

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

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

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 30/ 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 Eczema Severity and Quality of Life.

PRINCIPAL INVESTIGATOR/S:

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 | <input type="checkbox"/> |
| 2. Causes discomfort in participants beyond normal levels of inconvenience | Yes | <input type="checkbox"/> | No | X |
| 3. Examines potentially sensitive or contentious areas | Yes | <input type="checkbox"/> | No | X |
| 4. Uses therapeutic techniques | Yes | X | No | <input type="checkbox"/> |
| 5. Seeks disclosure of information which may be prejudicial to participants | Yes | <input type="checkbox"/> | No | X |

1. Title of Project

The Effects Of Emu Oil On Eczema Severity And Quality Of Life.

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:

Miss Laura Richardson, 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, when used topically, systemically and in combination, has any effects on:

- eczema severity, measured by the Patient Oriented Eczema Measure.
- health-related quality of life, measured using the Children's Dermatology Life Quality Index.
- photographic appearance of the area of skin affected by the eczema.

7. Plain language statement of project:

There is much anecdotal evidence to support the use of emu oil for people with eczema however to date there has been no scientific research conducted to investigate these claims. Atopic dermatitis (AD), the most common form of eczema, is a common condition in the Australian community, especially among children (Foley, Zuo, Plunkett & Marks, 2001). AD is a chronic inflammatory condition of the skin (Jenner, Campbell & Marks, 2004) and many of the common treatments currently being used have been shown to cause concern in some people due to the possibility of side-effects (Charman, Morris & Williams, 2000). Emu oil has been shown to have a number of effects that may be beneficial in the treatment of eczema including: anti-inflammatory properties (Snowden, O'Malley & Ellis, 1999), skin moisturizing properties (Zemtsov, Gaddis & Montalvo-Lugo, 1994), and may stimulate skin and hair regrowth (clinical study by Michael Holick, MD, PhD, Professor of Medicine, Physiology and Dermatology at Boston University School of Medicine).

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 titled: The effect of emu oil on osteoarthritic hands (HRETH.FDH.070/03).

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

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

The participants for this trial will be volunteers with eczema that have been diagnosed by their general practitioner or dermatologist. Participants will need to have a history of eczema affecting the back of their knees or the front of their elbows. Participants will be aged between 4 and 16 years of age. Parental consent will be gained for all participants and participants over 14 years of age will also be required to sign a consent form. Participants under 14 years of age will have the trial verbally explained to them by the principal investigator in the company of his/her parent/guardian, and verbal consent from the child will be required before the consent form is signed by the child's parent/guardian.

At the commencement of the trial, all participants will need to have visually evident active eczema. All

participants will be advised to continue taking their usual medications as they would normally. Participants will be excluded if they have used emu oil prior to the trial. This is required as emu oil has a characteristic consistency when stored. If participants have previously used emu oil, it may be possible for the participant to identify if they are using emu oil or the control oil. Due to emu oil being an animal product, vegetarian participants will also need to be excluded from the study.

Participants will be randomly allocated to one of six treatment groups by an Emu Spirit© employee. The emu spirit employee will be given a list of the participants and will allocate them into emu oil or placebo groups. Which participant will be in which treatment group will be recorded, placed in a sealed envelope and handed to the researchers. This list will be referred to at the end of data collection. The six treatment groups are: (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 will be vegetable oil.

Topical application of the oil will be limited to morning and evening, however the amount used will vary depending on the total body area affected by eczema. Participants will be shown how to apply a thin layer of oil to the eczema affected areas. Oral administration will be 5ml (teaspoon) of oil once. This mode of ingestion was chosen over the use of capsules due to participant ages. Ingestion of the oil may be easier for younger children and can be disguised in food and drink providing it is not used in cooking: for example it may be used on toast instead of margarine and then covered with the child's chosen spread.

Initially, all participants will need to undergo a skin and oral allergy testing to determine whether potential participants are allergic to the oils used in the study. 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. Both oils will also be applied to separate areas of skin that are not affected by eczema, such as the front of the forearm, and monitored for signs of an adverse reaction. The trial will last for 12 weeks, during which time the following information will be gathered:

Eczema severity will be measured using the patient-oriented eczema measure (POEM). Participants will be asked to complete this questionnaire before commencement of the trial and at the same time every week for the duration of the trial.

Participants will be asked to complete the cartoon version of the Children's Dermatology Life Quality Index (CDLQI), before commencement of the trial and then monthly for the duration of the trial.

The amount and dosage of the participants other eczema medications will also be recorded weekly in a table. All participants will be advised to continue taking their usual medications as they normally would. This section will be used to determine if any effect is due to the trial or due to fluctuations in the participants other medications.

Photographic evidence will be gained from a sample of 18 willing participants at the beginning and completion of the trial. Three participants will be randomly selected from each of the six treatment groups outlined above to make up this group of 18.

Participants will receive a courtesy telephone call each week for the first 4 weeks of the trial, and then every two weeks for the remainder of the trial. These telephone calls will give participants the opportunity to express any concerns and ask any questions they may have regarding the trial. These telephone calls will follow the format shown in Appendix 9.

