies that assessed HRQOL found that Children with SCD have poor HRQOL and the corresponding interventions to address this problem are very limited. There is a dearth of literature about the strategies that improve HRQOL of Children with SCD. Few studies tested interventions to improve the physical aspect of HRQOL and to reduce hospital readmission rates (Barakat, Schwartz, Salamon, Radcliffe, 2010; Hazzard, Celano, Collins, & Markov, 2002; Hines, Monica, Mitchell, Crosby, 2011; McClellan, Schatz, Sanchez, Stancil, 2009).

Five studies examined the effects of educational interventions on children with SCD. Except for one study that was done in Lebanon (Shahine et al., 2015), the majority of the studies were conducted in the United States (Frei-Jones et al., 2009; Hazzard et al., 2002; Mahat, Scoloveno, Barnette, & Donnelly, 2007; Reagan et al., 2011). The medium for the delivery of intervention was through 1) a powerpoint presentation that provided information about the disease to the caregivers of children with SCD (Shahine et al., 2015); 2) a self-study guide that also contained basic information about SCD for parents (Mahat et al., 2007); 3) written materials that outlined standard admission protocols for nurses (Frei-Jones et al., 2011; Reagan et al., 2011), and 4) a computer program called SMART BRIGHT -- the program included health education information about SCD, signs and symptoms, and complications, an interactive SCD games for children called *"The Sickle Cell Slime-O-Rama Game",* and a platform for interaction between children with SCD via chartrooms, video conferencing, and emails (Hazzard et al.,2002).

Shahine and colleagues (2015) 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.

Mahat and colleagues (2007) 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.

Two studies (Frei-Jones et al., 2009; Reagan et al., 2011) utilized a strategy that consisted of educational sessions and standardized pain medication orders for 6 months period. The intervention decreased the re-admission rate by (30%) compared to previous year records and improved treatment adherence (Frei-Jones et al., 2009). 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 (Frei-Jones et al., 2009). Although health education was part of the intervention, no information was provided about the nature of the education, the frequency and the duration. Readmission rate was the primary outcome and parental knowledge was not measured. The study also did not have a control group, and therefore, it is not clear whether the decrease in readmission rate was related to the intervention.

Reagan and colleagues (2011) 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. No information was provided regarding the nature, the frequency, and duration of the health education program. Also, the control group was a retrospective cohort who was admitted the previous year for SCD complications, suggesting that both groups may not be similar at the entry level and there might be group variations between the two groups that could have affected the results. In addition, the knowledge was not measured in this study and the primary outcome was the readmission.

Hazzard and colleagues (2002) used a computer program - *SMART BRIGHT* - to deliver educational materials to hospitalized children with SCD (*M* age= 11.7 years, *SD*= 2.71). The study found a significant difference in the level of knowledge on disease related information between the experimental group (*M*= 8.73, *SD*= 2.6) compared to the control group (*M*= 6.15, *SD*= 3.21, $p < .001$) before discharge from the hospital (Mean hospitalization = 5.1 days, SD= 2.41, Range= 3-15 days). A significant difference was also found in the perceived peer social support (*M*= 15.1, *SD*= 4.8 vs *M*= 11.5, *SD*= 4.5, between the intervention and the control group respectively, $p < .05$) and coping skills (*M*= 3.87,*SD*= 0.35 vs *M*= 3.61, *SD*= 1.12, intervention and control group, respectively, $p < .05$). A convenience sample was used, which limits the generalizability of the findings. Also, the measurement of posttest was inconsistent across the participants. Many children had the posttest very early (less than 5 days post admission), which may have influenced the results.

In summary, the educational intervention studies focused on improving the physical health of children with SCD. The educational interventions demonstrated improvement in parents' knowledge about symptom management at home and reduction in children's readmission rates. Although the mode of delivery varied across the studies (power point, written guide, and written instructions), all studies suggested improvements in the physical health of children with SCD. However, studies to improve other aspects of HRQOL (cognitive, emotional, social) were lacking. To date, there is no intervention designed to address these different dimensions of HRQOL in children with SCD.

Parental Self-Efficacy in SCD Management

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 (American Psychological Association [APA], 2016). 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 (Clay &Telfair, 2007). Dobson (2015) 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.

Parental Perceptions of Health-Related Quality of Life in Children with SCD

Parents reported lower perception of HRQOL of their children compared to the children's own perception Constantinou and colleagues (2014) 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 (Constantinou et al., 2014; Dale et al., 2011; Panepinto et al, 2009). The parents' level of education was a significant predictor of parent's perception of HRQOL of children with SC; parent's with high level of education, had better perception of their childrens' HRQOL (Smith et al., 2013; Palmero et al., 2008; Gill et al., 2000). Gill and colleagues (2000) reported that parents' educational level was a significant predictor of emergency room visits. Parents with high level of education were more likely to bring their children to emergency room for pain management (F=1.29, $p < .05$) than their counterparts.

Factors Associated with HRQOL in Children SCD.

Age & Gender. Studies suggest that age and gender were associated with quality of life. Older children were found to have lower HRQOL. Ahmed and colleagues (2016) found that Saudi male adolescents with SCD were reported to have higher percentages in the domains of physical functioning, bodily pains and social functioning compared to female patients (66.7% vs. 58%, $p = .03$). Dampier and colleagues (2011) also found that female adolescents had lower scores in the physical functioning (B= 3.54, $p < .01$), vitality (B= 3.3, $p <$

.01), and social functioning (B= 0.98, $p < .01$) compared to male adolescents. Similarly, Amr and colleagues (2011) found that physical functioning scores were significantly higher among male adolescents with SCD (*M*= 59.96, *SD* = 21.23, $p = .001$) compared to female adolescents (*M*= 53.41, *SD*= 18.58). The study also found that female adolescents had significantly lower scores in the emotional well-being than male adolescents respectively (*M*= 48.8, *SD*= 21.55 vs. *M*= 55.51, *SD*= 18.62, $p = 0.01$).

Educational level. Education was also associated with quality of life; low level of education was associated with lower HRQOL. Amr and colleagues (2011) found that Saudi adolescents with delayed education due to failing, school retention, and absenteeism had low quality of life scores. They found a significant educational delay ($p < .001$) with excessive failing and school retention while adolescents without SCD was significantly better. There were (15.0%) of adolescents with SCD who demonstrated delay (excessively retained in relation to their comparable peers) in the primary education (elementary=up to grade 6), compared to only (2.0%) among adolescents without SCD. There were 71/81 (87.7%) of adolescents with SCD in the preparatory stage (intermediate= up to grade 9) who were delayed compared to 8/39 (21.1%) among adolescents without SCD. This delay was attributed by the parents to excessive absenteeism from schools as a consequence of frequent hospitalizations, emergency room visits, and clinic appointments for checkups.

Mood. Emotion was another factor that was associated with quality of life. Children with SCD who had negative mood had experienced more intense pain, which consequently impacted on their quality of life (Valrie et al., 2008). Zempsky and colleagues (2013) found that positive affect over time was significantly associated with the adolescents' physical function scores (B= 0.24, 95% CI 0.12 to 0.35). In contrast, negative affect was positively associated with pain and inversely associated with physical function scores (B 1.58, 95% CI 0.23 to 2.93]).

PROBLEM STATEMENT

Interventions to improve HRQOL are lacking in SCD. Little is known about the impact of poor disease and symptom management on physical, emotional, and the cognitive aspects of HRQOL. There were no studies targeting parents as mediators to improve all aspects of HRQOL of children with SCD. It is not known whether parental knowledge and parental self-efficacy have effects on the HRQOL of children with SCD.

The proposed study evaluated the parents' knowledge and self-efficacy on their abilities to manage SCD and symptoms. The study developed and tested a *Parent Educational Intervention Program* (PEIP): a comprehensive educational program consisting of two short video clips that were accessed by a smartphone, addressing the physical health (SCD, signs and symptoms, triggering factors, complications, treatments), emotional health, cognitive health, and social health of children with SCD. The study targeted the parents of children with SCD, ages 8-12 years that provided comprehensive information not only addressing physical signs and symptoms, but also the social, emotional, and cognitive health of children with SCD. It was hypothesized that the educational intervention program *(PEIP)* would improve parental knowledge, parental self-efficacy, and parental perception of health related quality of life.

The Wilson and Clearly (1995) theoretical model of HRQOL was used to guide the development of the *PEIP*. The HRQOL model has five main constructs (physiological, functional status, symptoms, perception of health and quality of life) and two broader constructs (personal factors and environmental factors). The HRQOL model was disease focused, which was appropriate for addressing the content of the *PEIP* and to guide the study.

The Wilson and Clearly (1995) theoretical model of HRQOL lacks the self-efficacy component. The impact of PIEP on parents' self-efficacy and perceived HRQOL can be linked to social-cognitive learning theory (Bandura, 1986). The model suggests that increases in self-efficacy results in anxiety reduction as well as behavior change. Applying social cognitive learning theory to the PEIP intervention suggests that, improving parents' self-efficacy as a

result of improving their knowledge via PEIP will successfully lead to improvement in their ability to manage children's symptoms. The model predicts that for the knowledge to sustain, it requires a transformation of learning for parents to have a control over managing the symptoms and complications of SCD. The theory suggests reciprocity in which more confidant parents has better control of disease symptoms and management of SCD. Improvement in parents' confidence to manage symptoms at home, reduces their anxiety level, and therefore, it positively impacts their perception about their children's HRQOL.

Educational Programs in Oman. Educational information about SCD in Oman are available in pamphlets, booklets, and other printed materials. Nurses provide information to parents prior to discharge from the hospital or during clinic visits, but quality of information delivery about SCD is not consistent. The available booklets about SCD are lengthy and include general information regarding SCD definition, symptoms, causes, and complications. Specific information about disease management and how to improve HRQOL in children are not available. Furthermore, nurses in the pediatric units and hematology clinics, do not have the time to educate parents, as the priority is to meet the child's physical and medical needs. Therefore, innovative educational approaches such as videos accessible by smart phones that would be used to deliver the *PEIP* in this study, may be more effective in delivering a more comprehensive information, be more engaging, and could be accessed anytime and multiple times at home. Using technology that utilizes visual, sound, and interactive tools would facilitate understanding and retention of the information.

PURPOSE OF THE STUDY

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. The *PEIP* provided culturally-appropriate information to parents of children with SCD and included content on the physical aspects (disease and symptom management), as well as the psychosocial, emotional, and

cognitive aspects of HRQOL in children with SCD.

DESIGN OF THE STUDY

The proposed study was a randomized controlled trial with pre and post test design. The study had two groups of parents of children with SCD (N=72, dyad pair of parents and children). The intervention group (PEIP, n=37) was exposed to *PEIP* and the control group (SEP, n=35) received the standard education program (*SEP*), which were written materials distributed by nurses in the hematology clinic or acute care hematology unit of the hospital. *SEP* delieverd at baseline only; which was consistent with the standard of care. The duration of the study was four weeks with outcome measurements at baseline and 4 weeks post intervention.

SPECIFIC AIMS & HYPOTHESES

The specific aims and hypotheses of the study were:

1. To evaluate the effects of *PEIP* on parental knowledge and self-efficacy.

   Hypothesis 1.1: Parents in the *PEIP* group would have higher scores on the SCD Parental Knowledge Questionnaire compared to the scores of parents on *SEP group* at 4 weeks post baseline. .

   Hypothesis 1.2: Parents in the *PEIP* group would have higher scores on the SCD Parental Knowledge Questionnaire in the posttest compared to baseline.

   Hypothesis 1.3: Parents in the *PEIP* group would have higher scores on Parental Self-Efficacy compared to the scores of parents on *SEP group* at 4 weeks post baseline.

   Hypothesis 1.4: Parents in the *PEIP* group would have higher scores on the SCD Parental Self-Efficacy in the posttest compared to baseline.

2. To examine the effects of *PEIP* on parents' perception of HRQOL in children with SCD.

   Hypothesis 2.1: Parents in the *PEIP* group would have higher scores on their perception of the child's HRQOL compared to the scores of parents on *SEP group* at 4 weeks.

   Hypothesis 2.2: Parents in the *PEIP* group would have higher scores on the HRQOL scales in the posttest compared to baseline.

3. To identify predictors of HRQOL in children with SCD at 4 weeks post intervention.

Hypothesis 3.1: Parental knowledge and self-efficacy would be significant predictors of HRQOL-Generic scale.

Hypothesis 3.2: Parental knowledge and Self-efficacy would be significant predictors of HRQOL- SCD module.

IMPACT STATEMENT

The study provided data to support the effectiveness of the *PEIP* in improving the HRQOL in children with sickle cell disease. Nurses would be able to implement a comprehensive educational program that can be adopted for use by parents of children with SCD, regardless of geographical location within Oman and other Arabic-speaking population. The *PEIP* may also be used as a template for developing educational programs for children with other chronic illness (asthma, diabetes, chronic pain). Finally, the study highlighted the effectiveness of smart phone technology for delivering a high quality educational intervention program for parents and their families.

DEFINITION OF TERMS

SCD -- Sickle Cell Disease is a chronic, inherited hematological disorder that is associated with life- threatening complications that affect all major systems (Stuart & Nagel, 2004). This genetic disease is characterized by crescent-shaped red blood cells that block the circulation of blood to tissues, resulting in tissue hypoxia.

Parents of Children with SCD -- Parents of children (7 to 12 years) with SCD who will be recruited from the hematology clinic of Royal hospital in Oman.

PEIP -- *Parent Educational Intervention Program*: a comprehensive educational program consisting of four short video clips that were accessible by a smartphone, addressing the physical health (SCD, signs and symptoms, triggering factors, complications, treatments), emotional health, cognitive health, and social health of children with SCD.

SEP—*Standard Educational Program*: Written materials consisted of pamphlets,

booklets and other printed materials distributed by nurses in the hematology clinic or acute care hematology unit of the hospital.

Sickle Cell Disease Parents Knowledge Questionnaire (SCD-PKQ) -- Sickle Cell Disease Parents Knowledge Questionnaire is a 25 items questionnaire that measures knowledge about SCD, signs and symptoms, triggering factors, complications, treatments (16 items). It includes items to measure the psychological (4 items), social (3 items), and the cognitive problems (2 items) experienced by children with SCD. The first 16 items are True/False statements and the other 9 items are multiple-choice (A, B, C, D) type questions.

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. The Self-Efficacy Scale developed by Edwards, Telfair, Cecil, & Lenoci (2000) was modified (with permission) for parents as a measure of parental self-efficacy. The questionnaire has 9 items that measures disease specific perception of self-efficacy regarding the patients' ability to manage their child's disease, symptoms and pain related to SCD.

HRQOL -- Health-Related Quality of Life is a subjective perception of individuals' health, personal thoughts, feelings and the meaning of one's life. It is a multi-dimensional concept that represents the individuals' perception of their physical, emotional, social and cognitive health. HRQOL was measured by Pediatric Quality of Life Inventory Scale (HRQOL-GENERIC) developed by Varni (2003). It is a generic core scale that has 23 items to measure four dimesions of HRQOL 1) physical (8 items), 2) cognitive (5 items), 3) social (5 items), 4) emotional (5 items). A disease specific tool (HRQOL-SCD) was developed by Panepinto, Torres, and Varni (2012) for patients with SCD to measure HRQOL. The HRQOL-SCD module has 43 items, and nine scales: Pain & hurts (9 items), pain impact (10 items), pain management & control (2 items), worry I (5 items), worry II (2 items), emotion (2 items), treatment (7 items), communication I (3 items), and communication II (3 items). The scale has a 5-point likert type

response scale (0= never a problem, 1= almost never a problem, 2= sometimes a problem, 3=often a problem, 4= almost always a problem). The HRQOL-GENERIC and HRQOL- SCD module scales that are currently available are child self-report and parents proxy report format for each age group (2-7, 8-12, and 13-18 years). The parents' proxy report format for 8-12 version will be used for the study.

CHAPTER 2 – REVIEW OF THE LITERATURE

The purpose of this literature review was to examine and evaluate studies that examined the educational intervention programs to improve HRQOL in SCD. First, a literature review on the educational interventions done on children with SCD were discussed. Second, studies that assessed HRQOL of children with SCD were reviewed. Then, studies that evaluated self-efficacy on children with SCD were discussed. The review covers the period from 2000 to 2016. No studies were available in Oman that examined HRQOL in children with SCD. Only prevalence studies about different hematological disorders in the Omani population were available.

EDUCATIONAL INTERVENTION PROGRAMS IN SCD FOR PARENTS

Five studies conducted educational interventions for children with SCD. The majority of the studies evaluated the effects of educational interventions on symptom management (Mahat, Scoloveno, Barnette, & Donnelly, 2007; Shahine, Kurdahi, Karam, Abboud, 2015), coping skills (Hazzard et al., 2002) and hospitalizations (Frei-Jones et al., 2009;Reagan et al., 2011). Two studies (Mahat et al., 2007; Shahine et al., 2015) evaluated educational sessions for parents of children with SCD.

Shahine and colleagues (2015) utilized pre-post test designs to assess mothers' knowledge after an educational intervention that used powerpoint in the delivery of the educational program. The content of the educational material consisted of general information about SCD. These included the genetic basis of SCD, diagnosis, symptoms, complications, aggravating factors, prognosis, and treatment strategies such as penicillin prophylaxis, and immunizations. The educational session was given in a clinic in Lebanon by a pediatric nurse practitioner and lasted for 40-60 minutes. The mothers (n=43) of 57 children (*M* age= 11.6 years, *SD*= 7. 2) were asked to complete a knowledge questionnaire before the intervention and two months after the intervention. The knowledge questionnaire (reliability r= 0.76) consisted of 25 questions about SCD with items related to general information, disease symptoms, and

management. Results showed that the mothers' knowledge about SCD and symptoms management were significantly increased after the intervention *(M*= 23, *SD*= 3.6,) in comparison to pre intervention (*M*= 16, *SD*= 4.4, *p* = .001). The rate of re-admission was significantly decreased two months after the educational intervention as compared to pre intervention (*M*= 2, *SD*= 2.1 vs *M*=4, *SD*= 2.5, respectively; *p* < .05).

Mahat and colleagues (2007) used a survey design to measure the knowledge of 48 caregivers (*M age*= 35.3, *SD*= 9.6) of children with SCD. The caregivers were mothers (n=34), fathers (n=4), grandparents (n= 5), and others (n=4) who were given an educational guide about SCD. The guide was developed by the SCD advisory committee of New Jersey Department of Health, Special Child Health, and Early Intervention Services. It consisted of general information about SCD, signs and symptoms, complications, prognosis, medical care, and new approaches to SCD treatment. The guide was given to the caregivers during the clinical visit. However, there was no formal session given to the caregivers, and learning the information from the guide was self-directed. After two months using the guide, the caregivers were requested to respond to a survey that was developed by the researcher. The survey consisted of open-ended questions about SCD, diagnosis, signs and symptoms, prevention, management of fever and pain, and prognosis. Knowledge was assessed by asking the caregivers to respond to open-ended questions related to content (e.g. *" What would you do when the child has 101° fever?")*, how easy the guide was to follow, and how helpful was the guide. Results showed that the parents gained knowledge about SCD two months after using the 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. No baseline data were collected. It was not possible to verify whethere or not the participants read the guides. Therefore, it was not possible to make a conclusion regarding whether the increase in knowledge was related to the intervention.

MULTI-LEVEL INTERVENTION FOR CHILDREN WITH SCD

Two studies used a pre-post design to evaluate a multi-level intervention program (Frei-Jones et al., 2009; Reagan et al.,2011). The multi-level intervention program (MLIP) consisted of three components: (1) standardized SCD-pain admission orders; (2) monthly SCD-pain in-service for house physicians for 6 months; and (3) continuous patient/caregiver education that is routinely given by the nurses in the hospital.

Frei-Jones and colleagues (2009) assessed the effects of the MLIP on the re-admission rate (within 30 days of discharge) and the risk factors for the readmissions in a sample of 100 children with SCD (age range 1-20 years) who were recruited from The National Association of Children Hospital in the United States (US). The target of the intervention were the house physicians (SCD-pain admission order and SCD in-service) and parent/caregivers. The outcome was readmission rate. The study did not have a control group. The intervention was deliverd at the time of admission. The physicians were requested to follow the standardized SCD-pain management orders for each child and provide parent and child health education before discharge. The intervention lasted for 12 months and the readmission rate was compared to the rate of admission in the previous calendar year prior to the availability of pre-specified SCD-pain orders. Results showed a significant decrease ($p < .001$) in the admission rate during the 6-month following the intervention. The investigators reported that of a total sample of 100 children, only 30 children were re-admitted after starting 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. Although health education was part of the intervention, no information was provided in regards to the nature of the education given, the frequency and the duration. This study only evaluated the readmission rate as an outcome for the success of the MLIP.

Reagan and colleagues (2011) also evaluated the readmission rate of children with SCD following the MLIP used in the Frei-Jones et al, (2009) study. The study included a sample of

children with SCD (*M age*= 11.4, Range= 1-20) who were recruited from St. Louis Children's Hospital in the United States. The target of the intervention were the house physicians (SCD-pain admission order and SCD in-service) and parent/caregivers. The intervention group were the children who were admitted for SCD complications (N=102) and the control group was a retrospective cohort who was admitted the previous year for SCD complications (N=88, *M age*= 11.5, range= 1-20). The study reported a significant reduction in the readmission rate in the intervention group compared to the control group respectively (*M*= 2.3 vs *M*= 2.1, *p* =.003; SD not provided). Information regarding the nature, frequency, and the duration of the health education program was not provided. No other outcomes were reported, other than the re-admission rate.

EDUCATIONAL INTERVENTION FOR CHIDLREN WITH SCD USING TECHNOLOGY

Hazzard and colleagues (2002) used a pre-posttest design study to evaluate a computer SMART BRIGHT program to deliver educational materials in 47 children with SCD (*M* age= 11.7, *SD*= 2.7 years). The SMART BRIGHT program included health education information about SCD, signs and symptoms, and complications. An interactive SCD game for children were included, called *"The Sickle Cell Slime-O-Rama Game".* A computer platform allowed interaction between children with SCD via chartrooms, video conferencing, and emails. The study included a control group of 60 children (*M* age= 11.7, *SD*= 2.71 years) who received traditional recreational therapy activities using papers; which is arranged by nurses in the hospital. The Knowledge Questionnaire (r= .92; Kidcope questionnaire (r= .77) and Perceived Peer Social Support scale (r= .82) were measured to examine the effects of the intervention. There were significant differences in the level of knowledge of children on 1) disease information and pain control (*M*= 8.73, *SD*= 2.55, vs *M*= 6.15, *SD*= 3.21, *p* =.001); 2) perceived peer social support (*M*= 15.1, *SD*= 4.79 vs *M*= 11.5, *SD*= 4.5. *p* <.05), and 3) coping skills (*M*= 3.87, *SD*= 0.35 vs *M*= 3.61, *SD*= 1.12, *p* < .05) between the experiment and the control group, respectively

In summary, the educational interventions showed improvement in disease knowledge of children with SCD and their parents (Hazzard et al., 2002; Mahat et al., 2007). The improvement in knowledge led to improvement in symptom management at home (Shahine et al., 2015) and decreased hospitalization rates (Frei-Jones et al., 2009; Reagan et al., 2011). However, those studies had several methodological limitations. Two studies did not have a control group (Frei-Jones et al., 2009; Shahine et al., 2015), 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. The other studies were a pre- and post-test design. The limitation of pre-and post-test designs is the recall bias by the participants, which may account for the increased knowledge.

A convenience sample was used in all studies, which limits the generalizability of the findings. No power calculation was described in all the studies; therefore, it was not clear whether the sample sizes are adequate to represent the population. All of the studies recruited the sample from one hospital setting; therefore, findings may not be generalizable to other settings. Also, the studies recruited the intervention and the control group from the same setting, which could have resulted in the contaminiation of the intervention.

All of the studies failed to provide information about the data distribution, skewness, test assumptions, or any other problems found in the data and the actions that were taken to correct these before running the presented statistics. This information could help evaluate the appropriateness of the tests used in these studies.

Two studies (Regan et al., 2011; Shahine et al., 2015) tested the best predicated variables for the outcomes using linear regression, logistic regression, and general linear models; however, the model fitness was not explained and the adjusted R square, the F- test, and the sum of errors versus the variability percentages in the model were not explained. Therefore, it was not possible to determine whether or not the reported variables are significant predictors. For example, the Shahine et al. (2015) reported that none of the variables

(caregivers' education, gender, age, and type of SCD) were significant predictors for knowledge about the disease.

Lastly, the educational studies focused primarily on the physical aspect of HRQOL by improving the knowledge regarding SCD and pain management. Except for one study that measure coping and social support (Hazzard, 2002), the studies did not address other aspects of HRQOL (emotional, social, cognitive). The proposed study will provide a comprehensive health education program *(PEIP)* that will address not only the physical, but will also include information to address the emotional, social and cognitive health in children with SCD.

RESEARCH ON HRQOL IN SCD

Several studies were found that examined health-related quality of life (HRQOL) in children with SCD. These studies examined HRQOL and 1) pain (Beverung et al., 2014; Constantinou et al., 2014; Hijmans, Fijnvandraat, Oosterlaan, 2010; Panepinto et al., 2005; Gil et al., 2000); 2) cognitive aspects (Smith et al., 2013); 3) parents perceptions of HRQOL (Constantinou et al., 2014; Dale et al., 2011; Panepinto et al., 2009); 4) impact of treatment adherence (Al Joauni, AL Mubbayawi, Halawa, AL Mebatawi, 2013; Fisak, Belkin, Lehe, Bansal, (2010); and 5) hydroxyurea (Barakat, Lutz, Smith-Whitley, 2005). Fourteen studies used cross-sectional designs and one study used a prospective case control design. Six studies utilized the PedsQL for measurement of HRQOL (Beverung et al., 2014; Dale et al., 2011; Fisak et al., 2010; Panepinto et al., 2009; Panepinto et al., 2005; Smith et al., 2013), one used the Child Health Questionnaire (CHQ) (Wrotniak et al., 2012), and one utilized Generic Children's QOL (GCQ) questionnaire (Constantinou et al., 2014). Studies related to physical and psychosocial aspects of HRQOL will be reviewed first, followed by studies related to the cognitive aspects of HRQOL. Studies that examined HRQOL and hydroxyurea are included in the review under the physical and psychosocial aspects. Finally, studies related to parent perceptions of HRQOL will be reviewed.

PHYSICAL & PSYCHOLOGICAL ASPECTS OF HRQOL

Five studies reported that frequent pain crisis was the main indicator for decreased HRQOL (Beverung et al., 2014; Constantinou et al., 2014; Hijmans, Fijnvandraat, Oosterlaan, 2010; Panepinto et al., 2005; Gil et al., 2000). A cross-sectional study with a sample of 47 children (*M* age = 8.6, *SD*= 2.4 years) from Children Hospital of Philadelphia identified the predictors of poor HRQOL (Wrotniak and colleagues, 2012). Children completed the Child Health Questionnaire (CHQ-PF50) in the clinic. The CHQ-PF52 consisted of 52 items -- physical well-being (5 items), psychological well-being (6 items), mood and emotions (7 items), self-perception (5 items), autonomy (5 items), parent relation and home life (6 items), social support and peers (6 items), school environment (6 items), social acceptance/bullying (3 items), and financial resources (3 items). The overall all summary scale reliability of the tool was (0.72). Results showed that the physical and psychological health were the significant predictors for HRQOL. Physical health score was significantly low (*Beta*= 7.1, *p* = .02) in children who had been hospitalized at least once in the previous year. Also, the psychological health score was significantly low (*Beta*= 8.4, *p* = .003) in children who had SCD and other comorbidities. Due to hospitalization, cognitive health score was also significantly low *(Beta*= 8.5, *p* = .009).

Palermo and colleagues (2005) conducted a cross section study to identify the predictors of physical functioning in 56 children with SCD, who were recruited from a haematology clinic. Children (*M age*= 12.1, *SD*= 2.46 years) completed the CHQ-PF50, which consisted of 50 items. The findings suggested that physical and the psychosocial functioning were significant predicators for HRQOL *(F*(7.31= 4.57, *p* <.01); thus, suggesting that the lower physical and psychosocial functioning, the poorer the HRQOL. The study also found that, parents' high educational level was associated with better HRQOL scores of their children *(Beta*= 0.51, *p* < 0.01).

Beverung and colleagues (2014) conducted a cross sectional design to assess HRQOL

in a sample of 251 children with SCD who had mild, moderate and severe disease. They were recruited from five different clinics across the US. The recruited children *(M* age= 11.47, *SD*= 3.84 years) completed the PedsQL SCD module during a clinic visit. PedsQL consists of 23 items -- physical functioning (8 items), emotional functioning (5 items), social functioning (5 items), and school functioning (5 items)]. The internal consistency reliability of the tool was r= 0.95. Results showed that children with severe disease, defined as having history of stroke, acute chest syndrome, and hospitalizations, more than 3 times the previous 3 years had lower scores in the physical function of HRQOL (*M*= 46.53, *SD*= 12.89 on 0 to 100 scale) than children with mild/moderate disease (*M*= 89.28, *SD*= 9.40). Pain was the primary indicator of low physical functioning in the children with severe disease.

Hijmans and colleagues (2010) compared the HRQOL of 40 children with SCD (mean age= 11.7, *SD*= 3.1) and 40 healthy-children (*M age*= 11.6, *SD*= 3.4), who were recruited from a medical center in the Netherlands. The children completed the KIDSCREEN-52 questionnaire (r= .87), which consisted of 10 HRQOL dimensions: physical (5 items), psychological-well-being (6 items), mood and emotions (7 items), self-perception (5 items), autonomy (5 items),parent relations & home life (6 items), social support & peers (6 items), school environment (6 items), social acceptance/bullying) (3 items), and financial resources (3 items). Results showed that children with SCD who had frequent pain crisis had significantly lower scores (*M*=49, *SD*= 8.7) on 0 to 100 scale in the physical aspect of HRQOL compared to the healthy children (*M*= 54*, SD*= 11.4, $p < .05$). However, the sample was recruited from one hospital setting; therefore, generalization is limited.

Gil and colleagues (2000) examined pain intensity, drug use, and health care visits in 34 children and adolescents with SCD (*M* age= 11.1, *SD*= 3.4 years) who were recruited from the SCD clinic in North Carolina. Children completed a daily diary during a period of two weeks. Results showed that pain affected and interrupted activities of daily living. The children experienced at least one painful episode on an average of 2.5 days (*SD*= 1.5) per two weeks.

Children (63%) reported having pain medication on the days with pain (*SD*= 47). Social activities decreased during pain days. Children (35%) had also reported reduced school attendance due to frequent pain. Parents' educational level was a significant predictor of emergency room (ER) visits. Parents with high level of education were more likely to bring their children to ER for pain management ($F(1.29) = 4.62$, $p < .05$) compared to parents with low level of education. The pain diary was analysed and interpreted subjectively by the researcher; which may suggest personal bias in the results.

Treatment Adherence (for Physical Health). Three studies examined the impact of treatment adherence on the HRQOL in children with SCD (Al Joauni, AL Mubbayawi, Halawa, AL Mebatawi, 2013; Barakat, Lutz, Smith-Whitley, 2005; Fisak, Belkin, Lehe, Bansal, 2010). Fisak and colleagues (2010) examined the predictors of HRQOL in a sample of 78 children with SCD (*M age*= 11.3, *SD*= 3.92 years). Children completed the PedsQL during a clinic visit. The Adherence & Self-Care Inventory tool was used to measure the treatment adherence (no reliability data reported). Results showed that treatment adherence scores were highly correlated with HRQOL (R= .88). The treatment adherence was a significant predictor for the improvement in the HRQOL scores ($F(4,68) = 13.94$, $p = .001$).

A sample of 56 children with SCD (*M age*= 19.9, SD= 8.8) from Al Malik Fahad Hospital, Saudi Arabia were asked to complete World Health Organization Quality Of Life tool (WHOQOL-BRE, Reliability= 0.8) to evaluate the impact of treatment adherence on HRQOL (Al Joauni, et al, 2013). The WHOQOL-BREF instrument is comprised of 26 items, which measure the following broad domains: physical health, psychological health, social relationships, and environment. The treatment adherence was assessed subjectively through patients attendance to the clinic for follow-up and no formal tool was used. Results showed that children who delayed treatment or who were not adherent to treatment had significantly low HRQOL scores ($X 2 = 29.90$, $p < .001$).

Hydroxyurea and HRQOL. Nweniy and colleagues (2014) conducted a cross-sectional, retrospective study to examine the differences in HRQOL among 114 children (*M age*= 11.4, *SD*= 4.2 years) with SCD who were on hydroxyurea and 77 children (N= 77, *M age*= 9.1, *SD*= 5.1 years) not on hydroxyurea. Children were recruited from the SCD clinic, and were asked to complete the PedsQL tool. Results showed a significant difference (p =.001) in the HRQOL total scores between children who were taking hydroxyurea daily (HRQOL score *Median*= 75, IQR= 62.0- 86.4) and those who were not taking hydroxyurea (HRQOL score *Media*n= 69.0, IQR= 54.1- 81.6). The study also found that the physical functioning scores were significantly reduced in children who did not use hydroxyurea (Median= 71.4, Inter Quartile Range IQR= 58.6, p = .001) than children on hydroxyurea (*Median*= 79.7, IQR= 62.5).

Barakat and colleagues (2005) conducted a cross sectional study to identify the association between treatment adherence and HRQOL. The sample included 21 children with SCD, who were recruited from eastern part of the United States. Children (*M age* = 10.50, *SD*= 4.55 years) completed the PedsQL questionnaire during hospitalization. Nurses were asked to rate children's adherence during hospitalization by observation method. No checklist was used to measure the adherence. Treatment adherence in this study was defined as taking the prescribed medicine during hospitalization. The result was contrary to what was expected. It was found that treatment adherence was significantly (p < .001) associated with poorer quality of life, so that those children, who had high treatment adherence, had the low scores on the HRQOL of children with SCD *(M*= 3.45, *SD*= 0.45). The researchers concluded that treatment adherence may inhibit activities associated with a higher HRQOL.

COGNITIVE ASPECTS OF HRQOL IN CHILDREN WITH SCD

There was only one study that included cognitive aspect of HRQOL in SCD that included the memory status and attention in the classes. Smith and colleagues (2013) used a cross sectional design to assess the impact of SCD on the cognitive aspects of HRQOL in 82 children with SCD, who were recruited from two children's hospitals in north-eastern part of the

US. Children (*M age*= 8.42, *SD*= 2.10 years) completed the PedsQL during a clinic visit. Results showed that children with SCD had low HRQOL total scores (*M*= 70.49, *SD*= 15.21 on 0 to 100 scale). Parents' level of education, pain frequency, and stroke were significant predictors for the cognitive aspects of HRQOL in children with SCD (R^2 = .52, $F(5, 77) = 16.37$, $p < .01$). Children who experienced frequent painful crisis and stroke due to blood blockage in the brain, had low memory status and poor attention in the class. In addition, the study concluded that the parents with high level of education were associated with higher cognitive aspects of HRQOL for their children in relation to the memory status and good attention in the classrooms. Parents who were highly educated were able to recognize the effect of the disease on the children's memory and attention; consequently more care was taken by the parents to improve the child's attention and the memory status.

In summary, studies that examined HRQOL in children with SCD found that pain frequency, disease severity, complications (e.g. stroke), and treatment adherence predicted HRQOL (Beverung et al., 2014; Constantinou et al., 2014; Hijmans, Fijnvandraat, Oosterlaan, 2010; Panepinto et al., 2005; Gil et al., 2000). Frequent pain crisis negatively affected the psychosocial health of children with SCD (Wrotniak et al., 2012; Palermo et al., 2008). The improvement in HRQOL was attributed to adherence to treatments (Al Joauni et al., 2013; Fisak et al., 2010). Children who were adherent to hydroxyurea had better HRQOL compared to children who were not adherent (Nweniy et al., 2013). However, in one study (Barakat, et al, 2005), results indicated that increased treatment adherence was associated with a lower HRQOL. The speculation was that treatment adherence may inhibit activities associated with a higher HRQOL. However, the validity and reliability of the data collection tool used for measurement of treatment adherence was not reported, and mostly subjective measures were used. The treatment adherence was assessed by observation method and there was no tool or checklist used to measure adherence. Therefore, it was not possible to determine whether treatment adherence had effects on HRQOL. Children with SCD were found to have low

cognitive functioning (memory & class attention); which interfered with school attendance (Smith et al., 2013). Lastly, very limited research was available about the emotional and social aspects of HRQOL (Palermo, et al, 2008; Panepinto et al, 2009).

