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Effect of Foot Reflexology on Pain and Fatigue Levels Regarding Insulin Injection among Diabetic Children

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ABSTRACT

Background: Pain and fatigue are common side effects of insulin injections. Foot reflexology is a complementary therapy gaining popularity and acceptance since it seems to help with pain and weariness. **Methods:** This research aimed to evaluate the effect of foot reflexology on pain and fatigue levels regarding insulin injection among diabetic children. A quasi-experimental research design (Pre-test Post-test Design) used to conduct this study, and it was carried out at the Paediatric Medical Department at Sohag University Hospital. A convenient sample of 100 diabetic children who were receiving insulin injections will be recruited in this study; the studied children were randomly assigned into two groups, with 50 children in each group (the study and control groups). Three tools were used to collect data: Tool (1): A structured interviewing questionnaire. Tool (II): Numeric Pain Rating Scale (NPRS) and Tool (III): Fatigue Assessment Scale. **Results:** After receiving an insulin injection, over half of the diabetic children in the study group experienced minor pain, compared to just 8% in the control group, according to the current research. Additionally, the post-foot reflexology of the diabetic children under study showed a highly statistically significant difference in fatigue levels between the study and control groups. Also, the results demonstrated that following the foot reflexology intervention, the diabetic children under study had a very statistically significant ($P < 0.001$) decrease in their fatigue mean score in both the study and control groups and had very statistically significant variations in their pain scores after the foot reflexology intervention ($P = < 0.001$). **Conclusion:** Foot reflexology has an effect on pain and fatigue reduction regarding insulin injection among diabetic children. Foot reflexology could be used as a supplemental therapy and non-pharmacological approach to treat diabetic children's fatigue and pain from insulin injections.

Keywords: Diabetic Children; Fatigue; Foot Reflexology; Insulin Injection; Pain

INTRODUCTION

Type 1 diabetes (T1D) is a common chronic illness in children. It is an autoimmune disease that causes gradual loss of beta cells in the pancreas, which leads to insulin insufficiency and hyperglycaemia (Patterson *et*

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al., 2019). Over the past few decades, there has been an annual increase of 2.8% to 4.0% in the incidence rate of childhood T1D worldwide (Mahfouz *et al.,* 2018). However, because of the dearth of diabetes registries and inadequate detection of new cases, there isn't much epidemiological research addressing T1D in Egypt (Arafa & Alwakeel, 2020). The largest contribution to the total number of estimated childhoods T1DM cases among Eastern Mediterranean and Middle Eastern countries comes from Egypt. It accounts for about a quarter of the region's total; 8/100 000 per year in Egyptian children under the age of 15 years had T1DM (El-Ziny *et al.*, 2014).

According to McLenon and Rogers (2019), needle tiredness and apprehension are prevalent in early childhood but diminish with maturity, with a prevalence of 20% to 50% in teens (Hanberger *et al*. 2021). Pain and fatigue from insulin injections and/or blood draws have the potential to impair children's and adolescents' capacity to manage their diabetes (Göthesson *et al*., 2023). As they grow into adolescence, children are encouraged to progressively assume greater responsibility for diabetes-related duties so they can develop their self-management techniques (Rankin *et al*., 2018). In Kruger, LaRue and Estepa (2015) According to McMurtry *et al*. (2015), managing injection discomfort helps lessen anxiety and the development of needle phobias.

Applying pressure to the hands or feet can also reduce anxiety and weariness by closing the pain gate and preventing the transmission of pain by activating large-diameter fibres (Omara *et al*., 2018; Ghaljaei & Jalalodini, 2021). By stimulating cutaneous mechanoreceptors, foot reflexology activates vast primary afferents that release endorphins and Gamma-Aminobutyric Acid (GABA) (Jazayeri *et al.*, 2021). Additionally, the advantages of foot reflexology include improved circulation, which gives the body a calmer and more invigorated feeling (Chanif, Petpichetchian & Chongchareon, 2013).

