NICE National Institute for Health and Care Excellence

Surveillance review decision – Falls (2013) NICE guideline CG161

Surveillance report

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Surveillance decision

We will not update the guideline at this time.

Reason for the decision

We found 54 new studies relevant to the guideline through the surveillance process. We found one study which may impact recommendations relating to strength and balance training for falls prevention in older people living in the community. We subsequently discussed this with topic experts who noted that there would be a number of relevant studies in this area published in the community setting since the last review date in 2011. Additionally they made us aware of a highly relevant Cochrane review (Gillespie et al. 2012) which is being updated at the moment. Experts highlighted that being able to be more specific in terms of type and duration of intervention would add value to the guideline. However, in light of the update of this directly relevant Cochrane review, it is felt more appropriate to await the outcome of the review and reassess the guideline when this completes. NICE will liaise with the Cochrane Review Group to ensure the update includes the population that is directly applicable to NICE guideline CG161.

Topic experts also raised concerns that service delivery was not adequately covered as part of the 2013 guideline update that focused on falls in the hospital settings. However, a guideline on multimorbidity is in development (publication date September 2016) and it has been confirmed that this guideline will consider falls as a trigger to holistic assessment for frail older people. On that basis, it was felt appropriate to await the completion of this guideline and consider its impact on NICE guideline CG161 at that time.

In light of the above, the decision to update was deferred until both the Cochrane review and the multimorbidity guideline are published.

None of the remaining evidence considered in surveillance of this guideline was thought to have an effect on current recommendations.

See how we made the decision for further information.

Commentary on selected new evidence

With advice from topic experts we selected 4 studies for further commentary for the following sections of the guideline.

Preventing falls in older people – Strength and balance training

We selected the Sherrington et al. 2014 study for a full commentary because it indicates that single interventions of home-based lower limb balance and muscle strengthening exercises in older people recently discharged from hospital only are not successful in preventing falls in this group of people and may actually increase the rate of falls, potentially contradicting the recommendation in the guideline for strength and balance training for falls prevention in older people.

What the guideline recommends

The guideline recommends strength and balance training as one of the components of a successful multifactorial intervention programme for older people with recurrent falls or at increased risk of falling (recommendation 1.1.3.1). But recommendation 1.1.4.1 of the guideline also states that: "Strength and balance training is recommended. Those most likely to benefit are older people living in the community with a history of recurrent falls and/or balance and gait deficit. A muscle-strengthening and balance programme should be offered. This should be individually prescribed and monitored by an appropriately trained professional. "

Methods

Sherrington et al. 2014 was an Australian randomised controlled trial (RCT) that investigated the effects of a home-based exercise programme on falls and mobility among people aged 60 years and over (mean age of 81.2 years, 6.8 health conditions, 7.5 medications and 70% had fallen in the last year) that had recently been discharged from four public hospitals following admissions in geriatric, rehabilitation and orthopaedic wards (n=340).

Prospective candidates for the trial were approached during their admission in hospital and those that agreed to take part were contacted after discharge. Participants were stratified by hospital site and falls history, and block randomisation was used to allocate participants into an intervention group (n=171) and a control group (n=169). Trial investigators who conducted interviews and assessments, received calendars and questionnaires, made phone calls and entered data were blinded to participants' group allocation.

Both groups received usual care from health and community services and were given an education booklet about falls prevention. The intervention group participants were additionally asked to carry out a 20–30 minute programme of lower limb balance and strengthening exercises at home up to 6 times weekly for 12 months. Exercises were mainly conducted while standing, according to the Weight-bearing Exercise for Better Balance (WEBB) programme. Participants were supported by experienced physiotherapists with a total of 10 visits during the study period with more frequent visits at the beginning to ensure safety and enable tailoring and progression of the programme.

Primary outcomes were rate of falls, performance-based mobility and self-reported mobility. Secondary outcomes included additional measures of mobility, falls and risk of falling, strength, flexibility, quality of life, health system and community service contact, assistance required from others, difficulty with daily tasks, community participation and physical activity levels. The study also reported on adverse events of the exercise programme.

Rate of falls was calculated using records of falls completed by participants on monthly calendars and was assessed over the 12-month duration of the study. Performance-based mobility was measured using the Short Physical Performance Battery (score range 0 to 12, where a higher score is better), but data analysis was conducted using the lower extremity Summary Performance Score version of the tool, at baseline and 3 and 12 months post-randomisation (score range 0 to 3, where a higher score is better). Self-reported mobility was measured via a questionnaire that was completed monthly. Ease in performing eight mobility tasks was recorded using a five-point scale with the scores summed up (score range 0 to 40, where a higher score is better).