There are several methodological limitations in the reviewed studies. The studies were mostly cross-sectional designs, and therefore it is not possible to infer causality about the relationship between indicators (pain, treatment adherence) and the outcome (HRQOL). Longitudinal or prospective designs are needed to determine whether pain frequency and treatment adherence may improve HRQOL over time. The majority of the studies used the PedsQL (Varni et al., 2003) to measure HRQOL, which has well-established reliability (r= .95). One study used a non-standardized tool (daily diary) to collect data; which makes it difficult to compare QOL data (Gil et al., 2000). Diaries were analyzed subjectively suggesting the possibility of researcher bias during analysis.

PARENTS PERCEPTION OF HRQOL IN CHILDREN WITH SCD

Three studies evaluated parents' perceptions of HRQOL in children with SCD (Constantinou et al., 2014; Dale et al., 2011; Panepinto et al., 2009). Constantinou and colleagues (2014) used a cross sectional design to examine HRQOL of children with SCD and parents' (n=74) perceptions of the child's HRQOL, and compared them with a matched control group (n=65). The sample was recruited from London Hospital, United Kingdom. Children with SCD (*M age*= 10.6, *SD*= 3.1 years), healthy children and parents completed the Generic Children's Quality of Life Questionnaire (GCQ, r=0.78) during a clinic visit. The questionnaire consists of 25 items related to self-perception (satisfaction) and HRQOL items (physical, emotional, social). Results did not show significant differences in the HRQOL scores between children with SCD (*M*= 73.34, *SD*= 9.80, range 0 to 100) and the healthy children (*M*= 74.47, *SD*= 9.92, *p* = 0.27). However, 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.

Parents had lower perception of their children's HRQOL than the children's ratings of themselves.

Dale and collagenous (2011) also evaluated the HRQOL of children and adolescents with SCD and their parents' perceptions of HRQOL. Children (n= 124, *M*= 13.0, *SD*= 3.3 years) and their parents completed the PedsQL during a clinic visit. Results showed significant differences in HRQOL scores between the children (*M*= 83.9, *SD*= 12.5 on 0 to 100 scale) and their parents (*M*= 82.3, *SD*= 16, $p < .001$).

Panepinto and colleagues (2009) also used a cross sectional design to evaluate HRQOL in children with SCD and to compare the child's self-report to parents-proxy report using PedsQL tool. The sample was 178 children and parents (mean age of parents = 31.1, *SD*= 40.9) who were recruited from Midwest SCD centre. Results showed that the parents' PedsQL scores were significantly lower in the physical scores (odds ratio= 2.74, CI= 2.68, 11.97) compared to their children who reported better physical functioning scores (odds ratio=3.33, CI= 1.39-7.99).

Parents' perception of HRQOL indicated that the HRQOL of their children was poor (Constantinou et al., 2014; Dale et al., 2011; Panepinto et al, 2009) and that SCD interrupted the social functioning status of children with SCD (Panepinto et al, 2009; Palermo et al., 2008). Parents' level of education was a good predictor for the improvement in children's HRQOL; suggesting that the higher the parent's level of education, the better HRQOL (Smith et al., 2013; Palmero et al., 2008; Gill et al., 2000).

RESEARCH ON SELF-EFFICACY IN SCD

While no studies on parental self-efficacy were available, two articles evaluated self-efficacy in children with SCD (Dobson, 2015; Clay & Telfair, 2007). Dobson (2015) conducted a quasi-experimental study to assess the self-efficacy of children with SCD on their ability to manage SCD pain following a guided imagery intervention. The study was a pre- and post-

intervention design with no control group. The sample consisted of one group of children (N= 20, *M age*= 8.4, *SD*= 1.6 years) who were recruited from Children's Hospital at Montefiore. The children were trained for one month to use guided imagery (5-10 minutes), three times a day regardless of pain and with each pain episode. Sickle Cell Self-Efficacy Scale (Edwards, et al, 2000) which consisted of 9 items (r=.87) was used to collect the data. The findings suggested that the children perceived less pain intensity after using guided imagery intervention and had a greater self-efficacy following the training (*M*= 36.6, *SD*= 3.9) compared to pre-intervention scores *(M*= 26.4, *SD*= 8.3).

Clay & Telfair (2007) conducted a cross section study to examine the relationships between the demographic factors (age, gender, education), physical, and psychosocial symptoms and self-efficacy of adolescents with SCD (N= 148, *M age*= 15.68, *SD*= 1.88 years). The sample was recruited from a pediatric community medical center in northern USA. The SCSES was used to collect the data, which consisted of nine-items (internal consistency reliability was r=0.87). Children's age (*M*= 15.68, *SD*= 1.88), level of education, and gender were not significantly associated with self-efficacy. However, when controlling for age, gender, and education, self-efficacy was negatively associated with physical and physiological symptoms. The higher the self-efficacy, the lower the self-reported symptoms (Beta= -0.33, p = < .01).

Both studies had small sample sizes and the sample were recruited from one location, which limits the generalizability of the findings. There is also a design limitation in both studies. Quasi-experimental design lacks randomization; which may suggest selection bias. The cross sectional design of the two studies limited the ability to identify causal relationship between self-efficacy and other variables. No studies were found that evaluated the parents' self-efficacy to manage SCD symptoms.

A major gap in the literature was the lack of studies that examined the association

between parent education programs and parent's perceptions of HRQOL after interventions. There were no studies that examined whether the parental self-efficacy in disease management was associated with the child's HRQOL. The proposed study will evaluate the parents' self-efficacy to manage SCD and symptoms. The intervention (*PEIP*) will provide comprehensive information to the parents about SCD, signs and symptoms of, triggering factors, complications, and treatments, which aim to increase not only the parent's knowledge, but also their self-efficacy for SCD management, which would lead to improvement in child's HRQOL.

CHAPTER 3 -- THEORETICAL FRAMEWORK

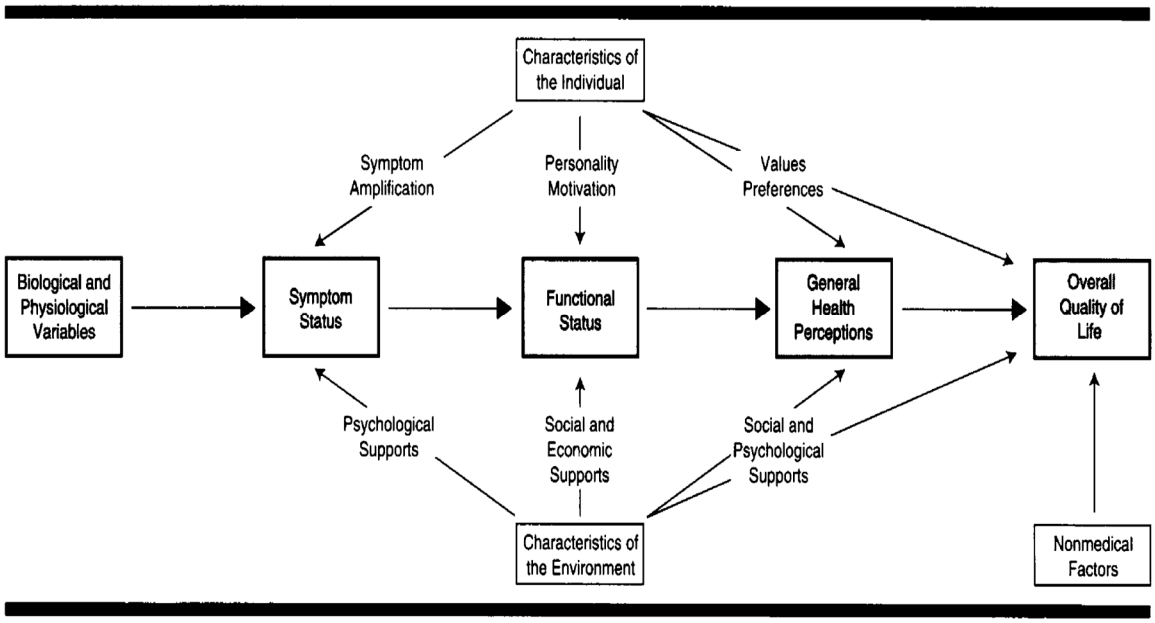
The Health Related Quality of Life (HRQOL) theoretical framework as proposed by Wilson and Clearly (1995) was used to guide the content for the development of the Parent Educational Intervention Program *(PEIP)* and the Social Cognitive Theory Learning Theory was used to explain the relationship between parental knowledge, self-efficacy, and perception of child's HRQOL (Bandura, 1986). The HRQOL model is an explanatory model in which the causal relationships among HRQOL components are explained. Health providers will be able to evaluate appropriate patient outcomes that reflect quality patient care (Sousa & Kwok, 2006). While HRQOL is often an outcome in clinical trials, there is still a limited understanding of its determinants. If its underlying causes are identified, interventions to improve patients' perceived HRQOL can be targeted to those causes (Wilson & Cleary, 1995).

Wilson and Cleary (1995) propose a comprehensive conceptual model for HRQOL that could be used to merge the biomedical and social science paradigms (Sousa & Kwok, 2006). In the clinical paradigm, the focus of the biomedical model is on etiologic agents, pathological processes, and biological, physiological and clinical outcomes. On the other hand, the social science paradigm (quality of life model) focuses on dimensions of functioning and individuals' overall perceptions of well-being. The linkage between these two paradigms was defined between the biological and other types of measures.

The constructs of the HRQOL framework consists of four health-related constructs that affect quality of life: 1) biological function, 2) symptoms status, 3) functional status, and 4) general health perception. The biological function includes the physiological factors (functions of cells and organ systems). Symptom status indicates the individual's perception of abnormal physical, cognitive, or emotional states (fear, frustration, worry). Symptom status is influenced

by physiological and biological factors. Both the biological and symptom status affect functional status -- the individual's ability to perform activities of daily living. General health perception is the individual's evaluation of his/her health status. The biological function, symptom status, and functional status, directly influence the individuals general health perception.

The four constructs affect the individual's HRQOL, which is the extent to which an individual is happy in life as a whole. In addition, characteristics of the individual as well as the environmental factors are included in the model as nonspecific predictive variables of symptom status, functional status, general health perceptions and overall quality of life (Ferrans, Zerwic, Wilbur, & Larson, 2005; Wilson & Cleary, 1995). While the model proposes a linear progression across the five concepts, the unidirectional arrows between concepts and between the nonadjacent levels do not imply that there are no reciprocal relationships. However, the arrows depict the proposed dominant causal associations between concepts (Wilson & Cleary, 1995).



Relationships among measures of patient outcome in a health-related quality of life conceptual model.

Figure 1: Wilson and Cleary model of HRQOL

In a more recent study by Villalonga-Olives and colleauges (2014), the Wilson & Clearly (1995) model was tested on a pediatric population to identify if the constructs in the model can

be a good predictor for HRQOL in children with chronic illness. The authors used structural equation modelling to investigate the goodness of fit of the model on German children with various health conditions (n= 214, *M*= 108, *F*=106; *M age*= 4.28, *SD*= 1.47). Results indicated that children's developmental status (*Beta* = 0.18, *p* = .00) and socioeconomic status (*Beta*= 0.59, *p* =.00) significantly predicted HRQOL. The study also found that, the environmental factor; (parents level of education) was a moderator for the developmental status (*Beta*= 0.44, *p* = .001), and the children's HRQOL (*Beta*= 1.05, *p*= .001). The parents' high level of education directly influenced the children's developmental status and their HRQOL positively. The study concluded that the model has an explanatory power to detect the variance exhibited in the model (Environmental factors, symptom status, functional status and characteristics of the individual). The goodness of fit (x2 = 5.5; df = 6; *p* = 0.48; SRMR = 0.01) suggests that, the constructs in the model could predict HRQOL in the pediatric population.

Biological and Physiological Function in Sickle Cell Disease

The first construct in the model is the biological and physiological function that focuses on the function of cells, organs, and organ systems. In SCD, the biological and physiological function are the Hemoglobin genotypes (HgbSS, HgbAS , HgbSC) and laboratory values, such as the red blood cells, hemoglobin and hematocrit values, iron levels, and erythrocytes (CDC, 2016). Red Blood Cells (RBCs) carry and circulate the oxygen throughout the body. Hemoglobin (Hgb) is the protein in the RBCs that carry oxygen from the lungs to the tissues. Iron is a mineral that is part of the hemoglobin molecule. The hematocrit is the proportion of red blood cells volume to the volume of blood (National Heart, Lung, and Blood Institute, NHLBI, 2015). The physiological factors in SCD include sickle red blood cells which decrease the ability of the RBCs to carry oxygen, vaso-occlusion which decrease the blood flow to lungs, muscles, brain, kidneys, and other organs, ischemia which results from low oxygen, glucose and nutrients needed for cellular metabolism, and tissue damage (Maakaron, 2016).

Vaso-occlusive Crisis. Physiological function in SCD is greatly affected as a result of

frequent vaso-occlusive crisis, which can result in various complications leading to severe organ failures in the spleen, liver, and bone marrow (NHLBI). One of the major complications during the crisis is splenic sequestration, which occurs when red blood cells are trapped in the spleen causing spleen enlargement and risk for hypovolemic shock. Damage to spleen leads to risk for serious bacterial infections that can be life-threatening. Another complication is aplastic anaemia, which results when the bone marrow stops producing new red blood cells (CDC, 2016).

Acute Chest Syndrome. Acute chest syndrome is a serious and common complication in SCD that results from blockage of blood vessels in the lungs, leading to oxygen deprivation to the lungs. In addition, injury to blood vessels in the lungs can increase the pressure in the lung blood vessels, which is called pulmonary hypertension (Gladwin & Vichinsky, 2008; Miller & Gladwin, 2012; Nansseu, et al., 2015).

Stroke. In SCD, brain cells can also be damaged when blood flow is blocked to some parts of the brain, causing stroke (Kassim et al., 2016; The Internet Stroke Center, 2016).

Cardiac Enlargement. The heart is also affected by SCD. Sickle cells obstruct the blood flow to the heart, leading to cardiac muscle enlargement (NHLBI, 2015).

Renal Damage. Also, frequent blood transfusion causes iron excess in the blood, and this may damage the heart. Red blood cell sickling affects the kidneys, leading to decrease kidney function and may result in kidney failure (Sharpe & Thein, 2014).

Retinal Damage. SCD can injure blood vessels in the eye and cause retinal damage. Also, retinal detachment can occur which may cause visual impairment and vision loss (Sambhara & Shah, 2016).

Liver & Gallbladder Complications. In addition, the life span of red blood cells in SCD is less than 120 days, which causes red cells to hemolyze, releasing haemoglobin that breaks down into bilirubin. Bilirubin can form stones that adhere to the gallbladder. The liver may also be injured in SCD due to blockage of sickle red cells in the liver preventing oxygen from

reaching liver tissue (Banerjee & DeBaun, 2016).

Muscle, Bone & Joint Complications. Joint complications are very common in SCD due to decrease oxygen flow to the bones and joints of the body, leading to a condition called aseptic necrosis. Moreover, sickle cells can cause leg sores or ulcers that may or may not heal (George & DeBaun, 2016; Junior et al., 2012).

In this study, the basic information about the biological and physiological function of sickle cells were included in the *Parent Educational Intervention Program (PEIP)*, and were presented in terms the parents are able to understand. The content would help explain the pain and symptoms that their child experiences during acute pain episodes. It would also help them understand how organ damage and complications related to having sickle cell disease can be prevented.

Symptom Status in SCD

Wilson and Cleary (1995) defines symptom status as the perception of the patients on their state of physical, emotional, or cognitive health. The symptoms are classified into either (1) physical symptoms, such as pain, difficulty with breathing, fatigue, lack of appetite, vomiting and others (CDC,2012); or (2) psychological symptoms, such as fear, worry, sadness, frustration, anger, sleep disturbance, and others (Anie, 2005; Edwards, Scales, Loughlin, Bennett, Harris-Peterson, Castro, Killough, 2005).

Physical Symptoms. The model suggests that symptom status is influenced by biological and physiological factors as well as characteristics of the individual and the environment. In the cross section study of Schlenz, Schatz, Roberts (2016), sickle cell genotype was found to be significantly associated with more pain intensity and health care utilization. Children with more severe genotypes (HgbSS, HbgSB) had higher pain intensity ratings (Babela; Nzingoula; Senga, 2005) during hospitalization (M = 7.48, SD= 1.64, p < .05 on 0 to 10 scale) and health care utilization (M= 4.02, SD = 4.09) compared to children with less severe genotypes (pain intensity ratings M= 6.58, SD= 1.70 on 0 to 10 scale; health care utilization (M=

2.08, SD= 3.60, *p* =.001). Additionally, the authors found that child negative thinking was positively associated with pain frequency and health care utilization. Approach or problem focused coping is also significantly associated with pain intensity and duration (*M*= 1.68, *SD*=0.58, α=0.86) compared to children who had positive thinking (*M*= 3.48, *SD*= 0.93, α=0.90).

Psychological Symptoms. The literature suggests that children with SCD experience psychological symptoms such as anxiety, worries, stress, social withdrawal, low self-esteem, and depression (Anie, 2005; Edwards, Sarlani, Wesselmann, Fillingim, 2005). In the case control design study of Sehlo & Kamfar (2015), 13% of the 60 children with SCD had increased depression scores as assessed by the Children's Depression Inventory scale (CDI) (*M*= 14.50 ± 1.19). A higher level of parent support was a significantly associated with decreased depressive symptoms, demonstrated by lower CDI scores. Better quality of life was shown by the associated higher total PedsQL 4.0 self-scores of children with SCD (*B* = −1.79, *p* = 0.01 and B = 1.89, *p* = 0.02 respectively).

Children with SCD can experience problems with psychological adjustment as a result of disease severity, the Hgb genotype, complications and pain frequency; these factors may increase the perceived daily stress for these children (Gil, Carson, Porter, Ready, Valrie, Redding-Lallinger, Daeschner, 2003). Gil and colleagues (2003) found that on pain days, adolescents reported significantly higher stress rating (*M*= 21.5, *SD* = 22.8, *p* <.0001) compared with non-pain days (*M*= 10.5, *SD* = 14.3).

Symptoms & HRQOL. The SCD symptoms are subjective experiences, and are weighted by the patients' perception of the symptoms' impact on their quality y of life. Individual factors can influence symptom status in SCD. Gil and colleagues (2003) found that child's mood is associated with the intensity of pain symptom. Increases in negative mood were significantly related to increases in pain (t = 8.55, *p* < .0001), while increases in positive mood were associated with decreases in pain (t = –10.09, *p* < .0001). In addition, Valrie and colleagues found (2008) that negative mood was related to high pain severity (r= .59, *p* < .01), and negative

mood was a significant predictor for increased pain severity (Beta= 0.15, $p < .01$). These findings are consistent with Zempsky and colleagues (2013) who examined the effect of mood on the physical function, indicating that positive mood predicted changes in pain and improved physical recovery (Beta= 0.24, 95% CI: 0.12 to 0.35).

Symptoms & Characteristics of the Individual. The self-report of symptoms are greatly influenced by children's demographic such as age, gender, and socio-economic status (Anie, 2005). Jenerette and colleagues (2011) reported that the sensitivity and tolerance of pain depend on several factors, including gender, ethnicity, personality and culture. Males are less likely to report pain, and express greater pain tolerance than females (Jenerette et al., 2011). Campbell, Edwards & Fillingim (2005) reported that Caucasians are less sensitive to pain than individuals of African and Hispanic descent. In the Japanese culture, there is an emphasis on the desirability of concealing pain and emotions (Campbell, France, Robinson, 2008). In some Arabic cultures, males are expected to be more tolerant of pain, to be patient when experiencing disease complications and not to cry while in pain; thus, ethnicity effect the way people respond to pain. People with neuroticism personality (harm avoidance) tend to show greater sensitivity to pain and reduced tolerance (Vossen, van Os, Lousberg, 2006).

Symptoms & Characteristics of the Environment. The environment surrounding the child also has an influence on the symptom status. Family functioning and the caregiver responses affect pain variability experienced by children with SCD (Palermo et al., 2004). Barakat and colleagues (2010) found that the adolescents who reported lower family functioning had increased disease severity and healthcare utilization ($p = .001$). In Oman, parents' ability to deal with their children's pain influences symptom status. However, due to lack of parents' knowledge to manage symptoms of SCD at home, it leads to increase healthcare utilization as well as hospitalization. Omani families who have children with chronic illnesses usually responses to children's pain initially using traditional practices such as herbs and oil massage. Most of the time, providing medicine to alleviate child's pain is given late after trying non-

pharmacological drugs. Some families may try tylenol; however, mostly parents prefer taking the sick children to the emergency department for pain management.

Religion. Religion tends to influence the acceptance of the disease and the daily experienced symptoms. In the qualitative study of Anie, Egunjobi, Akinyanju, (2010), it was found that religious beliefs play a positive part in psychological adjustments of Nigerian adolescents with SCD due to daily prayers, faith in God, and is considered a hopeful approach to health difficulties (Anie et al, 2010). In Oman, religious beliefs also play a significant role in accepting chronic illness as well as coping with disease complications. Muslims belief that having a child with hereditary disease is God's decision to test their patience and accepting what God had planned for them. Due to daily prayers, Omani families always have faith in God to heal their children's illness. One of the important practices that most families do when experiencing pain is to recite holy Quran on their children and make the sick children to hear audiotaped Quran to alleviate their pain and suffering. This spiritual practice (reading Quran) works most of the time and play a significant role on tolerating pain and suffering.

The *Parent Educational Intervention Program* (PEIP) that will be used in this study will include information, not only about the biological and physiological function of sickle cell disease but also the physical (pain, nausea, vomiting, sleep disturbance) and psychosocial symptoms (fear, worry, sadness, anger, depression) that the child may experience. Symptoms and strategies for management both physical and psychosocial symptoms will help minimize symptom burden and improve the symptom status experienced by children with SCD. Parents will be provided with information about the emotional problems experienced by children with SCD and guidelines to improve the emotional health of their children.

Functional Status in SCD

The third construct in the model is functional status, which is the ability of the individual to perform defined tasks and adjust to the environment. It represents the individual's activity level, sleep, bathing, and eating (American Thoracic Society, ATS, 2007). Functional status can

be measured subjectively or objectively over a given time frame (Wilson & Cleary, 1995). There are four main domains that represent the functional status of the individuals -- physical, social, role, and psychological function (ATS, 2007). The functional status in SCD is determined by the degree to which the disease impacts the children's physical, psychological, social health, and the role functioning.

Children with SCD have impaired physical functioning status due to recurrent pain episodes (Jacob, Miaskowski, Savedra, Beyer, Treadwell, Styles, 2006). During acute pain, performing activities of daily living (walking, eating, sleeping, dressing and toileting) may be impaired. Jacob and colleagues (2006) evaluated the functional status of 27 children who experienced painful pain episodes. Pain crisis interfered with sleep and children experienced short sleep duration and sleep disturbance because of pain (*M*= 4.5, *SD*= 1.5 on 0 to 10 scale). Severe pain also limited children's activities and mobility (*M*= 2.2, *SD*= 0.8 on 0 to 10 scale). Moreover, Zempsky and colleagues (2013) found a significant improvement in the physical function in children who had reduced pain during hospitalization (*B*=1.41, 95% CI: 0.08 to 2.84).

Physical functioning is greatly impacted by the psychological status of the individuals. Children with SCD may experience emotional problems such as anxiety, mood changes and depression that might impact on their physical functioning (Hoff et al., 2006). Zempsky and colleagues (2013) found that negative mood is associated with decreased functional status in children with SCD (n=25, *M*= 5,F=20; *M age* = 16.6, *SD*= 2.4 years) and that positive mood was significantly associated with physical functioning scores (*B*= 0.24, 95% CI: 0.12 to 0.35).

Social function is part of functional status (Ahmed et al., 2015). Acute pain episodes in SCD can interrupt children's social activities and may consequently interrupt the social functioning (Ahmed et al., 2015). In the cross section study by Ahmed and colleagues (2015), adolescents with SCD who reported frequent pain and other disease complications had low social functioning scores (*M*= 60.1, *SD*= 25 on 0 to 100 scale). They found that adolescents with low physical function and low vitality (*M*= 55.6, *SD*= 14.8 on 0 to 100 scale) had low social

function scores (*M*= 71.9, *SD*= 25 on 0 to 100 scale).

Functional Status & Individual/Environmental Characteristics. Although symptom status is an important determinant of functioning, some aspects of an individual's personal and social environment may also have important effects on functioning. Personal and environmental factors such as perceived self-efficacy, family role and access to health care or medical treatment can impact the individual's functional status (Dobson, 2015). Dobson (2015) evaluated the effects of Cognitive Behavioral Training on self-efficacy and found that children (N= 20, *M age*= 8.4, *SD*= 1.6 years) with greater self-efficacy had high physical and psychological functioning. Also children with higher self-efficacy had more control over their pain following cognitive behavioral training (*Mean* pre= *M*= 26.4, *SD*=8.3; post *Mean*= 36.6, *SD*=3.9).

Functional Status and Family. Family as an important factor in the children's environment plays an important role in the child's health that influence the child's functional status. Smith and colleagues (2013) evaluated cognitive functioning in children with SCD and found that parents who had high level of education were associated with higher cognitive functioning for their children in relation to the memory status and good attention in the classrooms. The results revealed that parents' level of education was a significant predictor for the cognitive functioning of children with SCD (R^2 = .52, *F(*5, 77) 16.37, $p < .01$). Highly educated parents were able to recognize the effects of the disease on the children's memory and attention; consequently more care was taken by the parents to improve the child attention and the memory status.

The Parent Educational Intervention Program (PEIP) that was used in this study included information about functional status, not only the physical, but also the emotional, social and cognitive status. By including information about the different aspects of functional status, the parents my employ strategies for improving the physical, emotional, social and cognitive status that may lead to improvement in the overall HRQOL in children with SCD.

General Health Perceptions

The fourth construct in the Wilson and Cleary model is general health perceptions, defined as a subjective self-rating of one's overall general health (Wilson & Cleary, 1995). General health perceptions are directly related to the functional status and indirectly related to symptom status and biological and physiological factors (Ferrans et al., 2005; Wilson & Cleary, 1995). General health perceptions are influenced by the characteristics of the individual and environment. General health perception in SCD is directly influenced by the children's current health status, prior health, health outlook, resistance to illness, sickness orientation, and health concerns (Ferrans et al., 2005). Ahmed and colleagues (2015) found that Saudi adolescents with SCD who experienced frequent acute pain episodes had high rates of hospitalization. The frequent hospitalizations were related to fever and infections (*M*= 54.4, *SD*= 28.4*, p* = .001), muscle pain and joint swelling (*M*= 56.4,*SD*= 28.8), and other symptoms, which consequently lead to negative general health perceptions among adolescents with SCD. Low vitality level and low physical and emotional functioning were also associated with poor general health perception (Ahmed et al., 2015).

Certain factors in the environment such as socio-economic status, family, and psychological support can influence the general health perception of children with SCD (Barakat et al., 2010; Zempsky et al., 2013). Fernandes and colleagues (2015) examined the socioeconomic status of patients with SCD (n=155; *M*= 82, *F*= 73, <5 years= 45, 6-10 years= 22, 11-15 years= 28, 16-20 years= 23, 21-30 years= 23, 31 years= 14) in Brazil and found that socioeconomic status is an important determinant of general health status among this vulnerable population. The study revealed that the majority of Brazilian children with SCD were from low socioeconomic status (*M*= 81, *SD*= 52.3 on 0 to 100 scale) that impacted on their perception of their health (Fernandes et al.,2015).

Family support is greatly influenced by the psychosocial health of people with SCD and impacted positively on their beliefs about health (Anie, 2005). In the qualitative study of Forrester, and colleagues (2015) patients with SCD (n=6) had reported that family and peer

support provided significant comfort for the participants. The participants attested that good family support allowed them to have a positive beliefs and attitude towards themselves and motivated them to better cope with their condition.

The *Parent Educational Intervention Program (PEIP)* that used in this study included information about family support and strategies that would help parents improve children's general health perception. Improving parental knowledge and including the different constructs of the model in the *PEIP* will positively influence the child's and parent's perception of general health.

Overall Quality of Life

The last concept in the Wilson and Cleary model is overall quality of life. Overall quality of life is the subjective perception of individuals' health, personal thoughts, feelings and the meaning of one's life (Wilson & Clearly, 1995). It refers to how happy and satisfied an individual is with his/her life as a whole. Quality of life (QOL) is also viewed as a multi-dimensional concept that represents the individuals' perception of their physical, psychological, social and cognitive health (Ameringer et. al, 2014; Beverung et. al, 2014; CDC, 2012; Dale et. al, 2011; Fisak et. al, 2010; Jackson et. al, 2014; Hijmans et. al, 2010; Lowry & Pakenham, 2008; Limbers & Skipper, 2014; Muszalik & Kędziora-Kornatowska, 2009; Panipento et. al, 2005; Palermo et. al, 2002; Sawyer et. al, 2005; Strine et. al, 2008; Schlenz et. al, 2012).

The physical aspects of HRQOL include physical function such as, walking, eating, bathing, and other activities of daily living. The psychological aspects include the emotional status such as, stress, anxiety, depression, worries and negative mood (Sehlo et al., 2015), as well as the coping abilities of the individual and the adaptation with the chronic illness (Forrester et al., 2015). The social aspects include the individual's interaction and relationships with families, peers and others (Sehlo et al., 2015). The cognitive aspects include the mental capacity to evaluate the individual's life or health (Wrotriak et al., 2012).

Overall quality of life is also determined by other salient life circumstance and

experiences (Wilson & Cleary, 1995). Quality of life in children with SCD is poor compared to the healthy children similar in age (Beverung et al., 2014, Panipento et al., 2005). Recurrent episodes of acute and/or severe pain are the hallmark characteristic of SCD (Panipento et al., 2013), which contributes to lower quality of life in children with SCD. Wrotniak and colleagues (2012) found that the physical and psychological health were significant predictors for HRQOL. Physical health was significantly low (*Beta*= 7.1, p = 0.02) in children who had been hospitalized at least once in the previous year. Also, the psychological health was significantly low (Beta= 8.4, p =.003) in children who had SCD and other comorbidities such as asthma (Wrotinak et al., 2012). Due to hospitalization, cognitive health also was significantly low *(Beta*= 8.5, p =.009).

Palermo and colleagues (2005) suggested that physical and psychosocial functioning were significant predicators for HRQOL [F(7.31= 4.57, p < .01]; the lower physical and psychosocial functioning, the poorer the HRQOL. Beverung and colleagues (2014) also found that children with severe disease, defined as having history of stroke, acute chest syndrome, and frequent hospitalizations more than 3 times the previous 3 years had lower scores in the physical aspects of HRQOL (*M*= 46.53, *SD*= 12.89 on 0 to 100 scale) than children with mild/moderate disease (*M*= 89.28, *SD*= 9.40). Pain was the primary indicator of low physical functioning in the children with severe disease (Hijmans, et al, 2010). Children with SCD who had frequent pain crisis had significantly lower scores (*M*= 49, *SD*= 8.7 on 0 to 100 scale) in the physical aspect of HRQOL compared to the healthy children (*M*= 54, SD= 11.4, p < .05).

Some studies reported that there were deteriorations in school competence for children with SCD, compared to healthy peers (Smith et al., 2013), contributing to low quality of life perception (Smith et al., 2013; Trzepacz et al., 2004). Smith and colleagues (2013) found that children with SCD had low HRQOL total scores *(M*= 70.49, *SD*= 15.21 on 0 to 100 scale). Pain frequency, and stroke were significant predictors for the cognitive functioning of children with SCD (R^2 = .52, F(5, 77) = 16.37, p < .01). Children who experienced frequent painful crisis and stroke due to blood blockage in the brain, had low memory status and poor attention in the

class. The deterioration in social and school competence contributed to low quality of life perception reported by children with SCD (Smith et al., 2013).

The *Parent Educational Intervention Program (PEIP)* that was used in this study included information about the different aspects (physical, psychological, social, cognitive) of HRQOL. Parents were provided with comprehensive information about SCD signs and symptoms, triggering factors, and symptoms management, and strategies to improve the social, psychological, and cognitive health of their children. Improving various dimensions of children's health would lead to improve parents' children's perception of HRQOL.

Characteristics of the Individual and Environment

HRQOL is influenced by the individual's experiences and circumstances and it changes when an individual's circumstances change (Wilson & Cleary, 1995). HRQOL is influenced by two other constructs in the theoretical framework: 1) characteristics of the individuals, and 2) characteristics of the environment (Ferrans et al.,2005; Wilson & Cleary, 1995). The characteristics of the individua1zl include age, gender, level of education, marital status, values preferences, personality, and motivation.

Age, Gender & HRQOL. The research on individuals with SCD suggests that increases in age is associated with low quality of life (Ahmed et al., 2016). In the cross section study of Ahmed et al (2016), older age was found to be associated with frequent emergency visits and low HRQOL scores (*RR*=1.013, *p* = .03). Gender was also found to influence quality of life perception. Male adolescents with SCD reported better scores in the domains of physical functioning, bodily pains and social functioning compared to female patients (Ahmed et al., 2016). Ahmed and colleagues (2016) found that Saudi male adolescents with SCD were reported to have higher percentages in the domains of physical functioning, bodily pains and social functioning compared to female patients (66.7% vs. 58%, *p* = .031). Dampier and colleagues (2011) also found that female adolescents had lower scores in the physical

functioning *(B*= 3.54, *p* < .01), vitality (*B*= 3.33, *p* < .01), and social functioning (*B*= 0.98, *p* < 0.01) compared to male adolescents. These findings are consistent with data from Amr and colleagues (2011) who found that physical functioning scores were significantly higher among male adolescents with SCD (*M*= 59.96,*SD*= 21.23, *p* = .001) compared to female adolescents (*M*= 53.41,*SD*= 18.58). Female adolescents also had significantly lower scores in the emotional well-being than male adolescents (*M*= 48.8, *SD*= 21.55 vs *M*= 55.51, *SD*= 18.62, *p* = .01, respectively).

Education and HRQOL. Low level of education was associated with lower HRQOL. In the study of Amr et al (2011), the results revealed that adolescents with delayed education due to failing, school retention, and absentiseem had low quality of life scores (Amr et al., 2011). In this study, Saudi adolescents with SCD showed a significant educational delay (*p* < .001) in terms of excessive failing and school retention while adolescents without SCD was significantly better; (15.0%) of adolescents with SCD demonstrated delay (excessively retained in relation to their comparable peers) in the primary (elementary=up to grade 6) education compared to only (2.0%) among adolescents without SCD, and 71/81 (87.7%) of adolescents with SCD in the preparatory stage (intermediate= up to grade 9) were delayed compared to 8/39 (21.1%) among adolescents without SCD. This delay was attributed by the parents due to excessive absenteeism from schools in response to frequent hospitalization, emergency admissions, and appointments for checkups (Al Nasiri, Al Mawali, Jacob, 2017).

Personality & HRQOL. Children with negative mood experienced intense pain, which consequently impacted HRQOL (Zempsky et al., 2013; Valrie et al., 2008). Positive affect over time was significantly associated with the adolescents' physical function scores (*B*= .24, 95% CI: 0.12 to 0.35]). Negative affect was positively associated with pain and inversely associated with physical function scores (*B* = 1.58 [95% *CI*= 0.23 to 2.93]).

Children with high self-efficacy have more control over their pain and had more

confident ability to carry out everyday activities (Dobson, 2015). Children perceived less pain intensity after using guided imagery intervention, and had a greater self-efficacy following the training compared to pre-intervention scores, with *M*= 36.6, *SD*= 3.9 vs *M*= 26.4, *SD*= 8.3 respectively (Dobson, 2015).

Characteristics of the Environment

The characteristics of the environment include parental, psychosocial support and the socioeconomic status. Parents are an important part of the social environment surrounding the child. Parent support was found to be significantly associated with better HRQOL of children with SCD (Sehlo et al., 2015). Sehlo and colleagues (2015) found that children with (n=60; *M* age= 11.93, *SD*= 1.72) with high level of parent support had decreased depressive symptoms (*B* = 1.79, *P* = .01) and high quality of life scores (B = 1.89, *p* = .02).

