

**Victoria University of Technology
Human Research Ethics Committee**

**Application for Approval of Project Involving Human
Subjects in Victoria University of Technology**

Introduction:

This form is available in electronic format (either via the Office for Research home page at address <http://research.vu.edu.au> or your disk). Contact ph. 9688-4710 for further details.

Notes to assist in completing the application are appended to the form.

This application form is included in the Human Research Register. If your project includes any information of a commercial or patentable nature, this information should be sent separately and marked confidential.

If an institution other than Victoria University of Technology is to be involved in the project, please provide with this application, evidence of ethics approval from the other institution.

If insufficient space is available on the form for your answer, please attach an additional page/s.

Applications to be typewritten and all questions answered.

To: Secretary, Human Research Ethics Committee
Office for Research
Victoria University of Technology,
PO Box 14428, MCMC Melbourne 8001

[The Office is located at 6 Geelong Road Footscray]

I attach a proposal for a project involving human subjects for the purposes specified on the attached sheets.

Data collection for this project is planned to commence upon receipt of ethics approval and to conclude on 01 / 06 / 2007.

Note: The Human Research Ethics Committee normally grants approval for periods of up to two years, subject to annual review. Consideration will be given to granting approval for a longer period in certain circumstances. Applications for extension of approval should be lodged prior to expiry of existing approval.

PROJECT TITLE:

The Effects Of Emu Oil On Psoriasis

PRINCIPAL INVESTIGATOR/S:

(Projects to be undertaken by students should list the Supervisor as the Principal Investigator)

Dr. Jim Kiatos M.B.B.S., Dip. App. Sci. (Naturopathy)

DEPARTMENT/S: AND CAMPUS

Health Sciences (Osteopathy): City Flinders campus

Office Use Only

Received by Secretary, University Human Research Ethics Committee - Date:

REGISTER NUMBER: HRETH

Period of approval:

Comments:

If project provisionally approved by the Executive, acting on behalf of the Human Research Ethics Committee:

The Secretary has noted that provisional approval has been extended by the Executive:

Date: Secretary:

Endorsed by the Human Research Ethics Committee,
Meeting No. / , held on

Principal Investigator notified: / /

Intrusiveness of Project:

- | | | | |
|---|-----|---|------|
| 1. Uses physically intrusive techniques | Yes | X | No |
| 2. Causes discomfort in participants beyond normal levels of inconvenience | Yes | | No X |
| 3. Examines potentially sensitive or contentious areas | Yes | | No X |
| 4. Uses therapeutic techniques | Yes | X | No |
| 5. Seeks disclosure of information which may be prejudicial to participants | Yes | | No X |

1. Title of Project

The Effects Of Emu Oil On Psoriasis

2. Principal Investigator/s:

(Projects to be undertaken by students should list the Supervisor as the Principal Investigator)

Dr. Jim Kiatos M.B.B.S., Dip. App. Sci. (Naturopathy)

3. Department/s:

Health Sciences (Osteopathy)

4 (a) Associate Investigator/s and/or Co-Investigator/s:

Dr. Ray Power, B.Sc. (Clin. Sc.), M.H.Sc. (Osteopathy)

(b) Student/s:

Rebecca Hay B.Sc. (Clin. Sc.)

5. Type of Project:

(please answer Yes or No to the following questions)

- (a) *Is application for a higher degree program?* Yes
- (b) *Is application for a pilot program of a higher degree?* No
[If yes, please note that a second application will be required for the full program]
- (c) *Is application for an honours program of an undergraduate degree?* No
If yes, please indicate semester dates: _____
- (d) *Is application for a funded research program?* No
If yes, please indicate source of funding: _____

Do you require ethical approval prior to funding being granted? No

If yes, attach any necessary form to be completed by the Ethics Committee and indicate grant closing date.

Date: _____

6. Aim of project:

To determine whether emu oil applied topically, orally and in combination, has any effect on:

- psoriasis severity
- health-related quality of life
- photographic appearance of the area of skin affected by the psoriasis

7. Plain language statement of project:

(It is recognised that in some areas of research, it may be appropriate that this statement is repeated elsewhere in this application form, and that it may comprise part of your response to questions 6, 8, 15, 16 and 17.) This section is to be stated in simple language and any terms or jargon must be accompanied by explanation.

