

**‘The effect of emu oil on psoriasis’**

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# **The Effect of Emu Oil on Psoriasis**

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### **Abstract**

Psoriasis affects more than 6% of Australian adults<sup>1</sup>. The predominant course of treatment is topical corticosteroids and retinoids; however these therapies impose a high risk of skin irritation and further side effects with longer term use<sup>15</sup>. This study examines the efficacy of emu oil, a natural product with no known side effects, in reducing the severity of psoriasis, improving quality of life and decreasing psoriasis medication requirements. The intervention oil was Emu Spirit™ Oil of Emu, supplied by Emu Spirit™, a company involved in the production and distribution of high quality emu oil.

A double blinded, placebo controlled, six group repeated measures design with 91 participants was used to establish the effects of emu oil in comparison to a placebo, cottonseed oil, when applied topically; ingested; or applied topically and ingested. Patient-reported severity and quality of life measures were recorded at baseline and thereafter weekly and monthly, respectively, for twelve weeks. Psoriasis medication diaries detailing dosage and frequency of medications external to the trial were completed by participants weekly.

Emu oil participants showed a larger and more consistent decline in mean severity scores than the placebo groups. Statistically, emu oil severity scores were significantly lower than placebo;  $F(20.58, 52.0) = 2.0, p = 0.008$  partial  $\eta^2 = 0.161$ . There was no significant difference between the groups for quality of life. Overall, emu oil participants required less additional psoriasis medication.

While emu oil is not a cure for psoriasis, the results of this trial suggest that emu oil may be effective in the management of psoriasis and reduce the need for additional, more toxic therapies.

**Key words:** psoriasis, emu oil, severity, quality of life, topical

## **Introduction**

Psoriasis is a common, chronic, inflammatory skin disease which affects more than 6% of Australian adults<sup>1</sup>. The most common form, psoriasis vulgaris, is characterised by dry, well-circumscribed, erythematous plaques of various sizes covered by silver, flaky scales<sup>2,3</sup>. The predominant symptoms are erythema, scaling, pruritus and skin tightness<sup>4</sup>.

While the exact pathogenesis of psoriasis is still unclear, it is thought to involve a chronic inflammatory cascade, causing keratinocyte hyperproliferation resulting in the formation of a complete new layer of epidermis in the affected area every 3-4 days, with substantial desquamation<sup>5,6,7</sup>.

Owing to the disfiguring nature of psoriasis, even mild forms can have a profound effect on all aspects of a sufferer's life, causing severe psychological and emotional distress<sup>8,9</sup>. A study by Heydendael et al (2005), found that psoriasis patients had a lower quality of life than a reference population<sup>10</sup>. As a result, personal and professional relationships may also be affected<sup>8,11</sup>.

Psoriasis is a life-long condition characterized by exacerbations and remissions, which make its management complex. In addition, there is great variability in individual response to treatments<sup>12</sup>. Often, patients are subjected to multi-drug regimes in order to achieve sufficient control<sup>13</sup>. The orthodox treatment of psoriasis can be divided into: Topical medications, UV Radiation (phototherapy) and Oral/Systemic Drugs<sup>14</sup>. Management usually begins with topical methods, such as corticosteroids, retinoids, coal tar and vitamin D analogues<sup>15</sup>. While these treatments have demonstrated effectiveness in improving the symptoms of psoriasis<sup>15</sup>, studies have found long-term use often causes local skin irritation, dermatitis and atrophy<sup>15</sup> and may even lead to adrenal gland suppression and carcinogenesis<sup>12</sup>.

In more severe cases, or where topical treatments fail, phototherapy and systemic therapies are prescribed<sup>14</sup>. Whilst these procedures are effective in many instances, they carry the risk of more severe side effects<sup>14</sup>. Exposure of the skin to artificial ultraviolet (UV) radiation during phototherapy

may result in many phototoxic side effects; however of most concern with long-term treatment is the increased incidence of cutaneous malignancies<sup>16,17,18</sup>. Studies have linked long-term use of systemic drugs with infections and rebound psoriasis, as well as potentially life-threatening complications, including organ toxicity, hypertension and teratogenicity<sup>5,19,2,21,22</sup>.

In the absence of a permanent cure for psoriasis, the primary aim of treatment is to reduce the severity of symptoms in order to minimize the impact on the patient's quality of life<sup>10,11</sup>. While there are a plethora of treatments available, compliance is limited due to a combination of side effects, inconvenience and lack of results<sup>4,6</sup>. Given this information, it is clear there is an imperative need for the development of non-toxic, user-friendly, efficacious alternatives to the current treatment regimes.

Emu oil has been used by indigenous Australians to treat joint and muscular pains, skin ailments and burns for thousands of years<sup>23</sup>. It is non-toxic and there have been no published reports of side effects with its use to date<sup>23,24,25</sup>. Approved by the Australian Therapeutic Goods Administration (TGA) in July 2002, as Aust L 92158, emu oil has since been used as both a topical and an oral anti-inflammatory agent.

In 1998, Whitehouse et al., found emu oil preparations demonstrated anti-inflammatory activity equivalent to or greater than the non-steroidal anti-inflammatory drug (NSAID), ibuprofen and activity that rivalled the corticosteroid, prednisolone. In addition, no adverse effects were observed with any of the tested emu oil preparations<sup>24</sup>.

Furthermore, emu oil was able to delay or prevent the onset of inflammation in rats without causing the gastro-intestinal irritation commonly associated with NSAIDs such as ibuprofen and naproxen. Orally administered emu oil actually soothed the gastric disturbance and bleeding caused by these drugs<sup>24,26</sup>.

A study by Zemstov et al, found emu oil to have superior texture, skin penetration and moisturizing qualities when compared to a mineral oil<sup>25</sup>. The additional benefit provided by these cosmetic qualities may improve the otherwise low compliance of topical treatments<sup>15</sup>.

There is much anecdotal evidence suggesting emu oil is effective in treating dermatological conditions, however to date there has been no scientific research to validate these claims.

This research project was undertaken to investigate the potential benefits the anti-inflammatory and skin moisturising qualities of emu oil may have for psoriasis sufferers.

### **Materials and Method**

The trial was a double blinded, placebo controlled, six group repeated measures design, with 91 participants, for a duration of twelve weeks. The intervention oil used was Emu Spirit™ Oil of Emu and the placebo was cottonseed oil, both supplied by Emu Spirit™, a company involved in the production and distribution of high quality emu oil (Emu oil analysis, App. 1).

#### ***Participants***

Ninety one volunteers were recruited between May and June 2006 via advertisements in two Melbourne based newspapers, “The Age” and “Herald Sun” and a segment on 3AW, a Melbourne based radio station during May and June, 2006. The participants were aged between 29 and 80 years of age, with a mean age of 55. All participants had a medical diagnosis of psoriasis vulgaris and visual evidence of active psoriasis at the time of their recruitment. Participants were excluded from the trial if they had psoriatic arthritis or had used emu oil previously.

