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# Cosmetic camouflage improves health-related quality of life in women with systemic lupus erythematosus and permanent skin damage: A controlled intervention study

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## Abstract

**Objective:** To investigate the effect of cosmetic camouflage in health-related quality of life (HRQoL) in women with systemic lupus erythematosus (SLE) and permanent facial skin damage.

**Methods:** This is a randomized controlled clinical trial (Universal Trial Number: U1111-1210-2554e) with SLE women from outpatients using ACR/1997 and/or SLICC/2012 criteria, aged over 18 years old, with modified SLEDAI 2k $< 4$ and permanent facial skin damage, recruited in two tertiary centers to use cosmetic camouflage ($n = 36$) or no intervention ($n = 20$). Endpoints were score variations in SLE Quality of Life (SLEQoL) (total and each domain), Dermatology Life Quality Index (DLQI), Rosenberg self-esteem scale and Hospital Anxiety and Depression Scale (HADS), after daily use of cosmetic camouflage for 12 +/−2 weeks (Phase I), "as needed" use of cosmetic camouflage for another 12 +/−2 weeks (Phase II), and during total follow up (24 +/−2 weeks). Univariate and multivariate linear regressions were conducted by protocol analysis.

**Results:** Both groups were similar at baseline regarding age, disease duration, socio-demographic, clinical, laboratory and treatment characteristics. The comparison of score variations between intervention and control groups showed an independent HRQoL improvement in total SLEQoL score after using cosmetic camouflage in Phase I [β −27.56 (CI 95% −47.86 to −7.27) $p = 0.009$] and total follow up [β −28.04 (CI 95% −48.65 to −7.44) $p = 0.09$], specifically in mood, self-image and physical functioning domains. Also, there was an improvement in DLQI scores during Phase I [β −7.65 (CI 95% −12.31 to −3.00) $p = 0.002$] and total follow up [β −8.97(CI95% −12.99 to −4.94) $p < 0.001$). Scores for depression [β −1.92 (CI 95% −3.67 to −0.16) $p = 0.033$], anxiety [β −2.87 (CI 95% −5.67 to −0.07] $p = 0.045$] and self-esteem [β 2.79 (CI 95% 0.13 to 5.46) $p = 0.041$] improved considering the total follow up. No significant changes occurred in the control group scores.

**Conclusion:** The use of cosmetic camouflage improved the HRQoL in female SLE patients with permanent facial skin damage.

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**Keywords**
SLE skin damage, cosmetic camouflage, health-related quality of life (HRQoL), Systemic Lupus Erythematosus Quality of Life (SLEQoL), Dermatology Life Quality Index (DLQI), Rosenberg self-esteem scale, Hospital Anxiety and Depression Scale (HADS)

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## World health organization record

Impact of the use of Cosmetic Camouflage on health-related quality of life in patients with Systemic Lupus Erythematosus and cutaneous manifestations – Universal Trial Number U1111-1210-2554.

## Introduction

Cutaneous manifestations occur in approximately 80% of patients with systemic lupus erythematous (SLE), may be classified as acute (ACLE), subacute (SCLE), and chronic (CCLE), and are the first sign of the disease in up to 25% of cases.[1] Some of them leave definitive scars, especially the chronic forms, characterizing a permanent disease damage.[2] Discoid lupus is the most common form of chronic cutaneous lesions and can occur as localized (80%), commonly involving the head and neck, particularly the scalp and ears, or as disseminated (20%) with lesions above and below the neck, usually involving the extensor forearms and hands.[3] Typically, acute LE does not cause scarring and dyspigmentation is frequently transient, especially in dark-skinned people. In SCLE, hypopigmentation may occur. Notably, many patients had lesions from more than one clinical category (ACLE, SCLE, or CCLE), and some had lesions from all three categories.[1]

SLE causes an important negative impact on the health-related quality of life (HRQoL) of affected individuals, changing their priorities, their life projects and even their body image.[4] Several factors are related to the low HRQoL such as disease activity, permanent damage index, psychological symptoms, body image, socioeconomic status and social support.[4–7] Moreover, the occurrence of lesions, which may be disfiguring on visible sun-exposed areas, is emotionally devastating and increases the psychological burden of the disease.[8] The presence of rashes can trigger feelings of low self-esteem, self-imposed isolation, depression, and anxiety at significantly higher rates than in healthy women.[9] Also, discoid lesions have been reported to have a dramatic negative impact on the patient's HRQoL, leading to physical and psychological disability.[10]

Patients with permanent skin damage develop strategies to conceal lesions, using clothes and cosmetics that provide body coverage.[11] The cosmetic camouflage therapy is a type of makeup used in clinical practice to cover disfigurements, such as contour and pigmentary skin defects. A good cosmetic cover should comprise the following properties: natural looking, fragrance free, waterproof, easy to apply, long-lasting, applicable to all skin types, non-irritating, non-sensitizing, non-photosensitizing, non-comedogenic and be affordable. Additionally, the products should be available in a multiplicity of shades so as to match all skin colors and skin conditions. One notable benefit of cosmetic camouflage is the immediate result and instant gratification that can be achieved after application of the product.[12–14] In some dermatological conditions, such as psoriasis, vitiligo and acne, cosmetic camouflage is already recommended by dermatologists on a regular basis.[15–19]

Few studies analyzed the impact of SLE cutaneous manifestations on HRQoL,[8,20–26] and only one of them investigated different therapeutic strategies to cover permanent skin damage in 15 SLE patients with inactive to mildly active disease and cutaneous involvement.[23]

The aim of our study was to analyze the impact of the cosmetic camouflage use on different dimensions of HRQoL in female SLE patients with permanent skin damage on the face.