Parental Pain & HRQOL. Other studies found that caregiver responses to pain plays a direct role in pain variation due to their ability to manage pain at home and their decision towards utilization of health care (Barakat et al., 2008). Barakat and colleagues (2008) conducted a cross section study to identify the associations between pain, psychological adjustment, and family functioning with health-related quality of life (HRQOL) in a sample of 42 adolescents with (SCD). They found that caregivers' ability to manage disease complications and treatment was found to be integral to adolescent adaptation to SCD in the context of pain. Their findings showed a significant association of family functioning and HRQOL of adolescents with SCD (*B*= .75, *p* < .001). They concluded that family functioning is essential for physical as well as psychological adaptation of adolescents with SCD.

Parental Education & Child' HRQOL. Certain characteristics in parents such as parents' education was found to be associated with HRQOL of children with SCD. High level of parents' education was associated with better quality of life of their children. Gil and colleagues (2000) examined pain intensity, drug use, and health care visits in 34 children and adolescents with SCD, and concluded that parents' educational level was a significant predictor of

emergency room (ER) visits. They found that parents with high level of education were more likely to bring their children to ER for pain management ($F(1.29)= 4.62$, $p < .05$) compared to parents with low level of education. Moreover, Smith and colleagues (2013) evaluated the impact of SCD on the cognitive functioning of 82 children with SCD and found that parents' level of education was a significant predictor for the cognitive functioning of children with SCD ($R^2 = .52$, $F(5, 77)$ 16.37, $p < .01$). They also concluded that the parents with high level of education had rated higher cognitive functioning for their children, related to the memory status and good attention in the classrooms. Parents who were highly educated were able to recognize the effects of the disease on the children's memory and attention. Consequently more care was taken by the parents to improve the child's attention and the memory status.

Parental Socio-Economic Status and Children's HRQOL. Parental socioeconomic status was also associated with HRQOL. Children and adolescents with low socioeconomic status were found to have lower HRQOL (Fernandes, et al, 2015). Fernandes and colleagues (2015) found that socioeconomic status is an important determinant of general health status among children with SCD. Low socioeconomic status ($M= 81$, $SD= 52.3$ on 0 to 100 scale) had effects on parental perception of the child's HRQOL.

Social-Cognitive Learning Theory

The impact of *PEIP* on parents' self-efficacy and perceived HRQOL can be linked to the Social-Cognitive Learning Theory (Bandura, 1986). In Bandura's theory human functioning is viewed as reciprocal interactions among behaviours, the environmental variables, cognition, and other personal factors. An important construct in Bandura's theory is perceived self-efficacy, which is the belief concerning one's capabilities to organize and implement actions necessary to attain designated performance level (Schunk, 1989). Based on this model, self-efficacy has two components: efficacy expectation and outcome expectation. An increase in self -efficacy leads to changes in performance, reduction in anxiety, and change in behavior. In the proposed study, improving parents' knowledge through the *Parent Educational Intervention Program* would lead

to increased self-efficacy, which would consequently lead to improvement in pain and symptom management for their child. Bandura's theory suggests reciprocity in which more confident parents will lead to an increase in their ability to manage SCD, treatments, symptoms, and complications. Improvement in management of physical (pain, symptoms) and psychological (fear, worry, anxiety) symptoms will lead to improvement in HRQOL for the child.

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 2). 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 (Shahine et al., 2015). Self-efficacy is considered the mediator that will facilitate parental learning and applying the knowledge as they manage SCD symptoms at home (Bandura, 1986).

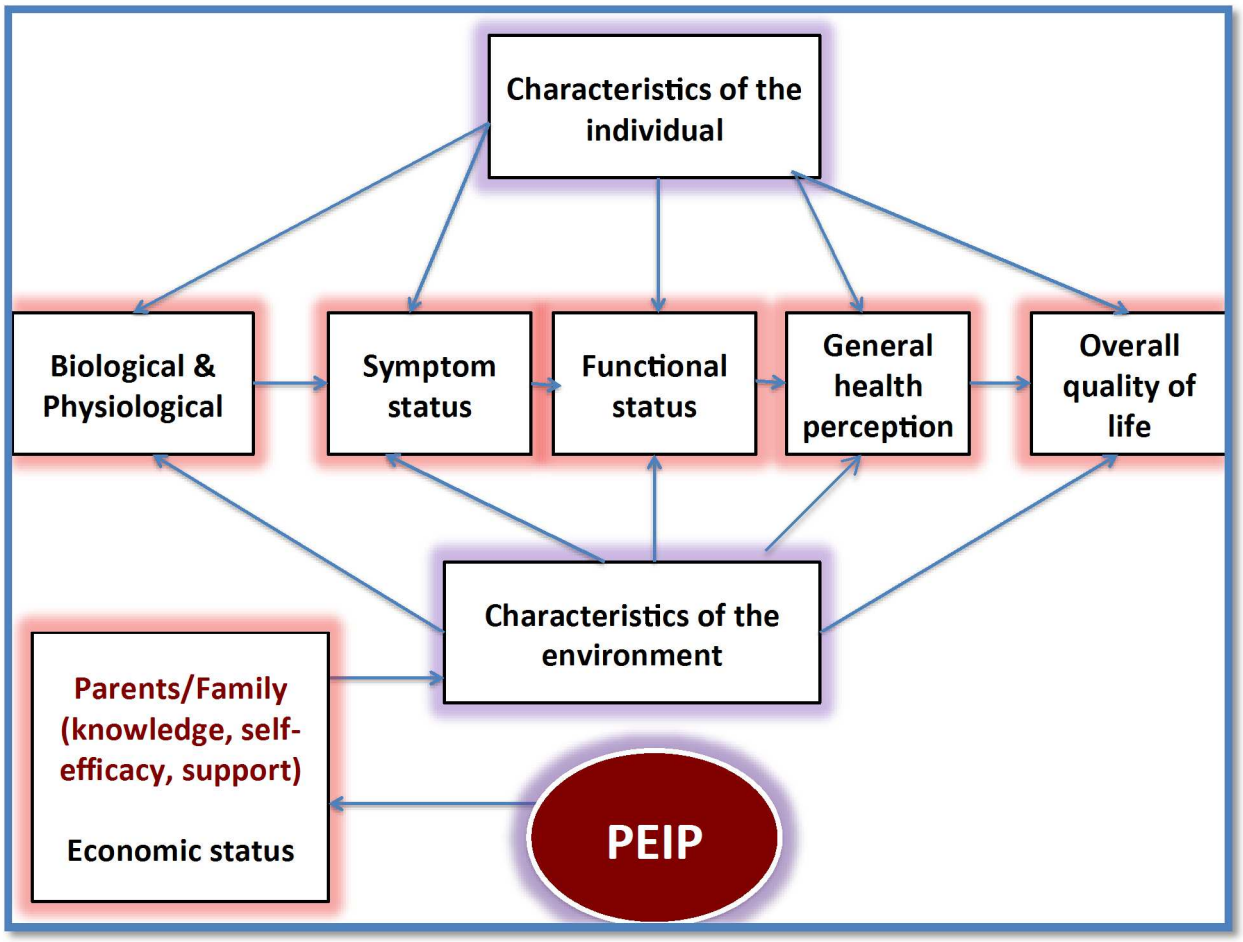


Figure 2: Impact of parental knowledge & self-efficacy on HRQOL

CHAPTER 4 – METHODS

The purpose of the study was to evaluate the effectiveness of a video-delivered entitled *Parent Education Intervention Program (PEIP*) delivered for parents of children with sickle cell disease (SCD). The overall goal was to improve knowledge of parents that could lead to improvement in their self-efficacy related to pain and symptom management at home, thereby improving the quality of life in children with SCD. The specific aims were to examine the effects of the *PEIP* on parental knowledge, self-efficacy, and parent and child's perceptions of health related quality of life (HRQOL) of children with SCD.

Design

The study was a randomized controlled trial (RCT) with two groups of parents of children with SCD. One group was randomly assigned to the *PEIP* group, and the other was the control (SEP) group. The *PEIP* consisted of two video clips; the first video addressed the physical aspects -- basic information about SCD, signs and symptoms, complications, potential triggering factors for sickle cell crisis, and the management of 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 by the PI 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 at the end of the intervention, which was 4 weeks after enrollment.

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. All parents of children with SCD who were followed in the hematology

clinics in these hospitals were invited to participate. Approximately, 300 children with SCD were seen annually in the hematology clinics at both Hospitals.

Sample

A convenience sampling approach was used to recruit parents of children with SCD. First, parents were eligible if the age of their child with SCD is between 8 to 12 years. In Oman, children until 12 years of age were seen in the pediatric clinics, and children ages of 13 and older were seen in the adult clinics. The rationale for selecting this age group was because school age children were able to report pain, and other symptoms related to the disease. Also, the information on the emotional, social, and cognitive health were more important for children in this age group. An assumption of the study was that parents, as the child's primary caregiver, would be able to apply the knowledge as they provide care for their child.

Second, the parents were eligible if they were Omani citizens because the *PEIP* was specifically designed so that it was culturally appropriate for Omanis. Therefore, parents from other nationalities, who did not speak Arabic and who came from different cultures were excluded. Parents were also excluded if they: 1) were not available for consenting procedures; 2) were not willing to participate in completing the study procedures; and 3) had physical, cognitive, and/or neurological impairments that prevented them from consenting and/or completing study procedures. The nurse screened the eligible participants for any neurological impairment using the Decision-Making Capacity Assessment tool (Appendix 1). This was done to assess the ability of parents who may have or may be experiencing cognitive impairments to make an informed decision about being part of the study. In the event that the Omani parents were not able to read, a nurse not involved in the study procedures would read the study materials.

The PEIP was delivered via a smartphone. Parents who did not have smartphones were included, and were provided with a smartphone for study use. A total of nine parents were excluded from the study as four of them were not Omanis and the other five were not willing to

participate in completing the study procedures.

Sample Size Calculation

The total number of parents that were enrolled were 74 (37 in each group). The sample size estimation was based on data from Shahine et al. (2015). The study reported a significant difference between the baseline score (M=16, SD=4.4), and the score post-educational intervention (M=23, SD=3.6). Using G-power, the sample size of 37 in each group was able to detect a 1.724 unit increase in the knowledge scores of the PEIP intervention group (d=.71) with power >0.80, as compared to no increase for the control group, using a paired t-test with 2 tailed alpha = 0.05. The sample size of 37 per group was adequate to detect a 0.71 effect size increase in HRQOL in the intervention group as compared to the control group, using a t-test with 2-tailed alpha=.05. The sample size was based on Nwenyi et al. (2014), who found a significant difference on HRQOL scores between children who used hydroxyurea (M=60.54, SD=9.10), and children who did not use hydroxyur 1`ea (M=37.01, SD= 11.32), an even larger effect size than detectable with the proposed sample. The sample size of 37 per group was adequate to detect a 0.59 increase in parent's self-efficacy, based on data from Dobson (2015) who found a significant difference on the self-efficacy between the pre intervention scores (M=26.4, SD=8.3) and the post-intervention scores (M=36.6, SD=3.9).

Recruitment & Screening Procedures

A trained nurse coordinator (research assistant), who worked in the hematology unit at the Royal Hospital, was hired to distribute the study flyers (Appendix 2, appendix 3 for arabic) in the inpatient units and in the clinics. In addition, a banner describing the study was placed by the entrance of the clinic (Appendix 4). The nurse coordinator identified the eligible parents based on the inclusion and exclusion criteria. Thereafter, the nurse screened the prospective participants to determine their eligibility for participation in the study using Decision-Making Capacity Assessment tool (Appendix 1). After screening, the nurse approached the eligible parents and provided information about the study. A list of children's names and their parents,

who were interested, were provided to the principal investigator (PI) for study and consenting procedures. In the event that a parent was not able to read, the nurse asked the parent during clinic visits, if the parent had seen a banner for a study related to the Parent Educational Intervention Program in Sickle Cell Disease. The nurse read the banner to the parent and asked if the parent was interested in learning about the details of the study.

Information and Consent Procedures

The PI met parents assigned to the intervention group in a private room in the clinic for 15 minutes. The meeting was arranged by the hematology unit coordinator. The PI explained the details of the study procedure to the parents and their children using the information sheet (Appendix 5, appendix 6 for arabic). Parents and their children who agreed to participate were asked to read the consent form. They were allowed to ask questions, and talk with family members and care providers as needed and were given time to think about participation as needed. 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. Parents received a $30 “Lulu” a shopping voucher (=12 OMR) for their participation at the end of the study. Parents willing to participate were then asked to sign the consent form when they were ready (Appendix 8, appendix 18 for arabic). When consenting process finished, the parents were directed to complete the study questionnaires, using paper and pen. If the child refused to participate, the parent was not included in the study. However, all children whose parents agreed to participate, also agreed to take part of the study and were asked to sign a child assent form (Appendix 7, appendix 8 for arabic).

The enrollment procedure occured at the hematology clinics when the parents came for a scheduled medical clinic appointment. The following study procedures occured after their medical clinic appointment in a private and quiet room.

Randomization Procedures: To minimize the risk of contamination, a cluster

randomization approach was used, with the intervention (PEIP) and the control groups (SEP) recruited and enrolled on separate days. A list of children's names and their parents, who were interested in participating, were collected by the nurse coordinator. The hematology clinic operates 2 days each week in each site. 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. If the coin landed heads-up, the parents who attend the clinic on the first day of clinic operation in that week were assigned to the PEIP group and those attending the clinic on the second day of clinic operation in that week were assigned to SEP. If the coin landed tails-up, the order of group assignment was the reverse.

All parents, regardless of group assignment were asked to complete the following pre-intervention assessments (Appendix 9-15, appendix 16- 22 for Arabic), using paper and pen at time of enrollment. Completion of the assessments took approximately 30 minutes**.**

- Parents Knowledge Questionnaire (PKQ) (10 minutes)
- PedsQL (Generic) (5 minutes).
- PedsQL SCD module (10 minutes).
- Self-Efficacy Scale (SES) (5 minutes)
- Demographics Questionnaire (2 minutes)

The children were asked to complete the following age appropriate PedsQL:

- PedsQL (Generic) (5 minutes).
- PedsQL SCD module (5 minutes).

Procedures for Delivery of *Parent Educational Intervention Program (PEIP)*. Following the pre-intervention assessments, parents assigned to the *PEIP* group were oriented by the PI and requested to navigate the educational materials on thier smartphones. Orientation was 20 minutes. First, the two video educational materials were downloaded to the parents' own smartphone. If parents did not have one, parents were provided with one; however, all parents

had smartphones and were not required to get another one. Downloading of the two videos into the smartphone took approximately 2-3 minutes depending on the network. The parents were allowed to practice accessing the materials and opening the videos.

Development of PEIP videos. The content in the videos were prepared by the PI. The following procedure was taken to develop the videos 1). The information was derived from the National Heart, Lung, and Blood Institute (NHLBI, 2014), 2). The animated videos and pictures on SCD were downloaded from the Internet. The scripts were written by the PI and verified by an expert in SCD. 3). The photo shot was taken by a professional photographer (hired by the PI) from Sama Company for Photography and Art Production and was captured in the Omani community. Some Omani children and adults (related to the PI) were asked to serve as the characters for the videos and were provided with gifts. Photos for the hospitalized child was taken from the Royal Hospital. Permission from the director of the Royal Hospital and the head of the hematology unit was taken. The child was asked to sign consent for accepting to be photoed. Her parents were also asked to counter sign for allowing taking photos for their child. Some photos were taken from Al Manahel School and the permission was taken from the headmaster, 4). The English scripts (part 1 & part 2) were narrated by school age children related to the PI and the Arabic scripts were narrated by a broadcaster from The General Authority of Radio and Television in Oman. The guide for making the videos was prepared by the PI. It consisted of guidelines for the development of the video such as order of the dimesions, sentences to be written under each photo, photos order, animations, slide transitions and script narration for the photos. 5). The videos were produced by Sama Company for Photography and Art Production. Content validity of the videos was done by 2 hematologists and 1 nurse. They were asked to rate the contents using content validity checklist (Appendix 23). Prior to the study, the vidoes were piloted on five parents (excluded from the study) for comprehension and clearity.

Content of the PEIP Videos. The first video included content related to the physical

health -- general information about SCD, pain and symptoms, triggering factors for acute pain crisis, complications, treatment, and symptoms management. The duration was 7 minutes.

The second video included content related to the emotional, social, cognitive health. The duration was 6 minutes (2 minutes each for the emotional, social, and cognitive health). The emotional health section explained the impact of the disease on emotional health. Information on the common emotional disturbances (fear, anxiety, worry, sleep disruptions) that may be experienced by children with SCD were included. In addition, the content provided important guidelines for the parents on how to improve the emotional health of their children. The social health section outlined the impact of SCD on the social health. The parents were provided with guidelines about symptoms that indicated changes in the social health (relationship with peers, siblings, ability to enjoy leisurely activities) as well as important tips to improve their children's social health. The cognitive health section included information on the influence of the disease on the cognitive health – the child's ability to do well in school, ability to communicate, solve problems, makes decisions, resolve conflicts. The parents were provided with important guidelines to improve their children's cognitive health (https://bit.ly/2HFAJ8O).

The contents in the video were designed to be culturally appropriate to Omani parents. There were three strategies (Peripheral, Linguistic, socio-cultural) that were utilized to make the educational contents in the videos culturally appropriate (Kreuter, Lukwago, Bucholtz, Clark, Thompson, 2003). The first one was peripheral strategy, in which the visual style of the health education materials reflected and described the Omani culture. In the videos, the educational materials (colors, images and pictures) clearly represented the appearance of Omani culture. Linguistic strategy was another category that was used to make the health education material relevant to Omani culture. The health education material was translated to Arabic language; which is the native language in Oman. Additionally, the orientation session was planned to fit within the norms and values of Omanis (Kreuter et al.,2003). In Omani culture, women do not mix with men. In the hospitals, for example, there are two separate waiting areas for men and

women. In this study, the orientation session was considered separately for both gender adhering to the norms and values of Omani culture. The third strategy was described as sociocultural, in which the material reflected the normative practices and beliefs of the Omani culture (Kreuter et al., 2003). This was reflected in the information provided for pain management by using some religious practices that believed in Oman, which was reciting or listening to 'Holy Quran'. This religious point added strength to the designed material that can be easily accepted by the Omani culture as it reflected their religious beliefs.

The parent was then allowed to ask questions, express thoughts/concerns. The videos were tested on different devices and it worked very well, no technical problems were encountered. In the event that a technical problem is encountered, the parents were able to contact the PI directly. No participant encountered a technical issue with the videos throughout the study.

After the orientation session, the PI informed the parents to watch both videos on their free time when they reached home and that the PI would contact them by a phone call once per week (every Wednesday), focusing on one section per week (physical, emotional, social, cognitive health) for four consecutive weeks, to remind parents to watch the videos, read the materials, and refer to the material about pain control. Parents were encouraged to refer to videos whenever needed.

Call duration was approximately 10- 12 minutes per participant. Most of the time, the parents picked up the phone call from the first time; however, some parents were approached after the second call. In the first 2 minutes of the call, the parents were asked to brief about the section they saw that week. This was done to ensure that parents have actually seen the assigned section and understood the information provided for them. Generally, all parents were able to provide information about the section they saw.

For the physical aspect, parents were asked about pain management for their child "what was done or what would be done" to minimize the child's pain and they were instructed to

refer to the video for pain management. Also, they were asked to list the precautions they have taken to prevent future pain for their children, and they were refered to watch the video for VOC triggering factors. If the child was on hydroxyurea, the parents were encouraged to give it on time and as prescribed. For the emotional aspect, after 2 minutes briefing about the section, the parents were asked if they have noticed any emotional changes in their children and how they responded to them. The PI requested the parents to refer to the information on the role parents on improving the emotional health for their children. Similar to the emotional aspect, for the social aspect, the parents were asked about the social problems or changes observed in their children and how they responded to them. Parents were reminded to refer to the material on the parents' role in enhancing the child's social health. For the cognitive aspect, parents were asked about the child's current school performance, any cognitive issues, and what was done to solve those issues. The PI emphasized on the importance to collaborate with the school for better cognitive outcomes and refer to the material on the cognitive health.

In addition, all participants' questions and concerns were addressed during the call. Any problem experienced by the parents in regards to the video were also addressed. Almost all the parents watched the videos 4-5 times throughout the intervention. A unique feature of the *PEIP* was the ability to allow parents the opportunity to openly talk about the child's health that were not routinely part of clinic visits, and reinforced different aspects of the HRQOL-- physical, emotional, social, cognitive health respectively during the four weeks.

Content validity of the *Parent Educational Intervention Program (PEIP)*

Content validity and inter-rater reliability were tested prior to delivery of the *PEIP* intervention. Four SCD experts (two hematologists, 1 senior nurse working with SCD patients, 1 educated parent of a child with SCD) were asked to rate the content, clarity, readability, comprehension, relevance, and whether the materials reflected the four aspects of HRQOL, using a checklist (Appendix 23). Inter-rater reliability was assessed by percentage of agreement among the experts. The inter-rater agreement for all items was 95% (>70% was considered

acceptable).

Procedures for Delivery of Standard Education Program in the SEP

To avoid contamination, the parents in the SEP were oriented separately in the Pediatric hematology clinic. The parents assigned to the SEP met with the PI for an orientation session at a private room in the hematology clinic. The PI explained the details of the study. Parents were allowed to ask questions, and talk with family members and care providers as needed. They were given time to think about participation as needed. The participants were informed that care would continue regardless of whether they participate in the study or not. They were also informed that the information would be kept confidential so that no one would know the individual responses to the questionnaires. Moreover, the parents were informed that the participation was voluntary and they had the right to withdraw anytime from the study. Parents received a $30 “Lulu” a shopping voucher for their participation at the end of the study. Parents willing to participate were then asked to sign the consent form when they were ready (Appendix 8, appendix 18 for arabic). When consenting process finished, the parents were instructed to complete the study questionnaires, using paper and pen.

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. Examples of the questions were: *“What diet should sickle cell patients follow? “What is the effect of cold temperature on people with SCD?” “How does warm temperature affect people with SCD?” “ Why should I take the vitamin folate?”* There were no videos accessible by smartphone, and no follow-up phone calls about their understanding of health education or allowing them to talk about the physical, emotional, social, and cognitive aspects of the child’s health.

To minimize the risk of contamination through information sharing between parents in

the PEIP and the SEP groups, the researcher coordinated with the registration department and the assigned physicians to schedule separate dates for the parents in the PEIP and the SEP group for the subsequent appointments during the 4-week period of participation in the study.

Post-Intervention & Closure of Study Procedures.

Week-4 assessments was scheduled after the orientation session. A reminder was sent at week 3. The nurse conducted the post-test assessments in a quiet and private room at the hematology clinic Parent knowledge to respond to the following questionnaires by using pen and paper:

- Parents Knowledge Questionnaire (PKQ) (10 minutes)
- PedsQL (Generic) (5 minutes).
- PedsQL SCD module (10 minutes).
- Self-Efficacy Scale (SES) (5 minutes)

The children were asked to complete the following age appropriate PedsQL:

- PedsQL (Generic) (5 minutes).
- PedsQL SCD module (5 minutes).

Parents were reminded that they may discontinue their participation at any time. In addition, parents who demonstrated unexpected cognitive impairment for any reason, or refused to respond to the weekly calls, may be withdrawn from the study. As a token of appreciation, the parents who completed the study, were provided with 12 R.O (equivalent to $30) “Lulu” shopping voucher at the end of the study.

Instruments

The data were collected using four questionnaires: 1) the Parent Knowledge questionnaire (PKQ); 2) Self Efficacy Scale (SES); 3) Health Related Quality of Life scale general module (HRQOL-GENERIC) and disease specific tool, the Health Related Quality of Life Sickle Cell Disease module (HRQOL-SCD). Description, administration, scoring,

interpretation, and psychometrics of each scale were described in the following section.

Outcome Measures

Parental Knowledge Questionnaire (PKQ).

The SCD parental Knowledge Questionnaire (Appendix 1, appendix 11 for Arabic) or SCD-PKQ (Shahine et., al (2015) tested the parents' knowledge before and after the intervention. There were 25 items; 16 items were True/False statements and 9 items were multiple-choice (A, B, C, D) type questions (MCQ). The items measured the knowledge about SCD, signs and symptoms, complications, treatment and triggering factors (16 items). Also, the tool included items to measure the psychological (4), social (3), and the cognitive problems (2) experienced by children with SCD. The questionnaire was administered by the nurse coordinator in a quiet and private room at the hematology clinic at the date of enrollment, and 4 weeks post enrollment. The completion of the questionnaire took approximately 10 minutes.

Scoring & Interpretation of SCD-PKQ. Each item on the questionnaire scored as 1. The maximum total score was 25 points. The total scores were obtained by summing responses for all 25 items; the range of scores was 0 to 25, with higher scores indicating higher knowledge.

Reliability & Validity of SCD-PKQ: The original content was developed, and validated by John Hopkins University Hospital (Shahine et al., 2015). The tool was designed to measure knowledge about SCD, symptoms, complications, and treatment. The original tool was translated by Shahine and colleagues (2015) in Arabic language. The internal consistency reliability of the tool showed a Cronbach alpha (0.75) after translation (Shahine, 2015). Additional items were added to include items related to the emotional, social and cognitive health. The content for the newly developed items was derived from the National Heart, Lung, and Blood Institute (NHLBI) Evidence-Based Management of Sickle Cell Disease guideline (NHLBI, 2014).

Because the English to Arabic translation and Arabic back to English translation was not done previously, this procedure was done prior to implementation by 3 experts (2 hematologists,

one nurse in Oman). After the translations, the Arabic tool was piloted on 5 parents who were excluded from the study. The internal consistency reliability using Cronbach alpha was (0.80) prior to commencement of the study and (0.87) 4 weeks post intervention. A Cronbach alpha of 0.7 and above was considered acceptable. Also, test-retest reliability, and estimating interclass correlation (ICC) for the tool was done. The period between the test-retest were two days in between. Two days was appropriate because children with SCD were prone for complications at any time; therefore, waiting for a longer period to conduct the retest may result in scores variation. The internal consistency reliability showed (0.85). The readability index for PKQ is appropriate for the 7th grader and above.

Pediatric Quality of Life Inventory (HRQOL-GENERIC).

The Pediatric Quality of Life Inventory (HRQOL-GENERIC) developed by Varni and colleagues (2001) was a generic core scale that had 23 items ara designed to measure four dimensions of HRQOL: 1) physical functioning (8 items), 2) emotional functioning (5 items), 3) social functioning (5 items) and 4) school functioning (5 items). The HRQOL-GENERIC module scales that were currently available were child self-report (Appendix 2, appendix 12 for Arabic) and parent proxy report format (Appendix 3, appendix 13 for Arabic) for each age group (2-7, 8-12, and 13-18 years). The parent proxy report format for 8-12 version was used for the study.

Reliability & Validity of HRQOL-GENERIC. The validity of the HRQOL-GENERIC was established using a known-groups comparison method to determine if the tool measures HRQOL. A comparison was made between children with (M= 77.19, SD=15.53) and without SCD (M=83, SD=14.79) and SCD children with acute and chronic form of SCD. High discriminant validity was demonstrated when those with high disease severity (hospitalized at least 3 times last year, had sever complications such as overt stroke, acute chest syndrome) had lower PedsQL scores (M=77.19, SD=15.53); and those with low disease severity had higher PedsQL scores (M=78.88, SD=14.03, p = 0.001). All items of the tool were correlated to estimate the reliability of the overall tool. The internal consistency reliability of HRQOL-

GENERIC tool showed evidence of reliability with Cronbach's alpha (0.93).

The HRQOL-GENERIC tool was previously translated to Arabic language, and was previously used in countries whose populations speak Arabic. Because there was no back translation from Arabic to English for the PedsQL tool, the back translation from Arabic to English was done prior to the study by 3 experts (2 hematologists, 1 nurse working at the hematology clinic in Oman). The Arabic translated tool HRQOL-GENERIC was piloted on 5 parents who were excluded from the study. The internal consistency reliability using Cronbach alpha was (0.8) prior the commencement of the study and (0.85) 4 weeks post intervention. A Cronbach alpha of (0.7) and above was considered acceptable. The tool was translated to more than 40 languages by the developers. The internal consistency reliability of the Arabic version is (0.80). The questionnaire was administered on the date of enrollment (Pre-intervention) and at 4 weeks post enrollment (Post-intervention). A nurse coordinator from the hematology clinic administered the questionnaire at a private room. The completion of the questionnaire took 5 minutes.

Scoring & Interpretation of HRQOL-GENERIC. The items on the HRQOL-GENERIC were scored from 0-4 scale, and rated as 0 is "*never a problem"*; 1 is "*almost never a problem"*; 2 is *"sometimes a problem"*, 3 is *"often a problem";* and 4 is "*almost always a problem".* Following the instructions for scoring, the 0 to 4 scores were reversely converted to the 0 to 100 scores for standardized interpretation, so that 0 was scored as 100; 1 was scored as 75; 2 was scored as 50; 3 was scored as 25 and 4 was scored as 0. The items were averaged so that the total scores ranged from 0 to 100; the higher the score, the better HRQOL (Varni et al., 1999). In addition, the Physical and Psychosocial Summary Scores were computed.

The child was asked to complete the translated HRQOL-GENERIC at the time of enrolment, and at 4 weeks after enrolment. Correlations between the parents' and children's PedsQL scores were computed. The correlations were (0.4), indicating moderate correlation.

Pediatric Quality of Life Inventory SCD (HRQOL-SCD)

The HRQOL-SCD module had 43 items, and nine scales: Pain & hurts (9 items), pain impact (10 items), pain management & control (2 items), worry I (5 items), worry II (2 items), emotion (2 items), treatment (7 items), communication I (3 items), and communication II (3 items) (Panepinto, Torres, and Varni, 2012). The scale had a 5-point likert type response scale (0= *never a problem*, 1= *almost never a problem*, 2= *sometimes a problem*, 3=*often a problem,* 4= *almost always a problem*). The HRQOL-SCD module scales that were currently available were child self-report (Appendix 4, appendix 14 for Arabic) and parent proxy report format (Appendix 5, appendix 15 for Arabic) for each age group (2-7, 8-12, and 13-18 years). The parent proxy report format for 8-12 version was used for the study.

Reliability & Validity of HRQOL-SCD module. The validity of HRQOL-SCD module was previously established by Panepinto and colleagues (2013). First, content validity was established by expert panel review, which consisted of six physicians, two nurses, two social workers. The experts reviewed the themes emerged, and then agreed on the items to be included on the scale. Thereafter, a cognitive debriefing technique (asking each respondent what each item means) was done to determine the clarity and understandability of the items and that there were no difficult items, confusing or upsetting items (Panipento, Torres, Varni, 2012). Second, construct validity was examined by an analysis of the interclass correlations among the HRQOL-GENERIC tool with the HRQOL-SCD Module scale in a sample of children with chronic illness (n=243, age: 8-18 years). The internal consistency reliability showed Cronbach's coefficient alpha=0.70 for children, which was considered acceptable. Internal consistency reliability coefficients for the HRQOL-SCD Module showed reliable with Cronbach's alpha (0.93) for children with SCD.

Sensitivity Of HRQOL-SCD module Instrument. The sensitivity of a HRQOL-SCD module was determined through conducting a cross-sectional design, and comparing patients with severe (n=243; age: 8-18 years) and mild SCD using independent samples t-tests. The disease status was classified a priori as mild or severe disease regardless of the child's SCD

genotype. Children were classified as having severe disease if they experienced one or more of SCD complications, which include overt stroke, acute chest syndrome, 3 or more hospitalizations for painful events in the previous 3 years. All others were classified as having mild disease. Thereafter, effect sizes were calculated to determine the magnitude of the differences between the severe and mild SCD sample means divided by the standard deviation. Effect sizes for differences in means are designated as small (0.20), medium (0.50), and large (0.80). The calculated effect size between mild and severe was 0.30.

HRQOL-SCD tool was recently developed and there is no translated version that exists in Arabic. Therefore, the tool was translated to Arabic, and was validated by 3 experts (2 hematologists, 1 nurse working at the hematology clinic) for content validity after translation. In addition, the tool was piloted, and the internal consistency reliability was (0.85) prior conducting the study and (0.89) 4 weeks post intervention. Translation and back translation from Arabic to English for the PedsQL SCD module was done by 2 hematologists, one nurse working at the hematology clinic in Oman. Also, test-retest reliability, and estimating interclass correlation (ICC) for the tool was done. The period between the test-retest was 2 days. Two days was found appropriate because children with SCD were prone for any complication at any time; therefore, waiting for a longer period to conduct the retest may result in scores variation. The internal consistency reliability was (0.9). The readability index for PedsQL is appropriate for the 7th grader level and above.

The questionnaire was administered pre and post intervention by the nurse coordinator at the hematology clinic. The questionnaire was administered on the date of enrollment, and at 4 weeks post enrollment. The completion of the questionnaire took 10 minutes.

Scoring & Interpretation of PedsQL. Similar to the HRQOL-GENERIC, the items on the HRQOL-SCD Module was scored from 0-4 scale, 0 was "*never a problem"*; 2 was "*almost never a problem"*; 3 was *"often a problem";* and 4 was "*almost always a problem".* Following the instructions for scoring, the 0 to 4 scores were reversely converted to the 0 to 100 scores for

standardized interpretation, so that 0 was scored as 100; 1 was scored as 75; 2 was scored as 50; 3 was scored as 25 and 4 was scored as 0. The items were averaged so that the total scores range from 0 to 100; the higher the score, the better HRQOL (Panepinto et al., 2013). In addition, the Physical and Psychosocial Summary Score were computed.

Parent SCD Self-Efficacy

The self-efficacy scale for parents (SES) was adopted and modified from self-efficacy instrument specific to sickle cell disease (SCSES) that was developed by Edwards, Telfair, Cecil, & Lenoci (2000) for use in adults with sickle cell disease. The original questionnaire has 9 items that measured disease specific perception of self-efficacy regarding the patients' ability to function on a day-to-day basis and to manage their child's symptoms and pain related to SCD. The items in the parent self-efficacy tool remained the same. However, wording was changed so the items reflect that it was the parent reporting (rather that child reporting) of their ability to manage the symptoms, and pain of their children on a day-to day basis (Appendix 6). The questionnaire was administered at the time of enrollment and 4 weeks post intervention. The nurse coordinator administered the questionnaire. The completion of the questionnaire took less than 5 minutes.

Reliability & Validity. The original sickle cell Self-Efficacy Scale (SC-SES) tool was tested on 83 adult patients with SCD (n=83; M=37, F=46, mean age=38.7 years, SD=12.8). Convergent validity was previously established by correlating the SC-SES with similar tools that measured the similar or related constructs (Self-esteem scale-SES, sense of mastery scale-SOM, and internal locus of control scale-IHLC). The correlations between these measures (SES, SOM and IHLC) and SCSES scores were statistically significant with positive correlations ($r=0.8$, $p < 0.01$). Thus, greater SC-SES total and subscale scores were associated with increased self-esteem, mastery and IHLC (Edwards et al., 1999).

Predictive validity was assessed by computing correlations between SC-SES scores and reported sickle cell pain severity in the previous 30 days as well as total SCD physical

symptoms. There was a negative correlation between SC-SES scores and pain severity (R=-0.3 p<0.01), and physical symptoms (r=-0.44*; p* < 0.01), indicating that higher self-efficacy was associated with decreased report of recent pain severity and lower reported levels of physical symptoms. In addition, predictive validity was assessed by computing the correlations between self-efficacy and reported health-care seeking behavior. The number of emergency visits and the number of physician visits in the prior 12 months were utilized as measures of health-care seeking behavior. There was a statistically significant correlation (r=-0.42; $p < 0.05$) between the number of physician visits in the prior 12 months and SCSES scores. A similar, marginally significant relationship(r=-0.25; $p < 0.05$) was noted between emergency visits and SCSES scores (Edwards et al.,1999).

