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The SSHeW study - Stopping slips among healthcare workers: a research study about slip resistant footwear in the NHS workplace

Submission date
13/03/2017

Recruitment status
No longer recruiting

Registration date
14/03/2017

Overall study status
Completed

Last Edited
26/04/2023

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Slips and falls are the main cause of accidents in the workplace. Last year, over 100,000 people hurt themselves as a result of having a slip, trip or fall at work. This is about 40% of all of the injuries which had to be reported to the Health and Safety Executive. These injuries can have a major effect on the individual as well as on employers due to lost days at work. It has been estimated that one million days were taken off work in 2012/13 due to injuries caused by slips, trips or falls. People working in health and social care report the highest numbers of workplace slips and trips, and hospital staff are more likely to slip because of the smooth flooring they walk on, which becomes slippery when it is wet or dirty.One possible way of reducing the number of slips people have could be for them to wear slip resistant shoes. The aim of this study is to find out if slip resistant shoes can stop NHS staff from slipping, falling or hurting themselves.

Who can participate?
Staff working in NHS trusts who have to follow a workplace dress code and who have a mobile phone.

What does the study involve?
After agreeing to take part, participants fill in a questionnaire and reply to text messages reporting if they have a slip at work. Those who complete the texts are then randomly allocated to one of two groups using a computer program. Those in the first group receive one free pair of slip resistant shoes to wear at work for 14 weeks. Those in the second group are asked to wear their own work shoes for the duration of the study. These participants are offered a pair of the slip resistant shoes at the end of the study period. All participants receive a text message once a week for 14 weeks to ask if they have had a slip in the last week. The first time a participant reports a slip by text message, they are telephoned by a researcher or sent a questionnaire in the post to obtain further details of the incident. Participants are given a paper diary in which to record details of any slips, falls or injuries. Once a month people wearing the slip resistant footwear are asked how often they are wearing them via text message. Participants are also sent a paper questionnaire at 14 weeks to collect further information. Some participants are asked to return their footwear so that it can be tested to see how worn the soles are.

What are the possible benefits and risks of participating?
There are no notable benefits or risks involved with participating.

Where is the study run from?
1. Leeds Teaching Hospitals NHS Trust (UK)
2. Cheshire and Wirral Partnership NHS Foundation Trust (UK)
3. York Teaching Hospitals NHS Foundation Trust (UK)
4. Nottingham University Hospitals Trust (UK)
5. Lancashire Care NHS Foundation Trust (UK)
6. University Hospitals of Derby & Burton NHS Foundation Trust (UK)
7. Harrogate and District NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2016 to March 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mrs Sarah Cockayne
sarah.cockayne@york.ac.uk

Study website
https://www.york.ac.uk/healthsciences/research/trials/research/trials/sshew/

Contact information

Type(s)
Public

Contact name
Mrs Sarah Cockayne

ORCID ID
http://orcid.org/0000-0002-1288-5497

Contact details
University of York
Dpt Health Sciences
York Trials Unit
ARRC Building Lower Ground Floor - A/RC005a
York
United Kingdom
YO10 5DD
+44 (0)1904 321736
sarah.cockayne@york.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
33569

Study information

Scientific Title
Does slip resistant footwear reduce slips among healthcare workers? A randomised controlled trial

Acronym
SSHeW

Study objectives
The aim of this study is to find out whether wearing slip resistant shoes can reduce the number of slips, falls and injuries NHS staff have at work.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of York, Dept Health Sciences Research Governance Committee, 02/12/2016, ref: HSRGC/2016/187/A

Study design
Randomised; Interventional; Design type: Prevention, Physical

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied

Specialty: Health services and delivery research, Primary sub-specialty: Health Services and Delivery Research; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions
All eligible consenting participants, who return a completed baseline questionnaire, will be sent a weekly text message requesting slips data. Eligible participants who return a valid baseline questionnaire and respond to at least two of the data collection texts requesting data on slips, irrespective of whether they experienced a slip, will be randomised into the trial. Participants will be randomly allocated using the York Trials Unit secure web-based randomisation system based on an allocation sequence generated by an independent data systems manager at the York Trials Unit, who is not involved in the recruitment of participants. The randomisation will be stratified by NHS Trust, and block randomisation within Trust will be used with variable block sizes. Participants will be allocated 1:1 to either the control or intervention group.

Control group: Participants will be asked to wear their usual work footwear for 14 weeks after they are randomised into the study. At the end of this period they will be offered a free pair of slip resistant shoes provided by 'Shoes for Crews' and paid for by the Trust.

