

Effect of Non-pharmacological Palliative Methods Training on Sickle Cell Anemia Outcomes

Fatemeh Maniavi¹, *Shahnaz Rostami², Bijan Keikhaei Dehdezi³, Bahman Cheraghian⁴

¹Nursing Student, Faculty of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran. ²Assistant Professor of Nursing, Nursing Care Research Center in Chronic Diseases, Faculty of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran. ³Professor of Hematology and Oncology Department, Thalassemia and Hemoglobinopathy Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran. ⁴Assistant Professor, Department of Statistics and Epidemiology, School of Public Health, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran.

Abstract

Background

Drugs used by patients with sickle cell anemia to relieve pain have side effects, so the use of non-pharmacological palliative methods (such as massage, muscle relaxation, heat, drinking fluids, etc.) can be considered. We aimed to determine effect of non-pharmacological palliative methods training among adolescents with sickle cell anemia.

Materials and Methods

In this clinical trial, 60 adolescents with sickle cell anemia attending Shafa Hospital in Ahvaz, Iran, in 2018 participated. After obtaining informed consent and expressing the objective of the research, patients were randomly divided into two equal groups of intervention and control. The intervention group received three 90-minute sessions training about non-pharmacological relief methods. Both groups completed the pain care form in the 4th, 6th and 8th week after the intervention. Data was analyzed using SPSS software (version 23.0).

Results

Results showed that the mean of pain severity in the studied periods was significantly different between the two intervention and control groups ($p < 0.05$). Overall, the mean pain intensity in the intervention group in the 4th, 6th and 8th weeks after the intervention was lower than the control group ($p < 0.05$). Rate of referrals in the intervention group significantly decreased after intervention, while in the control group, it increased significantly ($p < 0.05$).

Conclusion

Based on the results, non-pharmacological palliative methods (such as respectively, massage, muscle relaxation, heat, drinking fluids, thought deviation and guided imagery), can be used as a safe method for reducing pain.

Key Words: Adolescent, Pain, Training, Sickle cell disease.

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*Corresponding Author:

Dr. Shahnaz Rostami, Assistant Professor, Department of Nursing, Nursing Care in Chronic Diseases Research Center, Faculty of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran.

Email: Rostami-sh@ajums.ac.ir

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1- INTRODUCTION

Sickle cell anemia is a chronic disease and a blood disorder in which abnormal hemoglobin in the red blood cells, cause cellular alteration to the sickle-shaped form, which results in stopping the oxygen carrier blood supply (1). It is the most common genetic blood disease in the world (2). Specifically, 1 out of 12 people carry the sickle cell gene. According to the National Heart, Lung, and Blood Institute of America, there are approximately 70,000 to 100,000 Americans with sickle cell disease (3). In Iran, and in particular in Khuzestan province, it is the most common genetic disorder after thalassemia (2). About 30% of patients referred to the Shafa hospital, Ahvaz, Iran, were patients with sickle cell and sickle thalassemia. According to the latest statistics, there are about 500 sickle cell patients in the south of Iran, especially in Khuzestan province, Iran (4).

Children with sickle cell anemia face numerous medical complications such as chronic anemia, acute chest syndrome, jaundice, organs failure, and vascular events. Complications from the disease can be severe and life-threatening and can lead to disability and mortality (1), and management of these complications may require hospitalization or treatment at home (2). The most common side effect of the disease is frequent pain attacks. Pain experience may result in the child losing the ability to eat, sleep, do routine activities, and ultimately affect their quality of life. The occurrence of pain requires treatment with narcotic drugs or a combination of narcotic and non-narcotic drugs methods. Only in this disease that is associated with the pain syndrome, does the use of narcotic drugs start from childhood and continue until adulthood (5). One of the methods to improve the quality of life of adolescents with sickle cell anemia is the use of pain relief strategies, especially in the acute phase (2).

These interventions (pain control strategies) should minimize the patient's need for medication, increase his pain tolerance, and increase the patient's ability to perform his daily activities. One of these interventions (ways to control and relieve pain) is non-pharmacological methods. In these methods, cognitive behavioral interventions, heat, cold, massage and physiotherapy are recommended. Non-pharmacological interventions are important alongside drug treatments, and accelerate the process of pain control. These strategies are safe, non-invasive with fewer complications and there is no need to be hospitalized for receiving them (6). Non-pharmacological palliative care is also inexpensive and can help to reduce pain perception, tolerate pain, reduce anxiety, and enhance the effectiveness of the analgesics or reduce the dose of the drug. Today, non-pharmacological palliative methods are emphasized as the preferred strategy, because the use of this method also reduces the use of analgesics and drugs (7).