To determine discriminant validity, Pearson correlation coefficients was calculated between SC-SES scores and, the chance externality (CHLC) subscale [the extent to which fate or chance was perceived to determine physical health (r=-0.08; $p < 0.01$)] and powerful others externality subscale (POHLC) [the extent to which external authorities determine physical health (r=-0.14; $p < 0.01$]). Reliability of the tool was determined by computing all items of SC-SES. The internal consistency reliability showed a Cronbach's alpha of (r=0.89). In the study, experts assessed the modified tool for content; construct validity before and after translation to Arabic language. In addition, the tool was piloted on five participants who were excluded from the study, and the internal consistency reliability was measured by computing all items, the Cronbach's alpha was (0.9) prior conducting the study, and (0.95) 4 weeks post intervention.

Scoring & Interpretation. Response choices for each item on the SC-SES were 0="*Not at all sure"*, 1="*Not sure"*, 2= "*Neither*", 3= "*Sure"* , or 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.

Demographics & Medical Information Sheet

Parent demographics, which included age, gender, educational level, socio-economic

status, and marital status were collected by the nurse coordinator in the haematology clinic. In addition, demographics and medical information related to the children (age, gender, use of hydroxyurea, SCD diagnosis, history of SCD-related complications, including number of pain crisis requiring hospitalization the previous year were also collected (Appendix 7).

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 and the reliability of all tools were examined. While randomization should produce equivalent groups, preliminary analysis examined equivalence of PEIP and control groups on demographic and health characteristics and baseline values of outcome measures using t-test or chi-square as relevant to distributional characteristics. Variables showing non-equivalence were included as covariates in analyses testing hypotheses. Furthermore, attrition was examined for potential bias. In this study, the p-value ($p < .10$) was considered significant. I have selected a liberal alpha level of .10, because of the preliminary nature of this study as a first evaluation of the impact of PEIP and exploratory nature of the analysis of predictors of HRQOL in this population. Future randomized clinical trials and/or formal theory testing should adopt a more conservative alpha level.

To evaluate the effects of *PEIP* on parental knowledge and self-efficacy. The following hypotheses were tested:

Hypothesis 1.1: Parents in the *PEIP* group would have higher scores on the SCD Parental Knowledge Questionnaire compared to the scores of parents on *SEP group* at 4 weeks.

Hypothesis 1.2: Parents in the *PEIP* group would have higher scores on the SCD Parental Knowledge Questionnaire in the posttest compared to baseline.

Analysis 1.1 & 1.2: Two-Way Mixed ANOVA (repeated measures) test was used to compare the PedsQL scores between the intervention group and the control group as well as the scores between the baseline and the posttest. Covariates were added for variables on which the groups are found to differ as well as for potential confounding variables of parent education, gender, child medications, and whether child was taking hydroxyurea.

Hypothesis 1.3: Parents in the *PEIP* group would have higher scores on Parental Self-Efficacy compared to the scores of parents on *SEP group* at 4 weeks.

Hypothesis 1.4: Parents in the *PEIP* group would have higher scores on the SCD Parental Self-Efficacy in the posttest compared to baseline.

Analysis 1. 3 & 1.4: Two- Way Mixed ANOVA (repeated measures) test was used to compare the Self-efficacy scores between the intervention group & the control group as well as the scores between the baseline and the posttest. Covariates were added for variables on which the groups are found to differ as well as for potential confounding variables of parent education, gender, and whether child was taking hydroxyurea.

2. To examine the effects of *PEIP* on parents' perception of HRQOL in children with SCD. The following hypotheses were tested:

Hypothesis 2.1: Parents in the *PEIP* group would have higher scores on their perception of the child's HRQOL compared to the scores of parents on *SEP group* at 4 weeks.

Hypothesis 2.2: Parents in the *PEIP* group would have higher scores on the HRQOL scales in the posttest compared to baseline.

Analysis 2.1 & 2.2 : Two- Way Mixed ANOVA (repeated measures) test was used to compare PedsQL scores between the intervention group & the control group. Covariates were added for variables on which the groups are found to differ as well as for potential confounding variables of parent education, gender, and whether child was taking hydroxyurea.

3. To identify predictors of HRQOL in children with SCD at 4 weeks post intervention. The

following hypotheses were tested:

Hypothesis 3.1: Parental knowledge and self-efficacy would be significant predictors of HRQOL-Generic scale.

Hypothesis 3.2: Parental knowledge and Self-efficacy would be significant predictors of HRQOL-SCD module.

Analysis 3.1 & 3.2: Linear regression would be utilized to identify the predictors and describe the model goodness of fit. HRQOL scores at 4-weeks would be analysed to identify the predictors. Possible predictors such as child's age, gender, parents' age, gender, educational status, use of hydroxyurea were also included in the model.

The assumptions of repeated measures (Appendix 24), linear regression (Appendix 25) and MANOVA (Appendix 25) tests were checked prior the analysis of the data. The assumptions of linear regression and MANOVA were met; however, the independence of error and normality assumptions for mixed ANOVA were not met. Correction of data was not required because skewness (-1<skewness<1) and kurtosis were in the good or acceptable range (-2<kurtosis<2) (Appendix 23).

Discussion of Threats to Validity

Internal validity**.** The first threat to the internal validity was the risk for attrition. Parents may discontinue participation during the 4 week period. To minimize the risk for attrition, the PI contacted parents every week to encourage continued participation and address concerns as needed. The second threat to the internal validity was that pre testing could sensitize the parents to have higher scores in post testing due to a recall bias. To minimize the risk for sensitization, a second version of the test was made by changing the sequence of responses to the items that were administered during second testing on week 4. The third threat to the internal validity was that parents were selected by convenience sampling. To minimize selection

bias, the parents were randomly assigned (cluster randomization) to one of the groups. In addition, having a staff member administer the questionnaires to the parents is considered a threat to the study, as her interaction with the intervention and the control groups is never disclosed.

Construct validity. Potential confounding variables that might affect the data were level of parents' education, gender, medications that children were taking, and other medical conditions (such as asthma). Control for these variables were done during the statistical analyses. Disruption effects may occur with technology. The researcher taught the parents how to use and navigate the smartphone. Weekly contact was made my telephone to address technical problems with smartphone use and other concerns. The threat to construct validity from using self-administered questionnaire was minimized by pilot testing of all tools prior conducting the study and made sure that items were clearly stated and understood by the participants. In addition, the PI provided $30 gift vouchers to the participants and this may have led to compensatory rivalry; which means that the parents may have been more motivated and may have provided more positive results as a result of the compensation given. Only the principal investigator was providing information during orientation sessions related to the intervention, and made the weekly calls to all parents, to ensure consistent implementation of the intervention. Limitations on the construct validity were examined in hypotheses 1 and 2.

External validity. Findings would be generalizable only to parents of children with SCD in Oman.

Statistical conclusion validity**.** The translated measurement tools that were used to collect data were tested for validity and reliability prior to use in the study, with significant Cronbach alpha and Pearson correlation coefficients r >0.7. All tools had very good internal consistency reliability with Cronbach alpha > 0.7.

Research Timeline

All study activities were presented in the following table (Table 1). The research timeline incorporated five quarters. Three months were reserved for the dissemination of findings.

Table 1: Research timeline

Year / Quarter / **Activities**	Spring 2017	Summer 2017	Fall 2017	Winter 2018	Spring 2018	Summer 2018
IRB approval	X	X				
Screening, Recruitment, Enrollment, Pretest			X	X		
Delivery of Intervention			X	X		
Reinforcement of Intervention			X	X		
Post-test			X	X		
Data analysis					X	
Manuscript to write results & Interpretation					X	

PROTECTION OF HUMAN SUBJECTS

IRB Ethics 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).

Training of Personnel

The nurse coordinator from Royal hospital was trained about the recruitment procedure, screening for eligible parents for the study, and the consenting process. The nurse coordinator had BSN qualification in nursing. She was required to complete the Human Subjects Research [HSR] online training modules through the CITI – Collaborative Institutional Training Initiative. The online training modules were accessed by using the Universal Resource Locator (url): https://www.citiprogram.org. The HSR content that was designed for the social, behavioral, and educational disciplines was required, and covered the historical development of human subjects protections, and current information on regulatory and ethical issues. She was also required to complete the Information Privacy & Security module, which covered the principles of data protection, focusing on the healthcare-related privacy and information security requirements of the Health Insurance Portability and Accountability Act (HIPAA).

Preparation of Study Materials

The preparation of the study material was done by the principal investigator prior to conducting the study. It included the consent forms, the screening checklist for the parents, the study flyer, the material for the interventions and outcome measures for the intervention and the control group. All consent forms were placed in one folder. All other data collection materials were confidential and filed separately for each parent participant. Each folder was coded with numbers, and all materials within in the folders was coded with the same corresponding numbers. These folders did not have personal information that could be identified.

Human subject involvement and characteristics

The sample in this study was 72 parents of children with SCD. The trained nurse

coordinator who worked in the hematolgoy clinic was hired for the purpose of distributing the study flyers (Appendix 21 & 22) in the units, and pediatric clinic before starting the study. The trained nurse identified the eligible parents based on the inclusion and exclusion criteria. The nurse coordinator approached the eligible participants and informed them about the study. All interested parents were asked to contact the PI directly.

Sources of Research Material

The Data consisted of information collected by questionnaires from the parents' pre and post the intervention. A trained and CITI certified nurse who worked in a pediatric unit distributed the questionnaire to the participants. Each questionnaire was given a code number and was kept confidential.

Potential risks

The study was considered low risk, which involved collecting information from parents of children with SCD. There were no invasive procedures. There may be a risk of being tired when completing the questionnaires, and in this case, the parents and the children were asked to take a rest for 5 minutes and were provided with snacks. While collecting data, it might happen that a child with SCD might be depressed as may be indicated by PedsQL generic tool. In the event that parents may become aware that their child was experiencing negative emotional feelings (depression, anxiety), or any distress that warranted health care professional intervention, the parents were referred to their primary care provider for further evaluation, management, and referral to appropriate care providers. In the event that the parent was under stress or distress, the parents were referred to their primary care provider for further evaluation, management, and referral." During the study, no participant experienced negative emotional feelings or distress that required further evaluation.

ADEQUACY OF PROTECTION AGAINST RISKS

Recruitment and informed consents

The trained nurse coordinator identified the parents who met the inclusion criteria, approached the parents and also screened them for eligibility to participate. The principal investigator informed the eligible parents about the procedures for the data collection, the benefits of the study, the procedures for protecting their privacy and confidentiality, and informed them that participation was voluntary and they could withdraw any time from the study.

Privacy and Confidentiality

All data were given a code and were identified by the PI to ensure privacy and confidentiality. Parents contact numbers and their children's' hospital ID were immediately destroyed after data entry. Publications were planned to report only group data; parent names were kept confidential and would not be reported in the manuscripts or presentations.

POTENTIAL BENEFITS OF THE PROPOSED STUDY

The parents may have improved their knowledge about the disease and how to control for their child's pain and symptoms at home. The parents may also have improved their self-efficacy in the management of their child's disease, pain, and symptoms. Improvement in parents' knowledge and self-efficacy would consequently lead to improvement in child's HRQOL.

DATA MANAGEMENT

The data were kept in a locked cabinet and were accessed by the principal investigator only. The questionnaires were coded and given numbers and would be destroyed after dissemination of results.

CHAPTER 5 - RESULTS

The purpose of this randomized controlled trial 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 addition, predictors of HRQOL in children with SCD were also identified. The goal of the *PEIP* was to provide culturally-appropriate information to parents of children with SCD and include content on the physical aspects (disease and symptom management), as well as the emotional, social, and cognitive aspects of HRQOL in children with SCD.

A dyad pair of 74 Omani parents and children were recruited for the study from Royal Hospital (RH) and Sultan Qaboos University Hospital (SQUH) over a 6-month period. Parents were randomly assigned (cluster randomisation) to the intervention group (N=37) and to the control group (N=37). The intervention group received *PEIP* that were downloaded in to their smartphones; the control group received Standard Education Program (*SEP*) booklets that were typically distributed during clinic visits. The intervention lasted for 4 weeks.

DEMOGRAPHICS

A total of 72 parent and child participants were enrolled; 37 in the *PEIP* group and 35 in the *SEP* group (Table 2). Parental age ranged between 28 and 55 years. There were differences by sex in the parent groups, with more mothers in the *PEIP* (n=25; 68%) and more fathers in the *SEP* (n=24 69%). All parents (100%) in the *SEP* were married; 5% of the parents in the *PEIP* were divorced. 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 2). About half (52%) of the participants were residing in the northern region (Figure 3) in Oman, mostly from Batinah (27%) and Muscat (25%). About one third (31%) were from the west (Al Dhakilyah; 28%) and central (Al-Dahira; 3%). Few were residing in the east (17%), mostly from Sharqiyah (Figure 3). One participant from the South of Oman (Salalah) was enrolled; however, the parent withdrew from the study. The participant was

unable to attend the scheduled posttest from Salalah (12 hours from Muscat) because he missed the flight. Another participant from the West (4 hours from Muscat) also was unable to attend the posttest due to urgent personal circumstances. Throughout the study, only 2 participants withdrew from the study.

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, the medication for minimizing vaso-occlusive episodes in SCD. No significant age differences in parents and children between the *PEIP* and *SEP* groups.

PARENTAL KNOWLEDGE

Results indicated a significant group-by-time interaction ($F(1,66)= 363.7$, $p < .001$) in knowledge scores (Figure 4). The findings elicited a significant difference in change for the PEIP from baseline to 4 weeks posttest ($F(1,32)= 23.14$, *partial* $\eta 2 = .4$, $p < .001$). 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* $\eta 2 = .87$]. 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) (Figure 4). Thus, results supported Hypotheses 1.1 and 1.2.

SELF-EFFICACY

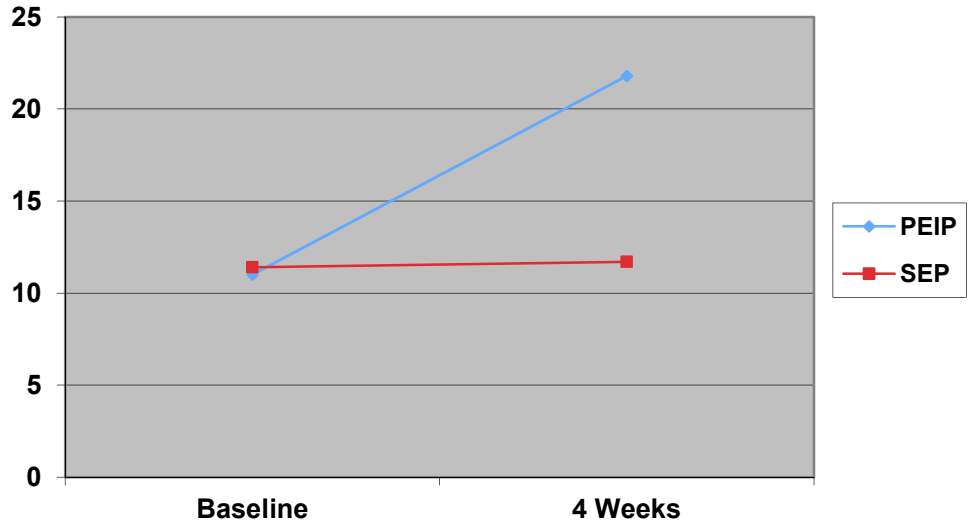
There was a significant group-by-time interaction in the self-efficacy scores [$F(1, 66)= 790.02$, $p = .001$] (Figure 5). The findings revealed a significant difference in change for the PEIP from baseline to 4 weeks posttest ($F(1,32)= 12.4$, *partial* $\eta 2 = .3$, $p < .001$). The *PEIP* had significantly 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* $\eta 2 = .91$, $p < .001$]. The *PEIP* had

significantly higher self-efficacy scores (30. 2± 2.3), compared to *SEP* group at 4 weeks. (15.1 ± 2.2) Thus, results supported Hypotheses 1.3 and 1.4.

Table 2. Demographics (N=72)

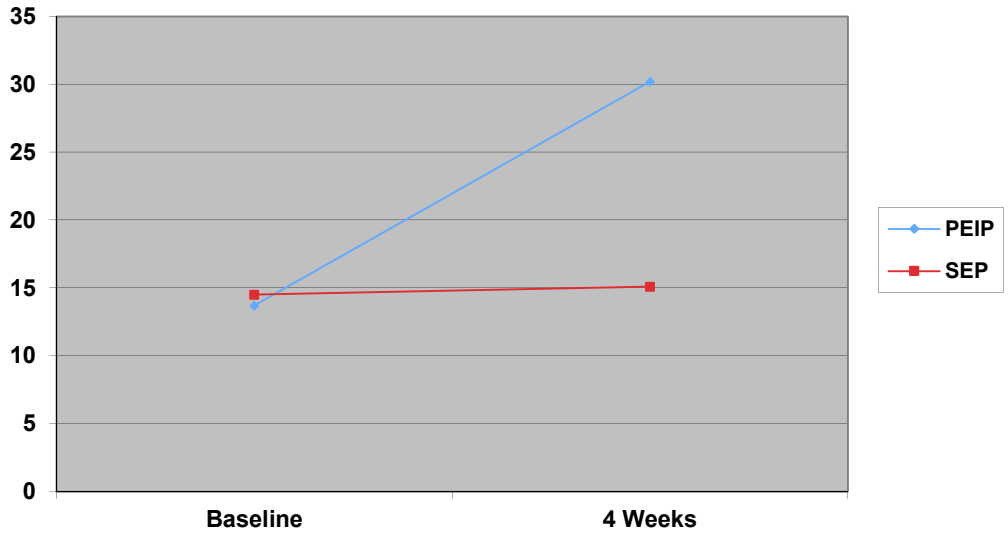
	PEIP (N=37)	SEP (N=35)
Parents		
Age Means (SD)	39 ±4.12	40 ±6.01
Sex		
Male	12 (32%)	24 (69%)
Female	25 (68%)	11 (31%)
Marital Status		
Married	35 (95%)	35 (100%)
Divorced	2 (5%)	0
Education		
≤ High School	24 (64%)	26 (75%)
Associate (AD)	7 (19%)	4 (11%)
Bachelor (BS/BA)	5 (14%)	4 (11%)
Master (MS/MA)	1 (3%)	1 (3%)
Children		
Age		
Means (SD) in years	10 ±1.3	10 ±1.2
Sex		
Male	19 (51%)	15 (43%)
Female	18 (49%)	20 (57%)
Hydroxyurea	15 (41%)	18 (49%)

Figure 3. Parents from different regions in Oman were able to participate.



**Within: *F*= 23.14, *η2* = .4, *p* = .001; Between: *F*= *477.9*, η2 = .87, p = .001. The *PEIP* group had a significant improvement in the knowledge scores at 4 weeks, compared to baseline. There were significant differences in the knowledge scores (*p* = 0.001) between the *PEIP* and *SEP* at 4 weeks.

Figure 4: Knowledge Scores at Baseline and 4 Weeks in *PEIP* & *SEP* Groups



**Within: *F*= 12.4, η2 = .3, *p* = 0.001; Between: *F*= 666.2, η2 = .91, *p* = 0.001. The *PEIP* group had a significant improvement in the self efficacy scores at 4 weeks, compared to baseline. There were significant differences in the self-efficacy scores (*p* = 0.001) between the *PEIP* and *SEP* at 4 weeks.

Figure 5: Self-Efficacy Scores at Baseline and 4 Weeks in *PEIP* & *SEP* Groups

HRQOL-SCD

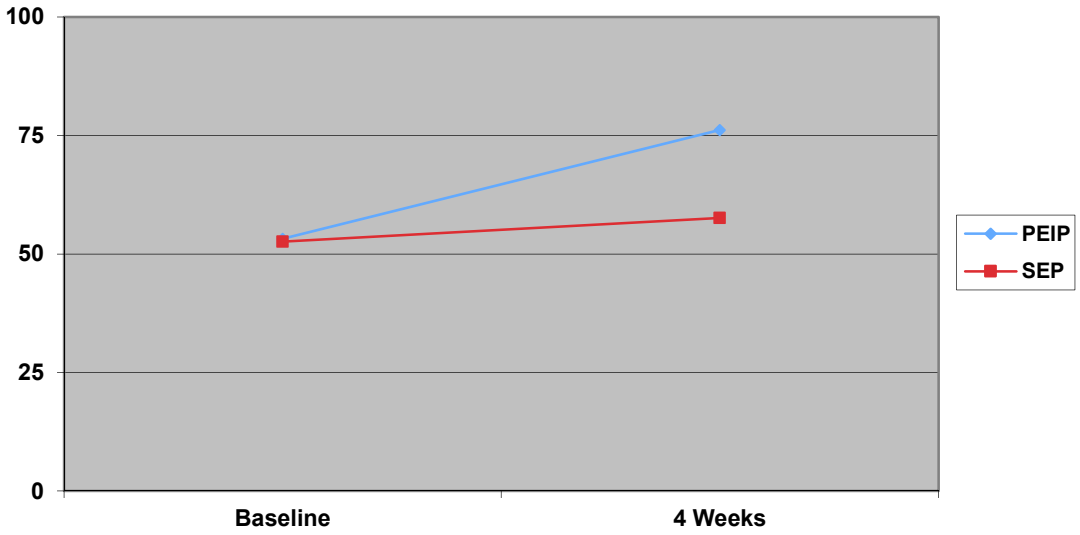
There was a significant group-by-time interaction in the health related quality of life (HRQOL-SCD) scores [*F*(2,69)= 187.9, *p* = .001] (Figure 6A). The findings revealed a significant difference in change for the PEIP from baseline to 4 weeks post intervention. The *PEIP* had significantly higher HRQOL-SCD 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-SCD scores at 4 weeks *F*(1,66)= 148.92, *p* = .001, partial η2 = .70. The *PEIP* had significantly higher HRQOL-SCD scores (76.2 ± 6.2) at 4 weeks, compared to the *SEP* group (57.6 ± 8.3) at 4 weeks, (Figure 6). Thus the results supported hypotheses 2.1, and 2.2.

HRQOL-GENERIC

Similarly, the findings elicited a significant group-by-time interaction in the health related quality of life (HRQOL-Generic) scores [*F*(1,70)= 349.74, *p* = .001] (Figure 6B). The *PEIP* had significantly higher HRQOL-Generic scores (78.2 ± 3.47) 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-Generic scores at 4 weeks [*F*(1, 66)= 317.26*, p = .001*, partial η2 = .8]. The *PEIP* had significantly higher HRQOL-Generic scores (78. 2 ± 3.47) at 4 weeks, compared to the *SEP* group (50.5 ± 10.96) at 4 weeks, (Figure 6B). Thus the results supported hypotheses 2.3, and 2.4.

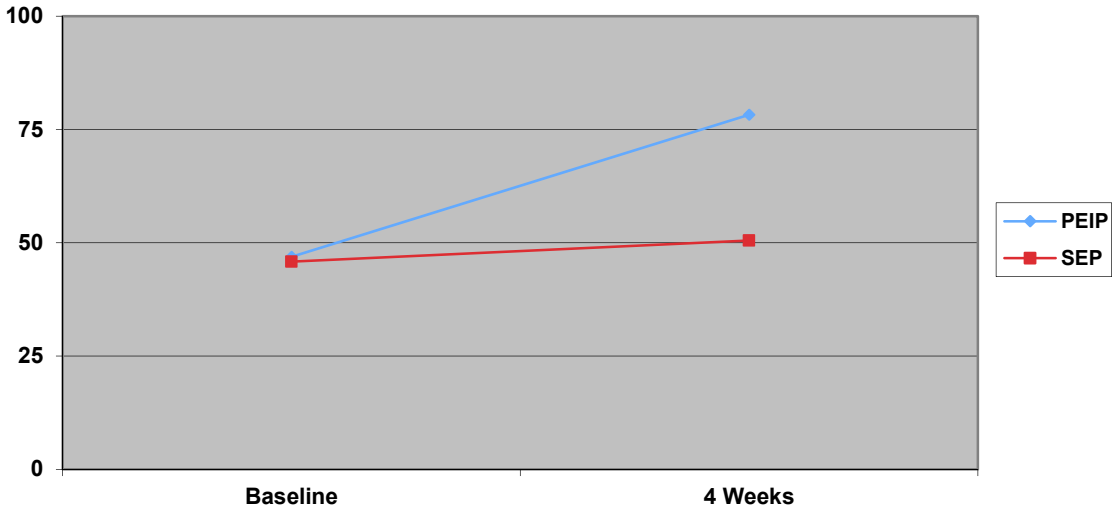
CORRELATION BETWEEN PARENT & CHILD HRQOL Scores

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) at baseline (physical=.4, emotional=.3, social=.4, cognitive=.5). The correlations were higher at 4 weeks for both HRQOL-SCD (r= .91) and HRQOL-GENERIC (overall r= .95) [physical= .8, emotional= .9, social= .9, cognitive= .8].



**Within: *F*= 10.91, η2 = .3, *p* = .001; Between: *F*=148.92, η2 = .7, *p* = .001. The *PEIP* group had a significant improvement in the HRQOL-SCD scores at 4 weeks, compared to baseline. There were significant differences in the HRQOL scores (*p* = .001) between the *PEIP* and *SEP* at 4 weeks.

Figure 6A: HRQOL-SCD Scores at Baseline and 4 Weeks in *PEIP* & *SEP* Groups



**Within: *F*= 13.16, *η2* = .3, *p* = .001; Between: *F*= 317.26, η2 = .8, *p* = .001.The *PEIP* group had a significant improvement in the self efficacy scores at 4 weeks, compared to baseline. There were significant differences in the self-efficacy scores (*p* = .001) between the *PEIP* and *SEP* at 4 weeks

Figure 6B. PedsQL-GENERIC Scores at Baseline and 4 Weeks in *PEIP* & *SEP* groups

PREDICTORS of HRQOL-SCD at 4 WEEKS (PARENT REPORT)

Several factors predicted HRQOL-SCD (Table 3A). Parent knowledge (Beta= 1.4, t= 3.88, $p < .001$, partial η2 = .44), child receiving hydroxyurea (Beta= 6.8, t= 4.30, $p = .001$, partial η2 = .48), and child's age (Beta= 2.6, t= 1.62, $p = .11$, partial η2 = .20) were significant predictors of parent reported HRQOL-SCD. The R^2 of .75, indicated that 75% of the variability in parent reported HQQOL-SCD may be explained by knowledge, use of hydroxyurea, and child's age, $R^2 = .75$, $F(8, 69) = 23.22$, $p < .001$ (Table 3A). Self-efficacy (Beta= .4, t= 1.70, $p = .09$, partial η2 = .21), parent age (Beta= -3.0, t= 1.68, $p = .09$, partial η2 =- .21), parent sex (Beta=-.9, t= -.55, $p = .57$, partial η2 = -.07, parent level of education (Beta= -2.7, t= -1.53, $p = .53$, CI (-6.3, 1.8), partial η2 = -.19) and child sex (Beta= -.4, t= .28, $p = .8$, partial η2 =.03) were not significant predictors of HRQOL-SCD.

PREDICTORS of HRQOL-GENERIC at 4 WEEKS (PARENT REPORT)

Several factors predicted HRQOL-Generic (Table 3B). Parent knowledge (Beta= .9, t= 2.02, $p = .04$, partial η2 = .25), self-efficacy (Beta= 1.7, t= 5.67, $p < .001$, partial η2 = .58), child age of child (Beta= 5.2, t= 2.54, $p < .01$, partial η2 = .31) and child sex (Beta= 2.9, t= 1.48, $p = .10$, partial η2 =.18) were all significant predictors of HRQOL-GENERIC. The R^2 of .86 indicated that 86% of the variability in the HRQOL-GENERIC, may be explained by knowledge, self-efficacy, child age, $R^2 = .86$, $F(8,69) = 46.15$, $p < .001$ (Table 3B). Parents age (Beta= -.6, t= -.25, $p = .80$, partial η2 =- .03, sex (Beta= .8, t= .38, $p = .70$, partial η2 = .04, use of hydroxyurea (*Beta*= 2.4, t= 1.22, $p = .2$, partial η2 = .15) and level of education (Beta= -.06, t= -1.23, $p = .2$, partial η2 = -.15) were not significant predictors of HRQOL-GENERIC.

PREDICTORS of HRQOL-SCD at 4 WEEKS (CHILD REPORT)

The same factors that predicted HRQOL-SCD in parents also predicted the child report of HRQOL-SCD (Table 3C). Parent knowledge (Beta= 1.5, t= 4.49, $p < .001$, partial η2 = .49), use of hydroxyurea (Beta= 5.2, t= 3.52, $p = .001$, partial η2 = .41), parent age (Beta= - 3.5, t= 2.07, $p = .04$, partial η2 = -.25) predicted the child reported HRQOL-SCD scores. Older parents

(age > 35 years) indicated lower child reported HQROL-SCD. The R^2 of .79 indicated that 79% variability in the child reported HRQOL-SCD were explained by the parent knowledge, and child receiving hydroxyurea, R^2 = .79, *F*(8,69)= 29.59, *p* < .001 (Table 3C). Parent self-efficacy (Beta= .4, t= 1.69, *p* = *.09*, partial η2 = .21), sex, (Beta= .8, t= .48, *p* = *.63*, partial η2 = -.06, child's age (Beta= - .03, t= -.02 , *p* = *.98*, partial η2 = -.00), child sex (Beta= 1.4, t= .94, *p* = *.34*, partial η2 =.12) and parent level of education (Beta= -.9, t= -.59, *p* = *.55,* partial η2 = -.07) were not significant predictors of child reported HQOL-SCD.

PREDICTORS of HRQOL-GENERIC at 4 WEEKS (CHILD REPORT)

The same factors that predicted HRQOL-SCD in parents also predicted the child report of HRQOL-GENERIC (Table 3D). Parent knowledge (Beta= 1.7, t= 4.19, *p* < *.001*, partial η2 =.47), self-efficacy (Beta= 1.1, t= 4.03, *p* = *.001*, partial η2 =.45), and child's age (Beta= 3.8, t= 2.06, *p* = *.04*, partial η2 = .09) were significant predictors of the child reported HRQOL-GENERIC. The R^2 of .87 indicated that 87% of the variability in the child reported HRQOL-GENERIC, were explained by parent knowledge, self-efficacy, child age, R^2 = .87, *F*(8, 69)= 52.4, *p-value* < *.001* (Table 3D). Parent age (Beta= -.7, t= -3.1, *p* = *.8*, partial η2 =- .04), sex (Beta= .9, t= .5, *p* = *.6,* partial η2 = .05), parent level of education (Beta= -1.5, t= - .73, p = .5, partial η2 =-.09), child sex (Beta= 2.5, t= 1.43, *p* = .2, partial η2 =.18), and receiving hydroxyurea (Beta= 2.4, t= 1.31, *p* = *.2*, partial η2 =.16) were not significant predictors of child reported HRQOL-GENERIC.

Table 3A. Predictors of HRQOL-SCD at 4 Weeks (Parent Report)

	Unstandardized Coefficients		Standardized Coefficients			95.0% CI for B	
	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound
Constant	36.041	5.309		6.788	.000	25.425	46.657
Use of hydroxyurea*	6.840	1.589	.290	4.304	**.000**	3.662	10.017
Child's age	2.576	1.589	.109	1.621	**.10**	-.601	5.752
Knowledge Scores *	1.374	.354	.637	3.882	**.000**	.666	2.081

**R square: .75, F-test = 23.22 and the p < 0.001

Table 3B. Predictors of HRQOL-GENERIC at 4 Weeks (Parent Report)

	Unstandardized Coefficients		Standardized Coefficients			95.0% CI for B	
	B	Std. Error	Beta	T	Sig.	Lower Bound	Upper Bound
Constant	2.941	6.780		.434	.666	-0.616	16.499
Self Efficacy	1.749	0.308	.696	5.677	**.000**	1.133	2.365
Gender_Child	2.923	1.965	.074	1.488	**.10**	-1.006	6.851
Age of Child	5.167	2.029	.130	2.547	**.01**	1.110	9.224
Knowledge	0.916	0.452	.252	2.028	**.04**	.013	1.820

**R square: .86, *F*-test = 46.15 and the *p* < .001

Table 3C. Predictors of HRQOL-SCD at 4 Weeks (Child Report)

	Unstandardized Coefficients		Standardized Coefficients			95.0% CI for B	
	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound
Constant							
Use of hydroxyurea	5.187	1.474	.216	3.520	**.001**	2.240	8.134
Parents' age	-3.531	1.706	-.129	-2.07	**.043**	-6.943	-.119
Knowledge Scores	1.475	.328	.672	4.496	**.000**	.819	2.131

**R square: .79, F-test = 29.59 and p < .001

Table 3D. Predictors of Child Reported HRQOL-GENERIC at 4 Weeks in Children with SCD

	Unstandardized Coefficients		Standardized Coefficients			95.0% CI for B	
	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound
Constant	4.481	6.138		.730	.468		
Self-Efficacy	1.125	.279	.468	4.033	**.000**	0.695	1.806
Child's age	3.796	1.837	.100	2.067	**.043**	0.252	2.956
Knowledge Scores	1.716	.409	.493	4.194	**.000**	0.761	2.377

**R square: .87, *F*-test = 52.4 and *p* < .001

Physical, Emotional, Social, Cognitive HRQOL (Child Report)

There were significant differences between males and females on the physical, emotional, social, and cognitive HRQOL scores (Child Report) at baseline, $F(4,69)= 7.73$, $p < .001$, Wilks' ^ = .690, partial η2 = .31 (Table 4). Females had significantly lower emotional [32 ± 12.53, $F(1,72) = 8.57$, $p = .005$, partial η2 = .10] and social scores [46 ±16.21, $F(1,72)= 3.79$, $p = .05$, partial η2 = .05] compared to males (Table 4). However, females had significantly higher cognitive scores (49 ± 11.6, $F(1,72)= 14.41$, $p = .001$, partial η2 = .16] and physical scores (39.0 ± 8.6, $F(1, 72)= .78$, $p = .3$, partial η2 = .01 compared to males (Table 4).

Table 4: Physical, Emotional, Social, Cognitive Scores by Sex

	Baseline		p-values	4 Weeks		p-values
	Male	**Female**		**Male**	**Female**	
Physical	37 ± 8.8	39 ± 8.6	0.3	69 ± 16.4	72 ± 14.6	0.5
Emotional	40 ± 11.9	32 ± 12.5	0.005	67 ± 25.2	64 ± 23.7	0.6
Social	52 ± 13.4	46 ± 16.2	0.05	74 ± 19.9	71 ± 20.2	0.5
Cognitive	37 ± 15.1	49 ± 11.6	0.001	63 ± 25.2	69 ± 16.7	0.2

The results showed no significant differences between males and females on the physical, emotional, social, and cognitive HRQOL scores (Child Report) at Week 4, [$F(4,67)= 4.87$, $p = .002$, Wilks' ^ = .774, partial η2 = .22 (Table 4). Females (72 ± 14.6) had slightly higher physical scores than males (69 ± 16.4), $F(1,72)= 8.57$, $p = .5$, partial η2 = .005. Females also had higher cognitive scores (69 ± 16.7) than males [63 ± 25.2, $F(1,70)= 1.59$, $p = .2$, partial η2 = .02]. However, females had lower social scores (71 ± 20.2) than males [74 ± 19.9, $F(1,70)= .378$, $p = .5$, partial η2 = .005 and also lower emotional scores, $F(1, 70)= .247$, $p = .6$, partial η2 = .004 than males (Table 4).

CHAPTER 6 - DISCUSSION

The purpose of the study was to compare the effects of *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*. The findings are consistent with other reports indicating significant improvements in knowledge after educational intervention programs (Al Nasiri, et al., 2017, Shahine, et al., 2015).

It is important to note that 75% of the parents had a high school education or less ; yet, they were able to learn about the disease and symptom management from the *PEIP*, and applied their knowledge as they cared for their children. Previous studies indicated that low educational status of parents was associated with adverse health outcomes in children (Shahine, et al., 2015, Yin et al., 2014;). The *PEIP* was also culturally-sensitive and used a simple language that could be understood by 5th grader and caregivers with low literacy level (Shahine, et al., 2015). Omani parents with low literacy status were able to understand the content. The cultural feature of the *PEIP* made it readily acceptable by the Omani parents since it reflected the Omani culture.

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 low resource settings, in relatively remote areas away from the Comprehensive Sickle Cell Center. 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. Consistent with findings from Hazzard and colleagues (2002), there was a significant difference in the knowledge and symptoms management between those who were exposed to a computer SMART BRIGHT educational program on SCD, compared to those who were given a traditional therapy activities using

papers. Use of innovative educational approaches, *such* as the PEIP which is accessible by smart phones, have demonstrated to be an effective mode of information delivery that is more comprehensive, more engaging than the traditional educational methods, and readily accessible multiple times at home (Jacob, et al, 2013).

