The SCIN (Skin Care Intervention in Nurses) Trial

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
13/06/2013		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/06/2013	Completed	[X] Results		
Last Edited 23/10/2019	Condition category Skin and Connective Tissue Diseases	[] Individual participant data		

Plain English summary of protocol

Background and study aims

Hand dermatitis (eczema) is a common cause of discomfort and loss of productivity in the NHS workforce with treatment costs amounting to £125 million/year. Different preventive measures are used to reduce hand dermatitis in healthcare workers but it is not clear how effective these are. To prevent infections spreading between patients, nurses have to wear gloves and wash their hands a lot of the time. This constant contact with detergents and water often leads nurses to develop hand dermatitis, which in turn may mean that they are more likely to carry harmful bacteria on their hands. The risk of getting hand dermatitis is particularly high in nurses with a past history of allergic disease such as asthma and childhood eczema and among nurses who work in intensive care units (ICUs) where patient contacts and hand washing are more frequent. Hand dermatitis can be reduced by avoiding unnecessary overuse of gloves and washing of hands, drying hands properly after washing, and regular use of hand creams (moisturisers). However, hand care by nurses is often poor. We will study nurses at high risk of hand dermatitis (student nurses with a past history of allergic disease and ICU nurses) and test the effectiveness and value for money of an online training programme (Behavioural Change Package or BCP) which aims to change nurses beliefs and behaviours in looking after their hands.

Who can participate?

This study aims to recruit, through the participating trust's Occupational Health (OH) department, at least 40 ICU nurses and 40 first year student nurses at each of 26 NHS trusts in England.

What does the study involve?

NHS trusts will be randomly allocated to one of two groups. 13 trusts will receive BCP and 13 trusts to act as controls. Nurses in the control trusts will be provided with the same written information as the nurses in trusts receiving BCP, and will be encouraged to report hand dermatitis early to their OH department. They will otherwise receive advice in accordance with their local trust's existing policies. Nurses receiving BCP will be encouraged to develop detailed plans to help them change their behaviours, supported by online reminders. The student nurses will be provided with personal tubes of moisturising cream. On ICU wards, facilities for washing and drying hands will be reduced and dispensers of moisturising creams installed. The participants will be asked to complete a questionnaire at the start of the study about past and current hand dermatitis, allergies, beliefs about hand care, use of gloves, soaps, alcohol hand rubs, moisturisers, activities outside work which may lead to dermatitis and current quality of

life. BCP will then be implemented in the allocated trusts. We will ask the nurses to complete a shorter questionnaire soon after they have received the BCP and again at the end of 12 months. In addition, any nurses who report hand dermatitis at any stage of the study will be asked to have their hands photographed and checked for harmful germs. Nurses with hand dermatitis will be treated according to normal practice in their trust. Two dermatologists from the study team will review the photographs to grade the severity of dermatitis. We will also randomly check the hands of nurses who do not have dermatitis.

What are the possible benefits and risks of participating?

All nurses participating in the study will benefit from intensive hand care advice. If the programme is effective, those in the BCP-receiving group will benefit from a lower risk of developing hand dermatitis. The results of the study will be circulated to the participants so that all nurses in the study will benefit from increased awareness of the importance of hand care at work. The study has been designed to have few, if any, adverse effects on the study participants. The programme is not painful or intrusive and should have little inconvenience. Once an individual has developed irritant hand dermatitis the outlook is poor. Individuals may develop sleep disturbance and hampered leisure activities.

Where is the study run from?

This study is being led by Guy's and St Thomas' NHS Foundation Trust but involves senior researchers and experts from King's College, London; the University of Southampton; Imperial College, London; University College London; the University of Manchester and Nottingham University Hospitals NHS Trust.

When is the study starting and how long is it expected to run for? After a feasibility study in a hospital in Wales, the main study will start in September 2014 and will last until May 2017.

Who is funding the study? The project is funded by the National Institute for Health Research (NIHR), UK

Who is the main contact? Dr Ira Madan Ira.madan@kcl.ac.uk

Contact information

Type(s)

Scientific

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Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers HTA 11/94/01

Study information

Scientific Title

A cluster randomised controlled trial of a behavioural change package to prevent hand dermatitis in nurses working in the National Health Service

Acronym

SCIN

Study objectives

It is hypothesised that a behavioural change intervention to improve hand care, based on the theory of planned behaviour and implementation intentions, coupled with provision of hand moisturisers, can produce a clinically useful reduction in the occurrence of hand dermatitis when compared to standard care in at-risk nurses working in the National Health Service (NHS).

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/119401 Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0006/81186/PRO-11-94-01.pdf

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee London - City Road & Hampstead, original application approved on 31/10/2013 (ref: 13/LO/09810) and substantial amendment application approved on 05/09/2014. Protocol v14 approved 05/11/2014.

