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The healing effects of an egg white formulation on pressure ulcers: A triple-blind clinical trial

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Abstract

Background: Pressure ulcers represent a significant health challenge for individuals with mobility impairments. The development of effective and cost-efficient treatments that can expedite the healing process is essential. Egg white is rich in the nutrients necessary for wound healing.

Objectives: This study aimed to assess the healing effects of an egg white formulation on pressure ulcers.

Methods: This triple-blind clinical trial was carried out over a span of nine months, from March 2022 to November 2023, at Golestan and Imam Khomeini hospitals in Ahvaz, Iran. A total of 78 patients with Grade II and III pressure ulcers were enrolled based on specific inclusion criteria. Participants were randomly assigned to either the intervention group, which received the egg white formulation, or the control group, which received standard treatment. The healing of ulcers was monitored using the Pressure Ulcer Scale for Healing (PUSH) tool at baseline and at the end of each week from the first to the fourth week. The healing progress between the two groups was analyzed using repeated measures analysis of variance, with all statistical tests performed using SPSS-25.

Results: The findings indicated no significant differences between the intervention and control groups regarding the mean scores for ulcer area (P=0.46), exudate amount (P=0.95), and overall ulcer healing (P=0.11). However, there was a statistically significant difference in the mean scores for ulcer tissue type (P<0.001).

Conclusion: While the overall difference in ulcer healing rates was not statistically significant, the intervention group demonstrated a greater mean improvement. Therefore, we recommend considering egg white formulation as a complementary treatment for pressure ulcers alongside standard therapies. Further research with larger sample sizes over extended periods is warranted to validate these findings.

Introduction

Treating pressure ulcers poses a significant challenge in healthcare due to their widespread occurrence and the associated costs. These ulcers, which develop from prolonged pressure on the skin, primarily affect individuals with mobility impairments.[1,2] Despite increased awareness and efforts to address this issue, pressure ulcers continue to be a major concern, impacting over 3 million adults in the United States alone.[3] In Europe, the prevalence ranges from 8.3% to 23%,[4] while in North America it falls between 12% and 19.7%.[5] Australia reports a prevalence of 2.5% to 7.7%.[6] A systematic review conducted in Iran found that the prevalence of pressure ulcers was 19%, with Grade 1, Grade 2, and Grade 3 ulcers accounting for 38%, 41%, and 9% respectively. The sacrum is the most common site for these ulcers, occurring in 54% of cases. Furthermore, the prevalence among patients with neurological conditions, movement disorders, and coma was reported at 25%, 19%, and 46%, respectively.[7]

Effective prevention and treatment are essential, yet managing pressure ulcers is complicated by the absence of standardized treatment protocols. A new rehabilitation approach focuses on preventing these ulcers by

maintaining skin integrity, repositioning patients regularly, ensuring adequate nutrition, and utilizing supportive tools.[8,9] Common treatment methods include various dressings, topical ointments and creams, as well as hyperbaric oxygen therapy to promote wound healing.[10] However, a review by Norman et al., highlights that the effectiveness of current treatments for pressure ulcers varies widely, often falling between low to very low due to insufficient research.[8,11]

Traditional medicine has sought to enhance skin wound healing through various remedies, but definitive treatments remain elusive. Ongoing studies are exploring the effects of both plant and animal products on wound healing.[12] Research has examined the efficacy of honey,[13] *Alkanna tinctoria* root extract, St. John's wort (*Hypericum perforatum*) oily extract,[14,15] and mummy[16] on pressure ulcer healing.

