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The Efficacy of a Cosmetic Preparation Containing Sheep Colostrum on Mature Skin: A Randomized Placebo-Controlled Double-Blind Study

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Abstract: Colostrum, the first milk produced by mammals, is rich in various bioactive components that provide numerous health benefits to newborns, such as growth factors, hormones, immunoglobulins, cytokines, and enzymes. Topical application of bovine or equine colostrum has been found to improve regeneration, accelerate cutaneous wound healing, and have moisturizing, protective, and anti-aging properties. The aim of this study was to examine the effect of a cosmetic preparation containing sheep colostrum on skin with signs of aging in mature women. Fifty-two women, aged 40–70, were randomized into two groups to receive either colostrum or placebo cream. The participants applied the cream for eight weeks. Skin hydration, TEWL, sebum, erythema, and tone were measured using a standardized Courage + Khazaka electronic GmbH Multi Probe Adapter; skin elasticity was measured with a cutometer, and images were taken by FotoMedicus. The treatment increased skin moisture, reduced TEWL, and improved skin firmness. These findings were confirmed by the subjective survey. The participants reported, *inter alia*, improved skin softness and less redness and hypersensitivity. Sheep colostrum cream was more effective at improving skin conditions than placebo cream. Colostrum creams can improve certain aspects of skin quality, especially the hydrolipid barrier, and overall rejuvenation.

Keywords: colostrum; skin; hydration; TEWL; firmness; mature skin; placebo-controlled

Citation: Kazimierska, K.; Erkiert-Polguj, A.; Kalinowska-Lis, U. The Efficacy of a Cosmetic Preparation Containing Sheep Colostrum on Mature Skin: A Randomized Placebo-Controlled Double-Blind Study. *Appl. Sci.* **2024**, *14*, 2862. https://doi.org/10.3390/app14072862

Academic Editors: José Machado and Jinchul Kim

Received: 8 January 2024
Revised: 14 February 2024
Accepted: 26 March 2024
Published: 28 March 2024

1. Introduction

As people age, their skin undergoes changes that result in reduced dermal hydration, elasticity, thickness, and density. These changes can be caused by various factors, including genetics and lifestyle, as well as environmental factors such as sun exposure, pollution, and smoking. As a result, there is a growing interest in the use of natural products to improve skin health [1].

Colostrum is the first milk produced by humans and other mammals after giving birth. It is rich in various bioactive components, such as growth factors, hormones, immunoglobulins, cytokines, and enzymes, which provide numerous health benefits to newborns. Colostrum contains high levels of insulin-like growth factor-1 (IGF-1), which stimulates cell growth and differentiation, and epidermal growth factor (EGF), which promotes the growth and repair of skin tissue. Additionally, colostrum contains several other growth factors that have been shown to play a crucial role in skin regeneration and repair, including transforming growth factor-beta (TGF-β), platelet-derived growth factor (PDGF), and fibroblast growth factor (FGF) [2,3]. In addition to its growth factor content, colostrum also contains several other bioactive components that provide various health benefits. For example, it contains lactoferrin, which has antibacterial, antiviral, and anti-inflammatory properties, and has been shown to promote wound healing. Colostrum also contains proline-rich

polypeptides (PRPs), which modulate the immune system and have been shown to improve skin barrier function [4].

Most of the studies concerning dairy foods have focused on bovine milk, the most common milk used in human nutrition. However, sheep colostrum contains higher levels of various bioactive molecules, such as immunoglobulins and growth factors, compared to bovine colostrum [5,6]. For example, sheep colostrum has been shown to have higher levels of insulin-like growth factor 1 (IGF-1), which plays a crucial role in tissue repair and regeneration [7].

Several studies have confirmed that colostrum influences skin health. Topical application of bovine colostrum improved skin regeneration and accelerated cutaneous wound healing [8]. Bovine colostrum promotes wound healing and reduces scar formation in rats [9]. Subsequent research suggests that exosomes sourced from bovine colostrum possess remarkable structural and functional stability, making them a promising natural remedy for mending age-related and sun-induced skin injuries [10].

One study found a cosmetic preparation containing a mixture of horse colostrum and horse milk to demonstrate a number of benefits for healthy and diseased skin. The effects included various anti-aging, moisturizing, protective, and smoothing effects, as well as pain relief, greater skin tension, and epithelial regeneration. It was found to be suitable for both healthy and diseased skin [11].

However, little is known about the effect of sheep colostrum on the skin. Therefore, the aim of the present study was to examine the effects of a cosmetic preparation containing 15% sheep colostrum lyophilizate on skin with signs of aging.

2. Results

2.1. Instrumental Measurement of Skin Parameters

The corneometry test demonstrated a statistically significant enhancement of skin hydration in the group receiving the cream with sheep colostrum (the colostrum cream group): mean skin hydration increased substantially from 35.9 to 51.1 units (Figure 1, Table 1). In contrast, in the placebo group receiving the cream without colostrum (placebo group), only a slight, insignificant change in hydration was noted (from 42.2 to 46.2 units).

