# TRIAL PROTOCOL

**Full title:** Does slip resistant footwear reduce slips among healthcare workers? A randomised controlled trial.

**Authorised by**
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National Institute for Health Research

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# 2. Trial summary

## 3.1 Summary Table

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| Acronym | Stopping Slips among Healthcare Workers (SSHeW) |
| Long title | Does slip resistant footwear reduce slips among healthcare workers? A randomised controlled trial. |
| Study design | A randomised controlled trial with an economic evaluation, including an internal pilot and embedded qualitative study. |
| Setting | NHS Trusts or NHS Boards in the United Kingdom and areas typically visited by NHS clinical staff, including hospitals, clinics and patient's homes. |
| Target population | NHS trust staff working in a general, clinical or catering environment who have to adhere to a Trust dress code policy. |
| Intervention | Intervention: Participants will be provided with one pair of 'Shoes for Crews' slip resistant footwear to be worn at work.<br><br>Control (the comparator) participants will wear their usual footwear for the 14 weeks they participate in the trial, after which time they will be offered a free pair of trial slip resistant footwear. |
| Primary outcome | The incidence rate of slips, not necessarily resulting in a fall or injury, in the workplace over 14 weeks, where a slip is defined as a loss of traction of your foot on the floor surface, which may or may not result in a fall. |
| Secondary outcomes | • The incidence rate of falls resulting from a slip in the workplace over 14 weeks<br>• The incidence rate of falls not resulting in a slip in the workplace over 14 weeks<br>• Proportion of participants who report a slip in the workplace over 14 weeks<br>• Proportion of participants who report a fall in the workplace over 14 weeks<br>• Proportion of participants who report a fracture over 14 weeks (numbers permitting)<br>• Time to first slip<br>• Time to first fall<br>• EQ-5D-5L<br>• Cost effectiveness |
| Estimated recruitment period | 22 months. |
| Duration per patient | 18 weeks: 4 weeks run in period plus 14 weeks follow up. |
| Estimate total trial duration | 38 months. |
| Planned trial sites | We will aim to recruit at least 5 NHS Trusts. Additional Trusts will be recruited if we are unable to achieve our sample size with 5 Trusts. |
| Number of participants | 4,400 |
| Main eligibility criteria | Inclusion criteria |

| | |
|---|---|
| | We will include all hospital staff employed by the Trust who work 60% WTE ( 22.5 hrs per week)[1] or more, adhere to a dress code policy, and work in a clinical, general or catering area. This will include doctors, nurses, ward clerks, porters and cleaners working in the hospital's general and clinical areas. Clinical areas include hospital wards, outpatient clinics, and service users'/patients' homes where clinical activity takes place. A catering area is defined as a place where food is prepared or served. General areas include all clinical and catering areas in addition to the hospital stairs and corridors.<br><br><u>Exclusion criteria</u><br>• are not employed by the NHS<br>• do not have a mobile phone or are unwilling/unable to receive/send text messages<br>• are provided with footwear by their employer<br>• are agency staff, or staff who have less than 6 months remaining on their employment contract<br>• work less than 60% WTE (less than 22.5hrs a week)<br>• are predominantly office or theatre based |

[1] 60% WTE refers to working 22.5hrs a week assuming a full time working week of 37.5 hrs/week, which is the standard NHS full time contract.

Months 0-8

## 2.2 Study Flow Chart

Recruitment to pilot

Potential trial participants at pilot sites are identified as follows:

- NHS staff working in general/clinical/catering areas who adhere to a dress code are given a recruitment pack containing an invitation letter; information sheet; baseline questionnaire; consent form; and a pre-paid envelope addressed to York Trials Unit (YTU).
- Packs are either: sent electronically via the R&D department, given out in the internal post, handed out by the research team or R&D at a recruitment stand in the trust e.g. wards, staff areas, or sent in response to posters or adverts within the Trust.

NHS staff wishing to take part send a completed paper consent form and baseline questionnaire to YTU. Baseline questionnaire contains eligibility questions and collects data on preferred trial shoe style and size.

YTU confirm participant eligibility. Eligible participants are then sent a copy of their consent form, a paper weekly slip diar and up to 4 weekly texts requesting slip and falls data. Participants who do not respond to any text will be sent a letter explaining that 2 additional texts will be sent to them. Participants will be randomised if they respond to at least 2 of the texts sent to them

Eligible participants who respond to at least 2 weekly texts are randomised into the pilot trial; footwear is ordered.

**Intervention Group**

**N = 400**

Group allocation notification text sent with details of when and where to pick up "Shoes for crews" (SFC) footwear

- Monthly text collecting compliance data sent at 6, 10 and 14 weeks post-randomisation
- Qualitative interviews undertaken
- 15 participants return shoes for 'wear' analysis at the Health & Safety Executive, at month 6, 9 and 12 i.e. 45 in total; new shoes provided
- Final compliance and follow-up questionnaire sent at 14 weeks

**Control Group**

**N = 400**

Group allocation notification text sent. Usual footwear worn

Week 8: text notification to say collect your SFC footwear in 6 weeks' time

Participant's sent text with details of how to collect SFC footwear at the end of the 14 week follow-up

- Final compliance and follow-up questionnaire sent at 14 weeks

Participants sent weekly text message requesting slips data (weeks 1 to 14) Participants reporting their first slip are phoned for further information. Attrition rate checked.

Participants sent weekly text messages requesting slips data (weeks 1 to 14) Sample size assumptions checked. Participants reporting their first slip are phoned for further information. Attrition rate checked.

Months 9-22

**Recruitment to the SSHeW main trial**

Potential trial participants at the other NHS Trusts are identified as follows:

- If possible trial runs consecutively in each of the trusts with recruitment over a year to allow for potential seasonal variations in slip rates; or runs concurrently to aid recruitment and to ensure trial completed on time.
- Hospital staff, working in general, clinical or catering areas, who adhere to a dress code, are given a recruitment pack containing an invitation letter; information sheet; baseline questionnaire; consent form; and a pre-paid envelope addressed to York Trials Unit (YTU)
- Packs are either: sent electronically via the R&D department, given out in the internal post, handed out by the research team or by R&D at recruitment stands in the trust e.g. wards, staff areas , or sent in response to posters or adverts within the Trust

NHS staff wishing to take part send a completed paper consent form and baseline questionnaire to YTU. Baseline questionnaire contains eligibility questions and collects data on preferred trial shoe style and size.

YTU confirm participant eligibility. Eligible participants are then sent a copy of their consent form, a paper weekly slip diary and up to 4 weekly texts requesting slip and falls data. Participants who do not respond to any text will be sent a letter explaining that 2 additional texts will be sent to them. Participants will be randomised if they respond to at least 2 of the texts sent to them

Eligible participants who respond to weekly texts for at least 2 out of the 4 weeks, are randomised to the main trial; footwear is ordered.

Participants sent weekly text messages requesting slips data (weeks 1 to 14) Participants reporting their first slip are phoned for further information.

**Intervention Group**
**N = 1800**

Group allocation notification text sent with details of when and where to pick up "Shoes for crews" (SFC) footwear

- Qualitative study to confirm participant acceptability at 2nd trust
- Monthly text collecting compliance data sent at week 6, 10 and 14 weeks post-randomisation
- Final compliance and follow-up questionnaire sent at 14 weeks

**Control Group**
**N = 1800**

Usual footwear worn

Week 8: text notification to say collect your SFC in 6 weeks' time

Participant's sent text with details of how to collect SFC footwear at the end of the 14 week follow-up

- Final compliance and follow-up questionnaire sent at 14 weeks

Participants sent weekly text messages requesting slips data (weeks 1 to 14). Participants reporting their first slip are phoned for further information.

