BURNS XXX (2017) XXX-XXX



Available online at www.sciencedirect.com

ScienceDirect



journal homepage: www.elsevier.com/locate/burns

Hypnosis for reduction of background pain and pain anxiety in men with burns: A blinded, randomised, placebo-controlled study

Hossein Jafarizadeh^a, Mojgan Lotfi^b, Fardin Ajoudani^{c,*}, Arezou Kiani^d, Vahid Alinejad^e

^a Patient Safety Research Centre, Urmia University of Medical Sciences, Urmia, Iran

^b Faculty of Nursing, Tabriz University of Medical Sciences, Tabriz, Iran

^c Faculty of Nursing and Midwifery, Urmia University of Medical Sciences, Urmia, Iran

^d Faculty of Medicine, Urmia University of Medical Sciences, Urmia, Iran

^e Department of Biostatistics, Urmia University of Medical Sciences, Urmia, Iran

ARTICLE INFO

Article history: Accepted 7 June 2017 Available online xxx

Keywords: Background pain Burn Hypnosis Pain anxiety

ABSTRACT

Introduction: 'Background pain' and 'pain anxiety' are among the numerous problems of patients with burns. Non-pharmacological and pharmacological interventions have been used to reduce background pain and pain anxiety. This study compared the effectiveness of hypnosis and 'neutral hypnosis' (as a placebo in the control group) in decreasing the background burn pain and pain anxiety of adult male survivors with burns.

Design: This is a blinded, randomised, placebo-controlled study.

Methods: Sixty men with burns were included in the minimisation method (30 individuals in the intervention group and 30 individuals in the control group). Four hypnotherapy sessions were performed every other day for each participant in the intervention group. Four neutral hypnosis sessions were performed every other day in the control group. Burn pain and pain anxiety of the patients in both groups were measured at the end of the second and fourth sessions. Repeated measures ANOVA was used for data analysis.

Results: There was no significant difference between the groups in the reduction in background pain intensity. There was a significant reduction in background pain quality and pain anxiety in the intervention group during the four hypnosis sessions. After two hypnotherapy sessions, a significant reduction was observed in the level of background pain quality and pain anxiety of participants.

Conclusion: Hypnosis is effective in reducing background pain quality and pain anxiety of men with burns.

© 2017 Elsevier Ltd and ISBI. All rights reserved.

* Corresponding author at: Faculty of Nursing and Midwifery, Nazloo Highway, Urmia, West Azerbaijan Province, Iran. E-mail address: fardin.ajodani@yahoo.com (F. Ajoudani).

http://dx.doi.org/10.1016/j.burns.2017.06.001

0305-4179/© 2017 Elsevier Ltd and ISBI. All rights reserved.

JBUR 5297 No. of Pages 10

ARTICLE IN PRESS

BURNS XXX (2017) XXX-XXX

1. Introduction

1.1. Background

Every year, more than 11 million people worldwide suffer from burns and undergo medical interventions such as hospitalisation. Three hundred thousand people lose their lives because of fire-related burns. In Iran, the statistics indicate that about 300,000 people suffer from different types of burns, and 24,000 people are hospitalised every year [1].

Burn is associated with several problems with both physical and mental aspects such as scarring, deformity, pain, anxiety and post-traumatic stress disorder [2]. Burn pain is one of the most difficult problems for patients with burns. They describe their burn pain as 'a living hell' [3]. Patients with burns experience three types of pain: procedural pain, background pain and breakthrough pain. Procedural pain is discomfort that occurs with procedures such as daily wound treatments, invasive line insertions, and physical and occupational therapy. Breakthrough pain is described as acute, strong and episodic pain. It is generally related to an activity or movement of the affected zone. Background pain is a type of discomfort that affects patients while resting and going through their daily routine. It is persistent, long-term and unpredictable, and patients describe it as a burning and throbbing pain. Background pain persists, and patients often feel it is unbearable [4]. In addition to the pain and repeated exposure to painful therapeutic measures, a type of predictive and anticipatory anxiety develops in these patients. There is a direct relationship between anxiety and pain, and the level of anxiety is affected by the perception of all three types of pain. There is a vicious cycle between anxiety and pain: pain causes anxiety and increased anxiety level causes increased pain perception, making it difficult to endure the pain [5].

Different pharmacological and non-pharmacological methods are used for pain control. Pharmacological interventions have been the focus of research in treating burnassociated pain. Because excessive consumption of narcotic drugs leads to some adverse effects such as respiratory depression and drowsiness, the use of other pain control methods such as non-pharmacological methods are being investigated [6]. Among the non-pharmacological interventions, hypnosis is considered a noteworthy pain-control method.

Hypnosis is an altered state of consciousness in which environmental unconsciousness and individual responsiveness to social cues reduces, with increase in the level of attention and local concentration. In other words, it is a method for altering thoughts, perceptions and actions by induction, which is carried out by a therapist after the patient enters a hypnotic state [7]. Although hypnosis has roots in the history of pain reduction and it has been used for a long time, it has not been discussed sufficiently in Iran.

