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A specially designed medical screen for children suffering from burns: A randomized trial of a distraction-type therapy

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ABSTRACT

Objective: To evaluate the impact of the specially designed medical dressing screen during wound dressing changes of children who suffered burns to their hand or foot.
Design: Randomized controlled trial.
Setting: Burns and Plastic Reconstruction Unit.
Participants: Children (N = 120) with burns on up to 1–5% of the total body surface area.
Interventions: The patients were selected and randomly allocated to 3 equal-sized groups as follows: control group (N = 40): the children received only regular dressing changes; computer group (N = 40): a touch-screen computer was used for children during dressing changes; medical screen group (N = 40): a medical screen combined with the touch-screen computer were used for children during dressing changes. All patients underwent a dressing change once per day for four days. Data were distributed four times: immediately after the initial dressing change (T1); and immediately after each times at next three consecutive days (T2–T4).
Main outcome measures: The Pain level of the children evaluated by medical staffs was the primary outcome, the Pain level of the children evaluated by children's parents and the satisfaction of wound therapist were used as second outcomes.
Results: The mean scores related to pain level at the medical screen group displayed significantly better results than those of control group and those of the computer group. Additionally, the results of the pain evaluated by parents and satisfaction score of the wound therapist at the medical screen group was also better than other groups.

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Abbreviations: CI, confidence interval; MBPS, modified behavioural pain scale; MD, mean difference; PPI, present pain intensity; SD, standard deviation; TBSA, total body surface area; VAS, Visual Analogue Scale; VNS, Verbal Numeric Scale.
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Conclusions: This study demonstrated ''that the'' application of the medical screen for burns can relieve the pain of 1–3 years old children suffering from a burns during dressing changes. Additionally, the application of the medical screen also increased the satisfaction of the parents and the wound therapist performing the dressing changes.

1. Introduction

In developing countries, children under the age of 5 can account for 50–80% of all children patients [1], while the morbidity rate of children 3 years old or younger with burn injuries is the highest in China [2–4]. Studies show that burns rank 5th among non-vulnerability injuries for children with resultant irreversible complications such as pain, anxiety and depression [5]. Of these complications, pain is considered to be among the most debilitating sequelae of the burn injury [6,7].

Burn pain is a special kind of pain with the fiercest intensity of all types. Specifically, pain during wound dressings can be excruciatingly painful and has been considered to be the most painful among all non-surgical procedures [8,9]. During wound dressing, children can express panic, crying, resistance, etc. due to dressing pain and fear of dressing because their psychological development is immature and lack the ability for autonomous cooperation, which resulted in great inconvenience for clinical work [10].

Pharmacological treatment is the primary approach for relieving pain related to burns, and several categories of drugs have been used to manage burn pain and psychological symptoms caused by pain. However, due to the variability of the intensity of pain in children, the symptoms remain undertreated [10]. Recently, much attention has been paid to pain management approaches with non-pharmacological therapies. Distraction is a common non-pharmacological pain treatment method that is commonly used in children. Currently, there are different types of distraction including music video, visual image, electronic games, etc., which can intervene with the pain when dressing changes are performed for children with burns, and the effect is relatively good [11–13]. Research studies have indicated that distraction can transfer the attention of children to something more attractive to relieve pain, what's more, it has an apparent effect in relieving pain for children with burns [11].

Medical screens are common tools in the clinics that is mainly used for sheltering and separation and are frequently applied to protect patients' privacy when examining and treating patients. However, the existing medical screens have a single design style and lack powerful function. In view of these, this study effectively combined the sheltering function of a screen with a touch-screen computer to design and build a medical dressing screen for children aged 1–3 years who are suffering from a burns on their hand or foot and require dressing changes, aimed to provide recommendations for future research and clinical practice.

2. Methods

2.1. Participants and design

The single-centre randomized controlled trial was conducted in our hospital from January 2019 to September 2019. The study was designed to compare the effect of a specially designed medical dressing screen's intervention with usual care or a touch-screen computer alone during wound dressing changes for children aged 1–3 years who suffering from burns on their hands or feet.