There is much anecdotal evidence supporting the use of emu oil in the treatment of psoriasis, however to date there has been no scientific research to substantiate these claims. Psoriasis is a common, chronic, inflammatory skin condition. It is incurable and the disfiguring nature of the disease can significantly affect a person's quality of life. People with psoriasis have expressed their dissatisfaction with current treatments due to their numerous side effects (Krueger et al., 2001; Menter et al., 2004).

Emu oil has been shown to have anti-inflammatory properties (Snowden, O'Malley & Ellis, 1999) as well as skin moisturizing and wound healing properties (Zemtsov, Gaddis & Montalvo-Lugo, 1994), which may be beneficial in treating psoriasis.

This trial will follow the same design and uses the same product as a research project entitled: "The effect of emu oil on osteoarthritic hands", conducted at Victoria University over 2003/4. The Faculty Human Research Ethics Committee granted approval of this study, HRETH.FHD.070/03.

This trial will include a group of participants using emu oil, and a second group who will be using a placebo, vegetable oil. The aim of the trial is to determine whether emu oil when applied topically, orally or a combination of topical and oral administration has any effects on:

- the severity of psoriasis
- health-related quality of life
- photographic appearance of the area of skin affected by the psoriasis

The trial will involve approximately 120 volunteers, aged between 18 and 80 years of age, who have been diagnosed by a medical practitioner or dermatologist with psoriasis vulgaris. At the commencement of the trial, all participants will be screened by the student investigator to ensure they have visually evident psoriasis. Participants will be excluded from the trial if they have other forms of psoriasis, psoriatic arthritis, or have used emu oil previously. Emu oil has a characteristic consistency when stored, thus if participants have used emu oil previously, they may recognise this trait and hence identify the oil. As emu oil is an animal product, vegetarian participants will also be excluded.

All eligible participants will be advised to continue their usual treatment regime and will be required to sign a Participant Informed Consent Form prior to commencement of the trial (Appendix 6).

Initially, all participants will undertake a skin test for allergic reaction to either oil. Both oils will be applied to separate areas of skin not affected by psoriasis such as the front of the forearm, and monitored for 2-3 hours.

Participants will be randomly allocated to one of the following six treatment groups by Emu Spirit™: (1) emu oil applied topically, (2) control oil applied topically, (3) emu oil taken orally, (4) control oil taken orally, (5) emu oil applied topically and taken orally, or (6) control oil applied topically and taken orally. The control oil to be used in this study is vegetable oil.

The trial will proceed for 12 weeks, during which the following information will be collected: Severity of psoriasis, determined by the 'Self-Administered Psoriasis Severity Index' questionnaire (SAPSI), which participants will be asked to complete at the initial meeting, prior to commencement and on the same day every week for the duration of the trial.

Quality of life will be assessed by participants completing the 'Dermatology Life Quality Index' (DLQI), prior to commencement and on the same day monthly throughout the trial.

Participants will be asked to complete a table detailing dosage of both existing psoriasis medication and their designated trial oil weekly, to ascertain any variation in psoriasis medication usage throughout the trial.

18 volunteers will additionally have their lesion surface area assessed via photography of a selected lesion. Photographs will be taken prior to the commencement of the oil treatment and again at the completion of the trial.

Throughout the trial, participants will receive phone calls from research assistants. The calls will conform to a prescribed script and serve to maintain interest and compliance (Appendix 9). For the first month, the phone calls will be weekly, and thereafter, fortnightly.

8. (a) Nature of research, including methodology and a list of all procedures to be used on human subjects. Please include a statistical power analysis statement if applicable.

Method

A double blinded, randomized, placebo controlled study with a six group repeated measures design, comparing the effects of emu oil against a placebo, (vegetable oil). The method to be used in this trial has previously received ethics approval at Victoria University by the Faculty of Human Development, Faculty Human Research Ethics Committee 2003, for the trial entitled: The effect of emu oil on osteoarthritic hands (HRETH.FDH.070/03).

Participants

The participants will be approximately 120 volunteers, aged between 18 and 80 years of age. All participants must have previously been diagnosed with psoriasis vulgaris by a medical practitioner or dermatologist. Also, all participants will be screened by the student investigator to ensure they have visual evidence of active psoriasis at the time of recruitment. Participants will be excluded from the trial if they have other forms of psoriasis, psoriatic arthritis or have used emu oil previously. Emu oil has a characteristic consistency when stored, thus if participants have used emu oil previously, they

may recognise this trait and hence identify the oil. As emu oil is an animal product, vegetarians will also be excluded.