All participants were advised to continue any pre-existing treatment regimes as required throughout the trial and were informed of their option to withdraw from the study at any time, without prejudice.

Fifty nine participants (41 male, 18 female) completed the trial.

#### ***Trial***

Initial meetings were held throughout Melbourne at Dandenong, Ringwood, Moonee Ponds, the Melbourne Central Business District and Werribee. As participants arrived at the

initial meeting, Emu Spirit™ staff recorded their name consecutively next to a trial number, in a table designed to randomly allocate participants to one of six groups:

1. Emu oil applied topically (twice/day) n=10
2. Emu oil ingested (5ml once/day) (This oil has Therapeutic Goods Administration (TGA) listing as an ingestible product, App.2) n=12
3. Emu oil applied topically and ingested (as for the above methods) n=11
4. Placebo oil applied topically (twice/day) n=9
5. Placebo oil ingested (5ml once/day) n=9
6. Placebo oil applied topically and ingested (as for the above methods) n=8

Both the emu oil and the control oil were supplied in identical, numbered containers, identified only by trial number, ensuring researchers and participants remained blinded to group allocation until the completion of the trial.

During the initial meeting, all participants were given detailed instructions on how to apply or ingest the oils and were shown how to complete the outcome measures by the researchers. The baseline measure was completed and collected. An allergy test was also conducted. Each participant applied a small amount of their trial oil either on the skin of the inner forearm or the inside surface of their cheek, or both, depending on the treatment group to which they had been allocated. The oil was left for 5-10 minutes and assessed by a physician. Additionally, participants were advised to observe the test areas for the next 24 hours for signs of allergy. Any participant exhibiting evidence of inflammation was advised to contact the researchers immediately, as their participation in the trial would have to be terminated.

To visually demonstrate any decrease in lesion surface area as a result of the trial, photographic evidence was obtained from volunteers who gave specific consent for this non-compulsory aspect of the trial. Each of these volunteers selected one lesion to be photographed at the beginning and end of the trial by a professional photographer provided by Emu Spirit™.

Throughout the trial, participants were telephoned by research assistants, to maintain compliance and ensure outcome measures were completed. It was proposed that for the first month, the phone calls would be weekly, and thereafter, fortnightly; however on average participants were contacted twice throughout the trial.

At the completion of the trial, another meeting was held at each of the above named locations, where all paperwork was collected and all participants received, gratis, a year's supply of emu oil. Participants were informed of this gift prior to commencement of the trial, to encourage full participation over the 12 weeks.

### ***Outcome measures***

To accurately measure psoriasis severity and the efficacy of treatment, it is necessary to include both objective clinical outcome measures and subjective measures that determine the patient's perception of the impact of the condition on their quality of life<sup>11</sup>.

#### *Severity*

Psoriasis severity was assessed by the Self-Administered Psoriasis Severity Index (SAPSI), (App. 3), prior to commencement of the trial and on the same day every week for the duration of the trial. The SAPSI was chosen over other self-reported measures of psoriasis severity because it is easy to administer, requires no special training, and was likely to be correctly used by participants even in the absence of specific direction from the researchers. The SAPSI is a modified version of the Psoriasis Area and Severity Index (PASI), which is regarded as the most validated measure of psoriasis severity; however it requires a trained dermatologist to administer<sup>27</sup>. The SAPSI demonstrates criterion validity and has shown similar responsiveness to changes in severity over time with treatment when contrasted with the PASI<sup>28</sup>. This instrument also shows construct validity and strong test-retest reliability ( $r = 0.82, p = 0.0001$ )<sup>27,28</sup>. Use of the SAPSI was explained to participants at the initial meeting. Measuring at the same time each week was suggested to maintain compliance.

#### *Quality of Life*

The Dermatology Life Quality Index, (DLQI), (App. 4), is a 10 item questionnaire that incorporates the patient's assessment of symptomatology, self-consciousness, treatment problems, and interference of their skin condition with activities of daily living, relationships and sexual function. This instrument was chosen again for its simplicity and likelihood of being correctly used by participants even in the absence of specific direction from the researchers. The psychometric properties (validity, reliability and responsiveness) of the DLQI have been well established, and it has been cited in more 130 research articles<sup>8,29,30</sup>.

#### *Psoriasis Medication*

Variation in psoriasis medication use was assessed by participants completing a table on the same day every week, detailing dosage and frequency of any psoriasis medication external to the trial (App 5).

#### *Lesion surface area*

A photographic record of a selected lesion was obtained from volunteers who gave specific consent, at the beginning and end of the trial. Assessment of the photos involved measuring the surface area of the lesion both before and after the trial, using a small ruler placed adjacent to the lesion in all photographs.

#### *Data Analysis*

The data were analysed with descriptive statistics and split plot design repeated measures analysis of covariances, (SPANCOVAs), for both the severity (6x12) and quality of life (6x3) outcome measures, using SPSS version 13.0. The covariate measures were the respective baseline data for each outcome measure. Severity data were further analysed using Tukey's-b post hoc test and a one-way ANOVA.  $P < 0.05$  was considered statistically significant.

## **Results**

### *Missing data*

Thirty two of the 91 participants did not complete the trial, and 3 did not complete the DLQI. For those that completed the trial, any missing data was replaced with mean data for that group. A larger number of placebo participants withdrew from the trial (emu oil groups, n = 33; placebo groups, n = 26).

### *Outliers*

Outliers were identified in the sample as a whole and were included in the analysis as they represent the extremes of the disease spectrum of psoriasis and its effect on quality of life. Outliers were not consistent over time which is an indication of the variable nature of psoriasis in regard to individual exacerbations and response to treatment<sup>12</sup>. Also, as there were six different groups, it is likely some of these numbers resulted from the the small within-group sample size, rather than being true outliers.

### *Severity*

Table 1 shows the mean severity scores for all groups decreased over the duration of the trial. A steadier decrease occurred with emu oil, (groups 1-3); where all groups show a greater reduction than placebo groups. Collectively, the difference of the average means of week 1 and week 12 for emu oil was 3.65. Placebo groups (4-6) mean scores fluctuated and concluded with an average difference of only 1.11 between week 1 and week 12.

Group 3 had the largest overall decrease in mean score, with a difference of 4.77. The largest change for placebo oil was 1.5 in group 6. The least change occurred in group 5, with a decrease of only 0.45.

The standard deviations of the placebo groups increase over the course of the trial, while the emu oil group's standard deviations are more stable.