2.1.1. Participants

The sample size was estimated to be 40 subjects for each group with 80% power, an alpha value of 0.05, and an attrition rate of 10% and *Cohen's d* = 0.59 (medium effect size) [14]. Following the children parents' agreement to participate, they were thoroughly screened for eligibility by the main researcher. Children between 1 and 3 years old with burns on their hands or feet who came to our department for treatment were selected for trial. Burns were limited to a single hand or foot, with the burnt area < 5% total body surface area (TBSA) and a burned depth of second- or third-degree. Children were excluded if (1) had a confirmed past of cognition or psychological disorders, (2) had an abnormal neurogenesis or abnormal cutaneous sensation, (3) previous burn injuries. A flow diagram of the study is shown in Fig. 2.

2.1.2. Ethical considerations

This study was approved by the Ethics Committee, in accordance to the principles of the Declaration of Helsinki. Written informed consent was obtained from the parents accompanied the children after a detailed introduction on the purpose and method of the study, children's parents were informed about the right to withdraw from the study at any time with no penalties or sanctions. All data collection and management procedures took into account the participants' right to privacy and confidentiality. The authors confirm that all ongoing and related trials for this intervention are registered.

2.1.3. Randomization

A total of 137 children were initial included in this study, as 5 children who did not meet the inclusion criteria and 12 parents refused to participate in the clinical experiment, 120 children were finally included in this study. Written informed consent was obtained from each parent after providing a detailed introduction of the study, but we did not provide a

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detailed explanation of the differences in intervention among groups. After obtaining informed consent, the children were randomly divided into 3 equal-sized groups according to the use of our permutation block design, which was created by a computer random number generator with a balanced randomized of 1:1:1, and the sample size of each group was 40.

2.2. Procedures

2.2.1. Interventions

For all groups, information was gathered from the parents about their child's daily interests and hobbies, including types and names of music, animation, videos, situational dialogues or electronic games. Additionally, the demographic and clinical characteristics of children were also recorded via a brief interview. The nurse also introduced actions of various parts of the medical screen to the parents; parents were taught how to utilize the function of the touch-screen computer to guide their children.

All experimental procedures lasted for four days, and dressing changes were conducted daily. The children were accompanied by their parents for pacification during the whole process of dressing (accompanied by the same parent).

On the initial day, a routine dressing change (T1) was performed (including all children were treated with the same oral narcotics (tramadol) based on weight (kg), and all the periods were administered by the same anaesthesiologist. However, different methods were used at T2–T4 as follows.

For the control group ($N = 40$), the children received only routine dressing changes as usual.

For the computer group ($N = 40$), in addition routine dressing changes as usual, a touch-screen computer was used during dressing changes (parents guided the child to watch the programme content on the touch-screen computer according to child's daily interests and hobbies which were prepared in advance.).

For the medical screen group ($N = 40$), in addition routine dressing changes, the medical screen combined with the touch-screen computer was used for children during the dressing changes. Before dressing changes, the medical dressing screen for burns was moved to the location of the dressing treatment. The universal wheel on the lower part of the screen was locked to firmly fix the screen so that its location could completely cover the wound therapist. The touch-screen computer was installed and powered on to play the content that was prepared for children in advance. The wound therapist entered the dressing room ahead of time to prepare. Then, the nurse informed the parents to take their child into the dressing room (only the parents and the child were allowed to enter the dressing area and to seat on the adjustable seat). Then, the parents guided the child to watch the programme content on the touch-screen computer according to child's daily interests and hobbies which were prepared in advance. When the child's attention was consumed by the touch screen programme on the computer according to child's dressing limbs and placed the child's dressing limbs inside the treatment window to the backside of the screen, then, the therapist detached the dressing for treatment (see Fig. 1).

The main body of the medical dressing screen is composed of a high-density plate, and the decorative surface is made of acrylic material. The screen contains 3 leaves (leaf A, leaf B and leaf C). Fold strips are located between each leaf so that the screen can be conveniently folded. The screen has a 20 cm length and 40 cm height window for dressing treatment for upper limbs and it is designed in the centre of leaf A and in the centre of leaf C. A bracket is designed in the centre of leaf B to provide a position for placing a device. Additionally, a 45 cm length and 50 cm height window for the dressing treatment of lower limbs is designed in the lower part of leaf B. Four universal wheels with locking capability are at the bottom of the screen, and the screen appearance is designed with an animation pattern. The screen is equipped with a height adjustable seat. Additionally, in order to facilitate wound dressing, the screen is also equipped with 3 windows for the right upper limb, the left upper limb and the lower limbs so that wounds can be conveniently exposed for dressing.