## 2.3 Assessment schedule

| | Baseline | 4 week run in period | Randomisation (Eligible patient + BLQ + I FT) | Weekly data collection | Monthly data collection | 14 weeks post randomisation | Qualitative | Long term follow up 6, 9 & 12 months | End of study |
|---|---|---|---|---|---|---|---|---|---|
| Eligibility screen by researchers at YTU | x | | | | | | | | |
| Informed consent via the post or pop-up shoe shops | x | | | | | | | | |
| Demographic questions: Date of birth, gender, Work related details: job title; contract details; main type of working environment; hours of work | x | | | | | | | | |
| Footwear related details: usual work style shoe, place of purchase, | x | | | | | | | | |
| Personal details: name, address, mobile telephone number | x | | | | | | | | |
| Paper diary for patient to keep at home | | x | | | | | | | |
| Copy of consent form returned to participant | | x | | | | | | | |
| Weekly slips data | | x | | x | | | | | |
| Details of first slip (cause, severity, location, injury, etc) | | | | x | | | | | |
| Notification of group allocation text | | | x | | | | | | |
| Receive footwear (timing depends on group allocation) | | | x | | | x | | | |
| Adherence to wearing new footwear data | | | | | x | x | x | | |
| Randomisation | | | x | | | | | | |
| Adverse events | | | | Ongoing | | | | | |
| Assessment of wear on sole of shoes | | | | | | x | | x | |
| Date of first fall; time of work during study; | | | | | | x | | | |
| Health economics data for participants having a serious injury | | | | | | | | x | |
| Send summary of results | | | | | | | | | x |

## 2.4 LAY SUMMARY

Slips, trips and falls are the main cause of accidents in the workplace. Last year, over 100,000 people hurt themselves as a result of a 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 the people who employ them. 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 slips and trips where they work. Hospital staff are more likely to slip because of the type of flooring they have to walk on. The floors are often smooth as the belief is that this makes them easier to keep clean and reduces the spread of diseases; however, these types of floors become very slippery when they are wet or dirty. Some staff visiting patients at home will have no control over the type or condition of the flooring they walk on. 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.

We will recruit staff working in NHS trusts in both general, clinical and catering areas who have to follow a workplace dress code and who have a mobile phone. These will include doctors, nurses, and ward clerks working both in the hospital and those who visit patients at their homes. Catering staff, cleaners and porters employed by the Trust will also be included. Staff will be sent an information sheet about the study and the contact details of the trial coordinator to ring for further information. Volunteers will be asked to sign a consent form and fill in a baseline questionnaire. We will aim to recruit at least 4,400 participants to the study, and they will have a four week run-in period where they will return weekly text messages to the team. Those who complete the texts will be randomly allocated into one of two groups using a computer program. Participants will either receive one free pair of slip resistant shoes to wear at work or they will be asked to wear their own work shoes for the duration of the trial follow up, but will be offered a free pair of slip resistant shoes when they have finished the study. We will text everyone once a week for 14 weeks post-randomisation to ask if they have had a slip in the last week. We shall define a slip as `a loss of traction in your foot on the floor surface, which may or may not result in a

fall'. The first time a participant reports a slip by text message, they will be telephoned by a researcher to obtain further details of the incident. Participants will be given a paper diary in which to record details of any slips, falls or injuries. Once a month (i.e. three times) we will ask the people wearing the intervention footwear (the intervention group) how often they are wearing them via text message. We will also ask about compliance in the final questionnaire. We will ask some participants to return their footwear so that we can test how worn the soles are.

Our team is experienced in running this type of study. It includes experts in slip and trip prevention, trial methodology and conduct, statistics and health economics. The Cheshire and Wirral Partnership NHS Foundation Trust's Ward Management Task and Finish Group have agreed to act as lay advisors for the study. We will send a summary of our findings to all of the trial participants and NHS Trusts managers where the study was run. We will also publish our findings in scientific journals, conferences and websites.

## 3. Background

Slips, trips and falls are a common cause of injuries in the workplace. In Great Britain (GB) it is estimated that over 100,000 people are injured due to a slip, trip or fall at work each year, and this represents around 18% of all self-reported non-fatal injuries to workers. [1] The injuries resulting from these incidents can have long-lasting effects. Furthermore, it has been estimated that nearly one million days a year are taken off work due to such injuries [2]. People working in health and social care have one of the highest number of non-fatal slips, trips and falls compared with other industries in GB. It is estimated that there are around 14,000 workers a year injured in this industry sector due to trips, slips and falls [3]. This is probably at least partly due to the nature of the flooring on health service premises which is often very smooth so as to be easier to clean than textured surfaces. These floor surfaces can become slippery when contaminated and during cleaning which is undertaken frequently for infection control purposes.

Slip risk and the effectiveness of footwear to mitigate it, are influenced by the slip resistance of the floor surface, the presence of contamination and the characteristics of that contamination, as well as the level and type of pedestrian activity. This proposed study will be undertaken in NHS Trusts. These are a challenging working environment, with predominantly smooth floor surfaces that become slippery when contaminated, where there are multiple sources and types of contamination, and where there is relatively high and varied types of pedestrian activity, e.g. walking, pushing and pulling. Many of the risk factors affecting the healthcare workers participating in the study will be shared by workers in other sectors, such as, retail, hospitality, education and manufacturing.. Whether it is appropriate to provide slip resistant footwear to control the slip risk can only be determined by means of a risk assessment. The findings of this study will help to inform the risk assessment process and the business case for investing in footwear. Many employers already provide footwear to help manage the risk of slips, but a lack of robust testing and reliable information can often lead to inappropriate footwear being selected, and instead of providing a solution, the footwear can add to the problem. This study may help to validate a system by which the slip resistance of footwear can be reliably assessed and gives procurers of footwear the information they need to select footwear with the appropriate level of slip resistance.

## 2.1 Existing research

There is some evidence that the number of slips occurring in the workplace can be reduced through the use of appropriate footwear. An observational study, in the USA, found that the use of slip resistant footwear was associated with a falls reduction of 54% [4]. A before and after study among fisherman suggested slip resistant boots led to a reduction in self-reported slips and falls [5] .. However, it can be difficult to specify footwear with appropriate levels of slip resistance because the standard method by which the slip resistance of footwear is assessed, as described in BS EN ISO 13287:2012, does not accurately replicate the action of a slip and the pass criteria do not reflect biomechanical data on the friction requirements for normal walking activities [6]. This has led some to question the validity of this test to predict pedestrian slip potential [7]. Testing footwear under more lifelike conditions allows a more accurate assessment to be made. This has

helped to inform the selection of footwear by some companies who have subsequently seen a reduction in accidents and personal liability claims. However, these findings are not in the context of a RCT.

## 2.2 Rationale for current study

As noted previously there is promising evidence in a different setting that slip resistant footwear can significantly reduce the burden of accidents at work. However, it is important to confirm these findings in a large pragmatic trial within a UK setting. Hospital environments often have smooth floors which are considered to be easier to clean than textured surfaces, thus minimising the infection risk, but can be slippery when wet or subject to other surface contamination. Therefore, NHS employees are often at risk of slipping in the work place.

The NHS is the UK's largest workforce and so represents an ideal setting in which to investigate whether providing slip resistant footwear reduces slips and falls among staff. The proposed pragmatic randomised controlled trial seeks to establish the effectiveness and cost-effectiveness of NHS Trusts routinely providing slip resistant footwear for its staff who work in a clinical, general and catering environment. The impact of the trial is twofold: first, if the intervention is effective it will reduce the number of work related injuries; second, as a consequence of this reduction fewer lost working days and litigation to the NHS and other industries will occur which will lead to a reduction in costs.

## 2.3 Aims and objectives

The main aim of this study is to establish whether wearing slip resistant footwear will lead to a reduction in the number of slips involving NHS staff working in clinical and catering areas, who adhere to a dress code policy.

### 2.3.1 Primary objective

The primary objective of this research is to assess whether or not the offer of slip resistant footwear to NHS employees working in general, clinical or catering areas will lead to a reduction in the incidence rate of self-reported slips over 14 weeks.

### 2.3.2 Secondary objectives

The secondary objectives of this study are:

(a) To undertake an internal pilot randomised controlled trial to: (i) check the feasibility of the study, including whether it is possible to recruit, randomise and follow up 800 participants; (ii) check the sample size calculation assumptions and the attrition rate; and (iii) explore and address any issues regarding footwear compliance.

(b) To assess whether or not slip resistant footwear will lead to a reduction in the number of falls (both resulting from a slip or not) over 14 weeks.

(c) To assess whether or not slip resistant footwear will lead to a reduction in the proportion of participants who experience a slip, fall or fracture over 14 weeks.

(d) To assess whether or not slip resistant footwear will lead to an increase in the time to first slip or fall from randomisation.

(e) To assess whether or not the provision of the footwear would be cost-effective.

(f) To disseminate the findings of this study using the Health and Safety Executive, NHS Trust managers and Health and Safety managers. This will be in addition to publishing the results of the study in key journals and in a National Institute for Health Research (NIHR) Public Health Research (PHR) report.

## 3. Study design

## 3.1 Study design

SSHeW is a pragmatic two arm, open randomised controlled trial, with an internal pilot, economic evaluation and a qualitative study.

## 3.2 The SSHeW pilot study

During the first six months of the study we will undertake a pilot trial. During this time we will

(a) Test and refine recruitment strategies for the study
(b) Check the sample size calculation assumptions by reviewing the proportion of participants who experience a slip in the control group
(c) Check the attrition rate
(d) Explore and address any issues regarding footwear compliance.

Upon successful completion of the internal pilot we will move seamlessly to the main trial.