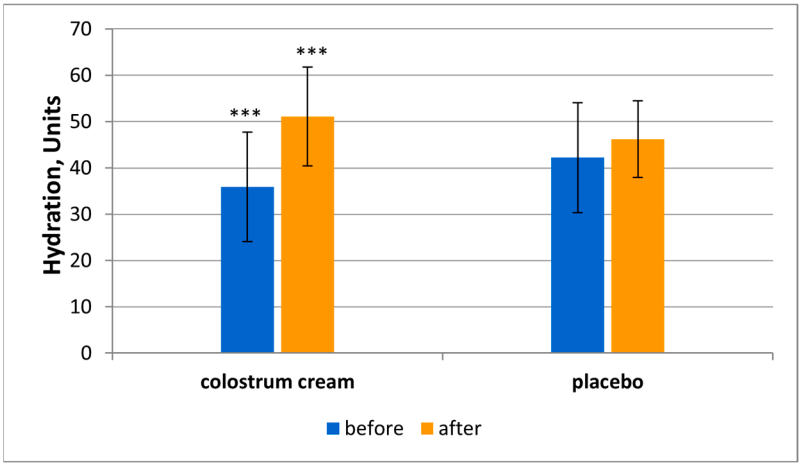

Figure 1. Skin hydration before and after treatment in the colostrum cream and placebo groups; *** $p < 0.0001$.

In order to accurately describe this skin parameter, the median and the interquartile range (median (25%; 75%)) of the percentage of changes between the first and second measurements for both groups were calculated (Table 2). The results indicate a significantly higher chance of improving skin hydration in the colostrum cream group (45.5%), compared to the placebo group (9.5%).

Table 1. Changes in skin parameters after eight weeks of treatment in the colostrum cream and placebo groups, expressed as mean ± SD.

Skin Parameter	Group	Measurement I (Week 0)	Measurement II (Week 8)	Statistical Significance (p)
Hydration	Colostrum cream (n = 30)	35.9 ± 11.8 [U]	51.1 ± 10.7 [U]	$p < 0.0001$
	Placebo (n = 18)	42.2 ± 11.9 [U]	46.2 ± 8.3 [U]	NS ($p = 0.147$)
TEWL	Colostrum cream (n = 30)	21.1 ± 12.3 [U]	15.3 ± 5.4 [U]	$p = 0.021$
	Placebo (n = 16)	20.8 ± 9.0 [U]	16.1 ± 6.2 [U]	$p = 0.030$
Erythema	Colostrum cream (n = 30)	351.9 ± 83.2 [U]	361.6 ± 92.5 [U]	NS ($p = 0.254$)
	Placebo (n = 18)	336.2 ± 78.1 [U]	359.0 ± 82.1 [U]	NS ($p = 0.115$)
Melanian content	Colostrum cream (n = 30)	111.7 ± 33.7 [U]	109.8 ± 33.3 [U]	NS ($p = 0.520$)
	Placebo (n = 18)	107.6 ± 31.0 [U]	104.5 ± 26.1 [U]	NS ($p = 0.517$)
Sebum	Colostrum cream (n = 28)	40.9 ± 35.0 [U]	39.0 ± 26.2 [U]	NS ($p = 0.684$)
	Placebo (n = 18)	42.1 ± 35.5 [U]	39.7 ± 27.8 [U]	NS ($p = 0.689$)
Firmness R0	Colostrum cream (n = 29)	0.201 ± 0.026 [U]	0.177 ± 0.021 [U]	$p < 0.0001$
	Placebo (n = 16)	0.207 ± 0.029 [U]	0.177 ± 0.031 [U]	$p = 0.001$
Firmness F0	Colostrum cream (n = 29)	32.6 ± 4.6 [U]	27.1 ± 3.0 [U]	$p < 0.0001$
	Placebo (n = 16)	31.6 ± 4.1 [U]	26.7 ± 3.5 [U]	$p < 0.0001$

Table 2. Percentage changes in skin parameters over the course of treatment in the colostrum cream and placebo groups, expressed as median and interquartile range, i.e., median (25%; 75%).

Skin Parameter	Colostrum Cream Group	Placebo Group	Statistical Significance (p)
Hydration	45.5 (12.3; 82.0) [%]	9.5 (−15.0; 34.3) [%]	$p = 0.008$
TEWL	−18.2 (−34.1; 2.8) [%]	−19.1 (−40.6; 2.9) [%]	NS ($p = 0.854$)
Erythema	4.6 (−5.2; 10.0) [%]	2.3 (−5.0; 13.4) [%]	NS ($p = 0.823$)
Melanin content	−3.5 (−10.0; 7.4) [%]	0.6 (−16.8; 12.1) [%]	NS ($p = 0.865$)
Sebum	5.4 (−34.6; 99.5) [%]	−6.1 (−38.1; 100.8) [%]	NS ($p = 0.536$)
Firmness R0	−10.8 (−17.6; −5.7) [%]	−15.7 (−23.5; −4.8) [%]	NS ($p = 0.448$)
Firmness F0	−17.2 (−25.5; −5.1) [%]	−15.9 (−24.7; −6.7) [%]	NS ($p = 0.652$)

The two groups demonstrated similar mean TEWL values before the application of the creams: *viz.*, colostrum 21.1 $g/h/m^2$ and placebo 20.8 $g/h/m^2$. After eight weeks of treatment, the TEWL values in both groups improved by about five units, i.e., from a normal level (15–25 $g/h/m^2$) to a healthy condition (10–15 $g/h/m^2$) [12]. These changes were statistically significant in both groups, $p < 0.05$ (Figure 2, Table 1).

