Slip-resistant footwear to reduce slips among health-care workers: the SSHeW RCT

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Declared competing interests of authors: Catherine Hewitt declares membership of the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Commissioning Committee (2015–20) and previous membership of the HTA Assessment Commissioning Sub-Board (Expression of Interest) (2016–17). Michael Zand, Gillian Frost, Mark Liddle, Emily Bain and Misbah Mogradia declare that the Health and Safety Executive run the GRIP rating scheme, which was used to identify the footwear and manufacturer used in the trial, and that Shoes for Crews (Europe) Ltd paid the Health and Safety Executive for testing of footwear under the GRIP rating scheme. David J Torgerson declares that he is Director of York Trials Unit, which receives clinical trials unit funding from NIHR, has previously been a member of various boards [a member of the NHS HTA Commissioning Board (from 2007 to 2010), a member of the NIHR Programme Grants for Applied Research Board (from 2007 to 2011) and a member of the MRC methodology research panel (from 2011 to 2013)] and was a member of the Clinical Trials Unit Standing Advisory Committee (2010–14).

Published February 2021
DOI: 10.3310/phr09030

Scientific summary

The SSHeW RCT

Public Health Research 2021; Vol. 9: No. 3
DOI: 10.3310/phr09030

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Scientific summary

Background

In Great Britain, 100,000 injuries due to slips, trips and falls on the level (as opposed to falls from a height, e.g. a ladder) occur in the workplace each year. They are the most common cause of non-fatal injury in the workplace, accounting for 30% of all those reported to the Health and Safety Executive. Nearly 1 million working days are lost because of slips, trips and falls each year.

There are several factors that can contribute to slips and resulting falls in the workplace. These include the floor surface, floor contamination, the cleaning regime, the level and type of pedestrian activity, footwear choice, the working environment and human factors. In the UK, employers have a duty to assess risks and decide what suitable and effective control measures will prevent slips. In many instances, straightforward measures, such as that ensuring floor surfaces are kept clean and dry, are sufficient. However, if it is not practicable to prevent the floor surface becoming slippery, employers may consider the use of slip-resistant footwear.

Aim

To assess the clinical effectiveness and cost-effectiveness of the offer and provision of 5-star, GRIP-rated, slip-resistant footwear in preventing slips in the workplace compared with usual footwear.

Methods

Study design

We undertook a multicentre, two-arm, randomised controlled trial with an internal pilot trial, economic evaluation and embedded qualitative study.

Participant recruitment

Recruitment took place within seven participating NHS trusts in England. NHS staff were given a recruitment pack inviting them to take part in the Stopping Slips among Health-care workers (SSHeW) trial. Staff who returned a baseline questionnaire and valid consent form were screened for eligibility against the following criteria.

Inclusion criteria for the main SSHeW trial

Staff were eligible to participate in the trial if they:

- were aged $\geq$ 18 years
- were employed by the participating NHS trust

- were required to adhere to a dress code
- worked in a clinical, general or catering area
- worked more than 30 hours per week (reduced mid-way through the trial to 22.5 hours per week)
- had a mobile phone and were willing to receive and send text messages for data collection.

Exclusion criteria for the main SSHeW trial

Staff were ineligible to participate if they:

- were provided with, and required to wear, protective footwear
- were agency staff or staff with < 6 months remaining on their employment contract
- were predominantly office or theatre based.

Pilot trial

An internal pilot trial was conducted during the first 6 months of the trial. The objectives of the pilot trial were to:

- test and refine recruitment strategies for the study
- check the sample size calculation assumptions by reviewing the proportion of control group participants who experienced a slip
- check the attrition rate
- explore and address any issues regarding footwear compliance.

Sample size

There were limited published data on which to base a sample size for this trial. A prospective cohort study found that 49 of 422 (11.6%) 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 expected that the proportion of workers who experienced any type of slip to be higher than this, but we conservatively assumed a proportion of 10% for the sample size calculation. We proposed to randomise 4400 participants using a randomisation ratio of 1 : 1. This sample size gave us 90% power to show a 30% relative reduction in the proportion of participants who reported at least one slip over a 14-week period (a 3-percentage-point absolute reduction from 10% to 7%), allowing for 20% attrition. It also gave us 80% power to see an absolute reduction of 2 percentage points in the risk of falls from 5.5% to 3.5%, allowing for 20% attrition. We considered a sample of 800 participants in the pilot trial to be sufficient to test the objectives.

Randomisation

Eligible participants who provided written consent, completed a baseline questionnaire and returned at least two of the weekly text messages providing slip data were eligible for randomisation. Participants were randomised using the York Trials Unit's secure, web-based randomisation system, based on an allocation sequence generated by an independent data systems manager at the York Trials Unit (the systems manager was not involved in the recruitment of participants). Block randomisation stratified by trust was used with variable block sizes. Participants were randomised at a particular site in batches of 1 : 1 between the intervention and control group (depending on when sites had capacity to order and deliver footwear). The block size was equal to the number of participants to be randomised at each time frame.