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-blind, randomized, placebo-controlled study with a six group repeated measures design involving 120 participants. Participants will be allocated a number and these numbers will then be randomly allocated into the 6 groups for the trial. These numbers will not be re-matched until data are being analyzed at the end of the trial.

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 titled: The effect of emu oil on osteoarthritic hands (HRETH.FDH.070/03).

Participants

The participants for this study will be volunteers with eczema that have been diagnosed by their general practitioner or dermatologist. Participants will need to have a history of flexural involvement to help limit participants to those with atopic dermatitis, as these are the predominate sites of involvement (Williams, 2001) Participants will be aged between 4 and 16 years of age. This age group was selected for several reasons; infantile eczema (<4y.o) raises issues of parental bias when using the selected questionnaires as well as proving problematic in distinguishing atopic dermatitis from other forms of eczema, as within this age group, the lesions may not affect the typical sites (Williams, 2001). Adults were excluded from the study due to the much lower incidence of AD in adults, and AD being primarily a childhood condition. Parental consent will be gained for all participants. Participants between 14 and 16 years of age will also be required to give written consent for their participation in this trial. Participants under 14 years of age will have the trial verbally explained to them by the principle investigator in the company of his/her parent/guardian, and verbal consent from the child will be required before the consent form is signed by the child's parent/guardian.

At the commencement of the trial, all participants will need to have visual evidence of active eczema and will be advised to continue taking their usual medications as they normally would. Participants will be excluded if they have used emu oil prior to the trial. This is required as emu oil has a characteristic consistency when stored. If participants have previously used emu oil, it may be possible for the participant to identify if they are using emu oil or the control oil. Due to emu oil being an animal product, vegetarian participants will need to be excluded from the study.

Recruitment

An extensive advertising campaign will be conducted to recruit participants for this trial such as radio advertising on 3AW, newspaper advertisements (refer to section 12) and posters (appendix 1).

Trial

Participants will be randomly allocated to one of six treatment groups by an Emu Spirit© employee. The emu spirit employee will be given a list of the participants and will allocate them into emu oil or placebo groups. Which participant will be in which treatment group will be recorded, placed in a sealed envelope and handed to the researchers. This list will be referred to at the end of data collection. The six treatment groups are:

- (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
- (6) control oil applied topically and taken orally.

Topical application of the oil will be limited to morning and evening, however dosage will vary depending on the total body area affected by eczema. Participants will be shown how to apply a thin layer of oil to the affected areas. Oral administration will be 5ml (teaspoon) of oil once per day. This mode of ingestion was chosen over the use of capsules due to participant ages. Ingestion of the oil may be easier for younger children and can be disguised in food and drink providing it is not used in cooking: for example it may be used on toast instead of margarine and then covered with the child's chosen spread.

Initially, all participants will need to undergo a skin and oral allergy testing to determine whether potential participants are allergic to the oils used in the study. 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. Both oils will also be applied to separate areas of skin that are not affected by eczema, such as the front of the forearm, and monitored for signs of an adverse reaction. An adverse reaction may potentially occur as a result of emu oil use however there are no published reports of this occurring. Participants that display any adverse reactions at this time will be excluded from the study. Adverse effects may include any of the following; a slight reddening or itching of the skin; urticaria characterized by white fluid filled blisters surrounded by areas of redness; contact dermatitis characterised by vesicles and scaling at the site of application (McCance & Huether, 2002). If any of these reactions develop, the participant will be referred back to their general practitioner for treatment, if required. In the rare and unlikely event a participant developed an anaphylactic reaction, characterised by vascular collapse, shock and often severe respiratory distress (Saunders, 2000), upon application of either of the oils used in this study, first aid would be administered immediately and an ambulance would be called to transport the participant to the nearest hospital, as this is a medical emergency.

Participants will be shown how to fill in the questionnaires and how to apply the oil to the skin. They will also be given ideas on ways to ingest the oil if it is to be taken orally. Participants will be asked to use 5ml

of the oil each morning, if it is to be taken orally, and topical application will be limited to morning and evening for the 12 weeks of the study.

Throughout the study, participants will be asked to provide information on the following:

- **Severity** - eczema severity will be measured using the patient-oriented eczema measure (POEM). The POEM was developed and validated in 2004 with the aim of developing a reliable severity measure that did not require a dermatologist to administer. Correlation validity was measured against the Children's Dermatology Life Quality Index, the Gold standard measure for quality of life, and similar language was used from validated measures investigating similar disease processes. The POEM was validated for use by children and the questions were designed to help parents to more accurately fill in the questionnaire if the child was unable to do it alone (especially infants <4y.o), for example: questions relating to pain were excluded as they were too hard for parents to accurately answer (Charman, Venn & Williams, 2004).

Participants will be asked to complete this questionnaire before commencement of the trial and at the same time every week for the duration of the trial.