Study design

Four-year cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Hand dermatitis

Interventions

- 1. Nurses in intervention trusts will receive the bespoke online behavioural change package (BCP). This will be developed by members of the study team with expertise in dermatology, occupational medicine, nursing, and health psychology and care will be taken to ensure compatibility with current guidance on infection control. It will include advice: on when and when not to use gloves; on when to use antibacterial hand rubs; on when and how to wash and dry hands; on when to use moisturising cream; and to contact OH early if hand dermatitis occurs. As part of the package, nurses will be asked to form implementation intentions for performing behaviours in their workplace. These will be recorded, and participants will subsequently be reminded of them and offered the opportunity to revise them. The package will be supported by provisions to encourage adherence, such as moisturising creams. It will be actively reinforced over the course of the study by consistent messages on skin care from local OH and control of infection teams, and from line management.
- 2. Nurses in control trusts will be provided with an advice leaflet about optimal hand care and encouragement to contact their occupational health department early if hand dermatitis occurs.

Intervention Type

Behavioural

Primary outcome measure

The primary outcome is the change in point prevalence of visible hand dermatitis from baseline to the end of follow up.

Methodology: All study participants will be asked to contact their occupational health department early if they develop hand dermatitis. Their hands, wrists and forearms will be photographed using a standardised method. The images obtained will subsequently be assessed independently by two dermatologists blinded to other information about the participant, to ascertain whether any hand dermatitis is present. A participant will be classed as a case if both observers note visible hand dermatitis. In the event of disagreement, between the two dermatologists a third arbitrator will be consulted.

Secondary outcome measures

Secondary outcomes will be the difference between intervention and control trusts in:

- 1. The incidence of new episodes of hand dermatitis presenting to the OH department over the 12-months of follow-up
- 2. Severity of visible hand dermatitis from baseline to the end of follow-up
- 3. Days lost from sickness absence and days of modified duties because of hand dermatitis per 100 days of nurse time during the 12-months of follow-up
- 4. The change in estimated prevalence of hand colonisation by pathogenic bacteria (with or without associated dermatitis) from baseline to the end of follow-up
- 5. The change from baseline to after completion of the BCP, and to the end of the 12-month follow-up in beliefs about dermatitis prevention behaviours.
- 6. The change from baseline to the end of follow-up in the reported frequency of use of alcohol hand rubs for hand cleansing, hand-washing with water, use of recommended techniques for drying hands after washing, use of moisturising creams and use of gloves for different durations (for student nurses, who will not have started clinical attachments at the beginning of the study, this will reduce to differences between the intervention and control trusts at the end of the follow-up)
- 7. The change from baseline to the end of follow-up in quality of life score

We will also document the reported participation in the behavioural change package, reasons given for not participating, and comments on its content.

Overall study start date

01/01/2014

Completion date

31/05/2017

Eligibility

Key inclusion criteria

- 1. All NHS trusts in England which train nurses, have an in-house occupational health (OH) service and have at least one intensive care unit (ICU)
- 2. First year student nurses and ICU nurses

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

2240

Total final enrolment

1956

Key exclusion criteria

In order to avoid the risk of student nurses moving placements from an intervention to a control trust (or vice versa), only one trust in each city or town will be invited to participate. London is an exception to this where three trusts were identified in which student nurses did not move to neighbouring trusts during their training.

Date of first enrolment

01/09/2014

Date of final enrolment

01/12/2015

Locations

Countries of recruitment

England

Scotland

United Kingdom

Wales

Study participating centre Guy's and St Thomas NHS Foundation Trust

The Education Centre 75-79 York Road Waterloo London United Kingdom SE1 7EH

Study participating centre

Cambridge University Hospitals NHS Foundation Trust

Cambridge Biomedical Centre Robinson Way and Long Road Cambridge United Kingdom CB2 0QQ

Study participating centre East Kent University Hospitals NHS Foundation Trust

Kent & Canterbury Hospital Ethelbert Road Canterbury United Kingdom CT1 3NG

Study participating centre Frimley Health NHS Foundation Trust

Frimley Peak Hospital
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

Study participating centre Homerton University Hospital NHS Foundation Trust

Homerton Row London United Kingdom E9 6SR

Study participating centre Hull and East Yorkshire Hospitals NHS Trust

OH Department Castle Hill Hospital Castle Road Cottingham United Kingdom HU16 5JQ

Study participating centre Industrial Diagnostics

Atherstone House The Sidings Merry Lees Industrial Est. Merry Lees United Kingdom LE9 9FE

Study participating centre Kettering General Hospital NHS Foundation Trust

Rothwell Road Kettering United Kingdom NN16 8UZ

Study participating centre Lancashire Teaching Hospitals Foundation NHS Trust

LTH Occupational Health Royal Preston Hospital Sharoe Green Lane Preston United Kingdom PR2 9HT