Skin firmness, assessed by the R0 and F0, improved in both groups over the course of the experiment. R0 represents the passive response of the skin to force, and F0 represents the firmness of the skin at the time of suction [13,14]. Mean R0 values decreased from 0.201 to 0.177 units in the colostrum cream group and from 0.207 to 0.177 units in the placebo group (Figure 3, Table 1). Similarly, mean F0 values decreased from 32.6 to 27.1 units in the colostrum cream group and from 31.6 to 26.7 units in the placebo group ($p < 0.001$) (Figure 4, Table 1).

No significant changes in erythema, melanin content, or sebum were observed at the end of this study in either the colostrum cream or placebo groups. Detailed data are presented in Tables 1 and 2.

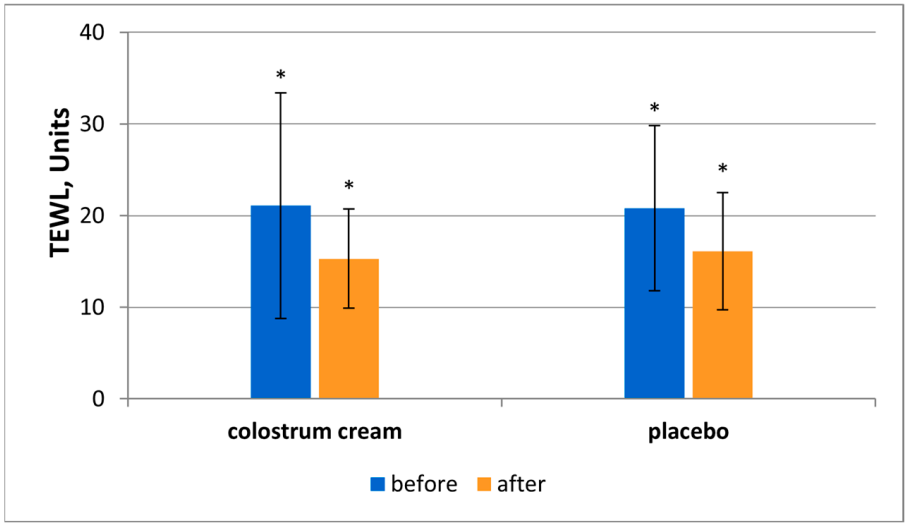

Figure 2. TEWL before and after treatment in the colostrum cream and placebo groups; * $p < 0.05$.

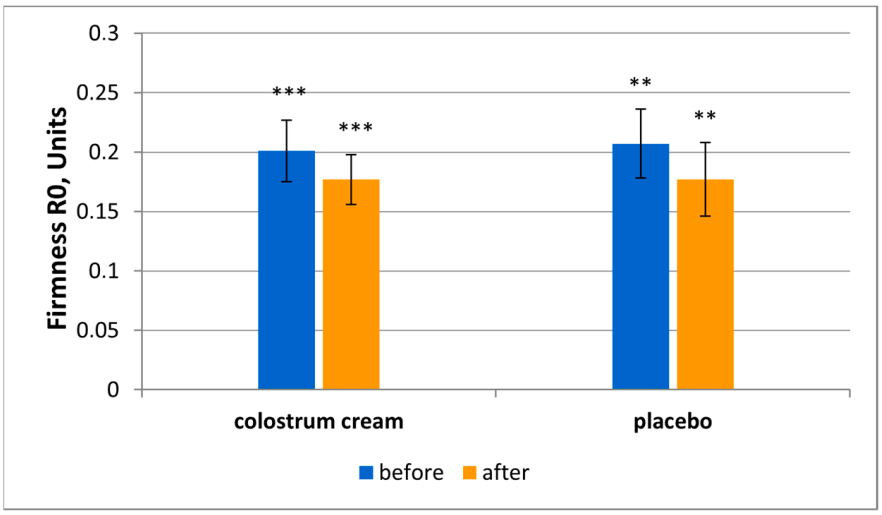

Figure 3. Skin firmness (R0) before and after treatment in the colostrum cream and placebo groups; *** $p < 0.0001$, ** $p < 0.001$.

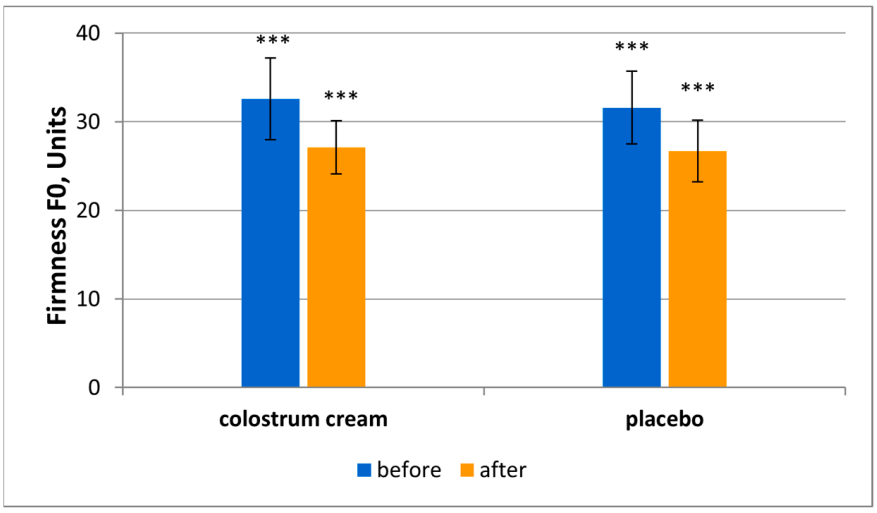

Figure 4. Skin firmness (F0) before and after treatment in the colostrum cream and placebo groups; *** $p < 0.0001$.