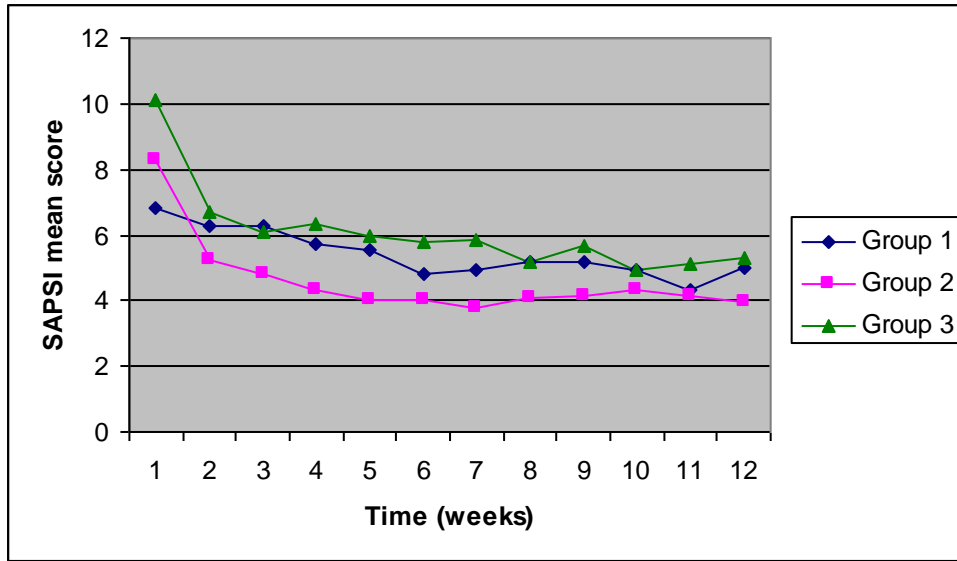
**Table 1.** SAPSI mean scores and standard deviations (SD)

SAPSI	Group 1		2		3		Ave. 1-3		4		5		6		Ave. 4-6	
	Mean	SD														
<b>Baseline</b>	5.85	2.36	6.38	2.40	7.82	2.74	<b>6.68</b>	<b>2.5</b>	7.67	1.87	6.67	1.70	8.13	2.12	<b>7.49</b>	<b>1.89</b>
<b>Week 1</b>	6.85	2.25	8.29	2.23	10.09	3.07	<b>8.41</b>	<b>2.52</b>	7.72	1.67	6.89	1.64	6.94	1.55	<b>7.18</b>	<b>1.62</b>
<b>Week 2</b>	6.30	1.96	5.21	2.47	6.73	1.86	<b>6.08</b>	<b>2.10</b>	7.17	1.56	7.44	1.61	6.06	2.34	<b>6.89</b>	<b>1.84</b>
<b>Week 3</b>	6.25	1.88	4.83	2.82	6.09	1.83	<b>5.72</b>	<b>2.18</b>	6.94	2.23	6.50	1.23	6.81	2.30	<b>6.75</b>	<b>1.92</b>
<b>Week 4</b>	5.75	2.14	4.33	1.91	5.64	1.85	<b>5.24</b>	<b>1.97</b>	6.67	1.62	6.33	1.27	7.0	2.56	<b>6.67</b>	<b>1.82</b>
<b>Week 5</b>	5.55	1.94	4.0	1.82	6.0	2.24	<b>5.18</b>	<b>2</b>	6.83	1.66	5.83	1.66	6.88	2.36	<b>6.51</b>	<b>1.89</b>
<b>Week 6</b>	4.8	1.83	4.08	2.28	5.77	1.92	<b>4.88</b>	<b>2.01</b>	6.56	1.76	6.61	1.32	6.25	2.19	<b>6.47</b>	<b>1.76</b>
<b>Week 7</b>	4.95	1.98	3.75	2.45	5.82	2.22	<b>4.84</b>	<b>2.22</b>	6.89	1.50	6.5	1.5	6.25	2.66	<b>6.55</b>	<b>1.89</b>
<b>Week 8</b>	5.15	2.44	4.08	2.36	5.18	2.37	<b>4.8</b>	<b>2.39</b>	6.44	1.47	6.39	2.10	5.50	2.51	<b>6.11</b>	<b>2.03</b>
<b>Week 9</b>	5.15	2.0	4.13	2.4	5.68	2.73	<b>4.99</b>	<b>2.38</b>	5.78	1.82	6.72	2.11	5.44	2.78	<b>5.98</b>	<b>2.24</b>
<b>Week 10</b>	4.95	1.85	4.33	2.22	4.91	2.58	<b>4.73</b>	<b>2.22</b>	6.0	2.44	7.22	1.86	5.44	3.35	<b>6.22</b>	<b>2.55</b>
<b>Week 11</b>	4.3	1.96	4.13	2.13	5.09	3.0	<b>4.51</b>	<b>2.36</b>	5.7	2.22	7	2.60	5.5	3.30	<b>6.07</b>	<b>2.72</b>
<b>Week 12</b>	5	2.97	3.96	2.07	5.32	3.12	<b>4.76</b>	<b>2.72</b>	6.33	2.83	6.44	2.44	5.44	3.04	<b>6.07</b>	<b>2.77</b>

SAPSI= Self-Administered Psoriasis Severity Index

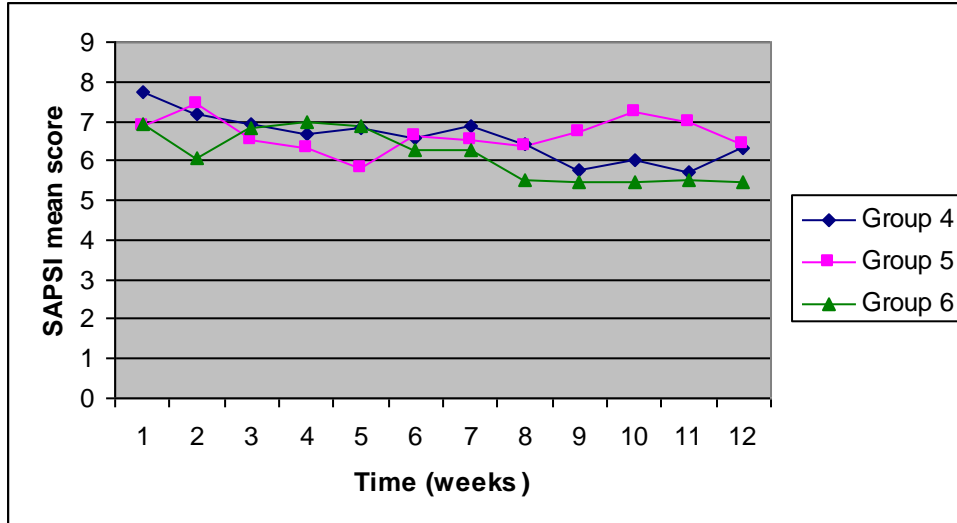
Figures 1 and 2 visually demonstrate the mean severity scores of emu oil and placebo groups, respectively. After week 6 there is a reduction in the rate of improvement in the severity scores for the emu oil groups, while the placebo groups' scores continue to fluctuate.