- **Quality of Life** – Participants will be asked to complete the cartoon version of the Children's Dermatology Life Quality Index (CDLQI). First developed in 1995 as a text only version, it was validated for use in children of school age (4 – 16 years) and has become the gold standard of quality of life measures for children with dermatological conditions. The cartoon version was validated in 2003 and retained the language and phrasing from the initial text version (Holme, Man, Sharpe, Dykes, Lewis-Jones & Finlay, 2003). Participants will be asked to complete the questionnaire before commencement of the trial and then monthly for the duration of the trial.
- The amount and frequency of the dosage of the participant's other eczema medications will also be recorded weekly in the table provided (Appendix 8). If the parent is administering the medication to the child this section may be completed by the parent. All participants will be advised to continue taking their usual medications as they normally would. This section will be used to determine if any effect is due to the trial or due to fluctuations in the participants other medications.
- Photographic evidence will be gained from a sample of 18 willing participants at baseline and at cessation of the trial. Three participants will be selected from each of the six treatment groups outlined above.

Participants and/or parents will receive a courtesy telephone call each week for the first 4 weeks of the trial, and then every two weeks for the remainder of the trial. These telephone calls will give participants and/or parents the opportunity to express any concerns and ask any questions they may have regarding the trial. (Appendix 9).

Data Analysis

Means and standard deviations for the data resulting from this trial will be analysed using repeated measures analysis of covariance (ANCOVA), using SPSS version 11.0.

The severity analysis will consist of seven 6x12 ANCOVA's, as the Patient Oriented Eczema Measure has seven subscales which require analysis.

The quality of life analysis will consist of ten 4x6 ANCOVA's. The cartoon version of the Children's Dermatology Life Quality Index (CDLQI) consists of ten subscales that will require analysis.

The co-variant's to be used will be base-line data from each outcome measure.

A pre-post ANCOVA for both measures will also be conducted, as will a time-plot for both measures.

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.)

- Patient-oriented eczema measure (POEM). Although there are a few patient oriented severity measures in use, none of these measures are considered to be the gold standard. The POEM has been shown to be both reliable and valid for use by both patients and parents (Charman, Venn & Williams, 2004). Please see appendix 11.
- The Cartoon version of the Children's Dermatology Life Quality Index (CDLQI), was validated by Holme et al in 2002; the text version was validated in 1995. Both versions are considered to be equivalent, however the cartoon version is quicker to complete and was preferred by both children and parents (Holme et al, 2002). Please see appendix 12.

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 and female children and young people, between 4 and 16 years of age, with eczema previously diagnosed by a medical practitioner (eg. Dermatologist or general practitioner).

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

Participants will be recruited from the general population living in Melbourne and surrounding suburbs. A variety of advertising modalities, outlined below, will be utilised in the recruiting phase of this trial.

- Radio Advertising - 3AW

This station will run an advertisement for the trial, including:

- Purpose of the research and institution - ie the trial is being undertaken as part of a Masters course at Victoria University.
- The title of the trial – “The effects of emu oil on eczema severity and quality of life.”
- The principal investigator and student investigator’s names.
- Approximate date for the trial and its duration.
- Criteria for participation – diagnosed eczema that has affected the back of knees and front of elbows; participants aged 4 -16 years; no previous history if emu oil use.
- Summary of the trial.

- Newspaper Advertising – Herald Sun/The Age

The information presented will include: -

- Purpose of the research and institution - ie the trial is being undertaken as part of a Masters course at Victoria University.
- The title of the trial – “The effects of emu oil on eczema severity and quality of life.”
- The principal investigator and student investigator’s names.
- Approximate date for the trial and its duration.
- Criteria for participation – diagnosed eczema that has affected the back of knees and front of elbows; participants aged 4 -16 years; no previous history if emu oil use.
- Summary of the trial.

- Poster Advertisement

- Poster advertisements (Appendix 1) will be placed throughout Victoria University campuses.
Prior permission to display posters will be sought from the relevant authorities.

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

If yes, how much?

Any further comments: At conclusion of the trial all participants will receive a complementary bottle 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

Exact locations in the following suburbs are being investigated but are yet to be finalised:

2. Essendon
3. Werribee
4. Dandenong
5. Ringwood

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.

Emu oil application will be completed in the participant's own home.

Completion of the Patient Oriented Eczema Measure, the Children's Dermatology Life Quality Index and the medication usage table will be completed in the participant's own home.

Photographic evidence will be collected at the initial and concluding meetings, to be held at the above listed premises.

15. **Dealing with potential risks:**

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

- i. Allergic reaction to the oils used in the study is a possible risk, however there are no published risks associated with ingesting 5mls once daily or massaging emu oil onto the skin twice per day.
- ii. Toxicity: Emu Spirit[®] Oil of Emu has TGA listing for the relief of the symptoms of eczema. The oil has undergone full oral toxic testing. (Pharmatox T2334) (Appendix 10).
- iii. A participants eczema might be exacerbated or worsen as a result of the oil used in this study.

- (b) *Indicate any **psychological risks** connected with the proposed procedures*
- i. Some participants may be uncomfortable exposing sensitive areas that are affected by their eczema.
 - ii. Some participants may be uncomfortable having photographs taken of sensitive areas.
 - iii. Gaining photographic evidence from participants may cause some distress or be against some participants' spiritual or religious beliefs.
- (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:

An initial skin and oral allergy test will be conducted on every participant at the initial meeting to screen for any allergies. It will be explained to all participants the symptoms they may experience if they have an allergic reaction to the oil, such as redness, heat, swelling and itchiness of the area the oil was applied to.