2.2. Photodocumentation

It is important to note that the researchers assessed blinded photos they did not know whether the subjects belonged to the placebo group or the colostrum cream group.

Significant intergroup differences were found for reduction in redness and smoothing of skin pores, $p < 0.05$. Assuming a score of 4, 3, or 2 indicated improvement, and 1 or 0 indicated no improvement (Figure 5), improved redness was observed by 25.0% in the colostrum cream group and 0% in the placebo group, and improved smoothing of skin pores was observed in 71.4% of colostrum and 38.9% in placebo.

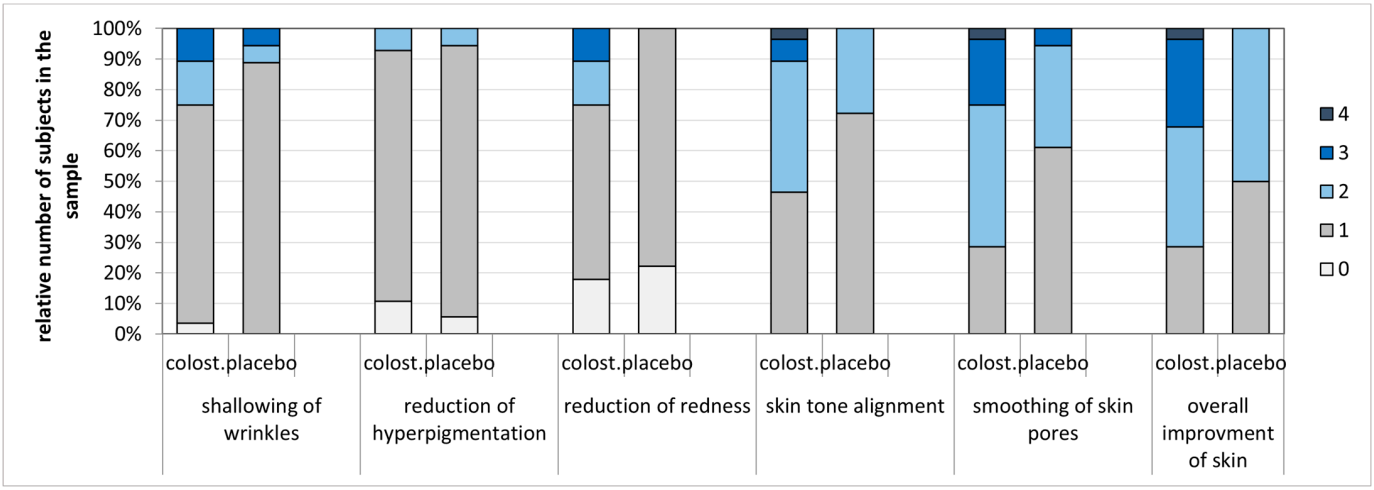

Figure 5. Comparison of the results of photo documentation between the colostrum cream and placebo groups.

In the colostrum cream group, major improvements were noted in "overall improvement", noted by 71.4% of participants, and "skin tone alignment", noted by 53.6%.

It is worth emphasizing that for each considered parameter, a greater improvement was observed in the colostrum cream group than in the placebo group.

Exemplary pictures of subjects before (left) and after (right) eight weeks of using the colostrum cream was shown in Figure S1.

2.3. Subjective Assessment of Skin Parameters

The results of the subjective assessment of skin parameters were presented as the percentage of subjects whose skin improved, worsened, or remained unchanged (Figure 6). Overall, more subjects in the colostrum cream group noted an improvement in skin condition (27.6–55.2%) than in the placebo group (17.6–40.0%). In the colostrum cream group, about 50% of the subjects reported an improvement in skin hydration, regeneration, and softness, as well as a reduction in redness and skin hypersensitivity. A statistically significant ($p < 0.05$) difference in softness was found between the colostrum cream and placebo groups. The subjective and objective measurements obtained similar results in terms of skin hydration and elasticity.

Among the colostrum cream group, three subjects with oily skin reported reduced sebum secretion after treatment. Indeed, these observations were consistent with the recorded sebum measurements, which improved from 126 units to 76 units in one participant, and from 142 to 100 units and 150 to 102 units in the others.