Eggs have long been recognized for their health and beauty benefits for the skin. Rich in vitamins and minerals, eggs are utilized in traditional medicine for their therapeutic properties, which include anti-inflammatory, antibacterial, and immunogenic effects. Studies indicate that egg white possesses antibacterial properties and promotes angiogenesis, thereby preventing infection and enhancing tissue healing.[17,18] The amino acid L-arginine found in eggs helps reduce wound inflammation and accelerates healing by promoting epithelial cell proliferation and lowering wound glucose levels.[19]

Research involving laboratory animals, particularly rats, has shown promising results regarding the impact of eggs on skin ulcer healing, especially in cases of burns. Both egg white and yolk have demonstrated significant improvements compared to control groups.[19-21] In 2019, Jahani et al., conducted the only clinical trial examining the effects of egg white on burn injury healing in humans. Their findings indicated that an egg white formulation positively influenced both the extent and speed of healing for Grade II burn injuries, with the intervention group experiencing faster recovery than the control group.[22]

Objectives

Given that most existing studies on wound healing have focused on burns in animal models and that only one clinical trial has investigated this topic in humans, the researchers were inspired by Jahani et al's study[22] and insights from ICU nurses in Ahvaz. This led to the design of a study aimed at evaluating the effects of an egg white formulation on the healing of pressure ulcers.

Methods

Study Design and Participants

This triple-blind clinical trial was conducted over nine months, from March 2022 to November 2023, to assess the impact of an egg white formulation on Grade II and III pressure ulcers. The study took place at Golestan and Imam Khomeini Hospitals in Ahvaz, Iran, involving a diverse group of male and female patients diagnosed with confirmed Grade II and III pressure ulcers.

Inclusion Criteria: Participants were required to be over 18 years of age and have a clinical diagnosis of Grade II or III pressure ulcers, as determined by a physician and documented in their medical records. Additional criteria included no history of egg allergy, consistent use of antibiotics across both groups, no use of immunosuppressive medications, and the absence of chronic conditions that could hinder ulcer healing, such as diabetes, severe vascular disease, lupus, rheumatoid arthritis, cancer, or renal failure.

Exclusion Criteria: Patients were excluded from the study if they died during the trial, were discharged from the hospital, or experienced allergic or inflammatory reactions to any components of egg white.

The sample size was calculated using Formula-1 for comparing two proportions, with α set at 0.05 and β at 0.2, based on previous research.[16] With anticipated proportions of P1=0.35 and P2=0.7, the initial sample size was determined to be 31 patients for each group. To account for a potential attrition rate of 20%, this number was increased to 39 patients per group, resulting in a total of 78 participants.

$$n = \frac{\left(z_{1-\frac{\alpha}{2}} + z_{1-\beta}\right)^2 p_{1(1-p_1)} + p_{2(1-p_2)}}{\left(p_{1-p_2}\right)^2}$$

Formula-1. Sample size calculation

Eligible patients were selected based on the inclusion criteria and randomly assigned to either the intervention or control group using a random block method with blocks of six. Within each block, three patients were allocated to the intervention group and three to the control group using WINPEPI version 11.4 until all patients were assigned. Ultimately, 78 patients were enrolled according to the inclusion criteria; however, six patients from each group (12 in total) were excluded for reasons detailed in Figure 1. Consequently, data analysis was performed on 66 patients.