In the pilot trial, we will aim to recruit 800 participants. We will use data from these participants to confirm expected recruitment rates, assess attrition and intervention compliance, and calculate the control slip rate. We will readdress the sample size calculation based on these data, and if needed will increase, but not decrease, the target sample size. We will calculate the proportion of participants who experience a slip in the 400 participants recruited to the control group. This sample size will allow us to calculate a 90% confidence interval which would include a 7% slip or fall rate with a 2% margin of error.

We will consult with the independent Trial Steering Committee (TSC) before we start recruitment into the trial to ask for their view on the stop/go criteria for progression to the main trial. We will suggest that in the pilot phase we will:

(1) Recruit at least 400 participants in six months.
(2) 80% of the participants will contribute at least 50% of the follow-up text data (i.e., respond to 7/14 weekly post-randomisation text messages)
(3) 90% will respond to at least one post-randomisation text.
(4) The slip rate in the control group will be at least 7%.

If the TSC consider these too ambitious, we will modify the criteria according to their recommendations.

## 3.3 Identification of sites

The study will be undertaken within NHS Trusts in the United Kingdom. NHS hospitals are useful organisations for this study as they are large and contain many different working environments. Any hospital has a big ecosystem of different 'sub-industries', which will make the trial results generalisable to other industries. For instance, they have large kitchens and staff that work in these are an exemplar of restaurant staff, they have staff working in slippery environments, such as cleaning staff, and these might be similar conditions that exist in food preparation factories. Hospitals have large numbers of portering staff who need to move heavy loads, similar to supermarket staff. Consequently there are few other institutions that have such a broad range of environments as a hospital. Furthermore, staff turn-over is likely to be relatively lower than in many other commercial organisations, thus minimising the loss to follow-up in our study. Finally, hospital staff are more likely to be used to engaging with research and, therefore, are more likely to take part than staff in other organisations.

We will aim to recruit at least four NHS Trusts in the United Kingdom. Cheshire and Wirral Partnerships NHS Trust and Leeds Teaching Hospitals NHS Trust have agreed to run this study in their Trust. Additional NHS Trusts will be identified, by either members of the SSHeW study team, who have contacts with NHS Trusts or via the Clinical Research Network.

## 3.4 Identification of participants

We will recruit 4,400 NHS staff from a variety of professions, who are subject to a Trust dress code, to the study. This will include doctors/consultants, nurses, allied health professionals and ward clerks, working in clinical areas e.g. hospital wards, outpatient clinics and service users or patient's homes where clinical activities take place. It will also include catering staff working in catering areas where food is either prepared or served and porters and cleaners who work throughout clinical, catering and general hospital areas. General area includes all clinical and catering areas in addition to the hospital stairs and corridors.

Potential participants will be given or sent a recruitment pack. The pack will contain an invitation letter, participant information sheet, consent form, baseline questionnaire and a pre-paid envelope addressed to the York Trials Unit (YTU).

The SSHeW study team will work with individual NHS Trusts, to determine the most appropriate way to approach potential participants about the study, within their NHS Trust. This may include the SSHeW team holding 'recruitment days' and giving out recruitment packs to staff, who are potentially interested in taking part in the study, or these may be put in the internal post to staff. In some Trusts the R&D department may wish to assist with the identification and sending out of recruitment packs to staff. R&D staff may request a list of NHS employees from their human resources department, and send them trial information electronically. The study may be further advertised to NHS staff as follows:

- Posters, which will include the contact details of the trial co-ordinator who can be contacted to arrange a recruitment pack to be sent to either their work or home address.
- Details put on the Trusts' intranet or social media pages, and included in Trusts' newsletters subject to local procedures and/or restrictions.
- The trial may be discussed at staff meetings

## 3.5 Declining participation in the study

Participation in the SSHeW study is voluntary. People who do not wish to take part in the study will not have to return any forms to the YTU.

## 3.6 People who wish to take part in the study

Participants who wish to take part in the study will be asked to complete the consent form and baseline questionnaire and return them by post to YTU or hand them to the trial team at the pop-up shoe shop.

### 3.6.1 Assessment of eligibility

Researchers at the York Trials Unit will assess the responses in the returned baseline questionnaire for participant eligibility for the study according to the criteria in section 5.1 and 5.2. If a person is found to be ineligible for the study, for example they are unable or unwilling to provide a mobile telephone number, or work less than 60% WTE (22.5 hrs/week), they will be informed in writing, email or by text message. No further correspondence will be sent to them from the YTU. If there are any data queries in the responses to any of the documentation returned by potential participants, then this will be clarified with the participant. Participants may be telephoned, sent letters, texts, or email. Some R&D Trust staff may assist with resolving data queries.

All eligible, consenting participants will be sent a copy of their signed consent form and a paper diary to record details of slips, falls and injuries as they occur, and any time off work as a result of an injury caused by a slip or fall. They will be sent a welcome text message followed by four weekly text messages requesting slip data. The wording of the welcome text will be as follows, or similar: “Welcome to the SSHeW trial. We very much value your agreement to participate. You will shortly start to receive text messages asking about any slips you have at work. These texts will always come from this number and will begin with the word SSHeW so that you can recognise them. Thank you."

Eligible participants who respond to at least two of the data collection texts requesting data on slips, irrespective of whether they experience a slip, will be randomised into the trial. Equal randomisation to the intervention group or the wait list control group will be implemented. The intervention group will be offered a pair of 5-star GRIP rated slip resistant work shoes by Shoes For Crews®. The control group are expected to wear their usual footwear to work, but will be offered a free pair of 5-star GRIP rated slip resistant shoes provided by Shoes For Crews and paid for by the Trust once their part in the study has ended.

During the pilot phase, it became apparent that some participants had consented to be in the study and provided baseline data, but did not respond to their pre-randomisation texts.

In some cases, this was due to a misunderstanding, as potential participants thought that they only had to reply to texts once they received their trial shoes. In order to ensure these participants are not excluded unnecessarily, participants who have not responded to their pre-randomisation texts, will be sent a letter explaining that two further weekly texts will be sent to them shortly. Participants will be eligible for the study if they respond to two out of the six texts sent to them.

### 3.6.2 Informed consent and completion of the consent form

If respondents require any further information about the study prior to giving their consent they will be able to contact members of the research team based either at the York Trials Unit (YTU) or HSE. Given the nature of the intervention and the fact that this is considered a low risk study, respondents will be able to consent to taking part in the study on the day they receive the trial information. Participation in the study is voluntary. People who wish to take part in the study will be asked to write their name, sign and date the consent form. They will also be asked to initial each of the statements to indicate they agree with them. If, however, a participant mistakenly places a tick or a cross in the boxes, these shall be taken as an indication of consent. Nevertheless, all due care will be taken to ensure that the participant provides consent to take part in the study. If the study team at the YTU has any doubts about whether a person wishes to take part in the study they will telephone, email, text or write to them to confirm. Copies of the consent forms will be stored at the YTU in a locked cabinet in a locked room, with restricted access to the study team only, and in accordance with the YTU Standard Operating Procedures. A copy of the completed consent form will be sent back to the participant.

## 3.7 Assessment of level of wet slip resistance in footwear worn by staff in general

In order to measure and categorise the level of slip resistance offered by footwear currently worn by NHS staff, the HSE team will test a sample of footwear worn by staff at the point that the last of the control participants at the individual sites are given their new footwear. HSE have developed a mobile machine, which can undertake this task. The machine will be

taken into the Trust and staff will be given the opportunity to have their current footwear tested. Written informed consent to test footwear will not be given but they will assent to have their footwear tested. The test takes a few minutes to perform and involves one shoe being placed onto a mechanical foot that pushes the shoe onto a smooth, water contaminated, inclinable surface at a speed and force similar to those generated during walking. The slope of the inclinable surface is increased until the mechanical foot slips. The result can then be used to calculate the coefficient of friction generated between the shoe and the surface. The type of shoe and the measured slip resistance will be recorded. Footwear will be given back to staff, undamaged, immediately after the test.

## 4.8 Pen sub-study

There is some evidence to suggest that including a pen with a postal questionnaire has a positive impact on response rates and number of reminders required [8]. Previous studies however have been undertaken in an elderly female population where questionnaire response rates were over 90%. Participants in the SSHeW study are younger (aged 18 and over) and the response rates to study questionnaires at the time of writing the protocol were approximately 50%. We will undertake an embedded randomised controlled trial in order to evaluate the effectiveness of including a pen with the 14 week follow up questionnaire on response rates to the SSHeW study. Participants will be randomised using simple randomisation in a 1:1 ratio. Generation of the allocation sequence will be undertaken independently by a researcher not involved with sending out the questionnaires. Participants allocated to the pen sub-study intervention group will receive a pen with the University of York/York Trials Unit logo on it with their 14 week questionnaire, whilst pen sub-study control participants will receive no pen.

