MUSCULOSKELETAL
RESEARCH CENTRE

Does podiatry have a role to play in falls prevention?

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Background

- Foot problems are common[1]
- Foot problems impair balance and gait[2]
- Foot problems increase the risk of falls[3-5]
  - Foot pain
  - Hallux valgus ('bunions')
  - Lesser toe deformity (hammer and claw-toes)
  - Toe flexor weakness
  - Reduced ankle range of motion

1. Dunn et al, *Am J Epidemiol* 2004;159:491.
2. Menz et al. *J Gerontol* 2005;60:M1546.
3. Menz et al. *J Gerontol* 2006;61:M866.
4. Mickle et al. *Clin Biomech* 2009;24:787.
5. Mickle et al. *J Am Geriatr* Soc 2010;58:1936.

Background

- Footwear influences balance[1]
  - High heels
  - Soft midsoles
  - Heel collar height (boot v shoe)
- Footwear associated with falls[2,3]
  - High heels
  - Reduced sole contact area
  - Inadequate fixation

1. Menant et al, *J Rehab Res Dev* 2008;45:1167.
2. Tencer et al. *J Am Geriatr Soc* 2004;52:1840.
3. Sherrington et al. *Age Ageing* 2003;32:310.

Background

- Falls prevention guidelines recommend referral to a podiatrist
- Very limited evidence of efficacy
  - Three trials including podiatry referral as part of multifactorial intervention
  - Two small trials of toe exercises on balance
  - One trial of footwear modification to prevent falls on icy surfaces
- Variability in podiatry treatments provided in falls clinics[1]

1. Menz et al, *J Am Podiatr Med Assoc* 2007;97:377.

Objective

- To conduct a high quality randomised trial to assess the effectiveness of a multifaceted podiatry intervention in improving balance and preventing falls
- Novel intervention designed to address key risk factors
  - Foot pain
  - Foot and ankle strength
  - Foot and ankle range of motion
  - Inappropriate footwear

Methods – trial design

Design
- Parallel group randomised controlled trial
- 6 month follow-up of secondary outcomes
- 12 month follow-up of primary outcomes
- Assessors blinded to group allocation

Randomisation
- Permuted block randomisation
- Interactive voice response telephone service
- NHMRC Clinical Trials Centre, USyd

Sample size calculation
- Based on number of fallers
- 30% difference between groups
- 15% drop-outs, $\alpha = 5\%$
- 286 participants

ACTRN12608000065391

1. Spink et al, *BMC Geriatr* 2008;8:30.

Methods - participants

Recruitment
- Health sciences clinic database
- Newspaper and radio advertisements

Inclusion criteria
- Foot pain and
- Increased risk of falling
  - Fall in previous 12 months
  - Physiological profile assessment score >1
  - Alternate stepping test score > 10 sec
- Intact cognition

Exclusion criteria
- Neurodegenerative disorders
- Lower limb surgery or amputation
- Inability to walk household distances

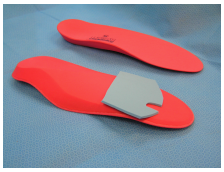
Methods – interventions

Control group
- "Usual care"
- General podiatry treatment for 12 months

Intervention group
- General podiatry treatment for 12 months
- Foot orthoses
- Footwear advice / provision
- Foot and ankle exercise program
- Falls prevention booklet

Methods – interventions

Foot orthoses
- Formthotics™
- Closed cell polyethylene foam
- Dual density
- Full length
- Heat-moulded to foot shape
- Customised to accommodate plantar lesions



Methods – interventions

Footwear advice/provision
- Outdoor footwear assessed1
- Considered inappropriate if:
  - Heel height > 4.5cm OR
  - Any two of:
    - No fixation
    - No heel counter
    - Heel counter compressed > 45°
    - Fully worn or smooth sole
    - Heel at least 20% narrower than foot
- Counselled on hazardous features
- Referred to medical grade footwear retailer
- AUD$100 footwear voucher

1. Menz et al, *Clin Rehabil* 2000;14:657.

Methods – interventions

Foot and ankle exercises
- Home-based
- 30mins, 3 times a week for 6 months
- Same prescription
- Instructed to ↑ reps or resistance at own pace
- DVD / booklet
- Monthly exercise diaries
- Contacted at 1, 4, 12 and 20 weeks

Methods – interventions

Foot and ankle exercises

Methods – outcome measures

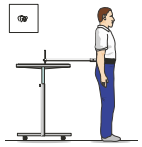
Primary outcomes

- Fallers, multiple fallers, falls rate, falls injury[1]
- Monthly calendars with follow-up phone calls