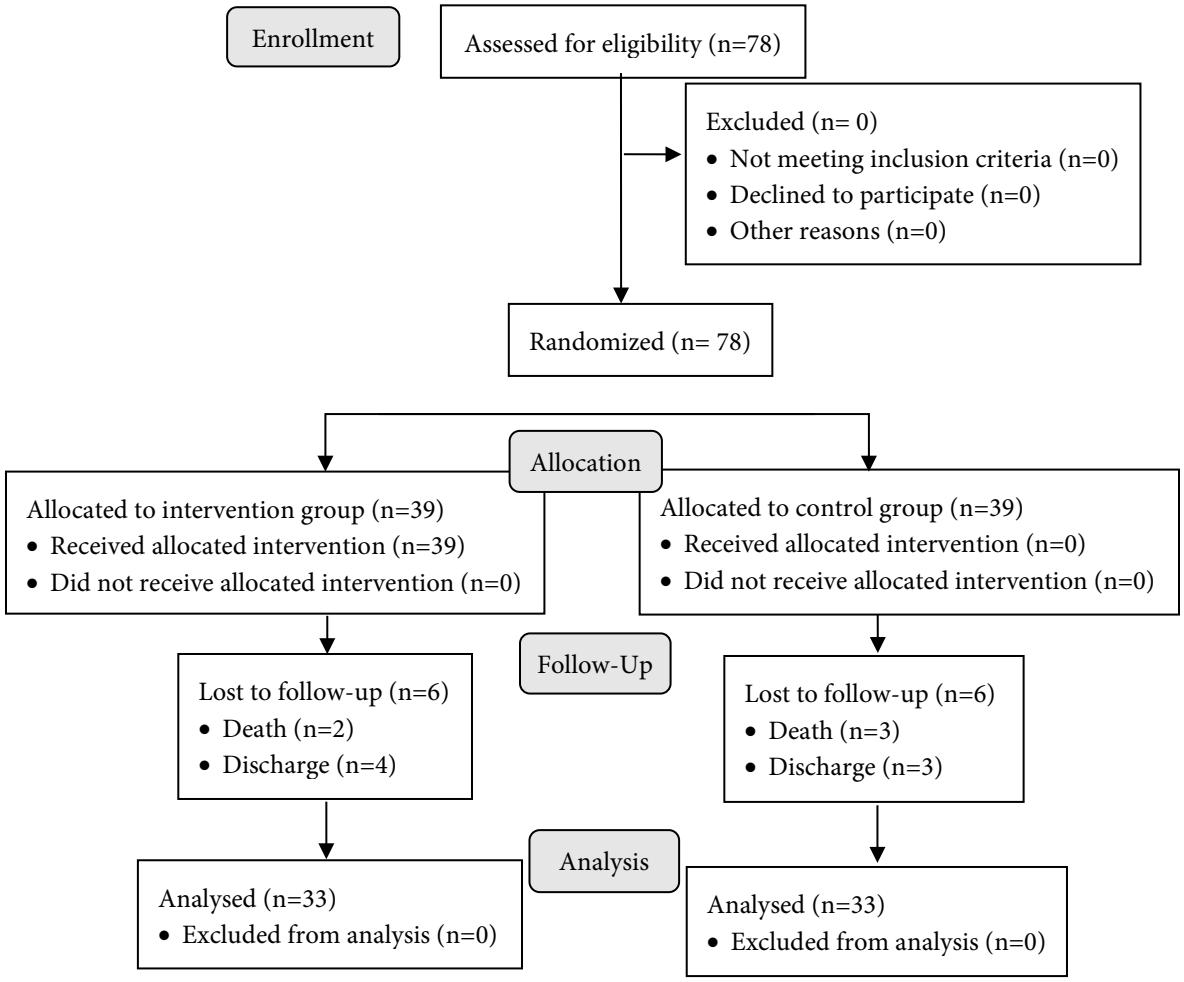

Figure 1. CONSORT chart illustrating the selection, evaluation, and follow-up process of participants

Intervention

A specialized local formulation was developed based on a cold cream base, which included ingredients such as methylparaben, beeswax, and borax, under the guidance of a pharmacologist.[17] In a sterile environment, we carefully broke the eggs and separated the egg whites (albumen). The albumen was then homogenized using a homogenizer and added to the cooled cream base. To ensure stability, the final product was stored in the laboratory for 48 hours before testing. After this period, the formulation was placed into 30-gram tubes and kept refrigerated until it was ready for application. Each batch of cream was freshly prepared and labeled with essential information for patients, including dosage and safety alerts.

A placebo cream was created under the same conditions, containing only the components of the cold cream without the egg white. Both formulations were indistinguishable in appearance and scent. The products were prepared at the Medicinal Herbs Research Center.