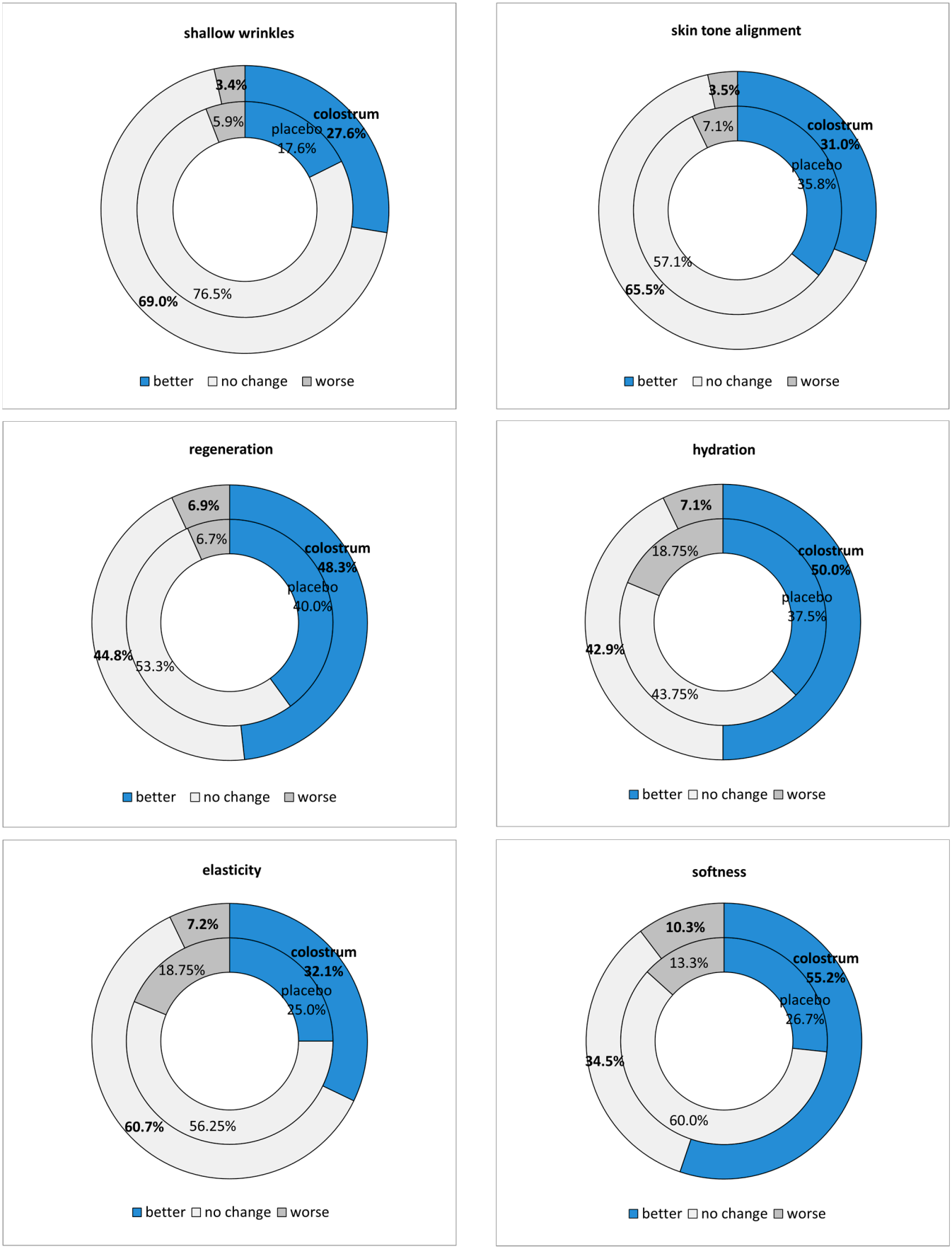

Figure 6. *Cont.*

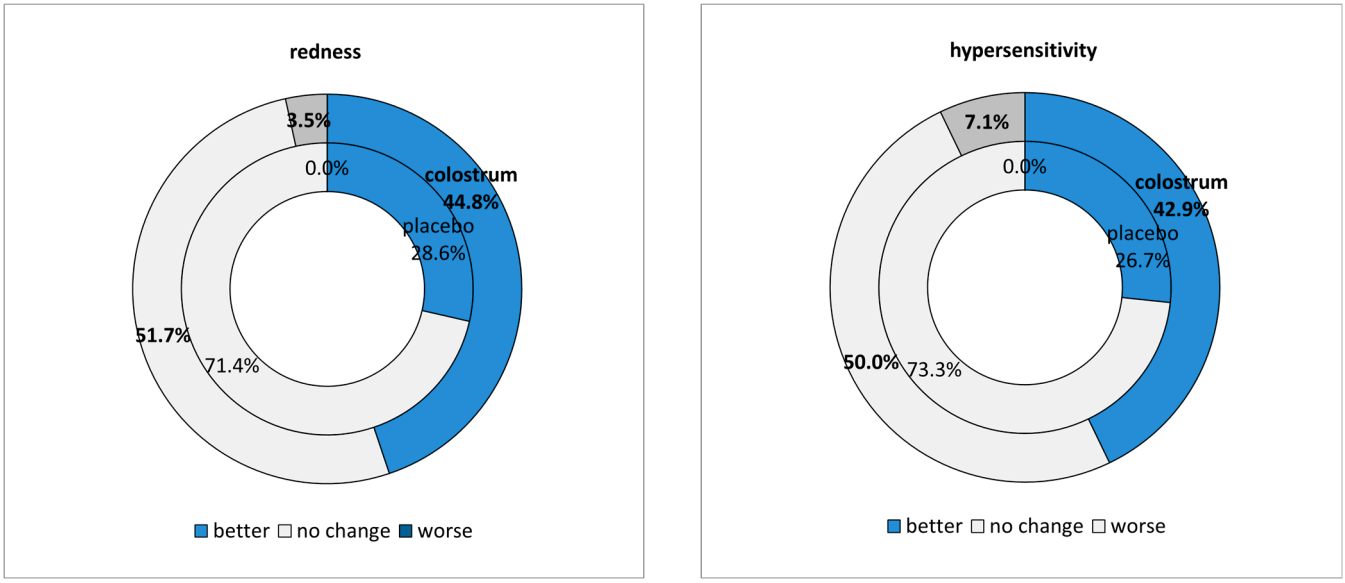

Figure 6. Changes in subjective evaluation of skin parameters; placebo group in the center ring; colostrum cream group in the outer ring.