Secondary outcomes

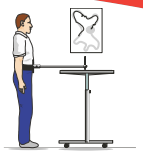
- Foot and ankle strength and range of motion
- Balance and functional ability
- Physiological profile assessment score
- Manchester Foot Pain and Disability Index
- Falls Efficacy Scale International
- Short Form 12

1. Lamb et al, *J Am Geriatr Soc* 2005;53:1618.

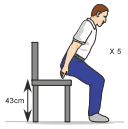


postural sway

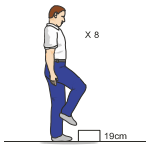
balance range



coordinated stability



sit to stand



stepping test

walking speed

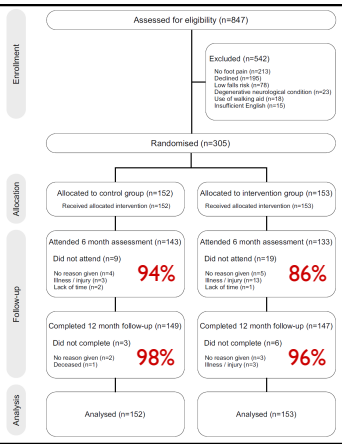
Methods – analysis

- Intention to treat
- Primary outcomes
  - Number of fallers and multiple fallers: relative risks
  - Falls rate: negative binomial regression[1]
- Secondary outcomes
  - Mean imputation for missing data
  - Linear regression approach to ANCOVA
  - Hochberg adjusted p-values
- SPSS and Stata

1. Robertson et al, *J Gerontol* 2005;60A:530.

Results

- n=305



Results – adherence

- Foot orthoses
  - 68% wore orthoses most or some of the time
- Footwear
  - n=41 (27%) had inappropriate footwear
  - 12 (29%) did not purchase new footwear
  - 22 (54%) wore new footwear most or some of the time
- Foot and ankle exercises
  - 53% completed 75% or more of the exercise sessions
- Podiatry treatments
  - Control group: 5.2 (3.0)
  - Intervention group: 4.4 (3.0)

Secondary outcome measures

	Control	Intervention	difference (95%CI)	p
Ankle dorsiflexion				
Baseline	152.1 (46.1)	154.7 (41.7)		
Follow-up	161.9 (44.7)	172.8 (46.0)	8.9 (2.3 – 15.4)	0.008
Ankle plantarflexion				
Baseline	199.0 (51.7)	206.2 (55.3)		
Follow-up	221.3 (50.8)	230.8 (52.3)	4.7 (-3.7 – 13.1)	0.269
Ankle inversion				
Baseline	102.9 (34.7)	100.7 (34.9)		
Follow-up	102.4 (31.5)	106.8 (35.2)	6.1 (1.7 – 10.5)	0.007
Ankle eversion				
Baseline	99.2 (30.6)	97.9 (29.1)		
Follow-up	101.0 (28.0)	108.5 (24.5)	8.5 (4.5 – 12.6)	<0.001
Lesser toe plantarflexion				
Baseline	68.0 (27.2)	68.0 (25.1)		
Follow-up	70.4 (27.2)	74.7 (29.8)	4.2 (-0.7 – 8.5)	0.054
Hallux plantarflexion				
Baseline	69.0 (28.0)	68.2 (27.0)		
Follow-up	69.7 (28.2)	69.9 (29.5)	0.9 (-2.9 – 4.6)	0.647

* all measurements in Newtons

Secondary outcome measures

	Control	Intervention	difference (95%CI)	p
Ankle dorsiflexion - extended				
Baseline	30.4 (6.3)	30.9 (5.6)		
Follow-up	31.0 (6.0)	33.0 (6.7)	1.6 (0.6 – 2.5)	0.001
Ankle dorsiflexion - flexed				
Baseline	38.7 (6.8)	40.0 (7.1)		
Follow-up	38.6 (6.1)	40.8 (7.5)	1.1 (0.3 – 1.9)	0.005
Ankle inversion/eversion				
Baseline	32.6 (9.7)	32.6 (9.5)		
Follow-up	33.6 (9.5)	36.5 (10.9)	2.9 (1.4 – 4.5)	<0.001
1st MTPJ				
Baseline	75.8 (16.7)	72.9 (18.8)		
Follow-up	78.8 (15.8)	76.2 (18.8)	0.0 (-1.8 – 1.8)	0.975