1.2. Rationale

Literature review reveals that most of the studies on the effect of hypnosis on burn pain were in the form of case studies, and they mainly focused on procedural pain reduction [8-10]. Some differences can be seen in various studies on pain reduction after hypnotherapy and in the number of sessions for hypnosis. In addition, standard methods of hypnosis have not been applied in most studies, and the interventions were merely a type of relaxation/imagination state [11]. To the best of our knowledge, thus far, only one study examined some suggestions for reducing pain anxiety in patients with burns [12]. Few studies examined the effect of hypnosis on the qualitative aspect of the pain in these patients. The limitations of prior research include sample size inadequacy, no application of a standard hypnosis technique to reduce burn pain, lack of assessment of the hypnotisability of participants and no application of a placebo in the control group. Attempts were made in this study to compensate for the weaknesses of the earlier studies and achieve further accurate results on the effect of hypnosis on pain and burn pain anxiety, especially through the application of the 'neutral hypnosis' method like the use of placebo in a control group. The present study examined the effectiveness of hypnosis in decreasing burn pain and pain anxiety in adult men with burns using 'neutral hypnosis' as a placebo in the control group.

1.3. Hypotheses

On the basis of the literature findings, the hypotheses designed and studied in this work are as follows:

- 1. Participants who receive hypnosis intervention will have greater reduction in pain intensity than participants in the neutral hypnosis group.
- 2. Participants who receive hypnosis intervention will have greater reduction in pain quality than participants in the neutral hypnosis group.
- 3. Participants who receive hypnosis intervention will have greater reduction in pain anxiety than participants in the neutral hypnosis group.

2. Methodology

2.1. Research design

A blinded, randomised, placebo-controlled clinical trial was designed to achieve the research objectives.

2.2. Sampling and randomisation strategy

In this study, patients were selected through convenience sampling, and they were placed in either the intervention or control group (IG and CG) using the minimisation method, which is a form of randomisation that allows the selection of small groups that are meticulously alike in terms of patient characteristics [13]. This study considered the variables of age, education, history of any type of psychotherapy, total body surface area (TBSA) and type of burn in the minimisation method. This research calculated a sample size of 25 in each group with respect to the study of Shakibaei and colleagues and inclusion of some data such as μ_0 =3.1 and μ_1 =3.3 SD=1.44

 α = 0.05 and 1 – β = 0.8 in the formula N = $4\delta^2 \frac{(Z_{\alpha/2}+Z_{\beta})^2}{(\mu_1-\mu_0)^2}$. Assuming

Please cite this article in press as: H. Jafarizadeh, et al., Hypnosis for reduction of background pain and pain anxiety in men with burns: A blinded, randomised, placebo-controlled study, Burns (2017), http://dx.doi.org/10.1016/j.burns.2017.06.001

2



BURNS XXX (2017) XXX-XXX

an approximate sample attrition of 30%, 32 patients were considered for each group. In the IG and during the hypnotherapy sessions, one individual was excluded as the patient was reluctant to continue the research and one individual was excluded because of discharge from hospital. In the CG, two patients were transferred to another burn centre. Finally, the study was continued with 30 individuals in each group (Fig. 1).

2.3. Inclusion and exclusion criteria

The hypnotherapist was a man and based on the culture and traditions of our country: a woman with a male stranger in a separate room would be considered indecorous; therefore, women were not included in this current study. Participants were between 18 and 50 years old, they had passed the emergency phase of treatment and they were in the acute phase of recovery. These participants had second- and third-degree burns with TBSA of 10%-40%, they spoke Persian or Azeri languages and they had no hearing or vision problems.

Patients with active psychiatric disorders were excluded. Those with a history of epilepsy were also excluded. Other exclusion criteria were unwillingness to participate in the study for any reason, transfer from the ward into the burn intensive care unit, and discharge or death.

2.4. Participants and setting

Sixty individuals hospitalised in Imam Khomeini Teaching Hospital of Urmia, capital of West Azerbaijan Province in northwest Iran, were included in the study. This centre is affiliated to Urmia University of Medical Sciences. The mean age of the participants was 30.5 ± 9.11 years, and the mean TBSA was $24.2\pm9.4\%$. Most patients had second-degree burns (58.3%), the most frequent cause of burn was fire (78.3%), and 90% of the patients had no previous hospitalisation due to burns. Most patients had primary education (45%), were employed (80%) and moderate incomes (56.7%). Only 3.3% did not have insurance coverage. Table 1 shows the demographic characteristics of the participants in each group.



Fig. 1 – Enrolment and allocation to study groups.

