

## Short Term Scientific Mission (STSM) Report

### STSM details

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| <b>Title</b>           | <b>SCIN Trial London</b>  |
| <b>Participant</b>     | <b>Maryam Soltanipoor</b><br>Coronel Institute of Occupational Health, Academic Medical Center (AMC),<br>Amsterdam, Netherlands   |
| <b>Host / Location</b> | Dr Ira Madan, SCIN Trial Operational Management Group at the<br>Occupational Health department, St Thomas' Hospital in London, UK |
| <b>Period</b>          | 11 – 16 May 2015  |
| <b>Reference code</b>  | ECOST-STSM-TD1206-110515-059986   |

### Background

Dr. Ira Madan, who was my host during the visit is an consultant in Occupational Medicine and chief investigator of the SCIN trial, provided very helpful insights and information. The agenda of the visit consisted mainly of in-depth explanation by the trial manager, Vaughan Parson, on the operation of the project. Countless valuable information was shared regarding the operational issues and barriers of the SCIN project, which are very useful for conducting my planned cluster RCT to improve skincare use in high-risk occupations in order to prevent hand dermatitis.

During the visit meetings were organized with various parties involved in the project:

- ✓ Clinical trials Unit at Kings College, who helps research teams across the UK carry out clinical trials to a high scientific standard. Mainly responsible for overseeing the methodology of the SCIN trial.
- ✓ Health Psychologist, involved in setting up research tools, the online Behavioral Change Package (BCP) and the Questionnaires.
- ✓ Fieldworkers on site: Recruiting Research Nurses at the Southampton Hospital reported on the day to day running of the project and barriers of recruitment.

### Objectives of the STSM

The purpose of the STSM was to analyse samples of the stratum corneum collected from the patients with atopic dermatitis, before and after therapy, by a novel technique. This technique is available at the Coronel Institute and not possible in Ireland. The aim was to discover the profile of inflammatory mediators in the skin. This of particular importance in atopic dermatitis. Furthermore, this is important in occupational contact dermatitis, where atopic dermatitis is the major predisposing risk factor.

### Assignments during the STSM

During the proposed STSM I mainly focused on the following aspects of the trial:

### **Project management**

A good organizational structure is practiced to ensure that the objectives of the study is achieved. This is done through segregating of the tasks of each specific research team contributing to the key project milestones.

- Operating management group
- Trial management group
- Trial steering committee (overall supervision)

### **Design and framework**

Cluster RCT, based on 27 sites as the unit of randomization. Sites are randomly selected to be an intervention plus or intervention light site. Study group one are student nurses with a history of atopic diseases or hand eczema. The second study group are the nurses working in ICU's.

**Intervention plus site** -centre on an online Behavioral change package (BCP) which will include **advice** on hand hygiene, hand care (use of moisturizers 3-5 times a day) supported by provision of personal supplies of hand cream for the student nurses and dispensers on the wards for the ICU nurses-

**Intervention light site** - no BCP, just advice leaflets about optimal hand care

### **Choice of moisturizing creams**

P45 crème and Diprobase were tested in a focus group of nurses.

p45 crème (which is an over the counter product) was selected for this study.

The student nurses were provided with own supplies, whereas the ICU nurses used the moisturizing cream dispensers at the wards.

### **The barriers to recruitment - Subject related**

- Low uptake of Questionnaire A in ICU- nurses.

A number of sites had not been able to recruit the target figures for participants (40 in each group). The fieldworkers have had some issues with recruiting the ICU nurses (to complete and return Questionnaire A and the Self-assessment Dermatitis Form), due to time constraints and workload pressures in the critical care department. Without returning these forms it was impossible to contact the participants for uptake of the online Behavioral Change Package (BCP). For the student nurses the response had been much higher. Probably due to easy accessibility of the student nurses. For example, at one site the student-nurses are approached during freshmen week. Furthermore a number of strategies are being considered to improve recruitment rate for ICU nurses.

### **The Implementation Barriers**

- Low uptake of the online BCP (intervention plus arm)

The uptake of the online BCP and also the response rate to questionnaire B (which is supposed to be completed 2 weeks after online BCP) had been lower than expected in both study groups (student-nurses 37%, ICU nurses 50%), mostly due to 'forgetting' or "accessibility" issues. Strategies to increase the uptake consists of displaying posters at the departments, by sending email-reminders, sending a hardcopy of questionnaire B is after 2 weeks, including a reminder leaflet to access the online BCP. Furthermore, reminding participant during their annual handwashing training in collaboration with infection control and performing ward based audits every 4-6weeks was part of the strategy.

## **Results of the STSM**

### **Interesting outcomes**

- So far, an surprising outcome of the trial has been that a much higher prevalence of self-hand eczema was reported after self-assessment (30%) compared to assessment by the dermatologists, which was surprisingly even lower than at population level.
- No difference in prevalence of hand eczema has been determined yet between the

intervention light and plus arm, though there seems to be more use of hand creams in the intervention plus arm.

## Studyprotocol changes

As a result of the outcomes of the feasibility study and experiences the following changes were made in the protocol:

Assessing cases by standardized photography protocol - Solely use of dermatologists' assessment (using Coenraads Photographic Guide) will be used to diagnose dermatitis. As a consequence all participants' hands will be photographed at baseline and 12 months after the BCP is taken. This is quite important since the impact of the trial will be evaluated from information collected by the photographs.

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