* all measurements in degrees

Secondary outcome measures

	Control	Intervention	difference (95%CI)	p
Postural sway - floor				
Baseline	114.4 (121.51)	137.8 (205.9)		
Follow-up	115.6 (125.1)	90.6 (61.3)	-30.3 (-50.8 – -9.7)	<0.001
Postural sway - foam				
Baseline	238.0 (235.4)	215.9 (203.3)		
Follow-up	210.2 (320.6)	151.0 (97.4)	-51.4 (-101.9 – -0.9)	0.025
Maximum balance range				
Baseline	108.4 (28.4)	116.2 (33.2)		
Follow-up	124.1 (27.0)	132.7 (31.7)	3.2 (-1.4 – 7.8)	0.167
Coordinated stability				
Baseline	10.2 (8.4)	9.2 (8.1)		
Follow-up	9.2 (7.9)	8.0 (7.6)	-0.6 (-1.7 – 0.6)	0.056
Lateral stability				
Baseline	63.6 (44.9)	58.4 (40.8)		
Follow-up	53.0 (40.4)	51.2 (38.3)	0.8 (-6.8 – 8.3)	0.959

Secondary outcome measures

	Control	Intervention	difference (95%CI)	p
Postural sway - floor				
Baseline	114.4 (121.51)	137.8 (205.9)		
Follow-up	115.6 (125.1)	90.6 (61.3)	-30.3 (-50.8 – -9.7)	<0.001
Postural sway – foam*				
Baseline	238.0 (235.4)	215.9 (203.3)		
Follow-up	210.2 (320.6)	151.0 (97.4)	-51.4 (-101.9 – -0.9)	0.025
Maximum balance range				
Baseline	108.4 (28.4)	116.2 (33.2)		
Follow-up	124.1 (27.0)	132.7 (31.7)	3.2 (-1.4 – 7.8)	0.167
Coordinated stability				
Baseline	10.2 (8.4)	9.2 (8.1)		
Follow-up	9.2 (7.9)	8.0 (7.6)	-0.6 (-1.7 – 0.6)	0.056
Lateral stability				
Baseline	63.6 (44.9)	58.4 (40.8)		
Follow-up	53.0 (40.4)	51.2 (38.3)	0.8 (-6.8 – 8.3)	0.959

* not significant following Hochberg adjustment

Secondary outcome measures

	Control	Intervention	difference (95%CI)	p
Alternate step test				
Baseline	11.6 (3.8)	12.0 (4.4)		
Follow-up	10.5 (3.9)	10.1 (4.0)	-0.7 (-1.2 – -1.6)	0.001
Sit to stand				
Baseline	13.4 (4.6)	13.4 (4.2)		
Follow-up	12.4 (5.7)	12.3 (6.4)	-0.1 (-1.1 – 0.9)	0.352
Six metre walk				
Baseline	1.0 (0.2)	1.0 (0.2)		
Follow-up	1.0 (0.2)	1.0 (0.2)	0 (0 – 0)	0.558
PPA falls risk score				
Baseline	1.4 (1.0)	1.3 (0.9)		
Follow-up	1.0 (1.0)	0.8 (0.9)	-0.2 (-0.4 – -0.1)	0.007

Secondary outcome measures

	Control	Intervention	difference (95%CI)	p
Alternate step test				
Baseline	11.6 (3.8)	12.0 (4.4)		
Follow-up	10.5 (3.9)	10.1 (4.0)	-0.7 (-1.2 – -1.6)	0.001
Sit to stand				
Baseline	13.4 (4.6)	13.4 (4.2)		
Follow-up	12.4 (5.7)	12.3 (6.4)	-0.1 (-1.1 – 0.9)	0.352
Six metre walk				
Baseline	1.0 (0.2)	1.0 (0.2)		
Follow-up	1.0 (0.2)	1.0 (0.2)	0 (0 – 0)	0.558
PPA falls risk score				
Baseline	1.4 (1.0)	1.3 (0.9)		
Follow-up	1.0 (1.0)	0.8 (0.9)	-0.2 (-0.4 – -0.1)	0.007

Secondary outcome measures

	Control	Intervention	difference (95%CI)	p
MFPDI – pain subscale				
Baseline	8.0 (4.4)	8.0 (4.4)		
Follow-up	6.3 (4.9)	5.5 (4.5)	-0.7 (-1.6 – 0.2)	0.117
MFPDI – function subscale				
Baseline	4.0 (2.0)	3.9 (2.0)		
Follow-up	3.3 (2.5)	2.7 (2.0)	-0.5 (-0.9 – -0.1)	0.029
Falls Efficacy Scale				
Baseline	13.4 (4.5)	13.1 (4.0)		
Follow-up	12.45 (4.0)	11.8 (4.2)	-0.4 (-1.1 – 0.2)	0.186
SF12 – physical				
Baseline	39.8 (9.3)	38.8 (10.1)		
Follow-up	39.5 (10.5)	40.3 (10.0)	1.6 (-0.3 – 3.1)	0.046
SF12 – mental				
Baseline	49.1 (10.4)	50.2 (11.1)		
Follow-up	50.2 (9.6)	50.9 (10.8)	0.0 (-1.7 – 1.8)	1.000