2.4. Side Effects of the Creams Used

Three subjects in the colostrum cream group and two subjects in the placebo group reported side effects such as dryness and tightness of the skin, skin redness, and a burning sensation. These symptoms subsided after a dozen or so minutes after applying the creams. Presumably, they were related to the fragrance present in both preparations. It was unlikely that the colostrum was responsible, as side effects were noted in both the colostrum and placebo groups.

Of the 52 subjects in this study, two from the placebo group were lost to follow-up for various reasons other than the treatment, and another two from the colostrum cream group due to adverse effects (skin dryness and irritation).

3. Discussion

Our study describes a preliminary evaluation of the use of cosmetic cream containing 15% sheep's colostrum lyophilizate on mature skin compared to placebo cream.

In a study of 15 healthy volunteers, nanoliposomes encapsulated with skimmed donkey milk creams demonstrated good results in hydration and epidermal water loss improvement, although the effects were not significantly better than placebo cream. Our research was conducted on a much larger group (forty-eight women finished the study), and in comparison to placebo cream, the colostrum one was significantly better at hydration improvement [15].

In addition, in seven patients with moderate atopic dermatitis, a 20% horse colostrum emulsion was found to demonstrate greater softening, moisturizing, soothing, and anti-inflammatory effects than commonly available emulsions when applied twice daily for 30 days; in addition, the treatment resulted in reduced erythema and pruritus, with no observed side effects [11]. Furthermore, cosmetic formulations combining horse colostrum and horse milk demonstrated various benefits, including anti-aging, moisturizing, protective, tensio-distensive, tonic, smoothing, anti-irritant, emollient, bleaching, decongestant, and sebostatic activities [11,16].

Lastly, products consisting of bovine or equine colostrum, hyaluronic acid or its salt, and inter alia olive oil (*Olea europea*) or vitamin E were found to reduce skin aging, improve skin elasticity and tension, and demonstrate moisturizing and antioxidant properties in the facial skin of elderly participants [16].

Hence, colostrum-based creams appear to effectively promote skin health. The increased skin hydration observed in our colostrum group can be attributed to the high levels of lipids, growth factors, vitamins, and minerals in sheep colostrum, which are present in greater amounts than in colostrum bovium. These substances promote the hydration, and nourishment of the skin [17,18]. The product also has a positive effect on skin hydration; the fatty acids in colostrum have beneficial effects on skin barrier function, manifested as a reduction in TEWL. Various miristic, palmitic, stearic, palmitoleic, oleic, and linoleic fatty acids are distributed throughout the stratum corneum. It is important to emphasize that while all acids are present in colostrum in high amounts, palmitic acid is both the main FFA in the epidermis and in the colostrum used in this study [19].

Our findings indicate a significantly better reduction in redness and improved smoothing of skin pores in the colostrum than in the placebo group. Also, the colostrum group reported better effects in the survey, including shallower wrinkles, softer skin, and lower hypersensitivity. Similarly, skin firmness was found to objectively improve, as measured by the cutometer.

The beneficial regenerative properties of colostrum could be due to the effects of its ingredients on fibroblasts or their antioxidative properties. Previous bovine colostrum studies noted increased fibroblast proliferation and migration and a slower telomere shortening rate, indicating delayed cellular aging. Under conditions of oxidative stress *in vitro*, colostrum appears to exert a protective effect against telomere length erosion and oxidative stress, thus preventing skin inflammation and textural changes [20,21].

In the context of the discussed study, it is worth mentioning the effect of colostrum or milk of various origins on skin cell lines. In particular, bovine colostrum stimulates keratinocyte proliferation and migration, suggesting its positive re-epithelializing effect at the wound site [22]. As bovine colostrum has the ability to induce the differentiation of keratinocytes, it may be helpful in the treatment of skin diseases characterized by impaired barrier function, such as dry skin in the elderly or people exposed to UV radiation [23]. The study conducted on skin fibroblast culture shows that donkey milk may be useful in the treatment of inflammatory skin diseases as well as in wound healing, regenerative, and aesthetic dermatology [24]. Mare's colostrum, especially its fat fraction [25] and bovine colostrum [26], strongly stimulates the proliferation of fibroblast culture. It is believed that they may affect the effectiveness of skin wound healing.

The *in vivo* wound healing ability of multifunctional bovine colostrum-conjugated nanofibrous dressings was confirmed in a rat wound model. Probably, high levels of immunoglobulins, lactoferrin, hormones, and cytokines played a significant role in wound healing [27].

Consideration should also be given to reports on the oral supplementation of dairy substances and products. Routine four-week intake of fermented milk products loaded with various lactic acid bacteria strains resulted in increased skin hydration [28]. Other evidence suggests that continuous supplementation with sphingomyelin (SM), a phospholipid found in milk fat globules, has the potential to boost skin hydration and elasticity [29].

An oral formula with high levels of milk proteins, growth factors, alpha-lactalbumin, lactoferrin, and immunoglobulins was found to diminish skin lesions in individuals with plaque psoriasis [30]. The same proteins are present in sheep colostrum [3].

An oral administration of bovine lactoferrin prevented transepidermal water loss, irregular epidermal thickening, cell apoptosis, and increased skin hydration in UVB-radiated hairless mice [31].

Many of the health-promoting effects on human skin have been attributed to the vitamins, minerals, and amino acids present in bovine colostrum [32]. Collagen production, wound healing, and antioxidant activity are believed to be supported by ascorbic acid (vitamin C), niacin (B3), biotin (B7), vitamin E, and retinol (A), while minerals like zinc and copper contribute to neutralizing free radicals and tissue regeneration. In addition, various amino acids, such as proline, threonine, methionine, and arginine, also promote skin health by

supporting anti-aging and wound healing activities [32]. It is also important to emphasize that sheep colostrum is as rich in minerals as bovine colostrum, and richer in protein [3].