In cases of sickness, reflexologists believe that pressing specific reflex sites on the sole can help break up calcium and uric acid crystals that have accumulated in nerve endings (van Dijk *et al*., 2016), clear nerve pathways, and enhance blood flow throughout the body (Ballard *et al*., 2019). Reflexology has been shown to offer several advantages, including lowering postoperative pain and anxiety (Öztürk *et al*., 2018), reducing pain and exhaustion, and improving sleep quality in lymphoma patients (Rambod, Pasyar & Shamsadini, 2019; Abbaszadeh *et al.*, 2018). As a nursing intervention, reflexology is one of the most important complementary therapies used by nurses. Also, it makes it easier for older kids to use and improves the patient's capacity for adaptation and tiredness reduction (Momeni *et al*., 2020). Also, Ramadan *et al*. (2023) stated that Foot reflexology massage has an effect on pain and anxiety reduction regarding insulin injection among diabetic children.

METHODOLOGY

Design and Setting

A quasi-experimental research design (pre- and post-test) was applied to carry out this research. It was conducted at the Paediatric Medical Department at Sohag University Hospitals.

Study Subjects

A convenient sample of 100 diabetic children who are receiving insulin injections was recruited in this study within six months; their ages are from 6 to 15 years old, and the studied children were randomly assigned into two groups, with 50 children in each group (the study and control groups). The randomisation achieved by asking each child to pick cards with numbers one and two will be given to the participants. Children who choose number one are assigned to the study group, while those who choose number two are assigned to the control group. The study group received foot reflexology in addition to routine care as a preparation before insulin injection, and the control group received only routine care from the department as a preparation before insulin injection.

Tools Used

Three tools were used to collect data for the current study as follows:

Tool (I): A structured interview questionnaire was developed by researchers in the study after reviewing the recent related literature and research studies. It included two parts:

Part (1): It included demographic data of diabetic children, such as age, educational level, and residence.

Part (2): It included items related to the medical history of children, such as age at diabetes diagnosis and diabetes duration.

Tool (II): Numeric Pain Rating Scale (NPRS)

McCaffery and Beebe (1989) adopted the NPRS: It was used to gauge how much pain children with diabetes were experiencing. It included a blank line with adjectives describing the extremes of pain at either end. Typically, a 10-cm line is utilised to make measurement easier. The NPRS is a horizontal bar with numbers ranging from 0 to 10 that shows how much pain the respondents are experiencing. On a scale of 0 (meaning "no pain") to 10 (meaning "severe pain"), respondents were asked to choose the whole number that most accurately represented the level of pain they experience. The respondent's score was classified and interpreted as follows: If "0" means "no pain", "1 to 3" means "mild pain", "4 to 6" means "moderate pain", and "7 to 10" means "worst or severe pains, The NPRS was validated earlier, and its use for assessing pain intensity had been anticipated.

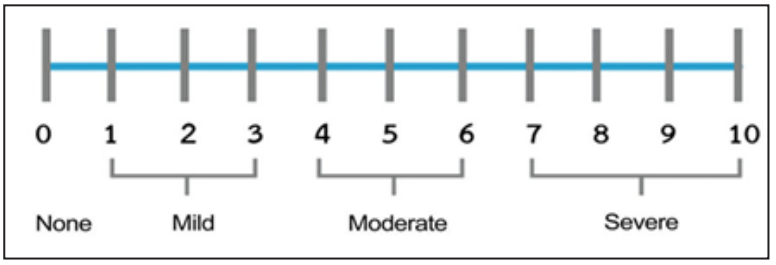


Figure 1: Fatigue Assessment Scale

The 10-item self-developed rating scale used by de Kleijn *et al*. (2011), from which this instrument was adopted, evaluated people's levels of physical, social, psychological, and spiritual fatigue during a week's worth of activities and how those levels related to the time of day. Scores may fall between 0 (no fatigue) and 10 (worst possible), with a total score range of 0 to 100. The following are indicated: light, moderate, severe, practically any, no weariness, and worst. Overall, the scale's dependability is considered good, with a Cronbach's alpha of 0.81.

Validity of Tools

The instruments were evaluated for content validity by five professors who have over five years of experience in paediatric nursing. In accordance with the experts' assessment of the tools' suitability, language structure, and item order, no changes were made.

Reliability of Tools

Utilising Cronbach's alpha, the tools' dependability was evaluated. The reliability of the tools was indicated by the reliability coefficients for tools II and III, which were 0.89 and 0.87, respectively.