Psychological risks:

- i. The information to participants form will make it clear that the researchers will need to visually inspect the areas of the body that are to be included in the intervention. Participants will thus have the opportunity to not participate if they are uncomfortable with exposing a particular part of their body.
- ii. Photographic evidence will only be gained from a small sample of approximately 18 participants. On the consent forms (see appendices 5&6), participants will be able to indicate if they are or are not willing to give photographic evidence as part of the trial. Of those participants who are willing to provide photographic evidence, a random sample of three from each treatment group will be selected to take part in this section of the trial.

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

Physical Risks:

Participants that display any adverse reactions on the initial skin and oral allergy test, will not be eligible to participate in the trial. Any adverse effects that develop during the trial, will be managed with immediate withdrawal from the trial and referral to their general practitioner. In the rare and unlikely event of an anaphylactic reaction developing, characterised by vascular collapse, shock and often severe respiratory distress (Saunders, 2000), first aid will be administered and an ambulance will be called for immediate transfer to the nearest hospital, as this is a medical emergency. People who get worse will be able to stop using the oil and withdraw from the study without prejudice.

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 adverse allergic reaction will occur during this trial, however this risk is small. The adverse effects of commonly used treatments for eczema, such as corticosteroids, include skin atrophy (Thom & Halbert, 2003) and systemic side-effects, such as adrenal cortisol suppression and bone weakening (van Grunsven, 2001), may be more severe than the potential for an allergic reaction.

Charman, Morris & Williams, (2000) conducted a study to assess the phobia associated with topical corticosteroid use. They found that 72.5% of patients expressed concern about using topical corticosteroids for their AD, with 33% of those admitting to non-compliance to treatment as a result. In a UK study conducted by Baron, Goodwin, Nicolau, Blackford & Goulden, (2005), it was shown that close up to 40% of dermatology patients were using Complimentary and Alternative Medicines (CAM), with up to 50% reporting they preferred to use CAM or they were concerned about side-effects of conventional medicines. From the statistics presented above, it is clear that there is a need for more research to be conducted into CAM in the treatment of eczema. Emu Oil has much anecdotal evidence relating to its benefits in the

treatment of eczema, and as such requires scientific research to be conducted to investigate these claims further. If the trial is successful, it will give AD sufferers a viable, inexpensive and safe alternative.

17. Informed Consent:

- (a) See Appendix 4 – Information to Participants
- (b) See Appendix 5 & 6– Consent Form. Appendix 6 to be completed only by those participants between 14 and 16 years of age. Participants under 14 years of age will have the trial verbally explained to them by the principal investigator (see appendix 13) in the company of his/her parent/guardian before the consent form is signed by the parent/guardian. Appendix 5 will be signed by all participants parent/guardian.

(c) **State the process you will use to obtain documentation of informed consent hereunder...**

At the initial meeting of participants 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 Investigator. Participants and parents/guardians will be asked to read an Information to Participants form (Appendix 4) and to sign a Consent Form (Appendix 5 & 6) before participating in the trial.

18. Confidentiality:

(a) *Describe the procedures you will adopt to ensure confidentiality.*

Raw data from this trial will remain the property of Victoria University. The trial sponsor, Emu Spirit®, will sign a Sponsorship Agreement Form stating that the company will have no access to raw data. Raw data will be the responsibility of the principal supervisor Dr. Jim Kiatos and will be stored in a locked university filing cabinet for five years after the trial.

When recording and analysing data, participants' names will be replaced by numbers. The data key will be secured in Dr Kiatos' office at Victoria University for the duration of the trial.

Emu Spirit® will be providing financial, advertising and equipment support for this trial. Without this support the trial would be unable to proceed. Emu Spirit® will not have direct contact with participants involved in this trial nor will they have any identifiable data or details of participants involved in this trial. Participants will not be affected now or in the future, by Emu Spirit® sponsorship of this trial.

(b) *Indicate who will be responsible for the security of confidential data, including consent forms, collected in the course of the research.*

Dr. Jim Kiatos

(c) *Indicate the period for which the data will be held. (Data must be held for at least 5 years post-publication. Please refer to section 3.2 of the University's **Code of Conduct for Research, 1995**).*

5 years

(d) *Name all people who will be granted access to the data and the reason for the access. People identified are required to maintain all aspects of confidentiality.*

Principal Investigator, Dr Jim Kiatos, Co-investigator, Dr. Ray Power and Student Investigator, Miss Laura Richardson will be the only persons allowed access to raw data. This will be for the purpose of conducting analysis of the data.

Emu Spirit will be provided data that has been de-identified and will consist of group means and standard deviations.

19. Privacy:

(a) *Does this project involve the use of personal information obtained from a Commonwealth department or agency?* **Yes** **No**

If YES you may need to comply with the requirements of the Privacy Act 1988.

20. Any other relevant comments:

Declaration

I, the undersigned, have read the current NH&MRC 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 NH&MRC 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.