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, discuss how the content may be applied as they provide care for their children with SCD. The weekly contact facilitated communications with parents and care provider as previously reported using smartphones (Jacob, et al, 2013). Due to the fact that parents were provided with individual attention for 4 weeks, this may have empowered them and increased 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 as proposed in the Social-Cognitive Learning Theory of Bandura (1986). 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 (Mahat, et al., 2007). Previous studies have demonstrated improvement in self-efficacy of children, with corresponding improvement in symptom management after educational interventions (Dobson, et al., 2015). To date, this study was the first study to evaluate parents' self-efficacy in SCD.

Findings from the study indicated improvement in the physical dimension of HRQOL. *PEIP* emphasized the physical dimension through content on avoiding the triggering factors for the acute pain episodes, the most distressing complication of SCD. Specific instructions were provided for parents to avoid 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. Badawy and colleagues (2017)

have previously reported that adherence to hydroxyurea was suboptimal due to poor understanding. The PEIP allowed parents in our study 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* provided parents with 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, must have indirectly affected their children' physical health.

Caregiver responses to pain plays a direct role in pain variation experienced by their children due to their ability to manage pain at home and their decision towards utilization of health care (Barakat et al., 2010). 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. However, the correlation between the parents' and the children on the physical aspects of HRQOL was stronger 4 weeks post intervention. 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. Adherence to hydroxyurea may have impacted the child's HRQOL due to the decreased frequency in the acute pain episodes.

We also found that the correlation between parents and children's' report on the emotional health was lower at baseline, compared to 4 weeks. The *PEIP* included information on emotional symptoms (fear, worry, sadness, anger, depression) that the child may experience

and strategies for managing those symptoms. The improvement in the children's emotional well-being at 4 weeks may be related to the parents increased awareness and ability to recognize early the emotional symptoms and responded accordingly as recommended in the *PEIP*. The parents' level of support, care and love provided in presence of emotional symptoms may have led to the improvement in the emotional health. This finding is consistent with data from Sehlo & Kamfar (2015), who reported high level of parents' support was a significantly associated with decreased depressive symptoms, and better HRQOL scores in children with SCD. It is also possible that the improvement in the emotional health was related to the improvement in physical health as described above. Increased frequency of pain led to decreased emotional health (Anie, 2005) and therefore, focusing on symptom management reduced the pain frequency that consequently led to improvement in the emotional health.

We found that parents' reported low social health scores in their children at baseline; which was most likely related to low physical health. Ahmed and colleagues (2015) reported that frequent pain and other disease related complications was associated with low social health scores in adolescents with SCD. In our study, the social health scores improved significantly at 4 weeks. Similar to other domains, the correlation of the parents and children scores on social health was low at baseline and improved at 4 weeks. *PEIP* included content on social health and provided instructions for parents to employ different strategies to engage their children with peers in the community.

Our findings indicate that children at baseline were found to have low cognitive health (memory & class attention); which interfered with school attendance. While low cognitive health scores may be related to pain and frequent hospitalization (Smith, et al., 2013), impairments in cognitive function in children with SCD were attributed to cerebral vascular injury since the early 1990s (Hariman, Griffith, Hurtig, & Keehn, 1991; Craft, Schatz, Glauser, Lee, & DeBaun, 1993; Cohen, Branch, McKie, & Adams, 1994; Armstrong et al., 1996; Watkins et al., 1998; Schatz et al., 1999;Bernaudin et al., 2000; Brown et al., 2000). Wang and colleagues (2001)

demonstrated that over the course of a 5-year period, magnetic resonance imaging (MRI) exams in brains of children with SCD were associated with declines in verbal IQ scores, psychomotor speed, focused attention and mathematics achievement. Several studies also reported that approximately 15% of children with hemoglobin type SS (HbSS) have silent cerebral infarcts with documented cognitive deficits by age 12 (Craft et al., 1993; Kugler et al.,1993; Armstrong et al., 1996; DeBaun et al., 1998; Watkins et al., 1998; Bernaudin et al., 2000; Brown et al., 2000; Wang et al., 2001).

In our study, parents' high level of education was associated with higher cognitive aspects of HRQOL. Parents who were highly educated may have been able to recognize the effect of the disease on the children's memory and attention; consequently more care was taken by the parents to improve the child's attention and memory (Smith et al., 2013). However, we also found that 75% of the parents in our study had lower educational level (less than or equivalent to high school), which may have contributed to lower cognitive health scores in their children. The study also found low correlation between the parents and children on the cognitive health scores at baseline. Parents reported slightly higher cognitive scores for their children than children themselves, indicating a gap between the parents and the child school performance. *PEIP* included content on cognitive health and information on how to improve the cognitive health, including to collaborating with the school for improving cognitive outcomes. The correlation between parents and children cognitive health scores were higher at 4 weeks. Parents were able to recognize the effects of SCD on the children's memory and attention. Consequently more care was taken by the parents to improve the child's attention and memory.

The total HRQOL scores were higher at 4 weeks compared to baseline, and were also higher in the *PEIP* compared to the *SEP*. The *PEIP* provided comprehensive information including specific information on the four important dimensions of HRQOL (physical, emotional, social, cognitive). The four dimensions of HRQOL were reflected in the information on SCD signs and symptoms, triggering factors for acute pain episodes, and symptoms management,

role of hydroxyurea, as well as strategies for improving the emotional, social, and cognitive health. Parents were instructed to employ different strategies for improving the physical, emotional, social and cognitive status that led to improvement in the overall HRQOL in children with SCD. This in turn led to improvement in parents' perception of their children's HRQOL. Knowledge learned impacted on the parents' self-efficacy; which consequently improved their perception of HRQOL. Self-efficacy was a moderator through which HRQOL was improved. The knowledge and self-efficacy were found to be significant predictors for improving HRQOL reported by the parents and were also significant predictors on the child's report that affected positively the children's overall HRQOL.

Additionally, the study examined the differences in the HRQOL scores on four dimensions between the child genders. The findings revealed a significant difference in all dimensions of quality of life between male and female children. Female children had lower scores on the emotional and social health compared to male children at baseline and 4 weeks. Male adolescents with SCD were found to report higher emotional and social health scores compared to female (Ahmed et al., 2016), while female adolescents had significantly lower scores in the emotional and social health than males (Dampier et al., 2011). Males were less likely to report pain, and express greater pain tolerance than females (Jenerette et al., 2011). Females, however were found to be more sensitive to pain than males.

Campbell and Colleagues (2005) reported that Caucasians were less sensitive to pain than individuals of African and Hispanic descent. In the Japanese culture, there is an emphasis on the desirability of concealing pain and emotions (Campbell et al., 2008). In Omani culture, males were expected to be more tolerant and not to cry while in pain. This may explain the higher emotional scores of Omani male children than females. In addition, in Omani culture, excessive shyness, limited interaction with males and communication, for example, were not seen as a social problem. In fact, these are desired attributes for some conservative Omani

families for their female children. Omani culture may explain the lower social scores for female than males. Interestingly, the emotional and social health scores for both genders improved significantly at 4 weeks, suggesting that the content on emotional and social health in the *PEIP* were useful.

Female children in our study had higher scores than males on the physical and the cognitive health scores at baseline and 4 weeks. This finding is in contrast to other studies that found physical health scores to be significantly higher among male compared to female adolescents with SCD (Ahmed et al., 2016; Amr et al., 2011). However, more than 50% of female children in our study were on hydroxyurea, which may explain the higher physical health scores in females. Other studies reported that high physical health score was a significant predictor of the emotional, social and cognitive health and overall improvement of HRQOL (Palermo et al., 2004; Wrotniak et al., 2012; Zempsky et al., 2013). High physical scores indicated less pain frequency and less hospitalization, which led to regular school attendance for females and better memory and attention status than males (Smith et al., 2013).

LIMITATIONS & RECOMMENDATIONS

The study was not able to examine the effects of *PEIP* on health care utilization (clinic, ER visits) and hospitalization in Omani children with SCD. The study also did not assess parents' satisfaction with the *PEIP*, the features that thought were most useful, the barriers for its use. The duration of the intervention was only for 4 weeks, and its effects over a longer period of time were not evaluated. Finally, the sample size was small and was conducted only in Oman; therefore, it is not possible to make generalizations to other settings. Future studies are therefore, recommended to evaluate the impact of *PEIP* on health care use, assess the most useful features of *PEIP* and barriers for implementation, determine whether the effects may be sustained beyond 4 weeks, and whether additional reinforcements may be required over a longer period of time. Replication and cultural adaptation of the *PEIP* to other languages,

cultures, regions, and settings are also recommended.

CONCLUSION

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.

IMPLICATIONS

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 smart phone technology for delivering a high quality educational intervention program for parents and their families.

Appendix 1:

UCLA OHRPP
Office of the Human Research Protection Program

DECISION-MAKING CAPACITY ASSESSMENT TOOL

INSTRUCTIONS: This form may be used to assess the decision-making capacity of potential subjects who may have or may be experiencing cognitive impairments.

Who should assess capacity? In general, the consent assessor should be a member of the research team or consultant familiar with dementias and/or cognitive impairment, and qualified to assess and monitor capacity to consent on an ongoing basis.

Potential Subject Name: _____ **IRB Protocol #:** _____

Study Title: _____

ASSESSMENT QUESTIONS:

1. Does the individual understand he/she would be participating in research and that research is voluntary?
   ☐ Yes ☐ No
2. Does the individual understand what will happen to him/her if he/she decides to participate?
   ☐ Yes ☐ No
3. Does the individual know how long he/she will be in the research study?
   ☐ Yes ☐ No
4. Can the individual explain one or two risks associated with the research study?
   ☐ Yes ☐ No
5. Can the individual explain what he/she should do to stop being in this research study?
   ☐ Yes ☐ No
6. Does the individual know who to contact if he/she experiences problems or has questions about the study?
   ☐ Yes ☐ No
7. **Interventional studies:** Can the individual explain what alternatives there are if he/she chooses not to participate?
   ☐ Yes ☐ No

INVESTIGATOR EVALUATION:

8. Does the individual express a choice about whether or not to participate?
   ☐ Yes ☐ No*
9. Does the individual have the decision-making capacity to give informed consent for this study?
   ☐ Yes ☐ No*

_____
Printed Name of Investigator Signature of Investigator Date

* **NOTE:** Potential subjects who are found to have diminished capacity must be excluded ***unless*** the UCLA IRB has approved the use of surrogate consent from legally authorized representatives for the study in question.

Version 8-22-2012

Appendix 2

Recruitment Flyer

UNIVERSITY OF CALIFORNIA LOS ANGELES

***Parent Educational Intervention Program (PEIP) for improving* Parental Knowledge, Self-Efficacy, & Parent Perception of Health Related Quality of Life in Children with Sickle Cell Disease**

You may be eligible to be part of a UCLA Research Study if you answer "Yes" to all the following questions:

- Does your child have Sickle Cell Disease?
- Is your child Omani?
- Is the age of your child between 8-12 Years?
- Are you able to speak and read the Arabic Language?

What will happen in the study:

- You will complete one of two educational programs related to Sickle Cell Disease.
- You will answer questions using 4 Questionnaires related to Sickle Cell Disease, Self-Efficacy, and Quality of Life at two time points: first, at the beginning of the program, and second, at 4 weeks at the end of the program.
- Your child will answer questions using 2 questionnaires related to quality of life at two time points: first, at the beginning of the program, and second at 4 weeks at the end of the program

Study Location:

- Royal Hospital
- Hematology Clinic

The Recruitment is for a "UCLA Research Study"

The purpose of the study is to examine the effects of a *Parent Educational Intervention Program* on parents' knowledge about sickle cell disease, self-efficacy and perception of health related quality of life in children with sickle cell disease.

IF INTERESTED CONTACT:
YUSRA AL NASIRI
TEL: 94445119
EMAIL:
YUSRA444@HOTMAIL.COM

Appendix 3

Study Flyer (Arabic)

Appendix 4

PEIP Banner

Appendix 5

UNIVERSITY OF CALIFORNIA LOS ANGELES
STUDY INFORMATION SHEET

Parents Educational Intervention Program (PEIP) for improving
Parental Knowledge, Self-Efficacy, & Parent Perception of Health Related Quality of Life in Children with Sickle Cell Disease

Yusra Sulaiman Al Nasiri, RN, PhD(c) is conducting a research study, under the supervision of Eufemia Jacob, PhD, RN, (Dissertation Chair), from the UCLA School of Nursing (UCLA).

You and your child were selected as a possible participant in this study because your child has sickle cell disease. The purpose of the study is to determine whether a parent educational intervention program will increase the parents' knowledge about managing the disease symptoms at home. Being part of the research study is voluntary. You and your child's participation in this study is not part of the child's treatment and the decision whether or not to participate will have no effect on that treatment nor their relationship with their physicians nor the clinic hospital.

Why is this study being done?

The study is designed to teach the parents of children with sickle cell disease about the different aspects of the sickle cell disease. It will teach the parents the effects of the disease on the child's physical health, feelings, ability to relate with others and school problems. The aim of the study is to increase your understanding about how to manage your child's pain and recognize symptoms early to prevent complications related to sickle cell disease.

What will happen if I and my child take part in this research study?

If you and your child volunteer to participate in this study, the researcher will ask you to do the following:

1. On your child's follow up visit at the clinic of the Royal hospital or Sultan Qaboos university hospital, you will be asked to complete Four questionnaires before the study starts:

   SCD-Knowledge Questionnaire: This questionnaire includes 25 questions about how much you know about sickle cell disease.

   Self-Efficacy Scale: This questionnaire has 9 questions about your ability and how sure you feel in managing your child's disease and symptoms at home.

   Generic Quality of Life Scale: This questionnaire has 25 questions to rate you child's general well-being.

   SCD Quality of Life Scale: This questionnaire has 42 questions to rate your child's well-being that is more specific to sickle cell disease.

2. Your child will also be asked to complete the child version of the Quality of Life Scale and the SCD Quality of Life Scale (similar to what you will complete as described above).

3. After you finish filling the questionnaires, the researcher will give you one version of the two

versions of the educational materials. One version is the materials that are distributed by the nurse coordinator in the clinic. The second version is in the form of two videos that may be seen on your smartphone. The version you will receive is randomly given.

If you receive the Parent Educational Intervention Program, two video segments will be downloaded in your smartphone. There are four parts to the video segments. You will watch one part, each week for four weeks. Each part is about 5-7 minutes long. The investigator will contact you by phone, once a week for four weeks, to remind you to watch the video segment, read the materials, and refer to the material about pain control.

If you don't have a smartphone, you will be provided with one, which will be yours to keep. You are not responsible to cover the cost of replacing the phone if it is lost, stolen, or broken.

If you receive the Standard Educational Program, you will be receive a 15 page booklet with questions and answers about sickle cell disease, signs and symptoms, treatments, diet. You will read about one topic per week for four weeks. You may contact your health care provider if you have thoughts and questions.

At four weeks after starting the study, you and your child will be asked to complete the same questionnaires that you completed before starting the study.

Your child may not elect to be part o the study even if you agree. In this case, if the child refuses to participate, you and your child will not be included in this study.

How long will I and my child be in the research study?

Participation will take a total of about 4 weeks. There will be no additional follow up in the future.

Are there any potential risks or discomforts that I and my child can expect from this study?

The anticipated risk or discomforts from being part of the study is low. You or your child may get tired when completing the questionnaires.

Are there any potential benefits if I and my child participate?

You will not directly benefit from your participation in the research.You may benefit from the study by increasing your knowledge about sickle cell disease. You may be able to understand how to manage your child's disease and symptoms at home, and increase the well-being of your child. You may be able to increase your awareness about the types of emotional and social experiences that your child may have. You may also become more aware if your child is having problems with remembering and concentrating at school.
The results of the research may benefit the society as the parents of sickle cell disease will be aware of how to improve their children's overall well-being.

Will I and my child be paid for participating?

You will receive $30 "Lulu" shopping voucher to thank you for being part of the study.

Will information about me and my child's participation be kept confidential?

Any information that is obtained in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. Confidentiality will be maintained by having no information that may identify you and your child. All information will have a code to ensure privacy and confidentiality. Publications will report group data; parent or child names will be kept confidential and will not be reported in the manuscripts or presentations.

What are my rights if I and my child take part in this study?

- You can choose not to participate in this study, and you may discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?

- **The research team:** If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact:

  Yusra Al Nasiri, Ministry of Health, Phone # 94445119, Email: yusra444@hotmail.com
  You may also contact Dr. Eufemia Jacob at the UCLA School of Nursing. Her email contact information is: ejacob@sonnet.ucla.edu

- **Centre of Research & Studies, Ministry of Health, Oman.**
  Dr. Adhra Al-Mawali
  Director of Studies and Research Centre,
  Tel:+968 24697551/ 24695921
  Fax: +968 24696702

  P.O.Box 393, PC 113 Muscat-Oman

Professor Mansour Al Manthari
Tel: +968 24143427
Email: mrec@squ.edu.om

- **UCLA Office of the Human Research Protection Program (OHRPP):**
  If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, please write to:

  UCLA Office of the Human Research Protection Program
  10889 Wilshire Blvd, Suite 800, Los Angeles, CA 90095-1406.

  You will be given a copy of this information ***to keep for your records.***

SIGNATURE OF STUDY PARTICIPANT

Name of Participant

Signature of Participant | Date

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent | Contact Number

Signature of Person Obtaining Consent | Date

Appendix 6

جامعة كاليفورنيا لوس أنجلوس

ورقة معلومات الدّراسة/ البحث

برنامج التدخّل التعليمي للوالدين لتحسين

البرنامج التعليمي للاباء لرفع المعرفة، وتعزيز الذات، وجودة الحياة المرتبطة بالصّحة

في الأطفال المصابين بمرض الخلايا المنجلية

جامعة كاليفورنيا لوس أنجلوس

ورقة معلومات الدّراسة/ البحث

البرنامج التعليمي للاباء لرفع المعرفة، وتعزيز الذات، وجودة الحياة المرتبطة بالصّحة

في الأطفال المصابين بمرض الخلايا المنجلية

الباحث الرّئيسي: يسرى سليمان الناصري، طالبة دكتوارة في السنة الثالثه بجامعة كاليفورنيا لوس أنجلوس، تقوم الباحثه يسرى الناصري بإجراء بحث وذلك تحت إشراف البروفيسوره يوفيميا جيكوب من كلية التمريض بجامعة كاليفورنيا لوس أنجلوس.

وقد اخترناك أنت وطفلك كمشاركين في هذه الدراسة لأنّ طفلك يعاني من مرض الخلايا المنجلية، والغرض من هذه الدراسة تحديد ما إذا كان برنامج التدخّل التعليمي للوالدين سيزيد من معرفة الوالدين حول التعامل مع أعراض المرض في المنزل. مع العلم أن مشاركتكم في هذه الدراسة تطوعية. مشاركتك أنت وطفلك في هذه الدراسه ليس جزءا من علاج طفلك، وقرار المشاركه لن يكون له أي تأثير على العلاج ولا علي العلاقه مع الاطباء ولا المستشفي ولا العياده.

لماذا هذه الدّراسة؟

أُعدت هذه الدّارسة لتعليم والديّ الأطفال الذين يعانون من مرض الخلايا المنجلية حول مختلف جوانب مرض الخلايا المنجلية. كما ستعمل هذه الدراسة على تعليم الوالدين حول آثار المرض على صحّة الطفل الجسدية، ومشاعره، وإمكانية تواصله مع الآخرين ومشكلات المدرسة. وتهدف الدّراسة إلى زيادة فهمك عن كيفية السيطرة على الألم الذي يتعرّض له طفلك والتعرّف على الأعراض في وقت مبكّر ومنع المضاعفات المرتبطه بمرض الخلايا المنجلية.

ماذا سيحدث لو شاركت في هذه الدّارسة البحثية؟

إذا تطوعت انت وطفلك للمشاركة في هذه الدّراسة، ستطلب منك الباحثة القيام بما يلي:

في زيارة المتابعة الخاصة بطفلك في عيادة الدم بالمستشفى السلطاني، سيُطلب منك **إكمال اربع استبيانات** قبل بدء الدّراسة وهي:

استبيان معرفة مرض الخلايا المنجلية: يشتمل هذا الاستبيان على 25 سؤال عن معرفتك بمرض الخلايا المنجلية.

4. **مقياس تعزيز الذّات:** يشتمل هذا الاستبيان على 9 أسئلة عن قدرتك ومدى شعورك بالثقة في التعامل مع مرض طفلك وأعراضه في المنزل.

مقياس جودة الحياة العامّة: يشتمل هذا الاستبيان على 25 سؤال لقياس الرفاهية العامّة لطفلك.

مقياس جودة الحياة الخاص بمرض الخلايا المنجلية: يشتمل هذا الاستبيان على 42 سؤال لقياس الرفاهية العامّة لطفلك، وتحديداً ما يتعلق بمرض الخلايا المنجلية.

5. سيطلب من طفلك كذلك إكمال نسخة الطفل الخاصة بمقياس جودة الحياة ومقياس جودة الحياة الخاص بمرض الخلايا المنجلية (شبيه بما ستكمله أنت كما وُصف أعلاه).

6. بعد إنتهائك من تعبئة الاستبيان، ستعطيك الباحثة نوع واحدة من نسختيّ المواد التعليمية. النوع الأول من المواد يتم توزيعها بواسطة منسّقة التمريض في العيادة، والنوع الثاني عبارة عن فيديوين إثنان يمكن مشاهدتها في هاتفك الذكي. المادة التعليمية التي ستحصل عليه يتم اختيارها عشوائياً.

إذا حصلت على نسخة الفيديو. سيتم إنزال الفيديوين في هاتفك الذكي. وسيتم إعطاءك هاتف ذكي لاستخدامه، إذا لم يكن لديك هاتفاً ذكياً. والمطلوب منك مشاهدة الفيديوين خلال فترة أربعة أسابيع. في كل أسبوع ستشاهد جزءً واحداً من الفيديو لمدّة 5 إلى-7 دقائق. إن لم يكن معك هاتف ذكي، سوف نمنحك واحدا. ولن تحتاج الى ارجاعه. كما انك غير مسؤل عن تغطيه التكلفه في حاله ضياع ، سرقه، كسر الهاتف.

إذا **حصلت على البرنامج التعليمي الثابت**، ستحصل على كتيب يحتوي على ١٥ صفحة أسئله وأجوبه عن مرض الخلايا المنجلية، أعراض المرض، العلاج، التغذيه. المطلوب منك قراءة واستيعاب محتوى واحد عن المرض كل اسبوع لمده أربع أسابيع. يمكنك التواصل مع مقدمي الرعايه الصحيه اذا عندك اي اقتراح أو إستفسار.

في زيارة طفلك للعيادة التي يتم جدولتها لأربع أسابيع بعد بدء الدّارسة ، سيطلب منك ومن طفلك إكمال نفس الاستبيانات التي أكملتها قبل بدء الدّراسة.

كم من الوقت سأكون انا وطفلي في الدّراسة البحثية؟

ستسغرق المشاركة حوالي 4 أسابيع، ولن تكون هناك متابعة إضافية في المستقبل.

هل هناك أيّ مخاطر أو مصاعب محتملة أتوقّعها انا وطفلي من هذه الدّارسة؟

المخاطر أو المصاعب الناجمة من كونك جزءً من الدّارسة قليلة. قد تتعب أنت أو طفلك أثناء إكمال الاستبيانات.

هل هناك ثمّة فوائد محتملة إذا شاركت انا وطفلي ؟

قد تستفيد من الدّراسة بزيادة معرفتك بمرض الخلايا المنجلية. ربّما يكون في مقدورك التعامل مع مرض طفلك وأعراضه في المنزل، وزيادة جوده الحياه الصحيه لطفلك. ربما يكون في مقدورك زيادة وعيك بأنواع المشاكل النفسيه والاجتماعية التي يمر بها طفلك. كما ستصبح أكثر إدراكاً ما إذا كان طفلك يعاني من مشكلات تتعلّق بالتذكّر والتركيز في المدرسة.

وقد تفيد نتائج البحث المجتمع حيث سيكون والديّ الأطفال المصابين بمرض الخلايا المنجلية مدركين لكيفية تحسين الصّحة العامّة لأطفالهم.

هل سأحصل انا وطفلي على مقابل إذا شاركت؟

ستحصل على قسيمة تسوّق من اللولو بمبلغ ١٠ ريالات أو كوبونات هدايا أو هدايا من بعض المؤسسات تعبيراً عن شكرنا لكونك جزء من الدّراسة.

هل سيتم الحفاظ على سرّية المعلومات التي شاركت بها انا وطفلي ؟

أي معلومات يتم الحصول عليها فيما يتصل بهذه الدّراسة ستكون سرّية. سيتم الإفصاح عنها فقط بموجب سماحك بذلك أو وفقاً لما يطلبه القانون. سيتم الحفاظ على السرّية بعدم الإفصاح عن المعلومات التي قد تشير إليك أو إلى طفلك. سيكون هناك شفرة لكافة المعلومات لضمان الخصوصية والسرّية. وسيتم الحفاظ على سرّية أسماء الوالدين والأطفال ولن يتم الإفصاح عنها في المواد المكتوبة أو المحاضرات.

ما هي حقوقي انا وطفلي إذا شاركت في هذه الدّراسة؟

- يمكن أن تختار عدم المشاركة في هذه الدّراسة، ويمكنك عدم مواصلة المشاركة في أيّ وقت.
- أيّاً كان القرار الذي تتخذه، لن تكون هناك عقوبة عليك، ولن تكون هناك خسارة للفوائد المستحقة لك.
- يمكنك رفض الإجابة على أيّ سؤال لا ترغب في الإجابة عليه، مع البقاء في الدّراسة.

مع من تتواصل إذا كانت لديك أسئلة عن هذه الدّراسة؟

- **فريق البحث:** إذا كانت لديك أيّ أسئلة، أو تعليقات، أو اهتمامات عن البحث، يمكنك التحدّث مع أحد الباحثين. الرّجاء التواصل مع:

يسرى الناصري، وزارة الصّحة، هاتف # 94445119، أو على البريد الإلكتروني: yusra444@hotmail.com

كما يمكنك الاتصال أيضاً بالدكتورة يوفيميا جيكوب، في كلية التمريض التابعة لجامعة كاليفورنيا لوس أنجلوس. على البريد الإلكتروني: ejacob@sonnet.ucla.edu

مركز الدراسات والبحوث، وزاره الصحه، عمان: مديره مركز البحوث ، الدكتوره عذراء المعولي، هاتف:+٩٦٨ ٢٤٦٩٧٥٥

اللجنه المعنيه بالموافقه على البحوث المتعلقه بالانسان، جامعه السلطان قابوس عمان، بروفيسور منصورالمنذري

ايميل: mrec@squ.edu.om هاتف:+٩٦٨-٢٤١٤٣٤٢٧

مكتب برنامج حماية البحوث البشرية التابع لجامعة كاليفورنيا لوس أنجلوس:مكتب برنامج حماية البحوث البشرية التابع لجامعة كاليفورنيا لوس أنجلوس، ١١٠٠٠ ويلشير بوليفارد الجناح ٨٠٠، ، لوس أنجلوس، كاليفورنيا٩٠٠٩٥-١٤٠٦

توقيع المشارك في الدّراسة

اسم المشارك

توقيع المشارك

التاريخ

توقيع الشخص الذي حصل على الموافقة

اسم الشخص الذي حصل على الموافقة

رقم الاتصال

توقيع الشخص الذي حصل على الموافقة

التاريخ

Appendix 7

UNIVERSITY OF CALIFORNIA LOS ANGELES

ASSENT TO PARTICIPATE IN RESEARCH

[*Parents Educational Intervention Program (PEIP) for improving*
Parental Knowledge, Self-Efficacy, & Parent Perception of Health Related Quality of Life
in Children with Sickle Cell Disease]

1. My name is Yusra Sulaiman Al Nasiri.

2. We are asking you to take part in a research study because we are trying to learn more about your pain and how do you feel about it. We want to see how you live overall being a child with sickle cell disease.

3. If you agree to be in this study we will ask you to answer some questions in two papers.

4. You may get tired while answering the questions, but you will be given some rests and snacks.

5. You may not get a direct benefit from participating from this research, but your parents will gain some information that will help in controlling your pain.

6. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say "yes" you can still decide not to do this.

7. If you don't want to be in this study, you don't have to participate. Remember, being in this study is up to you and no one will be upset if you don't want to participate or even if you change your mind later and want to stop.

8. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me [94445119] or ask me next time.

9. Signing your name at the bottom means that you agree to be in this study. You and your parents will be given a copy of this form after you have signed it.

_____ _____

Name of Subject Date

Appendix 8

المشاركة في البحث

برنامج التدخل التربوي للآباء (بيب) لتحسين المعرفة الأبوية، فعالية الذات، وتصور الوالدين لجوده الحياه في الأطفال الذين يعانون من مرض الخلايا المنجلية

1. اسمي يسرى سليمان الناصري.

2. نطلب منك أن تشارك في دراسة بحثية لأننا نحاول معرفة المزيد عن الألم وكيف تشعر حيال ذلك. نود أن نرى كيف كنت تعيش عموما كطفل مصاب بمرض الخلايا المنجلية.

3. إذا وافقت على أن تكون في هذه الدراسة سوف نطلب منك الإجابة على بعض الأسئلة في ورقتين.

4. قد تتعب أثناء الإجابة على الأسئلة، ولكن سيتم منحك بعض الراحه والوجبات الخفيفة.

5. قد لا تحصل على فائدة مباشرة من المشاركة من هذا البحث، ولكن والديك قد يحصلون على بعض المعلومات التي من شأنها أن تساعد في السيطرة على الألم.

6. يرجى التحدث مع والديك قبل أن تقرر ما إذا كان أو لم يشارك. سوف نطلب من والديك إعطاء إذنهم لك للمشاركة في هذه الدراسة. ولكن حتى لو قال والديك "نعم" لا يزال بإمكانك أن تقرر عدم القيام بذلك.

7. إذا كنت لا تريد أن تكون في هذه الدراسة، لم يكن لديك للمشاركة. تذكر، يجري في هذه الدراسة متروك لكم، وسوف لا يكون أحد بالضيق إذا كنت لا ترغب في المشاركة أو حتى إذا قمت بتغيير عقلك في وقت لاحق وتريد أن تتوقف.

8. يمكنك أن تسأل أي أسئلة لديك عن الدراسة. إذا كان لديك سؤال في وقت لاحق و أنك لم تفكر الآن، يمكنك الاتصال بي [94445119] أو تسألني في المرة القادمة.

9. توقيع اسمك في الاسفل يعني أنك توافق على أن تكون في هذه الدراسة. ستحصل أنت ووالدك على نسخة من هذا النموذج بعد التوقيع عليه.

_____ _____

الاسم التوقيع

Appendix 9

Parents Knowledge Questionnaire (PKQ)

Questions 1-16 please circle True OR False

1. Pain crisis can be prevented from happening. T/ F
2. If your child has a fever of 39 C, you can treat him at home. T/ F
3. If your child had pain in his/her leg, the best treatment is ice packs. T/ F
4. Children who have Sickle Cell Disease inherit one abnormal Sickle Hemoglobin gene from one parent. T/ F
5. Stress can lead to pain crisis T/ F
6. Your child can play during hot days T/ F
7. Giving your child lots of fluids to drink will prevent jaundice. T/ F
8. Hydroxyurea drug can reduce the frequency of pain crisis T/ F
9. Your child can be involved in vigorous exercise T/ F
10. Climbing mountains will not trigger pain crisis T/ F
11. Spleen enlargement is a dangerous complication in SCD T/ F
12. If your child has difficulty in breathing, coughing, chest pain, you can treat him at home with home remedies. T/ F
13. Lack of sleep and changing in eating habits are signs of depression T/ F
14. Feeling blue most of the time is normal at this age group T/ F
15. Morphine is the best medicine for treating painful crises in the hospital. T/ F
16. If your child is not interested in social activities, you will respect his choice T/ F

Questions 17-25, Please circle ONLY one answer

17. When both parents have SC trait, the chance of them having a child with SCD is:

    A. One in two (50%)
    B. One in one (100%)
    C. One in Four (25%)
    D. Depends on God's will

18. In persons with SCD, tissue damage and pain are caused by:

    A. The low hemoglobin in the blood
    B. Decreased oxygen to body organs
    C. Sickling of the red blood cells
    D. Bone infection

19. The most common complications of SCD in young children are:

    A. Spleen enlargement and stroke
    B. Anemia and leg ulcers
    C. Painful episodes and acute chest
    D. Infection and eye problems

20. One of the following may result due to effect of SCD on the cognitive function:

    A. Poor attention in the class
    B. Speech problem
    C. Difficulty in understanding
    D. Poor communication

21. Which of the following is a sign of social withdrawal?

    A. The child refuses to go to school
    B. The child can not make friends
    C. The child has excessive worries
    D. The child stays up a wake at night

22. All of the following are signs of depression **EXCEPT:**

    A. Thoughts of death
    B. Lack of energy
    C. Feeling sad
    D. Fail to have friends

23. If your child shows low academic performance, you will:

A. Complain about the teachers
B. Keep him to try his best
C. Assess the problems
D. Ask his friends to help him

24. One way to improve your child's emotional health is by:

A. Allowing the child to be with friends regularly
B. Appraising the child when doing good work
C. Getting the child whatever he/she wants
D. Making the child closer to you than other siblings

25. If the friends of your child tease him for having SCD, you will:

A. Respond to the friends' reaction
B. Ask your child to face them
C. Tell the child it is a normal reaction
D. Ignore the friends reaction

The questionnaire adopted from the study of: Shahine, R. Kurdahi, L., Karam, D., Abboud. M. (2015) Educational Intervention to Improve the Health Outcomes of Children With

Appendix: 10

ID#
_____

Date:_____

PedsQL™

Pediatric Quality of Life Inventory

Version 4.0

CHILD REPORT (ages **8-12**)

DIRECTIONS

On the following page is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has this been for you …*

ABOUT MY HEALTH AND ACTIVITIES *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to walk more than one block	0	1	2	3	4
2. It is hard for me to run	0	1	2	3	4
3. It is hard for me to do sports activity or exercise	0	1	2	3	4
4. It is hard for me to lift something heavy	0	1	2	3	4
5. It is hard for me to take a bath or shower by myself	0	1	2	3	4
6. It is hard for me to do chores around the house	0	1	2	3	4
7. I hurt or ache	0	1	2	3	4
8. I have low energy	0	1	2	3	4

ABOUT MY FEELINGS *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad or blue	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

HOW I GET ALONG WITH OTHERS *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. I have trouble getting along with other kids	0	1	2	3	4
2. Other kids do not want to be my friend	0	1	2	3	4
3. Other kids tease me	0	1	2	3	4
4. I cannot do things that other kids my age can do	0	1	2	3	4
5. It is hard to keep up when I play with other kids	0	1	2	3	4

ABOUT SCHOOL *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I miss school because of not feeling well	0	1	2	3	4
5. I miss school to go to the doctor or hospital	0	1	2	3	4

Appendix 11

ID#
_____

Date:_____

PedsQL™

Pediatric Quality of Life Inventory

Version 4.0

PARENT REPORT for **CHILDREN** (ages **8-12**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month,** how much of a **problem** has your child had with …*

PHYSICAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Getting along with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

Appendix 12

ID# _____

Date:_____

PedsQL™

Sickle Cell Disease Module

Version 3.0

CHILD REPORT (ages **8-12**)

DIRECTIONS

On the following pages is a list of things that might be a problem for you. Please tell us **how much of a problem** each one has been for you during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month**, how much of a **problem** has this been for you*

ABOUT MY PAIN AND HURT *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. I hurt a lot	0	1	2	3	4
2. I hurt all over my body	0	1	2	3	4
3. I hurt in my arms	0	1	2	3	4
4. I hurt in my legs	0	1	2	3	4
5. I hurt in my stomach	0	1	2	3	4
6. I hurt in my chest	0	1	2	3	4
7. I hurt in my back	0	1	2	3	4
8. I have pain every day	0	1	2	3	4
9. I have pain so much that I need medicine	0	1	2	3	4

