Critical Review Form

Therapy

Prevention of Falls in the Elderly (PROFET): a randomized controlled trial, *Lancet* 1999; 353: 93-97

Objective: **"To ascertain whether a structured bidisciplinary assessment of elderly people, who live in the community and attend an accident and emergency department with a primary diagnosis of a fall, could alter outcome and decrease the rate of further falls during the 12-month follow-up period ". (p. 93)**

Methods: **Single center London UK randomized controlled trial enrolling community-residing adults age 65 and older presenting to the ED after a fall between December 1995 and June 1996. Exclusion criteria included abbreviated mental test (AMT) <7 (cognitively impaired) if no regular caregiver was available. Additional exclusion criteria included non-local residence and non-English speaking. Patients were not enrolled from the ED. Instead, investigators identified participants by review of the King's College Hospital computerized registration system and contacted them approximately 3-days later by telephone. Patients admitted to the hospital were also eligible, but were not enrolled until after hospital discharge. The following medical and OT assessments occurred only in the intervention group.**

Baseline data collected were collected in the day hospital and included index fall details, past fall history, concurrent disorders, medication history, pre-fall functional ability, cognitive status, and "socio-demographic details". Each participant was given a 12-month falls diary. Medical assessment occurred in the hospital and included assessment of visual acuity, balance (one-leg balance test) cognition (MMSE≤ 26 was "abnormal"), depression, and "prescribing practice". Postural hypotension was also evaluated, defined as decrease in systolic BP ≥ 20 mm Hg when rising from sitting to standing. After completion of this assessment, a primary cause of the fall was assigned and referral was made to relevant services – if multi-disciplinary input was felt appropriate then referral to the Day Hospital was made. Medication changes were initiated by direct contact with the primary care physician.

A single home visit by Occupational Therapy (OT) occurred after the above medical assessment to evaluate function (Barthel index), environmental hazards, and psychological consequences of the fall. After completion of the OT home assessment, recommendations were provided to modify home to decrease fall risk.

Randomization occurred via a random-numbers table using a list not held by the investigators. Follow-up to identify subsequent falls was by mail at 4-month

intervals for one-year. The postal survey asked about falls, fall injuries, doctor visits, and hospital admission. Assuming an average of 2 falls/year and a 25% attrition rate, a sample size of 352 would have 90% power to detect a 30% reduction in falls with an α error of 0.05. Multiple logistic regression was used to compare differences between groups after adjusting for baseline differences in functional status and dementia. Data were analyzed using an available data analysis rather than ITT or per-protocol.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?**	
1.	Were patients randomized?	Yes. "(R)andomization was by a random-numbers table and the list was held independently of the investigators." (p. 94)
2.	Was randomization concealed (blinded)?	Yes, as above investigators had no way of knowing to which group patients would be allocated.
3.	Were patients analyzed in the groups to which they were randomized?	No. "Participants who remained in the study at 12 months were included in the subsequent analysis," This is an "available data analysis" as opposed to a per-protocol or Intention to Treat analysis.
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	No. "Barthel index and AMT scores were slightly higher in the intervention group than in the control group (Table 2), but the authors do not explain whether these differences are statistically or clinically relevant. (p.95)
B.	**Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?**	
1.	Were patients aware of group allocation?	Yes, no blinding.
2.	Were clinicians aware of group allocation?	Yes, no blinding.
3.	Were outcome assessors aware of group allocation?	Uncertain since not described so assume yes.

4.	Was follow-up complete?	No. "At 12-month follow-up, 163 (77%) of 213 in the control group and 141 (77%) of 184 in the intervention group remained in the study. The control and intervention groups did not differ significantly in the proportions followed up or not followed up for various reasons (p=0.81)". (p. 95-96) The authors do not provide any details about whether those lost to follow-up were more functionally dependent or cognitively impaired.
II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	• 1031 consecutive patients were in the ED for evaluation following a standing level fall during this period, representing 20% of all attendees for this age-group. Ultimately, 39% were randomized and the leading cause of non-enrollment was inability to contact by telephone (19%), nursing home (11%), and refused to consent (12%). **Medical Assessment** • Only 83% had a medical assessment, noting the following prevalence of co-morbidities: cardiovascular/circulatory disorders 17%, visual impairment 59%, poor stereoscopic vision 62%, cataract 35%, decreased leg strength 28%, dementia 34%, depression 18%, and abnormal one-leg stand in 72%. **OT Assessment** • 12 intervention patients who had medical assessment refused home assessment. • Mean Barthel index 18 (SD 2.5) and median falls handicap score 19. Only 10 patients (7%) denied any handicap after the fall.