Pilot Study

10% of the sample (10 children with diabetes) participated in a pilot study to determine the most efficient and thorough method of gathering the required data. The study tested the applicability and feasibility of the tool's various elements. The full research sample includes the pilot study participants.

Data Collection Procedure

A formal letter from the dean of the nursing faculty was sent to the study setting's directors, obtaining the required official approvals for data collection. Six months, from the start of March 2023 to the conclusion of August 2023, were used to gather the data. Every Sunday and Thursday from 9:00 am to 1:00 pm, the researchers came to the study location. The study was carried out by means of planning, interviewing, evaluating, implementing, and assessing.

Preparation for the Study

A comprehensive analysis of relevant recent national and international literature has been conducted to

develop data-gathering instruments. The relevant authorities also granted formal approval to carry out the study.

For two months, the researcher received specialised training in foot reflexology under the guidance of a physical medicine, rheumatology, and rehabilitation specialist trainer. This training taught the researcher how to accurately identify the foot's reflection points and how to apply pressure. Thus, the technique of operation was accepted. Apply foot reflexology to volunteers and a few of her relatives before doing so with youngsters who have diabetes.

The chosen reflexology points for the feet: The first was the solar plexus point, which was situated between the middle and upper thirds of the sole. Known as the relaxation point, it interacts with the entire nervous system and has the power to reduce stress and anxiety while also producing a significant calming impact. The brain point, situated near the tip of the big toe, was the second point. It helps the body deal with the effects of stress and anxiety by promoting the parasympathetic nervous system's optimal functioning. It also helps the body alleviate pain by increasing the release of endorphins and enkephalins, which are the body's natural painkillers (Hull, 2023). The third point was the adrenal point, which is situated halfway between the diaphragm and waistline, just above the kidney point on the foot. It helps the body deal with stress and reduces pain. The fourth point is the pituitary point, which is situated in the middle of the big toe and helps to balance all of the body's hormones by controlling and regulating their activities and preventing low energy levels.

Interview and Assessment

After introducing herself to the mothers and children under study for the first time and outlining the goal of the study, the participants were split into two groups: 50 diabetic children made up the control group, while another 50 made up the study group.

Each diabetic child and their mother are interviewed separately by the researchers using a structured interviewing questionnaire (Tool I) to gather information on demographics and medical history. About fifteen to twenty minutes were needed to finish this evaluation.

Implementation

The control group's diabetic children got standard treatment prior to the insulin injection in accordance with the hospital's care policy. Prior to receiving the insulin injection, the diabetic children in the trial group received both standard medical care and foot reflexology for 20 minutes. Prior to using foot reflexology on the study group, the researcher established the following conditions for the children and surroundings:

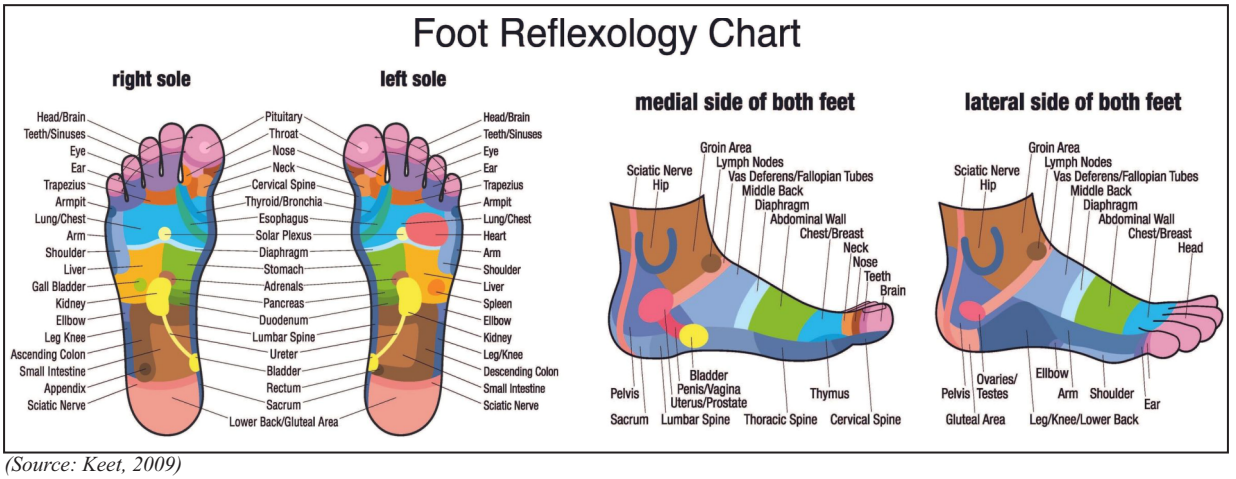
For the foot reflexology intervention, set up a cosy, quiet, and well-ventilated space. Explain the foot reflexology technique in detail, including its purpose, advantages, length, and reflexology points for the moms and children under study. Before starting an intervention, ask the kids with diabetes to wash their feet with warm water and soap.