### *Inclusion criteria*

Any participant who is due to be sent their 14 week follow up questionnaire will be included in the sub-study.

### *Exclusion criteria*

Participants who withdraw from follow-up before their 14 week questionnaire is due, or those who had already received their follow-up questionnaire prior to the start of the pen sub-study will be excluded.

### *Outcome measures*

The primary outcome will be the proportion of participants in each group who return the questionnaire. Secondary outcomes will include time to response (length of time taken to return the questionnaire), completeness of response (the number of questions completed) and whether a reminder notice is required (number of participant requiring a reminder mailing divided by the number of participants who were sent a questionnaire).

### *Sample size for the pen-sub-study*

As is usual with an embedded trial within a trial, no formal power calculation will be undertaken for the study, as the sample size will be constrained by the number of participants sent a 14 week questionnaire. This sub-study was introduced during the recruitment period for the main trial when approximately 2,000 participants had already completed their 14 week follow up; only participants due to be followed up after this point were included in the sub-study.

### *Statistical analysis*

Binary data will be compared using logistic regression, time to response by a Cox proportional hazards model, and completeness of response by a linear regression model. All models will adjust for main trial allocation.

# 4. Eligibility criteria for the SSHeW trial

## 4.1 Inclusion criteria

Potential participants will be included in the study if they fulfil all of the following criteria:

- Are NHS employees,
- Aged 18 years and over
- Are required to adhere to a dress code policy
- Work at least 60% WTE(22.5hrs/week)

- 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). This will include doctors, consultants, nurses, ward clerks, porters and cleaners.
- Have a mobile phone and agree to receive and send outcome data via text messages

## 4.2 Exclusion criteria

We will exclude staff who fulfil any of the following criteria:

- are not employed by the NHS
- do not have a mobile phone or are unwilling/unable to receive/send text messages
- are provided with footwear by their employer
- are agency staff, or staff who have less than 6 months remaining on their employment contract
- work less than 60% WTE (22.5hrs/week)
- are predominantly office based, or theatre based

## 4.3 Primary outcome

The primary outcome in this study is the incidence rate of self-reported slips, not necessarily resulting in a fall or injury, in the workplace over a 14 week period, as reported via weekly text messages. A slip is defined as 'a loss of traction of your foot on the floor surface, which may or may not result in a fall'.

To aid reporting of these events, participants will be given a paper personal weekly diary in which to record if they have a slip or fall, and any resultant injuries. This diary will be sent to them at the start of the study. A fall will be defined as 'an unexpected event in which you come to rest on the ground, floor, or lower level'.

## 4.4 Data collection for the primary outcome for the trial

Data will be collected via text messages, sent to/from the participant. Participants will be sent one weekly text message with the following content (or similar):

*"SSHeW trial: How many slips did you have at work between DD/MM/20YY and DD/MM/20YY? Please provide a single number (e.g. 2) or 0 if you did not slip. Thank you."*

An explanation of what the researchers consider to be a slip and a fall will be included in the participant information sheet and included on the calendar participants are provided with at the start of the trial.

## 4.5 Secondary outcomes

In addition to weekly text messages, participants will be sent a questionnaire at the end of their follow-up to collect data on compliance with the footwear and reasons for wearing/not wearing the shoes (directed at intervention participants only), whether participants have had time off work (annual leave or sick) during the follow up period, and to ask how many slips and how many falls they have had at work in total over the previous 14 weeks. This will allow us to potentially collect data from participants who have failed to respond to the weekly text messages. We will also use this questionnaire to collect details of date of first fall, any injuries sustained as a result of a slip or fall at work, consequences of these injuries (e.g., hospitalisation, days off work), and resource use).

Secondary outcomes include:

- The incidence rate of falls resulting from a slip in the workplace over 14 weeks
- The incidence rate of falls not resulting in a slip in the workplace over 14 weeks
- Proportion of participants who report a slip over 14 weeks
- Proportion of participants who report a fall over 14 weeks
- Proportion of participants who report a fracture over 14 weeks (numbers permitting)
- Time to first slip
- Time to first fall
- EQ-5D-5L
- Cost-effectiveness

Other important information collected includes:

- Reason for slip/fall, location of fall, type of flooring and if wet or dry, consequence of slip/fall i.e. superficial wound (bruising sprain, cut, abrasions), fractures and type of fractures; severity of fall; type of footwear worn at time of slip/fall
- Number of days off work, due to the slip or fall
- Footwear worn at time of first slip
- Number of hospital admissions
- Number of days in hospital
- Compliance and reasons for non-compliance
- Any minor injuries resulting from ill-fitting shoes
- Style of footwear worn
- Wear on soles of 45 intervention shoes at six, nine and twelve months post randomisation
- Slip resistance of a sample of the current footwear worn by NHS staff

## 4.6 Data collection for secondary outcomes

After the first reported slip from the weekly text messages, participants will receive either a letter or a telephone call from the YTU team who will collect additional information about the incident. This will include date and type of incident (slip without falling, slip and fall), where the slip occurred, type of floor covering, consequence of the slip e.g. superficial would (bruising, mild swelling, cut, abrasions), muscle/ligament strain or sprain, fractures – including type, hospital admissions, days off work, what footwear was being worn, and EQ-5D-5L. A reminder letter may be sent to participant who have not returned their questionnaire after two weeks.

Intervention participants will be sent a text message to collect data on compliance with the footwear at 6, 10 and 14 weeks post-randomisation. The wording of the compliance text will be similar to the following 'SSHeW trial. In the past month, how often have you worn your

trial shoes at work? Reply 0, 1 or 2 (0=none of the time, 1=some of the time, 2=all of the time).

In order to assess the typical service life of the footwear we will ask 45 intervention participants who have reported wearing their trial footwear, to give their trial shoes to the Health and Safety Executive researchers, so that an assessment of wear can be undertaken. Some participants will be asked to return their shoes at approximately six, nine and 12 months after they were randomised (15 participants at each time pint). These participants will be offered a free replacement pair of shoes. The slip resistance of the worn footwear will be assessed and the resulting co-efficient of friction will be compared with that generated by new intervention footwear and known standards for assessing slip risk.

## 4.7 Participant withdrawal

Participants can withdraw from the trial at any point during the course of the study by directly contacting the trial coordinator at the York Trials Unit. If a participant indicates that they wish to withdraw from the study, they will be asked whether they wish to withdraw from the intervention only (i.e., withdrawal from wearing trial shoes) or withdraw fully from the study. Where withdrawal is only from the intervention then follow-up data will continue to be collected. The reason for the participant wishing to withdraw from the study will not have to be stated, however, if the participant indicates the reason this will be recorded. Data provided by participants who withdraw will be retained for analysis.

## 4.8 Randomisation

Participants who fulfil the eligibility criteria, provide written consent to take part in the study, complete a baseline questionnaire and return at least two, weekly texts providing slips data, irrespective of whether they report a slip, will be eligible for randomisation. 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. There will be no limit to the size of the block use. This will be dependent on the number of participants to be randomised at the time. Participants will be allocated 1:1 to either the intervention group, to receive a free pair of slip resistant footwear or the control group who will be asked to wear their own work footwear for the duration of the study, and offered a free pair of slip resistant shoes after completing their follow-up. Participants will be randomised at a particular site in batches, according to when sites state they have capacity to order and deliver footwear. Participants will be notified of their group allocation by a text message, email and/or letter from the York Trials Unit. We anticipate that the intervention group will receive their shoes two weeks post-randomisation.

## 4.9 Blinding

Blinding of participants to group allocation will not be feasible, nor is blinding of the members of the study team who are actively involved in the administration of the study, the statistician or health economist. Data entry staff will be blind to group allocation.

## 4.10 Usual care group

Participants allocated to the control group 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.

We are aware that there is the potential for control group participants to purchase and wear the shoes being evaluated in the trial, as the footwear is commercially available. We believe the likelihood of this happening will be minimised by the fact that control participants will be offered a free pair of trial shoes, when their participation in the study has ended. This information will be clearly stated in the study information sheet and control participants will be sent a text six to eight weeks after randomisation, reminding them that

they will receive their new 'Shoes for Crews' footwear at the end of follow-up'. The wording of the text will be similar to the following " SSHeW trial:Thank you for your continued participation in this study. You will be contacted in about 10 weeks' time about collecting your trial shoes'. The duration of the study was kept relatively short to specifically avoid the potential problem of cross-over and this was recommended by our PPI group.