Once the egg white formulation and placebo cream were ready, participants were assigned to either the intervention or control group. Informed consent was obtained from all patients or their legal guardians if they were unable to provide consent themselves. We also collected demographic information and assessed the grade of each patient's ulcer using a pre-designed questionnaire. At baseline, ulcer severity was evaluated using the Pressure Ulcer Scale for Healing (PUSH), and the scores were recorded in a structured table.

Before applying the creams, a patch test was conducted to rule out any allergic reactions to egg white. To administer the creams, we repositioned each patient, removed any existing dressings, and reassessed the ulcer site. After donning sterile gloves, we cleaned the ulcer with saline solution and gently dried it using sterile gauze. It is important to note that all participants continued to receive their standard treatments. Phenytoin ointment was used as part of the usual care for Grade II and III pressure ulcers in both groups. In addition to this standard treatment, the intervention group received the egg white formulation while the control group received the placebo. After application, the wounds were bandaged.

Wound healing was monitored weekly over a four-week period. To maintain consistency in dressing techniques,

the same researcher performed all dressing changes for every patient. Recognizing that environmental factors could influence observations, two independent observers evaluated and scored the ulcers. Additionally, ulcers were photographed digitally, and a third observer -blinded to which treatment was applied- reviewed these images to assess healing progress.

Alongside monitoring ulcer healing, we evaluated each patient's overall health and examined the ulcer site for any complications at the end of each week using a comprehensive checklist.

Data Collection Instruments

Three primary tools were employed for data collection in this study:

1. Demographic Questionnaire: This questionnaire gathered essential information, including participants' age, sex, body mass index (BMI), ulcer site, level of consciousness, mobility, feeding method, and the admission ward.

2. Pressure Ulcer Grading Tool: We utilized the grading tool established by the National Pressure Ulcer Advisory Panel (NPUAP), which categorizes pressure ulcers into four grades based on the characteristics of the ulcer tissue and area. This tool has been recognized as the most valid criterion for grading in pressure ulcer prevention guidelines.[23,24] Research by Bloorchifard et al. has confirmed its reliability with a coefficient of 0.88.[25]

3. Pressure Ulcer Scale for Healing (PUSH): The PUSH tool is a dependable method for assessing the healing progress of pressure ulcers over time. It effectively differentiates between healing and non-healing ulcers, offering clinicians valuable insights into changes in ulcer status. When applied weekly, PUSH provides an evidence-based approach for monitoring healing and facilitates timely interventions and modifications to treatment plans. As illustrated in Table-1, the PUSH tool evaluates three criteria: ulcer area, exudate amount, and tissue type.[26] Several prospective studies have validated its effectiveness, with reliability ratings ranging from 97% to 100%.[27,28] In this study, all participants, researchers, and analysts were blinded to ensure objectivity regarding the subjects in both the study and control groups.

Table 1. Protocol for the Pressure Ulcer Scale for Healing (PUSH) tool.

Length	**0**	**1**	**2**	**3**	**4**	**5**	
×Width	0 cm^2	<0.3 cm^2	0.3-0.6cm^2	0.7-1.0 cm^2	1.1-2.0 cm^2	2.1-3.0 cm^2	Sub-score
	6	**7**	**8**	**9**	**10**		
	3.1-4.0 cm^2	4.1-8.0 cm^2	8.1-12.0 cm^2	12.1-24.0 cm^2	>24.0 cm^2		
Exudate	**0**	**1**	**2**	**3**			Sub-score
Amount	Noe	Light	Moderate	Heavy			
Tissue	**0**	**1**	**2**	**3**	**4**		Sub-score
Type	Closed	Epithelial Tissue	Granulation Tissue	Slough	Necrotic Tissue		

Data analysis

Descriptive statistical methods were employed to analyze the study variables, including frequency distribution tables, diagrams, and numerical indices such as mean and standard deviation. We examined the relationships between qualitative variables (age, sex, BMI, admission ward, mobility, feeding method, level of consciousness, ulcer site, and ulcer grade) using Chi-square or Fisher's exact tests. To compare quantitative values before and after the intervention, we utilized the paired t-test; for comparisons between two groups, we employed either the independent t-test or its non-parametric counterpart, the Mann-Whitney test. Additionally, Mauchly's sphericity test was conducted as a prerequisite for repeated measures analysis of variance to assess the homogeneity of variances among groups. The healing process within each treatment group was evaluated using the Greenhouse intragroup test, while comparisons between intervention and control groups were made using repeated measures analysis of variance. All statistical analyses were performed using SPSS-25, with a significance level set at <0.05.