The participants will be advised to continue using their current treatment regimes throughout the trial, as needed. All participants will also be advised that they are free to withdraw from the study at any time, without needing to provide reason and without prejudice.

Trial

Once potential participants have expressed interest in participating in the study, they will be mailed an Information to Participants form (Appendix 5) and a Participant Informed Consent Form (Appendix 6) to complete and return to the university prior to the initial trial meeting.

Meetings will be held at the commencement and conclusion of the trial at one of five locations spread throughout the Melbourne metropolitan area, to encourage both participation and compliance. Specific venues will be selected in the following areas: Dandenong, Ringwood, Essendon, Werribee and the Melbourne Central Business District (Flinders Lane).

At the initial meeting, prior to commencement of the trial, all participants will be tested for allergic reaction both orally and topically to both the emu oil and the control oil. The control oil to be used in this study is vegetable oil. All participants will be asked if they have an allergy to any common vegetable oils. Participants with known allergies to these oils will be excluded. Each participant will rub a small amount of the oils on the inside surface of their cheek, as well as apply 5ml to separate areas of skin not affected by psoriasis, such as the inner forearm and monitored for a period of 2-3 hours. If a reaction occurs, the participant will be excluded from the trial.

Eligible participants will be randomly allocated a number at the initial meeting by Emu Spirit™ (not involved in the analysis of trial data). This number will then be randomly placed into one of the following six treatment groups:

- (1) topically applied emu oil;
- (2) ingested emu oil;
- (3) both topically applied and ingested emu oil;
- (4) topically applied control oil;
- (5) ingested control oil;
- (6) both topically applied and ingested control oil.

Both the emu oil and the control oil will be supplied in identical, numbered containers. Emu Spirit™ will distribute the oils to participants and record the container numbers with the participant number. The matched numbers of participants and oils will not be available to the principal supervisor and student investigator until completion of the trial.

The trial details and all procedures including administration of the oils and completion of the outcome measures will be explained in detail by the Student Investigator. Participants in the topical administration groups may apply the oil morning and evening, while participants in the oral administration groups will be asked to ingest 5ml of the oil each morning, in a variety of methods. For example, as a substitute for another fat such as butter or margarine, stirred into dairy products, with fruit/vegetable juice, etc.

All participants will receive their allocated container of oil, 12 Self-Administered Psoriasis Area and Severity Indexes, 6 Dermatology Life Quality Indexes, and the medication tables to take home (Appendices 9,10,11).

Also at the initial meeting, 18 volunteers for the lesion surface area photographs will be randomly selected from the participants who gave their consent for this non-compulsory aspect of the trial (Appendix 6).

The trial will proceed for 12 weeks. Throughout this time, participants will receive phone calls from the research assistants. The calls will conform to a prescribed script designed by the Student Investigator (Appendix 9) that will serve to maintain interest and compliance by reminding participants to complete outcome measures and medication tables, as well as giving participants the opportunity to express any concerns or queries they have regarding the trial. For the first month, the phone calls will be weekly, and thereafter, fortnightly.

At the completion of the trial, all participants will be presented with a complimentary 200ml container of emu oil.

Outcome measures

Throughout the trial, the following information will be collected:

- Severity – Psoriasis severity will be measured by the Self-Administered Psoriasis Severity Index (SAPSI) prior to commencement of the trial and on the same day every week for the duration of the trial (Appendix 10)
- Quality of life – Participants will be asked to complete the Dermatology Life Quality Index (DLQI) prior to commencement and on the same day monthly throughout the trial. (Appendix 11)
- Variation in amount and frequency of psoriasis medication will also be assessed by participants completing a table on the same day every week, detailing use of both existing medication and their designated trial oil (Appendix 12). All participants will be advised to continue their current psoriasis treatment regime throughout the trial.
- Photographic evidence will be obtained from 18 volunteers who have given specific consent for this non-compulsory aspect of the trial (Appendix 6). Each of these volunteers will select one lesion to be photographed at this time and again at the end of the trial by research assistants provided by Emu Spirit™. Photographic variables such as distance and lighting will be controlled as much as possible, by replicating the participant's position, light conditions, using the same photographer, film type etc.

