

An RCT to determine an effective skin regimen aimed at improving skin barrier function and quality of life in those with pododermatitis in Ethiopia.

Dr. Jill Brooks, PhD, Visiting Research Fellow, University of York. UK.

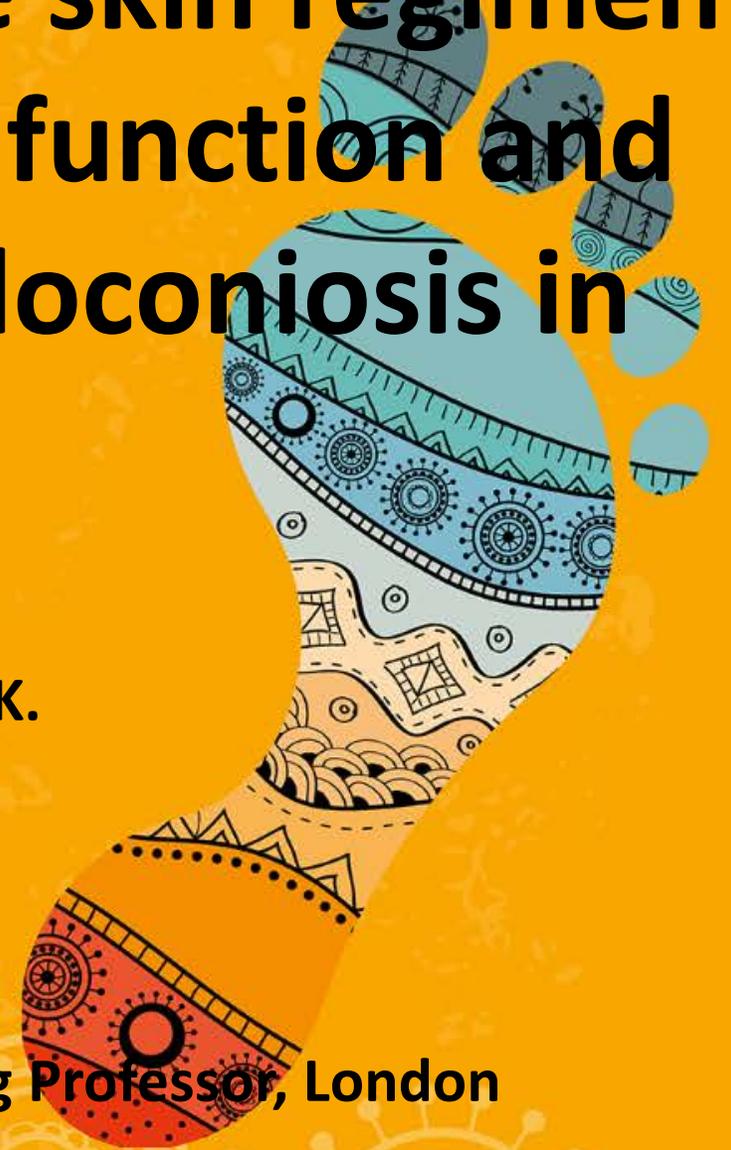
Professor Steven Ersser, PhD, University of York, UK

Professor Fiona Cowdell, DProf, Birmingham City University, UK

Dr. Eric Gardiner, PhD, University of Hull, UK

Anteneh Mengistu, MPH, Ethiopia,

Dr. Paul Matts, PhD, Research Fellow, Procter and Gamble, Visiting Professor, London University.





RESEARCH DESIGN

Based in 2 matched APA clinics in Gamo Gofa region in Southern Ethiopia.

Stratified to ensure:

- Equal numbers from each clinic
- Equal number of males and females
- Equal numbers with less severe/moderate disease (stage 1,2,3) and severe disease (stage 4,5) (Tekola, Ayele et al. 2008)

Control group (n=97), experiment group (n=96) = (n=193).



OUTCOME MEASURES

Measures pre-treatment (1st visit) and post treatment (4th visit) were compared.