BURNS XXX (2017) XXX-XXX

Table 1 – Characteristics of participants in both intervention (n=30) and control (n=30) groups.										
Group Variable		Intervention n (%)	Control n (%)	Test results	Sig.					
Age	Mean \pm SD	30.3±9.57	30.96±8.76	t=0.39 ^a	p=0.69					
TBSA	$Mean\pm SD$	24.66±10.34	23.75±8.53	$t = -0.37^{a}$	p=0.71					
Hypnotisability	$M\!ean\!\pm\!SD$	3.03±0.78	2.82±0.79	$t = -1.03^{a}$	p=0.30					
Depth of burn	Degree II Degree III Degree II and III	17 (56.7) 6 (20) 7 (23.3)	18 (60) 4 (13.3) 8 (26.7)	X ² =0.49 ^b	p=0.78					
Cause of burn	Flame Hot liquid Electricity Chemical Touch	22 (37.3) 4 (13.3) 1 (3.3) 1 (3.3) 2 (6.7)	25 (83.3) 4 (13.3) 1 (3.3) 0 0	Fisher exact	p=0.52					
Past history of burn hospitalisation	Yes No	4 (13.3) 26 (86.7)	2 (6.7) 28 (93.3)	$X^2 = 0.74^{b}$	p=0.38					
Level of education	Illiterate Primary High school BS	6 (20) 12 (40) 10 (33.3) 2 (6.7)	4 (13.3) 15 (50) 10 (33.3) 1 (3.3)	X ² =1.06 ^b	p=0.78					
Occupational status	Inactive Active	8 (26.7) 22(73.3)	4 (13.3) 26 (86.7)	X ² =1.66 ^b	p=0.19					
Income status	Low Moderate High	11 (36.7) 17 (56.7) 2 (6.7)	8 (26.7) 17 (56.7) 5 (16.7)	X ² =1.75b	p=0.41					
Insurance coverage	Without insurance Insured	2 (6.7) 28 (93.3)	0 30 (100)	Fisher exact	p=0.49					
^a Independent t-test. ^b Chi-square test.										

2.5. Measurements

2.5.1. Pain intensity

The intensity of background pain was examined by the visual analogue scale (VAS). The scale includes a 100-mm horizontal line, which indicates a continuum with the marked ends of 'painless=0' and 'intolerable pain=100'. The participants were asked to put a mark on the point of the line in proportion to their pain intensity or utter its numerical value to the researcher. The distance was estimated in millimetres, and the pain intensity was recorded.

2.5.2. Pain quality

This research used the short form-McGill pain questionnaire (SF-MPQ) for pain quality measurement [14]. Its major contents included 15 descriptors (11 sensory items and 4 emotional items) and 6 pain intensity criteria (from painless to torturous). The scale has been used in several studies for various types of pain. In the study by Stephenson and colleagues, there was an appropriate correlation between this questionnaire and the initial McGill pain scale (r=0.86), and it had a good reliability (Cronbach's alpha=0.9) [15]. In Iran, Khosravi and colleagues

[16] translated the questionnaire through the intercultural adaptation model while maintaining its main structure. They then assessed the reliability, which was over 0.8 for all fields of the questionnaire.

2.5.3. Pain anxiety

'Pain anxiety', which is a type of pain-related anticipatory anxiety, was studied by the short-form Burn Specific Pain Anxiety Scale (BSPAS). The scale consists of 5 items, and the patients were requested to specify their reply for any item on a 0-100mm VAS within the range of 'never=0' to 'the worst imaginable=100'. The mean score of 5 items of the BSPAS, which were marked on the VAS, specifies the final score of pain anxiety. Taal and colleagues [17] designed this tool, for which they reported a Cronbach's alpha coefficient of 0.9, indicating its appropriate reliability. A Cronbach's alpha coefficient of 0.7 was also reported in a study conducted in Iran [18].

2.5.4. Hypnotisability

This research used the Stanford Hypnotic Clinical Scale for adults for hypnotisability of the patients. The questionnaire that was used for measuring the hypnotisability of individuals

Please cite this article in press as: H. Jafarizadeh, et al., Hypnosis for reduction of background pain and pain anxiety in men with burns: A blinded, randomised, placebo-controlled study, Burns (2017), http://dx.doi.org/10.1016/j.burns.2017.06.001

4

has 5 items: moving hands together, a dream, age regression, a posthypnotic suggestion, and posthypnotic amnesia. The measure is reliable and valid. Cronbach's alpha was 0.66 for internal consistency. The clinical scale requires approximately 20min for administration [19]. The Cronbach's alpha for the questionnaire in our study was 0.79.

2.5.5. Demographic questionnaire

A self-reported demographic questionnaire was used to obtain the personal information of the participants. It provided data such as age, TBSA, depth of burn, cause of burn, history of hospitalisation, level of education, occupation status, level of income, insurance status and history of psychotherapy.

2.6. Ethical considerations

This research was approved by the Committee of Ethics of Urmia University of Medical Sciences (Code: ir.rec.umsu.1395.3). After providing the patients with sufficient explanation of the project, written informed consents were obtained from them. The participants were informed that they would be able to withdraw at any stage of the research without causing any problems in their course of treatment. The participants were assured of the confidentiality of the obtained information.