It is possible that participants in the control group are already wearing what some would class as slip resistant footwear. The baseline questionnaire will request details of their current footwear style, brand and place of purchase which will indicate if contamination of the control group has occurred. In addition, concerns have been raised about the mechanical tests previously used to classify the slip resistance properties of shoes. The scientific community now question whether this type of test can predict slip potential. The Health and Safety Executive (HSE) have refined the method used to classify slip resistance and have produced a new GRIP rating scheme for footwear, which uses rigorous scientific testing to measure and grade slip resistant footwear. Footwear is rated on a scale of 1 to 5 stars (with 5 stars being the highest rating) which helps manufacturers objectively distinguish the performance of the slip resistant properties of the footwear. Since the GRIP scheme is new, to date only a few manufacturers have signed up to the scheme and had their footwear rated. It is therefore unlikely that the control group will be wearing footwear which has a 5-star GRIP rating.

## 4.11 Intervention

The trial interventions are 5-star GRIP rated slip resistant footwear provided by 'Shoes for Crews' free of charge to the participant. The footwear intervention has been identified through the use of the HSE GRIP Scheme (www.hsl.gov.uk/products/grip), which measures and categorises the level of wet slip resistance offered by footwear. The 5-star rating is the most effective footwear available. This testing is not part of the normal certification procedure for occupational footwear, but has been shown to be an effective way to differentiate between footwear with remarkably different slip resistance.

Participants will receive one free pair of shoes, which will be selected from a catalogue specifically designed for the trial and produced by Shoes for Crews in conjunction with the trial research team. Footwear will not be selected directly from the website as some footwear such as trainers with webbing may be deemed unsuitable for a healthcare setting as they may pose an infection risk. In order to assist with the fitting of the footwear advice provided on the Shoes for Crews website (http://www.sfceurope.com/uk/Footer-Links/About-Us/Shoe-Sizing-Tipsa) will be followed. A measuring guide may also be used to assist with the process.

The participating NHS Trust will order and pay for the footwear directly from the company 'Shoes for Crews'. The company have agreed a free sale and return policy for participants who need to exchange footwear that does not fit or is uncomfortable. Replacement footwear can be sent either to the participant's place of work, or home address, according to the participant's preference. Footwear will be delivered to a designated place at the NHS trust for participants to pick up from their place of work. Posters reminding staff to wear their new footwear may be placed in staff areas.

# 5. Data collection

## 5.1 Quantitative data collection

We plan to randomise eligible participants four weeks into the run-in period. Participants will then be asked to continue replying to their weekly slip text messages for a further 14 weeks. We anticipate that a 14 week follow-up will ensure enough time for the shoes to be ordered, delivered and collected and still allow for at least 12 weeks exposure to the intervention (i.e. wearing the shoes for the intervention group).

Demographic data on the following will be collected at baseline: age, gender, average number of hours worked per week, time spent on feet at work, working environment e.g. ward/clinical/office based, description of current job role or profession, history of slipping/falling, height, weight, ethnicity and education, type of footwear worn at baseline, and how long work shoes normally last.

Participants in the intervention group will receive a monthly text requesting compliance data. All participants will be sent a final questionnaire at 14 weeks post randomisation to collect data on compliance with the footwear and reasons for wearing/not wearing the shoes (intervention participants only), and for secondary outcome data collection (all participants). A reminder will be sent to participants that have not responded, two weeks after the questionnaire is due by either letter, email or text.

We will ask approximately 45 participants to attend the pop up shoe shop at the end of follow-up, so that we can evaluate the wear on the sole of the shoes.

## 6.2 Qualitative data collection

### 6.2.1 Qualitative sample

We will purposively select a sample of 30-40 intervention participants, who have completed follow-up, partial and non-adherers (as indicated by their follow-up data) across clinical (e.g., nursing/medical staff) and non-clinical specialties (cleaning/portering staff) for a brief telephone interview. Potential participants, who have expressed a willingness to take part in a qualitative interview about their experiences about being in the study, will be sent a participant information sheet (specific to the qualitative component of this study) and a consent form (to take part in the telephone interview) by members of the research team at the York Trials Unit. In addition we may ask the research teams at participating Trust sites to help identify potential participants to interview. Research staff are in a good position to do this as they have had contact with trial participants through the day to day running of the trial and also work among the trial participants at the NHS Trusts. The research staff in the Trust will send a list of ID numbers of potential participants to the study team at the York Trials Unit using the University of York DropOff system or other agreed secure method of transferring data. Participants sent an invitation will be followed-up by telephone call, email or text message and, if they are willing to take part, an interview will be arranged at a date and time convenient to the participant. To thank participants for their time, those who complete a telephone interview will be sent a £20 high street shopping voucher. During the interview we will explore acceptability of the footwear, reasons for wearing or not wearing

the footwear and views on the impact of the footwear including unintended consequences. We will also explore any contextual influences on the acceptability of the footwear. For instance, are there certain staff groups for whom it is difficult to store the footwear at work (e.g., absence of personal lockers). We will also interview relevant health service managers, at least one per site, regarding the contextual influences on the use of the footwear.

Semi-structured interviews, with participants will be conducted over the phone, after they have worn their study shoes for at least a month. The maximum variation sampling approach will ensure a collection of a wide range of views [9]. Interviews will be conducted using a topic guide to ensure consistency – although the format will be flexible in order to allow participants to generate naturalistic data on what they see as important.

### 6.2.2 Qualitative analysis

All interviews will be audio recorded digitally and transcribed verbatim. A computer package such as ATLAS-ti or Nvivo may be used to manage the data. Initially following transcription the data will be analysed using the constant comparison method through thematic coding of the data [10]. Coding will take place using a combination of prior themes and emergent themes. Negative cases will be actively sought throughout the analysis and emerging ideas themes modified in response [11]. Integration of these interview findings with the quantitative data collected in the acceptability questionnaire will be done using a 'triangulation protocol' [12]. This will be done at the data interpretation phase, [13] the data having first been analysed independently. A convergence matrix will be created to display the quantitative and qualitative findings to maintain a sharp focus on the relevance of findings to evaluating the mechanisms of impact for the intervention..

## 7 Statistical considerations

### 7.1 Sample size

There are limited published data on which to base a sample size for this trial. A prospective cohort study [4] found that 49 of 422 workers in a restaurant setting in the USA reported at

least one “major” (i.e. resulting in a fall and/or injury) slip over a 12 week follow-up period. We therefore expect that the proportion of workers that experienced any type of slip to be higher than this, though the exact figure is not reported. For our sample size calculation, we require an estimate of the proportion of individuals in the control group that will experience at least one slip over a 14 week follow-up period; we have conservatively assumed a proportion of 10%. We propose to recruit and randomise 4,400 participants using a randomisation ratio of 1:1 (i.e. 2,200 per group). This sample size will give us 90% power to show a 30% relative reduction in the proportion of participants that report at least one slip over a 14 week period (3 percentage point absolute reduction from 10% to 7%) allowing for 20% attrition. It will give us 80% power to see an absolute reduction of 2 percentage points in the risk of falls from 5.5% to 3.5% [4] also allowing for 20% attrition. Although we have based the sample size calculation on detecting a difference in proportions, the primary outcome is the incidence rate of slips over the 14 weeks and so we propose to use a mixed effects Poisson or negative binomial regression model, as appropriate, to compare this outcome between the two groups, which we anticipate will remain adequately powered.

## 7.2 Statistical analysis for the main SSHeW trial

There will be two analyses. A descriptive analysis of the internal pilot data and a single effectiveness analysis of the main trial data at end of follow-up of all participants. All analyses will be conducted in STATA v15 or later (StataCorp, 4905 Lakeway Drive, College Station, Texas 77845 USA). Analyses will be described in detail in a Statistical Analysis Plan drafted by the study statisticians and reviewed by the Trial Steering Committee. It will be signed by the Chief Investigator and the study statisticians prior to the analysis being undertaken. The main planned analyses are summarised below.

The trial will be reported according to the CONSORT guidelines for clinical trials (Consolidated Standards Of Reporting Trials statement (http://www.consort-statement.org/). Baseline data (sex, age, job role, etc.) will be summarised descriptively overall and by randomised arm, both as randomised and as included in the primary analysis. No formal statistical comparisons of baseline data will be undertaken between the trial arms. Continuous measures will be reported as means and standard deviations whilst

categorical data will be reported as counts and percentages. Data will be processed and stored according to the University of York, York Trials' Units Standard Operating Procedures. Analyses will be conducted following the principles of intention-to-treat with participant's outcomes analysed according to their original, randomised group, where data are available, irrespective of deviations based on non-compliance, unless otherwise stated.