The conditions of all groups should be matched as closely as possible to control for confounding variables and minimal-to-no interruptions occurred. To reduce rater bias, dressing changes were performed by the same skilled wound therapist according to the specific wound type in the same treatment

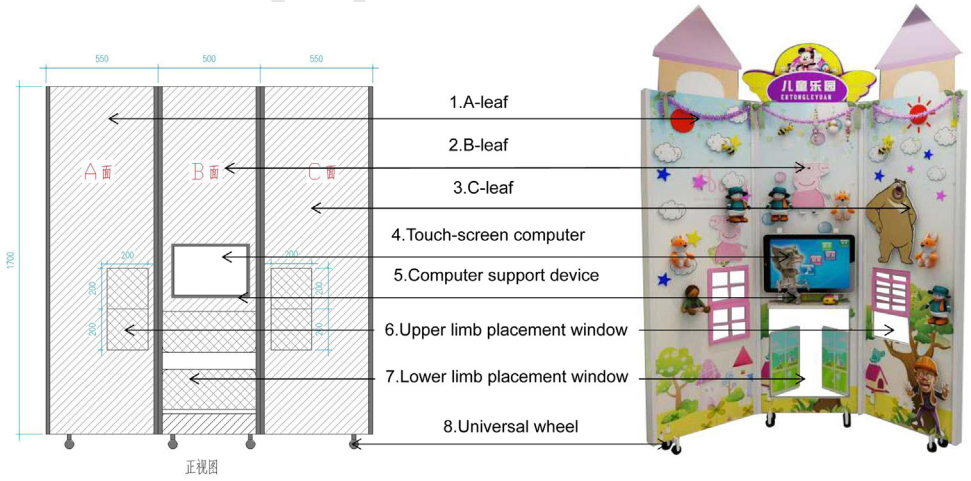

Fig. 1 – Composition of the medical dressing screen.

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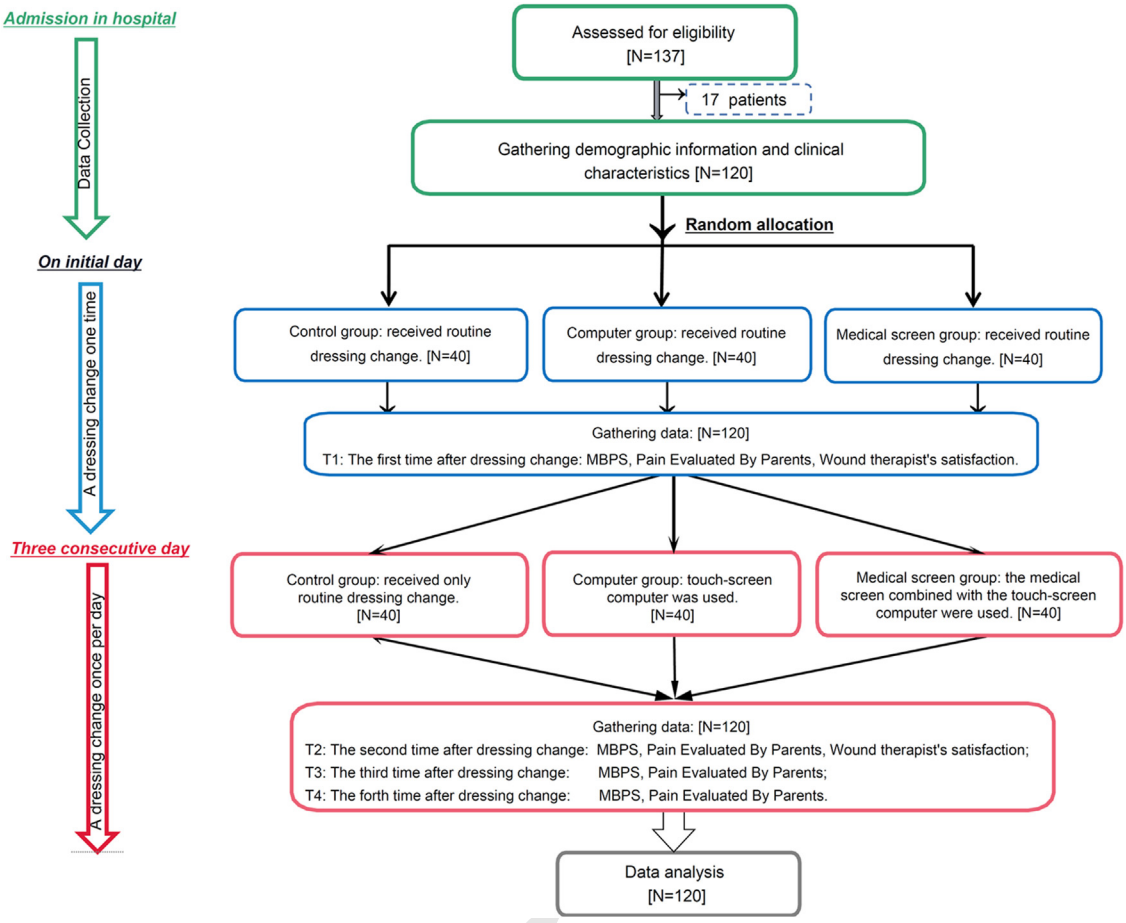