Although toxicological studies on our raw material, sheep colostrum, have not been assessed, they were carried out on colostrum of bovine origin. Toxicological evaluations of an ultrafiltered bovine colostrum product, i.e., a mixture of native colostrum and a unique subset of concentrated low-molecular-weight proteins (≤10 kDa), confirmed its safety [33]. Studies on rats fed for 90 days with food enriched with 3% and 10% bovine colostrum also confirmed the safety of the colostrum, as no biochemical, physical, or histopathological abnormalities were observed in rats [34]. It is worth mentioning that before conducting this eight-week study on volunteers, the potential sensitizing and irritating effects of our cream with 15% sheep colostrum were tested on a group of 25 people. The results of this study showed that the cosmetic preparation did not cause any side effects in dermatological tests.

Side effects of topical use colostrum can be the result of an allergy to colostrum components. Anaphylaxis after a cream with bovine colostrum was described [35], but what is worth noticing is that sheep milk is characterized by a lower content of frequent allergens [3,36].

4. Materials and Methods

The research was registered at clinicaltrials.gov, where it received the identifier: NCT06305923.

4.1. Preparation of Cosmetic Formulations: Colostrum Cream and Placebo Cream

4.1.1. Colostrum Raw Material

The raw material was collected within the first 24 h after the birth of the sheep, then frozen and lyophilized. The manufacturing process of sheep colostrum was based on rigorous quality control protocols to ensure the safety and efficacy of the end product, making it suitable for various applications, including skincare.

4.1.2. Colostrum Cream

The formulation of the cream was developed specifically for this study. The content of individual components is described in Table 3. The formulation used in this study is an O/W type emulsion.

Table 3. Cosmetic formulation of the cream based on sheep colostrum.

Phase	INCI Name	Function	Percentage
IA	Aqua	Solvent	Till 100.0
	Acrylates/C10–30 alkyl Acrylate Crosspolymer	Thickener	0.2
IB	Pentylene Glycol	Humectant, maintenance booster	3.0
II	Isononyl Isononanoate	Emollient	7.0
	Cetearyl Olivate, Sorbitan Olivate	Emulsifier	4.5
	Glyceryl Stearate Citrate	Co-emulsifier	2.0
	Tripelargonin	Emollient	7.0
	Helianthus Annus Seed Oil, Tocopherol	Antioxidant	0.1
III	Parfum	Fragrance	0.7
	Colostrum	Active ingredient	15.0
	Aqua, Sodium Lactate	Humectant, pH regulator	0.5
	Aqua, Potassium Sorbate, Sodium Benzonate	Preservative	1.5
IV	Aqua, Citric Acid	pH regulator	1.3–1.5

A water phase (I) was prepared as follows: the thickening agent (Acrylates/C10–30 alkyl Acrylate Crosspolymer) was sprinkled into the water, left to ensure complete wetting, and then mixed; it was then heated to 70–75 °C and entered phase IB (Pentylene Glycol).

The ingredients of fatty phase II were then heated to 75 °C and mixed to obtain a homogeneous liquid. Phase II was combined with phase I and homogenized under vacuum.

After the mixture cooled to below 40 °C, the phase III ingredients, including the active ingredient, colostrum, were added successively with continuous mixing. Finally, citric acid solution (phase IV) was added to adjust the pH to the range of 4.7–5.2.

4.1.3. Placebo Cream

The placebo cream was prepared using the same process and ingredients as the colostrum cream, but without the colostrum. Its composition included: Aqua, Acrylates/C10–30 Alkyl Acrylate Crosspolymer, Pentylene Glycol, Isononyl Isononanoate, Cetearyl Olivate, Sorbitan Olivate, Tripelargonin, Helianthus Annuus Seed Oil, Tocopherol, Parfum, Aqua, Sodium Lactate, Aqua, Potassium Sorbate, Sodium Benzoate, Aqua, and Citric Acid.

The resulting products were subjected to a series of tests in accordance with the requirements of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products by an accredited laboratory. The scope of testing includes microbiological purity testing, testing of the effectiveness of the preservative system used, stability and compatibility testing with packaging, as well as dermatological testing (semi-open test). The tests confirmed the safety of the products, which have been approved for use in humans.

4.2. Selection of Participants

The research was carried out on a group of 52 healthy volunteers, selected in accordance with the guidelines of the Helsinki Declaration of 1964, with subsequent additions and with the approval of the Bioethics Committee of the Medical University of Lodz No. RNN/275/21/KE of 14 December 2021. We obtained written informed consent from each subject to participate in this study. The inclusion and exclusion criteria are as follows in Table 4.

Table 4. Inclusion and exclusion criteria for selecting the participants.

Inclusion	Female Age between 40 and 70 Signs of skin aging: wrinkles, loss of skin elasticity, discolorations, dryness Signed informed consent
Exclusion	Pregnant or breastfeeding Allergic to milk proteins Suffer from neoplasms, contagious infections, autoimmunologic diseases Suffer from face skin diseases Have had an aesthetic procedure on the skin of the face during the last two months Have been treated with isotretinoin or other oral retinoids during the last six months

In total, 52 subjects participated in this study. Two people from the placebo group were lost to follow-up because of random reasons, and two from the colostrum cream group did not complete the study due to adverse effects (dryness and irritation of the skin).

