**Supplementary file 2.** Complete case analysis of primary and secondary outcome measures at baseline and follow-up. Values are mean (SD).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | n | Sham insert group (total n=51) | Shoe-stiffening insert group (total n=49) | Adjusted mean difference (95% CI)\* | *p* |
| FHSQ – pain domain† |  |  |  |  |  |
| Baseline | 100 | 47.8 (17.1) | 47.1 (16.3) |  |  |
| 4 weeks | 91 | 55.6 (18.6) | 65.3 (17.1) | 10.94 (4.59, 17.30) |  |
| 12 weeks | 85 | 63.3 (16.4) | 69.4 (17.3) | 6.91 (0.40, 13.42) | 0.038 |
| 24 weeks | 78 | 65.2 (20.2) | 75.0 (13.9) | 9.89 (2.36, 17.42) |  |
| 52 weeks | 77 | 67.3 (20.4) | 73.4 (17.7) | 6.48 (-1.96, 14.91) |  |
| FHSQ – function domain† |  |  |  |  |  |
| Baseline | 100 | 67.8 (23.4) | 64.9 (23.3) |  |  |
| 4 weeks | 91 | 77.1 (19.9) | 78.8 (15.7) | 4.32 (-1.39, 10.03) |  |
| 12 weeks | 85 | 81.4 (18.3) | 84.1 (17.7) | 4.51 (-2.17, 11.19) | 0.183 |
| 24 weeks | 78 | 82.5 (16.9) | 88.3 (14.8) | 6.64 (-0.02, 13.31) |  |
| 52 weeks | 77 | 85.6 (17.7) | 86.1 (18.7) | 1.38 (-6.81, 9.58) |  |
| Pain severity while walking - VAS‡ |  |  |  |  |  |
| Baseline | 100 | 51.8 (15.6) | 50.8 (14.9) |  |  |
| 4 weeks | 91 | 38.6 (21.2) | 32.0 (20.1) | -6.58 (-14.25, 10.90) |  |
| 12 weeks | 85 | 31.9 (20.9) | 24.3 (20.9) | -7.83 (-16.51, -0.86) | 0.077 |
| 24 weeks | 78 | 27.6 (22.4) | 16.8 (14.9) | -10.70 (-19.27, -2.13) |  |
| 52 weeks | 78 | 24.3 (21.8) | 17.7 (21) | -6.62 (-16.18, 2.95) |  |
| Pain severity at rest - VAS‡§ |  |  |  |  |  |
| Baseline | 100 | 27.3 (19.9) | 29.9 (17.0) |  |  |
| 4 weeks | 91 | 21.6 (20.4) | 20.2 (19.0) | -3.40 (-10.58, 3.78) |  |
| 12 weeks | 85 | 12.3 (13.4) | 13.4 (16.4) | 0.35 (-5.92, 6.63) | 0.911 |
| 24 weeks | 78 | 16.3 (18.6) | 9.8 (16.7) | -6.76 (-14.75, 12.40) |  |
| 52 weeks | 78 | 14.9 (19.8) | 12.0 (19.5) | -3.54 (-12.36, 5.28) |  |
| Physical activity - IPAQ§ |  |  |  |  |  |
| Baseline | 100 | 13.8 (9.9) | 13.2 (11.1) |  |  |
| 4 weeks | 91 | 15.9 (11.9) | 14.1 (10.2) | -1.57 (-5.51, 2.38) |  |
| 12 weeks | 85 | 14.5 (13.8) | 16.6 (15.0) | 2.24 (-3.47, 7.95) | 0.438 |
| 24 weeks | 78 | 15.3 (13.1) | 14.7 (12.6) | -0.69 (-4.98, 3.60) |  |
| 52 weeks | 78 | 13.4 (8.7) | 15.6 (11.5) | 2.48 (-1.57, 6.53) |  |
| SF12 - physical† |  |  |  |  |  |
| Baseline | 100 | 45.9 (9.1) | 46.8 (9.9) |  |  |
| 4 weeks | 91 | 48.6 (8.1) | 48.0 (10.3) | -0.29 (-2.94, 2.37) |  |
| 12 weeks | 85 | 47.1 (9.1) | 49.9 (8.5) | 2.77 (-0.09, 5.62) | 0.058 |
| 24 weeks | 78 | 49.9 (7.5) | 50.5 (10.1) | -0.03 (-3.27, 3.21) |  |
| 52 weeks | 77 | 50.6 (7.1) | 49.9 (8.5) | -0.74 (-3.65, 2.17) |  |
| SF12 - mental† |  |  |  |  |  |
| Baseline | 100 | 54.0 (9.1) | 53.0 (9.3) |  |  |
| 4 weeks | 91 | 53.0 (8.6) | 53.2 (8.7) | 0.82 (-2.05, 3.67) |  |
| 12 weeks | 85 | 53.7 (8.0) | 53.8 (8.4) | 0.84 (-2.22, 3.89) | 0.587 |
| 24 weeks | 78 | 54.9 (6.9) | 52.0 (8.8) | -1.40 (-4.39, 1.59) |  |
| 52 weeks | 77 | 53.7 (8.4) | 52.6 (9.7) | 0.51 (-2.73, 3.75) |  |
| EQ-5D-5L VAS† |  |  |  |  |  |
| Baseline | 100 | 76.0 (15.7) | 80.1 (13.7) |  |  |
| 4 weeks | 91 | 78.2 (15.2) | 81.0 (13.1) | 0.69 (-3.30, 4.67) |  |
| 12 weeks | 85 | 80.8 (11.4) | 83.4 (13.2) | 1.20 (-3.43, 5.83) | 0.607 |
| 24 weeks | 78 | 82.1 (12.7) | 83.0 (12.2) | -0.22 (-5.15, 4.72) |  |
| 52 weeks | 78 | 83.6 (9.8) | 81.9 (17.4) | -2.29 (-8.54, 3.96) |  |
| FHSQ=Foot Health Status Questionnaire; VAS=visual analog scale; SF-12=Short Form 12 Health Survey; IPAQ=International Physical Activity Questionnaire; EQ-5D-5L VAS=EuroQol 5 dimension-5-level visual analogue scale  \* adjusted for baseline score and intervention group using analysis of covariance  † higher scores indicate better symptoms/function  ‡ higher scores indicate worse symptoms  § data skewed so analysis performed on log transformed variable | | | | | |