Study participating centre NHS Lothian

NHS Lothian Occupational Health Service Astley Ainslie Hospital Grange Loan Edinburgh United Kingdom EH9 2HL

Study participating centre

Luton and Dunstable University Hospital NHS Foundation Trust

Luton & Dunstable University Hospital Lewsey Road Luton United Kingdom LU4 0DZ

Study participating centre Milton Keynes NHS Foundation Trust

Milton Keynes Hospital Standing Way Milton Keynes United Kingdom MK6 5LD

Study participating centre Norfolk and Norwich University Hospitals NHS Foundation Trust

20 Rouen Road Norwich United Kingdom NR1 1QQ

Study participating centre Northampton General Hospital NHS Trust

Occupational Health Department Billing House Cliftonville Northampton United Kingdom NN1 5BD

Study participating centre North Tees NHS

University Hospital of North Tees Hardwick Stockton on Tees United Kingdom TS19 8PE

Study participating centre Nottingham University Hospitals NHS Trust

Queens Medical Centre Campus Nottingham Occupational Health Derby Road Nottingham United Kingdom NG7 2UH

Study participating centre Oxford University Hospital NHS Trust

John Radcliffe Hospital Headington Oxford United Kingdom OX3 9DU

Study participating centre Papworth Hospital NHS Foundation Trust

Papworth Everard Cambridge United Kingdom CB23 3RE

Study participating centre Pennine Acute Hospital NHS Foundation Trust

North Manchester General Hospital Delaunays Road Crumpsall Manchester United Kingdom M8 5RB

Study participating centre Plymouth Hospitals NHS Trust

Kingstor House Derriford Hospital Plymouth United Kingdom PL6 8DH

Study participating centre Royal Berkshire NHS Foundation Trust

21 Craven Road Reading United Kingdom RG1 5LE

Study participating centre St George's Healthcare NHS Trust

St George's Healthcare NHS Trust Blackshaw Road Tooting London United Kingdom SW17 0QT

Study participating centre The Ipswich Hospital NHS Trust

Heath Road Ipswich United Kingdom IP4 5PD

Study participating centre The Leeds Teaching Hospitals NHS Trust

St. James's University Hospital Beckett Street Leeds United Kingdom LS9 7TF

Study participating centre

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Campus for Aging and Vitality (NGH) Westgate Road Newcastle Upon Tyne United Kingdom NE4 6BE

Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Woodlands Nurses Home Selly Oak Hospital Raddlebarn Birmingham United Kingdom B29 6JF

Study participating centre University Hospitals of Leicester NHS Trust

Leicester Royal Infirmary Infirmary Square Leicester United Kingdom LE1 5WW

Study participating centre

University Hospital Southampton NHS Trust

Southampton General Hospital Tremona Rd Southampton United Kingdom SO16 3YD

Study participating centre Sheffield Hospital NHS Trust

Northern General Hospital Herries Road Sheffield United Kingdom S5 7AU

Study participating centre York Teaching Hospital NHS Foundation Trust

Centurion House
Centurion Park
Tribune Way
Clifton Moor
York
United Kingdom
YO30 4RY

Study participating centre University of Manchester

The Mill Sackville Street Manchester United Kingdom M13 9PL

Study participating centre University of Salford

Allerton Building Frederick Road Campus Salford United Kingdom M6 6PU"

Study participating centre Wye Valley NHS Trust

County Hospital Stonebow Rd Hereford United Kingdom HR1 3AW

Study participating centre West Suffolk NHS Foundation Trust

West Suffolk Hospital Hardwick Lane Bury St Edmunds United Kingdom IP33 2QZ

Study participating centre Old Nurses Home

Glangwilli General Hospital Carmarthen United Kingdom SA31 2AF

Study participating centre Ty Hafren Bronglais

General Hospital Aberystwyth United Kingdom SY23 1ER

Study participating centre Prince Philip Hospital

Dafen Road Llanelli United Kingdom SA14 8QF

Study participating centre Withybush General Hospital

Fishguard Road Haverfordwest

Sponsor information

Organisation

Guy's and St Thomas' NHS Foundation Trust (UK)

Sponsor details

c/o Ms Karen Ingatian R&D Department 16th Floor, Tower Wing Guy's Hospital Great Maze Pond London England United Kingdom SE1 9RT

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/00j161312

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

2018 results to be presented at the Healthcare Risk Management meeting (South East England).

2018 results to be presented at the European Society of Contact Dermatitis scientific meeting.

2018 results presented at the Occupational Health Annual Scientific conference.

2018 results presented at the 'Hand in Glove' launch event at the Royal College of Nursing.

2018 results presented at International Congress in Occupational Health conference.

2017 results presented at the SCIN trial dissemination conference.

Intention to publish date

01/02/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	17/03/2016		Yes	No
Results article	results	01/10/2019	23/10/2019	Yes	No
HRA research summary			28/06/2023	No	No