Data Analysis

The means and standard deviation of the resultant data will be calculated and tabulated. The data will be analysed by a repeated measures analysis of covariance (ANCOVA) for both the severity and quality of life outcome measures, using SPSS version 11.0. The severity analyses will be 3 x12 ANCOVAs, as there are 3 subscales in the severity measure. Analyses of quality of life will be 10 x6

ANCOVAs, as there are 10 subscales. The covariate to be used will be the baseline data for each outcome measure. A pre-post ANCOVA will also be conducted.

A timeplot of each group will be incorporated to illustrate any trends in the data over time.

Power Analysis

The effect size expected in this study is assumed from a trial assessing the effect of emu oil on osteoarthritis in humans, conducted at Victoria University in 2003 and 2004.

Effect Size: $R^2 = 0.13$, $f = 0.4$

This is a large effect. With a large effect size expected, groups will need to include 20 participants to maintain power at approximately 80%.

8. (b) Description of those techniques which are considered by the profession to be established and accepted. Please give details of support for their application:

(If, in the course of your research, procedures are significantly varied from those stated here, the Human Research Ethics Committee must be informed.)

- Self-Administered Psoriasis Severity Index (SAPSI). Self –assessment of the severity of psoriasis, by the surface area affected and degree of psoriatic symptoms including colour, induration and scaliness. The SAPSI is a modified version of the psoriasis area and severity index (PASI). While the PASI is regarded as the most validated measure of psoriasis severity, it requires a trained dermatologist to administer. The SAPSI correlates highly with the PASI and has shown similar responsiveness to changes in severity over time with treatment when contrasted with the PASI. Thus, it is recognised as a reliable measure of disease severity (Fleischer et al., 1996; Feldman et al., 1996; Sampogna, Sera & Abeni, 2004).
- Dermatology Life Quality Index (DLQI). This measure incorporates patient’s assessment of symptomatology, self-consciousness, treatment problems, and interference of their skin condition with activities of daily living, relationships and sexual function. The psychometric properties of the DLQI have been well established, and it has been cited in more 130 articles (Finlay, 2004; Shikier et al., 2003; Badia, Mascaro & Lozano, 1999).

9. Date of commencement of project:

Upon receipt of ethics approval.

10. Expected duration of project:

2 years

11. Number, type and age range of subjects:

Approximately 120 male or female adults, aged 18-80, with psoriasis vulgaris previously diagnosed by a medical practitioner (e.g. general practitioner, or dermatologist).

12. Source of subjects, and means by which subjects are to be recruited:

The participants will be sourced from the general population. Extensive advertising will be undertaken as follows -

- Posters will be placed around the university Osteopathic Medicine Clinic (Appendix 1)
- National Psoriasis Foundation Magazine (Appendix 2)

A 1/6th page advertisement requesting volunteers to participate in the trial. The advertisement will include:

- the Victoria University logo,
 - the title of the trial,
 - the principal investigator and student investigator names,
 - approximate date for the trial and its duration,
 - criteria for participation (psoriasis vulgaris diagnosed by medical practitioner, no psoriatic arthritis, no previous emu oil use)
 - summary of the trial,
 - contact details for the expression of interest in participation
- Newspaper Advertising (Herald Sun/The Age) (Appendix 2)

The information presented will include:

- the Victoria University logo,
- the title of the trial,
- the principal investigator and student investigator's names,
- approximate date for the trial and its duration,
- criteria for participation (psoriasis vulgaris diagnosed by medical practitioner, no psoriatic arthritis, no previous emu oil use)
- summary of the trial,
- contact details for the expression of interest in participation

- 3AW am Radio (To be confirmed)

The station will advertise the trial, including:

- the purpose of the research i.e. the trial is being undertaken as a Masters Project for Victoria University,
- the title of the trial,
- the principal investigator and student investigator names,
- approximate date for the trial and its duration,

- criteria for participation (psoriasis vulgaris diagnosed by a medical practitioner, no psoriatic arthritis, no previous emu oil use)
- summary of the trial,
- contact details for the expression of interest in participation

13. Is there any payment of subjects proposed: **Yes** **No**

X

If yes, how much?

Any further comments: At the completion of the trial, all participants will be presented with a complimentary 200ml container of emu oil.