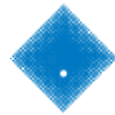
1** The Associate Investigator will assume responsibility for the project in the absence of the

Principal Investigator

References:

- Baron, S.E., Goodwin, R.G., Nicolau, N., Blackford, S., & Goulden, V. (2005). Use of complimentary medicine among outpatients within Yorkshire and South Wales, United Kingdom. *Journal of the American Academy of Dermatology*, 52, 589-594.
- Charman, C.R., Morris, A.D., & Williams, H.C. (2000). Topical corticosteroid phobia in patients with atopic eczema. *British Journal of Dermatology*, 142, 931-936.
- Charman, C.R., Venn, A.J. & Williams, H.C. (2004). The patient oriented eczema measure: Development and initial validation of a new tool for measuring atopic eczema severity from the patients perspective. *Archives of Dermatology*, 140, 1513-1519.
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Do you, or your child, Have Eczema?

Victoria University, with the support of Emu Spirit©, is seeking volunteers with eczema for a study to be conducted for the 3 months between June and August 2006. The study will investigate the effects of emu oil on eczema severity and quality of life of the participants.

To be eligible to participate, participants must:

- Be aged between 4-16 years, and have full consent from a parent/guardian.
- Have eczema that has been diagnosed by a dermatologist or General Practitioner.
- Not have used emu oil previously.
- Have current symptoms at the commencement of the trial.

All volunteers will continue taking current medications, as required.

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

For further information please contact

Laura Richardson on 9919 1191 Or laura.richardson@students.vu.edu.au

Appendix 2: Telephone Inquiry Format

The Effects of Emu Oil on Eczema Severity and Quality of Life

Principle Investigator – Dr. Jim Kiatos

Student Investigator – Miss Laura Richardson

Telephonists Name _____

Callers Name _____

Address _____

_____ Postcode _____

Telephone _____ Mobile _____

Email Address _____

Age _____ (Participant must be aged between 4 and 16)

Has the Eczema been formally diagnosed? Yes (if yes, by who? Dermatologist or GP)

No (not eligible for study at this time)

Is the front of the elbows or back of the knees affected?

Yes

No (not eligible for study)

Has Emu Oil been used before?

Yes (not eligible for study)

No

Are you a vegetarian?

Yes (not eligible for study as it involves animal product)

No

What meeting point is most convenient for you? (Circle)

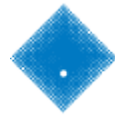
Dandenong, Ringwood, Essendon, Werribee or Flinders Lane

Would you like to be sent further information about the trial, including times for the initial meeting as well as a consent form?

Yes

No

Appendix 3: Cover Letter to Participants



**VICTORIA
UNIVERSITY**

**A NEW
SCHOOL OF
THOUGHT**

Date:.....

Dear.....

Thank you for your interest in the clinical trial “The Effects Of Emu Oil On Eczema Severity And Quality Of Life”.

Please find enclosed :-

- 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 attend this meeting, please call (phone number) 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.

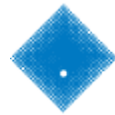
Sincerely,

Laura Richardson 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 Laura Richardson (Student Investigator), BSc (Clinical Sciences) (tel. 9919-1111) laura.richardson@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 4: Information To Participants



**VICTORIA
UNIVERSITY**

**A NEW
SCHOOL OF
THOUGHT**

Information to Participants:

Project Title:

The Effects Of Emu Oil On Eczema Severity And Quality Of Life

You are invited to be a part of a study into the effects of emu oil on eczema.

Is your child aged between 4 and 16 years of age and been diagnosed with eczema that does or has affected the front of their elbows and/or the back of their knees, as well as other regions of their body, and has not previously used emu oil? Then they are invited to participant in the research project named above.

The healthcare professional currently treating your child's eczema will continue to do so for the duration of the trial and your child's current medication regime will not be changed, unless this is deemed necessary by your healthcare professional.

Aim:

The aim of this study is to assess the value of emu oil in the treatment of eczema. This study will determine if emu oil, when applied topically (on the skin), ingested (eaten) or used in a combination of these methods, has any effects on:

- Eczema severity.
- Quality of life.
- Photographic appearance of the area of skin affected by the eczema. Only those wishing to have their eczema photographed need participate in this aspect of the trial.

Method:

The participants for this trial will be volunteers between the ages of 4 and 16 with diagnosed eczema, which does, or has, affected the back of the knees, the front of the elbows, or both. Participants will need to have signs of active eczema at commencement of the trial. People who are vegetarian, who have previously used emu oil and those who display or develop any adverse reaction to the oils will be excluded from the trial.

Participants will be randomly allocated to one of six groups:

1. Emu oil applied topically
2. Vegetable oil applied topically
3. Emu oil ingested

4. Vegetable oil ingested
5. A combination of topical and ingested emu oil
6. A combination of topical and ingested vegetable oil

Topical application of the oil will be morning and evening and the amount used will vary depending on how many areas of the body are affected by eczema. Participants will be shown how to apply a thin layer of oil to the eczema affected areas. Oral administration will be in 5ml (teaspoon) of oil once a day. The oil can be disguised in food and drink providing it is not used in cooking: for example it may be used on toast instead of margarine and then covered with the participants chosen spread.