## 7.3 Primary outcome for the main SSHeW trial

Although we have based the sample size calculation on detecting a difference in proportions, the primary outcome is the incidence rate of slips over the 14 weeks of follow-up and so we propose to use a mixed effects Poisson, or negative binomial, regression model (as appropriate depending on the presence of over-dispersion) to compare this outcome between the two groups, which will give us a more powerful analysis. The regression model will adjust for pertinent baseline covariates such as gender, age, job role, and baseline slip rate ascertained from the run-in period. NHS trust will be included as a random effect to account for potential clustering by recruitment site. The number of weeks for which the participant provided weekly slip data and the number of hours worked in those weeks will be accounted for in the model. Point estimates in the form of an incident rate ratio and their associated 95% confidence intervals will be provided.

## 7.4 Secondary Outcomes for the main SSHeW trial

All secondary outcomes and other important collected data will be summarised descriptively overall and by trial arm.

The incidence rate of falls (both resulting and not resulting from a slip) over 14 weeks will be analysed in the same way as described above for slips. The following outcomes will be analysed using a mixed effects logistic regression adjusting for the same covariates as the primary analysis and NHS trust as a random effect: (i) the proportion of participants who slip at least once over 14 weeks; (ii) the proportion of participants who fall at least once over 14 weeks; and (iii) subject to a sufficient number of events, the proportion of

participants who experience a fracture over the follow-up over 14 weeks. Odds ratios and their associated 95% confidence intervals will be provided.

Time to first slip and the time to first fall will be calculated. Participants who do not report a slip or fall will be treated as censored at their date of trial exit (completion of follow-up or withdrawal). The proportion of participants yet to experience a slip/fall will be summarised by a Kaplan Meier survival curve for each group. Time to slip/fall will be analysed using Cox Proportional Hazards regression, with shared centre frailty and adjusting for the same covariates as in the primary analysis model. Hazard ratios and their associated 95% confidence intervals will be provided. The proportional hazards assumption will be evaluated using Schoenfeld residuals.

### 7.5 Subgroup analyses

We will consider whether the intervention affect differs by gender by repeating the primary analysis including gender and an interaction term between gender and group allocation.

### 7.6 Missing data

The amount of missing data will be reported for each randomised arm, and we will also compare the baseline characteristics of participants who are included in the primary analysis to ensure that any attrition has not produced any imbalance in the groups in important variables. To account for any possible selection bias, a logistic regression will be run to predict non-response (no outcome data received during follow-up) including all variables collected prior to randomisation. The primary analysis will then be repeated including as covariates all variables found to be significantly predictive of non-response to determine if this affects the parameter estimates.

### 7.7 Intervention adherence

A Complier Average Causal Effect (CACE) analysis to assess the impact of compliance on treatment estimates will be undertaken. CACE analysis allows an unbiased treatment

estimate of, in this case, the incidence rate ratio of slips between the two groups in the presence of non-compliance with the shoes. It is less prone to biased estimates than the more commonly used approaches of per protocol or 'on treatment' analysis as it preserves the original randomisation and uses the randomisation status as an instrumental variable to account for the non-compliance.

## 7.8 Economic Analysis

The health economic evaluation will aim to establish the cost-effectiveness of slip resistant footwear in terms of preventing falls/slips. The economic evaluation will be undertaken in the form of a cost-utility analysis (CUA). It will be conducted from a societal perspective but will also distinguish costs which directly draw on the NHS budget. The trial Health Economist will write a detailed analysis plan prior to any analysis being conducted. This will be reviewed by the TMG and TSC/DMEC and signed by the Chief Investigators and the Health Economist.

The analysis will estimate total net intervention costs, accounting for (i) implementation costs, primarily footwear purchase costs; and (ii) avoided costs arising from the change in slip rates observed in the trial (reductions in: lost working time due to absenteeism; medical treatment costs; and compensation and legal costs).

We will use data collected during the trial on the consequences of slips, such as type of injury, duration of time off work, time spent in hospital, and model the effectiveness of the intervention beyond the 14 week time horizon of the trial. With the agreement of the participant we will collect long term follow up data on the health state (EQ-5D-5L), healthcare resource use, and absence from work, once a month after the 14 week final follow up, on participants reporting an injury. If the participant reports an injury between randomisation but before the 14 week questionnaire, then EQ5D-5L data, information about whether the participants considers they have recovered from the injury and number of days ago they recovered will be collected. Data collection will stop when the injury has resolved, the participant no longer wishes to be contacted or the trial ends. The duration of

modelling will depend on the expected lifetime of the footwear. We will gather information on this by asking 15 pilot participants to continue to wear their trial shoes for a further six, nine and 12 months (45 participants in total) and then assess the wear of these shoes. This will inform the modelling period used for the economic evaluation. In order to help identify which participants we will invite to have their shoes tested for wear, and to provide further information about the long-term use of the shoes, we will send out an additional questionnaire to intervention participants. This will be sent approximately 18 months after the first participant was randomised into the study. The questionnaire will collect data on how long they have worn their shoes in the past 4 weeks, and if they would be willing to have their shoes tested for wear.

Table 1 provides an overview of data sources for each of the impacts that will be assessed in the economic evaluation. We will be able to complement this with data from the Health and Safety Executive's Costs to Britain of workplace fatalities and self-reported injuries and ill health ('Costs to Britain') model, which is an established framework used to estimate the economic costs of workplace injuries and ill health for the purposes of annual National Statistics publications and regulatory impact assessments (http://www.hse.gov.uk/research/rrhtm/rr897.htm).

Table 1 Data sources for economic evaluation

| **Impact** | **Data required** | **Data source** |
|---|---|---|
| *Intervention costs* | | |
| Footwear purchase costs. At the societal level, the purchase of the intervention footwear will displace the purchase or wear of other footwear, so additional costs are likely to be minimal. | Pairs of footwear distributed, unit cost of footwear, effective lifetime of footwear. | Purchase costs already known. Data on effective lifetime of footwear to be collected during follow up of 45 trial participants. |
| Managerial and staff time incurred in distributing footwear and communicating the | Given that the NHS already has dress requirements and provides staff uniform, we expect that any additional staff time incurred in rolling out the slip-resistant footwear will be negligible, so we do not propose to quantify this impact. | |

| Impact | Data required | Data source |
|---|---|---|
| intervention | | |
| Avoided costs (benefits) | | |
| Loss of productivity/output due to worker absence. Loss of 'production' (in terms of services provided) to the NHS is likely to be minimised where hospitals recruit agency/bank staff to temporarily replace absent workers. The main costs to the NHS from worker absence would therefore be the costs of replacement agency/bank staff.<br><br>At the societal level, a worker unable to work due to injury represents a reduction in the productive capacity of the economy. | Number of full-time equivalent working days lost due to slip-related injuries by type of worker. Average daily costs of agency / bank workers by role (including agency fees) | Trial data on reduction in slip injuries and full-time equivalent days lost, supplemented by data from the Labour Force Survey on working days lost due to slips, trips and falls in the healthcare sector .<br><br>Maximum rates for agency wages published by NHS Improvement. Pay rates for bank staff published by NHS Trusts. |
| | | |
| Staff sickness payments made to workers absent due to slip-related injury. This is not a cost at the societal level, since the payments are a transfer from employer (NHS) to employees. | Expected reduction in injuries resulting from slips in the NHS (using data from trial or modelled as discussed later in this protocol), the reduction in time off work associated with these avoided injuries, and NHS occupational sick pay policy (the trial excludes temporary / agency staff).<br><br>Average daily staff costs (wages plus non-wage costs, such as national insurance and pensions contributions). | Trial data on full time-equivalent days lost as above.<br><br>NHS occupational sick pay policy is set out in the NHS Terms of Conditions and Service Handbook. This will be used to model sickness payments based on time off work and staff wage rates.<br><br>NHS staff wage rates by job band publically available. Supplemented by data from the Annual Survey of Hours and Earnings (ASHE) and the ONS/Eurostat Labour Costs Survey (for non-wage costs). |
| Healthcare treatment costs incurred due to slip-related injuries | Healthcare resource use, unit healthcare treatment costs. | Data on healthcare resource use to be collected in the study trial (14-week questionnaire). This will be costed using NHS Reference |

| Impact | Data required | Data source |
|---|---|---|
| | | Costs unit costs database. Supplemented where necessary by published data on healthcare treatment costs for relevant injury types from published sources where available. and HSE 'Costs to Britain' estimates of healthcare treatment costs for injuries. |
| Compensation (including legal) costs, arising from staff claims following injury under the NHS Liabilities to Third Parties Scheme (LTPS).. At the societal level, the analysis will account for the transfer payment from staff claimants via the scheme. | Average compensation costs to NHS per case due to slip related injuries. This will be based on historical data as any claims from injuries sustained during the trial period are unlikely to be determined before the completion of the study | NHS Resolution data on non-clinical compensation claims and payments under the NHS Libilities to Third Parties Scheme (LTPS) arising from slip-related staff injuries.. |
| Administrative costs – reporting of slip injuries (RIDDOR), processing sickness payments, dealing with insurance and compensation claims | Amount of staff time spent processing payments, claims etc, plus wage rates of staff. | This is likely to be a small, if not negligible, impact. Could be valued using generic estimates from HSE Costs to Britain model of the typical costs per injury case. |

The costing framework applied will ensure that transfers between groups are accounted for (for example, sickness payments), and that costs are not double-counted.