2.7. Procedure

In the first session, the researcher explained the research objectives to the patients at their bedsides and obtained informed consents from them. Baseline data including demographic characteristics, background pain intensity and background pain quality (in the afternoon), and pain anxiety (in the morning and before dressing) were obtained from both groups in the first session. Participants were not told whether they were receiving neutral hypnosis or hypnosis, and they did not know which group they were randomised to. In both groups, hypnosis (or neutral hypnosis) was performed along with routine nursing care. Research assistants collected the data during all 3 assessment times of study. Therefore, the hypnotherapist was blind to the gathered data during this whole period. Administration of analgesics was continued as before. Four hypnotherapy (or neutral hypnotherapy) sessions were performed every other day for each participant in both groups. The time of hypnotherapy varied with respect to patients' suggestibility and the time needed to develop a proper depth of trance. Different standard induction techniques were performed, dictated by patient characteristics such as age and hypnotisability. Hypnotherapy sessions were performed between 16:00 and 20:00 (local time) when the patients were not tired and were comfortable in a ward and in a room with moderate temperature and sufficient light on an armchair. The corresponding author, who is a nurse specialising in burn care, performed the hypnosis. The hypnotherapist received his certificate from the Iranian Scientific Society of Clinical Hypnosis. Pain and pain anxiety in the intervention and control groups were measured before starting hypnotherapy intervention and at the end of the second and the fourth sessions.

2.7.1. Intervention group

Various techniques such as eye fixation, progressive muscle relaxation, Chiasson's technique and hand levitation were used to begin hypnotherapy and induction in this group. Imagination, dissociation and progressive muscle relaxation techniques were used for deepening the trance. Induction and trance deepening techniques were different based on the participant characteristics in this study. In the suggestion delivery phase of hypnosis—which is the therapeutic component of hypnosis—we used a standardised script for burns based on the script for Rapid Induction Analgesia that has been used in earlier trials [20]. The participants were also requested to repeat the techniques during the day. The patients were not aware of being in the IG (blinding).

2.7.2. Control group

It is necessary to use a placebo-controlled group in pain treatment trials [21]. Unlike the placebos used in drug trials, which mimic the original drug in all aspects except the main ingredient, it is difficult to find such a placebo for hypnotherapy [22]. As the main content of therapy in hypnosis includes specific suggestions of a disease, some studies introduced a type of hypnosis suitable for a control group called neutral hypnosis by including general and non-therapeutic suggestions after the induction process and typical trance [23,24].

Neutral hypnosis with non-therapeutic suggestions was performed in this trial in the CG. All processes of induction, trance deepening and altering phase were performed similar to those in the IG. Suggestions such as imagining being on a beach and/or in a garden were used instead of the therapeutic suggestions for burn pain and pain anxiety. The participants were not aware of being in the CG (blinding).

2.8. Data analysis

Data were analysed using the software SPSS (version 23). All the data were reported using descriptive statistics. Quantitative and qualitative data are shown as mean±standard deviation and frequency (%), respectively. The Kolmogorov-Smirnov test was used to identify the normal distribution of data. The independent t-test, Chi-square test and Fisher's exact test were used in the demographic characteristics for examining the differences between the two groups. The independent t-test was used for comparing the major variables of the research before starting hypnosis (baseline data). Repeated measures ANOVA was used for studying the changes in the level of main variables during the fourth session of hypnotherapy. A p < 0.05 was considered significant. Data analysis was performed by an assistant unaware of participant allocation to each group (blinding).

3. Results

3.1. Pain intensity

The independent t-test showed no significant difference between the baseline data (before starting hypnosis) of the IG and CG with regard to the background pain intensity (t=0.781, p=0.438). The first measurement was carried out

BURNS XXX (2017) XXX-XXX

before starting the sessions, the second measurement was made after the second session and the third assessment was made after the fourth session. Repeated measures ANOVA was used for studying the effect of hypnosis on pain intensity during the fourth session. The test results showed no significant differences between the groups with regard to the background pain intensity reduction (F=0.742 and p=0.392). Fig. 2 shows no significant difference in the IG (F (2, 58)=2.19, p=0.12) and CG (F (1.29, 37.52)=2.23, p=0.13) in pain intensity during the four sessions of hypnotherapy. Therefore, the first hypothesis was rejected.

3.2. Pain quality

The independent t-test showed no significant difference between the baseline data of both groups with regard to the background pain quality (t=0.217, p=0.829). The results of repeated measures ANOVA showed a significant difference between the groups in terms of background pain quality reduction during the four sessions of hypothesis (F=4.902, p=0.031). Fig. 3 shows a significant reduction in the mean score in the IG during the four sessions (F (1.628, 47.219)=47.356, p < 0.0005). Despite the slight reduction in the mean scores between the baseline data and after the second session, the Bonferroni post-hoc test showed that the difference was not significant (p=0.153). The test also indicated a notable significant difference between the mean scores of the second and the fourth sessions (p < 0.0005). In the CG, no significant change was seen in the mean scores over time (F (1.607, 46.59) =0.02, p=0.994). Therefore, the second hypothesis was confirmed.