## Patients and methods

### *Study design*

This was an open controlled trial study conducted in two Rheumatology outpatient clinics in tertiary public hospitals (Hospital das Clínicas of the Universidade Federal of Minas Gerais – UFMG and Santa Casa of Belo Horizonte), reported according to Consolidated Standards of Reporting Trial (CONSORT).[27]

The study was approved by the UFMG Research Ethics Committee (protocol number 1833077 - CAAE 48357515.7.0000.5149) and by the Santa Casa Group of Belo Horizonte (protocol 1901295 - CAAE:

48357515.7.3001.5138), and it was registered at the World Health Organization (Universal Trial Number U1111-1210-2554)[28] and at the Brazilian Clinical Trial Register (RBR-59H84G).[29]

Initially, 24 patients, allocated by convenience to the cosmetic camouflage group (n = 17) or control group (n = 7), were included based on the day of their visit to the Rheumatology outpatient clinic at the Hospital das Clínicas of the UFMG. The data obtained during this pilot study were used for sample calculations. Afterwards, patients from the two involved Rheumatology clinics were randomly allocated, using the random number table, to complete the sample size.

Patients were allocated to use cosmetic camouflage or no intervention (control group), for a total of 24 ± 4 weeks. The study was divided in two phases: Phase I – T0 to T1 (12 ± 2 weeks) and Phase II – T1 to T2 (12 ± 2 weeks) (Figure 1(a)).

At T0, all patients in the intervention group were trained to use the cosmetic camouflage. The product was applied by the patients themselves after having cleaned their faces, following instructions provided by the researchers. Patients were instructed to use cosmetic camouflage daily during Phase I. For Phase II, they were instructed to use it based on their personal needs.

Adherence to the proposed treatment was investigated by phone contact made by one of the researchers (FAPO) at the end of the first and second months (Phase I) and of the fourth and fifth months (Phase II). The contact was successful for 85.7% of the patients in the first month, 92.9% in the second,