**Figure 1.** SAPSI mean scores for emu oil



SAPSI= Self-Administered Psoriasis Severity Index

**Figure 2.** SAPSI mean scores for placebo oil



SAPSI= Self-Administered Psoriasis Severity Index

Once the Huynh-Feldt epsilon was applied to correct the violation of sphericity, all assumptions for the severity SPANCOVA were met<sup>31</sup>. This less conservative approach was employed to accommodate the small sample sizes in each group<sup>32</sup>.

*Within Groups*

The effect of time on severity scores within groups and the change of severity scores within groups over time were both statistically significant, with large effect sizes; ( $F_{5,52} = 4.88$ ,  $p = 0.000$ ), partial  $\eta^2 = 0.086$ ; and ( $F_{25,52} = 2.0$ ,  $p = 0.004$ ), partial  $\eta^2 = 0.161$ , respectively.

*Between Groups*

Further investigation of between group differences employed Tukey's-B post hoc test and a one-way ANOVA. In week 1, the topical emu oil group scored significantly lower than the topical/ingestion emu oil group,  $F(5, 54) = 3.51$ ,  $p = 0.008$ . In weeks 4 and 5 the ingestion emu oil group scored significantly lower than placebo topical/ingestion,  $F(5, 54) = 2.52$ ,  $p = 0.041$  and  $F(5, 54) = 3.01$ ,  $p = 0.018$ , respectively. In week 7 the mean score for ingested emu oil was significantly lower than placebo topical,  $F(5, 54) = 3.30$ ,  $p = 0.011$ . The interaction effect was not significant.

*Quality of life*

Quality of life results are illustrated in Table 2. Again, all groups display a decrease in mean scores. An interesting result is the greatest decrease occurring in group 4, placebo oil applied topically. This result contributes to the slightly greater overall decrease in mean scores among placebo oil participants, even though the mean for group 5, placebo oil ingested, is the same pre- and post-intervention. On the contrary, figures 3 and 4 below show greater consistency in mean scores for emu oil participants.

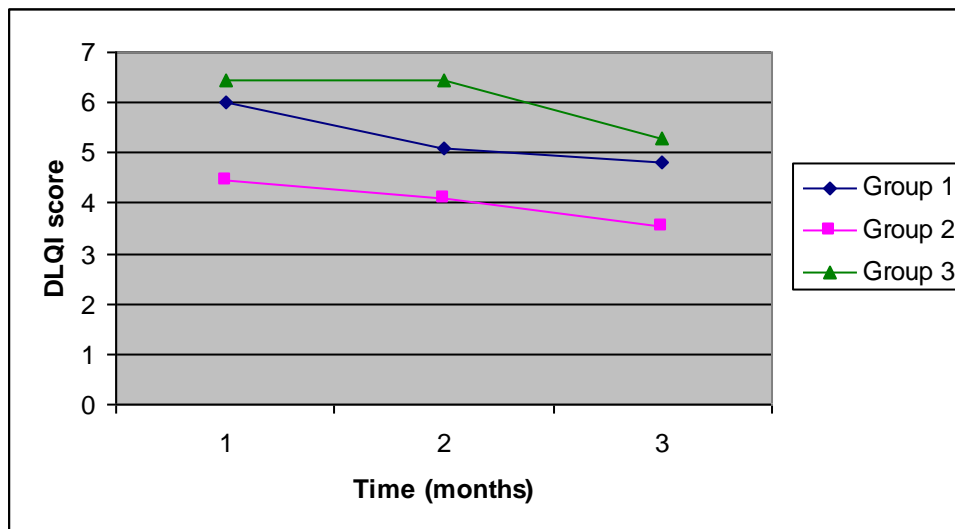
This consistency is supported by the similar standard deviations among emu oil groups. Whilst overall, there is a decline in mean scores for the placebo groups, the larger standard deviations indicate a greater variation among scores within these groups.

**Table 2.** DLQI mean scores and standard deviations (SD)

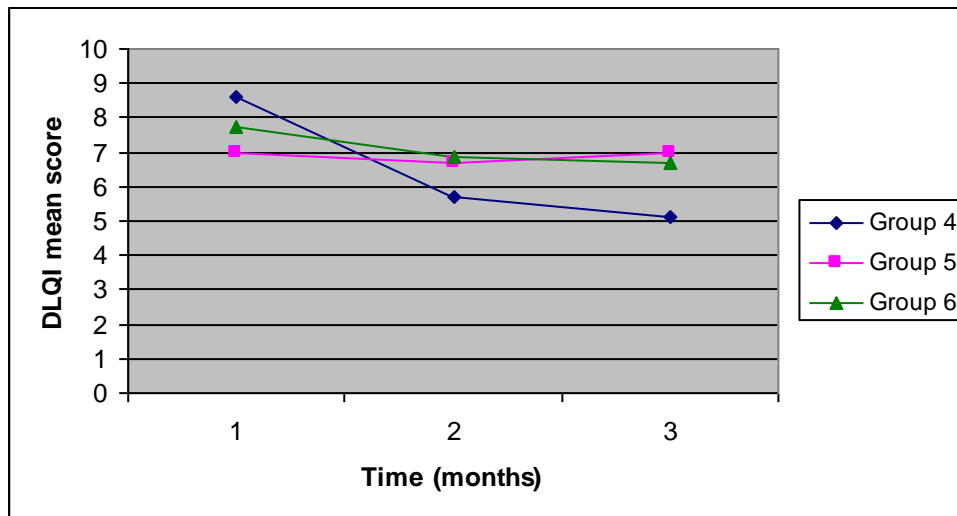
SAPSI	Group 1		2		3		Ave. 1-3		4		5		6		Ave. 4-6	
	Mean	SD														
<b>Baseline</b>	7.7	3.61	6.18	3.89	8.55	3.45	<b>6.68</b>	<b>3.65</b>	9	5.03	7	6.48	7.14	6.22	<b>7.71</b>	<b>5.91</b>
<b>Month 1</b>	5.93	4.45	4.45	3.98	6.64	3.23	<b>5.67</b>	<b>3.89</b>	8.6	4.62	7	5.39	7.71	6.21	<b>7.77</b>	<b>5.41</b>
<b>Month 2</b>	5.10	2.38	4.09	3.48	6.45	3.91	<b>5.21</b>	<b>3.26</b>	5.7	3.37	6.67	6.38	6.86	5.76	<b>6.41</b>	<b>5.17</b>
<b>Month 3</b>	4.80	3.26	3.55	3.59	5.27	3.26	<b>4.54</b>	<b>3.37</b>	5.1	3.54	7	6.12	6.71	4.82	<b>6.27</b>	<b>4.84</b>

DLQI= Dermatology Life Quality Index

**Figure 3.** DLQI mean scores for emu oil



DLQI= Dermatology Life Quality Index

**Figure 4.** *DLQI mean scores for placebo oil*

DLQI= Dermatology Life Quality Index

As for severity, the Huynh-Feldt epsilon was applied to correct the violation of sphericity, and thus all assumptions for the quality of life SPANCOVA were met<sup>31</sup>.