3.3. Pain anxiety

Despite the insignificance of the difference between the baseline data of both groups (t=0.479, p=0.634), there was a significant difference between the groups in terms of pain anxiety reduction during the four sessions of hypnosis (F=4.163, p=0.046). Fig. 4 shows a considerable reduction in mean scores during the four sessions in IG (F (2, 58)=35.215, p < 0.0005). Despite the slight reduction in the mean scores

between the baseline data and the second session, the Bonferroni post-hoc test showed that the difference was not significant (p=0.62). The test also indicated a notable significant difference between the mean scores of the second and the fourth sessions of hypnosis (p<0.0005). No significant change was seen in the mean scores in the CG over time (F (1.451 & 42.068)=0.02, p=0.784). Therefore, the third hypothesis was confirmed. All the detailed results are summarised in Table 2.

4. Discussion

This study aimed at examining the effect of hypnosis on reducing background pain and pain anxiety in men with burns. Attempts were made to achieve further accurate results on the effect of hypnosis on burn pain and pain anxiety by applying neutral hypnosis in the CG. The findings showed that the level of pain and pain anxiety in this study was at a moderate level, which is consistent with the results of other studies in Iran [25,26]. As the patients had passed the emergency phase and were in the following treatment phases, their background pain was not severe. Being in a strange environment and experiencing painful procedures and expecting to experience them again resulted in the patients having medium level of pain anxiety.

The research results clearly show that hypnosis is generally effective for the treatment of pain and pain anxiety, which is consistent with many studies confirming the effect not only on burns but also on many other types of acute or chronic diseases [27–29]. Although the mechanism of the effect of hypnosis on pain reduction has not yet become clear, studies with positron emission tomography have shown blood flow increase at the time of inductions in the extra striate areas, the anterior cingulated cortex, thalamus, and upper-frontal gyrus and simultaneous flow reduction in the somatosensory cortex [30,31].

The main variables of the study in the IG decreased considerably in comparison with the CG (despite a reduction in the mean values of the CG during 4 sessions). This finding is inconsistent with the study of Askay and colleagues [12]. In their study, reduction of pain and pain anxiety in both groups



BURNS XXX (2017) XXX-XXX





Fig. 4 - Pain anxiety.

Table 2 – Means, standard deviations, p-values and effect sizes of main variables.													
		Group	Time of measurement					Sig.	$\pmb{\eta}_{partial}^2$				
			First evaluation (baseline)		Second evaluation (second session)		Third evaluation (forth session)						
			Mean	SD	Mean	SD	Mean	SD					
Variables Intensit	y of pain	IG	51.33	15.18	50.16	15.35	49.96	14.82	p=0.12 ^a	0.07			
		CG	54.80	18.98	53.33	18.64	54.60	18.64	p=0.11 ^b	0.07			
Quality	of pain	IG	27.7	9.08	27.83	8.97	19.3	7.82	$p < 0.0005^{b}$	0.62			
		CG	30.23	9.95	30.26	8.73	30.2	8.98	p=0.99 ^b	0.00			
Pain an	xiety	IG	46.56	17.26	43.60	14.75	28.46	12	$p < 0.0005^{a}$	0.54			
		CG	48.83	19.35	48.86	21.87	47.66	23.26	p=0.78 ^b	0.005			

IG: Intervention group, CG: Control group, $\eta^2_{partial}$: Partial eta squared (effect size). ^a Mauchly's Test of Sphericity indicated that the assumption of sphericity had not been violated.

^b Mauchly's Test of Sphericity indicated that the assumption of sphericity had been violated, and therefore, a Greenhouse-Geisser correction was used.

7

8

ARTICLE IN PRESS

BURNS XXX (2017) XXX-XXX

was significant. In explaining this finding, we can highlight the role of applying neutral hypnosis in current study. As a placebo for the CG, neutral hypnosis can be used, in which completely general suggestions irrelevant to pain reduction and pain anxiety are used for the patients instead of therapeutic suggestions.

Contrary to the findings of Shakibaei and Frenay [32], hypnosis had no significant effect on pain intensity reduction (measured by pain VAS), which is one of the key findings of this study. Some points can be mentioned regarding the interpretation of this finding. There are relationships among pain intensity, pain receptor input and an individual's sensory experience of pain; however, some suggestions were used in this study, which had no relationship with the pain sensation of an individual, and the term 'pain sensation' was never used in the inductions. Despite having the same pain intensity, pain quality reduced considerably in the IG. This finding is quite consistent with the study of Askay and colleagues. In addition, Price and Barber believed that hypnosis might alter both intensity and quality of pain and that the change depends upon the nature of the suggestions [33]. His finding has been confirmed by brain imaging [34]. Pain intensity suggestions are effective in the somatosensory cortex, and pain quality inductions affect areas related to emotions. In this study, the hypnotherapist provided an overall image of the qualitative and emotional state of the participants using the data obtained from the SF-MPQ for evaluating the baseline data of the IG patients and presented appropriate therapeutic suggestions based on the standardised script for Rapid Induction Analgesia.