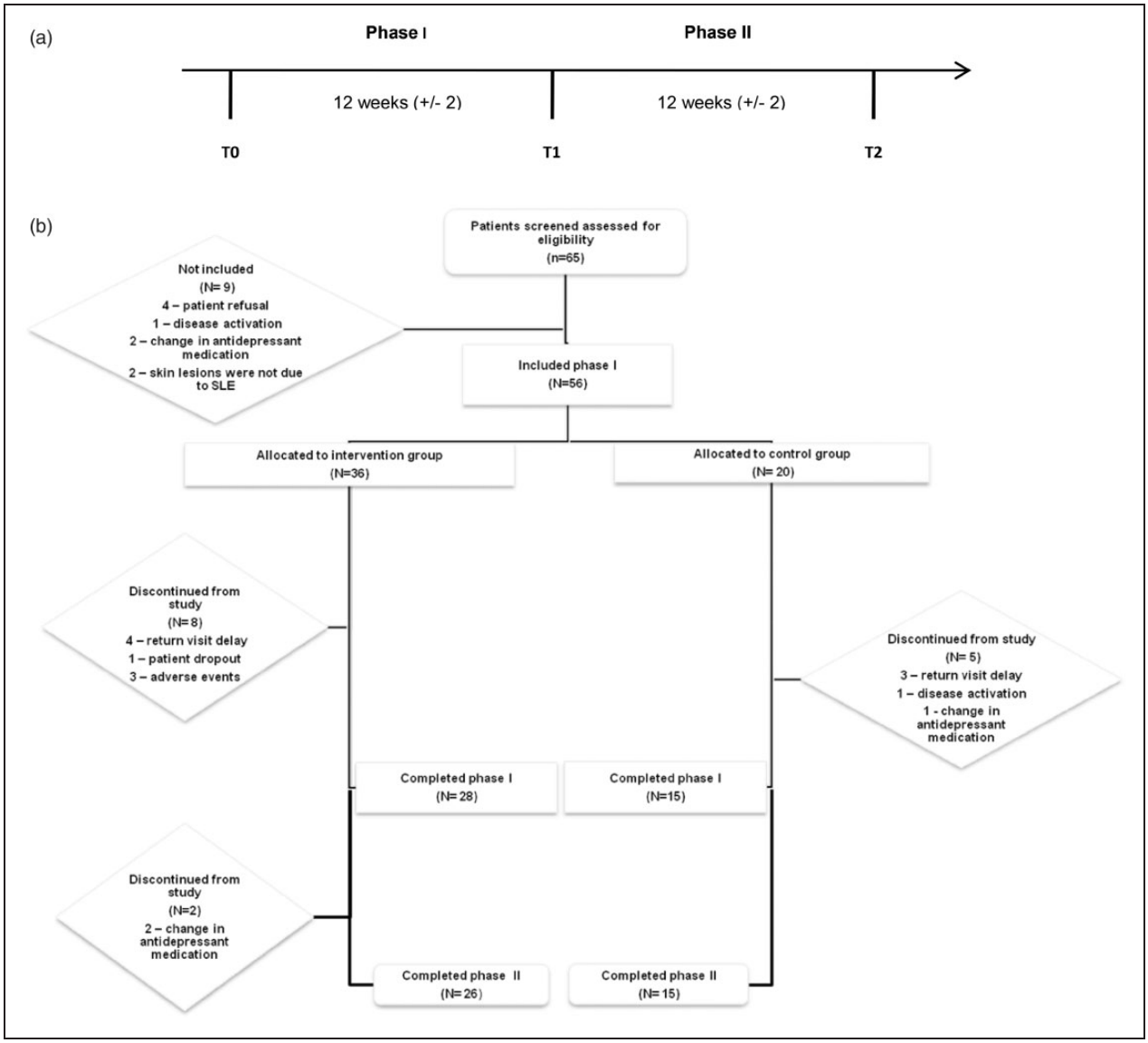


**Figure 1.** (a) Study design and (b) Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

96.2% in the fourth, and 84.6% in the fifth month of the study.

*Cosmetic camouflage.* All the cosmetic camouflage products were provided free of charge. The products are non-comedogenic water-in-oil face foundation, matte, fragrance-free and available in seven different shades. These products were donated by the compounding pharmacy Amphora (registered under corporate taxpayer number 38.659.082/0001-53), who had no contact with the patients and no involvement in the study design, patient inclusion, data analysis and the preparation of manuscript.

## Patients

After providing written informed consent, patients recruited from October 2015 to November 2018 were included according to the following criteria: (a) SLE diagnosis, based on American College of Rheumatology (ACR) 1982/97 and/or Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC) 2012 classification criteria[30–32] (b) being 18 years of age or older; (c) exhibiting permanent cutaneous lupus erythematosus damage on the face, defined as the presence of hypopigmented or hyperpigmented lesions and/or skin atrophy associated with previous episodes of active disease in the same region.[33] At any time during the trial, patients were excluded in case of (a) no understanding of the questionnaires; (b) presenting moderate to severe lupus activity (Modified Systemic Lupus Erythematosus Disease Activity Index – modified SLEDAI-2k $>4$)[34]; (c) initiating psychological and/or psychiatric treatment, with or without drug prescription drugs; and (d) exhibiting allergic reactions to the cosmetic product used in the study.

## Instruments and assessments

Socio-demographic characteristics, clinical-laboratory manifestations, and the therapy for SLE were recorded on a standardized form on the day the patients were included (T0). The modified Systemic Lupus Erythematosus Disease Activity Index (modified SLEDAI-2k), without serologic items, was used to evaluate the disease activity at T0, T1 and T2[35–37] and the Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index (SLICC/ACR-DI) was used to identify permanent damage secondary to SLE inflammatory activity and/or its treatment at T0.[2]

Assessment of HRQoL was done at T0, T1 and T2, using the following validated to Brazilian-portuguese instruments:

- Systemic Lupus Erythematosus Quality of Life (SLEQoL): a SLE specific HRQoL questionnaire consisting of 40 items, answered based on the previous seven days, grouped into six domains: physical functioning (6 items), activities (9 items), symptoms (8 items), treatment (4 items), mood (4 items), and self-image (9 items). Answers are given on a 1 to 7-point Likert scale, with higher scores representing worse HRQoL.[38,39]
- Dermatology Life Quality Index (DLQI): a generic questionnaire developed to be used in patients with any skin disease, comprising ten questions including symptoms and feelings, daily activities, clothing, leisure, work and school, personal and sexual relationships, and the side effects of treatment to be answered considering the previous seven days, in a 0 to 3-point Likert scale, with higher score meaning worse HRQoL.[40,41]
- Rosenberg self-esteem scale: consisting of ten questions answered in a 1 to 4-point Likert scale, with lower scores indicating worse self-esteem.[42]
- Hospital Anxiety and Depression Scale (HADS): divided into two sub-scales (HADS-anxiety and HADS-depression), each with seven items answered using a 0 to 3-point scale. HADS-anxiety and HADS-depression scales are categorized as follows: 0-7, absence of signs of anxiety and/or depression; 8–10, doubtful cases; 11–21, presence of signs of anxiety and/or depression.[43]

## Endpoints

*Primary endpoints* were the score variations in SLEQoL, DLQI, Rosenberg self-esteem and HADS between T0 and T1 (Phase I).