Ethical considerations

This research adhered to the ethical guidelines outlined in the Declaration of Helsinki. All procedures involving participants were approved by the ethics committee of Ahvaz Jundishapur University of Medical Sciences (Approval Code: IR.AJUMS.REC.1401.066). The study was registered in Iran's clinical trial database under registration number IRCT20220522054960N1 on June 12, 2022. Participants were assured of data confidentiality, the safety of interventions, the voluntary nature of their involvement, and their right to withdraw at any time. Prior to data collection, all participants provided written informed consent.

Results

The findings summarized in Table 2 reveal that 45.45% of the participants were aged between 46 and 60 years, with a predominance of males at 72.7%. Additionally, 43.9% of the participants had a body mass index (BMI) ranging from 20 to 25, and a significant majority, 84.8%, were admitted to the intensive care unit (ICU). Local ulcers were most commonly located in the buttock region, affecting 30.3% of the participants, and 66.7% presented with grade 2 wounds.

Statistical analysis using the Chi-square test and Fisher's exact test indicated no significant differences between the intervention and control groups regarding age (P=0.99), sex (P=0.99), BMI (P=0.99), admission ward (P=0.49), ulcer site (P=0.63), and ulcer grade (P=0.99). All patients in both groups were immobile, unconscious, and received enteral feeding.

As shown in Table 3, the Mann-Whitney test revealed no statistically significant differences in the mean ulcer area (P=0.22), exudate amount (P=0.57), tissue type (P=0.11), or overall healing status (P=0.22) at baseline, confirming that the ulcers were comparable at the start of the study. The homogeneity of variances was assessed using Mauchly's test, which indicated significant differences across all study criteria (P<0.001). According to the Greenhouse test results, there was a notable decrease over time in ulcer area, exudate amount, tissue type, and overall healing status (P<0.001).

The Mann-Whitney non-parametric test demonstrated no significant differences in the mean ulcer area and exudate amount at the end of each week; however, there were statistically significant improvements in tissue type by the end of all four weeks, as well as in overall ulcer status at the end of the third (P=0.004) and fourth weeks (P=0.03).

Table 2. Comparison of demographic information between the intervention and control groups

Demographic information		Groups				Total		P-value
		Control		Intervention				
		Frequency	Percent	Frequency	Percent	Frequency	Percent	
Age, year	18-30	2	6.06	0	0	2	3.03	0.99[a]
	31-45	10	30.30	9	27.28	19	28.79	
	46-60	12	36.36	18	54.54	30	45.45	
	61-80	9	27.28	6	18.18	15	22.73	
Sex	Male	24	72.70	24	72.70	48	72.70	0.99[a]
	Female	9	27.30	9	27.30	18	27.30	
BMI, kg/m^2	BMI>25; Obese	9	27.30	9	27.30	18	27.30	0.96[a]
	20<BMI<25; Fit	14	42.40	15	45.40	29	43.90	
	BMI<25; Lean	10	30.30	9	27.30	19	28.80	
Admission ward	ICU	29	87.90	27	81.80	56	84.80	0.49[a]
	Non-ICU	4	12.10	6	18.20	10	15.20	
Gastric tube (total)		33	100	33	100	66	100	
Ulcer site	Sacrum	3	9.10	3	9.10	6	9.10	0.63[b]
	Ankle	6	18.20	9	27.30	15	22.70	
	Knee	3	9.10	3	9.10	6	9.10	
	Tight	0	0	1	3.00	1	1.50	
	Head	3	9.10	0	0	3	4.50	
	Heel	6	18.20	3	9.10	9	13.70	
	Leg	3	9.10	3	9.10	6	9.10	
	Buttock	9	27.20	11	33.30	20	30.30	
Ulcer grade	II	22	66.70	22	66.70	44	66.70	0.99[a]
	III	11	33.30	11	33.30	22	33.30	