Unlike the findings of Askay and colleagues, hypnosis had a considerable effect on reducing anxiety in the IG patients. This phenomenon can be explained in two ways. The first is provision of proper therapeutic suggestions, which were used for pain anxiety reduction. The second could be the breaking of the vicious cycle of pain and anxiety in the participants. That is, hypnosis reduced pain anxiety in the patients following the reduction of pain perception or pain quality. In other words, patients whose perceptions have been reduced anticipate tolerating a lower level of pain, which reduces their anxiety.

Consistent with the study of Shakibaei on patients with burns and other studies in other fields [35-37], no significant results were seen in pain reduction or other study variables in the early hypnotherapy sessions. A significant reduction in SF-MPQ and BSPAS scores was seen from the second to the fourth (final) session of hypnotherapy, and there was no significant difference between the baseline and the second session. This might be because the patients had become accustomed to the hypnotherapy room atmosphere and hypnosis process after the early sessions. Conditioning techniques were used at the end of the second session for the participants; consequently, the entry and deepening stages of trance occurred earlier, and the hypnotherapist had more time to provide therapeutic suggestions. More than two hypnotherapy sessions are necessary for acceptable reduction in pain and pain anxiety.

4.1. Clinical applications

This study showed that hypnosis could be used at the clinic because it is safe [38] and requires no special and expensive

equipment or tools. The major problem with using hypnosis at the clinic is that a psychotherapist capable of performing hypnotherapy is not always available, and the treatment performed by them is expensive. As recommended by some studies, hypnotherapy by a specialist nurse (a nurse trained in hypnotherapy) is a more cost-effective solution because of its availability and the low cost [39,40]. Holistic nursing theories support the use of hypnotherapy by nurses and provide a framework for it [41]. The measures known as mind-body treatments such as distraction, deep breathing, mental imagery and relaxation are already part of nursing care [42], and these are the integral parts of hypnosis.

4.2. Limitations

While having strengths, this study has some limitations. Because of the cultural limitations in Iran, this study was conducted only on men. It is recommended that future studies include both men and women to elucidate the probable differences in response to hypnosis in both genders. Although the sample size in this study exceeded that of the earlier studies, the use of a larger sample size in future studies will provide further accurate results. One of the major limitations of the trial was the difficulty in making the necessary measurements after each session because there were a limited number of interviewers; therefore, measurements were only made after the second and the fourth sessions. This limitation hindered our ability to specify accurately after which session pain reduction or pain anxiety reduction started. The morphine dosage of the patients, as a pain reliever, was not recorded and analysed in this research. Consequently, we were unable to find out the possible role of morphine in reducing the pain of the participants. However, all the patients in the burn ward of our hospital receive morphine at their request (PRN) if there is no contraindication. We recommend that morphine dosage is recorded and analysed accurately in further studies. To provide clearer results on the advantages of the intervention on pain and anxiety management, future studies may divide participants into 'medication only', 'hypnotherapy and medication' and 'hypnotherapy alone' groups.

Those patients who qualified received early excision and grafting in the study setting; it seems that this measure also reduced their pain. Because the surgical process was not considered in the inclusion/exclusion criteria, we were unable to measure its role in relieving the pain of the participants. We also excluded patients with active psychiatric disorders. This limitation hindered our ability to truly understand the clinical utility of the intervention, particularly given the rates of premorbid mental health issues in burn survivors [43].

5. Conclusion

Clinical trial results showed that hypnotherapy considerably reduced pain and pain anxiety in the men. Although this study is an evidence-based report for the nursing staff, who attempt to reduce the pain and pain anxiety of patients with burns, it is necessary to conduct further complementary studies to clarify

BURNS XXX (2017) XXX-XXX

different aspects of the effect of hypnosis on different variables and population groups.

Conflict of interest

The researchers have no conflict of interest with any individual or organisation.

Funding

This manuscript has been derived from the results of the master's thesis of the corresponding author in medicalsurgical nursing, which was financed by the research department of the university. This trial was registered in the website of the National Registry for Clinical Trials (Registration No. IRCT2016100830214N1).

Acknowledgements

We express our appreciation to all the patients who participated in this trial. We thank all the staff of the burn ward of Imam Khomeini Teaching Hospital in Urmia for cooperating in this project. Special thanks to Mr Naser Sheykhi who assisted us in performing the complex statistical analysis for this research.