#### *Within Groups*

There was a significant effect of time on quality of life scores within groups, ( $F_{1,5,51} = 7.80, p = 0.003$ ), with a large effect size, partial  $\eta^2 = 0.13$ . However, there was no statistically significant change in quality of life scores within groups over time, ( $F_{7,51} = 0.38, p = 0.92$ ), and the effect size was small, partial  $\eta^2 = 0.036$ .

#### *Between Groups*

There was no significant difference between the emu oil and placebo groups for quality of life, ( $F_{5,51} = 1.63, p = 0.17$ ). A large effect size of partial  $\eta^2 = 0.138$  was found.

#### ***Psoriasis Medication***

Analysis of medications focused on the most commonly and consistently used, and the more potent medications. Medications were grouped according to their mode of action, as follows: Elocon, Eleuphrat, Novasone and Diprosone are classified as high potency topical

corticosteroids (HPTC); Aristocort, EGO cortisone cream (Hydrocor) and Celestone are classified as moderately strong topical corticosteroids (MPTC); Daivonex is a non-steroidal antipsoriatic agent and Methoblastin is a form of methotrexate, an antimetabolite<sup>33</sup>.

There were a greater number of emu oil participants using additional medications as there were a greater number of participants in each emu oil group. Overall, 56 % of participants who completed the study were using at least one other form of treatment for their psoriasis in addition to the trial oils. 64% of those participants were using multiple treatments. At the completion of the trial, 53% of emu oil participants who were using treatment modalities external to the trial oils decreased their use of these additional treatments, while 47% used the same amount throughout the twelve weeks. There were no increases in usage of additional treatments. From the placebo oil participants using other psoriasis treatments initially, 21 % increased their use of these additional treatments, 57% used the same amount and 21% decreased their use.

High and moderate potency topical corticosteroid creams were the most popular treatments. 42% of emu oil participants decreased their requirement for these creams, versus 35% of placebo oil participants; while 14% of placebo oil participants actually increased their usage of high to mid potency topical corticosteroids. Table 3 indicates that overall, emu oil participants required less additional medications while the majority of placebo oil participants required the same amount throughout the trial.

**Table 3.** *Psoriasis medications*

Medications / dosage	Emu Oil			Placebo		
	Increased	Same	Decreased	Increased	Same	Decreased
HPTC		3	6	2	2	1
MPTC			3		2	2
Antipsoriatic		2	4		1	
Antimetabolite				1		
Total	0	5	13	3	5	3

HPTC= high potency topical corticosteroids; MPTC= moderate potency topical corticosteroids

### ***Correlation***

Correlation coefficients for SAPSI and DLQI indicated strong correlation between the two outcome measures in groups 1-4 and 6, ( $r= 0.893, 0.979, 0.897, 0.736, 0.597$ ) respectively, while group 5 is moderately correlated, ( $r= 0.303$ ). In the emu oil group, there is a strong positive correlation between the SAPSI and medication usage ( $r= 0.84$ ), and the DLQI shows a small to moderate positive correlation, ( $r= 0.39$ ). For placebo participants, there is a moderate positive correlation for both outcome measures and medication ( $r= 0.45$  (SAPSI)) and ( $r= 0.43$  (DLQI)). See tables 4 and 5 below.

**Table 4.** *Correlation between outcome measures and mediations for emu oil*

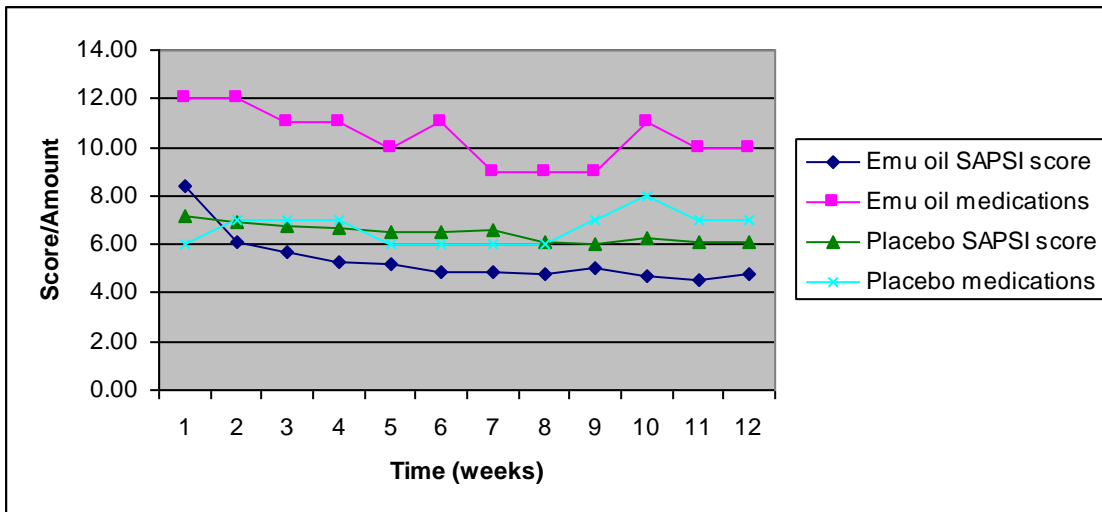
		SAPSI	DLQI	Medications
SAPSI	Pearson Correlation	1	.826	.840
	Sig. (2-tailed)		.381	.365
	N	3	3	3
DLQI	Pearson Correlation	.826	1	.388
	Sig. (2-tailed)	.381		.746
	N	3	3	3
Medications	Pearson Correlation	.840	.388	1
	Sig. (2-tailed)	.365	.746	
	N	3	3	3

**Table 5.** *Correlations between outcome measures and medications for placebo*

		SAPSI	DLQI	Medications
SAPSI	Pearson Correlation	1	1.000(*)	.447
	Sig. (2-tailed)		.016	.705
	N	3	3	3
DLQI	Pearson Correlation	1.000(*)	1	.425
	Sig. (2-tailed)	.016		.721
	N	3	3	3
Medications	Pearson Correlation	.447	.425	1
	Sig. (2-tailed)	.705	.721	
	N	3	3	3

SAPSI= Self-Administered Psoriasis Severity Index; DLQI= Dermatology Life Quality Index

Figure 5 shows a steady decline in mean severity scores for the emu oil groups, as well as a decrease in medications used. This relationship is substantiated by the strong positive correlation shown above in table 3. Where the medications increase, there is a slight further decrease in mean severity score. There does not seem to be any relationship between severity score and amount of medication required for the placebo groups despite a moderate positive correlation.