Trial intervention

Participants allocated to the intervention arm were offered and provided with a free pair of 5-star, GRIP-rated, slip-resistant shoes to wear for the 14-week trial period. The GRIP rating scheme was developed by the Health and Safety Executive. Slip resistance of shoes is rated on a scale of one to five stars, with five stars being awarded to those shoes with the highest level of slip resistance. Those participants allocated to the control group were asked to continue to wear their usual work footwear for the 14-week trial period. They were informed that they would receive a free pair of 5-star, GRIP-rated, slip-resistant shoes at the end of the 14-week trial period.

Follow-up

Participants were followed up with weekly text messages for 14 weeks post randomisation to collect slip data (i.e. the number of slips participants had at work in the past week). Participants were sent a group-specific postal questionnaire at 14 weeks post randomisation. Participants who reported a slip in their weekly text response were sent a questionnaire for further details about their first reported slip, including any resultant injury, health service use and time off work. Any participant who reported an injury was asked to complete, on a monthly basis until the injury was resolved or the trial ended, the EuroQol-5 Dimensions, five-level version, as well as a questionnaire that asked whether or not the participant had recovered from the injury, date of recovery and health-care use.

Primary outcome

The primary outcome for the trial was 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 (or the 14-week questionnaire when no slip text message data were provided). A slip was defined as 'a loss of traction of your foot on the floor surface, which may or may not result in a fall'.

Secondary outcomes

Secondary outcomes included the incidence rate of falls (both resulting and not resulting from a slip) over 14 weeks; the proportion of participants who reported a slip, fall or fracture over 14 weeks; time to first slip and fall; and health-related utility, as measured by the EuroQol-5 Dimensions, five-level version.

Other data collected

Compliance data on how often participants were wearing their trial shoes were collected at 6, 10 and 14 weeks. Any adverse events relating to being in the study or wearing the trial shoes that were reported to the York Trials Unit were recorded.

Statistical methods

All analyses were conducted in Stata v15 (StataCorp LP, College Station, TX, USA) following the principles of intention to treat, with participants' outcomes analysed in accordance with their original, randomised group. Significance tests were two-sided at the 5% level. The trial was reported in accordance with the Consolidated Standards of Reporting Trials guidelines for parallel-group randomised trials. Baseline data were summarised descriptively overall and by randomised arm.

The primary outcome was analysed using mixed-effect negative binomial regression, adjusting for gender, age, job role and baseline weekly slip rate as fixed effects and centre as a random effect.

Two-stage, instrumental variable, complier-average causal effect analyses were used (with randomised group as the instrumental variable) to obtain an unbiased treatment estimate. Three separate models were run defining compliance in the following ways: receipt of the trial shoes within 7 weeks of randomisation, receipt of trial shoes within 14 weeks of randomisation, and as a continuous measure incorporating amount of wear.

Subgroup analyses considered whether or not the intervention effect differed by gender and area of work by repeating the primary analysis, including the factor and an interaction term between the factor and group allocation in the primary model.

The incidence rate of falls (both resulting and not resulting from a slip) over 14 weeks was analysed in the same way as described for the primary outcome.

The following outcomes were analysed using mixed-effects logistic regression, adjusting for the same fixed-effect covariates as the primary analysis, with centre as a random effect. First, the proportion of participants who slipped at least once over 14 weeks (two separate analyses: one in accordance with weekly slip text message data or 14-week questionnaire if no text message data were provided; and one using only 14-week questionnaire data). Second, the proportion of participants who fell at least

once over 14 weeks. The number of participants who reported a fracture was small and, therefore, no formal analyses of this outcome were undertaken.

Time to first slip was analysed using Cox proportional hazards regression, with shared centre frailty and adjusting for the same covariates as in the primary analysis model. Time to first fall was not formally analysed because a valid date of fall was provided for relatively few falls.

Adverse events are summarised descriptively by treatment arm.

Qualitative study

A qualitative study was undertaken via interviews to explore participants' thoughts about, and personal experiences of, slips and slip prevention within the NHS workplace, experiences of the trial footwear and being a trial participant. Topic guides were developed based on the study's research questions and provided the framework for the interviews.

Sampling strategy and recruitment

A purposive sample of 35 intervention trial participants, from all participating trusts, took part in the qualitative study. Participants who indicated that they would be willing to participate in the interview were sent a patient information sheet and invitation letter in the post or by e-mail or contacted directly by members of the trust's research and development department.

Interview design

The interviews lasted between 10 and 35 minutes, were semistructured and were conducted over the telephone.

Analysis

Following transcription, the interviews were analysed thematically.