ABOUT MY PAIN IMPACT *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to do things because I might get pain	0	1	2	3	4
2. I miss school when I have pain	0	1	2	3	4
3. It is hard for me to run when I have pain	0	1	2	3	4
4. It is hard to have fun when I have pain	0	1	2	3	4
5. I have trouble moving when I have pain	0	1	2	3	4
6. It is hard to stay standing when I have pain	0	1	2	3	4
7. It is hard for me to take care of myself when I have pain	0	1	2	3	4
8. It is hard for me to do what others can do because I might get pain	0	1	2	3	4
9. I wake up at night when I have pain	0	1	2	3	4
10. I get tired when I have pain	0	1	2	3	4

ABOUT MY PAIN MANAGEMENT AND CONTROL *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for me to manage my pain	0	1	2	3	4
2. It is hard for me to control my pain	0	1	2	3	4

ABOUT MY WORRYING I *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. I worry that I will have pain	0	1	2	3	4
2. I worry that others will not know what to do if I have pain	0	1	2	3	4
3. I worry when I am away from home	0	1	2	3	4
4. I worry I might have to go to the emergency room	0	1	2	3	4
5. I worry I might have to stay overnight in the hospital	0	1	2	3	4

Appendix 13

ID#_____

Date:_____

PedsQL™

Sickle Cell Disease Module

Version 3.0

PARENT REPORT for **Children** (ages **8-12**)

DIRECTIONS

On the following pages is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month,** how much of a **problem** has your child had with*

PAIN AND HURT *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. Hurting a lot	0	1	2	3	4
2. Hurting all over his/her body	0	1	2	3	4
3. Hurting in his/her arms	0	1	2	3	4
4. Hurting in his/her legs	0	1	2	3	4
5. Hurting in his/her stomach	0	1	2	3	4
6. Hurting in his/her chest	0	1	2	3	4
7. Hurting in his/her back	0	1	2	3	4
8. Having pain everyday	0	1	2	3	4
9. Having so much pain that he/she has to take medicine	0	1	2	3	4

PAIN IMPACT *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for him/her to do things because he/she might get pain	0	1	2	3	4
2. Missing school when he/she has pain	0	1	2	3	4
3. It is hard for him/her to run when he/she has pain	0	1	2	3	4
4. It is hard for him/her to have fun when having pain	0	1	2	3	4
5. Having trouble moving around when he/she has pain	0	1	2	3	4
6. It is hard for him/her to stay standing when he/she has pain	0	1	2	3	4
7. It is hard for him/her to take care of himself/herself when he/she has pain	0	1	2	3	4
8. It is hard for him/her to do what others can do because he/she might get pain	0	1	2	3	4
9. Waking up at night when he/she has pain	0	1	2	3	4
10. Getting tired when he/she has pain	0	1	2	3	4

PAIN MANAGEMENT AND CONTROL *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for him/her to manage his/her pain	0	1	2	3	4
2. It is hard for him/her to control his/her pain	0	1	2	3	4

WORRY I *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. Worrying that he/she will have pain	0	1	2	3	4
2. Worrying that other people will not know what to do if he/she has pain	0	1	2	3	4
3. Worrying when he/she is away from home	0	1	2	3	4
4. Worrying he/she might have to go to the emergency room	0	1	2	3	4
5. Worrying he/she might have to stay overnight in the hospital	0	1	2	3	4

*In the past **ONE month,** how much of a **problem** has your child had with*

WORRY II *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. Worrying he/she might have a stroke	0	1	2	3	4
2. Worrying he/she might have a chest crisis	0	1	2	3	4

EMOTIONS *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling mad about having sickle cell disease	0	1	2	3	4
2. Feeling mad when he/she has pain	0	1	2	3	4

TREATMENT *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for him/her to remember to take his/her medicine	0	1	2	3	4
2. Not liking how he/she feels after taking medicine	0	1	2	3	4
3. Not liking the way his/her medicine tastes	0	1	2	3	4
4. Medicine making him/her sleepy	0	1	2	3	4
5. Worrying about whether his/her medicine is working	0	1	2	3	4
6. Worrying about whether his/her treatments are working	0	1	2	3	4
7. Medicine not making him/her feel better	0	1	2	3	4

COMMUNICATION I *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for him/her to tell others when he/she is in pain	0	1	2	3	4
2. It is hard for him/her to tell the doctors and nurses how he/she feels	0	1	2	3	4
3. It is hard for him/her to ask the doctors and nurses questions	0	1	2	3	4

COMMUNICATION II *(problems with)*	Never	Almost Never	Some-times	Often	Almost Always
1. It is hard for him/her when other people do not understand about his/her sickle cell disease	0	1	2	3	4
2. It is hard for him/she when others do not understand how much pain he/she feels	0	1	2	3	4
3. It is hard for him/her to tell others that he/she has sickle cell disease	0	1	2	3	4

Appendix 14

Self- efficacy scale for Parents of children with SCD

	Not sure at all 0	Not sure 1	Neither 2	Sure 3	Very Sure 4
1. How sure are you that you can do something to cut down on most of the pain your child has when having a pain episode?					
2. How sure are you that you can help your child keep doing most of the things he/she does day –to –day?					
3. How sure are you that you can help your child keep Sickle cell pain from interfering with your child's sleep?					
4. How sure are you that you can reduce your child's sickle cell pain by using methods other than giving extra medication?					
5. How sure are you that you can control how often when your child gets tired?					
6. How sure are you that you can do something to help your child feel better if he/she is feeling sad or blue?					
7. As compared with other people with Sickle cell disease, how sure are you that you can manage your child's life from day-to-day?					
8. How sure are you that can manage your child's sickle cell symptoms so that she/he can do things she/he enjoy doing?					
9.How sure are you that you can deal with your child's frustration of having Sickle Cell Disease?					

Note: The questionnaire was adopted and modified from the self efficacy instrument specific to sickle cell disease that was developed by Edwards, Telfair, Cecil, & Lenoci (2000). http://www.sciencedirect.com/science/article/pii/S0005796799001400

Appendix 15

Demographic data sheet

Place mark a check mark (/) inside the box to indicate your response.

1. Region:

1. Muscat ☐ **2. Salalah** ☐ **3. North Batinah** ☐

4. South Batinah ☐ **5. Al Sharqiah** ☐ **6. Al –Dakhliah** ☐

7. Musandam ☐ **8. Al Wusta** ☐ **9. Al Dhahira** ☐

2. Sex: 1. Male ☐ **2. Female** ☐

3. Age : _____

4. Marital status: 1. Single ☐ **2. Married** ☐ **3. Divorced** ☐ **4. Widow** ☐

5. Level of Education: 1. Elementary ☐ **2. Secondary** ☐

3. Diploma ☐ **4. Baccalaureate** ☐ **5. Master** ☐

6. Doctoral ☐

Appendix 16

الملحق 11: Arabic translation of PKQ

الاستبيان لتقييم المعرفه بمرض الخلايا المنجلية:

الأسئلة 1.–16 الرجاء وضع دائرة على صحيح أو خطأ

1. يمكن تقليل نوبة الألم من الحدوث. صحيح/خطأ
2. إذا أُصيب طفلك بحمّى بدرجة 39 درجه مئوية، يمكن علاجه في المنزل. صحيح/خطأ
3. إذا أُصيب طفلك بألم في ساقه أوساقها، أفضل علاج هو وضع قوالب الثلج. صحيح/خطأ
4. يرث الأطفال المصابين بمرض الخلايا المنجلية جين واحدغير طبيعي لهيموجلوبين الخلايا المنجلية من أحد الوالدين. صحيح/خطأ
5. يمكن أن يؤدّي التعب لأزمة الألم. صحيح/خطأ
6. يمكن أن يلعب طفلك خلال الأيام الحارّة. صحيح/خطأ
7. إعطاء طفلك الكثير من السوائل سيمنع مرض (بو صفار) صحيح/خطأ
8. يمكن لدواء الهيدروكسيوريا أن يخفّض نوبه الألم. صحيح/خطأ
9. يستطيع طفلك أن يمارس التمارين الشاقه. صحيح/خطأ
10. لا يؤدّي تسلّق الجبال لنوبه الألم. صحيح/خطأ
11. تضخّم الطحال يعتبر أحد المضاعفات الخطرة في مرض الخلايا المنجلية. صحيح/خطأ
12. إذا تعرّض طفلك لصعوبة في التنفّس أو الكّحة أو ألم الصدر يمكنك علاجه بعلاجات منزلية. صحيح/خطأ

13. من علامات الاكتئاب عدم النوم وتغيير العادات الغذائية. صحيح/خطأ

14. الشعور بالكآبة في معظم الوقت هو طبيعي في هذه الفئة العمرية. صحيح/خطأ

15. المورفين هو أفضل علاج لمعالجة أزمات الألم في المستشفى. صحيح/خطأ

16. إذا لم يكن طفلك راغباً في الأنشطة الاجتماعية، ستحترم خياره. صحيح/خطأ

السؤال 17–25: الرجاء وضع دائرة على إجابة واحدة فقط

17 إذا كان كل من الوالدين حامل لمرض الخلايا المنجلية، فإنّ فرصة ولادتهم لطفل مصاب بمرض الخلايا المنجلية هي:

أ. ١٠٠ ٪
ب. ٥٠ ٪
ج. ٢٥ ٪
د. يعتمد الأمر على إرادة الله

18 . في الأشخاص المصابين بمرض الخلايا المنجلية، يحدث تضرّر الخلايا والألم بسبب:

أ. انخفاض الهيموجلوبين في الدّم
ب. إنخفاض الأوكسجين لأعضاء الجسم
ج. تولّد الخلايا المنجلية في خلايا الدّم الحمراء
د. الالتهاب المتكرر في العظام

19. الأعراض الأكثر شيوعاً لمرض الخلايا المنجلية في الأطفال الصغار هي:

أ. تضخّم الطحال والسكتة

ب. فقر الدّم وتقرّحات الساقين
ج. نوبات الألم الحاد في الصدر
د. العدوى ومشاكل العين

20. قد يحدث أحد الأشياء التالية للطفل نتيجة تأثير مرض الخلايا المنجلية في الوظائف العقليه:

أ. ضعف الانتباه في الفصل
ب. مشاكل الطّحال
ج. صعوبة الفهم
د. تدنّي مستوى التواصل

21. أي واحد من هذه الأشياء تُعتبر علامة للعزله الاجتماعيه عند الأطفال:

أ. رفض الطفل الذهاب إلى المدرسة
ب. عدم قدرة الطفل على عمل صداقات
ج. لدى الطفل قلق مفرط
د. يظل الطفل مستيقظاً خلال الليل

22. كل ما يلي من علامات الإكتئاب **ماعدا**:

أ. أفكارمتعلقه بالموت
ب. قله النشاط البدني
ج. الشّعور بالحزن
د. الفشل في عمل صداقات

23. إذا كان أداء طفلك التعليمي متدنّيا، فإنك سوف:

أ. تشتكي من المدرّسين
ب. تحثّة ليحاول القيام بالأفضل
ج. تعمل على تقييم المشكلات
د. تطلب من أصدقائه مساعدته

24. أحدى الطرق التي تساعد من تحسين صّحة طفلك العاطفية هي من خلال:

أ. السماح له بأن يكون مع أصدقائه على نحوٍ منتظم
ب. امتداح الطفل حينما يقوم بعمل جيّد
ج. إعطاء الطفل أيّ شيء يرغب/ترغب فيه
د. تقريب الطفل إليك أكثر من إخوته الآخرين

25. إذا كان أصدقاء طفلك يضايقونه بسبب إصابته بمرض الخلايا المنجلية، فإنك سوف:

أ. تستجيب لرد فعل الأصدقاء
ب. تطلب من طفلك مواجهتهم
ج. تخبر الطفل بأنّ ذلك رد فعل طبيعي
د. تتجاهل رد فعل الأصدقاء

هذا الاستبيان مستوحى من دارسة: شاهين آر. قرداحي، إل. كرم، دي، عبود إم. (2015) التدخّل التعليمي لتحسين المخرجات الصحية للأطفال الذين يعانون من مرض الخلايا المنجلية. دورية العناية الصّحية الخاصة بطب الأطفال 29 (54-60)

Appendix 17

Translation to Arabic & back translation to English of the tool was performed

TM
PedsQL

Version 4.0 - Arabic (Kuwait)

تقرير الأطفال
8--12

تعليمات

في الصفحة التالية قائمة بالأشياء التي يمكن أن تكون مشكلة بالنسبة لك.
من فضلك قل/قولي لنا **ما حجم المشكلة** التي كان يمثلها كل مما يلي بالنسبة لك خلال **الشهر الماضي** بوضع دائرة حول الرقم الصحيح:

0 إذا كان لا يمثل مشكلة أبدًا
1 إذا كان نادرًا **ما يمثل مشكلة**
2 إذا كان أحيانًا **ما يمثل مشكلة**
3 إذا كان معظم الوقت **ما يمثل مشكلة**
4 إذا كان دائمًا تقريبًا **ما يمثل مشكلة**

لا توجد إجابات صحيحة أو خاطئة.
إذا كنت لا تفهم/ تفهمين سؤالاً، فمن فضلك اطلب/اطلبي المساعدة.

*خلال **الشهر الماضي**، ما حجم **المشكلة** التي كان يمثلها لك ما يلي...*

عن صحّتي ونشاطاتي *(مشاكل مع...)*	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. من الصعب بالنسبة لي أن أمشي مسافة تزيد عن 100 متر	0	1	2	3	4
2. من الصعب بالنسبة لي أن أجري	0	1	2	3	4
3. من الصعب بالنسبة لي أن أمارس الأنشطة الرياضية أو التمارين	0	1	2	3	4
4. من الصعب بالنسبة لي أن أرفع شيئاً ثقيلاً	0	1	2	3	4
5. من الصعب بالنسبة لي أن أستحم بنفسي	0	1	2	3	4
6. من الصعب بالنسبة لي أن أقوم بأعمال في المنزل	0	1	2	3	4
7. أشعر بألم أو وجع	0	1	2	3	4
8. أشعر أن طاقتي منخفضة	0	1	2	3	4

عن شعوري *(مشاكل مع...)*	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. أشعر بالخوف	0	1	2	3	4
2. أشعر بالحزن	0	1	2	3	4
3. أشعر بالغضب	0	1	2	3	4
4. أجد صعوبة في النوم	0	1	2	3	4
5. أقلق من ما سيحدث لي	0	1	2	3	4

كيف أتعامل مع الآخرين *(مشاكل مع...)*	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. أجد صعوبة في التعامل مع الأطفال الآخرين	0	1	2	3	4
2. الأطفال الآخرون لا يريدون أن يكونوا أصدقائي	0	1	2	3	4
3. الأطفال الآخرون يستفزونني	0	1	2	3	4
4. لا أستطيع أن أعمل الأشياء التي يستطيع الأطفال الآخرون في مثل سني أن يعملوها	0	1	2	3	4
5. من الصعب بالنسبة لي منافسة الأطفال الآخرين عندما ألعب معهم	0	1	2	3	4

عن مدرستي *(مشاكل مع...)*	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. من الصعب أن أنتبه في الفصل	0	1	2	3	4
2. أنسى الأشياء	0	1	2	3	4
3. أجد صعوبة في إنهاء واجباتي المدرسية في الوقت	0	1	2	3	4
4. أتغيَّب عن المدرسة بسبب شعوري بالمرض	0	1	2	3	4
5. أتغيَّب عن المدرسة للذهاب إلى الطبيب أو إلى المستشفى	0	1	2	3	4

Appendix 18

رقم التعريف:_____

التاريخ:_____

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استبيان جودة الحياة
لطب الأطفال

Version 4.0 - Arabic (Kuwait)

تقرير الوالدين عن الأطفال (للأعمار 8-12)

تعليمات

في الصفحة التالية قائمة بالأمور التي قد تكون مشكلة **لطفلك\طفلتك**.
الرجاء أن تُخبرنا عن **حجم** المشكلة الناتجة **لطفلك\طفلتك** عن كل واحدة منها خلال **الشهر الماضي** بوضع دائرة حول:

0 إذا لم تكن مشكلة **أبداً**
1 إذا لم تكن مشكلة **في معظم الأحيان**
2 إذا هي مشكلة **في بعض الأحيان**
3 إذا هي مشكلة **في أحيان كثيرة**
4 إذا هي مشكلة **في معظم الأحيان**

لا توجد إجابات صحيحة أو خاطئة.
إذا لم تفهم أي سؤال، الرجاء طلب المساعدة.

PedsQL 2

خلال **الشهر الماضي**، ما حجم **المشكلة** الناتجة لطفلك\طفلتك مع...

الصحة والأنشطة الجسمانية *(مشاكل بخصوص ...)*	ليست مشكلة أبدًا	ليست مشكلة في معظم الأحيان	هي مشكلة في بعض الأحيان	هي مشكلة في أحيان كثيرة	هي مشكلة في معظم الأحيان
1. المشي لمسافة تزيد عن 100 متر	0	1	2	3	4
2. الركض	0	1	2	3	4
3. المشاركة في أنشطة أو تمارين رياضية	0	1	2	3	4
4. رفع شيء ثقيل	0	1	2	3	4
5. الاستحمام بدون مساعدة الآخرين	0	1	2	3	4
6. القيام بأعمال المنزل	0	1	2	3	4
7. الشعور بأوجاع	0	1	2	3	4
8. الشعور بالتعب	0	1	2	3	4

الحالة المعنوية *(مشاكل بخصوص ...)*	ليست مشكلة أبدًا	ليست مشكلة في معظم الأحيان	هي مشكلة في بعض الأحيان	هي مشكلة في أحيان كثيرة	هي مشكلة في معظم الأحيان
1. الشعور بالخوف	0	1	2	3	4
2. الشعور بالحزن	0	1	2	3	4
3. الشعور بالغضب	0	1	2	3	4
4. صعوبة في النوم	0	1	2	3	4
5. القلق مما قد سيحدث له\لها؟	0	1	2	3	4

الأنشطة الاجتماعية *(مشاكل بخصوص ...)*	ليست مشكلة أبدًا	ليست مشكلة في معظم الأحيان	هي مشكلة في بعض الأحيان	هي مشكلة في أحيان كثيرة	هي مشكلة في معظم الأحيان
1. الانسجام مع الأطفال الآخرين	0	1	2	3	4
2. الأطفال الآخرون لا يريدون أن يكونوا أصدقاءه/ها	0	1	2	3	4
3. الأطفال الآخرون يضايقونه/ها ويسخرون منه/ها	0	1	2	3	4
4. لا يستطيع عمل الأشياء التي يستطيع الأطفال الآخرون في مثل سنه أو سنها أن يعملوها	0	1	2	3	4
5. مجاراة الأطفال الآخرين خلال اللعب	0	1	2	3	4

الأنشطة المدرسية *(مشاكل بخصوص ...)*	ليست مشكلة أبدًا	ليست مشكلة في معظم الأحيان	هي مشكلة في بعض الأحيان	هي مشكلة في أحيان كثيرة	هي مشكلة في معظم الأحيان
1. الانتباه في الصف	0	1	2	3	4
2. نسيان الأشياء أو نسيان عمل أشياء معيَّنة	0	1	2	3	4
3. إنهاء الواجبات المدرسية	0	1	2	3	4
4. التغيب عن المدرسة بسبب مرض	0	1	2	3	4
5. التغيب عن المدرسة للذهاب إلى الطبيب أو إلى المستشفى	0	1	2	3	4

Appendix 19

PedsQL™

وحده مرض الخلايا المنجليه

Version 3.0 - Arabic (Oman)

تقرير الأطفال (سن 8--12) -

تعليمات

في الصفحة التالية قائمة بالأشياء التي يمكن أن تكون مشكلة بالنسبة لك.
من فضلك قل/قولي لنا **ما حجم المشكلة** التي كان يمثلها كل مما يلي بالنسبة لك خلال **الشهر الماضي** بوضع دائرة حول الرقم الصحيح:

0 إذا كان لا يمثل مشكلة أبدًا
1 إذا كان نادرًا **ما يمثل مشكلة**
2 إذا كان أحيانًا **ما يمثل مشكلة**
3 إذا كان معظم الوقت **ما يمثل مشكلة**
4 إذا كان دائمًا تقريبًا **ما يمثل مشكلة**

لا توجد إجابات صحيحة أو خاطئة.
إذا كنت لا تفهم/ تفهمين سؤالاً، فمن فضلك اطلب/اطلبي المساعدة.

-

الالم وحدته(*(مشكال مع . . . . .)*	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. أتألم كثيزا	0	1	2	3	4
2. يؤلمني في كل أنحاء جسمي	0	1	2	3	4
3. يؤلمني في ذراعي	0	1	2	3	4
4. يؤلمني في قدمي	0	1	2	3	4
5. يؤلمني في بطني	0	1	2	3	4
6. يؤلمني في صدري	0	1	2	3	4
7. يؤلمني في ظهري	0	1	2	3	4
8. عندي ألم كل يوم	0	1	2	3	4
9. عندي ألم شديد ولذلك أحتاج إلي الدواء	0	1	2	3	4

تأثير الألم *(مشكال مع . . . . .)*	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يصعب علي فعل الأشياء لانني يمكن أن أصاب بألم	0	1	2	3	4
2. أتغيب عن المدرسة عندما يكون عندي ألم	0	1	2	3	4
3. يصعب علي الركض عندما يكون بي ألم	0	1	2	3	4
4. يصعب علي الاستمتاع عندما يكون بي ألم	0	1	2	3	4
5. أواجه مشكله في التحرك عندما يكون بي ألم	0	1	2	3	4
6 . يصعب علي أبقى واقفا عندما يكون بي ألم	0	1	2	3	4
7 . يصعب علي العنايه بنفسي عندما يكون بي ألم	0	1	2	3	4
8 . يصعب علي عمل الأشياء التي يستطيع الأطفال الآخرون في مثل سني أن يفعلوها لانه قد يحدث معي ألم	0	1	2	3	4
9. أستيقظ بالليل عندما يكون بي ألم	0	1	2	3	4
10. أصاب بالتعب عندما يكون بي ألم	0	1	2	3	4

إداره الألم والسيطره عليه *(مشكله مع . . .) . .*	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يصعب علي إداره ألمي	0	1	2	3	4
2. يصعب عاي السيطره على ألمي	0	1	2	3	4

قلق 1 *(مشكله مع . . . . .)*	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. أنا قلق فقد أصاب بألم	0	1	2	3	4
2. أنا قلق لان الاخرين لن يعلموا ماذا يفعلون عندما يكون بي ألم	0	1	2	3	4
3. أنا قلق عندما أكون بعيد عن البيت	0	1	2	3	4

4. أنا قلق فقد يتوجب علي الذهاب الي غرفه الطوارئ	0	1	2	3	4
5. أنا قلق فقد يتوجب علي المكوث ليلا في المستشفي	0	1	2	3	4

قلق 2 ***(مشكله مع . . . . .)***	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. أنا قلق فقد يكون معي جلطه دماغيه	0	1	2	3	4
2.. . أنا قلق فقد يكون لدي أزمه في الصدر	0	1	2	3	4

المشاعر ***(مشكله مع . . . . .)***	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. أشعر بجنون أنا مصاب بمرض الخلايا المنجليه	0	1	2	3	4
2. أشعر بجنون عندما يكون بي ألم	0	1	2	3	4

العلاج (مشاكل مع...)	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يصعب علي أن أتذكر بأن آخذ دواءي	0	1	2	3	4
2. لا يعجبني كيف أشعر بعد أن أتناول الدواء	0	1	2	3	4
3. لا يعجبني مذاق دوائي	0	1	2	3	4
4. دوائي يجعلني أشعر بالنعاس	0	1	2	3	4
4. أنا قلق حول ما إذا كان دوائي قد يعمل	0	1	2	3	4
5. أنا قلق حول ما إذا كان العلاج يعمل	0	1	2	3	4
5. دوائي لا يجعلني أشعر بتحسن	0	1	2	3	4

التواصل ١ ***(مشاكل مع . . . . .)***	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يصعب علي إن أخبر الاخرين عندما أتألم	0	1	2	3	4
2. يصعب علي إن أخبر الاطباء والممرضات كيف اشعر	0	1	2	3	4
3. يصعب علي إن أسأل الاطباء والممرضات أسئله	0	1	2	3	4

التواصل ٢ ***(مشاكل مع . . . . .)***	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يصعب علي عندما الاخرون لا يفهمون عن اصابتي بمرض بالخلايا المنجليه	0	1	2	3	4
2. يصعب علي عندما اللاخرون لا يفهمون مدى الالم الذي أشعر به	0	1	2	3	4
3. يصعب علي أن أخبر الاخرين ان لدي مرض الخلايا المنجليه	0	1	2	3	4

Appendix 20

TM PedsQL

وحده مرض الخلايا المنجليه

Version 3.0 - Arabic (Oman).

تقرير الأطفال (سن 8--12) -

تعليمات

في الصفحة التالية قائمة بالأشياء التي يمكن أن تكون مشكلة بالنسبة لك.
من فضلك قل/قولي لنا **ما حجم المشكلة** التي كان يمثلها كل مما يلي بالنسبة لك خلال **الشهر الماضي** بوضع دائرة حول الرقم الصحيح:

0 إذا كان لا يمثل مشكلة أبدًا
1 إذا كان نادرًا **ما يمثل مشكلة**
2 إذا كان أحيانًا **ما يمثل مشكلة**
3 إذا كان معظم الوقت **ما يمثل مشكلة**
4 إذا كان دائمًا تقريبًا **ما يمثل مشكلة**

لا توجد إجابات صحيحة أو خاطئة.
إذا كنت لا تفهم/ تفهمين سؤالاً، فمن فضلك اطلب/اطلبي المساعدة.

-

الالم وحدته(*(مشكال مع . . . . .)*	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يؤلم كثيزا	0	1	2	3	4
2. يؤلم كل أنحاء جسمه/ جسمها	0	1	2	3	4
3. يؤلم في ذراعه / ذراعها	0	1	2	3	4
4. يؤلم في قدمه / قدمها	0	1	2	3	4
5. يؤلم في بطنه / بطنها	0	1	2	3	4
6. يؤلم في صدره / صدرها	0	1	2	3	4
7. يؤلم في ظهره / ظهرها	0	1	2	3	4
8. عنده ألم كل يوم	0	1	2	3	4
9. عنده ألم شديد ولذلك يحتاج إلي الدواء	0	1	2	3	4

تأثير الألم *(مشكال مع . . . . .)*	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يصعب عليه/ عليها فعل الأشياء لانه/لانها يمكن أن يصاب بألم	0	1	2	3	4
2. يتغيَّب عن المدرسة عندما يكون به ألم	0	1	2	3	4
3. يصعب عليه /عليها الركض عندما يكون به/ بها ألم	0	1	2	3	4
4. يصعب عليه /عليها الاستمتاع عندما يكون به/ بها ألم	0	1	2	3	4
5. يواجه مشكله في التحرك عندما يكون به/ بها ألم	0	1	2	3	4
6 . يصعب عليه /عليها أن يبقى واقفا عندما يكون به/ بها ألم	0	1	2	3	4
7 . يصعب عليه /عليها العنايه بنفسه/ نفسها عندما يكون به/ بها ألم	0	1	2	3	4
8 . يصعب عليه /عليها عمل الأشياء التي يستطيع الأطفال الآخرون في مثل سنه أن يفعلوها لانه/لانها يمكن أن يحدث معه ألم	0	1	2	3	4
9. يستيقض بالليل عندما يكون به/ بها ألم	0	1	2	3	4
10 . يصاب بالتعب عندما يكون به/ بها ألم	0	1	2	3	4

إداره الألم والسيطره عليه *(مشكله مع . . .)* . .	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يصعب عليه /عليها إداره ألمه /ألمها	0	1	2	3	4
2. يصعب عليه /عليها السيطره على ألمه /ألمها	0	1	2	3	4

قلق 1 *(مشكله مع . . . . .)*	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. قلق فقد يصاب/ تصاب بآلم	0	1	2	3	4
2. قلق لان الاخرين لن يعلموا ماذا يفعلون عندما يكون به/ بها ألم	0	1	2	3	4
3. قلق عندما يكون / تكون بعيد عن البيت	0	1	2	3	4

4. قلق فقد يتوجب عليه/ عليها الذهاب الي غرفه الطوارئ	0	1	2	3	4
5. قلق فقد يتوجب عليه/ عليها المكوث ليلا في المستشفي	0	1	2	3	4

قلق 2 ***(مشكله مع . . . . .)***	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. قلق لانه /لانها قد يكون معه جلطه	0	1	2	3	4
2.. قلق لانه /لانها قد يكون معه أزمه في الصدر	0	1	2	3	4

المشاعر ***(مشكله مع . . . . .)***	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يشعر بجنون للاصابه بمرض الخلايا المنجليه	0	1	2	3	4
2. يشعر بجنون عندما يكون به / بها ألم	0	1	2	3	4

العلاج (مشاكل مع...)	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يصعب عليه/ عليها أن يتذكر أن يأخذ دواءه / دواءها	0	1	2	3	4
2. لا يعجبه /يعجبها كيف يشعر / تشعر بعد تناول الدواء	0	1	2	3	4
3. لا يعجبه /يعجبه طريقه مذاق ادويته / أدويتها	0	1	2	3	4
4. الدواء يجعله / يجعلها تشعر بالنعاس	0	1	2	3	4
4. قلق حول ما إذا كان الدواء يعمل	0	1	2	3	4
5. قلق حول ما إذا كان العلاجات تعمل	0	1	2	3	4
5. الدواء لا يجعله /يجعلها تشعر بتحسن	0	1	2	3	4

التواصل ١ ***(مشاكل مع . . . . .)***	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يصعب عليه /عليها إن يخبر الاخرين عندما يكون معه / معها ألم	0	1	2	3	4
2. يصعب عليه /عليها إن يخبر الاطباء والممرضات كيف يشعر/ تشعر	0	1	2	3	4
3. يصعب عليه /عليها إن تسأل الاطباء والممرضات أسئله	0	1	2	3	4

التواصل ٢ ***(مشاكل مع . . . . .)***	أبدًا	نادرًا	أحياناً	معظم الوقت	دائمًا تقريبًا
1. يصعب عليه /عليها عندما الاخرون لا يفهمون عن اصابته/ اصابتها بمرض الخلايا المنجليه	0	1	2	3	4
2. يصعب عليه /عليها عندما الاخرون لا يفهمون مدى الالم الذي يشعر به	0	1	2	3	4
3. يصعب عليه /عليها إن يخبر الاخرين ان لديه / لديها مرض الخلايا المنجليه	0	1	2	3	4

Appendix 21

Arabic translation of SES

مقياس تعزيز الذات لوالدي الأطفال المصابين بمرض الخلايا المنجلية

	غير متأكّد إطلاقاً 0	غير متأكّد 1	محايد 2	متأكّد 3	متأكّد تماماً 4
1. إلى أي مدى أنت متأكّد بأنّه بوسعك خفض معظم الألم الذي يتعرّض له طفلك عندّ إصابته بنوبة ألم؟					
2. إلى أي مدى أنت متأكّد بأنّه في وسعك جعل طفلك يفعل معظم الأشياء التي يفعلها يومياً؟					
3. إلى أيّ مدى أنت متأكّد بأنّه في وسعك مساعدة طفلك في إبعاد الألم الناتج عن مرض الخلايا المنجلية بدون أن يتعارض مع نوم الطفل؟					
4. إلى أيّ مدى أنت متأكّد بأنّه في وسعك استخدام طرق متعدده للتقليل من الألم الذي يعاني منه طفلك نتيجه مرض الخلايا المنجلية بدون اعطاء جرعه اضافيه من الدواء؟					
5. إلى أيّ مدى أنت متأكّد بأنّه في وسعك السيطرة على التعب الذي يصيب طفلك؟					
6. إلى أيّ مدى أنت متأكّد بأنّه في وسعك فعل شيء ما لمساعدة طفلك بالشعور بأنّه أفضل حالاً عندما يشعر بالحزن أو الكآبة؟					
7. مقارنة بالناس الآخرين المصابين بمرض الخلايا المنجلية، إلى أيّ مدى أنت متأكّد بأنّه في وسعك إدارة حياة طفلك اليومية مع وجود الالم؟					
8. إلى أيّ مدى أنت متأكّد بأنّه بإمكانك التعامل مع الأعراض التي يعاني منها طفلك نتيجة لإصابته بمرض الخلايا المنجلية لكي يجد المتعه في حياته؟					
9. إلى أيّ مدى أنت متأكّد بأنّه يمكنك التعامل مع الإحباط الذي يعاني منه طفلك نتيجة اصابته بمرض الخلايا المنجلية؟					

تنويه: تم إستيحاء هذا الاستبيان وتعديله من أداة الفعّالية الذاتية المقتصرة على مرض الخلايا المنجلية التي استحدثها إدواردز، تيلفير، سيسيل ولينوسي (2000)

http://www.sciencedirect.com/science/article/pii/S0005796799001400

Translation to Arabic & back translation to English of the tool was performed

Appendix 22

المحلق 5: صفحة البيانات الديموغرافيه:

ضع علامة (/) داخل الصندوق الذي يوضّح إجابتك

1. الولاية:

1. مسقط ☐ 2. صلالة ☐ 3. شمال الباطنة ☐

4. جنوب الباطنة ☐ 5. الظاهرة ☐ 6. الدّاخلية ☐

7. مسندم ☐ 8. الوسطى ☐ 9. شمال الشرقية ☐

10. جنوب الشرقية ☐ 11. البريمي ☐

2. النوع 1. ذكر ☐ 2. أنثى ☐

3. العمر: _____

4. الحالة الاجتماعية ١.عازب ☐ ٢.متزوّج ☐ ٣. مطلق ☐ ٤.أرمل ☐

5. المستوى التعليمي 1. إبتدائي ☐ 2. اعدادي ☐ 3ثانوي ☐

3. دبلوم ☐ 4. بكالوريوس ☐ 5. ماجستير ☐ 6. دكتوارة ☐

Appendix 23

SCD content validity

Based on your review of Sickle Cell Disease teaching content,
Please specify your ratings for the following:

The criteria	Poor = 1	Good =2	V.good = 3	Excellent =4	Rater 1	Rater 2	Rater 3
1. The content clearly represents the important aspects of SCD							
2. The content is comprehensive							
3. The content is clear for the readers							
4. The content is easy to understand							
5. The content is appropriate for the parents of children with SCD							
6. The content is not redundant							
Total =24							

_____ X 100= _____%

24

Appendix 24

TESTING FOR ANOVA, MANOVA, LINES REGRESSION ASSUMPTIONS

The data were analyzed by SPSS (version 24, Chicago, IL). Initially, a descriptive analysis was performed to ensure that adequate numbers or responses were available for each variable that were included in the analyses and to check for missing values. Variables with missing values were excluded from the analyses. A statistical value $P \leq 0.5$ was considered significant. A mixed model ANOVA/ General Linear Model (repeated measures) was used to examine the differences in the HRQOL scores by the group level (Intervention & control) and by two time points (Baseline & posttest). The test was appropriate to determine the effects of the intervention between and within subject factors, and to determine significant interactions between and within subjects. Potential confounding variables were added as covariates and included parent education, age, gender, and child age, gender, and whether child was taking hydroxyurea.

The assumptions of linearity, homogeneity of variance, independence of observation and sphericity were met for knowledge, self-efficacy and HRQOL-SCD. Homogeneity of variance was violated for PedsQL scores; therefore, Greenhouse-Geisser was considered when reporting the PedsQL values. Generally, the independence of error and normality assumptions were violated as confirmed by significant results of Shapiro-Wilk test (<0.05). However, the residuals for a general linear model for repeated measures with groups, time (pre-post), and groups-by-time interaction, residuals for self-efficacy, knowledge, PedsQL, SCD-parents, all had a mean of zero and good skewness (-1<skewness<1). Kurtosis was in the good or acceptable range (-2<kurtosis<2).

A linear regression test was used to identify the possible predictors in the HRQOL scores at the posttest. The asumptions of linearity, normality of errors, homoscedacity of errors, independence of errors, and multicollinearity were all met.