Fig. 2 – Flow chart of participants through the study.

room. In addition, the medical screen for burns was disinfected after each dressing change. Any complications and adverse effects related to intervention were also recorded.

2.3. *Outcome measures*

In this study, collected baseline data were demographics and clinical characteristics.

The modified behavioural pain scale (MBPS) [15] was adopted o assess the pain of children. The main indexes include the following. (1) Facial expression: a grade of 0 is for good expressions, such as smiling; a grade of 1 is for neutralized expressions; a grade of 2 is for mildly bad expressions, such as a distorted grimace; and a grade of 3 is for clearly bad expressions, such as frowning, closed eyes, etc. (2) Situations of crying: a grade of 0 is for laughing, a grade of 1 is for groaning, a grade of 2 is for crying not exceeding the benchmark, and a grade of 3 is for crying exceeding the benchmark. (3) Action situations: a grade of 0 is for normal actions or relaxed and quiet; a grade of 1 is for slight tension, peristalsis, arc positions, clenching of fists or limb tension; a grade of 2 is for shrinking limbs for avoiding pain; and a grade of 3 is for dysphoria or stiffness of the head and limbs. The sum of all the scores for all items is the score of the patients, the higher the score, the more severe the pain.

Pain Evaluated By Parents was evaluated by the Verbal Numeric Scale (VNS) [16], from 0 to 11 scores, 0 represents no pain, and 11 represents a lot of pain. The children's parents selected a number from 0 to 11 to represent the child's pain scores during the dressing, the higher the score, the more severe the pain.

In addition, wound therapist's satisfaction score (pain levels) was also evaluated by the VNS, from 0 to 11 scores, the higher the satisfaction, the higher the score.

The evaluation of MBPS during dressing changes was performed by 2 nurses with more than 10 years of experience and 1 doctor with more than 10 years of experience by examining the children's performance in the video during the dressing change (we did not provide a detailed explanation of the differences in intervention among groups). The pain evaluated by parents was evaluated by the accompanying parents after each dressing change immediately (T1–T4). The wound therapist's satisfaction score was evaluated by the wound therapist after T1–T2 dressing changes.

All scales data gathering and entry was blinded to group information, what's more, an independent statistician, who is

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blinded to the treatment allocation, will complete the analysis for the main outcomes.

2.4. Data analysis

Descriptive statistics, including the mean and standard deviation (SD) for numerical variables and the percentages of different categories were obtained. For comparing categorical data, a Chi square (X2) test was performed, and an exact test was used instead when the expected frequency was less than 5. The normality of variables was assessed using the Kolmogorov-Smirnov test or the Student's t test for comparison of two normally distributed independent quantitative variables; for quantitative data that did not show a normal distribution, the Kruskal–Wallis test was used. The Bonferroni method was used to perform pairwise comparisons of repeatedly measured data at different measurement times in three groups. The effect size of the intervention was calculated in the form of *Cohen's d*. *P* value < 0.05 was considered statistically significant. The endpoints included the mean difference (MD) and 95% confidence interval (CI). The Statistical Package for the Social Sciences (SPSS; SPSS Inc. Chicago, IL, USA) version 25.0 was used to analyze the study data.