14. Premises on which project is to be conducted:

If using an institution/s other than Victoria University of Technology, attach a copy of documents giving approval to use subjects or premises in the relevant institution/s.

The initial and concluding meetings will be held on the following premises:

1. Victoria University, City Flinders Campus
2. Dandenong
3. Ringwood
4. Essendon
5. Werribee

The exact premises of locations 2-5 is yet to be finalised.

Participants may attend the meetings at the location which is most convenient, however participants will be asked to attend the same location for both the initial and concluding meetings.

Treatment oils will be self-administered at the participant's home.

The Self-Administered Psoriasis Area and Severity Index, Dermatology Life Quality Index and medication table will be completed by participants at their homes.

Photographic evidence will be obtained at the initial and concluding meetings at the premises listed above.

15. Dealing with potential risks:

(a) *Indicate any **physical risks** connected with the proposed procedures*

- i. Allergic Reaction: There is a minor risk of allergic reaction to the oils used in this study. There are no published risks associated with ingesting or massaging 5mls of emu oil twice per day.
- ii. Toxicity: Emu Spirit™ Oil of Emu has Therapeutic Goods Administration (TGA) listing as a non-toxic substance for topical application and ingestion for the relief of the effects of psoriasis. (Appendix 8).

Aust L 92158

iii. Psoriasis might get worse rather than better. exacerbation

(b) *Indicate any **psychological risks** connected with the proposed procedures*

- i. Some participants may feel uncomfortable exposing sensitive areas that are affected by psoriasis.
- ii. Having photographs taken of lesions may cause distress for some participants.

(c) *Indicate any **social risks** connected with the proposed procedures*

None identified

(d) *Indicate any **legal risks** connected with the proposed procedures*

None identified

(e) *Indicate if there are any **other risks** connected with the proposed procedures*

None identified

(f) *Management of potential risks - indicate how each of these potential risks will be minimised and/or managed if they occur.*

(i) how risks are to be minimised:

Physical risks:

All participants will undergo an oral and a skin test for allergic reaction at the initial meeting. The possible symptoms of such an allergic response to the oils will be explained to all participants, such as redness, heat, swelling and itchiness of the area the oil was applied to. Participants who get worse over the course of the trial will be able to stop using the oil and withdraw from the study without prejudice.

Psychological risks:

- i. The Information to Participants form (Appendix 5) will make it clear to participants that the researchers will need to visually inspect the areas of the body that are to be included in the study. Participants will thus have the opportunity not to participate in the trial if they are uncomfortable with exposing a particular part of their body.
- ii. Photographic evidence will only be obtained from a sample of volunteers who have given their consent. The Participant Informed Consent form will clearly indicate that this aspect of the trial is not compulsory, and thus participants may select not to have a lesion photographed (Appendix 6). If they initially choose to be a part of the photography group, participants will be able to withdraw at any time. As participants will be able to select the lesion to be photographed, they will have a second opportunity to avoid photography of lesions they wish to avoid being photographed.

(ii) how adverse events would be managed if they were to occur:

Physical risks:

Participants who display any adverse reactions to the skin or oral allergy test or throughout the trial will be immediately withdrawn from the trial and instructed to seek medical attention if required. In the rare and unlikely event of an anaphylactic reaction, first aid will be administered and an ambulance will be called for immediate transfer to the nearest hospital.

Psychological risks:

If an adverse psychological event occurs as a result of this study, the participant will be referred to Associate Professor Mark Andersen, a psychologist, who has kindly agreed to make himself available in the event that participants become distressed. Participants can contact Associate Professor Mark Andersen on (03) 9919 5413.

(g) *If you consider there to be no potential risks, explain fully why no potential risks have been identified.*

16. If you consider the subjects to be ‘at risk’, give your assessment of how the potential benefits to the subjects or contributions to the general body of knowledge would outweigh the risks.

To date there have been no adverse reactions recorded as a result of emu oil use. There is a potential risk that an allergic reaction will occur during this trial, however this risk is minimal. The adverse effects of common psoriasis treatments, such as topical corticosteroid creams, include skin atrophy and systemic side-effects, which may be more severe than the potential for an allergic reaction (van de Kerkhof, 2005; *Topical steroids*, 2004).

Psoriasis affects more than 6% of Australian adults (Cowen, 2001). While there are many available therapies for psoriasis, the results of a National Psoriasis Foundation Survey in 1998, showed that 74% of patients were dissatisfied with their current treatments due to the side effects experienced (Krueger et al., 2001).