Results

Ninety-two per cent of participants (n=312) completed the 12-month assessment; 49% (n=168) reported a total of 300 falls during the study period, with participants in the

intervention group reporting significantly more falls than the control group (177 falls versus 123 falls; incidence rate ratio 1.43, 95% confidence interval [CI] 1.07 to 1.93, p=0.017). There were 98 fallers in the intervention group (57%), compared to 70 in the control group (41%), risk ratio 1.38, 95% CI 1.11 to 1.73, p=0.004. However, no participants reported a fall while they were doing the home-based exercises.

There was a small but statistically significant improvement in performance based mobility at 12-months in the intervention group compared to the control group (difference between groups change in mean score after adjusting for baseline performance 0.13, 95% CI 0.04 to 0.21, p=0.004). There was no significant difference between the intervention and control groups for self-reported ease in undertaking mobility tasks over the study period (difference between groups change in mean score 0.49, 95% CI -0.91 to 1.90, p=0.488).

Strengths and limitations

Strengths

A strength of this study is that it is an RCT with a low risk of bias due to random sequence generation, adequate allocation concealment and blinding of outcome assessment, and only a small loss to follow up at 12 months (<10% of participants were lost to follow up at study completion, with similar numbers lost in both groups).

Limitations

One limitation of the study could be that although it is of a relatively large sample size (n=340), it may still not be adequately powered as recruitment was stopped 10 participants short of the calculated sample size of 350 participants. Another limitation may be that it relies on self-reported data, with no indication of the severity of the falls.

Impact on guideline

This is a single intervention in a highly specific clinical context – post discharge. In this population of older people recently discharged from hospital, this RCT found that home-based lower limb balance and strengthening exercises improved performance-based mobility but also significantly increased the rate of falls and number of fallers. The findings suggest, therefore, that this form of home exercise cannot be recommended as a standalone or single, 'blanket' intervention for fall prevention for this group. This result,

however, may be out of step with other studies on exercise in falls prevention but most are done in healthier older people.

Preventing falls in older people during a hospital stay - Predicting patients' risk of falling in hospital

We selected the Healey and Haines 2013 study for a full commentary because it lends important support to the existing recommendation not to use risk prediction tools to predict inpatients' risk of falling in hospital.

What the guideline recommends

The guideline does not recommend the use of falls risk prediction tools to predict inpatients' risk of falling in hospital.

Methods

The Healey and Haines 2013 study assessed the predictive values of the Morse falls score (MFS) in an acute general hospital in the UK. Age, ward speciality of admission, most recently completed MFS, and any falls in the subsequent 7 days were collected through case note review and incident reporting systems for analysis.

Six variables make up the MFS. There are: history of falling (scored as 0 or 25), secondary diagnosis (scored as 0 or 15), ambulatory aid (scored as 0, 15 or 30), intravenous therapy (scored as 0 or 20), gait (scored as 0, 10 or 20) and mental status (scored as 0 or 15). A total score of 0–20 denotes no or low risk, ≥25 denotes at least medium risk and ≥55 denotes high risk.

Analyses were carried out for MFS ≥25 and ≥55. Subgroup analyses by age (patients aged <75 years or ≥75 years) and specialty (patients on geriatrician-led wards or not on geriatrician-led wards) were also carried out. The Youden Index (YI) and its 95% confidence intervals (CIs) were used to determine the total predictive value of the MFS for the overall sample as well as for each of the pre-planned subgroups; sensitivities and specificities were also derived.

Results

Records from 467 patients were assessed; 35% (n=162) were on geriatrician-led wards. 116 patients were excluded from the data analysis as they didn't have a recent or completed MFS. Results showed a non-significant result for MFS ≥25 in the total sample (YI 0.15, 95% CI −0.04 to 0.32) or in any of the pre-planned subgroups.

An MFS ≥55 was significantly better than chance for predicting falls in the total sample (YI 0.39, 95% CI 0.20 to 0.58), in patients ≥75 years (YI 0.31, 95% CI 0.10 to 0.51) and in geriatrician-led wards (YI 0.37, 95% CI 0.15 to 0.58), although either sensitivity or specificity fell below 70% in each of these groups.

Strengths and limitations

Strengths

As the authors point out, in the assessment of a tool's predictive values, a potential confounder is that interventions may have been applied on the basis of the score; therefore, low predictive values may actually indicate successful falls prevention. A strength of this study therefore is that this study took advantage of a situation where the above scenario was unlikely, as the hospital had introduced the MFS and a system of increased checks on patients by nurses, nine months prior to the study, but had seen no subsequent reduction in falls or injurious falls, indicating that the intervention had no effect on falls.

Limitations

A limitation of the study is that it relied on the MFS as calculated by ward nurses which the authors suggested may result in lower accuracy than in trials where research nurses calculate the MFS, although the authors also suggested that this may have made the results more generalisable to clinical practice.