**Figure 5.** SAPSI scores and medication usage for emu oil and placebo

SAPSI= Self-Administered Psoriasis Severity Index

### *Lesion surface area*

Due to a large number of participants not completing the trial, there were insufficient pre- and post-intervention photographs to allow for comparison between the emu oil and the placebo. On this basis, all photographs were omitted from the study.

## Discussion

### *Severity*

Collectively, emu oil participants recorded higher severity scores in week 1, however, from week 2 onwards the mean scores were consistently lower for emu oil than placebo oil. Each emu oil group had greater reductions in mean severity scores than the corresponding placebo group, and the greatest improvement of all groups over the course of the trial was the combined emu oil topical application /ingestion. This combination proved the most beneficial for both oils when looking at mean scores. The standard deviations for severity scores were more consistent for emu oil than for placebo, indicating a steady improvement in severity for participants using emu oil, as expected. Placebo groups mean scores fluctuated, as evidenced by the larger standard

deviations. This result was not surprising as a greater than expected number of participants reported improvement (see below).

All groups showed a significant difference in severity scores over time. Post hoc analysis of the main effect for group revealed significant differences between emu oil and placebo groups in weeks 4, 5 and 7. Although the emu oil topical application /ingestion group had the most improved mean severity score overall, it was the emu oil ingestion group which had the significantly lower mean SAPSI score than placebo oil in these weeks. This conflict in significance can best be attributed to different sample sizes per group, with  $n$  ranging from 8-12, and/or the fact that the topical/ingestion emu oil group had a larger initial mean severity score. Thus it is difficult to ascertain which method of administration of emu oil is the most effective in reducing the severity of psoriatic symptoms. Future research may consider larger, equal sample sizes within groups to minimise inconsistencies and ascertain the most successful mode of administration.

### *Quality of Life*

There was no statistically significant effect of emu oil over the placebo in improving quality of life. However a large effect size was noted indicating some change between the groups. Whilst some improvement in quality of life was expected as research has demonstrated the large psychological impact of psoriasis<sup>8,9</sup>, another study found no significant correlation between disease severity and quality of life<sup>10</sup>. The results of the present study show similar trends between severity and quality of life mean scores. The average scores and the standard deviations were lower among the emu oil groups in comparison to the placebo. This indicates more consistent gains in quality of life for participants using emu oil while again, placebo groups exhibit fluctuating scores. The topical placebo group showed the greatest improvement in quality of life. This unexpected result may be explained by the presence of outliers in this group, possibly due to smaller sample size.

Many of the placebo participants reported improvement in severity and quality of life. Improvement in the placebo groups may potentially be explained by “the placebo effect”, a psychological expectation of improvement<sup>37</sup>. Furthermore, oils naturally reduce dryness and flakiness, and have a general soothing effect on inflamed skin<sup>38</sup>. In addition, participants were instructed to continue their psoriasis treatment regimes in addition to the trial oils. A number of placebo participants increased the amount of high potency corticosteroids and methotrexate (an antimetabolite) medication they were using, which may also explain the improvement in their condition. These treatments have been proven to be effective in improving the symptoms of psoriasis<sup>14,15</sup>.

### *Medications*

The analysis of psoriasis medications external to the trial concentrated on the most popular and treatments that pose the greatest risk of side effects<sup>12,14,15,19,20</sup>. The majority of participants were using high to moderate potency corticosteroids and a vitamin D derivative anti-psoriatic cream.

Table 3 and figure 5 show that overall, emu oil participants decreased their requirement for high and moderate potency corticosteroids and anti-psoriatic medication, while the majority of placebo participants used the same amount, clearly indicating that the emu oil exerted an ameliorating effect on the participant’s psoriasis. This result is extremely positive, as out of the 33 participants using additional psoriasis medication, 64% were using more than one treatment, some up to five different therapies at a time. Multiple treatments regimes become costly, time consuming and impose a cumulative risk of side effects<sup>13</sup>. Thus while emu oil is not a cure for psoriasis, the results of this trial suggest that using emu oil decreases the requirement for these therapies, which would make treating psoriasis safer, cheaper and more efficient.

There was a strong positive correlation between the SAPSI and medication usage for the emu oil groups, implying that as severity improved, less additional medication was required. An unexpected result was the moderate positive correlation between SAPSI and medication usage for

the placebo groups. This may be attributable to a large number of placebo participants reporting improvement in their condition.

Unfortunately, over 1/3 of all participants did not complete the trial. The reasons cited for withdrawing from the study were one case of illness unrelated to the trial, and one participant reported a mild reaction to the placebo. It is possible that despite the measures taken to encourage participants to continue with the trial, such as provision of one year's supply of emu oil for all participants who completed the trial, and regular reminder phone calls to encourage continued participation, the researchers suspect that many participants who dropped out of the trial were simply unwilling to commit for the full 12 weeks. The fact that the rate of improvement in severity scores of emu oil groups tended to decrease after week 6, while placebo groups' scores fluctuated throughout the trial could lend credence to this hypothesis. A larger number of placebo participants withdrew from the trial indicating that an insufficient rate of improvement may have led to their decision to drop out.

As a result of the high drop out rate, there were insufficient pre- and post-intervention lesion surface area photographs to allow for comparison between the emu oil and placebo. Photographs were taken in a sample of the participants, as an extensive photographic record was beyond the financial scope of the trial, however the researchers believe that future investigation into the effects of emu oil on psoriasis should include such photographs to visually illustrate any improvement in lesion scaliness, redness and surface area in all participants. The reason for this is that the outcome measures used in the trial did not always agree, and hence a further measure could provide a clearer view of the results.

The body map of the SAPSI was also omitted from the statistical analysis as it was incorrectly or not completed by nearly half of participants. This poor compliance may have been due to participants not having ongoing instruction from the researchers, instead only receiving an average of 2 reminder phone calls throughout the trial, as previous studies have not encountered this problem<sup>9,28</sup>.

Further investigation into the efficacy of emu oil in the treatment of psoriasis may employ outcome measures that are completed by a dermatologist or other health care professional to better display small increments of change over the course of the intervention. While self assessment of disease activity is considered valid<sup>35</sup>, the physician completed PASI is considered the most validated measure of psoriasis severity<sup>27</sup>. Also, having a dermatologist complete the outcome measures would reduce the amount of missing data, and eliminate the need for weekly and fortnightly phone calls to participants. It was more difficult than expected to contact all participants regularly and as such, participants were contacted on average twice throughout the trial. The initial aim of the calls was to maintain compliance and ensure accurate and full completion of the outcome measures. The phone calls proved unsuccessful in this endeavour as there was a large amount of missing or incomplete data.