It is anticipated that avoided costs will be driven primarily by avoidance of slips resulting in injury. An estimate from Labour Force Survey data shows that the injury rate from 'slips, trips and falls' in SIC 86 the 'Human Health Activities' is 0.46 % (95% C.I. 0.38% - 0.55%, averaged 2008/09-2016/17). The rarity of injurious events means that it is likely we will need to model the impact of falls reduction on fall related injuries; data collected from the trial study is likely to be insufficient to enable us to infer a relationship between slips and injuries. Given that the study is unlikely to provide statistically significant results on the change in the injury rate or types of injuries, a central scenario will be to assume that the change in injury rate is commensurate with the observed change in slip rate (i.e. 30% fall in

slips results in 30% fall in injuries, and a 30% reduction in across all injury types/severities). To facilitate this analysis, we will complement the data
collected during the survey with national data on slips reported the Labour Force Survey, which are held by HSE under licence from the Office of National Statistics. The LFS provides nationally representative data on self-reported injuries, including the severity of injuries, measured by time off work.

To enable a cost-utility analysis to be undertaken, we will collect EQ-5D-5L data from participants who report an injury and will produce health state profiles, which we will be converted to utility scores using published NICE/EuroQol 'standard tariffs' [14]. We will validate this where possible, with published studies on the health-related quality of life effects of comparable injuries. We will compare this with age/gender population level data of EQ-5D scores to derive the utility loss associated with slip-related injuries. This will enable the standard cost per QALY measure of cost-effectiveness to be derived. We feel it too onerous and costly to collect EQ-5D from the total trial population as is usual in a trial based economic evaluation, as the vast majority of the participants are healthy and working, will not have an injury, and will return a high utility score. It is proportionate therefore to use existing general population data from published sources.

Two 'threshold' tests will be undertaken:
1. The change in injury rate required to achieve a cost per QALY equal to the NICE threshold of £20,000 to £30,000; and
2. The 'break-even' change in injury rate from the perspective of NHS costs.

The analysis will produce the following results:

- Total net intervention costs (implementation costs minus avoided costs) to the NHS and to society.
- Cost per QALY gained, from both NHS budget and societal perspective.
- Threshold tests, as above.

## 7.9 Definition of the end of the trial

The end of the study is defined as the date when the last randomised participant is due to respond to their 14 week follow up text message. The trial will be stopped prematurely if:

- Funding for the trial ceases
- The Trial Steering Committee recommends it
- It is mandated by the Research Ethics Committee or University of York's Research Governance Committee
- It is mandated by the University of York's, Department of Health Sciences Research Governance Committee

The University of York's Department of Health Sciences Research Governance Committee Research Ethics Committee will be notified in writing if the trial has been concluded or terminated early.

# 8. Adverse Event Reporting

## 8.1 Adverse Events (AEs)

This study will record and report only details of any serious adverse events (SAEs) that are required to be reported to the Health Research Authority (HRA) i.e., events which are related to taking part in the study and are unexpected. Non-serious adverse events will not be recorded or reported for this study unless they are related to being in the study or are related to the intervention.

The most common Adverse Event likely to occur within this study relates to falls and slips, which are being recorded as an outcome measure of the trial. If a participant has a fall or slip, an AE form will not be completed as data are collected elsewhere.

## 8.2 Definition of Serious Adverse Events

For this trial a Serious Adverse Event (SAE) is defined as any untoward occurrence that:

(a) Results in death

(b) Is life threatening

(c) Requires hospitalisation or prolongation of existing hospitalisation

(d) Consists of a congenital anomaly or birth defect; or

(e) Is otherwise considered medically significant by the investigator

## 8.3 Expected Events

It is expected that some participants may experience minor injuries resulting from ill-fitting shoes. This may include: blisters, corns, calluses, foot pain, athlete's foot, in grown toe nails, and general foot pain/discomfort. Occasionally, ill-fitting shoes can cause more persistent foot complaints such as: plantar fasciitis, Morton's neuroma, bursitis or capsulitis which will present as pain and sometimes numbness in the toes: this will require a change of footwear to alleviate the symptoms and heal the injured area. Structural changes over time can also occur from ill-fitting footwear, for example; flat foot or toe deformities such as retracted/hammer/claw/mallet toes and bunions. The person is likely to experience pain/discomfort and discontinue use of the footwear before these structural foot complaints can take effect. It is worth noting, that the participant may also already have these foot deformities for which the shoe style will need to accommodate their altered foot shape. If they are not easily accommodated with the appropriate style of shoe, we can expect that minor injuries will occur and similarly, discontinuation of the footwear required. It is expected that some participants will slip, trip or fall during the trial. As a result of such events, participants may require medical treatment, for example treatment of sprains, damage to ligaments, tendons or muscles, or fractures, and may require time off work. In rare cases participants may require hospitalisation or in extremely rare cases, may be permanently injured or die as a result of a fall or slip.

It is also expected that there may be incidents of hospitalisations, illnesses, disabling/ incapacitating/ life-threatening conditions, aging-associated diseases (such as cancer, cardiovascular disease, diabetes, arthritis, osteoporosis, dementia) and other common illnesses such as depression, and rarely deaths in the study population, such events which are deemed unrelated to the study, will not be reported.

### 8.4 Definition of a related event

An event is defined as 'related' if the event was due to the administration of any research procedure. An 'unexpected event' is defined as a type of event not listed in the protocol as an expected occurrence. The relatedness of an event will be reviewed by the Chief Investigator and the Trial Steering Committee.

### 8.5 Reporting adverse events

Details of any SAEs reported to the York Trials Unit by the participant which are related and unexpected, will be recorded using a trial adverse event form. The AE reporting period for this trial begins as soon as the participant consents to be in the study and ends approximately 14 weeks after they are randomised i.e., after they are sent their final data collection text message. Adverse events will continue to be collected for participants who agreed to long term follow up, and continue to wear their study shoes. For those participants who are not randomised, the reporting period will end once the participant is informed that their participation in the study has ended.

The following events will not be recorded or reported:

- Hospitalisation that was planned prior to entry into the study
- Hospitalisation that cannot be attributed to taking part in the study
- Prolongation of an existing hospitalisation due to social reasons
- Pre-existing conditions (i.e., a disorder present at the start of the study)

## 9. Trial monitoring

### 9.1 Site monitoring

Site monitoring visits for this study will not be undertaken on behalf of the sponsors since:

(a) the eligibility for the study is undertaken by review of potential participant's self-reported data by researchers based at the York Trials Unit

(b) consent is taken via the post

(c) the majority of source data for this study is patient self-reported data, provided participants who complete either questionnaires or falls calendars

(d) data on adverse events will collected via participant self-report data sent to the York Trials Unit.

Participating sites may be asked to assist in trial related monitoring when required for example audits, ethics committee review and Research and Development regulatory inspections.

### 9.2 Standard Operating Procedures

The study will be run in accordance with the University of York, Dpt Health Sciences, York Trials Unit's Standard Operating Procedures.

## 10. Service User Involvement

Members of Cheshire and Wirral Partnership's NHS Foundation Trust's Ward Management Task and Finish Group have agreed to act as the Service user group for the study. The group consist of approximately 20 ward managers who meet every other month. Members of the SSHeW research team will attend the Task and Finish Group's meeting, requesting service user input, on a minimum of three occasions: before the start of the study, during the course of the study, and near the end of the study. The meetings will be held at times when input from the group is most needed in order to optimise their involvement with the study.

They will be asked to provide input to all elements of the research study, including the design of questionnaires and finalisation of the trial methods. In particular, their help will be essential in assisting with the production of and reviewing all patient information, including the participant information sheet, informed consent forms, and any dissemination activity that results from the study. The training needs of the group will be assessed so that tailored training can be arranged if required. Input from the group will help with the setup and conduct of the study, and provision of the footwear at sites thereby helping to minimise any delay in undertaking the study. Minutes of the service user involvement group will be sent to the Trial Steering/Data Monitoring and Ethics Committee.