*Secondary endpoints* were the score variations during Phase II, after the "as needed" orientation for cosmetic camouflage use, and during the total period of follow up.

*Statistical analysis.* A sample of at least 19 patients in the intervention group, and nine in the control group, with an error margin of $\alpha = 0.05$, would yield 80% statistical power to detect a variation of at least 25 units in the SLEQoL score, which corresponds to the minimum clinically significant difference required to consider a change of the HRQoL.[39]

Categorical variables were described as numbers and proportion (%), while the continuous variables were identified by their median and interquartile range (IQR). The comparison between the groups at the baseline, of socio-demographic, clinical, laboratory, and treatment characteristics, as well as between patients who remained in the study and patients who were excluded (data not shown), was performed using the

U-Mann-Whitney tests, for continuous variables, and the Fisher's exact test, for categorical variables.

End points were investigated per-protocol analysis using two analytical strategies:

(1) Score variations considering T0, T1, and T2 in each individual group, using Friedman's test and if significant, the paired comparisons (T0-T1, T1-T2 e T2-T0) using Wilcoxon's test with Bonferroni correction (significant p value $<0.16$).

(2) Differences in score variations ($\Delta =$ score at the end of interval minus score at the beginning of that interval) between the cosmetic camouflage and control groups, using linear regression models. First, univariate regression analysis (model 0) was performed for each outcome variable. Then, multivariate models (model 1) were adjusted for age and SLICC/ACR-DI as permanent damage may interfere in the HRQoL[44] and there was a difference between the groups regarding this variable at the baseline (Table 1). The multivariate model adjusted by the allocation form (convenience or randomized) was also tested and there were no significant differences in the results (data not shown).

All analyses were performed using IBM SPSS Statistics software (Statistical Package for Social Sciences, version for Windows SPSS Inc. Chicago, IL, USA), version 19.0.0. 2-sided p value $<0.05$ was considered significant.

## Results

### *Patients, baseline characteristics and adherence to the protocol*

From the 65 patients initially eligible for the study, 56 were included, 36 in the cosmetic camouflage group, 20 in the control group (Figure 1(b)). At the end of Phase I, 28 patients were still in the intervention group and 15 in the control group. The permanent skin damage on the face of all those patients were related to discoid (42/43–97.7%) or bullous lesions (1/43–2.3%). During Phase II, two patients in the intervention group were excluded due to changes in the antidepressant prescription, thus reducing the group to 26 participants (Figure 1(b)). No differences were found between patients who completed at least the study's Phase I and those who did not (data not shown).

Baseline (T0) socio-demographic, clinical, laboratory and disease treatment characteristics per group were

**Table 1.** Baseline (T0) socio-demographic, clinical-laboratory, and therapy for the total sample and per groups.

| Variables | Total N =43 | Intervention N = 28 | Control N = 15 | p-value[a] |
|---|---|---|---|---|
| Age (years)[b] | 46.0 (38.0–55.0) | 45.0 (37.3–55.7) | 50.0 (43.0–55.0) | 0.575 |
| Age at diagnosis (years)[b] | 29.0 (21.0–39.0) | 26.5 (21.2–37.5) | 35.0 (20.0–40.0) | 0.364 |
| Disease duration(years)[b] | 15.0 (8.0–23.5) | 17.5 (7.3–26.5) | 15.0 (9.0–17.0) | 0.452 |
| Education level[c] | | | | |
| ≤8 years of study | 22 (51.2) | 14 (50.0) | 8 (53.4) | 0.741 |
| >8 years of study | 19 (48.8) | 14 (50.0) | 7 (46.6) | |
| Cutaneous manifestations elsewhere than the face | | | | |
| Acute lupus[c] | 5 (21.0) | 4 (14.3) | 1 (6.7) | 0.643 |
| Subacute lupus[c] | 2 (4.7) | 0 (0) | 2 (13.3) | 0.116 |
| Chronic lupus (discoid)[c] | 21 (48.8) | 16 (57.1) | 5 (33.3) | 0.203 |
| Non-scarring alopecia[c] | 6 (14.0) | 4 (14.3) | 2 (13.3) | 1.000 |
| Scarring alopecia[c] | 19 (44.2) | 14 (50.0) | 14 (93.3) | 0.349 |
| Mucous ulcer[c] | 1 (2.3) | 1 (3.6) | 0 (0) | 1.000 |
| Serositis[c] | 1 (2.3) | 1 (3.6) | 0 (0) | 1.000 |
| Leukopenia/lymphopenia[c] | 12 (27.9) | 9 (32.1) | 3 (20.0) | 0.665 |
| Modified SLEDAI 2k[b] | 2 (0–2) | 0 (0–2) | 2 (0–2) | 0.301 |
| SLICC/ACR-DI[b] | 2 (1–3) | 3 (2–4) | 1 (1–2) | 0.001 |
| Prednisone dose (mg)[b] | 5.0 (2.5–7.5) | 5.0 (0.6–6.9) | 5.0 (5.0–7.5) | 0.499 |
| Immunosuppressant[c] | 30 (69.8) | 21 (75.0) | 9 (60.0) | 0.324 |
| Antimalarial[c] | 28 (65.1) | 18 (64.3) | 10 (66.7) | 1.000 |
| Antidepressant[c] | 16 (37.2) | 11 (39.3) | 5 (33.3) | 0.181 |

Leukopenia: Global leucocyte count $<4000/mm^3$; lymphopenia: Lynfocyte count $<1000/mm^3$; Modified SLEDAI-2k: Systemic Lupus Erythematosus Disease Activity Index without complement level and ds-DNA. SLICC/ACR-DI: Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index for Systemic Lupus Erythematosus.