In conclusion, the results of this trial suggest that emu oil reduces the severity of psoriasis symptoms of redness, thickness and scaliness; and enables psoriasis sufferers to decrease the amount and frequency of corticosteroid treatment.

### **Acknowledgements**

Thank you to Emu Spirit™ for supplying the oils used in the trial and the photographer, for allocating participants to groups, for paying the cost of the advertising and assisting with administrative tasks such as answering phones and sending out information to participants.

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**Appendix 1**

Food Laboratories (Aust.) Pty Ltd

Sample:

**Emu Oil**

Batch No: ES031203

Tested On: 18/12/03

Report No: 283690

Moisture	0.1 %
Acid Value	0.5
Peroxide value	1.7 meq O <sub>2</sub> /kg
Refractive Index	1.4635
Weight per mL	0.910 g/mL
Saponification Value	195.6
Ester Value	195.1
Totox Value	9.1
Iodine Value	64.1

Fatty Acid Profile:

C12:0	0.1 %
C14:0	0.4 %
C16:0	24.0 %
C16:1	4.4 %
C18:0	10.3 %
C18:1	51.0 %
C18:2	9.2 %
C18:3	less than 0.1 %
C20:0	0.2 %
C20:1	0.4 %

Microbiological Analysis:

standard plate count per mL (72h at 30°C)	less than 10
standard plate count per mL (5 days at 20°C)	less than 10

Testing performed by chemist G.M. Brown, B.App.Sc. M.R.A.C.I.

**Appendix 2**

Therapeutic Goods Administration listing for Emu Oil

Emu Spirit – Omega 369 Oil of Emu Capsules

ELF ID: 33057-23/08/2002-OE728-1

Item [27] Listing of Coded Indications

	Code	Description
	PSOR1	Relief of the effects of psoriasis on the skin. [Warning S required] *

\* Warning S: If symptoms persist, seek medical advice

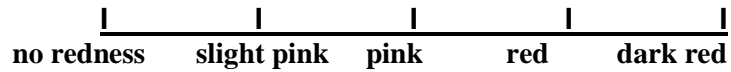
Emu Spirit Oil of Emu: Aust L 92158

**Appendix 3<sup>27</sup>**

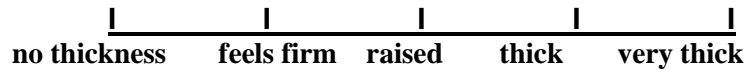
**Self Administered Psoriasis And Severity Index**

Below are three visual analogue scales, one each for the colour, thickness and scaliness of your psoriasis. Place a cross (X) on the line at the point that best describes each aspect of your psoriasis *for the past week*.

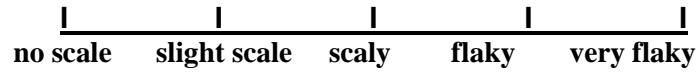
**1. Colour**



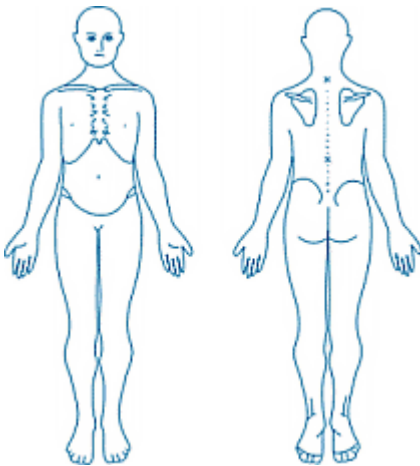
**2. Thickness**



**3. Scaliness**



Please shade in the areas that have been affected by psoriasis *over the past week*.



**Appendix 4:**

**DERMATOLOGY LIFE QUALITY INDEX** <sup>36</sup>

**DLQI**

Name:

Date:

Score:

**The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST MONTH. Please tick one box for each question.**

1.	Over the last week, how <b>itchy, sore, painful</b> or <b>stinging</b> has your skin been?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
2.	Over the last week, how <b>embarrassed</b> or <b>self conscious</b> have you been because of your skin?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
3.	Over the last week, how much has your skin interfered with you going <b>shopping</b> or looking after your <b>home</b> or <b>garden</b> ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
4.	Over the last week, how much has your skin influenced the <b>clothes</b> you wear?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
5.	Over the last week, how much has your skin affected any <b>social</b> or <b>leisure</b> activities?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
6.	Over the last week, how much has your skin made it difficult for you to do any <b>sport</b> ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
7.	Over the last week, has your skin prevented you from <b>working</b> or <b>studying</b> ?	Yes No	<input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
	If "No", over the last week how much has your skin been a problem at <b>work</b> or <b>studying</b> ?	A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	
8.	Over the last week, how much has your skin created problems with your <b>partner</b> or any of your <b>close friends</b> or <b>relatives</b> ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
9.	Over the last week, how much has your skin caused any <b>sexual difficulties</b> ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>
10.	Over the last week, how much of a problem has the <b>treatment</b> for your skin been, for example by making your home messy, or by taking up time?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Not relevant <input type="checkbox"/>

**Appendix 5****Psoriasis Medication Usage Diary**

	Medications	Dosage	Frequency
Example:	Coal tar	Topical application	2x day
Week 1			
Week 2			
Week 3			
Week 4			
Week 5			
Week 6			
Week 7			
Week 8			
Week 9			
Week 10			
Week 11			
Week 12/Conclusion			

**Appendix 6: Information to Participants**



*The Effects Of Emu Oil On Psoriasis*

If you:

- are between 18 and 80 years of age,
- have been diagnosed with psoriasis vulgaris, by a doctor
- do not suffer from psoriatic arthritis and
- have not used emu oil previously,

You are invited to participate in this research project. You are free to continue with any psoriasis treatment you are currently using, throughout the trial.

**Aim of project:**

To determine whether emu oil, when applied to the skin, orally or in combination, will:

- Decrease the severity of psoriasis
- Improve health-related quality of life
- Produce a corresponding decrease in medication usage.

As a supplement to the trial, photographs will be taken of volunteers to show visual evidence of reduction in surface area of a psoriatic plaque. This aspect of the trial is not compulsory.

**Method:**

The participants will be volunteers, aged between 18 and 80 years of age, who have been previously diagnosed with psoriasis vulgaris by a medical practitioner or dermatologist. Participants with other forms of psoriasis, psoriatic arthritis or previous use of emu oil will be excluded. All participants will undertake a skin test for allergic reaction to emu oil and the control oil, prior to inclusion in the trial.