Among these non-pharmacological palliative interventions, deviation of thought, guided imagery or mental imaging, massage and relaxation can be referred. Thought deviation includes visual deviation (such as watching television, guided mental imagery), audio deviation (such as listening to music and joking), touch types (such as massage, soft and gentle breathing, using toys), mental types (such as crosswords and puzzles, playing cards, collecting stamps, using a bubble maker and writing stories). Deviation causes one to focus on the stimulus rather than on pain (8). Non-pharmacological palliative treatments for this disease in internal and external studies refer to methods such as deviation of thought (9), mental imagery (8), guided imagery (10), progressive muscle relaxation (11), and massage therapy (12).

Patients with sickle cell anemia expressed their experiences, during the onset of pain, parents ask them to stay home and manage their pain, so it is very important to educate these people and their families for caring about illness and pain (2). Since pain is such a complex phenomenon, learning about its relief methods must be undertaken in several ways, nowadays integration of several methods are used to achieve better results. Therefore, in order to teach the desired relief strategies, it is better to use combination training methods (13). Combined training is in fact a combination of methods that helps to increase the efficiency and effectiveness of educational content, and it uses various methods such as group training, face to face and virtual education, question and answer, lecture and presentation of compact discs, educational booklet or pamphlets (14).

Various researches have been conducted on the effect of each non-pharmacological reliever on pain relief in patients with sickle cell, but for the use of several non-pharmacological palliative methods and giving patients suffering from sickle cell disease the right to choose a method for its effect on the severity of pain no studies were found. Therefore, due to the lack of research or information about this title in the world, Iran and especially in Khuzestan (Iran), and due to the high prevalence of this disease in Khuzestan province and repeated referral of patients to the hospital because of pain due to illness and high complications of long-term use of analgesic drugs and non-steroidal anti-inflammatory drugs (NSAIDs), we conducted a research to determine the effect of teaching non-pharmacological palliative methods on pain intensity and referral to hospital visits (due to pain attacks) in adolescents with sickle cell.

2- MATERIALS AND METHODS

2-1. Study design and population

In this randomized clinical trial study (IRCT20180128038531N1), 60 adolescents with sickle cell anemia aged 12 to 19 years old referring to Shafa Hospital, Ahvaz, Iran (in 2018), participated. After obtaining permission from Ahvaz Jundishapur University of Medical Sciences, samples were selected based on inclusion criteria that included: having no other acute and chronic physical and mental illnesses, having no mental or emotional disorder, being alert to answering the questions of questionnaire, having the history of repeated and frequent visits to the clinic or admission to the hospital due to pain (at least once a year), no history of receiving education about pain management, using only oral non narcotics such as Acetaminophen or Ibuprofen. Patients with sickle cell anemia with an infection that exacerbated pain were excluded.

Initially, the research goals and the confidentiality of information about them and the right to withdraw from the study at any time, and other ethical codes of conduct were explained to the subjects. Then written consent was taken from children with sickle cell anemia and their parents. In order to determine the sample size, the formula used for comparison of the meanings was used with $\beta = 0.01$, $\alpha = 1.0$ and based on the results of previous studies (15), and $X_1 = 8.34$, $X_2 = 9.50$, $S_1 = 1.23$, $S_2 = 0.56$. The sample size was equal to the two groups of 22, which, with a 25% probability of dropping during the study, sample size ultimately reached 30 for each group (totally 60). In order to determine the sample size based on the researches, pain was estimated at a high level.