The principal investigator will explain the details of the trial, how to apply the oil twice per day (morning, and evening), or orally administer the oil once per day and how to fill in the questionnaires and medication chart at the initial meeting to be held at (your preferred meeting place).

The trial will last for 12 weeks and will measure the following: -

- **Severity** - eczema severity will be measured using a questionnaire called the patient-oriented eczema measure (POEM). Participants will be asked to complete this questionnaire before commencement of the trial and at the same time every week for the duration of the trial.
- **Quality of Life** – Participants will be asked to complete a second short questionnaire, the cartoon version of the Children’s Dermatology Life Quality Index (CDLQI). Participants will be asked to complete the questionnaire before commencement of the trial and then monthly for the duration of the trial.
- The amount and dosage of the participants other medications will also be recorded weekly in a table to be provided.
- Photographic evidence will be gained from a sample of 18 willing participants at the start and at the end of the trial. Only interested participants may volunteer for this part of the trial.

Completion of these questionnaires will take approximately 10 minutes.

Assuming the trial is successful all participants will be offered complimentary emu oil on completion of the trial.

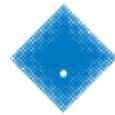
No therapy is completely risk free. Every effort has been made to reduce the risks associated with the therapies used in this trial.

Emu Spirit® will be providing financial, advertising and equipment support for this trial. Without this support the trial would be unable to proceed. A person employed by the company will randomly allocate your child to either a placebo or emu oil group. This will be done so that the researchers will not know which participants are taking the emu oil. The company and its employees will have no further contact with your child, nor will they be given any further identifying information about you. Participants will not be affected now or in the future, by Emu Spirit® sponsorship of this trial.

Participation in this study is voluntary. You are free to withdraw your child from this trial 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 Laura Richardson (Student Investigator), BSc (Clinical Sciences) (tel. 9919-1111) laura.richardson@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 14 - 16 years old



**VICTORIA
UNIVERSITY**

**A NEW
SCHOOL OF
THOUGHT**

Information to Participants:

Project Title:

The Effects Of Emu Oil On Eczema Severity And Quality Of Life

You are invited to be a part of a study into the effects of emu oil on eczema.

We are looking for people aged 14 - 16 years of age with diagnosed eczema that has affected the front of their elbows and/or the back of their knees, as well as other regions of your body. Specifically we are looking for people who have not previously used emu oil for any condition. If you meet these conditions, you are invited to participate in the research project named above.

The doctor currently treating your eczema will continue to do so for the duration of the trial and your current medication will not be changed, unless your doctor decides it is necessary to do so.

Aim:

The aim of this study is to assess the value of emu oil in the treatment of eczema. This study will determine if emu oil, when rubbed into the skin, eaten or when used in a combination of these methods, has any effects on:

- Eczema severity.
- Quality of life.
- Photographic appearance of the area of skin affected by the eczema. - Only those wishing to have their eczema photographed need participate in this aspect of the trial.

Method:

The participants for this trial will be volunteers between the ages of 14 and 16 with diagnosed eczema, which does, or has, affected the back of the knees, the front of the elbows, or both. Participants will need to have signs of eczema at the start of the trial. People who are vegetarian, who have previously used emu oil and those who display or develop any adverse reaction to the oils will be excluded from the trial. Participants will be randomly allocated to one of six groups:

1. Emu oil applied to the skin
2. Vegetable oil applied to the skin
3. Emu oil ingested (eaten)

4. Vegetable oil ingested (eaten)
5. A combination of emu oil on the skin and eaten
6. A combination of vegetable oil on the skin and eaten

Use of the oil on your skin will be morning and evening and the amount used will vary depending on how many areas of the body are affected by eczema. Participants will be shown how to apply a thin layer of oil to the eczema affected areas. Oral administration, where the oil will be eaten, will be a 5ml (teaspoon) of oil once a day. The oil can be added to food and drink providing it is not used in cooking: for example it may be used on toast instead of margarine and then covered with the participant's chosen spread.

The principal investigator will explain the details of the trial, how to apply the oil twice per day (morning, and evening), or orally administer the oil once per day and how to fill in the questionnaires and medication chart at the initial meeting to be held at (your preferred meeting place).

The trial will last for 12 weeks and will measure the following: -

- **Severity** - eczema severity will be measured using a questionnaire called the patient-oriented eczema measure (POEM). Participants will be asked to complete this questionnaire before commencement of the trial and at the same time every week for the duration of the trial.
- **Quality of Life** – Participants will be asked to complete a second short questionnaire, the cartoon version of the Children's Dermatology Life Quality Index (CDLQI). Participants will be asked to complete the questionnaire before commencement of the trial and then monthly for the duration of the trial.
- The amount and dosage of the participants other medications will also be recorded weekly in a table to be provided.
- Photographic evidence will be gained from a sample of 18 willing participants at baseline and at cessation of the trial. Only interested participants may volunteer for this part of the trial.

Completion of these questionnaires will take approximately 10 minutes.