[a]U-Mann-Whitney or Fischer's exact test.

[b]Median (IQR).

[c]N (%).

similar, except for SLICC/ACR-DI, higher for the intervention group (Table 1). Further analysis investigating each damage index domain separately showed statistical difference only for the musculoskeletal domain, despite the median being zero for both groups [cosmetic camouflage: 0 (0-0.8) *versus* control: 0 (0-0), $p = 0.037$]. Except for the Rosenberg Scale, all the other questionnaires' scores, including SLEQoL domains' scores, were higher in the intervention group, although not statistically significant (Table 2).

At the end of Phase I all patients in the intervention group stated they had used the cosmetic camouflage. Twenty five (89.3%) of them used it at least once a day and three (10.7%) used it only for social or leisure activities. In Phase II analysis, 18 (69.3%) patients stated that they continued to use cosmetic camouflage at least once a day, six (23.0%) used it only for social or leisure activities, and two (7.7%) used it during work and social activities.

### Enpoints

HRQoL questionnaires scores at T1 and T2 and Δ-scores for the T0-T1 (Phase I), T1-T2 (Phase II) and T0-T2 (total follow up) observation periods are presented in Supplementary Material Tables 1 and 2.

### SLEQoL and DLQI

In the paired sample analysis considering the three periods of the study there was a significant reduction of the total SLEQoL score of the cosmetic camouflage group during the entire follow up (Friedman's test $p = 0.005$), with a significant improvement of HRQoL during Phase I (Wilcoxon T0-T1 $p = 0.001$) (Figure 2(a)). The scores decreased especially in mood (total follow up Friedman's test $p = 0.003$, specifically in Phase I Wilcoxon $p = 0.026$) and self-image (total follow up Friedman's test $p = 0.009$, specifically in Phase I Wilcoxon $p = 0.010$) domains (Supplementary Material – Figure 1). The same was noted for DLQI score (total follow up Friedman's test $p = 0.012$, with the difference in Phase I - Wilcoxon $p < 0.001$) (Figure 2(b)). There were no changes neither in the DLQI nor in the SLEQoL scores (total and domains) between Phase I and II (Wilcoxon T2-T1) (Figure 2(a) and (b) and Supplementary Material – Figure 1). No significant changes on SLEQoL and DLQI scores were observed in the control group.

The comparison of score variations (Δ) between intervention and control groups showed an independent HRQoL improvement for total SLEQoL and DLQI scores after using cosmetic camouflage in Phase I and total follow up (Table 3). Again, the SLEQoL domains positively affected were mood and self-image, plus physical functioning (Supplementary Material Table 4).

### Self-esteem and psychological symptoms

Considering the paired analysis of the Rosenberg self-esteem scale score and of the HADS anxiety symptoms score, no significant changes were observed in any of the groups during the total follow up (Figure 2(c) to (e)). However, Friedman's p-value was borderline for the depression scale the intervention group ($p = 0.054$) (Figure 2(d)). The paired comparisons using Wilcoxon's test with Bonferroni correction showed no differences in the Phases I and II.

There were no changes, neither in self-esteem nor in psychological symptoms, during Phase I and Phase II using multivariate linear regression models. However,

**Table 2.** Baseline (T0) questionnaires scores of the total sample and of both groups.

| Variable[a] | Total (N = 43) | Intervention (N = 28) | Control (N = 15) | p-value[b] |
|---|---|---|---|---|
| Final SLEQoL score | 111.0 (82.0–152.0) | 118.0 (91.0–153.5) | 89.0 (72.5–116.5) | 0.083 |
| SLEQoL physical functioning | 13.0 (8.0–18.0) | 15.0 (7.5–20.0) | 10.0 (8.0–15.0) | 0.163 |
| SLEQoL activities | 23.0 (14.0–31.0) | 25.5 (14.5–32.5) | 18.0 (13.0–28.0) | 0.230 |
| SLEQoL symptoms | 23.0 (14.0–30.0) | 24.5 (18.0–30.8) | 23.0 (12.0–28.0) | 0.358 |
| SLEQoL treatment | 10.0 (8.0–14.0) | 11.0 (8.0–14.0) | 9.0 (8.0–14.0) | 0.908 |
| SLEQoL mood | 14.0 (10.0–20.0) | 14.5 (11.3–22.0) | 13.0 (6.0–17.0) | 0.070 |
| SLEQoL self-image | 26.0 (15.0–36.0) | 28.5 (15.0–36.8) | 18.0 (13.0–29.0) | 0.129 |
| DLQI Score | 8.0 (3.0–14.0) | 8.5 (4.0–16.0) | 8.0 (3.0–12.0) | 0.197 |
| Rosenberg Score | 29.0 (27.0–31.0) | 27.0 (24.0–28.5) | 27.0 (23.8–30.0) | 0.465 |
| HADS depression score | 7.0 (5.0–9.0) | 8.0 (6.0–11.0) | 5.0 (3.0–9.0) | 0.107 |
| HADS anxiety score | 9.0 (5.0–12.0) | 9.0 (6.0–11.0) | 6.0 (2.0–12.0) | 0.215 |