The age of the subjects who completed the study ranged from 40 to 70 years. The mean age of the group was 50.4 years, the median was 48.0 years, and the interquartile range (45.5, 54.0).

Participants were enrolled randomly in the colostrum cream (32 people) or placebo groups (20 people) and were not informed which group they belonged to.

Participants were given the creams and asked to apply one –two doses in the evening after nighttime facial cleaning. They were also asked to use sunscreen during the day.

4.3. Instrumental Measurements of Skin Parameters

During the first visit and after eight weeks of everyday use of the tested cream, the skin parameters were measured three times on both cheeks, and the results were averaged.

The skin was measured at standardized temperature and humidity using a Courage + Khazaka electronic GmbH Multi Probe Adapter with the use of the following probes:

1. Corneometer® CM825 probe: measuring skin hydration based on water content in the stratum corneum;
2. Tewameter® TM probe: assessing transepidermal water loss;
    - Mexameter® MX18 probe: measuring the level of hemoglobin (erythema) and melanin, the two main dyes responsible for skin color;
    - Sebumeter® SM 815 probe: measuring skin sebum level, independent of water content;
3. Cutometer® MPA 580 probe: measuring the viscoelastic properties of the skin. The R0 and F0 parameters were chosen. R0 represents the passive response of the skin to force, lower values indicate greater firmness. F0—firmness of the skin at the time of suction. Lower values indicate more elastic skin.

4.4. Photodocumentation

The skin was subjected to photodocumentation at the first and last visit with the use of the Photomedicus system. The photos were taken in standard light with standardized face positions. The photos were compared using the following scale: 0 means no improvement (the same as the initial picture), 1—slight improvement, 2—moderate improvement, 3—marked improvement (marked improvement in appearance from the initial condition, but not completely optimal), and 4—greatest possible improvement (optimal aesthetic result).

4.5. Subjective Assessment of the Skin

All participants, i.e., in both groups, subjectively assessed their skin condition after eight weeks of treatment. Participants rated smoothing of shallow wrinkles, skin tone alignment, regeneration, hydration, elasticity, softness, redness reduction, and hypersensitivity reduction; they indicated either improvement, deterioration, or no change. Finally, the results in each group were presented as the percentage of subjects with improved, worsened, or unchanged skin.

4.6. Statistical Analysis

The mean and standard deviation (mean ± SD) or median and interquartile range (median (25%; 75%)) were applied as appropriate for the description of parameters. Changes in skin parameters compared to baseline were calculated based on the following formula: $(([x(t_1) - x(t_0)]/x(t_0))*100)$.

Differences in skin parameters over time were evaluated using the paired *t*-test for normally distributed data and Wilcoxon's signed rank test for non-normal data. For unpaired data, the *t*-test or Mann–Whitney test were used, depending on the distribution. The Chi-square test, or Fisher's exact test where appropriate, was used to compare differences between categorical variables. *p* values of less than 0.05 were considered statistically significant.

5. Conclusions

The study of the effect of sheep colostrum cream on mature skin, in comparison to placebo cream, is highly innovative research because no cosmetic preparation with colostrum of sheep origin has previously been tested.

This study also indicates that the issue of preparing an appropriate placebo cream is crucial. Our placebo product, with the same composition as our colostrum cream but without an active component, also slightly improved hydration and TEWL in subjects. However, the placebo cream should not improve skin condition, but on the other hand, it should ensure comfortable application to patients throughout the study period.

Sheep colostrum cream demonstrates greater effectiveness in improving skin conditions compared to placebo cream. Its use results in substantial enhancements in hydration, TEWL, and elasticity, suggesting potential dermatological and aesthetic applications.

The subjective assessment of skin condition and photo documentation confirm the results of the objective measurements, revealing that the colostrum cream demonstrates significant activity in, *inter alia*, improving skin softness, smoothing skin pores, and reducing redness.

6. Patents

As a result of the work described in this manuscript, the Polish patent application No. P.446801, "Cosmetic composition, method of its production, and application" was filed on 22 November 2023.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/app14072862/s1, Figure S1: Exemplary pictures of subjects before (left) and after (right) eight weeks of using the colostrum cream.

Author Contributions: Conceptualization, K.K. and U.K.-L.; methodology, A.E.-P.; formal analysis, K.K., A.E.-P. and U.K.-L.; investigation, K.K., A.E.-P. and U.K.-L.; data curation, A.E.-P. and U.K.-L.; writing—original draft preparation, K.K., A.E.-P. and U.K.-L.; writing—review and editing, A.E.-P. and U.K.-L.; visualization, U.K.-L.; supervision, U.K.-L.; project administration, U.K.-L. All authors have read and agreed to the published version of the manuscript.

Funding: This research was supported by the Medical University of Lodz, grants No. 503/3-066-02/503-31-001 and 503/3-066-01/503-31-001.

Institutional Review Board Statement: This study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Bioethics Committee of Medical University of Lodz. Poland (protocol code RNN/275/21/KE, date of approval 14 December 2021).

Informed Consent Statement: Informed consent was obtained from all subjects involved in this study.

Data Availability Statement: The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding authors.

Acknowledgments: We would like to thank Łukasz Bobak from the Wroclaw University of Environmental and Life Science for the lyophilization of the colostrum.

Conflicts of Interest: The authors declare no conflicts of interest.

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