There is much anecdotal evidence supporting the benefits of treating psoriasis with emu oil. Further scientific research is required to substantiate these claims. If this trial is successful, emu oil may offer psoriasis sufferers a viable, inexpensive and safe treatment option.

17. Informed Consent:

- (a) See Appendix 5 – Information to Participants
- (b) See Appendix 6 – Consent Form
- (c) **State the process you will use to obtain documentation of informed consent hereunder...**

At the initial meeting of participants in January 2006, to be held at the locations listed under section 14 of this proposal, the trial and all procedures will be explained in full by the Principal

Declaration

I, the undersigned, have read the current NHMRC Statement on Human Experimentation and the relevant Supplementary Notes to this Statement, or Code of Ethics for the Australian Psychological Society, (or *) and accept responsibility for the conduct of the experimental and research procedures detailed above in accordance with the principles contained in the Statement and any other condition laid down by the Human Research Ethics Committee.

Principal Investigator _____
Date

Principal Investigator _____
Date

Associate Investigator** _____
Date

**If the project is to be undertaken by a student,
student's signature:** _____
Date

Co-Investigator _____
Date

Co-Investigator _____
Date

I, the undersigned, understand that the above person/s have read the current NHMRC Statement on Human Experimentation and the relevant Supplementary Notes to this Statement, or Code of Ethics for the Australian Psychological Society, (or *) and that responsibility is accepted by the above person(s) and by this Department for the conduct of the experimental and research procedures detailed above in accordance with the principles contained in the Statement and any other condition laid down by the University Human Research Ethics Committee and fully support the project undertaken within the Department and Faculty.

Head of Department _____
Date

The Faculty Ethics Committee:

- forwards this application directly to the University Human Research Ethics Committee for consideration; or
- has considered this application and forwards it to the University Human Research Ethics Committee for consideration; or
- has approved this application.

Chair of Faculty Ethics Committee

Date

- * If NHMRC Statement or APS Code are not appropriate to your project, please identify your professional code of ethics under which this project would operate.
- ** The Associate Investigator will assume responsibility for the project in the absence of the Principal Investigator

References

- Badia, X., Mascaro, J.M., & Lozano, R. (1999). Measuring health-related quality of life in patients with mild to moderate eczema and psoriasis: clinical validity, reliability and sensitivity to change of the DLQI. *British Journal of Dermatology*, 141, 698-702.
- Cowen, P. (2001). Management of Psoriasis. *Australian Family Physician*, 30(11), 1033-1038.
- Feldman, S.R., Fleischer, A.B.(jr), Reboussin, D.M., Rapp, S.R., Exum, M.L., Clark, A.R. et al. (1996). The self-administered psoriasis area and severity index is valid and reliable. *The Journal of Investigative Dermatology*, 106(1), 183-186.
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- Finlay, A.Y. 2004. Quality of life indices. *Indian Journal of Dermatology Venereology and Leprology*, 70, 143-148.
- Krueger, G., Koo, J., Lebwohl, M., Menter, A., Stern, R.S. & Rolstad, T. 2001. The impact of Psoriasis on quality of life – results of a 1998 National Psoriasis Foundation Patient-Membership Survey. *Archives of Dermatology*, 137(3), 280-284.
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- Sampogna, F., Sera, F., Abeni, D. & the IDI Multipurpose Psoriasis Research on Vital Experiences (IMPROVE) Investigators. 2004. Measures of clinical severity, quality of life and psychological distress in patients with psoriasis: A cluster analysis. *Journal of Investigative Dermatology*, 122, 602-607.

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- Snowden, J.M., O'Malley, P.J. & Ellis, T.M. 1999. Emu oil. Its anti-inflammatory properties. *Rural industries Research and Development Corporation*.
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- Zemstov, A., Gaddis, M. & Montalvo-Lugo, V. 1996. Moisturising and cosmetic properties of emu oil: A double blind study. *Australasian Journal of Dermatology*, 37(3), 159-61.

Appendix 1: Advertisement



Do you have Psoriasis?

Victoria University, with the support of Emu Spirit™, is seeking volunteers with psoriasis to participate in a research project to be conducted for 3 months between January and April 2006.