3. Results

None of the children in the study were lost to follow-up, and no side effects were reported. The mean age of the control group, the computer group and the medical screen group was 1.89(0.77), 1.94(0.83) and 2.00(0.80). Most of the children had suffered second- or third-degree burns, where a flame was the most common cause of burns. The demographic and clinical characteristics of the three groups are shown in Table 1. The results showed no significant differences of all the demographic and clinical variables in three groups.

As indicated in Table 2, there were significant differences in the scores of MBPS at T2, T3 and T4 by inter-group comparison (*all* $p < 0.001$), but no difference at T1 ($p = 0.499$).

As shown in Table 3, there were differences in the scores of MBPS at the medical screen group and computer group from T1 to T4 by intra-group comparison ($p = 0.033$, *0.026 respectively*), but no difference at control group ($p = 0.461$). What's more, the medical screen group had lower pain scores at T2, T3 and T4 when compared with T1: T2 vs.T1 [*MD = 2.125, 95% CI (1.776–2.474)*]; T3 vs.T1 [*MD = 3.15, 95% CI (2.58–3.72)*]; and T4 vs.T1 [*MD = 3.81, 95% CI (3.342–4.258)*]. The computer group had lower pain scores at T2, T3 and T4 when compared with T1: T2 vs.T1 [*MD = 1.1, 95% CI (0.744–1.456)*]; T3 vs.T1 [*MD = 2.12, 95% CI (1.557–2.693)*]; and T4 vs. T1 [*MD = 2.775, 95% CI (2.323–3.227)*].

Table 4 shows the overall satisfaction of the wound therapist, there were significant differences between medical screen group and computer group by intra-group comparison at T1 and T2 (*all* $p < 0.001$), but no difference at control group ($p = 0.564$). In addition, there was significant differences at the wound therapist score at T2 by inter-group comparison ($p < 0.001$), but no difference at T1 ($p = 0.13$).

The pain scores evaluated by parents from T1 to T4 are shown in Fig. 3, with the medical screen group showing significantly pain elimination than other groups, with the computer group showing less pain level than the control group.

4. Discussion

In our observations, large numbers of children from age 1 to 3 with burns to the clinic (about 400–900 people per year). As shown in Table 2, although the conventional analgesics were injected, the pain experience during the dressing change in both groups was very strong. Duo to physicians often prescribe inadequately potent analgesics or inadequate doses of analgesics. The reasons for this are multi-factorial, with the primary concern that the use of drugs may harm children, as a result, the limited control of pain [17,18]. In addition to being intrinsically very painful, repeated dressing changes can promote anxiety, making subsequent changes even more distressing [11,12,18].

Additionally, psychological expressions, such as panic, crying and screaming result from a lack of a sense of safety due to the memory of pain from past treatment when face medical workers [19]. Thus, if patients do not receive effective pain

Table 1 – The demographics and clinical characteristics of the three groups.

Variables		Groups (N, %)			Statistical results (Chi-square)	P-value
		Control group (N = 40)	Computer group (N = 40)	Medical screen group (N = 40)		
Age(year)	Mean(SD)	1.89(0.77)	1.94(0.83)	2.00(0.80)	1.999	0.341[a]
Sex	Female	24(60.00%)	18(0.83)	23(65.38%)	3.83	0.28
	Male	16(40.00%)	22(0.83)	17(34.62%)		
Burn factors	Water and steam	15(27.50%)	13(32.50%)	23(57.50%)	3.361	0.277
	Flame	25(62.50%)	27(67.50%)	17(42.50%)		
Burn locations	Hand(yes)	22(55.00%)	20(50.00%)	23(57.50%)	0.127	0.882
	Foot(yes)	18(45.00%)	20(50.00%)	17(42.50%)		
TBSA (%)	Mean(SD)	3.35(0.16)	3.47(0.21)	3.27(0.11)	5.984	0.117[a]
Burn degree	2	20(50.00%)	12(30.00%)	13(32.50%)	Fisher's exact test	0.124
	3	5(12.50%)	4(10.00%)	4(10.00%)		
	2–3	15(37.50%)	24(60.00%)	23(57.50%)		

TBSA, total body surface area.
[a] Kruskal–Wallis test.