- **TRANS-EPIDERMAL WATER LOSS (TEWL) AND STRATUM CORNEUM HYDRATION (SCH).**

A decrease in TEWL and an increase in SCH indicate an improved skin barrier function (SBF).

Measures were taken with non-invasive probes (Vapometer[®] and MoistureMeter[®]) at 3 specific points on both outer lower legs and on top of the feet at monthly intervals every month for 3 months (4 measures).





OTHER MEASURES

- **LARGEST LOWER LEG AND LARGEST FOOT CIRCUMFERENCE**
- **NUMBER OF WOUNDS ON LOWER LEG AND ON TOP OF FOOT (breach in skin's integrity)**
- **NUMBER OF DAYS OF WORK LOST DUE TO ACUTE DERMATOLYMPHANGIOADENITIS (ADL)**
- **QUALITY OF LIFE** - Amharic version of Dermatology Life Quality Index (DLQI)



CONTROL - CURRENT TREATMENT

- Washing lower legs/feet with soap (pH 8.5)
- Soaking in 6 litres of water with 15mls bleach (sodium hypochlorite - 5% NaOCl) for 30 minutes (~0.0125% dilution)
- Air dry
- Petrolatum applied thinly

EXPERIMENTAL TREATMENT

Based on a literature search and results of a pilot study. Treatment was the same as the control treatment except:

- **Used only 1 litre (1/6th) of soaking water with 2% glycerine (a very effective humectant) added.**

BOTH GROUPS

Encouraged to elevate their legs, exercise and wear shoes and socks. Antifungal given to those with fungal infections (Whitfield's ointment).



RESULTS TEWL

LOWER LEG TEWL

Mean reduced in both groups over the 3 months treatment at all 3 points on the lower leg.
Decease was greater in the experimental group.
Group difference was highly significant ($p < 0.001$) in favour of the experimental group.

FOOT TEWL

Mean reduced in both groups over the 3 months treatment.
Decease was greater in the experimental group.
Group difference was highly significant ($p = 0.002$) in favour of the experimental group.



RESULTS - SC HYDRATION

Increased in both groups at all points on the leg/foot over the 3 months.

Increase was greater in the experimental group.

The group difference was highly significant at all points on the leg/foot ($p < 0.001$) in favour of the experimental group.



LEG/FOOT CIRCUMFERENCE

Mean lower leg circumference.

This reduced in both lower legs in both groups.

No significant group difference.

Mean foot circumference

This reduced in both feet in both groups.

The reduction in foot circumference was greater in the experimental group. The group difference was highly significant $p < 0.001$ in favour of the experimental group.

NUMBER OF WOUNDS (breach in skin's integrity)

The mean number of wounds in both lower legs/feet reduced in both groups.

The mean reduction in leg/foot wounds was greater in the experimental group. The group difference was highly significant ($p = 0.005$) in favour of the experimental group.



DAYS OF WORK LOST DUE TO ACUTE DERMATOLYMPHANGIOADENITIS (ADL)

The mean number of work days of work lost in previous month due to ADL reduced over 3 months for all participants.

It reduced by 4.48 days for the control group and 4.43 days for the experimental group.

At Visit 4 no participants in either group lost any work days in the previous month due to ADL.

QUALITY OF LIFE

(Amharic version of Dermatology Life Quality Index (DLQI))

In the control group the mean DLQI reduced from 21.61 to 4.12 In the experimental group the mean DLQI reduced from 21.07 to 3.94. **The difference was not statistically significant.**



CONCLUSION

- **The addition of a 2% dilution of glycerine to the soaking water resulted in a significantly greater improvement in TEWL, SC hydration and foot circumference when compared to the existing treatment.**
- **There was also a significantly greater reduction in wounds on the lower leg/foot when compared to the exiting treatment.**
- **The study demonstrated that water volume can be reduced from 6 litres to 1 litre for each water soak treatment, a very significant saving in a resource-poor environment.**

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Thank you for listening

Dr. Jill Brooks