2-2. Measures

2-2-1. Demographic and Clinical Questionnaire

The tools used in this study were: Demographic and Clinical questionnaire and self-pain assessment using Visual Analog Scale (VAS), and Weekly Checklist for Pain Evaluation (Pain Care). The demographic questionnaire included four sections; the first part contains the patient's individual characteristics (age, gender, educational level, type of sickle cell disease, ethnicity, place of residence, contact number, family type); the second part includes clinical information related to the disease (history of chronic diseases such as kidney, heart, and respiratory tract disease, asthma, number of visits to outpatient clinic due to pain per year, frequency of hospitalization due to pain per year, date of last hospitalization, interval between hospitalization period, type of medication used), the third part contains the history of vaccination and blood transfusion (history of vaccination according to country routine, history of specific vaccination against hepatitis, meningococcal, influenza, history of blood transfusion, etc.); and the fourth part includes a history of receiving pain education and information resources. In order to determine the scientific validity, a demographic information questionnaire was provided to 10 faculty members of the Faculty of Nursing and Midwifery of Jundishapur University of Medical Sciences (Ahvaz, Iran), and after applying corrective comments the questionnaire was given to adolescents.

2-2-2. Visual Analog Scale (VAS)

This tool is a 10 cm ruler, the left side of which has the number zero, indicating no pain and the right side has 10, indicating a very severe and intolerable pain. A score of 1-3 indicates mild pain, 4-6 moderate pain and 7-9 indicates severe pain and a score of 10 indicates very severe pain. Pain information is measured using this tool. The pain scale has been widely used in

pain-related research and its validity and reliability have been repeatedly confirmed (16, 17).

2-2-3. Pain Evaluation weekly checklist (Pain Care)

This form includes information such as the time of pain onset, pain score (visual analog scale assessment), pain relief actions (including drug and non-pharmacological actions), and the time of relief of pain or referral to a clinic or hospital. Validity of weekly checklist for pain evaluation was obtained through content validity ratio (CVR) and content validity index (CVI). CVR items were 0.9 and CVI items were kept up to 0.9. In order to measure the reliability of the questionnaire, the t-test and retest methods (pretest/post-test) were used (18, 19).

2-3. Procedures

The researcher explained how to complete the questionnaire of demographic and clinical information and the pain assessment method using the visual analog scale and how to record it weekly in the form of pain evaluation (care), and then asked participants to complete the pain evaluation (care) form for 4 weeks and give them back to the researcher. In the next step, the training sessions for the intervention group were arranged.

2-4. Intervention

Meetings (training sessions) were held in the hall of the hospital clinic. Subjects in the intervention group were invited to attend educational sessions according to schedules. At the first session, subjects (intervention group) were provided with explanations on how the training sessions were taught and implemented. In order to understand the patient's perception of the illness, the discussion was conducted through questioning and then the educational needs of the intervention group were determined. During the second session, educational materials (provided by

research team) about the sickle cell, the mechanism of initiation of pain, causes, complications and problems associated with it, effective factors in the occurrence and exacerbation of pain such as stress, anger, smoking, etc., pain control methods (pharmaceutical and non-pharmacological) were presented with group lecture method using slides or face-to-face presentation. In the third session, the training was focused on learning a variety of non-pharmacological methods for pain control such as muscle relaxation (progressive muscle or abdominal respiration), thought deviation (visual, auditory, mental and tactile), massage (light stroke), heat, drinking fluids, guided imagery, and so on. In third session educational videos and practical exercises of that technique were used to train the subjects and techniques (**Table.1**). Teaching the above techniques to the participants and in the presence of parents/companions was done using slides and practical exercises. Participants were allowed to use any of the techniques or a combination of several techniques of their choice to relieve pain at the time of its occurrence. The method of surface stroke massage was taught to the researcher by a physiotherapist. A family member (father-mother-brother or sister) accompanied him/her for learning the massage. During this session, the weekly pain evaluation checklist, which was described as part of

the presentation of the training material, was provided to the subjects (intervention group). Each training session was held for 90 min and a time was considered for questions and answers at the end of each training session, and educational content was reviewed by having the subjects repeat them. At the end of the third session, a re-examination of the knowledge level of the intervention group was carried out to ensure learning of the topics. The participants of intervention group were asked to practice and repeat techniques daily and use them at the time of pain, then record their pain information (date and time, pain start hour, severity of pain, type of drug, type of non-pharmacological relief, pain reduction hour, referral to a clinic or hospital) in a pain care form. To minimize the possibility of transferring information between the two study groups, the program of training sessions was held on different days. Pain care checklist was completed at the intervals of 4, 6 and 8 weeks after the end of the training sessions of the intervention group, by the two groups (control and intervention), and were returned to the researcher. At the end of the study, educational materials were provided to the control group as a booklet. Subjects in the intervention group were also allowed to use oral painkiller medications such as Acetaminophen and Ibuprofen.