Economic analysis

An economic evaluation was conducted to assess whether or not the intervention was cost-effective in reducing the risk of slips. The primary outcome measure for the economic evaluation base case was injuries due to slips, as slips that do not result in injury are unlikely to lead to material economic costs. The following incremental cost-effectiveness ratios were estimated from the perspectives of the NHS budget and of society: cost per quality-adjusted life-year, cost per averted injury and cost per averted slip.

The analysis modelled the impact of slip-resistant footwear on the expected number of slip-related injuries across the trial population, and mean unit costs per injury were estimated by aggregating the outcome data across treatment groups. The costing framework accounted for intervention costs in addition to the costs of health-care resource use, worker absenteeism and expected compensation claims, using data collected via trial questionnaires and from secondary sources. Health-related quality-of-life data were collected using the EuroQol-5 Dimensions, five-level version, and converted to utility values consistent with the three-level value set using the van Hout *et al.*'s 'crosswalk' approach (van Hout B, Janssen MF, Feng YS, Kohlmann T, Busschbach J, Golicki D, *et al.* Interim scoring for the EQ-5D-5L: mapping the EQ-5D-5L to EQ-5D-3L value sets. *Value Health* 2012;**15**:708–15).

Results

A total of 8524 recruitment packs were handed out between March 2017 and November 2018. A completed baseline form was received from 5309 (62.3%) potential participants, of whom 498 (9.4%) were ineligible. A total of 4554 participants were randomised (an increase of 154 participants on the 4400 participants planned). One participant was discovered to be ineligible after randomisation and so was immediately withdrawn, resulting in 2275 participants in the intervention group and

2278 participants in the control group. The recruited participants were predominantly female ($n = 3869$, 85.0%) and the average age was 42.7 (range 18–74) years. Participants worked a median of 37.5 hours per week and qualified nurse or midwife was the most represented job role ($n = 1937$, 42.5%). At baseline, just over one-third of participants reported experiencing a slip at work in the previous 12 months (median of two slips), of whom 10.7% had suffered an injury as a result of one of these slips.

Overall, weekly response rates to the 14 post-randomisation slip text messages exceeded 86%. In total, 6743 slips were reported: 2633 over 28,002 person-working weeks in the intervention group (mean 1.16 per participant, standard deviation 2.9, median 0, range 0–36) and 4110 over 28,595 person-working weeks in the control group (mean 1.80 per participant, standard deviation 4.6, median 0, range 0–83). There was a statistically significant reduction in the slip rate in the intervention group, relative to the control group (incidence rate ratio 0.63, 95% confidence interval 0.57 to 0.70; $p < 0.001$). A total of 1523 (66.9%) intervention participants received a pair of trial shoes within 7 weeks of randomisation and 1930 (84.8%) participants received a pair of trial shoes within 14 weeks. The median time to receipt of shoes was 27 days after randomisation. The complier-average causal effect estimate for receiving a pair of shoes within 14 weeks was (incidence rate ratio) 0.65 (95% confidence interval 0.59 to 0.73; $p < 0.001$). On receipt of shoes, around 50% of intervention participants reported wearing the trial footwear all of the time when at work. Further complier-average causal effect analysis indicated that those who received the shoes earlier and/or wore them more often were more likely to have a reduced slip rate.

Statistically significant differences were also observed in falls resulting from a slip in the workplace (incidence rate ratio 0.51, 95% confidence interval 0.28 to 0.92; $p = 0.03$), the proportion of participants who reported a slip (odds ratio 0.58, 95% confidence interval 0.50 to 0.66; $p < 0.001$) or fall (odds ratio 0.73, 95% confidence interval 0.54 to 0.99; $p = 0.04$) and time to first slip (hazard ratio 0.73, 95% confidence interval 0.67 to 0.80; $p < 0.001$).

There were no related serious adverse events.

An incremental cost per quality-adjusted life-year in the base case was estimated at £38,900 from the NHS perspective and –£60,400 from the societal perspective (i.e. cost saving). One- and two-way sensitivity analyses indicated that the intervention would be cost-effective at plausible values from the NHS perspective at a threshold of £30,000 per quality-adjusted life-year.

Conclusions

The slip-resistant shoes used in this study reduced the number of slips, and falls resulting from slips. The results indicate that the intervention could be cost-effective at the £30,000 per quality-adjusted life-year threshold from the NHS perspective and is cost saving from the societal perspective. The majority of participants found the shoes comfortable.

Trial registration

This trial is registered as ISRCTN33051393.

Funding

This project was funded by the National Institute for Health Research (NIHR) Public Health Research programme and will be published in full in *Public Health Research*; Vol. 9, No. 3. See the NIHR Journals Library website for further project information. The Health and Safety Executive provided some research costs.

Public Health Research

ISSN 2050-4381 (Print)

ISSN 2050-439X (Online)

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Editorial contact: journals.library@nihr.ac.uk

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This report

The research reported in this issue of the journal was funded by the PHR programme as project number 15/05/28. The contractual start date was in October 2016. The final report began editorial review in December 2019 and was accepted for publication in April 2020. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

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