[a] Chi-square test, [b] fisher exact test

Table 3. Comparison of mean ulcer area, exudate level, tissue type, and overall healing status between the intervention and control groups at the beginning and end of weeks one to four of the study

Ulcer evaluation criteria		At baseline		First week		Second week		Third week		Fourth week		P-value [b]
		Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
Ulcer area	Control group	7.97	1.62	7.97	1.62	7.97	1.62	7.70	1.97	7.13	1.79	0.46
	Intervention group	8.40	1.44	8.16	1.63	7.61	1.99	6.82	2.06	6.11	2.46	
	P-value [a]	0.22		0.52		0.72		0.07		0.15		
Exudate amount	Control group	1.52	0.97	0.73	0.67	0.12	0.33	0	0	0	0	0.95
	Intervention group	1.40	0.1	0.64	0.79	0.24	0.44	0.06	0.24	0	0	
	P-value [a]	0.57		0.47		0.32		0.15		0.99		
Tissue type	Control group	2.66	0.48	2.66	0.48	2.66	0.48	2.28	0.45	1.91	0.23	<0.001
	Intervention group	2.42	0.50	2.33	0.48	1.90	0.30	1.45	0.50	1.33	0.54	
	P-value [a]	0.11		0.02		<0.001		<0.001		<0.001		
Ulcer healing general status	Control group	12.18	2.28	11.30	2.07	10.70	1.81	9.94	2.04	9.03	1.84	0.11
	Intervention group	12.18	2.42	11.12	2.37	9.79	2.31	8.33	2.24	7.45	2.81	
	P-value [a]	0.89		0.90		0.14		0.004		0.03		

[a] Mann-Whitney test, [b] Repeated data analysis of variance test

While Table 3 and Figures 2, 3, 4 and 5 indicate that the intervention group experienced greater reductions in ulcer area, exudate amount, and overall healing compared to the control group, repeated measures analysis revealed no statistically significant differences in ulcer area (P=0.46), exudate amount (P=0.95), or overall healing status (P=0.11). However, there was a statistically significant difference in tissue type scores between the two groups (P<0.001), suggesting that skin integrity improved more significantly in the intervention group than in the control group. Figure 6 illustrates the healing process of an ulcer within the intervention group.

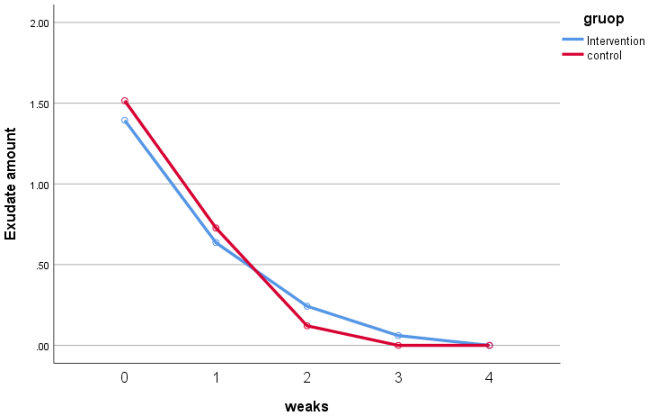

Figure 3. Comparison of mean exudate amount at baseline and at the end of weeks one to four between the intervention and control groups.