Intervention group: Participants will receive one pair of 5-star GRIP rated slip resistant footwear provided by 'Shoes for Crews' free of charge to the participant. Footwear will be selected from a trial specific catalogue.

All participants will be followed up for 14 weeks during this time they will receive a weekly text asking for slips data. Participants reporting their first slip will be phoned (added 28/02/2018: or sent a questionnaire by post) and further information collected. In addition the intervention group will receive a monthly text asking about footwear compliance. All participants will be sent a questionnaire 14 weeks after randomisation to collect secondary outcome data. We will evaluate the wear on the sole of the shoes. 15 consenting participant will be asked to continue wearing their intervention footwear beyond the trial period for a further 6, 9 and 12 weeks (45 in total). A qualitative study will be undertaken to explore the acceptability of the footwear, reasons for wearing or not wearing the shoes and views on the impact of the footwear.

Added 12/05/2020:
Sub study
The SSHeW trial will also include a Study within a Trial (SWAT) to investigate if including a pen with a postal follow-up questionnaire increases the response rate.

Intervention Type
Other

Primary outcome measure
Incidence rate of self-reported slips in the workplace reported via weekly text messages over 14 weeks

Secondary outcome measures
Current secondary outcome measures as of 31/05/2018:
1. Time in days from randomisation to date of first fall as reported on final questionnaire at 14 weeks
2. Time in days from randomisation to date of first slip as reported via weekly text messages and follow-up telephone call

3. Incidence rate of self-reported falls resulting from a slip in the workplace reported on final questionnaire at 14 weeks
4. Incidence rate of self-reported falls not resulting from a slip in the workplace reported on final questionnaire at 14 weeks
5. Proportion of participants who report at least one fall on final questionnaire at 14 weeks
6. Proportion of participants who report at least one slip via weekly text messages over 14 weeks
7. Proportion of participants who report a fracture over 14 weeks (numbers permitting)
8. Footwear purchase cost
9. Footwear distribution cost (if significant)
10. Number of full time working days lost due to slip-related injuries over the 14 weeks of the trial, supplemented by Labour Force Survey data on working days lost due to slips, trips and falls. This will be used to estimate temporary staff replacement costs and sickness payments.
11. Healthcare resource use over the 14 weeks of the trial, including hospital admissions, measured by self-report, costed using NHS Reference Costs unit costs database and supplemented where necessary by published data on healthcare treatment costs from relevant injury types
12. NHS Resolution data on non-clinical compensation claims and payments relating to slips under the NHS Liabilities to Third Parties Scheme
13. Duration of cost-effectiveness modelling determined by service life of shoes, estimated from wear on sole of intervention shoes. Measured by participant feedback, visual inspection and slip resistance testing for 15 participants after 6, 9 and 12 months of wear
14. Change in health-related quality of life, measured by EQ-5D-5L for those reporting an injury over the 14 weeks of the trial, compared with general population health

Previous secondary outcome measures as of 10/05/2018:
1. Time in days from randomisation to date of first fall as reported on final questionnaire at 14 weeks
2. Time in days from randomisation to date of first slip as reported via weekly text messages and follow-up telephone call
3. Incidence rate of self-reported falls resulting from a slip in the workplace reported on final questionnaire at 14 weeks
4. Incidence rate of self-reported falls not resulting from a slip in the workplace reported on final questionnaire at 14 weeks
5. Proportion of participants who report at least one fall on final questionnaire at 14 weeks
6. Proportion of participants who report at least one slip via weekly text messages over 14 weeks
7. Proportion of participants who report a fracture over 14 weeks (numbers permitting)
8. Cost-effectiveness

Previous secondary outcome measures:
1. Time in days from randomisation to date of first fall as reported on final questionnaire at 14 weeks
2. Time in days from randomisation to date of first slip as reported via weekly text messages and follow-up telephone call
3. Incidence rate of self-reported falls resulting from a slip in the workplace reported on final questionnaire at 14 weeks
4. Incidence rate of self-reported falls not resulting from a slip in the workplace reported on final questionnaire at 14 weeks
5. Proportion of participants who report at least one fall on final questionnaire at 14 weeks
6. Proportion of participants who report at least one slip via weekly text messages over 14 weeks
7. Number of days off work due to a slip or fall as reported on final questionnaire at 14 weeks
8. Footwear compliance is measured via text messages at 6, 10 and 14 weeks, and on final questionnaire at 14 weeks

