

Flip-flop footwear with a moulded foot-bed for the treatment of foot pain: a randomised controlled trial



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Aim

- ▶ 1 in 5 people over 45 years experience frequent foot pain (1)
- ▶ Foot pain shown to affect ADL's, QoL, impair balance and functional ability and increase risk of falls in older adults (2-6)
- ▶ Flip flop generally not considered for foot pain
 - ▶ No support, protection or motion control (7-8)
- ▶ Manufacturing methods changed allowed contoured foot beds

Efficacy of flip-flop style footwear with a moulded foot-bed in reducing foot pain in comparison to usual footwear

Methods

Control group

General advice on footwear

Correct fitting

Wear their usual footwear for 12 weeks

Intervention group

General advice on footwear

Issued pair of flip flops

Foot Bio-tec©, Silverwater, NSW

**Wear flip flops as much as possible for 12
weeks**

Footwear diary



Methods

Recruitment

- **Patients at the University of Newcastle podiatry clinic at Wyong Hospital**

Inclusion criteria

- **Foot pain**
 - **defined as preventing them from doing at least one of their normal activities**

Exclusion criteria

- **Peripheral neuropathy**
- **Neurodegenerative disorders**
- **Lower limb surgery or amputation**
- **History of falls**

Methods



Flip flops

- ▶ **Moulded foot-bed**
- ▶ **Heel cup**
- ▶ **Wide straps**

**Foot Bio-tec©,
Silverwater, NSW**

Methods

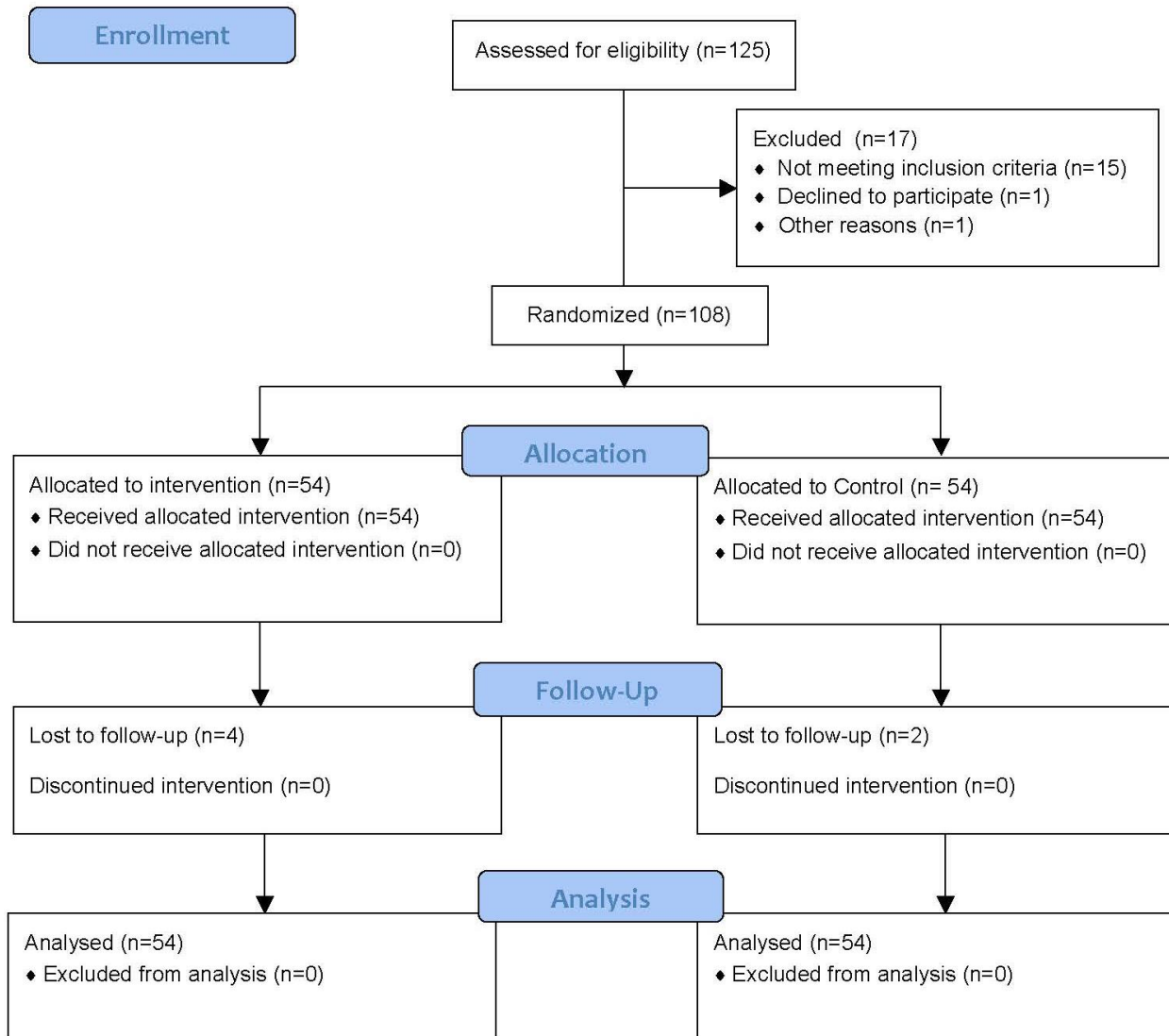
Primary outcomes

- ▶ **Foot Health Status Questionnaire (FHSQ)**
 - ▶ **Four scales**
 - ▶ **Foot pain, foot function, footwear and general foot health**
- ▶ **Visual Analogue Scale (VAS) for pain**

Secondary outcomes

- ▶ **VAS for comfort**
 - ▶ **Overall comfort**
 - ▶ **Comfort level of rearfoot, midfoot and forefoot**

Methods



Multiple
imputation
for missing
data

Participant characteristics

| Characteristic | Control (n=54) n(%) | Flip-Flop (n=54) n(%) |
|---------------------------------|---------------------|-----------------------|
| Gender | Female 31 (57) | Female 27 (50) |
| Age (mean \pm SD in years) | 48.7 \pm 17.1 | 48.4 \pm 13.4 |
| Does regular exercise | 47 (87) | 46 (85) |

Key results

Primary outcome measure - **PAIN**

| Scale | Adjusted mean (95% CI) | | Mean difference (95% CI) | P Value | Effect size |
|----------|------------------------|---------------------|--------------------------|---------|-------------|