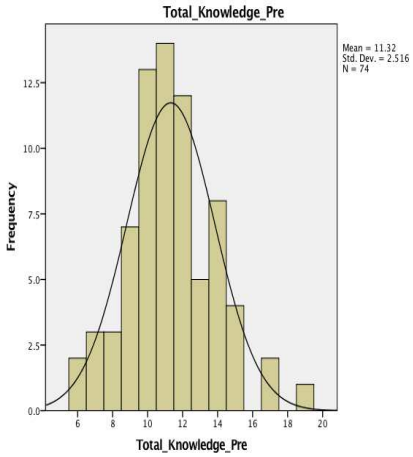
In addition, the study examined the differences in the quality of life scores (physical, emotional, social and cognitive) by child-gender. MANOVA was conducted and all assumptions were met.

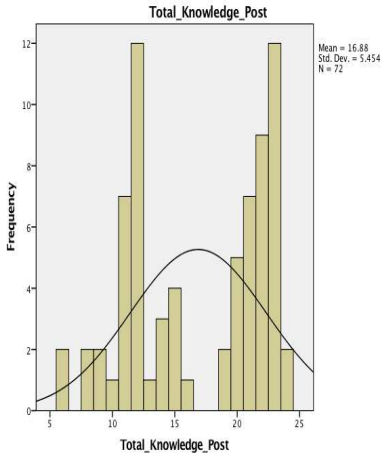
Two way mixed ANOVA (Repeated Measure) Assumptions

1. Outcome measure: Knowledge

Assumption	Analysis	Results of analysis
Normally distributed DV, No outliers	Looking at the histogram below, the knowledge scores at the baseline looks normally distributed; however, it is not normally distributed in the post-test. To confirm normality distribution, Shapiro-Wilk test was done and revealed non significant (0.166) at the baseline data. However it revealed significant (P = 0.000) post intervention. Also, the boxplot shows some outliers at the baseline for the intervention group and in the post-test for the control group.	Assumption not met
Independent Observation	The score for each participant across the 2-time period is considered independent from the previous observation.	Assumption met
Equal [error] variances across the 2 times period	Test of Equality of covariance matrices of the dependent variables across the groups reveals significant (P = 0.002). The residual covariance matrix shows that, the errors were almost equal across the 2 times period (see the table below).	Assumption not met
Sphericity	With 2 levels of repeated measures, there is no need to conduct the Mauchly's test of sphericity, the assumption of Mauchly's sphericity will be met under this situation.	Assumption met
Homogeneity of DV covariance	Levene test showed 0.16, 0.41 (>0.05).	Assumption met

1. Normality Assumption

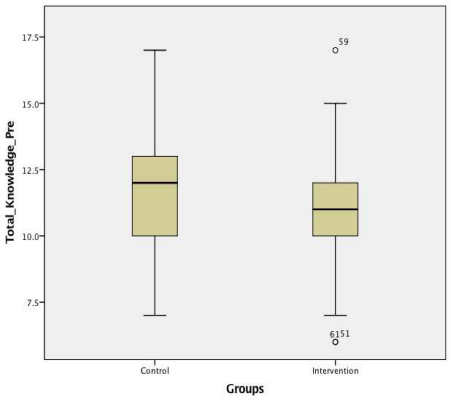


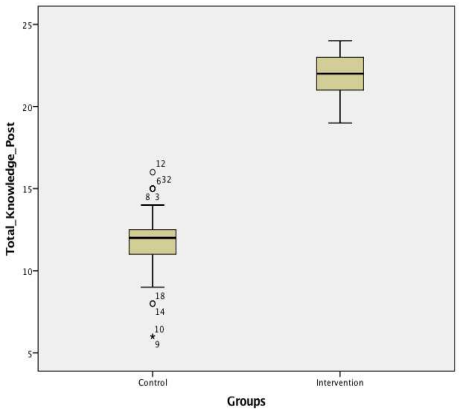


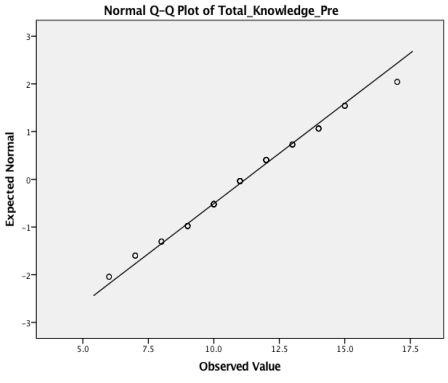
Tests of Normality

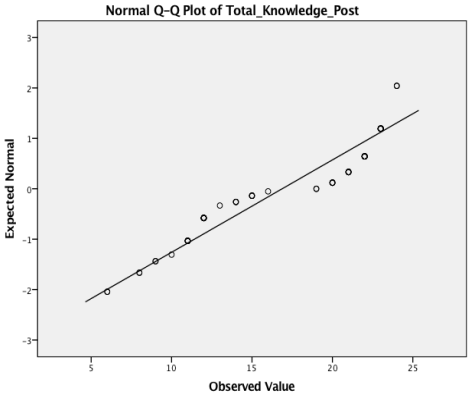
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	Df	Sig.	Statistic	df	Sig.
Total_Knowledge_Pre	.118	72	.014	.975	72	.166
Total_Knowledge_Post	.203	72	.000	.875	72	.000

a. Lilliefors Significance Correction









Levene's Test of Equality of Error Variances[a]				
	F	df1	df2	Sig.
Total_Knowledge_Pre	2.015	1	70	.160
Total_Knowledge_Post	.681	1	70	.412

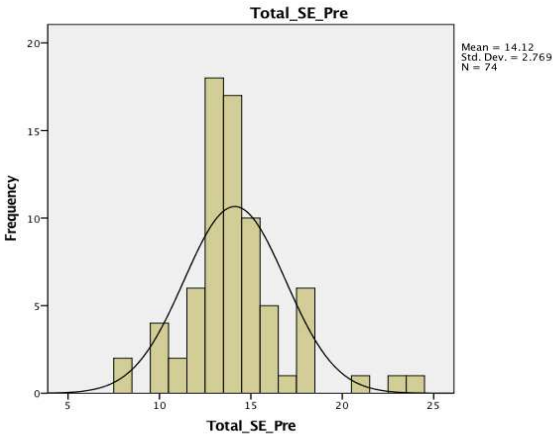
Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

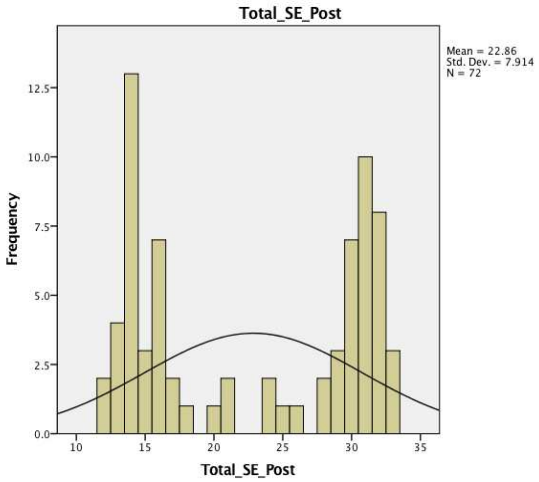
a. Design: Intercept + Age_Parents + Educa_staus + Hydroxyurea + Gender_parents + Groups
Within Subjects Design: Time

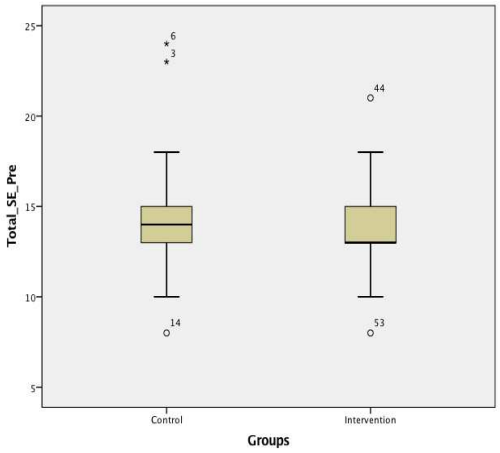
2. Outcome Measure: Self-Efficacy

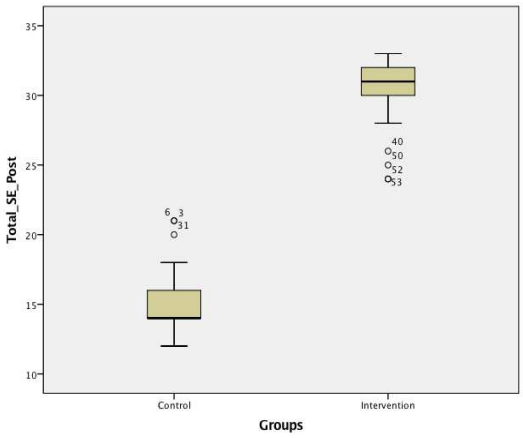
Assumption	Interpretation of the assumption	Results of analysis
Normally distributed DV, No outliers	Looking at the histogram below, the self-efficacy scores at the baseline looks normally distributed; however, Shapiro-Wilk test revealed significant (P = 0.000), which suggests that it is not normally distributed. The scores at the post test looks not normally distributed. Shapiro-Wilk test was done and revealed significant (P = 0.000). Also, the boxplot shows outliers at the baseline and post intervention for both groups.	Assumption violated
Independent Observation	The score for each participant across the 2-time period is considered independent from the previous observation.	Assumption met
Equal [error] variances across the 2 times period	Test of Equality of covariance matrices of the dependent variables across the groups reveals significant (P = 0.02). The residual covariance matrix shows that, the errors were almost equal across the 2 times period (see the table below).	Assumption not met
Sphericity	With 2 levels of repeated measures, there is no need to conduct the Mauchly's test of sphericity, the assumption of Mauchly's sphericity will be met under this situation.	Assumption met
Homogeneity of DV covariance	Levene test showed 0.66, 0.73 (>0.05).	Assumption met

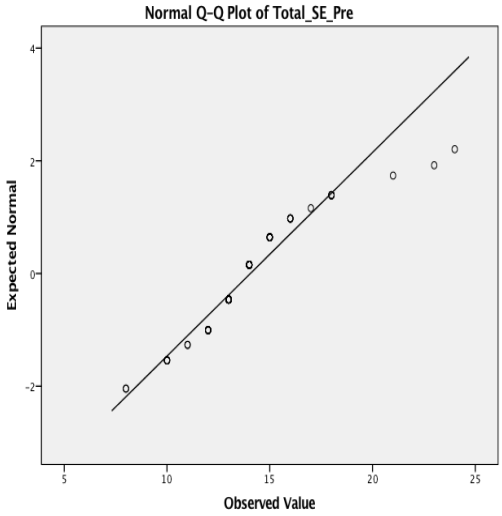
1. Assumption of Normality

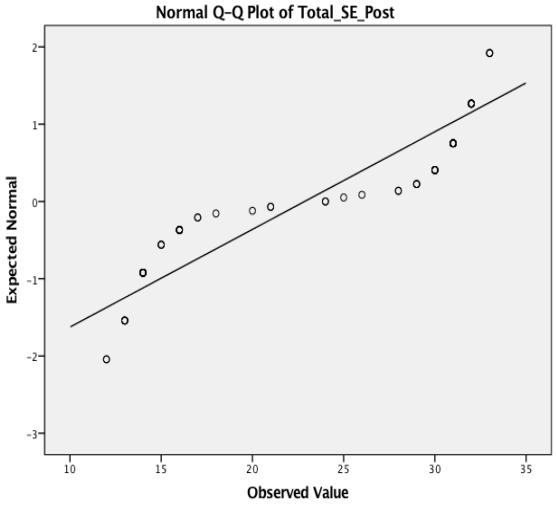












Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	Df	Sig.	Statistic	df	Sig.
Total_SE_Pre	.189	72	.000	.899	72	.000
Total_SE_Post	.212	72	.000	.815	72	.000

a. Lilliefors Significance Correction

Levene's Test of Equality of Error Variances[a]				
	F	df1	df2	Sig.
Total_SE_Pre	.192	1	70	.663
Total_SE_Post	.118	1	70	.732

Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

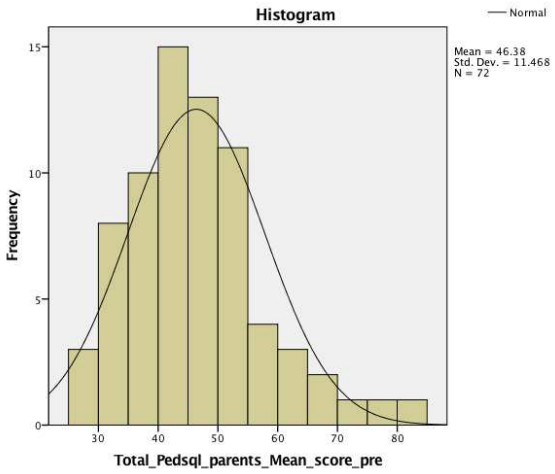
a. Design: Intercept + Age_Parents + Educa_staus + Hydroxyurea + Gender_parents + Groups
Within Subjects Design: Time

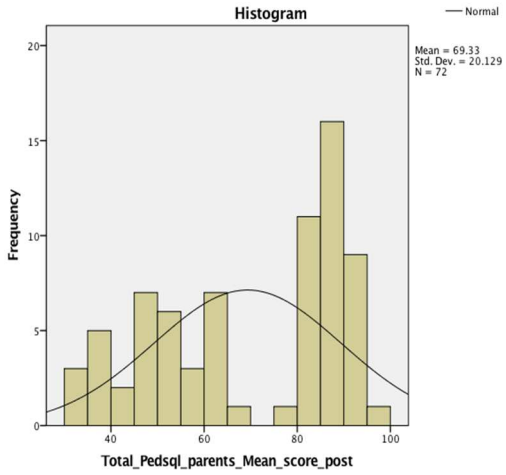
3.Outcome measure: HRQOL-GENERIC (Parents)

Assumption	Interpretation of the assumption	Results of analysis
Normally distributed DV, No outliers	Looking at the histogram below, the Pedsql scores at the baseline skewed to the right; Shapiro-Wilk test revealed significant (P = 0.009), which suggests that it is not normally distributed. The scores at the post test looks not normally distributed. Shapiro-Wilk test was done and revealed significant (P = 0.000). Also, the boxplot shows outliers at the baseline for both groups and showed no outliers at the posttest for both groups.	Assumption not met
Independent Observation	The score for each participant across the 2-time period is considered independent from the	Assumption met

	previous observation.	
Equal [error] variances across the 2 times period	Test of Equality of covariance matrices of the dependent variables across the groups reveals significant (P = 0.000). The residual covariance matrix shows that, the errors were almost equal across the 2 times period (see the table below).	Assumption not met
Sphericity	With 2 levels of repeated measures, there is no need to conduct the Mauchly's test of sphericity, the assumption of Mauchly's sphericity will be met under this situation.	Assumption met
Homogeneity of DV covariance	Levene test showed 0.66 at the baseline; which indicates the assumption is met (>0.05). However, the test revealed significant (p = 0.00) at the post test, which suggest that it is violated.	Assumption not met

1. Assumption of Normality (PedsQL_parents).

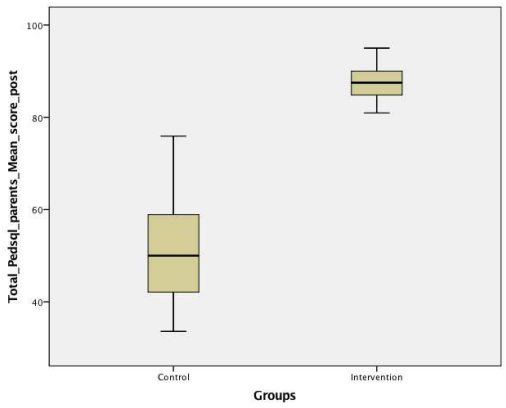


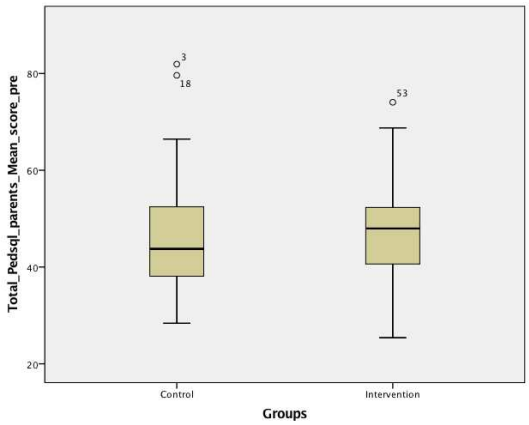


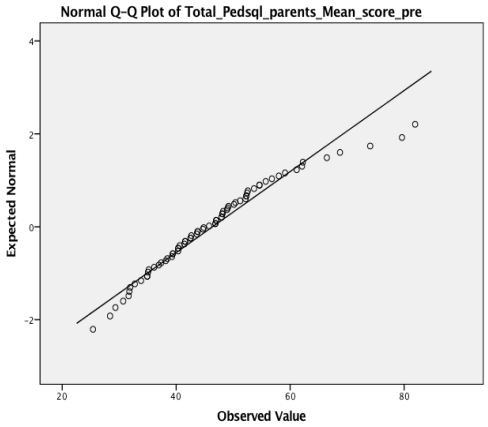
Tests of Normality

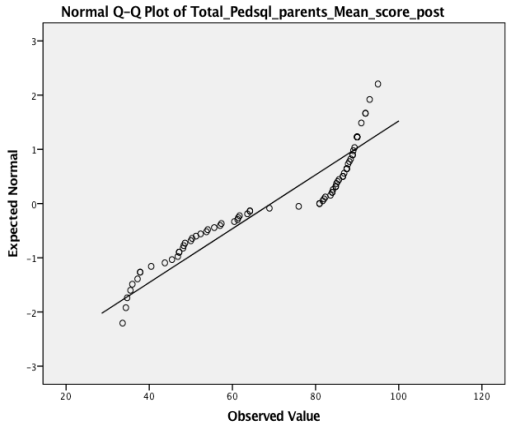
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	Df	Sig.	Statistic	df	Sig.
Total_Pedsql_parents_Mean_score_pre	.086	72	.200*	.953	72	.009
Total_Pedsql_parents_Mean_score_post	.232	72	.000	.864	72	.000

*. This is a lower bound of the true significance.
a. Lilliefors Significance Correction







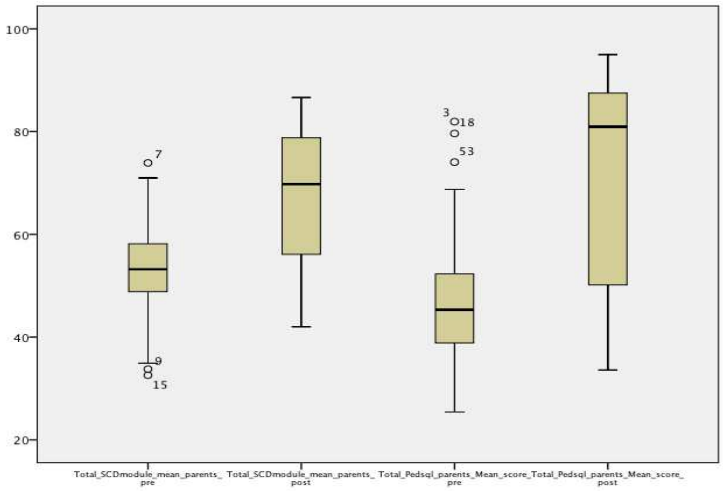


Levene's Test of Equality of Error Variances[a]

	F	df1	df2	Sig.
Total_Pedsql_parents_Mean_score_pre	.175	1	70	.677
Total_Pedsql_parents_Mean_score_post	25.200	1	70	.000

Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

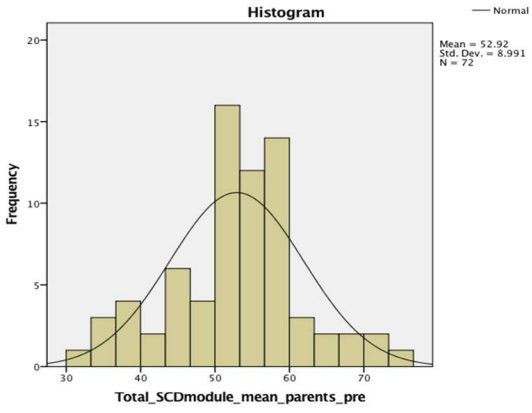
a. Design: Intercept + Educa_staus + Age_Parents + Hydroxyurea + Groups
Within Subjects Design: time

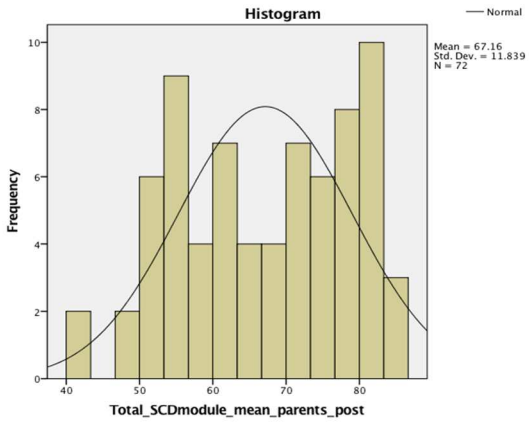


4. Outcome measure: HRQOL-SCD (Parents)

Assumption	Interpretation of the assumption	Results of analysis
Normally distributed DV, No outliers	Looking at the histogram below, the SCD_module scores at the baseline and the posttest look normally distributed. To confirm normality, Shapiro-Wilk test was run and revealed significant (P = 0.005) only at the posttest; which suggests that posttest scores are not normally distributed. Also, the boxplot shows outliers at the baseline for intervention group and at the posttest for both control group.	Assumption not met
Independent Observation	The score for each participant across the 2-time period is considered independent from the previous observation.	Assumption met
Equal [error] variances across the 2 times period	Test of Equality of covariance matrices of the dependent variables across the groups reveals significant (P = 0.000). The residual covariance matrix shows that, the errors were almost equal across the 2 times period (see the table below).	Assumption not met
Sphericity	With 2 levels of repeated measures, there is no need to conduct the Mauchly's test of sphericity, the assumption of Mauchly's sphericity will be met under this situation.	Assumption met
Homogeneity of DV covariance	Levene test showed 0.88 , 0.90 which indicates the assumption is met (>0.05).	Assumption met

1. Assumption of Normality

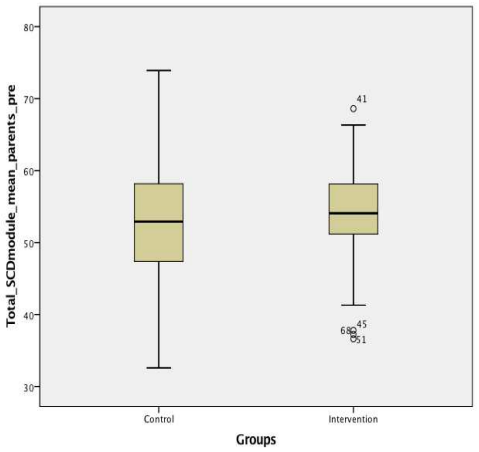


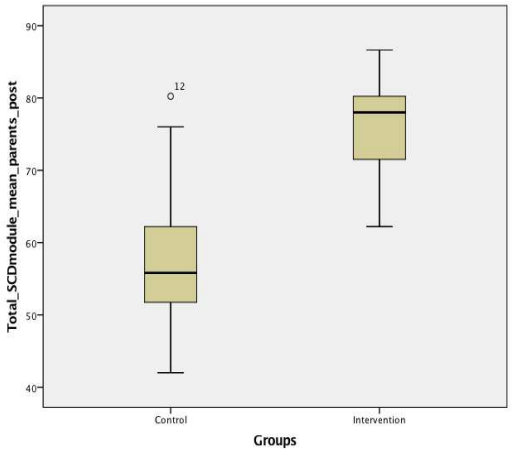


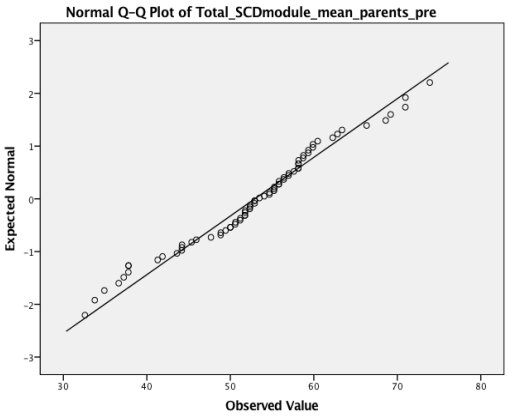
Tests of Normality						
	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	Df	Sig.	Statistic	df	Sig.
Total_SCDmodule_mean_parents_pre	.095	72	.179	.973	72	.128
Total_SCDmodule_mean_parents_post	.101	72	.066	.948	72	.005

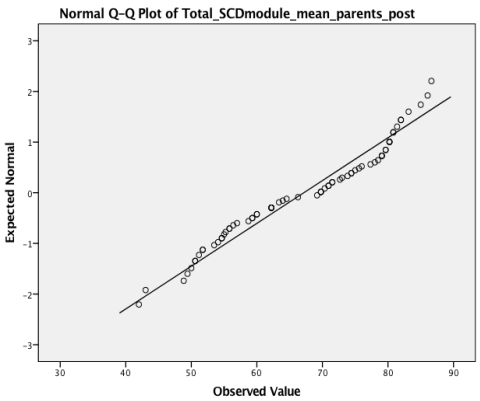
*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction









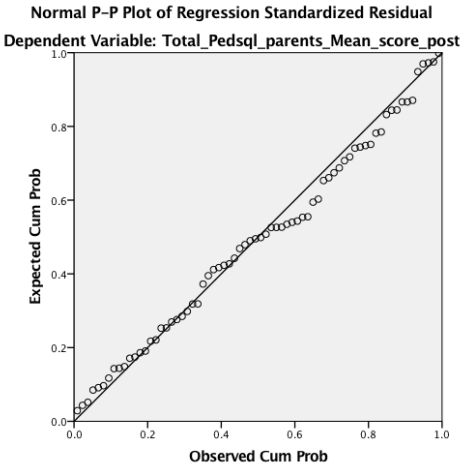
Levene's Test of Equality of Error Variances[a]				
	F	df1	df2	Sig.
Total_SCDmodule_mean_parents_pre	.021	1	70	.885
Total_SCDmodule_mean_parents_post	.016	1	70	.900

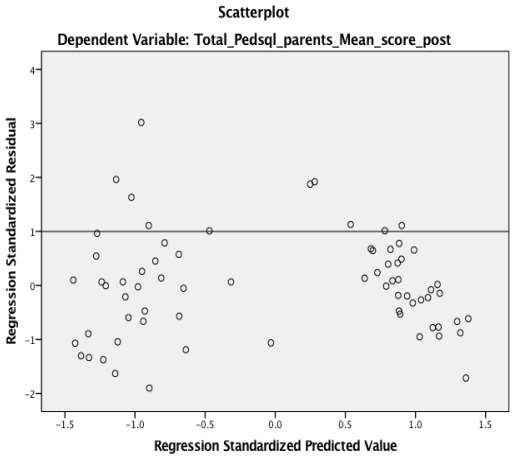
Appendix 25

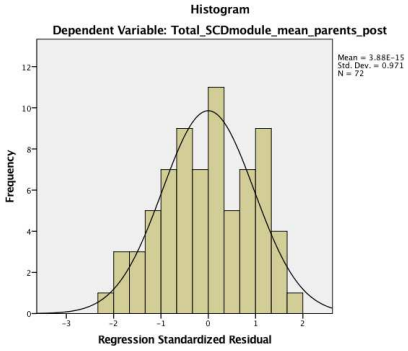
Assumptions for Linear Regression

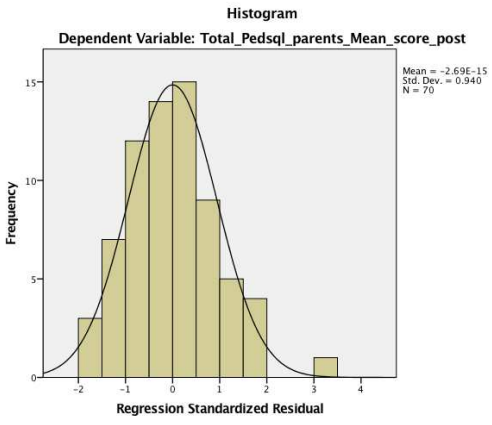
1. Outcome: SCD_Module_parents

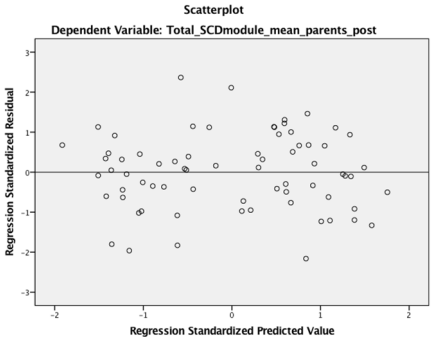
Assumptions	Interpretation of the assumption	Met or Not
Linearity	The plot of predicted vs. residuals shows that there is no pattern in the points, the points looks symmetrically distributed around the horizontal line (scattered)	Assumption met
Normality of errors	The graph represents a normal bell curve shape with no skewedness and the normal p-p plot shows that the points almost follow the line with some little outliers, so the errors are normally distributed.	Assumption met
Homoscedacity of errors	The plot of predicted vs. residuals, looks scattered and there is no pattern seen in the points.	Assumption met.
Independence of errors	Durbin-Watson =2.18 The normal must be between (1.4-2.6).	Assumption met
Multicollinearity	IVF= 1 (<10) Tolerance =1 (>0.02)	Assumption met

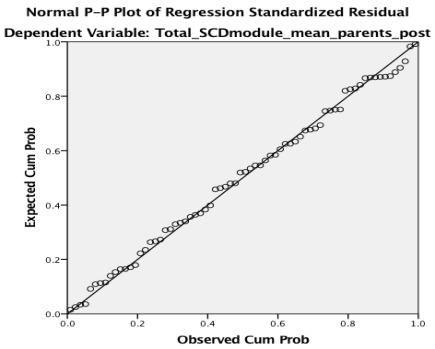












Coefficients[a]

Model	Unstandardized Coefficients		Standardized Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
	B	Std. Error	Beta	T	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1 (Constant)	36.041	5.309		6.788	.000	25.425	46.657					
Gender_Child	.435	1.538	.019	.283	.778	-2.641	3.511	-.071	.036	.018	.944	1.059
Gender_ Parents	-.960	1.717	-.041	-.559	.578	-4.392	2.473	.234	-.071	-.036	.756	1.323
Use of hydroxyurea	6.840	1.589	.290	4.304	.000	3.662	10.017	.214	.483	.274	.893	1.119
Total_SE_Post	.411	.241	.276	1.706	.093	-.071	.894	.763	.213	.109	.155	6.469
Age-parents_new	-3.093	1.840	-.115	-1.681	.098	-6.772	.586	.150	-.210	-.107	.861	1.162
age_child_new	2.576	1.589	.109	1.621	.110	-.601	5.752	.056	.203	.103	.894	1.118
Total_Knowledge_Post	1.374	.354	.637	3.882	.000	.666	2.081	.803	.445	.247	.150	6.651
Educational_status_new	-2.716	1.775	-.103	-1.530	.131	-6.265	.833	.089	-.192	-.097	.894	1.119

a. Dependent Variable: Total_SCDmodule_mean_parents_post

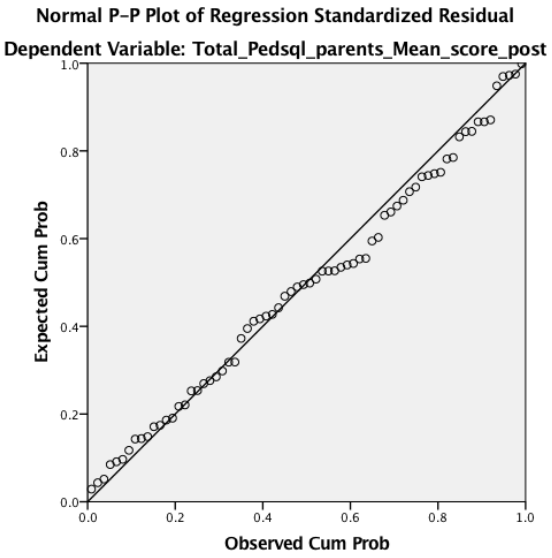
Model Summary[b]

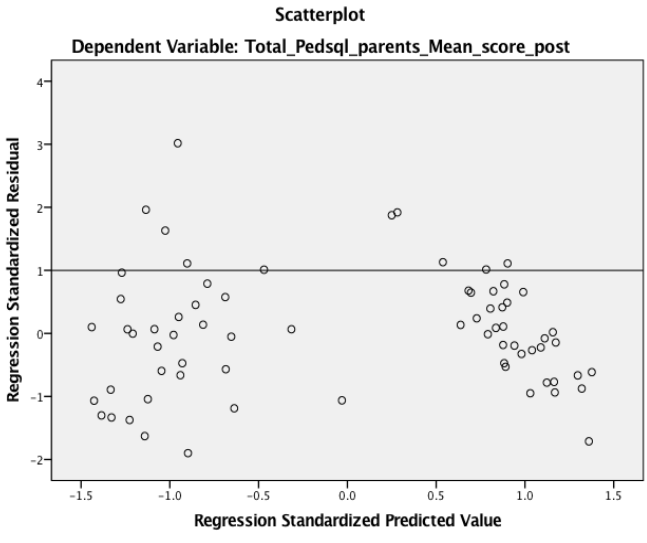
Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
1	.868[a]	.753	.720	6.243	2.185

a. Predictors: (Constant), Educational_status_new, Gender_ Parents, Age-parents_new, Gender_Child, age_child_new, Use of hydroxyurea, Total_SE_Post, Total_Knowledge_Post
b. Dependent Variable: Total_SCDmodule_mean_parents_post

Outcome: PedsQL_Parents

Assumptions	Interpretation of the assumption	Met or Not
Linearity	The plot of predicted vs. residuals shows that there is no pattern in the points, the points looks symmetrically distributed around the horizontal line (scattered)	Assumption met
Normality of errors	The graph represents a bell curve skewed to the right. the normal p-p plot shows that the points almost follow the line with some little outliers, so the errors are normally distributed.	Assumption almost met
Homoscedacity of errors	The plot of predicted vs. residuals, looks scattered and there is no pattern seen in the points.	Assumption met.
Independence of errors	Durbin-Watson =1.4 The normal must be between (1.4-2.6).	Assumption met
Multicollinearity	IVF= 1 (<10) Tolerance =1 (>0.02)	Assumption met





Coefficients[a]												
	Unstandardized Coefficients		Standardized Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
Model	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1 (Constant)	2.941	6.780		.434	.666	-10.616	16.499					
Gender_Child	2.923	1.965	.074	1.488	.142	-1.006	6.851	-.025	.187	.072	.944	1.059
Gender_ Parents	.835	2.192	.021	.381	.704	-3.548	5.219	.361	.049	.018	.756	1.323
Use of hydroxyurea	2.486	2.030	.062	1.225	.225	-1.572	6.544	-.048	.155	.059	.893	1.119
Total_SE_Post	1.749	.308	.696	5.677	.000	1.133	2.365	.908	.588	.274	.155	6.469
Age-parents_new	-.590	2.350	-.013	-.251	.803	-5.288	4.109	.256	-.032	-.012	.861	1.162
age_child_new	5.167	2.029	.130	2.547	.013	1.110	9.224	.106	.310	.123	.894	1.118
Total_Knowledge_Post	.916	.452	.252	2.028	.047	.013	1.820	.864	.251	.098	.150	6.651
Educational_status_new	-2.793	2.266	-.063	-1.232	.223	-7.325	1.739	.082	-.156	-.059	.894	1.119

a. Dependent Variable: Total_Pedsql_parents_Mean_score_post

Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
1	.926[a]	.858	.840	7.973	1.478

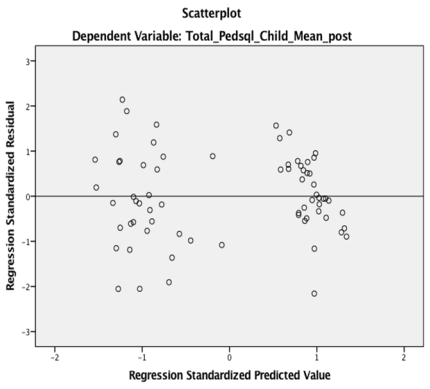
a. Predictors: (Constant), Educational_status_new, Gender_ Parents, Age-parents_new, Gender_Child, age_child_new, Use of hydroxyurea, Total_SE_Post, Total_Knowledge_Post