DLQI: Dermatology Life Quality Index; SLEQoL: Systemic Lupus Erythematosus – Specific Quality Of Life Scale; HADS: Hospital Anxiety and Depression Scale.
[a]Median (IQR).
[b]U-Mann-Whitney.

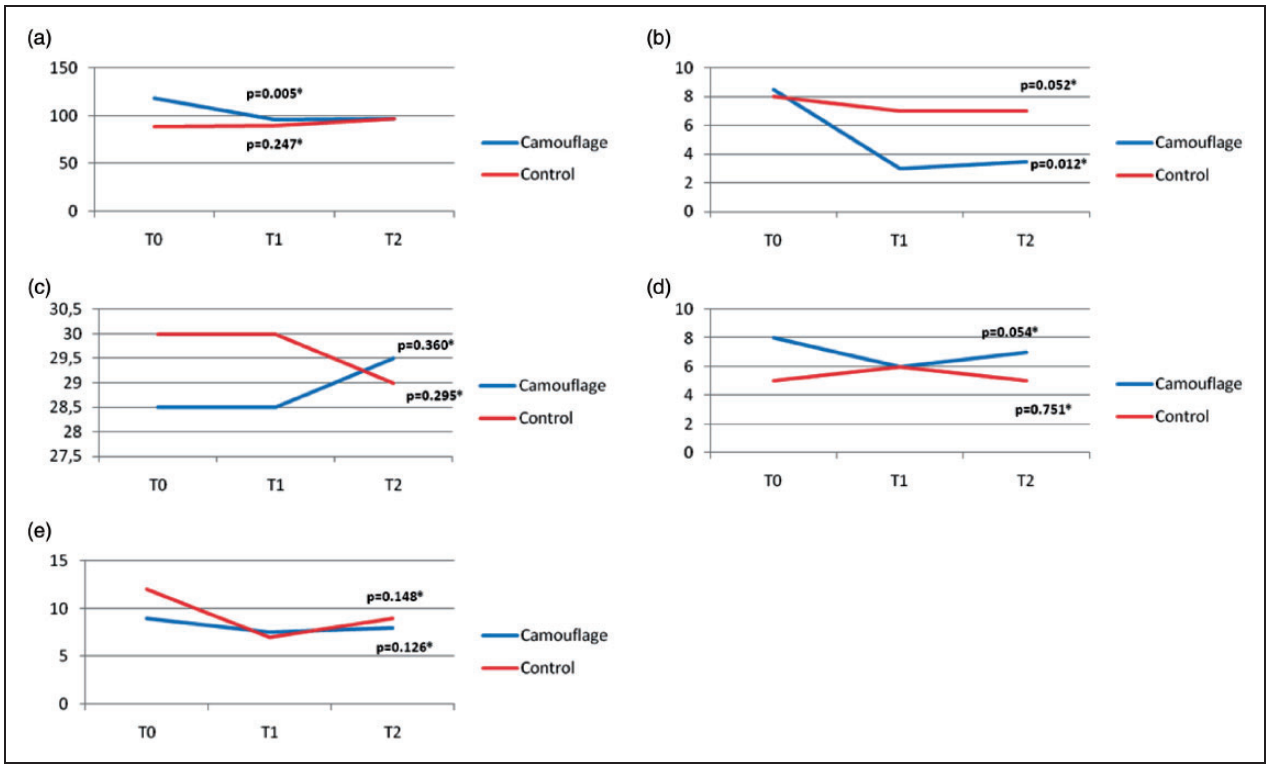


**Figure 2.** Paired sample analysis: median of scores for each HRQoL questionnaire in the three study periods, in the cosmetic camouflage group and control group: SLEQoL (a), DLQI (b), Rosenberg self-esteem scale (c), HADS – depression (d), and HADS – anxiety (e).
*Friedman's test.

in the cosmetic camouflage group there was a significant and an independent improvement of self-esteem ($p = 0.041$), depression ($p = 0.033$) and anxiety ($p = 0.045$) even after adjustments, considering the study's total follow up (Table 3).