Before touching the child, the researcher should wash her hands, lubricate them, remove any jewellery, and keep her nails neat and short. Thereafter, take a broad look at the feet, examining their colour, warmth, and variations in skin texture. Lastly, move the feet to assess their flexibility and range of motion (Hull, 2023).

In front of the children with diabetes, the researcher sat in a relaxed and comfortable position. Thereafter, the patient was told to lie down in a comfortable position, usually in the supine position. The patient had a pillow beneath their foot. The patient's feet were first assessed for sensitivity and pain. The researcher then applied a small amount of non-therapeutic baby lotion to her palm to help her massage, beginning with her right foot. Thereafter, the feet are given a general massage to warm them up. Additionally, the child's leg was massaged on the sole, back, and toes using the researcher's fingers and palm on one hand; these motions were done multiple times. This technique is used to relax the feet and legs and help with the preparation of the child for specific reflexology. It took two minutes.

Following that, pressure was administered to the foot spots that represent the body's weariness and

suffering. These four key foot reflexology points are the brain, pituitary, adrenal, and solar plexus. Using the rotating thumb approach, the researcher placed four fingers on the patient's foot's dorsal side while allowing the thumb to work on the sole. Applying firm pressure with the thumb tip to the point to be worked on while rotating the thumb clockwise requires bending the thumb from the first joint to an angle between 75 and 90 degrees, making sure the thumbnail doesn't dig into the flesh, then lifting the thumb, moving to the next point and repeating the procedure. so, the basic movement is pressing in, rotating, lifting and moving. Reflexology was performed by the researcher for 8 minutes on each foot. The cycle of foot reflexology was applied in the second foot as the first foot for 10 minutes. Total: 20 min for both (Keet, 2009).



(Source: Keet, 2009)

Figure 2: Plantar Foot Map Indicating Reflexology Points Corresponding to Various Body Organs

Evaluation

Fatigue Scale for Children (Tool III) and Numeric Pain Rating Scale (Tool II) were explained by the researcher to the studied diabetic children in both groups and were scaled for children by the researcher.

The level of fatigue was assessed by Tool III by the subjects in the presence of the researcher for old children, but for younger children, it was scaled by the researcher. For the study group before and after received foot reflexology for 20 minutes (10 min for each foot) in addition to routine care as a preparation before insulin injection, whereas for the control group it was estimated before and after receiving routine care only as a preparation before insulin injection.

The intensity of the pain level was estimated by the Numeric Pain Rating Scale (Tool II) by the subjects in the presence of the researcher during and after insulin injection for both groups.

Finally, the mean of the data was compared between the study and control groups.

Statistical Analysis

A computer was used to organise, code, and enter the collected data. The statistical program for social science, version 26.0 (SPSS, Chicago, IL), was used for all statistical analyses. For quantitative variables, the arithmetic mean, and standard deviation were employed to quantify the dispersion of results around the mean and to characterise the central tendency of observations. When comparing two variables with continuous quantitative data, the student's t-test was employed; when comparing more than two variables with continuous quantitative data, the one-way analysis of variance (ANOVA) test was employed. To compare variables with categorical data, the chi-square [X^2] test was employed. The threshold for statistical significance was $p < 0.05$.

Ethical Consideration

The research obtained ethical clearance from the Ethical Research Committee of Paediatric Medical Department, Sohag University Hospitals, Egypt with reference number 153 on 12th of December 2023.