Assuming the trial is successful all participants will be offered a complimentary 200ml bottle of emu oil on completion of the trial.

No therapy is completely risk free. Every effort has been made to reduce the risks associated with the therapies used in this trial.

Emu Spirit® will be providing financial, advertising and equipment support for this trial. Without this support the trial would be unable to proceed. A person employed by the company will randomly allocate you to either a placebo or emu oil group. This will be done so that the researchers will not know which participants are taking the emu oil. The company and its employees will have no further contact with you, nor will they be given any further identifying information about you. Participants will not be affected now or in the future, by Emu Spirit® sponsorship of this trial.

Participation in this study is voluntary. You are free to withdraw from this trial 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 Laura Richardson (Student Investigator), BSc (Clinical Sciences) (tel. 9919-1111) laura.richardson@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: Consent form for Parents

Participant Informed Consent Form



CERTIFICATION BY PARENT/GUARDIAN

I, _____ the parent or legal guardian of _____
certify that my child is aged between 4 and 16 years of age and that I am voluntarily giving consent for
my child to participate in the study entitled:

The Effects of Emu Oil on Eczema Severity and Quality of Life

Being conducted at Victoria University by:

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

Laura Richardson B.Sc.(Clin.Sc.)

I certify that the objectives of the research, 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
Laura Richardson and that I freely consent to my child's participation, involving the use of my child,
in these procedures.

Procedures:

- a. Self application of oil onto the areas of skin affected by eczema lesions and/or ingestion
of the oil.
- b. Written completion of the cartoon version of the Children's Dermatology Life Quality
Index (CDLQI), each month in the trial period.
- c. Weekly completion of the patient-oriented eczema measure (POEM).
- d. Recording of any medication usage during the trial period in a table.

I also give consent for photographs to be taken of my child's eczema (this is optional, and not all
participants will be involved in this section).

Please circle. Yes No Please Sign _____

I certify that I and my child have had the opportunity to have any questions answered and that I
understand that I can withdraw my child from this study at any time and without penalty.

I have been informed that the information I provide will be kept confidential and that no personally
identifying information will be available to anyone outside the research team. I have also been

informed that the results of this research will be published, but no personally identifying information will be used.

I am also aware Emu Spirit® will be providing financial, advertising and equipment support for this trial and that a person employed by the company will randomly allocate my child to either a placebo or emu oil group. Emu Spirit® will not have direct contact with me or my child nor will they have any identifiable data or details of our participation in this trial. Neither I nor my child will be affected now or in the future, by Emu Spirit's® sponsorship of this trial.

Signed: _____

Date: _____

Witness other than researcher: _____

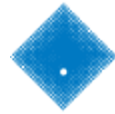
Is your child 4 – 14 years old? If so, please sign below if your child has given permission verbally to participate in this trial after having had the procedure explained to them in a way they are able to understand.

Signed: _____

<p>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 Laura Richardson (Student Investigator), BSc (Clinical Sciences) (tel. 9919-1111) laura.richardson@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).</p>

Appendix 7:

Participant Informed Consent Form



**VICTORIA
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**A NEW
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CERTIFICATION BY PARTICIPANT

I, _____

certify that I am aged between 14 and 16 years of age and that I am voluntarily giving consent to participate in the study entitled:

The Effects Of Emu Oil On Eczema Severity And Quality Of Life

Being conducted at Victoria University by:

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

Laura Richardson B.Sc.(Clin.Sc.)

I certify that the objectives of the research, 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 **Laura Richardson** and that I freely consent to my participation in these procedures.

Procedures:

- a. Self application of oil onto the areas of skin affected by eczema lesions and/or ingestion of the oil.
- b. Written completion of the cartoon version of the Children's Dermatology Life Quality Index (CDLQI), each month in the trial period.
- c. Weekly completion of the patient-oriented eczema measure (POEM).
- d. Recording of any medication usage during the trial period in a table.

I also give consent for photographs to be taken of my eczema (this is optional, and not all participants will be involved in this section).

Please circle. Yes No Please Sign _____

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 without penalty.

I have been informed that the information I provide will be kept confidential and that no personally

identifying information will be available to anyone outside the research team. . I have also been informed that the results of this research will be published, but no personally identifying information will be used.

I am also aware Emu Spirit® will be providing financial, advertising and equipment support for this trial and that a person employed by the company will randomly allocate me to either a placebo or emu oil group. Emu Spirit® will not have direct contact with you nor will they have any identifiable data or details of your participation in this trial. You will be affected now or in the future, by Emu Spirit® sponsorship of this trial.

Signed: _____

Date: _____

Witness other than 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 Laura Richardson (Student Investigator), BSc (Clinical Sciences) (tel. 9919-1111) laura.richardson@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 8: Eczema Medication Usage Table for Participants



The Effect Of Emu Oil On Eczema Severity And Quality Of Life.

Eczema Medication Usage Table

	Medications	Dosage	Frequency
Example:	Hydrocortisone cream	0.5%	Twice daily
Commencement			
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			

Please Note: If you require more room than is allocated please attach another page, clearly indicating which week the medications correspond to.