Table- 1: Timetable and educational contents for participants.

Subjects	Content	Teacher	Time
30 adolescents with sickle cell anemia	The first session described how to train and identify educational needs.	Researcher with the help of a hematologist (from research team)	90 min
	The second session: 1. Provided educational materials on the sickle cell anemia 2. The mechanism of initiation of pain, the causes, complications, the factors affecting the occurrence and exacerbation of pain such as stress, anger, smoking, etc. 3. Pain palliative methods (pharmacological and non-pharmacological).		
	The third session: taught the use of non-pharmacological pain control methods such as: 1. Muscle relaxation (progressive muscle or abdominal respiration) 2. Thought distraction (visual, auditory, mental and tactile) 3. Guided imagery 4. Massage (superficial stroke) 5. Heat 6. Drinking fluids.		

Meeting Place: Educational healing center of Shafa hospital, Ahvaz, Iran.

2-5. Assurance of procedural consistency and integrity

The researcher allowed the subjects to telephone for any question, ambiguity or current problem and, if necessary, refer to the clinic of Shafa Hospital for further guidance. The instruction booklet was given to the intervention group at the end of the training sessions; educational materials were provided to the intervention group as a booklet (practical-theory). In order to ensure the implementation of techniques and to complete the pain care checklist, the researcher was in contact with participants by calling and sending messages (cell phone).

2-6. Ethical consideration

This study was approved by the Ethics Committee for Medical/Health Research, Faculty of Nursing and Midwifery, Ahvaz Jundishapur University of Medical Sciences, Shafa Hospital/Shafa Clinic. Adolescents with sickle cell disease and their parents provided written consent.

2-7. Data analysis plan

To analyze the data, firstly, statistical methods such as frequency distribution tables, central and appropriate dispersion indicators such as mean and standard deviation (SD) were used to describe the variables studied. Normality of quantitative data was checked by Kolmogorov-Smirnov test. The relationship between qualitative variables was investigated using Chi-square test. Comparison of changes in quantitative variables in each group was performed using paired t-test and between two groups with independent t-test with nonparametric equivalents. To compare pain severity in the two groups of study in the 4 weeks before and 4, 6 and 8 weeks after the intervention Greenhouse-Geisser test was used. If needed, covariance analysis was used to control potential confounding factors. The significance level of the tests

was considered to be less than 0.05. Data analysis was performed with SPSS software version 23.0.

3- RESULTS

In this study, 60 adolescents with sickle cell participated. Participants were 43.3% (n=13) female and 56.7% (n=17) male in the intervention group, 50% (n=15) male and 50% (n=15) female in the control group. Subjects at least 12 years and at most 19 years old were divided into two groups: intervention (n=30) and control (n=30) groups. All subjects were Arab. In this study, Chi-square test was used to compare the frequency distribution of gender, marital status, education, occupation and ethnicity between intervention and control groups, which was not statistically significant between the two groups in terms of demographic variables with ($p>0.05$). Therefore, the two groups were homogeneous and comparable from demographic data (**Table.2**).

The mean age of subjects in the intervention group and control group was 16.83 ± 2.79 and 15.87 ± 3.04 years, respectively. The mean number of family members in the intervention group was 5.72 ± 1.57 and in the control group was 5.83 ± 1.48 , there was no significant difference between the two groups using independent t-test ($p> 0.05$). None of the members of the two groups had any other chronic diseases. 45% (n=27) of participants had a history of blood transfusion. Among the subjects in this study, 25 % (n=15) had a history of receiving pain relief training, and 75 % (n=45) had not received any training. To compare the mean pain intensity before and 4, 6, and 8 weeks after intervention in both intervention and control groups, the Greenhouse-Geisser test was used. The severity of pain in the intervention group was different from that of the control group (**Table.3**). This Table shows that the mean of pain severity during the studied

periods has a significant difference between the two intervention and control groups ($p < 0.001$) and in general, the mean

pain intensity in the intervention group was lower than the control group ($p = 0.004$).