## Discussion

The use of cosmetic camouflage improved the HRQoL in female SLE patients with permanent facial skin damage and low systemic disease activity. The improvement was observed in a specific SLE questionnaire (SLEQoL) as well as on a generic questionnaire for skin conditions (DLQI). Interestingly, the modification of the frequency of cosmetic camouflage used from daily (Phase I) to "as needed" (Phase II) did not change the results meaning that positive impact on HRQoL persisted during the total study period. Also, an improvement was observed in self-esteem as well as in signs of depression and anxiety during total follow up. These results confirmed the study's initial hypothesis that cosmetic camouflage would provide improvement of HRQoL.

Interventions to improve HRQoL in such individuals are important due to the high frequency of cutaneous manifestations in SLE and the negative association already proven between permanent skin damage and HRQoL, in the affective, professional and social dimensions.[20,45,46] In some reports, the evaluation of the relationship between permanent skin damage and HRQoL suggests that this is not the main factor impacting the HRQoL of SLE patients.[21,23,24] However, interventions in those patients demonstrated an improvement in HRQoL.[16,26]

In this context, studies to test new strategies to minimize the burden of permanent skin damage are necessary. Only two studies have assessed the impact of cosmetic camouflage use in the HRQoL of SLE patients presenting permanent skin damage.[16,26] Boehncke et al. studied 20 patients with face disfiguring dermatosis, including only two with discoid lupus, and demonstrated the positive impact of cosmetic camouflage on HRQoL using the DLQI questionnaire.[16] The other was a pilot study conducted by Jolly et al. including exclusively SLE patients with skin damage - 10 individuals in the intervention group and 5 in the control group.[26] In this study, the authors showed an improvement of body image, psychological well-being, and quality of life in the intervention group. However, besides cosmetic camouflage other

**Table 3.** Univariate and multivariate linear regression models for the outcomes of SLEQoL, DLQI, Rosenberg scale, and HADS questionnaires.

| | Model 0 | | Model 1 | |
|---|---|---|---|---|
| HRQoL questionnaire | $\beta$ (CI 95%) | p-value | $\beta$ (CI 95%) | p-value |
| SLEQoL score | | | | |
| ΔPhase I | –26.47 (–44.44 to –8.50) | 0.005 | –27.56 (–47.86 to –7.27) | 0.009 |
| ΔPhase II | 3.21 (–14.43 to 20.86) | 0.715 | –0.62 (–20.34 to 19.10) | 0.950 |
| ΔTotal | –23.91 (–42.54 to –5.29) | 0.013 | –28.04 (–48.65 to –7.44) | 0.009 |
| DLQI Score | | | | |
| ΔPhase I | –7.01 (–11.11 to –2.91) | 0.001 | –7.65 (–12.31 to –3.00) | 0.002 |
| ΔPhase II | –0.22 (–2.80 to 2.36) | 0.865 | –1.65 (–4.33 to 1.03) | 0.221 |
| ΔTotal | –6.63 (–10.55 to –2.70) | 0.001 | –8.97 (–12.99 to –4.94) | <0.001 |
| Rosenberg Score | | | | |
| ΔPhase I | 0.14 (–3.73 to 4.00) | 0.943 | 0.79 (–3.54 to 5.13) | 0.713 |
| ΔPhase II | 1.18 (–0.83 to 3.18) | 0.242 | 1.48 (–0.77 to 3.74) | 0.190 |
| ΔTotal | 2.51 (0.03 to 5.00) | 0.048 | 2.79 (0.13 to 5.46) | 0.041 |
| HADS depression score | | | | |
| ΔPhase I | –0.08 (–2.71 to 1.13) | 0.411 | –0.33 (–2.49 to 1.83) | 0.758 |
| ΔPhase II | –0.83 (–2.49 to 0.84) | 0.320 | –1.49 (–3.30 to 0.31) | 0.101 |
| ΔTotal | –1.76 (–3.35 to –0.18) | 0.030 | –1.92 (–3.67 to –0.16) | 0.033 |
| HADS anxiety score | | | | |
| ΔPhase I | –0.72 (–3.24 to 1.80) | 0.568 | –0.50 (–3.37 to 2.36) | 0.726 |
| ΔPhase II | –1.20 (–3.64 to 1.25) | 0.327 | –2.29 (–4.88 to 0.31) | 0.082 |
| ΔTotal | –2.02 (–4.57 to 0.54) | 0.118 | –2.87 (–5.67 to –0.07) | 0.045 |

ΔPhase I: T1 score – T0 score; ΔPhase II: T2 score – T1 score; ΔTotal: T2 score – T0 score.
HRQoL: Health Related Quality of Life; DLQI: Dermatology Life Quality Index; SLEQoL: Systemic Lupus Erythematosus Quality Of Life; HADS: Hospital Anxiety and Depression Scale.
Model 0: Univariate linear regression.
Model 1: model 0 + SLICC/ACR-DI and age.

interventions were adopted, such as training with a dress/appearance coach associated with cognitive-behavioral therapy. It was not possible to individualize the contribution of each specific intervention component to the observed improvement.[26] To our knowledge, the present study is the first one to investigate and demonstrate an improvement of HRQoL due to this specific intervention – cosmetic camouflage – in an exclusive sample of SLE patients with low disease activity and permanent skin damage on the face.