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 Laura Richardson (Student Investigator), BSc (Clinical Sciences) (tel. 9919-1111) laura.richardson@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 9: Courtesy Call Form

The Effect of Emu Oil on Eczema Severity and Quality of Life

Courtesy Call Form

Principle Investigator – Dr. Jim Kiatos

Co-Investigator – Miss Laura Richardson

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 still have enough oil or are you beginning to run out?

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: Therapeutic Goods Administration listing for Emu Oil

Emu Spirit – Omega 369 Oil of Emu Capsules (Oral administration of Emu Oil capsules for systemic use).

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

Item [27] Listing of Coded Indications

	Code	Description
	ECZ	Relief of the symptoms of eczema. [Warning S required] *

* Warning S: If symptoms persist, consult your healthcare practitioner.

Emu Spirit Oil of Emu: Aust L 92158

Patient-Oriented Eczema Measure					
Please circle one response for each of the seven questions below. Young children should complete the questionnaire with the help of their parents. Please leave blank any questions you feel unable to answer.					
1. Over the last week, on how many days has your/your child's skin been itchy because of the eczema?					
No Days	1-2 Days	3-4 Days	5-6 Days	Every Day	
2. Over the last week, on how many nights has your/your child's sleep been disturbed because of the eczema?					
No Days	1-2 Days	3-4 Days	5-6 Days	Every Day	
3. Over the last week, on how many days has your/your child's skin been bleeding because of the eczema?					
No Days	1-2 Days	3-4 Days	5-6 Days	Every Day	
4. Over the last week, on how many days has your/your child's skin been weeping or oozing clear fluid because of the eczema?					
No Days	1-2 Days	3-4 Days	5-6 Days	Every Day	
5. Over the last week, on how many days has your/your child's skin been cracked because of the eczema?					
No Days	1-2 Days	3-4 Days	5-6 Days	Every Day	
6. Over the last week, on how many days has your/your child's skin been flaking off because of the eczema?					
No Days	1-2 Days	3-4 Days	5-6 Days	Every Day	
7. Over the last week, on how many days has your/your child's skin felt dry or rough because of the eczema?					
No Days	1-2 Days	3-4 Days	5-6 Days	Every Day	
Total Score (maximum 28) _____					

... .. Responses are scored as

Appendix 12 – Children’s Dermatology Life Quality Index (Man, Sharpe, Dykes, Lewis-Jones & Finlay, 2003).

Trouble with Skin

The aim of the questionnaire is to measure how much your skin problem has affected you **OVER THE LAST WEEK**. Please ✓ one box for each question.

OVER THE LAST WEEK



How itchy, 'scratchy', sore or painful has your skin been?

- Very much

 Quite a lot

 A little

 Not at all



How upset or embarrassed, self conscious or sad have you been because of your skin?

- Very much

 Quite a lot

 A little

 Not at all



How much has your skin affected your friendships?



How much have you changed or worn different or special clothes/shoes because of your skin?

- Very much

 Quite a lot

 A little

 Not at all



How much has your skin trouble affected going out, playing or doing hobbies?



How much have you avoided swimming or other sports because of your skin trouble?

Children's Dermatology Life Quality Index



OVER THE LAST WEEK



Either

If school time: How much did your skin affect your **school work**?

Very much

Quite a lot

A little

Not at all



Or

If holiday time: How has your skin problem interfered with your **holiday plans**?



How much trouble have you had because of your skin with other people **calling you names, teasing, bullying, asking questions** or **avoiding you**?

Very much

Quite a lot

A little

Not at all



How much has your **sleep** been affected by your skin problem ?

Hospital No.:

Name :

Age:

Address:

Diagnosis:

Date:

CDLQI SCORE:

CDLQI © M.S. Lewis-Jones, A.Y. Finlay, June 1993
Illustrations © Media Resources Centre, UWCM, Dec 1996

Very much

Quite a lot

A little

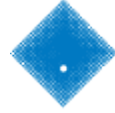
Not at all



How much of a problem has the **treatment** for your skin been ?

Please check that you have answered EVERY question. Thank you.

Appendix 13: Script of Information to Child Participants.



**VICTORIA
UNIVERSITY**

**A NEW
SCHOOL OF
THOUGHT**

Hello, what is your name? My name is Laura.

Has mummy or daddy told you why you are here today?

We are trying some new medicine for your eczema to see if it will get better. What we would like you to do is (insert mode of application relevant to child. Example: rub the oil onto your skin) in the morning and before bed for three months, but you don't have to if you don't want to and you can stop whenever you would like to.

I would also like you to answer some questions about your eczema (show the child the questionnaires) once a week (give example of day dependant on when first meeting is). It will only take 10 minutes to answer all questions.

Mummy/Daddy will be able to sit with you while you do the questions but we would like you to answer them if you can. Mummy/daddy will also be helping to write down what other medicine you have had.

Would you like to do this? Do you have any questions you would like to ask me?

If parent/guardian agrees to be involved in photographic evidence:

Would it be ok if we take a photo of your eczema with this camera?

Please Note:

The amount and way in which information is presented will be highly dependant upon the participants age and maturity. The above is the minimum amount of information to be provided to children involved in this study.