| | Control | Intervention | | | |
| VAS (mm) | 53.3 (50.6 to 55.9) | 43.9 (41.2 to 46.6) | -9.4* (5.6 to 13.1) | < 0.01 | 0.33 |
| FHSQ | 51.2 (48.7 to 53.4) | 60.9 (58.3 to 63.5) | 9.6 (5.6 to 13.3) | < 0.01 | 0.64 |

Significant improvements in both FHSQ and VAS

VAS greater than minimal clinical difference (9mm)

FHSQ less than minimal clinical difference (14pts)

Key results

Primary outcome measure

FUNCTION and GENERAL FOOT HEALTH

| Scale | Adjusted mean (95% CI) | | Mean difference (95% CI) | P Value | Effect size |
|---------------------------------|------------------------|---------------------|--------------------------|---------|-------------|
| | Control | Intervention | | | |
| FHSQ Function | 59.4 (56.9 to 62.0) | 67.8 (65.1 to 70.3) | 8.7 (4.8 to 11.7) | < 0.01 | 0.44 |
| FHSQ General Foot Health | 26.4 (23.4 to 29.5) | 35.4 (32.3 to 38.4) | 8.9 (0.6 to 13.3) | < 0.01 | 0.41 |

Significant improvements in FHSQ function and general foot health scale

Function greater than minimal clinical difference (7pts)

General Foot Health less than minimal clinical difference (9pts)

Key results

Secondary Outcome measure – **COMFORT**

Well tolerated – as assessed using a VAS scale

Overall comfort – 72.1mm

Forefoot comfort – 69.2mm

Midfoot – 74.0mm

Heel comfort – 67.6mm

No reported adverse effects or dropouts related to problems with footwear

Mean hours of use over 12 weeks = 183.0 (SD=75.7)

Mean hours per week = 15.25 hours

Discussion

- **Small but significant reduction in foot pain**
- **Pain relief may be due to**
 - **Contoured footbed providing pressure reduction at forefoot and rearfoot**
 - **Shorter stride → slower walking speed → reduced plantar pressure**
 - **Open design – increased comfort & reduced pressure on bony prominences**

Limitations

- ▶ 12 week intervention period
 - ▶ Long term benefits?
- ▶ All foot pain included – would some causes of foot pain be more responsive than others
 - ▶ Transient foot pain v Chronic pain
 - ▶ e.g. Plantar fasciitis v Osteoarthritis
- ▶ Primary outcome recorded by Self-report
 - ▶ Bias?

Conclusion

MOULDED FLIP-FLOPS

- ▶ **Relatively cheap, easily available, well tolerated intervention**
- ▶ **Can reduce foot pain and improve foot function**



**Jump in the deep end –
give it a go**

Thank you!

References

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