If you:

- are aged between 18 and 80 years,
- have been diagnosed with psoriasis vulgaris by a medical practitioner,
- do not have psoriatic arthritis and
- have not used emu oil previously,

you are invited to participate in this study investigating **the effects of emu oil on psoriasis severity and health-related quality of life.**

Participants are free to continue their current psoriasis treatment regime throughout the trial.

Participants will be required to attend a meeting at the commencement and conclusion of the trial. There will be five meeting points, located in Dandenong, Ringwood, Essendon, Werribee and the Melbourne Central Business District (Flinders Lane).

For further information please contact

Rebecca Hay on 9919 1191 Or rebecca.hay@students.vu.edu.au

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 or Rebecca Hay (Student Investigator), BSc (Clinical Sciences) (tel. 9919-1111) rebecca.hay@students.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 2: Advertisement for National Psoriasis Foundation Magazine/Newspaper



Do you have Psoriasis?

Victoria University, with the support of Emu Spirit™, is seeking volunteers with psoriasis to participate in a research project to be conducted over 3 months between January and April 2006.

Project Title: The Effects of Emu Oil On Psoriasis

Principle Investigator: Jim Kiatos M.B.B.S., Dip. App. Sci.(Naturopathy), Fellow ANTA

Student Investigator: Rebecca Hay B.Sc. (Clin.Sc.)

If you:

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

you are invited to participate in this study investigating **the effects of emu oil on psoriasis severity and health-related quality of life.**

This trial will include a group of participants using emu oil, and a second group who will be using a placebo oil. Participants are free to continue their current psoriasis treatment regime throughout the trial.

Participants will be required to attend a meeting at the commencement and conclusion of the trial. There will be five meeting points, located in Dandenong, Ringwood, Essendon, Werribee and the Melbourne Central Business District (Flinders Lane).

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Appendix 3: Telephone Enquiry Format



The Effects Of Emu Oil On Psoriasis.

(a) Principal Investigator: Dr Jim Kiatos
Co-Investigator: Rebecca Hay

(b) Telephonist's Name _____

Caller's Details:

Name _____

Address _____

_____ Postcode _____

Telephone _____ Mobile _____

Email address _____

Age _____ (to be eligible must be between 18 and 80 years)

Diagnosed Psoriasis Vulgaris? YES (if YES) Year Diagnosed? _____

NO (if NO - ineligible for study.)

Diagnosed Psoriatic Arthritis? YES (if YES - ineligible for study.)
NO

Have you used emu oil before? YES (if YES - ineligible for study.)

NO

Vegetarian?

NO

YES

Objection to photographs?

NO

YES

Availability for initial meeting. (Tick one or more boxes.)

Afternoon

Monday

Evening

Tuesday

Wednesday

Thursday

Friday

Saturday

Sunday

Any questions regarding the study?

Appendix 4: Cover Letter to Participants



Date:

Dear

Thank you for your interest in the clinical trial “The Effects Of Emu Oil On Psoriasis”.

Please find enclosed:-

- Information to Participants form, which outlines the details of the trial
- Consent Form (please sign and bring to the initial meeting)
- Details of the initial meeting

There will be several initial meeting places and dates. You have elected to attend the meetings to be held at (Suburb). This meeting will be held at the (location) on the (date) at (time). If you are unable to make this meeting, please call 9919-1111 to arrange another meeting point or time.

Please bring along a small carry bag (plastic bag will be fine) to take your oil home in.

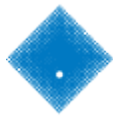
Thank you in anticipation for your support of the trial.

Sincerely,

Rebecca Hay
B.Sc. (Clin. Sc.)
Student Investigator

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 or Rebecca Hay (Student Investigator), BSc (Clinical Sciences) (tel. 9919-1111) rebecca.hay@students.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 5: Information to Participants



**VICTORIA
UNIVERSITY**

**A NEW
SCHOOL OF
THOUGHT**

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 your current psoriasis treatment regime throughout the trial.