REFERENCES

- [1] Vaghardoost R, Kazemzadeh J, Rabieepoor S. Epidemiology of burns during pregnancy in Tehran, Iran. Burns 2016;42:663-7, doi:http://dx.doi.org/10.1016/j.burns.2015.10.001.
- [2] Meyer III W, Blakeney P, Russell W, Thomas C, Robert R, Berniger F, et al. Psychological problems reported by young adults who were burned as children. J Burn Care Res 2004;25:98-106.
- [3] Morse JM. Using qualitative methods to access the pain experience. Br J pain 2015;9:26-31, <u>doi:http://dx.doi.org/</u> <u>10.1177/2049463714550507</u>.
- [4] Zor F, Ozturk S, Bilgin F, Isik S, Cosar A. Pain relief during dressing changes of major adult burns: ideal analgesic combination with ketamine. Burns 2010;36:501–5, <u>doi:http://</u> dx.doi.org/10.1016/j.burns.2009.08.007.
- [5] Adams MH, Lovejoy TI, Turk DC, Dobscha SK, Hauser P, Morasco BJ. Pain-related anxiety mediates the relationship between depressive symptoms and pain interference in veterans with hepatitis C. Gen Hosp Psychiatry 2015;37:533-7, doi:http://dx.doi.org/10.1016/j.genhosppsych.2015.07.003.
- [6] De Jong A, Middelkoop E, Faber A, Van Loey N. Nonpharmacological nursing interventions for procedural pain relief in adults with burns: a systematic literature review. Burns 2007;33:811–27, <u>doi:http://dx.doi.org/10.1016/j.</u> burns.2007.01.005.
- [7] Lloyd G. Textbook of psychosomatic medicine. 3 ed. United States: American Psychiatric Pub; 2006. p. 308-500.
- [8] Hirsch JA. Virtual reality exposure therapy and hypnosis for flying phobia in a treatment-resistant patient: a case report. Am J Clin Hypn 2012;55:168-73, <u>doi:http://dx.doi.org/10.1080/</u> 00029157.2011.639587.
- [9] Teeley AM, Soltani M, Wiechman SA, Jensen MP, Sharar SR, Patterson DR. Virtual reality hypnosis pain control in the

treatment of multiple fractures: a case series 1. Am J Clin Hypn 2012;54:184-94, <u>doi:http://dx.doi.org/10.1080/</u>00029157.2011.619593.

- [10] Vanhaudenhuyse A, Laureys S, Faymonville M-E. The use of hypnosis in severe brain injury rehabilitation: a case report. Acta Neurol Belg 2015, <u>doi:http://dx.doi.org/10.1007/s13760-015-0459-3.</u>
- [11] Montgomery GH, DuHamel KN, Redd WH. A meta-analysis of hypnotically induced analgesia: how effective is hypnosis? Int J Clin Exp Hypn 2000;48:138–53, <u>doi:http://dx.doi.org/10.1080/</u> 00207140008410045.
- [12] Askay SW, Patterson DR, Jensen MP, Sharar SR. A randomized controlled trial of hypnosis for burn wound care. Rehabil Psychol 2007;52:247–53, <u>doi:http://dx.doi.org/10.1037/0090-5550.52.3.247</u>.
- [13] Altman DG. Practical statistics for medical research. 3 ed. London: CRC Press; 2010.
- [14] Melzack R. The short-form McGill pain questionnaire. Pain 1987;30:191–7, <u>doi:http://dx.doi.org/10.1016/0304-3959(87)</u> 91074-8.
- [15] Stephenson NL, Herman J. Pain measurement: a comparison using horizontal and vertical visual analogue scales. Appl Nurs Res 2000;13:157–8.
- [16] Khosravi M, Sadighi S, Sh M, Zendehdel K. Persian-McGill pain questionnaire; translation, adaptation and reliability in cancer patients: a brief report. Tehran Univ Med Sci 2013;71:53-8 [Persian].
- [17] Taal L, Faber A, Van Loey N, Reynders C, Hofland H. The abbreviated burn specific pain anxiety scale: a multicenter study. Burns 1999;25:493-7, <u>doi:http://dx.doi.org/10.1016/ S0305-4179(99)00034-0</u>.
- [18] Ghezeljeh TN, Ardebili FM, Rafii F, Hagani H. Translation and psychometric evaluation of Persian versions of burn specific pain anxiety scale and impact of event scale. Burns 2013;39:1297–303, <u>doi:http://dx.doi.org/10.1016/j.</u> <u>burns.2013.02.008</u>.
- [19] Morgan AH, Hilgard JR. The Stanford hypnotic clinical scale for adults. Am J Clin Hypn 1978;21:134-47, <u>doi:http://dx.doi.org/</u> 10.1080/00029157.1978.10403968.
- [20] Wright BR, Drummond PD. Rapid induction analgesia for the alleviation of procedural pain during burn care. Burns 2000;26:275-82, <u>doi:http://dx.doi.org/10.1016/S0305-4179(99)</u> 00134-5.
- [21] Miller FG, Rosenstein DL. The nature and power of the placebo effect. J Clin Epidemiol 2006;59:331–5, <u>doi:http://dx.doi.org/</u> 10.1016/j.jclinepi.2005.12.001.
- [22] Jensen MP, Patterson DR. Control conditions in hypnoticanalgesia clinical trials: challenges and recommendations. Int J Clin Exp Hypn 2005;53:170–97, <u>doi:http://dx.doi.org/10.1080/</u> 00207140590927536.
- [23] Bryant RA, Kapur A. Hypnotically induced emotional numbing: the roles of hypnosis and hypnotizability. Int J Clin Exp Hypn 2006;54:281–91.
- [24] Gholamrezaei A, Emami MH. How to put hypnosis into a placebo pill? Complement Ther Med 2008;16:52-4, <u>doi:http://</u> <u>dx.doi.org/10.1016/j.ctim.2007.04.005</u>.
- [25] Fakhar FM, Rafii F, Orak RJ. The effect of jaw relaxation on pain anxiety during burn dressings: randomised clinical trial. Burns 2013;39:61–7, <u>doi:http://dx.doi.org/10.1016/j.</u> burns.2012.03.005.
- [26] Amiri MH, Tavousi S, Mazlom S, Manzari Z. Effect of transcranial direct current stimulation on pain anxiety during burn wound care. Burns 2016;42:872-6, <u>doi:http://dx.doi.org/</u> 10.1016/j.burns.2016.01.006.
- [27] Ahmad TS. Hypnotherapy and accupressure for brachial neuralgia. BMC Proceedings: BioMed Central Ltd 2015;81–2.
- [28] Flik CE, van Rood YR, Laan W, Smout AJ, Weusten BL, Whorwell PJ, et al. A randomised controlled trial on hypnotherapy for irritable bowel syndrome: design and