Impact on guideline

This study concluded that overall, the Morse falls score (MFS) risk scoring tool was not satisfactory for predicting falls in hospital. The study findings are consistent with the guideline which does not recommend the use of falls risk prediction tools to predict inpatients' risk of falling in hospital. Therefore, this new evidence is unlikely to impact on

guideline recommendations.

Preventing falls in older people during a hospital stay - Assessment and interventions

We selected the Sahota et al. 2014 study for a full commentary because this RCT of assistive technology found that bed and bedside pressure sensors using radio-paging as a single intervention do not reduce falls rates in hospital.

What the guideline recommends

The guideline recommends that for patients at risk of falling in hospital a multifactorial assessment and a multifactorial intervention should be considered. The guideline defines a multifactorial intervention as having multiple components that aim to address the risk factors for falling that are identified in a person's multifactorial assessment.

Methods

Sahota et al. 2014 was a randomised controlled trial (the REFINE trial) of bed and bedside chair pressure sensors compared with standard care in older people (mean age at randomisation 84.6 years) admitted to acute, general medical wards, in Queen's Medical Centre, Nottingham, United Kingdom. Both groups received standard care comprising routine geriatric medical care. The intervention comprised of battery-operated bed and bedside chair pressure sensor linked wirelessly to a handheld battery-operated radio-pager. When a participant left the bed or bedside chair, a radio signal alert was transmitted from a transmitter box attached to the foot of the participant's bed, to the radio-pager carried by a member of the nursing team, which provided the location of the participant. An absence of pressure on the sensor of 5 seconds or more triggered an alert. A central receiver on each ward recorded all alerts, which were collected by the research team.

All patients admitted to the hospital from the medical admissions unit to three acute, general medical elderly care wards within 24 hours were eligible for inclusion into the trial. Patients permanently bed bound prior to admission, moribund/unconscious, on end of life care or previously included in the trial on an earlier admission were excluded.

Participants were randomised to the intervention group (n=918) or the control group

(n=921) using a web based service that utilised a permuted-block randomisation schedule for allocation to groups. Blinding of participants or those providing medical or nursing care to the intervention or control group was not carried out as a feasibility study prior to the trial showed that staff were able to identity patients with dummy or active sensors.

The primary outcome measure was the number of in-patient bedside falls per 1,000 bed days from time of randomisation to date of discharge, death or study withdrawal, whichever occurred soonest. A bedside fall was defined as an unexpected event in which the participant came to rest on the ground, floor or lower level in the area around the bedside, with the bedside being defined as the area encompassed by the curtained area surrounding the bed. For patients in side rooms, the bedside was defined as the area of the room.

Secondary outcome measures were: number of injurious in-patient bedside falls per 1,000 bed days, activities of daily living, fear of falling, length of hospital stay, residential status on discharge and health related quality of life. Mean costs of the intervention/control and QALY gains per patient were also reported.

Results

Of the eligible patients, 918 patients were randomised to the intervention group and 921 to the control (n=1839). Results for the primary outcome were as follows:

- intervention group – 85 bedside falls (65 fallers), falls rate 8.71 per 1,000 bed days
- control group –- 83 bedside falls (64 fallers), falls rate 9.84 per 1,000 bed days, resulting in an adjusted incidence rate ratio (IRR) of 0.90, 95% CI 0.66 to 1.22, P=0.50.

There was no significant difference between the two groups with respect to time to first bedside fall (adjusted hazard ratio (HR), 0.95, 95% CI 0.67 to 1.34, P=0.12). None of the secondary outcomes differed significantly between the two groups.

The mean cost per patient in the intervention group was £7199 compared with £6400 in the control group, mean difference in QALYs per patient was 0.0001; 95% confidence interval -0.0006 to 0.0004, P=0.67.

Strengths and limitations

Strengths

The strengths of the REFINE trial are its UK setting, its RCT design with a relatively low risk of selection bias due to random sequence generation, a large sample size and no loss to follow up.

Limitations

However, blinding was not done and it is unclear whether allocation concealment was carried out prior to assignment, although the web based randomisation service is probably fine. Also, the authors reported that primary outcome data was collected from the mandatory incident reporting system operating within the hospital which may be affected by underreporting of falls, and that the power of the study may be inadequate to detect a smaller reduction in bedside falls than that used in the power calculation (a 35% reduction in the rate of bedside falls was used).

Impact on guideline

This UK RCT of assistive technology found that bed and bedside pressure sensors using radio-paging as part of a single intervention do not reduce falls rates. This study helps raise awareness of the limitations of such interventions. These are important negative findings which lend support to the existing recommendation. The guideline recommends that for patients at risk of falling in hospital a multifactorial assessment and a multifactorial intervention should be considered. Therefore, this new evidence is unlikely to impact on guideline recommendations.