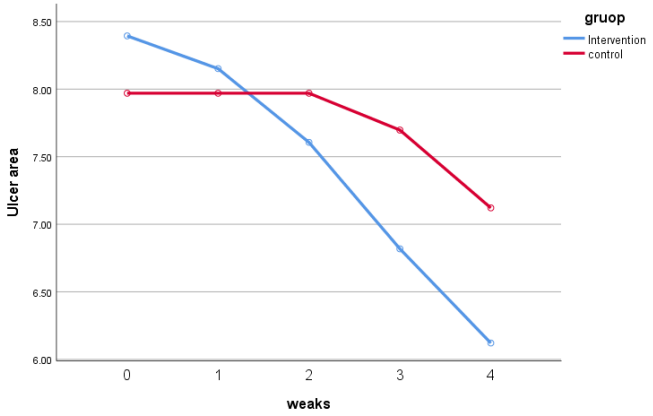

Figure 2. Comparison of mean ulcer area at baseline and at the end of weeks one to four between the intervention and control groups.

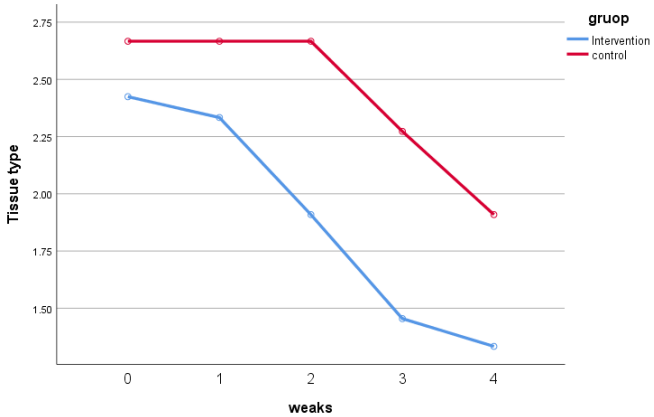

Figure 4. Comparison of mean tissue type at baseline and at the end of weeks one to four between the intervention and control groups.

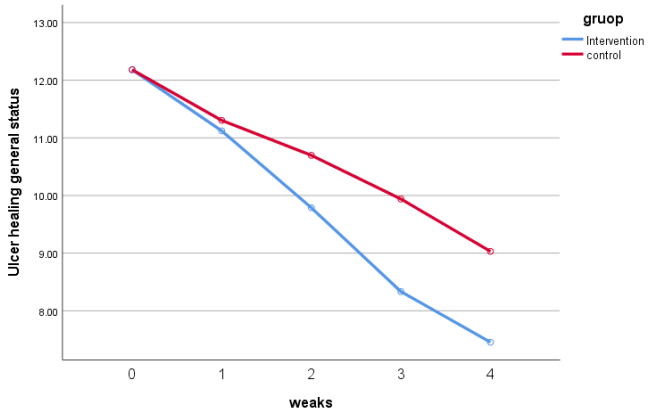

Figure 5. Comparison of mean ulcer healing status at baseline and at the end of weeks one to four between the intervention and control groups.

Before the intervention **After the intervention**

Figure 6. Effect of egg white formulation on second-degree wounds created adjacent to the knee.

Discussion

In this study, we aimed to evaluate the effects of a local formulation containing egg whites on Grades II and III pressure ulcers. To interpret our findings, we compared them with those of similar studies. However, we did not identify any research specifically addressing the effects of egg whites on pressure ulcers in the existing literature. Therefore, we drew parallels with studies examining the impact of egg whites on burn injuries and other traditional medicinal compounds used for treating pressure ulcers.

Our results indicated a reduction in ulcer area over time in both groups, with numerical data and visual representations suggesting that the intervention group experienced a more significant decrease. Nevertheless, the difference between the groups was not statistically significant, which may be attributed to the limited sample size. In a study by Jahani et al.,[22] which focused on the effects of egg whites on burn wound healing, no statistically significant differences in ulcer size were observed between the intervention and control groups from the first to the third week.