Although the median of the questionnaires' scores at the baseline were higher in the intervention group, suggesting that the patients of this group had worse HRQoL, the analyses showed that the difference was not statistically significant (Table 2).

Our choice for the SLEQoL questionnaire was based on the fact it is suitable for the evaluation of specific SLE manifestations and, therefore, more sensitive to the identification of changes in HRQoL due to problems or conditions inherent to this disease.[38,39] In the present study, improvement of HRQoL with cosmetic camouflage use was demonstrated in the specific SLEQoL domains, namely physical functioning, mood and self-image. Physical functioning domain questions included activities associated with the need for leaving home and facing social exposure. For the mood domain, questions investigated signs of depression and anxiety (feeling different from other people, feeling sad, depressed, anxious), and for self-image assessment the questions were related to the desire for hiding the disease, to the feeling of inferiority in relation to others and to being ashamed due to the disease.[38] The other domains of SLEQoL referred to disease activity and treatment and, therefore, remained unchanged after the intervention. Similar to what was shown by SLEQoL analyses, there was a reduction in the DLQI score after cosmetic camouflage use demonstrating an improvement of HRQoL. The variation in the median of the DLQI scores in the total follow up [−4.0 (−10.0–1.3)] and in Phase I [−3.0 (−10.8–0.0)] was consistent with the minimal clinically important difference (MCID), ranging from 3 to 5 in different reports,[47] meaning that camouflage use provided a positive impact on HRQoL.

Interestingly, the improvement of HRQoL according to SLEQoL and DLQI was evident during the first $12 \pm 2$ weeks of cosmetic camouflage "daily use" and did not change after the orientation to "as needed" use of the camouflage, suggesting that the product

application had become a habit and, also, that it could provide a long-lasting benefit.

Considering the Rosenberg self-esteem scale and the HADS, the positive impact was observed only after the entire study period which suggests the need for a longer period of time for psychological symptoms to improve. Besides that, at baseline, as up to 88.4% of patients were in the high self-esteem category, 46.5% had symptoms of depression and 55.8% of anxiety, it is possible that the observed ceiling effect had compromised a psychometric property of the questionnaires – responsiveness – in a short interval assessment.[48]

This study had some limitations. First, the present study recruited patients from two tertiary Rheumatology Units who might not represent all SLE individuals with permanent facial skin damage. Nevertheless, we believe cosmetic camouflage is replicable and the results described here are easily achievable. Second, because of operational constraint, the study was unmasking and with no placebo use in the control group. Third, we did not include an in-depth qualitative assessment of patients' reports concerning their experience and results of cosmetic camouflage use in their daily functioning. We think that the improvement of HRQoL could be even greater than that reported in this article if patient's perspective had been considered, once some aspects of HRQoL were not captured by the standardized questionnaires used here.[48,49] We addressed the lack of qualitative analyses as a limitation of the present study. Finally, a floor effect could explain the lack of improvement of SLEQoL and HADS' scores in the control group during the follow up. Such floor effect would, probably, justify the differences in the score variations of those questionnaires in the analyses between groups. Nonetheless, when using paired analytical strategy, an improvement of HRQoL was indeed observed in the intervention group. Considering the DLQI and Rosenberg questionnaires analyses neither floor nor ceiling effects occurred.

The main strengths of this study were: 1- its originality; 2- the appropriate sample calculation and randomization after the pilot study; 3- the adoption of strict inclusion/exclusion criteria in order to obtain a homogeneous sample regarding disease activity and permanent facial skin damage; 4- the comparison of outcomes with a control group which assured that the HRQoL improvement was not a consequence of physician-patient communication or simply an effect of time; 5- the use of different questionnaires to assess several dimensions of HRQoL, one of them specific for SLE.

Cosmetic camouflage is an effective intervention that should be recommended by the rheumatologists as a routine care for lupus patients. We are aware that the cost of the products is not covered by the public or private health systems, which could limit its continuous use by lower socioeconomic income patients. We believe that by increasing awareness and knowledge of cosmetic camouflage benefits, physicians will be able to offer additional services and treatment options for lupus patients suffering from permanent skin lesions, helping them to build confidence in the patient-physician relationship, improving patient HRQoL, and also increasing compliance with concurrent medical therapies. Based on this study, further research is needed to analyze the effectiveness of cosmetic camouflage in a larger SLE population. Efforts should be made to make the intervention accessible in a cost-effective way to a greater number of SLE patients.

In conclusion, this study suggests that the use of cosmetic camouflage is effective in improving HRQoL, especially for the physical functioning, self-image, and mood domains, besides the self-esteem and the signs of anxiety and depression, in SLE patients with low disease activity and permanent facial skin damage.

## *Protocol*

The entire protocol used in the research may be requested via email to the researcher.

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## Supplemental material

Supplemental material for this article is available online.

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