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Table 2 – Comparison of mean scores of pain [MBPS] inter-groups.

Variables	Groups Control group		Computer group		Medical screen group		Statistical results	P-value[a]
Times	Mean(SD)	[95%CI]	Mean(SD)	[95%CI]	Mean(SD)	[95%CI]		
T1	8.95(0.22)	[8.88,9.02]	8.875(0.33)	[8.77,8.98]	8.9(0.30)	[8.80,8.99]	1.389	0.499
T2	8.45(0.51)	[8.29,8.61]	7.775(0.80)	[7.52,8.03]	6.78(0.82)	[6.52,7.03]	56.78	<0.001
T3	7.7(0.63)	[7.49,7.91]	6.75(1.32)	[6.33,7.17]	5.75(1.31)	[5.33,6.17]	40.52	<0.001
T4	6.95(1.43)	[6.49,7.41]	6.1(0.98)	[5.79,6.41]	5.09(0.94)	[4.79,5.41]	25.87	<0.001

MD: mean difference; CI: confidence interval;
[a] Kruskal–Wallis test.

Table 3 – Comparison of mean scores of pain [MBPS] intra-groups.

Variables	Times										
Groups	T1	T2	T2 vs. T1		T3	T3 vs. T1		T4	T4 vs. T1		P-value[b]
	Mean	Mean	MD	[95%CI]t	Mean	MD	[95%CI]t	Mean	MD	[95%CI]t	
Control group	8.95	8.45	0.5	[0.29,0.70]6.25	7.7	1.25	[1.01,1.49]12.54	6.95	2.0	[1.413,2.587]8.518	0.461
Computer group	8.85	7.78	1.1	[0.74,1.46]7.73	6.75	2.12	[1.56,2.69]9.36	6.1	2.775	[2.323,3.227]15.35	0.034
Medical screen group	8.9	6.78	2.125	[1.78,2.47]15.23	5.75	3.15	[2.58,3.72]13.82	5.09	3.81	[3.342,4.258]20.73	0.026
P-value[a]	0.499	<0.001			<0.001			<0.001			

MD: mean difference; CI: confidence interval.
[a] Kruskal–Wallis test.
[b] Repeated measures-ANOVA.

Table 4 – Assessment of the wound therapist score in three groups at T1 and T2.

Variables	Groups							
	Control group		Computer group		Medical screen group		Statistical results	P-value[a]
Times	Mean (SD)	[95%CI]	Mean (SD)	[95%CI]	Mean (SD)	[95%CI]		
T1	3.088(0.206)	[2.766,3.409]	3.138(0.318)	[2.972,3.30]	3.125 (0.328)	[2.956,3.294]	8.623	0.13
T2	3.205(0.395)	[2.887,3.523]	6.3(0.508)	[5.946,6.654]	8.2 (0.121)	[7.969,8.431]	64.42	<0.001
MD [95%CI]	0.118 [-0.291,0.526]		3.16 [2.76,3.57]		5.013 [4.716,5.309]			
P-value	0.564		<0.001		<0.001			

MD: mean difference; CI: confidence interval.
[a] Kruskal–Wallis test.

relief, physiological problems may result and negatively affect their perseverance in treatment [20]. Therefore, to reduce children's crying during the procedure, an intervention should be performed to reduce children's memory of pain resulting from the medical staff.

As Table 2 shown, there were significant differences in the scores of pain at T2, T3 and T4 by inter-group comparison (*all* $p < 0.001$), but no difference at T1 ($p = 0.499$). The findings indicate that with respect to phenomena related to burn dressing changes, the medical screen have a significant influence in comparison with other groups as Table 2 shown.

In addition, it could be observed from the videos that most of the children in the control or computer group started to have expressions including frowning, closing their eyes, limb tensions, crying, screaming and other escaping resistance actions when they entered the dressing room even before the dressing change was performed. On the contrary, most of the children in the medical screen group were immediately guided to watch the programme content played on the computer screen after they entered dressing room thereby the expressions above were reduced. Interestingly, it could be seen that most of children's crying could be reduced in the medical screen group after the parents played many kinds of programmes on the screen for pain intervention when the dressing was uncovered and bound up, except for when the wound was disinfected.