Once selected for the trial, the participants will be randomly allocated to one of six groups:

1. Emu oil applied topically,
2. Vegetable oil applied topically,
3. Emu oil taken orally,
4. Vegetable oil taken orally,
5. Emu oil applied topically and taken orally,
6. Vegetable oil applied topically and taken orally.

The Principal Investigator will explain the trial in full, with details on how to apply or ingest the oil and complete the Self-Administered Psoriasis Area and Severity Index, (SAPSI), the Dermatology Life Quality Index, (DLQI) and the medication log books at the initial meeting.

The trial will proceed for twelve weeks and will measure:

- The **severity** of psoriasis, self-assessed by a simple questionnaire called the Self-Administered Psoriasis Severity Index (SAPSI), and on the same day every week for the duration of the trial.
- The extent to which psoriasis affects your **quality of life**, measured using a second short questionnaire called the Dermatology Life Quality Index (DLQI), prior to commencement of the trial and then on the same day fortnightly throughout the trial.
- Any variation in psoriasis medication use, gauged by completing a table of medication usage on the same day every week, detailing use of both existing medication and designated trial oil.
- Changes in the size of a single area of psoriasis which has been selected by volunteers for photography. Photographs will be taken of the same area of skin at the beginning and end of the trial. This aspect of the trial is not compulsory.

If at the completion of the trial the outcome is positive for the emu oil it will be offered, free of charge, to all participants who have not had the opportunity to use it.

Participation in this study is voluntary. Participants are free to withdraw at any time, without needing to provide a reason, and without fear of prejudice.

Any queries about your participation in this project may be directed to the researchers Dr Jim Kiatos (Principal Investigator), (MB.BS) (tel. 9919 1191) jim.kiatos@vu.edu.au. If you have any queries or complaints about the way you have been treated, you may contact the Secretary, University Human Research Ethics Committee, Victoria University Of Technology, PO Box 14428MC, Melbourne, 8001 (Telephone no: 03 9919-4710).



**Appendix 8: Sponsorship Agreement**



I, \_\_\_\_\_  
of \_\_\_\_\_

agree to provide sponsorship for the clinical trial entitled:

***The Effects Of Emu Oil On Psoriasis***

being conducted at Victoria University of Technology by:

**Jim Kiatos M.B.B.S., Dip. App. Sci.(Naturopathy)  
Student Investigator**

I agree to pay the full cost of: -

1. Advertising space in National Psoriasis Foundation Magazine
2. Expenses associated with employing a Call Centre to receive phone calls immediately after television exposure and to make weekly phone calls for the first month then fortnightly calls to all participants for the twelve weeks;
  - to inform participants of the initial meeting times and places.
  - to remind participants to complete the Self Administered Psoriasis Area and severity Index, the Dermatology Life Quality Index and their medication log books.
  - to monitor progress of participants and remind them to call the Principal Investigator if requiring assistance.
  - to remind participants of the concluding meeting.
3. Emu oil and vegetable oil used in the trial and emu oil gifted to the control participants after the trial.

I agree that this sponsorship will not be used to influence the methods or results of this trial in any way. I agree not to suppress publication regardless of the outcome of the study.

**RAW DATA**

I have been provided a copy of the Human Research Ethics requirements of Victoria University and the National Health and Medical Research Council (NHMRC), and agree to abide by the conditions set out in the guidelines. I am aware that I will not be able to access any raw data but that I will have access to de-identified tabulated data only. I am aware that in order to obtain raw data I will have to apply formally to Victoria University upon conclusion of the study.

Signed: \_\_\_\_\_ Witness: \_\_\_\_\_

Print name \_\_\_\_\_ Date \_\_\_\_\_

Position \_\_\_\_\_

## **Appendix 9: Instructions to Authors**

### **Evidenced-based Complimentary and Alternative Medicine**

#### **Original Articles**

Original articles should include new findings in the areas covered by the Journal. Methods and data used should be clarified, and evidence must be critically evaluated. An original article should not much exceed 5000 words, and should include an Abstract, Introduction, Materials and Methods, Results, Discussion and References, in that order.

#### **Article Format**

Manuscripts should be written in clear and concise, grammatical English. A contributor whose native language is not English is recommended to have the manuscript checked by a native speaker of English. The Editor-in-Chief and Managing Editor will not assume the responsibility of making extensive revisions so that manuscripts are clear for referees.

All documents should be double-spaced. A clear, legible single font (Times/Times New Roman, Helvetica/Arial preferred) and point size of 11 should be used throughout. All submitted manuscripts should be page numbered.

In original articles and reviews, authors should submit three to five keywords that do not occur in the title of the article. Very general terms like 'bacteria' and terms already present in the title should be avoided, as should nonstandard abbreviations.

#### **Title Page**

The title page should carry:

1. the title of the article
2. authors' names with institutional affiliations
3. corresponding author's name with phone and fax numbers and E-mail address
4. a running head of no more than 50 characters including spaces.

#### **Abstract**

The second page should carry an abstract of no more than 250 words. The abstract of an original article should be structured into four paragraphs. Do not use headings for these paragraphs.

#### **Tables**

Number tables consecutively in the order of their first citation in the text and supply a brief title for each. Place explanatory matters in footnotes, not in the heading. Explain in footnotes all nonstandard abbreviations that are used in each table.

#### **Figures**

Figures should be professionally drawn and photographed. Letters, numbers and symbols should be clear, consistent throughout, and large enough that when reduced for publication each item will still be legible. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, identify and explain each one clearly in the legend.

Colour photographs will principally be published with the full cost borne by the authors.

Manuscripts submitted with colour photographs will be reviewed on the assumption that the authors will cover the publication cost if accepted. The reproduction of colour figures will be charged at £350/\$665.

### **Supplementary Data**

Files containing supplementary data (for example large tables or a questionnaire) will be linked with the article published online as an extra resource for readers. Please contact the Editorial Office for further details.

### **Abbreviations and Nomenclature**

Nonstandard nomenclature and abbreviations should be defined at the first occurrence. Introduce abbreviations only where multiple use is made.

### **Statistics**

The methods of statistical analysis should be described in sufficient detail. The word "significant" should be used only if a result is statistically significant and where exact P values are given. In clinical articles, outcome variables should be given as point estimates, with 95% confidence intervals rather than standard deviations or standard errors.

### **References**

Number references consecutively in the order in which they are first mentioned in the text. The titles of journals should be abbreviated according to the style used in Index Medicus.

List all authors, but if the number exceeds six, give names of six followed by "et al." When citation of articles written in languages other than English is unavoidable, enter the language in parenthesis at the end of the reference.

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**Professor Edwin L. Cooper**

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