9. Reason for slip/fall is measured by follow-up telephone call
10. Footwear worn at time of first slip is measured by follow-up telephone call to first slip
11. Hospital admissions is measured by self-report at 14 weeks
12. Number of days in hospital is measured by self-report at 14 weeks
13. Wear on sole of intervention shoes is measured by participant feedback, visual inspection and slip resistance testing for 15 participants after 6, 9 and 12 months of wear

Overall study start date
01/10/2016

Completion date
31/05/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 02/08/2018:
1. Aged 18 years and over
2. Are NHS employees, who have at least six months remaining on their work contract
3. Are required to adhere to a dress code policy
4. Work at least 60% WTE
5. Work in clinical areas (including wards, outpatient clinics, patients' homes), cafeterias, food preparation areas or areas where food is served or in the general hospital environment (including all clinical/catering areas in addition to the hospital stairs and corridors)
6. Have a mobile phone and agree to receive and send outcome data via text messages

Previous inclusion criteria:
1. Aged 18 years and over
2. Are NHS employees, who have at least six months remaining on their work contract
3. Are required to adhere to a dress code policy
4. Work at least 80% WTE
5. Work in clinical areas (including wards, outpatient clinics, patients' homes), cafeterias, food preparation areas or areas where food is served or in the general hospital environment (including all clinical/catering areas in addition to the hospital stairs and corridors)
6. Have a mobile phone and agree to receive and send outcome data via text messages

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 4400; UK Sample Size: 4400

Total final enrolment
4553

Key exclusion criteria
Current exclusion criteria as of 02/08/2018:
1. Do not have a mobile phone or are unwilling/unable to receive/send text messages
2. Are provided with protective footwear by their employer
3. Temporary or agency staff
4. Staff who have less than 6 months remaining on their employment contract
5. Staff who work in office based areas
6. Staff who are not employed by the NHS
7. Staff who work less than 0.6 WTE

Previous exclusion criteria from 28/02/2018 to 02/08/2018:
1. Do not have a mobile phone or are unwilling/unable to receive/send text messages
2. Are provided with protective footwear by their employer
3. Temporary or agency staff
4. Staff who have less than 6 months remaining on their employment contract
5. Staff who work in office based areas
6. Staff who are not employed by the NHS
7. Staff who work less than 0.8 WTE

Previous exclusion criteria:
1. Do not have a mobile phone or are unwilling/unable to receive/send text messages
2. Are provided with protective footwear by their employer
3. Required to wear prescribed orthopaedic footwear or their footwear requires modifications to their work shoes by an orthotist
4. Temporary or agency staff
5. Staff who have less than 6 months remaining on their employment contract
6. Staff who work in office based areas
7. Staff who are not employed by the NHS
8. Staff who work less than 0.8 WTE

Date of first enrolment
10/03/2017

Date of final enrolment
10/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Teaching Hospitals NHS Trust
St James' Hospital

Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Cheshire and Wirral Partnership NHS Foundation Trust
Academic Unit St Catherine’s Hospital
Church Road
Birkenhead
United Kingdom
CH42 0LQ

Study participating centre
York Teaching Hospitals NHS Foundation Trust
York Hospital,
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
Nottingham University Hospitals NHS Trust
C Floor South Block
Queen's Medical Centre Campus
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Lancashire Care NHS Foundation Trust
The Lantern Centre
Vicarage Lane
Fulwood
Preston
United Kingdom
PR2 9DW

Study participating centre

University Hospitals of Derby & Burton NHS Foundation Trust
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Harrogate and District NHS Foundation Trust
Lancaster Park Road
Harrogate
United Kingdom
HG2 7SX

Sponsor information

Organisation
University of York

Sponsor details
Research and Enterprise Directorate
Innovation Centre
York Science Park
York
England
United Kingdom
YO10 5DG
+44 (0)1904 435154
michael.barber@york.ac.uk

Sponsor type
University/education

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study protocol and results will be reported and disseminated in high impact peer-reviewed scientific journals approximately one year after the overall end of the trial. The findings may also be presented at health and safety conference. The Health and Safety Executive will disseminate the findings through their website (www.hse.gov.uk).

Intention to publish date
01/09/2020

Individual participant data (IPD) sharing plan
The datasets analysed during the current study will be available upon request from the Chief Investigator, Professor David Torgerson at david.torgerson@york.ac.uk.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v3	03/03/2017	14/03/2017	No	Yes
Protocol article	protocol	15/11/2018	25/11/2019	Yes	No
Results article	results	15/01/2021	18/01/2021	Yes	No
Results article	results of embedded SWAT	09/06/2020	18/01/2021	Yes	No
Results article		01/02/2021	26/04/2023	Yes	No