Research recommendation: Environmental adaptations aimed at reducing the risk of falling in older inpatients

We selected the Drahota et al. 2013 study for a full commentary because it is a relevant pilot project endorsing the recommendation for further research.

What the guideline recommends

The guideline endorses the need to understand which improvements to the inpatient environment are the most effective and cost-effective for preventing falls and injuries in hospital, and the factors that architects should take into account when designing new hospitals. Therefore, a research recommendation with the following wording, "What environmental adaptations can be made in existing inpatient units, and should be considered when inpatient units are built, to reduce the risk of falls and injuries in older inpatients?", was made in the guideline.

Methods

Drahota et al. 2013 conducted a non-blinded pilot cluster RCT to assess the feasibility, potential benefits and harms and to guide further research on the use of shock-absorbing flooring for fall-related injury prevention in elderly care wards.

Participants were identified and recruited in eight hospitals in England. One bay at each site was assigned as the 'study area' for 1 year. Block randomisation, using a computer-generated random list, was used to allocate hospital sites into intervention and control groups. The study investigators were blinded to the randomisation blocks and sequence until the sites had been allocated.

All adults admitted to a bed in the study area were eligible. Hospital wards predominantly for elderly care in England were eligible for inclusion, with no other location restrictions. No exclusion criteria were applied.

Intervention sites received an 8.3-mm vinyl floor over fibreglass mat with PVC foam backing which was installed in bedroom areas only. Control sites received no change in flooring. All sites had concrete subfloors. Data were collected for 2 to 5 months (median=4 months) before the floors were laid. Then, data were collected for a further 12–13 months.

The primary outcome was the fall-related injury rate per 1,000 occupied bed days (OBD). Secondary outcomes were: injury severity; fall rate per 1,000 OBD and adverse events.

Results

During the intervention period, 225 participants were recruited to the intervention group and 223 to the control group. Baseline characteristics showed similar medication usage

across groups but the control group had more comorbidities associated with falls risk.

Of 35 falls (31 fallers) in the intervention group, 22.9% were injurious, compared with 42.4% of 33 falls (22 fallers) in the control group (injury incident rate ratio (IRR) 0.58, 95% CI 0.18 to 1.91). There were no moderate or major injuries in the intervention group and six in the control group. There were more falls in the intervention group compared to the control group (fall IRR 1.07 (95% CI 0.64 to 1.81). It is worth noting that both of these results were not statistically significant for the reported outcomes.

No adverse events were reported for participants but staff at intervention sites raised concerns about pushing equipment, with one documented case of a back injury. No adverse events related to flooring were reported from control sites.

Strengths and limitations

Strengths

The strengths of this study are its robust RCT design with a relatively low risk of selection bias as a result of random sequence generation and allocation concealment, with no loss to follow up.

Limitations

The study was not blinded and this could have increase the risk of detection bias. For example, although internal transfers were discouraged, high risk fallers may have been moved into the study areas much more frequently at intervention sites compared to control sites. Another limitation, according to the study authors, is that as staff were aware of the shock absorbing floor, performance bias could also have occurred from staff feeling re-assured about patients' safety in the intervention sites and relaxing their observation upon them.

Impact on guideline

This UK pilot cluster RCT of shock-absorbing flooring to reduce injuries from falls in wards for older people found a higher rate of falls in the intervention compared to the control group, although this was not significant. There was a lower rate of injurious falls in the intervention group and higher rate of moderate or major injuries in the control group,

although, again, the results were not statistically significant. The authors concluded that further research is required to assess to the risk of increasing fall rates with a shock-absorbing floor. Hence although this pilot study adds to the evidence base on preventing falls in older people during a hospital stay, further research is needed to answer the research recommendation in the guideline.

How we made the decision

We check our guidelines regularly to ensure they remain up to date. We based the decision on surveillance 2 years after the publication of Falls in older people: assessing risk and prevention (2013) NICE guideline CG161.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual'.

New evidence

We found 48 new studies in a search for randomised controlled trials published between 1 September 2012 and 21 April 2015. We also considered 6 additional studies identified by members of the Guideline Committee who originally worked on this guideline. From all sources, 54 studies were considered to be relevant to the guideline.

We also checked for relevant ongoing research, which will be evaluated again at the next surveillance review.

See appendix A: decision matrix for summaries and references for all new evidence considered.

Views of topic experts

We considered the views of the topic experts, including those who helped to develop the guideline. This included a meeting with experts to discuss potential areas for update.

Views of stakeholders

Stakeholders are consulted only if we decide not to update the guideline following checks at 4 and 8 years after publication. Because this was a 2-year surveillance review, and the decision was not to update, we did not consult on the decision.

See ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual' for more details on our consultation processes.

Date of next surveillance

Our next surveillance to decide whether the guideline should be updated is scheduled for 2017.

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