Overall, the amount of exudate decreased over time and eventually stopped in both groups; however, our findings showed no statistically significant difference between them in this aspect. Based on our observations, exudate levels dropped within 2 to 3 days after initiating treatment and ceased by the end of the second or third week. We attribute this reduction to the active compounds used, consistent ulcer care, and sterile dressing techniques. According to the manufacturers, both the egg white formulation and the placebo cream -composed of all ingredients except for egg white- contained beeswax, which may have contributed to reducing exudate in both groups. In a study by Mehrababni et al., honey dressings effectively cleaned ulcers and reduced exudate within 48 hours; however, some ulcers remained infected and exuded even after the study concluded in the hydrocolloid dressing group.[13] Thus, the cream base used in both groups may have played a role in decreasing exudate.

Notably, our findings revealed that skin integrity improved significantly more in the intervention group compared to the control group. Observations and photographic evidence indicated that new pink tissue began to form over the ulcer one week after treatment commenced. This new tissue appeared shiny, moist, and slightly blood-stained, with visible blood vessel development and granulation tissue forming on the ulcer's surface. Jahani et al.,[22] also reported a statistically significant difference in granulation tissue formation between the egg white formulation and control groups in their study on burn injuries. Similarly, Hassanzadeh et al.,[20] noted some epidermal formation in the egg white group, although stratum corneum was not observed, and the wound surface was predominantly covered by pink granulation tissue.

The degree of vascularization is a critical factor influencing wound healing. Factors that enhance new blood vessel formation through biochemical and pharmacological mechanisms can improve tissue circulation in affected areas, thereby accelerating wound healing and preventing further deterioration.[29-31]

Our analysis revealed that while the healing rate in the intervention group was notably higher by the end of the third and fourth weeks, the difference between the two groups was not statistically significant. The researcher speculated that a larger sample size might yield a more pronounced difference. Additionally, the ingredients in the placebo cream used for the control group may have influenced the outcomes, as they were also applied to the ulcers. In studies examining the effects of egg whites on

burn injuries, intervention groups consistently demonstrated a significantly higher healing rate.[20,21] For instance, Mehrabani et al. noted a steeper decline in healing rates in the honey treatment group; however, no statistically significant difference was found when comparing the hydrocolloid and honey dressing groups regarding ulcer healing rates.[13] Similarly, Esmaili et al. reported pressure ulcer healing occurring during the third and fourth weeks with calendula officinalis cream.[31]

This study faced several limitations, including challenges in accessing patients' ulcers -particularly those located on the sacrum and buttocks- which required assistance from caregivers due to patients' limited mobility. Additionally, the small sample size may have impacted the results.

Conclusions

Although the differences in ulcer area reduction, exudate levels, and healing rates between the two groups were not statistically significant, both graphical representations and numerical data indicated a more favorable healing trend in the intervention group. Given the beneficial properties of egg whites in promoting ulcer healing, their accessibility, and the growing interest in natural remedies, we propose that an egg white formulation could serve as an effective adjunct to conventional therapies for treating pressure ulcers. To enhance these findings, we recommend conducting further studies with larger sample sizes and extended observation periods.

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Competing interests

The authors declare that they have no competing interests.

Abbreviations

Body Mass Index: BMI; National Pressure Ulcer Advisory Panel: NPUAP; The Pressure Ulcer Scale for Healing: PUSH; Intensive Care Unit: ICU.

Authors' contributions

All authors read and approved the final manuscript. All authors take responsibility for the integrity of the data and the accuracy of the data analysis.

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Role of the funding source

None.

Availability of data and materials

The data used in this study are available from the corresponding author on request.

Ethics approval and consent to participate

This research adhered to the ethical guidelines outlined in the Declaration of Helsinki. All procedures involving participants were approved by the ethics committee of Ahvaz Jundishapur University of Medical Sciences (Approval Code: IR.AJUMS.REC.1401.066). The study was registered in Iran's clinical trial database under registration number IRCT20220522054960N1 on June 12, 2022. Prior to data collection, all participants provided written informed consent.

Consent for publication

By submitting this document, the authors declare their consent for the final accepted version of the manuscript to be considered for publication.

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