Table-2: Relative frequency distribution and percentage of studied units based on demographic characteristics in two groups of intervention and control

Variables		Group		Total Frequency (%)	P-value (Chi-square test)
		Intervention	Control		
		Frequency (%)	Frequency (%)		
Gender	Male	17 (56.7)	15 (50)	32 (53.3)	0.61
	Female	13 (43.3)	15 (50)	28 (46.7)	
Marital status	Single	27 (90)	30 (100)	57 (95)	0.24
	Married	3 (10)	0	3 (5)	
Education	Primary	6 (20)	1 (3.3)	7 (11.7)	0.26
	Junior high school	4 (13.3)	12 (40)	16 (26.7)	
	High school	11 (36.7)	6 (20)	17 (28.3)	
	Diploma	9 (30)	11 (36.7)	20 (33.3)	
Occupation	Student	14 (46.7)	18 (60)	32 (53.3)	0.21
	Employed/ student	1 (2.3)	0 (0)	1 (1.7)	
	Employed	3 (10)	0 (0)	3 (5)	
	Unemployed	12 (40)	12 (40)	24 (40)	
Ethnicity	Arab	30 (100)	30 (100)	60 (100)	0.999
	Non -Arab	0	0	0	

Table-3: Comparison of mean of pain severity of the units under study before and after intervention in two groups

Time	Group		P-value
	Intervention	Control	
4 weeks before intervention	0.95±0.33	0.50±0.24	<0.001
4 weeks after intervention	0.20±0.12	0.58±0.20	<0.001
6 weeks after intervention	0.25±0.18	0.50±0.53	<0.001
8 weeks after intervention	0.14±0.20	0.41±0.40	<0.001
P-value, (Greenhouse-Geisser test)	P=0.004		

(A score of 1-3 represents mild pain, 4-6 moderate pain and 7-9 indicates severe pain and a score of 10 indicates a very severe pain); total score of pain= 10.

To compare the mean of referrals before and after intervention in intervention and control group, paired t-test was used. There was a significant difference between the mean of referrals before and after the intervention in both groups ($p < 0.001$). However, the rate of referrals significantly decreased after intervention in the intervention group ($p < 0.001$), while in the control group, this increased significantly ($p = 0.001$) (**Table.4**). In order to investigate the effect of intervention, the comparison of mean of pain intensity

changes and the number of referrals between intervention and control groups was performed using independent t-test. There was a significant difference in pain score scores between the two groups, so that in the intervention group, mean scores of pain reduced more than that of control group ($p < 0.001$) (**Table.5**). Pain severity changes were significantly different between the two groups, so that in the intervention group, the severity of pain scores decreased more than the control group ($p < 0.001$).

Table-4: Comparison of mean of referrals before and after intervention in two groups of participants

Variable	Statistic	Intervention		Control		*P-value
		Before intervention	After intervention	Before intervention	After intervention	
Rate of referrals	Mean ± SD	0.24±0.20	0.02±0.06	0.06±0.11	0.14±0.05	<0.001
	P-value	<0.001		0.001		

SD: Standard deviation, *Paired t-test.

Table-5: Comparison of the mean of pain severity and the referral rate before and after intervention between the two groups

Difference	Intervention Mean ± SD	Control Mean ± SD	P-value (independent t-test)
Pain severity	-0.74±0.30	-0.003±0.3	<0.001
Referral rate	-0.22±0.16	0.07±0.11	<0.001

SD: Standard deviation.

4- DISCUSSION

This study was conducted to determine the effect of non-pharmacological palliative methods training on the severity of pain and the number of visits in adolescents with sickle cell anemia. According to the results of this study, following the training of non-pharmacological palliative care methods (massage, muscle relaxation, heat, and drinking fluids thought deviation and guide imagery), the severity of pain and the number of referrals in the intervention group decreased. Non-pharmacological palliation methods reduced the severity of pain and the number of referrals in intervention group. This findings are indicative of the positive effect of these non-pharmacological palliation methods (p<0.001). These results were consistent with the study of Shaban et al. (2011) about the effect of two non-pharmacological methods (progressive muscle relaxation and music therapy) on the pain rate in cancer patients. In addition, Shaban et al.'s study showed that there was a significant difference between the two groups after the intervention regarding the intensity of pain in each group of the

relaxation and music therapy at the time (18). Sinha et al. (2013), also showed that the use of non-pharmacological methods such as deviation of thought reduces the amount of pain caused by wound sutures in children (19). The study of Thomas et al. (2013), about therapeutic touch showed non-pharmacological methods such as therapeutic touch only on the fourth day after intervention significantly reduced the pain intensity of patients with sickle cell anemia with acute pain in the intervention group compared with the control group (p = 0.031) (20), which in this regard, only on the fourth day after intervention is consistent with the present study.