		• After medical and OT assessment a primary attributable fall-cause was identified in 72% of patients, led by external hazards then internal hazards. • Only 16% of assessments led to no further action, while there were 67 referrals to outpatient clinics and 38 day hospital referrals. • Significantly less patients in intervention group reported falls (32% vs. 52%, NNT=5 [95% CI 3-10, p=0.0002]) and 3 or more falls (11% vs. 26%). • No significant differences were noted for injurious falls (4% vs. 8%, p=0.26) primary care physician visits (487 vs. 668, p=0.33), hospital visits (438 vs. 524, p=0.55), or hospital admissions (69 vs. 97, p=0.78). • Logistic regression demonstrated significant lower risk of 12-month falls with adjusting for baseline differences in Barthel index and AMT score (OR 0.39, 95% CI 0.23-0.60). In addition, with adjusting for these same variables the intervention group trended towards lower risk of any hospital admission (OR 0.61, 95% CI 0.35–1.05) and lower risk of recurrent falls (OR 0.33, 95% CI 0.16-0.68). (p. 96)
2.	How precise was the estimate of the treatment effect?	See 95% CI above
III.	**How can I apply the results to patient care (answer the questions posed below)?**	
1.	Were the study patients similar to my patient?	Yes, geriatric community-dwelling ED patients with a fall.
2.	Were all clinically important outcomes considered?	No. Multiple components of ED-risk assessment were not contemplated. • How would other EDs incorporate/replicate these findings without a call-back service or Day Hospital?

		• What are the costs ($ and unintended consequences) of this intervention? • Is this a service that patients desire? • Is it a cost-effective injury prevention intervention? • How does this compare with other ED-based fall prevention interventions and what further research is required?
3.	Are the likely treatment benefits worth the potential harm and costs?	Uncertain – the authors did not assess costs or harms.
4.	How will you communicate the findings of this study with your patients to facilitate shared decision-making?	One British study in 1999 demonstrated effective geriatric fall prevention following an episode of ED care for a fall with an intensive OT home safety assessment and access to a one-stop (Family Medicine, Cardiology, Radiology, Surgery, PMR, etc.) clinic. Using this intervention, 5 patients like you would need to be evaluated and treated to prevent one fall that would otherwise occur. This study has not been replicated and we're uncertain what these interventions cost or if unintended harm (side effects) occurs.

Limitations

1) **Insufficient details about medical evaluation (who conducted the evaluation, what training did they receive) and lost to follow-up patients.**

2) **Uncertain reproducibility and external validity on multiple levels:**
   a. **This was not an ED-based study; instead enrollment occurred by telephone *after* the ED visit.**
   b. **Most EDs lack access to a falls log, home OT assessment, or Day Hospital. The latter is a key component of the UK Healthcare System, but non-existent in the U.S. system.**

3) **Lack of internal validity on multiple levels.**
   a. **Assessment for dementia did not use ED-validated instrument**
   b. **No assessment for delirium.**
   c. **No assessment for baseline fall-risk.**

d. **No assessment for frailty, co-morbid illness burden, or health literacy.**

4) **No assessment of pre-existing ED fall prevention trials or elaboration on priorities for future trials.**

5) **No assessment of cost or unintended consequences.**

6) **Use of "available data" rather than ITT analysis.**

Bottom Line

Community-dwelling adults over age 65 who visit the ED following a fall demonstrate reduced fall rates (NNT=5) with an intensive medical evaluation and occupational therapy home safety assessment in the weeks following the index fall. Replication of these results necessitates a universal healthcare system where every patient has insurance and a primary care physician, as well as access to a one-stop shopping Day Hospital for multi-disciplinary assessment when indicated based on the medical evaluation. In addition to these system-level requirements, future studies should evaluate real-time ED based interventions, using validated fall-risk screening instruments, and assess frailty, dementia and health literacy as confounding variables.