As the degree of physical and mental development of children varies from person to person, even at the same age, there are varying degrees of difference [21]. Therefore, individual differences should be considered in the selection of targets [22]. That's why the first time before dressing change, information was gathered from the parents on their children's daily interests and hobbies, so that the nurse can prepared corresponding content in the touch-screen computer.

At present, however, there is limited scientific data for the comparison of the findings in previous studies. However, our findings may indicate the future direction of preclinical and clinical research [11]. In summary, the pain scores' trend in each group at each time point in Fig. 3 and the inter-group and intra-group comparisons in Tables 2 and 3 both showed that

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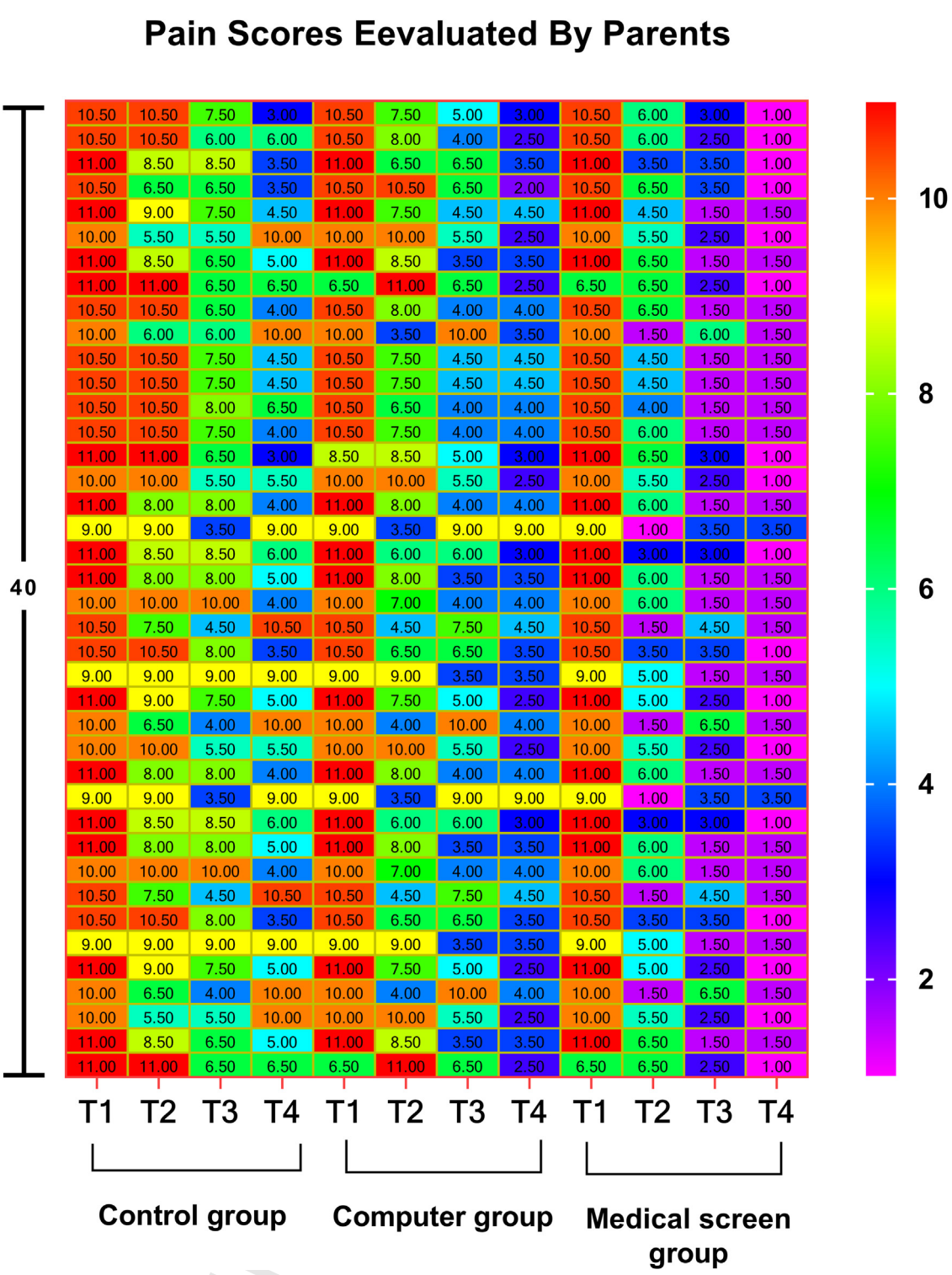