Secondary outcome measures

	Control	Intervention	difference (95%CI)	p
MFPDI – pain subscale				
Baseline	8.0 (4.4)	8.0 (4.4)		
Follow-up	6.3 (4.9)	5.5 (4.5)	-0.7 (-1.6 – 0.2)	0.117
MFPDI – function subscale*				
Baseline	4.0 (2.0)	3.9 (2.0)		
Follow-up	3.3 (2.5)	2.7 (2.0)	-0.5 (-0.9 – -0.1)	0.029
Falls Efficacy Scale				
Baseline	13.4 (4.5)	13.1 (4.0)		
Follow-up	12.45 (4.0)	11.8 (4.2)	-0.4 (-1.1 – 0.2)	0.186
SF12 – physical*				
Baseline	39.8 (9.3)	38.8 (10.1)		
Follow-up	39.5 (10.5)	40.3 (10.0)	1.6 (-0.3 – 3.1)	0.046
SF12 – mental				
Baseline	49.1 (10.4)	50.2 (11.1)		
Follow-up	50.2 (9.6)	50.9 (10.8)	0.0 (-1.7 – 1.8)	1.000

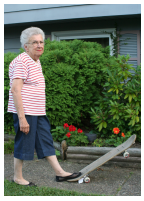
* not significant following Hochberg adjustment

Secondary outcome measures

Significant improvements in:

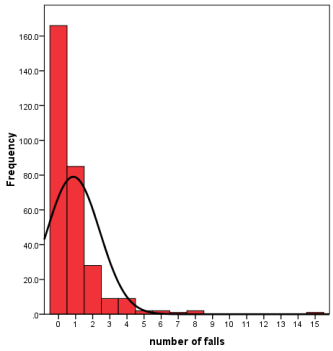
- **Strength**
  - Ankle inversion, eversion, dorsiflexion
- **Range of motion**
  - Ankle dorsiflexion and inversion/eversion
- **Balance**
  - Postural sway on floor and foam*
- **Functional ability**
  - Alternate step test
- **Physiological falls risk**
- **Health-related quality of life**
  - MFPDI function* and SF-12 physical scales*

Primary outcome measures



- **264 falls during study**
  - 8 fractures
  - 10 hospitalisations
  - 7 ED presentations
- **Number of fallers**
  - Control: **49.3%**
  - Intervention: **41.8%**
  - RR = 0.848 (95%CI 0.662 to 1.085), p=0.188
- **Number of multiple fallers**
  - Control: **21.7%**
  - Intervention: **13.7%**
  - RR = 0.632 (95%CI 0.384 to 1.041), p=0.068

Primary outcome measures



Primary outcome measures

- Falls rate
  - Falls / person / exposure
  - IRR=0.640 (95%CI 0.451 to 0.910), p=0.013
  - 36% fewer falls in the intervention group
- After excluding outlier:
  - IRR=0.702 (95%CI 0.499 to 0.988), p=0.042
  - 30% fewer falls in the intervention group

Discussion

- First RCT of an intervention specifically targeting foot and footwear risk factors
- Improvements in several measures of strength, range of motion, balance and functional ability
- 36% fewer falls in intervention group
- Retention and adherence was generally good

Discussion

- Multifaceted, so cannot delineate relative contribution of each component
- Exercises likely to have been key component
  - Improvements in strength and range of motion
- Low number of participants wearing inappropriate footwear (27%)
  - Podiatry patients
  - 17% of the intervention group purchased shoes
- Foot orthoses
  - Direct effect on balance
  - Indirect, via reduction in foot pain

Discussion

Limitations

- Participants not blinded
- Did not consider indoor footwear
- Some foot risk factors not addressed

Generalisability / translation

- Community-dwelling
- Foot pain and increased risk of falling
- Podiatry patients
- Costs covered by the trial
- No economic evaluation performed (yet)

Conclusion

- Podiatry does have an important role to play in falls prevention
- A multifaceted intervention reduces the incidence of falls by 36%
- Translation into clinical practice

Acknowledgements

- NHMRC Primary Care Project Grant
- La Trobe Central Large Grant Scheme
- Foot Science International
- Podiatry clinic staff

Thankyou

"I want my money back – these only shuffle"