RESULTS

Table 1: Frequency Distribution among Studied Diabetic Children in Both Groups Regarding Demographic Data

Demographic Data	Study Group (n=50)		Control Group (n=50)		X^2	*P*-value
	No.	%	No	%		
Gender:						
Boys	30	60.0	25	50.0	0.31	0.523 NS
Girls	20	40.0	25	50.0		
Age:						
6- < 10	19	38.0	16	32.0	0.99	0.567 NS
10 < 15	20	40.0	22	44.0		
≥15	11	22.0	13	26.0		
Educational level:						
Primary level	8	16.0	11	22.0	2.55	0.355 NS
Preparatory level	32	64.0	34	68.0		
Secondary level	10	20.0	5	10.0		
Residence:						
Rural Urban	37	74	36	72	2.0	1.35 NS
	13	26	14	28		

T-test, X2test, NS-non-significant

A total of 100 children with diabetes participated in the study, as indicated in Table 1; 60% of the study group were boys, compared to 50% in the control group; 40% of the study group and 44% of the control group were between the ages of 10 and 15; 64% of the study group's children were at the preparatory educational level, compared to 68% of the control group; and the same table indicates that nearly three-quarters of the studied children (74%) lived in urban areas, compared to 72% of the control group. No significant differences were found between the two groups for demographic data.

Table 2: Frequency distribution among Studied Diabetic Children in Both Groups Regarding Medical History

Medical History	Study Group (n=50)	Control Group (n=50)	*t*-test	*P*-value
	Median (Min-Max)	Median (Min-Max)		
Age at diabetes diagnosis in years	6.4 (0.5-15)	6.3 (0.5-15)	0.543	0.534 NS
Diabetes duration in years	6.0 (0-16)	6.0 (0-16)	0.429	0.342 NS

T-test, X^2 test, NS-non-significant

Table 2 shows that among the children with diabetes in the study group, the median age at diabetes diagnosis in years was 6.4, whereas in the control group, it was 6.3. In terms of years with diabetes, it was found that the median duration of diabetes in both groups was 6.0.

Table 3: Comparison between Mean Pain Score (NPRS) during and after Insulin Injection between Both Study and Control Groups

Mean Pain Score	Study Group (n=50)	Control Group (n=50)	*t*-test	*P*-value
	Mean ±SD	Mean ±SD		
During insulin injection	7.0 ± 0.4	7.1 ± 0.5	0.556	0.660
After insulin injection	6.1 ± 1.3	8.1 ± 0.3	4.67	<0.001 *

**Statistically significant level at P <0.0001*

The mean NPRS pain scores for the two groups of diabetic children under study are shown in Table 3 both during and after insulin administration. The results demonstrated that the two groups under study had very statistically significant variations in their pain scores after the foot reflexology intervention (*P* = <0.001).

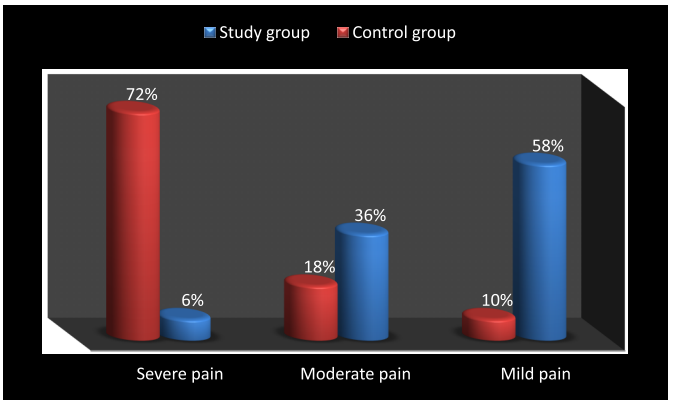


Figure 3: Percentage Distribution of Diabetic Children Regarding Their Pain Levels after Insulin Injection

The distribution of diabetic children's pain levels following insulin injections between the study group and the control group is shown in Figure 3. Compared to 10% in the control group, 58% of the study group's diabetic children experienced minor pain. Additionally, in the study group, 36% of participants experienced moderate pain, while in the control group, 18% did so. Additionally, less than three-quarters of the control group experienced severe pain, but only 6% of the research group experienced severe pain.