BURNS XXX (2017) XXX-XXX

- [29] Wallen GR, Middleton KR, Ames N, Brooks AT, Handel D. Randomized trial of hypnosis as a pain and symptom management strategy in adults with sickle cell disease. Integr Med Insights 2014;9:25.
- [30] Faymonville M-E, Boly M, Laureys S. Functional neuroanatomy of the hypnotic state. J Physiol Paris 2006;99:463-9, <u>doi:http://</u> dx.doi.org/10.1016/j.jphysparis.2006.03.018.
- [31] Rainville P, Hofbauer RK, Bushnell MC, Duncan GH, Price DD. Hypnosis modulates activity in brain structures involved in the regulation of consciousness. J Cogn Neurosci 2002;14:887– 901, doi:http://dx.doi.org/10.1162/089892902760191117.
- [32] Frenay M-C, Faymonville M-E, Devlieger S, Albert A, Vanderkelen A. Psychological approaches during dressing changes of burned patients: a prospective randomised study comparing hypnosis against stress reducing strategy. Burns 2001;27:793-9, doi:http://dx.doi.org/10.1016/S0305-4179(01) 00035-3.
- [33] Price DD, Barber J. An analysis of factors that contribute to the efficacy of hypnotic analgesia. J Abnorm Psychol 1987;96:46-51, doi:http://dx.doi.org/10.1037/0021-843X.96.1.46.
- [34] Rainville P, Carrier BT, Hofbauer RK, Bushnell MC, Duncan GH. Dissociation of sensory and affective dimensions of pain using hypnotic modulation. Pain 1999;82:159-71, <u>doi:http://dx.doi.org/10.1016/S0304-3959(99)00048-2</u>.
- [35] Abrahamsen R, Baad-Hansen L, Zachariae R, Svensson P. Effect of hypnosis on pain and blink reflexes in patients with painful temporomandibular disorders. Clin J Pain 2011;27:344– 51, doi:http://dx.doi.org/10.1097/AJP.0b013e3181ffbfcb.

- [36] Lew MW, Kravits K, Garberoglio C, Williams AC. Use of preoperative hypnosis to reduce postoperative pain and anesthesia-related side effects. Int J Clin Exp Hypn 2011;59:406-23, doi:http://dx.doi.org/10.1080/ 00207144.2011.594737.
- [37] Picard P, Jusseaume C, Boutet M, Dualé C, Mulliez A, Aublet-Cuvellier B. Hypnosis for management of fibromyalgia. Int J Clin Exp Hypn 2013;61:111–23, <u>doi:http://dx.doi.org/10.1080/</u> 00207144.2013.729441.
- [38] Häuser W, Hagl M, Schmierer A, Hansen E. The efficacy, safety and applications of medical hypnosis: a systematic review of meta-analyses. Deutsches Ärzteblatt Int 2016;113:289-96.
- [39] Bremner H. Nurse-led hypnotherapy: an innovative approach to irritable bowel syndrome. Complement Ther Clin Pract 2013;19:147–52, doi:http://dx.doi.org/10.1016/j. ctcp.2013.01.001.
- [40] Smith GD. Effect of nurse-led gut-directed hypnotherapy upon health-related quality of life in patients with irritable bowel syndrome. J Clin Nurs 2006;15:678-84, <u>doi:http://dx.doi.org/</u> 10.1111/j.1365-2702.2006.01356.x.
- [41] Dossey BM, Keegan L. Holistic nursing. fifth edition United States: Jones & Bartlett Publishers; 2012.
- [42] Watson J, Smith MC. Caring science and the science of unitary human beings: a trans-theoretical discourse for nursing knowledge development. J Adv Nurs 2002;37:452-61, <u>doi:http://</u> dx.doi.org/10.1046/j.1365-2648.2002.02112.x.
- [43] Logsetty S, Shamlou A, Gawaziuk JP, March J, Doupe M, Chateau D, et al. Mental health outcomes of burn: a longitudinal population-based study of adults hospitalized for burns. Burns 2016;42:738-44, <u>doi:http://dx.doi.org/10.1016/j.</u> <u>burns.2016.03.006</u>.

10