# 11. Ethical issues

We do not consider that there are any ethical issues with this study. Participation in the study is voluntary. Participants will be able to withdraw from the study at any point without prejudice by contacting the trial coordinator. Participants taking part in the study are required to wear slip resistant footwear as part of their dress code. Intervention participants will be given a pair of shoes once randomised and will be able to keep them after the trial. Control patients will be provided with a pair of the shoes once their part in the study is completed. Footwear will be provided free of charge to both the intervention and control participants. Those participants who give their footwear to the study team to allow the wear on the sole to be tested will be provided with free replacement footwear.

Whist this study will be conducted in the NHS, as the participants in this study are NHS staff, NHS Research Ethics approval for the study is not required. However, ethical approval for the study will be sought from the University of York, Department of Health Sciences, Research Governance Committee.

## 11.1 Obtaining consent

Participation in the study will be entirely voluntary. Potential participants will be given/receive an information pack. The pack will contain an invitation letter, participant information sheet, a consent form, baseline questionnaire and pre-paid envelope. Potential participants will be given the York Trials Unit trial coordinator's or HSE's trial coordinator's telephone number to phone if they have any queries about taking part in the study. The qualitative researcher will obtain informed consent from the participant for the qualitative part of the study. Written informed consent to have non-trial footwear tested for assessment of slip resistance will not be obtained, but assent will be obtained.

Due to the nature of the intervention of the pen sub-study it will not be possible to ask participants to give their informed consent to enter the study. However, we do not consider this to be a major ethical issue.

Notwithstanding the above, from the 25th May 2018 personal data and special category personal data will be processed in connection with this study under the legal bases of Article 6(1) (e) and Article 9(2) (j) of the General Data Protection Regulation (GDPR), respectively for processing for the performance of a task carried out in the public interest, and as necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, with Article 9(2) j operating in conjunction with the safeguard requirements set out in Article 89(1) of the GDPR.

## 11.2 Anticipated risks and benefits

This study does not involve any invasive/potentially harmful procedures and is therefore considered low risk for participants. It is possible, but unlikely, that slip resistant shoes may increase the risk of slips, trips or falls which may result in minor injuries. However, all of the existing evidence suggests that the opposite will occur with a reduction in slips and falls.

As well as potentially reducing the risk of injury the intervention participants will retain the trial footwear whilst the control participants will be offered a pair of the intervention shoes when they complete the trial.

## 11.3 Informing participants of anticipated risks and benefits

The participant information sheet will provide information about the possible benefits and anticipated risks of taking part in the study. Participants will be given the opportunity to discuss participation with the trial manger or trial support officer prior to consenting to participate. Participants will be informed of any new information which comes to light that may affect their willingness to participate in the study.

## 11.4 Retention of study documentation

All data will be stored for a minimum of five years after the end of the main analysis of the trial in accordance with the current York Trials Unit's Standard Operating Procedures. All paper records will be stored in secure storage facilities. Personal identifiable paper records will be stored separately from anonymised paper records. All electronic records will be stored on a password protected server within the York Trials Unit.

# 12. Oversight

## 12.1 Sponsorship

The University of York will act as the sponsor for the study.

## 12.2 Indemnity

The University of York will provide legal liability cover for their employed staff. Non negligent harm will not be covered.

## 12.3 Funding

Research funding has been secured from the National Institute of Health Research (NIHR) Public Health Research Programme (PHR) and the Health and Safety Executive.

## 12.4 Independent Steering Committee

Due to the low risk nature of this study, approval has been sought from the funders to set up one Independent Steering and Monitoring Committee to undertake the roles traditionally undertaken by the TSC and the DMEC. This committee will comprise of an Independent Chair who will be a clinician with expertise in falls prevention, a statistician, a podiatrist, a member of the Patient Reference Group, the Chief Investigator and Trial Coordinator/Manager. Other study collaborators may also attend the meeting. The role of this committee will include the review of all serious adverse events which are thought to be

treatment related and unexpected. The committee will meet at least annually or more frequently if the committee requests.

### 12.5 Trial Management Group (TMG)

A TMG will be set up. It will consist of the Chief Investigator (who will be in overall charge of the study), the trial manager (who will be in charge of the day-to-day management of the study); the study's grant co-applicants and the Principal Investigators or delegated person at sites delivering the intervention. Regular meetings will be held according to the needs of the trial. Trial progress will also be reviewed at the York Trials Unit, Trial coordinator meetings. These meetings are held by the Director of the York Trials Unit approximately every two months.

## 13. Publication policy

The study protocol and results will be reported and disseminated in high impact peer-reviewed scientific journals. Publication in journals such as the Nursing Times, Health Services Journal and HospitalDr website will also be considered in order to raise awareness of the findings across the general nursing profession and hospital doctors. The funders, the NIHR PHR, currently publish all monographs on their website and it is anticipated that the full trial report will be available approximately one year after the final report is submitted.

The findings of this trial will be presented at health and safety conferences, for example The Royal Society for the Prevention of Accidents (ROSPA); Institution of Occupational Safety and Health (IOSH) and The National Examination Board in Occupational Safety and Health (NEBOSH).

The Health and Safety Executive (HSE) will disseminate the findings of the study through their website (www.hse.gov.uk) and through direct communications to interested parties. The HSE hold databases of contacts for Health & Safety managers, categorised by interest in specific topics, such as slips and trips, or interest in particular sectors, such as food manufacturing, paper manufacturing, hospitality, etc. The slips e-Bulletin, for example, has a

distribution of 22,000 subscribers. They will also disseminate the findings as part of the on-going promotion of the 'GRIP' scheme, including on the HSL.gov.uk website, at health and safety exhibitions, through publication of a white paper, and publication in the trade journals, such as Health & Safety Matters, Health & Safety At Work, etc. The results of the study will also inform the contents of the 'Slips and Trips - Falls Prevention' training course run by the HSE.

We will produce a short summary of the results of the study which can be distributed to all trial participants and hospital managers at participating trusts.

## 14. List of abbreviations

| Abbreviation | Explanation |
|---|---|
| AE | Adverse event |
| ASHE | Annual Survey of Hours and Earnings |
| CACE | Complier Average Causal Effect |
| CONSORT | Consolidated Standards of Reporting Trials |
| CUA | Cost-utility analysis |
| GP | General Practitioner |
| HSE | Health and Safety Executive |
| LTPS | Liabilities to Third Parties Scheme |
| IOSH | Institution of Occupational Safety and Health |
| NEBOSH | National Examination Board in Occupational Safety and Health |
| NICE | The National Institute for Health and Care Excellence |
| NIHR | National Institute of Health Research |
| PHR | Public Health Research Programme |

| Abbreviation | Explanation |
|---|---|
| QALY | Quality-adjust life year |
| RIDDOR | Reporting of Injuries, Diseases and Dangerous Occurrences Regulations |
| ROSPA | Royal Society for the Prevention of Accidents |
| SAE | Serious Adverse Event |
| SSHeW | Stopping Slips among Healthcare Workers |
| TMG | Trial Management Group |
| TSC | Trial Steering Committee |
| YTU | York Trials Unit |

## 15. Changes to the trial protocol

Changes from version 2 to version 3

- Day to day management clarification: inclusion of a welcome text and wording for compliance text.
- Clarification about eligibility criteria – theatre based, use of protective footwear and temporary staff with less than 6 months on their contract
- Clarification about resolution of data queries
- Clarification about data collected from participants reporting an injury

Changes from version 3 to version 4

- A reminder letter may be sent to participants who have not returned either their slip data collection questionnaire or 14 week questionnaire, two weeks after the questionnaire was originally sent out.
- Two additional texts will be sent to participants who have not responded to their pre-randomisation texts. If participants respond to two out of the six texts they will then be eligible for the study.

Changes from version 4 to version 5

- Change in the eligibility criteria that participants have to work 60%FTE rather than 80% FTE to be included in the trial
- Background section updated
- Clarification to the flowchart; secondary objectives and outcomes; analysis of secondary outcomes; economic analysis
- Inclusion of a Study within a Trial (pen sub-study)
- Additional information about the method of randomisation included

- Inclusion of references

Changes from version 5 to version 6.0

- Changing 60% FTE which could be interpreted as 60% of 40 hrs week to 60% WTE which means 22.5 hrs (60% of a full time working week of 37.5 hrs which is the standard NHS Full time contract.

Changes from version 6 to v7.0

- Sending out extra questionnaire to help identify participants for shoe testing

Changes from version 7.0 to version 8.0

- The recruitment period has been amended, from 13 to 22 months and estimated trial length from 30 to 38 months to account for the changes resulting from the funded extension.
- Qualitative participants will be given £20 to thank them for their time in taking part in the qualitative study.
- In order to help recruitment to the qualitative study, we will ask sites, that have capacity if they will help identify potential participants.

# 16. References


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