Aim of project:

To determine whether emu oil when applied topically, orally or a combination of topical and oral administration has any effects on:

- the severity of psoriasis
- health-related quality of life

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 12 weeks and will measure:

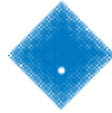
- The **severity** of psoriasis, self-assessed by a simple questionnaire called the Self-Administered Psoriasis Severity Index (SAPSI), and on the same day every week for the duration of the trial.
- The extent to which psoriasis affects your **quality of life**, measured using a second short questionnaire called the Dermatology Life Quality Index (DLQI), prior to commencement of the trial and then on the same day monthly 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 or Rebecca Hay (Student Investigator), BSc (Clinical Sciences) (tel. 9919-1111) rebecca.hay@students.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 6: Participant Informed Consent Form



**VICTORIA
UNIVERSITY**

**A NEW
SCHOOL OF
THOUGHT**

CERTIFICATION BY PARTICIPANT

I, _____
of _____

certify that I am between 18 and 80 years of age and that I am voluntarily giving my consent to participate in the study 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), Fellow ANTA
Rebecca Hay B.Sc. (Clin.Sc.)**

I certify that the objectives of the study, together with any risks and safeguards associated with the procedures listed hereunder to be carried out in the research, have been fully explained to me by **Rebecca Hay** and that I freely consent to participation involving the use on me of these procedures.

Procedures:

- Self application of emu oil on affected areas of skin or ingestion of oil
- Completion of the Self-Administered Psoriasis Severity Index, the Dermatology Life Quality Index and the medication table.

I consent to photography of a selected lesion, once prior to the commencement of the oil treatment and again at the completion of the trial. (please tick)

Yes No

I certify that I have had the opportunity to have any questions answered and that I understand that I can withdraw from this study at any time and that this withdrawal will not jeopardise me in any way.

I have been informed that the information I provide will be kept confidential.

Signed: **Date:**

Witness (other than the researcher):
.....

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 or Rebecca Hay (Student Investigator), BSc (Clinical Sciences) (tel. 9919-?) rebecca.hay@students.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 7: 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), Fellow ANTA
Rebecca Hay B.Sc. (Clin. Sc.)**

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 12 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 8: 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 9: Sample script for courtesy calls throughout the trial.



Project Title: "The Effects Of Emu Oil On Psoriasis"

Principle Investigator – Dr. Jim Kiatos

Student Investigator – Miss Rebecca Hay

Telephonists Name _____

Participants Name _____

Have you remembered to:

- apply the oils? Yes No (if no, on how many days? _____)
- fill in the two questionnaires? Yes No
- fill in the medications table? Yes No

Have you experienced any difficulties:

- apply the oils? Yes No
- fill in the two questionnaires? Yes No
- fill in the medications table? Yes No
- other Yes No

Details: _____

Do you have enough oil for the remainder of the trial?

Yes, have enough No, require more

Are there any other problems or questions you have at this point regarding the trial?

Does this participant require further follow up from the principle or student investigator?

Yes No

Appendix 10: Self Administered Psoriasis Area and Severity Index

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

no redness slight pink pink red dark red

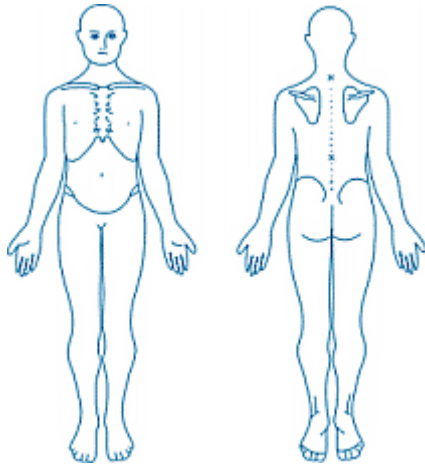
2. Thickness

no thickness feels firm raised thick very thick

3. Scaliness

no scale slight scale scaly flaky very flaky

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



**Appendix 11:
DERMATOLOGY LIFE QUALITY INDEX**

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 itchy, sore, painful or stinging 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 embarrassed or self conscious 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 shopping or looking after your home or garden ? | 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 clothes 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 social or leisure 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"/> |
| 1. | Over the last week, how much has your skin made it difficult for you to do any sport ? | 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"/> |

| | | | | |
|----|---|--|--|---------------------------------------|
| 2. | Over the last week, has your skin prevented you from working or studying ? | 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 work or studying ? | A lot A little Not at all | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | |
| 3. | Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives ? | 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 caused any sexual difficulties ? | 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 of a problem has the treatment 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 12: Psoriasis medication usage table.



The Effects Of Emu Oil On Psoriasis.

Psoriasis Medication Usage Table

| | 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 | | | |