Effects of unstable shoes on chronic low back pain in health professionals: a randomized clinical trial

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Disclosure

• The company Masai Barefoot Technology has offered the shoes for all the participants
• Masai Barefoot Technology has not in any way influenced the study design, the measurement procedures, the data analysis, or the interpretation of the results
• This project was supported by a grant from Clinical Research Center, University of Geneva and Geneva University Hospitals (PRD 10-II-8).
Introduction

• Low back pain (LBP) in healthcare professionals
  – Very common complaint \((\text{Gonge et al. 2001; Genevay et al. 2011})\)
  – Responsible for an important absenteeism from work \((\text{Pheasant and Stubbs, 1992})\)
  – Reach elevated annual cost \((\text{Courvoisier et al., 2011; Genevay et al., 2011})\)

• Management of LBP
  – Drugs, surgery, physical therapy \((\text{van Middelkoop et al., 2011, White et al., 2011})\)
  – Difficulty with conventional exercise training \((\text{Nigg et al., 2009})\)
    • Rate of compliance
    • Time commitments
    • Availability of the equipment
    • Degree of motivation
Introduction

• Unstable shoes
  • Modification of gait and balance (Nigg et al., 2006)
  • Modification of muscles activation (Romkes et al., 2006)
  • Significant reduction of LBP among golfers (Nigg et al., 2009)

• Optimal solution for exercise intervention?
  • Not require any equipment
  • Can be used in daily life activities
Aim

• The aim of this study was to evaluate the effectiveness of unstable shoes in reducing LBP in health professionals
Method

• Design:
  – Randomized controlled trial (RCT)
  – Two arms
    • Intervention: Wearing during 6 weeks MBT shoes
    • Control: Wearing during 6 weeks conventional sport shoes (addidas – Bigroar)

• Population:
  – 40 participants among employees of a Swiss hospital
  – Chronic non-specific LBP
Method

• Measurements
  – Primary outcome
    • Levels of pain (Visual Analog Scale – VAS)
  – Secondary outcomes
    • Satisfaction
    • Disability questionnaire (Roland-Morris)
    • Quality of live (EQ-VAS)

• Statistics
  – mean change with T-test or Mann-Whitney U
  – Fisher exact test for proportion
  – Intention to treat with imputation by last observation carried forward
Results - recruitment

Interested in participating (n=144)

In/Exclusion Criteria

NO

Undergo the telephone interview

YES

In/Exclusion Criteria

NO

Included and Randomized (n=40)

Excluded (n=72)
- low level of pain (22)
- low % of walking during work time (3)
- other pathologies (18)
- not working at least at 80% (14)
- neurological symptoms (1)
- already have unstable shoes (7)
- at present not working (1)

Included and Randomized (n=40)

Excluded (n=32)
- low level of pain (2)
- other pathologies / other pain more important (12)
- neurological symptoms (4)
- have unstable shoes (1)
- injured / at present not working (3)
- interested to continue (12)

Included and Randomized (n=40)

Pre-intervention Allocation

Intervention group (n=20)
- Evaluation 1 (n=20)
- Dropout: due to ankle injury (1)
- Evaluation 2 (n=19)

Control group (n=20)
- Evaluation 1 (n=20)
- Dropout: due to ankle injury (1), foot pain in shoes (3)
- Evaluation 2 (n=16)
## Results - Baseline

<table>
<thead>
<tr>
<th>General Characteristics</th>
<th>Intervention group (n=20)</th>
<th>Control group (n=20)</th>
<th>P value (t-test or Fisher)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>44.5 ± 7.9 (31-58)</td>
<td>46.8 ± 8.8 (32-62)</td>
<td>0.400</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>162.1 ± 9.13 (144-180)</td>
<td>164.8 ± 7.8 (155-187.7)</td>
<td>0.312</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>66.2 ± 11.3 (50-90)</td>
<td>71.6 ± 13.7 (52.5-106)</td>
<td>0.183</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>25.1 ± 3.9 (20.1-32.5)</td>
<td>26.5 ± 5.5 (19.1-40.8)</td>
<td>0.340</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pain</th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Pain last 24h</td>
<td>4.2 ± 1.9 (1.0-7.4)</td>
<td>4.1 ± 1.8 (0.6-7.6)</td>
<td>0.333</td>
</tr>
<tr>
<td>In-lab pain during walking with shoes</td>
<td>1.87 ± 1.6 (0-5)</td>
<td>2.29 ± 1.6 (0-5)</td>
<td>0.443</td>
</tr>
<tr>
<td>In-lab pain during barefoot walking</td>
<td>2.28 ± 1.9 (0-6)</td>
<td>2.7 ± 2.1 (0-7)</td>
<td>0.555</td>
</tr>
<tr>
<td>Pain killers intake (n)</td>
<td>7</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Low back pain before this episode (n)</td>
<td>20</td>
<td>18</td>
<td>0.825</td>
</tr>
</tbody>
</table>
Results – Pre-Post intervention

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
<th>P values (t-test)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>n Baseline</td>
<td>Follow-up</td>
<td>n Baseline</td>
</tr>
<tr>
<td><strong>Pain</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Last 24 h (VAS 0-10)</td>
<td>4.3 ± 1.9</td>
<td>2.8 ± 2.3</td>
<td>4.1 ± 1.8</td>
</tr>
<tr>
<td>In-lab walking barefoot</td>
<td>2.3 ± 2.0</td>
<td>0.8 ± 1.1</td>
<td>2.7 ± 2.1</td>
</tr>
<tr>
<td>In-lab walking shoes</td>
<td>1.9 ± 1.6</td>
<td>0.3 ± 0.8</td>
<td>2.3 ± 1.6</td>
</tr>
<tr>
<td>Daily logbook</td>
<td>3.7 ± 2.3</td>
<td>1.8 ± 1.67</td>
<td>3.5 ± 1.4</td>
</tr>
<tr>
<td><strong>Functional disability</strong></td>
<td></td>
<td></td>
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<tr>
<td>Roland-Morris (0-24)</td>
<td>7.5 ± 3.2</td>
<td>5.1 ± 4.9</td>
<td>7.6 ± 3.1</td>
</tr>
<tr>
<td><strong>Quality of life</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>EQ-VAS (0-100)</td>
<td>79.0 ± 12.7</td>
<td>81.4 ± 15.5</td>
<td>76.6 ± 13.4</td>
</tr>
</tbody>
</table>
Results

LBP assessed for 6 weeks with a daily logbook

Pain management satisfaction

Control Group  Intervention Group

Very satisfied  Satisfied  Neutral  Unsatisfied  Very unsatisfied

Pain level (VAS)
Conclusions

Unstable shoes compared to control shoes:

✓ Reduction of LBP
✓ Good satisfaction
✓ No effect on disabilities and quality of live

Perspectives:

- Evaluation during larger and longer trials
- Understanding the effect during gait and standing
- Identify the profile of the responders