Table 4: Frequency and Percentage Distribution of Pretest and Post-test Fatigue Levels among Studied Post-Studied Diabetic Children (n=100)

Fatigue Level	Study Group (n=50)		Control group (n=50)		*T*	*P*-value
	No	%	No	%		
No fatigue (0)	9	18	0	0.0	22.89	<0.001**
Very little (1-9)	11	22	0	0.0		
Mild (10-30)	16	32	0	0.0		
Moderate (3- 60)	14	28	23	46		
Severe (61-80)	0	0.0	15	30		
Worst (81-100)	0	0.0	12	24		

Table 4 shows a significant difference in fatigue levels, with the investigated diabetic children having much lower fatigue level scores.

Table 5: Fatigue Mean Scores among Studied Diabetic Children in Study and Control Groups after Foot Reflexology Intervention

Items	Study Group (n=50)	Control Group (n=50)	*P*-value
Fatigue Score	16.02+ 1.22	27.33+ 2.02	0.129 (0.0001*)

**Highly Significant at 0.0001 levels*

Table 5 demonstrates that following the foot reflexology intervention, the diabetic children under study had a very statistically significant ($P < 0.001$) decrease in their fatigue mean score in both the study and control groups.

Table 6: Comparison of Pretest and Post-Test Fatigue Levels among Studied Diabetic Children in Study and Control Groups after Foot Reflexology Intervention

Group	Fatigue level				X^2	*p*-value
	Pretest		Post-test			
	Mean Score	SD	Mean Score	SD		
Study Group	4.33	1.07	2.24	1.08	56.4	<0.001**
Control Group	4.79	1.02	3.31	0.45	0.59	1.63 NS

*NS=Non-significant, *= significant at p<0.05 level*

Table 6 shows a statistically significant difference between the pretest and post-test mean fatigue levels for the diabetic children under study at the <0.05 level.

DISCUSSION

According to Majidi, Driscoll and Raymond (2015), evaluation of optimal practices is still required to reduce painful needle-related experiences and fatigue effects in children with T1D (Craig *et al.*, 2022). Thus, assessing the impact of foot reflexology on reducing pain and fatigue related to insulin injection in children with diabetes was the aim of the study. In line with the findings of the research, almost two-fifths of the intervention and control groups were in the 10–15 age range. The findings are consistent with those of Myśliwiec *et al*. (2018). They found that 40% of patients under the age of 18 were children between the ages of 10 and 14. Furthermore, the study's conclusions showed that the two groups' demographic features did not differ much. Karamisefat *et al.* (2021) aligned with the present findings, demonstrating that there were no notable variations in the demographic characteristics of the children in the two groups. From the researchers' point of view, this showed that the two groups' baseline levels of pain and fatigue issues were similar.

This study indicated that the median age at diabetes diagnosis was 6.0 years (0–16 years) and the median duration of diabetes was 6.2 years (0.5–15 years) for both study groups. The results of Hanberger *et al.* (2021) are consistent with this.

The results of this research showed that less than 10% of the diabetic children who took part experienced severe pain following the application of foot reflexology, compared to less than 75% of the children in the control group. The findings of a literature by Bakir, Samancioglu and Gursoy (2018) that showed that foot reflexology is useful in lowering pain symptoms in patients with rheumatoid arthritis confirmed this conclusion. This outcome also concurred with another study conducted by Ghaljaei and Jalalodini (2021), which found that after 20 minutes of foot reflexology, leukemic children's pain mean scores were much lower. Additionally, the current findings were consistent with those of a prior study by Taheri *et al*. (2019), which found that foot reflexology positively affected pain reduction. According to the researcher, reflexology has positive effects on reducing pain and fatigue because vital energy travels through the feet to all areas of the body. Eventually, any obstruction to this flow will result in sickness. By releasing morphine-like substances, reflexology stimulation can inactivate the pain pathways and break down these barriers in the canal flow, releasing energy in each foot (Karamisefat *et al*., 2021).