Fig. 3 – Variation of the pain scores evaluated by parents at T1–T4.

the medical screen group has a significant influence on burn dressing change-related pain in comparison with other groups.

By observing the trend of the results, it is not difficult to find compared with two other groups, the pain scores' trend in each group at each time point in Fig. 3 (pain evaluated by parents) and the inter-group and intra-group comparisons in Table 3 (pain evaluated by medical staffs [MBPS]) all showed that the medical screen showed the most and similar effect in reducing pain scores. Moreover, the effect of medical screen group is obviously better than other groups.

In our view, the working pressure for medical workers in the burn department is higher than that in other specialties

[23], and the mental stress is mainly from children's degree of cooperation during dressing and the degree of recognition from parents [24]. The application of the medical screen for burn children in this study not only reduced such pain expressions as children's crying, screaming, and tension in the medical screen group but also separated the children's expression from dressing personnel so that the dressing personnel could operate with more relaxation and devotion, prevent them from being stressed by the child's crying and increasing the total satisfaction of the wound therapist related dressing changes as shown in Table 4.

This study has shown that this method is effective and user-friendly, however, the study results should be interpreted in light of its limitations. In this small sample clinical trial study, the use of a single site may be considered study limitations. Second, as patients are likely to be lost to continued monitoring, this study only assessed the effect of a 3-day intervention. Therefore, it is essential that future research for longer periods of time. Third, the lack of blinded assessments by the clinicians should be a limitation (although complete blinding may not be possible). Additionally, perhaps there were differences in pain levels to begin with (as the cause of burn differed slightly, though not significantly), this should be another limitation. Last but not the least, in the early stage of this study, all ages of children were included, and it was found that children aged 1–3 were the most affected, so the age was set at 1–3 years old. In this regard, a large number of studies still need to be further explored.

5. Conclusion

According to the result of the present study, this paper strengthens relevant research, which might open the door to the development of methods that can treat children burn patients in the future and so it stands to reason that the special designed medical screen could have longer term efficacy. Despite the limited number of previous studies investigating this topic [11], the current results provide further evidence that the special designed medical screen is more effective than touch computer or usual care, suggesting that this will be a powerful and effective complement treatment method for minimizing pain in children burn patients related to dressing changes. Based on the findings of the current study, we recommend the special medical screen can be used as a method of complement due to its non-pharmacological and non-invasive features. In this regard, future research should, if possible, be anchored on the other areas of nursing such as (department of) paediatrics, intravenous infusion, wound care, etc.

Authors' contributions

All authors have made substantial contributions to all of the following,conception and design of the study: Chang-Lei Cui, Xiu-Hang Zhang; acquisition of data: Chang-Lei Cui, Xiu-Hang Zhang, Xin-Xin Chen; analysis and interpretation of data: Xiu-Hang Zhang, Chang-Lei Cui, Kai-Ki Lee; drafting the article: Xiu-Hang Zhang, Chang-Lei Cui;All authors read and approved the final manuscript.

Conflict of interest

None.

Funding

None.

Hypothesized

It was hypothesized that burn patients who received the specially designed medical dressing screen during wound dressings will demonstrate lower pain levels than burn patients who received other distraction type therapy during dressing changes.

Suppliers' list

The medical dressing screen (Chinese invention patent No. ZL201720200623.2, IPC No. A47G5/00; G06F3/041, made by Suzhou Institute of Biomedical Engineering and Technology, Chinese Academy of Sciences, Suzhou, China).

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We thank all the contribution of medical workers in the battle against coronavirus (COVID-19). ''Keep it up, Wuhan! You are not alone, we are all with you.''

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