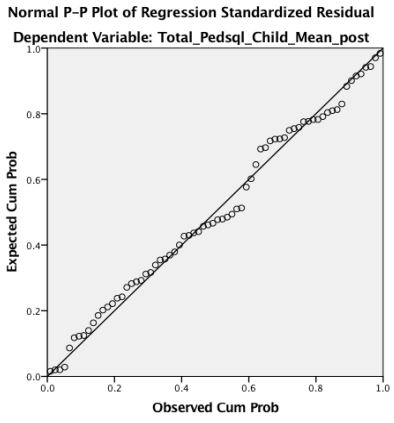
b. Dependent Variable: Total_Pedsql_parents_Mean_score_post

Model Summary[b]

Outcome: Pedsql_Child report

Assumptions	Interpretation of the assumption	Met or Not
Linearity	The plot of predicted vs. residuals shows that there is no pattern in the points, the points looks symmetrically distributed around the horizontal line (scattered)	Assumption met
Normality of errors	The graph represents a normal bell curve shape with no skewedness and the normal p-p plot shows that the points almost follow the line with some little outliers, so the errors are normally distributed.	Assumption met
Homoscedacity of errors	The plot of predicted vs. residuals, looks scattered and there is no pattern seen in the points.	Assumption met.
Independence of errors	Durbin-Watson =1.6 The normal must be between (1.4-2.6).	Assumption met
Multicollinearity	IVF= 1 (<10) Tolerance =1 (>0.02)	Assumption met





Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
1	.934[a]	.873	.857	7.218	1.636

a. Predictors: (Constant), Educational_status_new, Gender_ Parents, Age-parents_new, Gender_Child, age_child_new, Use of hydroxyurea, Total_SE_Post, Total_Knowledge_Post

b. Dependent Variable: Total_Pedsql_Child_Mean_post

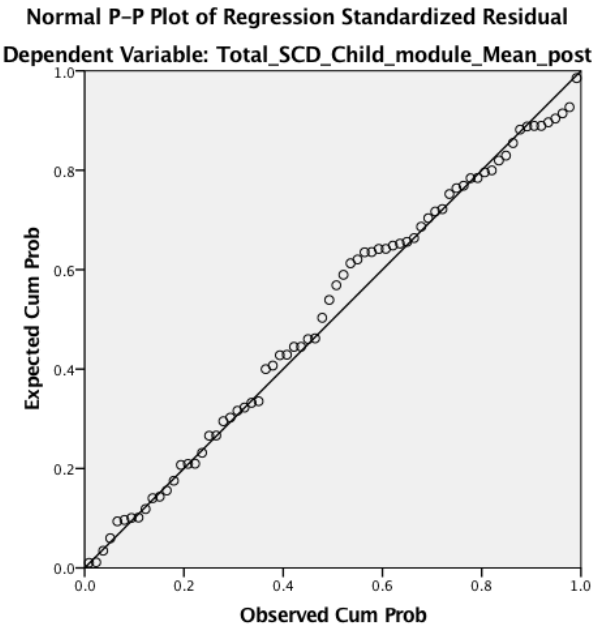
Coefficients[a]

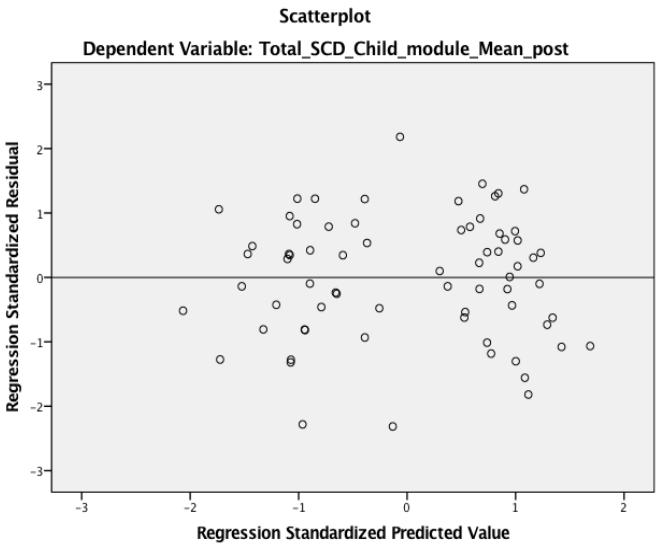
Model		Unstandardized Coefficients		Standardized Coefficients			Correlations			Collinearity Statistics	
		B	Std. Error	Beta	t	Sig.	Zero-order	Partial	Part	Tolerance	VIF
1	(Constant)	4.481	6.138		.730	.468					
	age_child_new	3.796	1.837	.100	2.067	.043	.064	.256	.094	.894	1.118
	Age-parents_new	-.660	2.127	-.015	-.310	.757	.244	-.040	-.014	.861	1.162
	Educational_status_new	-1.506	2.052	-.035	-.734	.466	.131	-.094	-.033	.894	1.119
	Gender_ Parents	.921	1.985	.024	.464	.644	.365	.059	.021	.756	1.323
	Gender_Child	2.547	1.779	.067	1.432	.157	-.024	.180	.065	.944	1.059
	Total_Knowledge_Post	1.716	.409	.493	4.194	.000	.905	.473	.191	.150	6.651
	Total_SE_Post	1.125	.279	.468	4.033	.000	.905	.459	.184	.155	6.469
	Use of hydroxyurea	2.407	1.837	.063	1.310	.195	-.033	.165	.060	.893	1.119

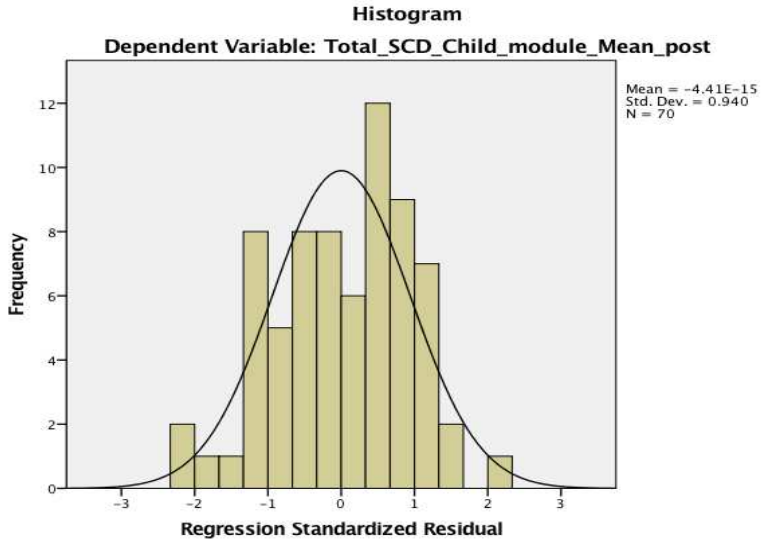
a. Dependent Variable: Total_Pedsql_Child_Mean_post

Outcome: SCD_Module_child report

Assumptions	Interpretation of the assumption	Met or Not
Linearity	The plot of predicted vs. residuals shows that there is no pattern in the points, the points looks symmetrically distributed around the horizontal line (scattered)	Assumption met
Normality of errors	The graph represents a normal bell curve shape with no skewedness and the normal p-p plot shows that the points almost follow the line with some little outliers, so the errors are normally distributed.	Assumption met
Homoscedacity of errors	The plot of predicted vs. residuals, looks scattered and there is no pattern seen in the points.	Assumption met.
Independence of errors	Durbin-Watson =1.4 The normal must be between (1.4-2.6).	Assumption met
Multicollinearity	IVF= 1 (<10) Tolerance =1 (>0.02)	Assumption met







Model Summary[b]

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Durbin-Watson
1	.892[a]	.795	.768	5.789	1.493

a. Predictors: (Constant), Use of hydroxyurea, age_child_new, Total_Knowledge_Post, Gender_Child, Educational_status_new, Age-parents_new, Gender_ Parents, Total_SE_Post

b. Dependent Variable: Total_SCD_Child_module_Mean_post

Coefficients[a]

Model	Unstandardized Coefficients		Standardized Coefficients			95.0% Confidence Interval for B		Correlations			Collinearity Statistics	
	B	Std. Error	Beta	t	Sig.	Lower Bound	Upper Bound	Zero-order	Partial	Part	Tolerance	VIF
1 (Constant)	35.064	4.923		7.122	.000	25.219	44.908					

Educational_status_new	-.986	1.646	-.037	-.599	.551	-4.277	2.304	.168	-.077	-.035	.894	1.119
age_child_new	-.031	1.473	-.001	-.021	.983	-2.976	2.915	-.062	-.003	-.001	.894	1.118
Age-parents_new	-3.531	1.706	-.129	-2.070	.043	-6.943	-.119	.106	-.256	-.120	.861	1.162
Gender_Child	1.353	1.427	.057	.948	.347	-1.500	4.205	-.018	.121	.055	.944	1.059
Gender_ Parents	.765	1.592	.032	.481	.632	-2.418	3.948	.306	.061	.028	.756	1.323
Total_SE_Post	.380	.224	.251	1.699	.094	-.067	.827	.808	.213	.098	.155	6.469
Total_Knowledge_Post	1.475	.328	.672	4.496	.000	.819	2.131	.858	.499	.261	.150	6.651
Use of hydroxyurea	5.187	1.474	.216	3.520	.001	2.240	8.134	.124	.411	.204	.893	1.119

a. Dependent Variable: Total_SCD_Child_module_Mean_post

ANOVA[a]

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	7933.381	8	991.673	29.590	.000[b]
	Residual	2044.357	61	33.514		
	Total	9977.738	69			

a. Dependent Variable: Total_SCD_Child_module_Mean_post

b. Predictors: (Constant), Use of hydroxyurea, age_child_new, Total_Knowledge_Post, Gender_Child, Educational_status_new, Age-parents_new, Gender_ Parents, Total_SE_Post

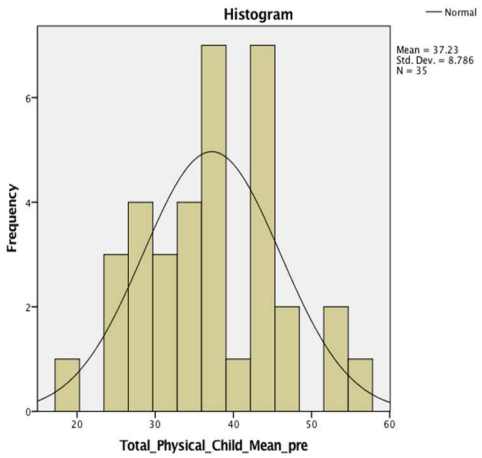
Appendix 26

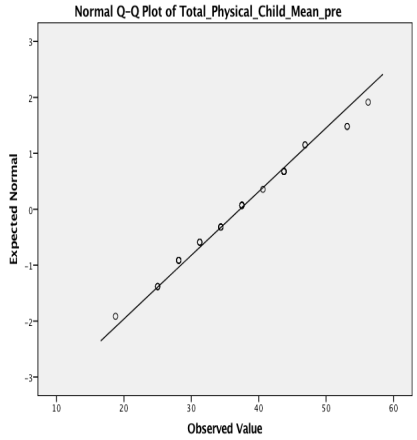
Assumptions for MANOVA

1. At the Baseline

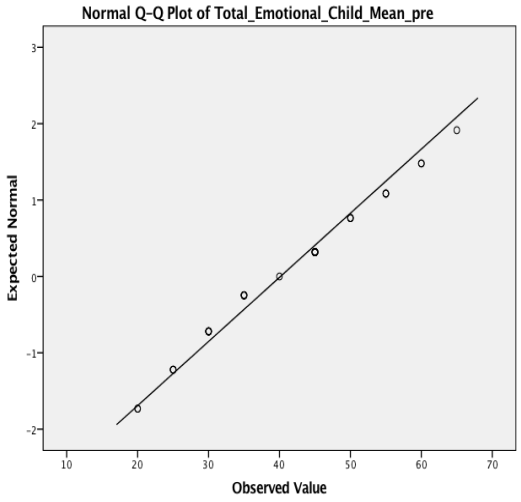
Assumption	Analysis	Results of analysis
Dependent variables	All variables are continues.	Assumption met.
Normality within groups	Looking at the histograms below, all dependent variables for both gender look normally distributed. To confirm normality, Shapiro_Wilk test was done and revealed significant for social scores (male) and cognitive scores (female). This indicates that, these two variables are not normally distributed. Also , the boxplots showed outliers for the female emotional, social and cognitive scores.	Assumption Violated for social and cognitive scores
Independence of observation	The data were independent and collected from independent sample, the data points are not paired or matched.	Assumption met.
Homogeneity of variance	Levene test, revealed not significant (>0.05). for all outcomes expect for the cognitive scores (0.02).	Assumption violated for the cognitive scores

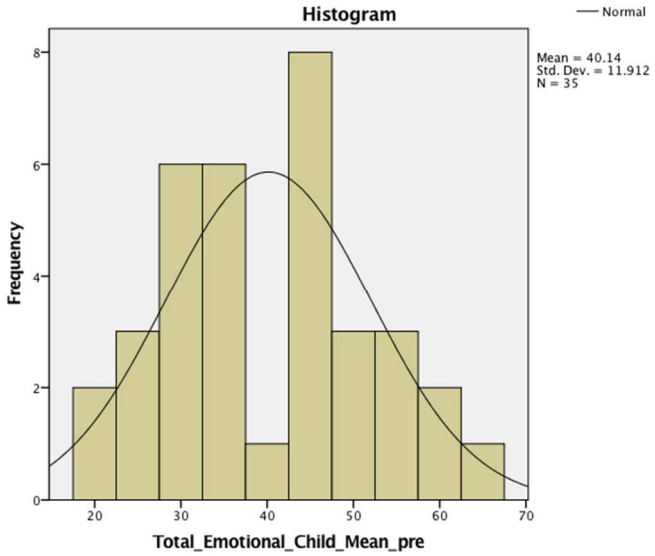
Normality: physical scores (Male)



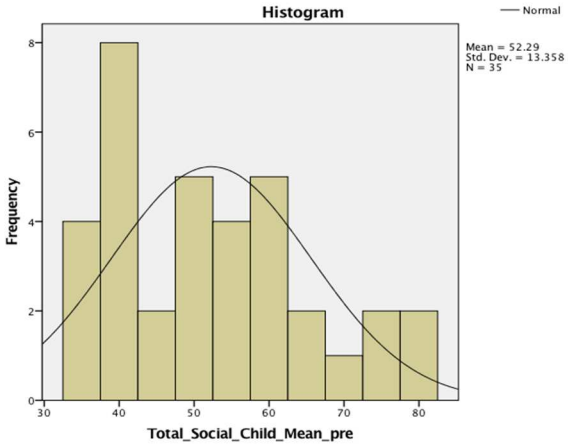


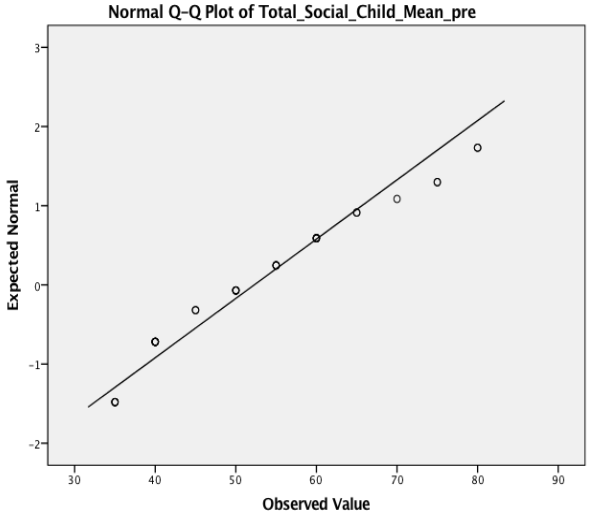
2. Emotional Scores (Male)



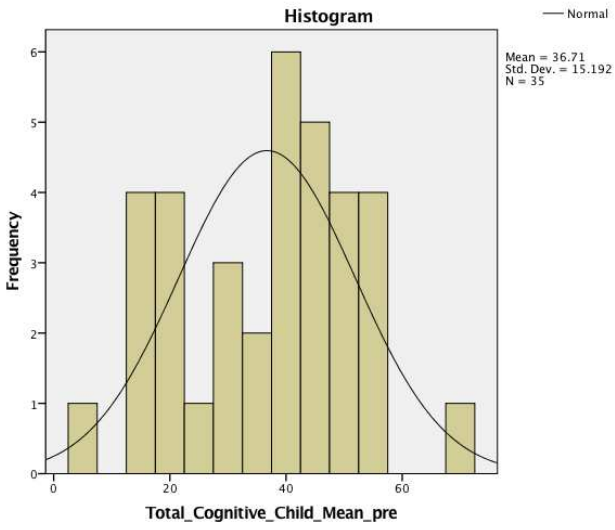


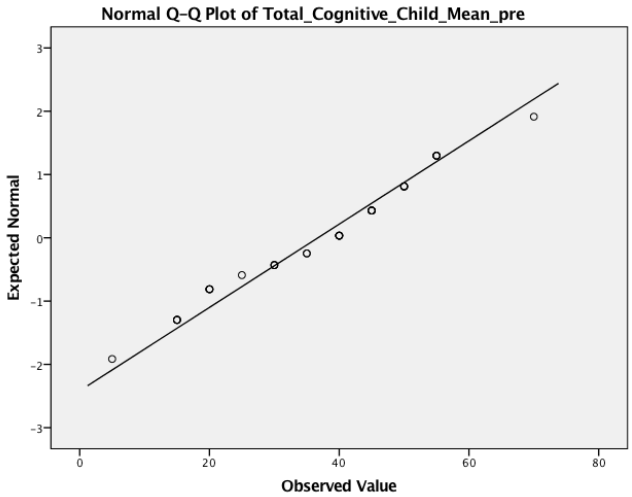
3. Social scores (Male)

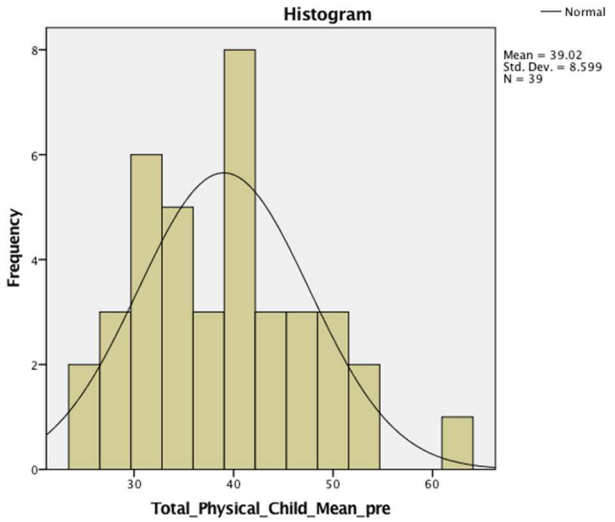


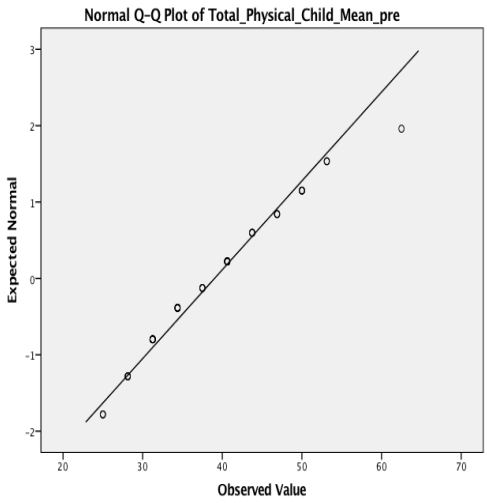


4. Cognitive scores (Male)

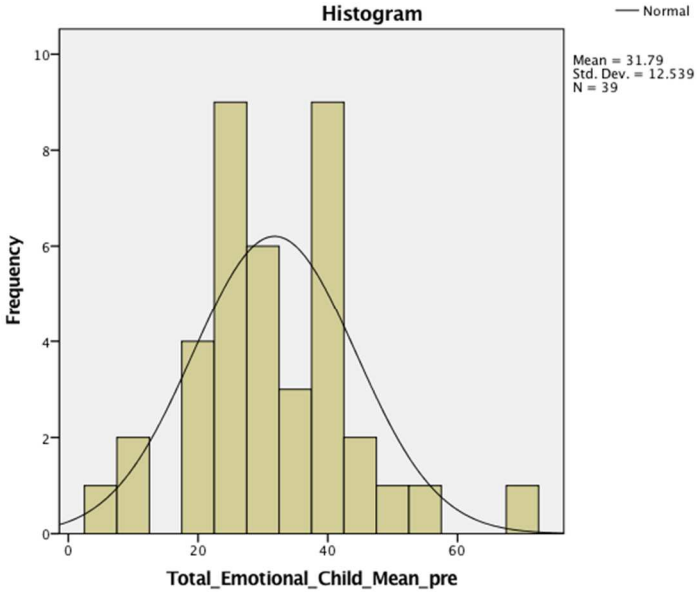


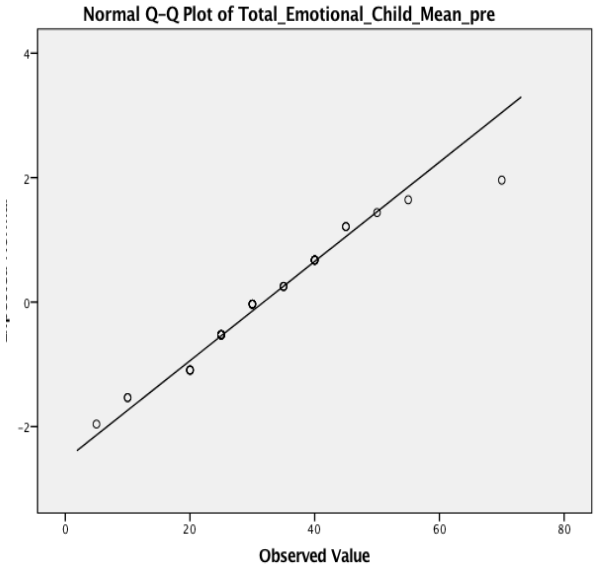




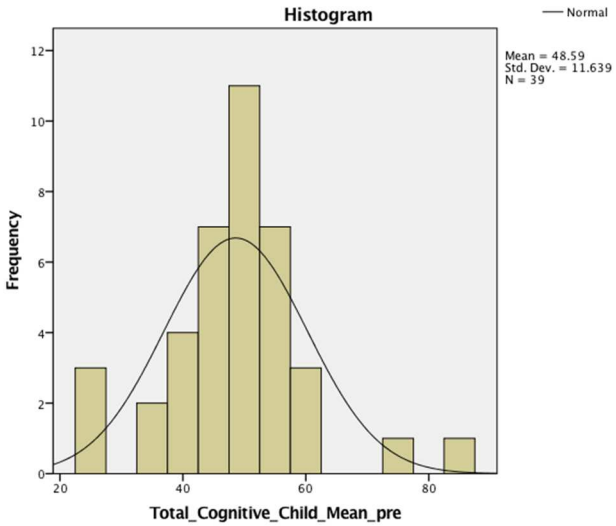


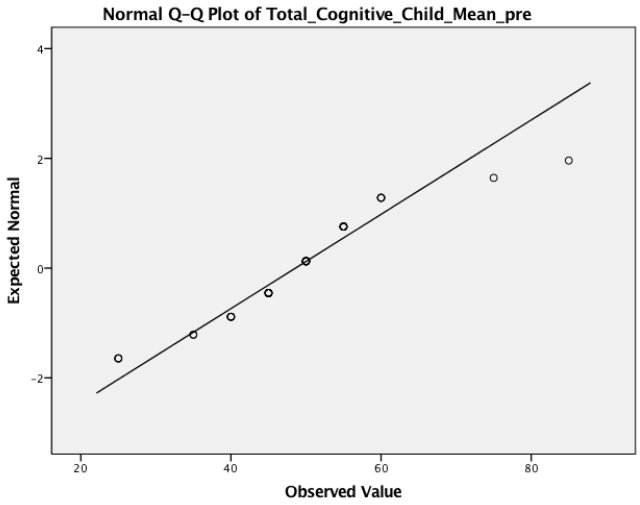
Emotional scores (Female)





Cognitive scores (Female)





Tests of Normality

		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Gender_Child	Statistic	df	Sig.	Statistic	df	Sig.
Total_Physical_Child_Mean_pre	Male	.116	35	.200*	.973	35	.537
	Female	.118	39	.183	.963	39	.220
Total_Emotional_Child_Mean_pre	Male	.153	35	.038	.958	35	.195
	Female	.128	39	.106	.953	39	.101
Total_Social_Child_Mean_pre	Male	.164	35	.018	.923	35	.018
	Female	.128	39	.107	.950	39	.084
Total_Cognitive_Child_Mean_pre	Male	.157	35	.029	.958	35	.199
	Female	.163	39	.011	.915	39	.006

*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

Test of Homogeneity of Variance

		Levene Statistic	df1	df2	Sig.
Total_Physical_Child_Mean_pre	Based on Mean	.000	1	72	.987
	Based on Median	.000	1	72	.990
	Based on Median and with adjusted df	.000	1	71.987	.990

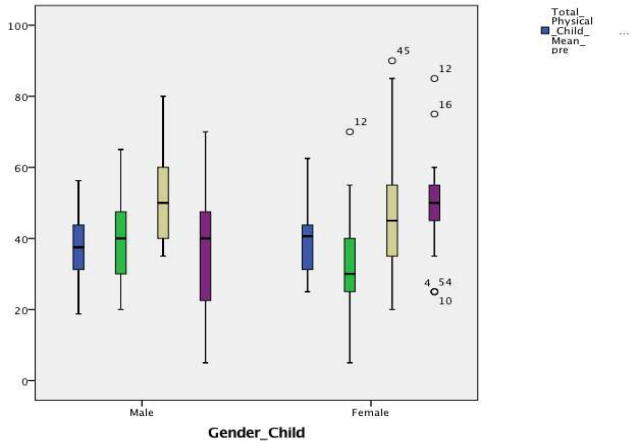
	Based on trimmed mean	.000	1	72	.993
Total_Emotional_Child_Mean_pre	Based on Mean	.070	1	72	.792
	Based on Median	.150	1	72	.700
	Based on Median and with adjusted df	.150	1	65.948	.700
	Based on trimmed mean	.083	1	72	.774
Total_Social_Child_Mean_pre	Based on Mean	.435	1	72	.512
	Based on Median	.450	1	72	.505
	Based on Median and with adjusted df	.450	1	67.394	.505
	Based on trimmed mean	.386	1	72	.536
Total_Cognitive_Child_Mean_pre	Based on Mean	5.600	1	72	.021
	Based on Median	4.203	1	72	.044
	Based on Median and with adjusted df	4.203	1	71.373	.044
	Based on trimmed mean	5.438	1	72	.023

Levene's Test of Equality of Error Variances[a]

	F	df1	df2	Sig.
Total_Physical_Child_Mean_pre	.000	1	72	.987
Total_Emotional_Child_Mean_pre	.070	1	72	.792
Total_Social_Child_Mean_pre	.435	1	72	.512
Total_Cognitive_Child_Mean_pre	5.600	1	72	.021

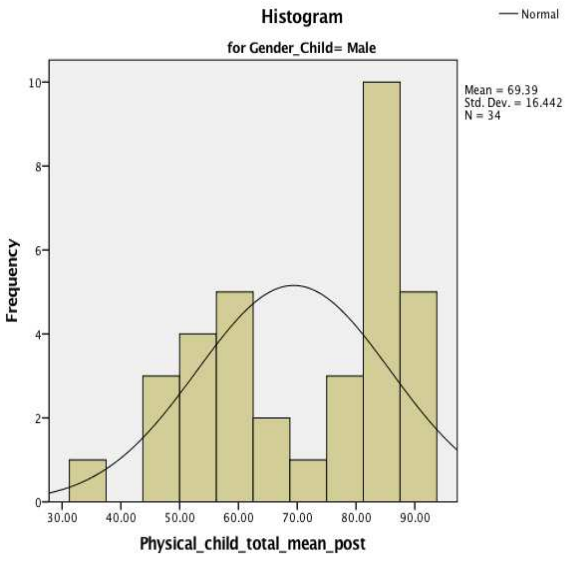
Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

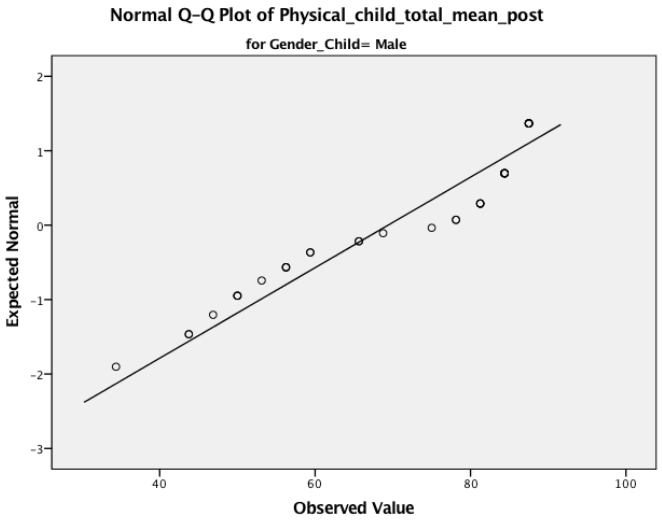
a. Design: Intercept + Gender_Child

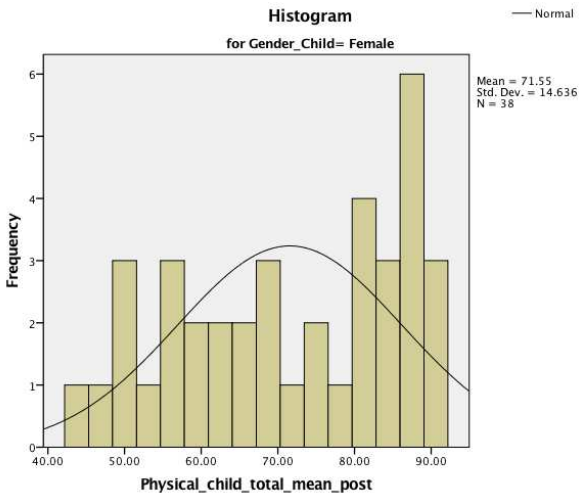


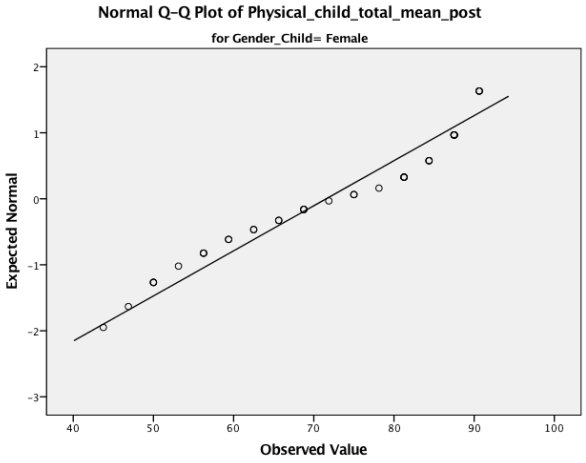
Assumption for MANOVA: Post_intervention

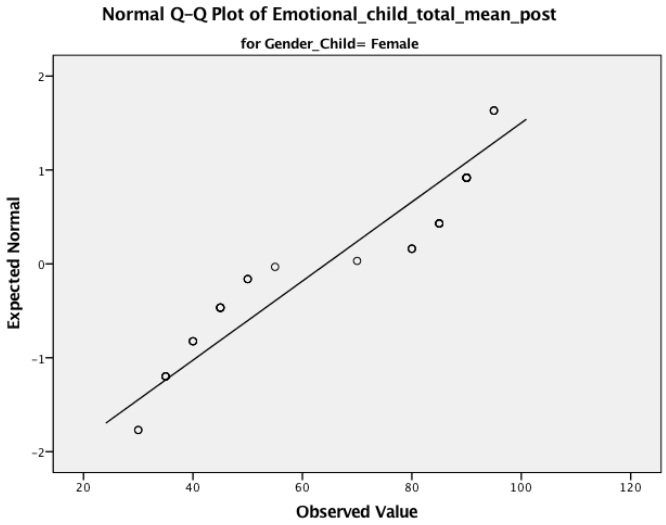
Assumption	Analysis	Results of analysis
Dependent variables	All variables are continues.	Assumption met.
Normality within groups	Looking at the histograms below, all dependent variables for both gender are not normally distributed. To confirm normality, Shapiro_Wilk test was done and revealed significant for all variables. This indicates that, these two variables are not normally distributed. Boxplot shows no outliers.	Assumption Violated
Independence of observation	The data were independent and collected from independent sample, the data points are not paired or matched.	Assumption met.
Homogeneity of variance	Levene test, revealed not significant (>0.05). for all outcomes expect for the cognitive scores (0.000).	Assumption violated for the cognitive scores

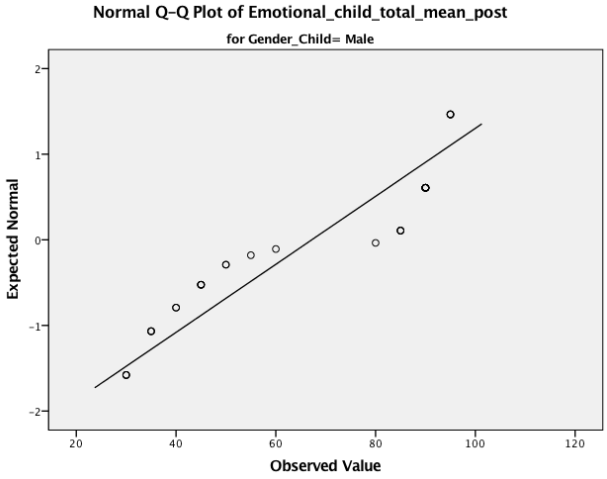












Tests of Normality

		Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Gender_Child	Statistic	df	Sig.	Statistic	df	Sig.
Physical_child_total_mean_post	Male	.206	34	.001	.878	34	.001
	Female	.167	38	.009	.918	38	.009
Emotional_child_total_mean_post	Male	.260	34	.000	.810	34	.000
	Female	.219	38	.000	.841	38	.000
Social_child_total_mean_post	Male	.239	34	.000	.877	34	.001
	Female	.228	38	.000	.889	38	.001
Cognitive_child_total_mean_post	Male	.176	34	.009	.872	34	.001
	Female	.149	38	.033	.932	38	.024

a. Lilliefors Significance Correction

Test of Homogeneity of Variance

		Levene Statistic	df1	df2	Sig.
Physical_child_total_mean_post	Based on Mean	1.452	1	70	.232
	Based on Median	.597	1	70	.442
	Based on Median and with adjusted df	.597	1	60.843	.443
	Based on trimmed mean	1.377	1	70	.245
Emotional_child_total_mean_post	Based on Mean	.704	1	70	.404
	Based on Median	.035	1	70	.853
	Based on Median and with adjusted df	.035	1	43.600	.853
	Based on trimmed mean	.660	1	70	.419
Social_child_total_mean_post	Based on Mean	.166	1	70	.685
	Based on Median	.289	1	70	.592
	Based on Median and with adjusted df	.289	1	52.175	.593
	Based on trimmed mean	.198	1	70	.658
Cognitive_child_total_mean_post	Based on Mean	16.371	1	70	.000
	Based on Median	7.805	1	70	.007
	Based on Median and with adjusted df	7.805	1	56.470	.007
	Based on trimmed mean	15.521	1	70	.000

Levene's Test of Equality of Error Variances[a]

	F	df1	df2	Sig.
Physical_child_total_mean_post	1.452	1	70	.232
Emotional_child_total_mean_post	.704	1	70	.404
Social_child_total_mean_post	.166	1	70	.685
Cognitive_child_total_mean_post	16.371	1	70	.000

Tests the null hypothesis that the error variance of the dependent variable is equal across groups.

a. Design: Intercept + Gender_Child

Appendix 27

Link to PEIP videos on google drive :

https://drive.google.com/drive/folders/1TBx7M6ifwbPP5RXpU5H_kGsIXxLB4vMy

Appendix 28

Link to PEIP material and SEP material (Booklet)

https://bit.ly/2HFAJ8O

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