Regarding the mean pain scores, the present research showed that the two groups' NPRS pain scores were statistically similar during insulin injection, but that the study group and the control group pain scores were 6.4 ± 1.1 and 8.2 ± 0.8, respectively, following insulin injection, and that the differences between the two groups' pain scores showed a highly statistically significant difference. This is consistent with Koç and Gözen (2015), who reported that the FLACC (face, legs, activity, cry and consolability) pain score was statistically similar between groups before vaccination and that the reflexology group of the infants under study had a pain score of 5.47 ± 2.11 following vaccination, compared to 9.63 ± 0.85 in the control group. Thus, scientists deduced that utilising foot reflexology before vaccination decreased the amount of pain that infants had following immunisation.

The effect of foot reflexology on postoperative pain in patients undergoing tibia plating surgery was also confirmed by Öztürk *et al*. (2018), who conducted a randomised controlled trial. They found that the intervention and control groups' baseline pain scores were 8.1 ± 0.9 and 8.4 ± 0.9, respectively, but that these groups' pain scores decreased to 6.9 ± 1.1 and 8.1 ± 1.0, respectively, after performing foot reflexology for 10 minutes, an hour before surgery. Similarly, Sayari, Nobahar and Ghorbani (2021), the experimental group's average pain score was statistically lower than the control group's at 30 and 60 minutes after applying reflexology. Additionally, a significant difference was observed between the average pain scores on the first, second, and third days following surgery when patients in the experimental group received reflexology.

According to the findings lo this study, the diabetic children's post-foot reflexology application fatigue levels in the study and control groups differed in a highly statistically significant way. This might have been a reference to reflexology, a theory founded on the idea that energy moves from the body's organs into the head through vertical zones. Thus, nerve stimulation and massage promote relaxation, remove tension, restore bodily balance, and lessen weariness (Kishore *et al.*, 2021).

In coherence with the conclusion of this research, the fatigue levels of the diabetic children under investigation fluctuated, declined, and improved dramatically. The sedative and analgesic effects of the peptides released during foot reflexology are the cause of this result. The sympathoadrenal system, which is triggered during stressful situations like surgery, is thus less active (Kotani *et al.*, 2021). From the viewpoint of the researchers, it illustrated how foot reflexology might improve and lessen fatigue. The main goals of the foot reflexology intervention were confirmed by these significant improvements in the fatigue levels of the diabetic youngsters under study.

According to the researcher, applying pressure on certain foot relaxation sites, such as the solar plexus, improves blood flow and allows energy to be released from tense areas of the body, which can help patients feel better physically and psychologically. According to Mao *et al*. (2018), long-term fatigue frequently only requires one follow-up survey, and even years after treatment, the prevalence and severity of fatigue are higher in studied diabetic children than in healthy populations.

Limitation

This study faced limitations, including non-participation and poor follow-up compliance among some children, which may have affected data reliability. The relatively small sample size limits the generalisability of the findings. The use of self-reported measures for pain and fatigue introduces potential subjectivity, and variations in the application of reflexology could have influenced outcomes. Additionally, the research focused only on short-term effects. Future research should consider larger, more diverse samples, standardised intervention protocols, and long-term follow-up to better assess the sustained impact of reflexology.

CONCLUSION

The study suggests that foot reflexology significantly reduces both pain and fatigue related to insulin injections in children with diabetes. Children who received reflexology in addition to standard care experienced lower levels of pain and fatigue compared to those who received only routine care. This non-pharmacological approach appears to be an effective complementary therapy for managing the discomfort associated with insulin injections, improving both physical well-being and the overall diabetes management experience.

Foot reflexology offers a holistic approach to care, addressing the physical and emotional challenges faced by children with diabetes. Given its potential to alleviate pain and fatigue, it can be a valuable, low-cost, and accessible method for enhancing comfort during insulin therapy. Future research should focus on optimising the technique and evaluating its long-term benefits. Integrating reflexology into paediatric diabetes care can significantly improve the quality of life for children managing Type 1 diabetes.

Recommendation

In light of the findings, it is suggested that foot reflexology be considered as a supplemental therapy and non-pharmacological approach to treat fatigue and pain associated with insulin injections in diabetic children. Additionally, the creation and implementation of a reflexology training programme for mothers and other caregivers should be explored to empower them to effectively administer this technique. To further validate the results, the study should be replicated in different contexts and with a larger, more diverse sample, allowing for more generalised findings and broader applicability of the intervention.

Conflict of Interest

The authors affirm that there are no conflicting objectives.

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