In justifying the differences in the results of study of Thomas et al. with our study, the research community and non-pharmacological relief methods can be mentioned. In the Thomas et al. study, non-pharmacological methods such as massage were used by parents on children, while in our study, several non-pharmacological palliation methods such as muscle relaxation, thought deviation, heat, drinking fluids, mental imaging, etc. were used simultaneously (20).

Elia Dobson et al. studied the effect of mental imaging on perception of pain and the rate of use of painkillers in children with sickle cell. Findings of Elia Dobson et al.'s study showed that the mean of frequency of pain onset in one month before intervention was significantly different compared to after intervention ($p=0.03$). The severity of pain before and after intervention was also significantly different ($p=0.00$). Participants were allowed to use painkillers such as acetaminophen and ibuprofen. The results of Elia Dobson et al.'s study are consistent with the results of our study (21). In Bagherian et al.'s study (2012), non-pharmacological palliative methods such as bubbling and regular breathing exercises were used to reduce the pain intensity of injectable procedures in children with thalassemia. The positive effect of using these two methods on pain reduction was shown, which corresponded to the results of our study (22).

In adolescents with sickle cell anemia, the pain crisis has been reported as one of the most common complications that is a major cause of hospitalization. Pain usually occurs 1 to 15 times a year, and it resolves in most patients during about 5-7 days, but it may take several weeks to several months in some patients. Pain affects the quality of life and social functioning in these patients. Therefore, the control of pain in patients with sickle cell anemia is an important nursing care and non-pharmacological methods can be used to relieve it in order to reduce complications and costs (11, 12). On the other hand, the results our study showed that there was a significant difference between the mean number of referrals in the intervention group before and after the intervention ($p < 0.001$), so that the referral rates in the intervention group significantly decreased after the intervention, while in the control group it increased significantly. Therefore, it is concluded that the teaching

of non-pharmacological palliation methods (respectively massage, muscle relaxation, heat, drinking fluids thought deviation and guided imagery) has significantly changed the number of referrals in adolescents with sickle cell anemia. The results of our study are consistent with the study of Laal et al. (2017) about the effect of training and follow-up after the discharge of patients with heart failure in re-attending to physician and hospitalization. In the Laal et al.'s study, the findings showed that there was a significant difference between the case and control groups in terms of outpatient visits, meaning that the number of referrals in the case group after the intervention was less than that of the control group (23).

In the study of Gharaati and colleagues (2017) about effect of educational intervention by telephone along with self-care behaviors in patients with major thalassemia, it was shown that there was no significant difference in the rate of referrals between intervention and control group after the educational intervention via mobile phone in patients with major thalassemia ($p=0.39$). After intervention, the rate of referral to the hospital increased significantly in the intervention group (24), hence, one of the reasons for the inconsistency of the results of that study with the present study may be the difference in the teaching method.

Forouzesh and colleagues (2017) reported that telephone follow-up on the number of visits due to complications for post-operative coronary artery bypass graft in the intervention group was lower than the control group ($p < 0.001$) (25). In our study, the rate of referrals due to pain after the intervention and continuous follow up of the researcher in the intervention group was significantly decreased and the result of the study was consistent. A study by Winter et al. (2015) showed that the pain and the number of referrals in the intervention group using a non-

pharmacological reliever (music therapy) was significantly lower than the control group (26). The findings of our study in pain severity and the number of referrals were consistent with the results of Winter et al.'s study.

5- CONCLUSION

The findings of this study showed that the use of non-pharmacological palliative methods (such as massage, muscle relaxation, heat, drinking fluids thought deviation and guided imagery, respectively) can be effective as a safe and non-invasive method to reduce pain, need for painkiller use and the number of visits of patients with sickle cell; so it is recommended that nurses use this non-pharmacological approach to relieve pain in patients with acute and chronic pain.

6- CONFLICT OF INTEREST: None.

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