**Figure 1.** Flow chart of the study participants throughout the al-Ándalus trial. ITT: Intention-to-treat

**Table 1.** Baseline descriptive characteristics of the study participants in the al-Ándalus trial

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|   | All  |   | Land-based  |   | Water-based  |   | Control  |   |
| (*n*=250) | (*n*=83) | (*n*=85) | (*n*=82) |
|  | mean | (SD) |  | mean | (SD) |  | mean | (SD) |  | mean | (SD) | *P-value* |
| Age (years) | 50.8 | 7.6 |  | 49.8 | 7.2 |  | 52.3 | 8.2 |  | 50.4 | 7.2 | 0.069 |
| Body Mass Indez (kg/m2) | 28.6 | 5.6 |  | 27.7 | 5.2 |  | 29.5 | 5.6 |  | 28.6 | 5.9 | 0.115 |
| Disease Impact (FIQR, 0-100)† | 65.5 | 15.9 |  | 66.4 | 15.9 |  | 63.7 | 15.5 |  | 66.5 | 16.3 | 0.446 |
| Dimensions of fatigue |  |  |  |  |  |  |  |  |  |  |  |  |
| General Fatigue (MFI, 4 - 20)† | 18.3 | 2.2 |  | 18.4 | 2.3 |  | 18.1 | 2.3 |  | 18.5 | 2.1 | 0.549 |
| Physical Fatigue (MFI, 4 - 20)† | 17.0 | 2.8 |  | 17.1 | 2.9 |  | 17.2 | 2.5 |  | 16.7 | 2.9 | 0.383 |
| Reduced Activity (MFI, 4 - 20)† | 13.2 | 4.8 |  | 13.5 | 4.7 |  | 13.0 | 4.8 |  | 13.1 | 4.8 | 0.802 |
| Reduced Motivation (MFI, 4 - 20)† | 13.3 | 3.8 |  | 13.5 | 3.7 |  | 13.1 | 3.5 |  | 13.1 | 4.2 | 0.690 |
| Mental Fatigue (MFI, 4 - 20)† | 14.4 | 2.2 |  | 14.4 | 2.2 |  | 14.1 | 2.3 |  | 14.7 | 2.1 | 0.295 |
| Dimensions of sleep quality |  |  |  |  |  |  |  |  |  |  |  |  |
| Subjective sleep quality (PSQI, 0 -3)† | 2.1 | 0.7 |  | 2.2 | 0.7 |  | 2.0 | 0.7 |  | 2.1 | 0.7 | 0.167 |
| Sleep latency (PSQI, 0 -3)† | **2.0** | **0.9** |  | **2.2 a** | **0.9** |  | **1.8 a** | **0.9** |  | **2.0** | **0.8** | **0.035** |
| Sleep duration (PSQI, 0 -3)† | 1.8 | 0.9 |  | 1.9 | 0.8 |  | 1.8 | 0.9 |  | 1.7 | 0.9 | 0.437 |
| Sleep efficiency (PSQI, 0 -3)† | 1.7 | 1.2 |  | 1.8 | 1.1 |  | 1.7 | 1.2 |  | 1.7 | 1.2 | 0.887 |
| Sleep disturbances (PSQI, 0 -3)† | 2.2 | 0.6 |  | 2.2 | 0.6 |  | 2.1 | 0.7 |  | 2.2 | 0.6 | 0.849 |
| Sleep medication (PSQI, 0 -3)† | **2.1** | **1.2** |  | **1.9 a** | **1.3** |  | **2.0** | **1.3** |  | **2.4 a** | **1.0** | **0.020** |
| Daytime dysfunction (PSQI, 0 -3)† | 1.6 | 0.7 |  | 1.6 | 0.8 |  | 1.6 | 0.7 |  | 1.7 | 0.8 | 0.439 |
| Sleep quality global score (PSQI, 0 -21)† | 13.6 | 3.8 |  | 13.7 | 3.9 |  | 13.1 | 3.7 |  | 13.9 | 3.7 | 0.314 |
| Time since diagnosis |  |  |  |  |  |  |  |  |  |  |  |  |
| Less than 1 year | 20 | 8.2 |  | 6 | 7.5 |  | 6 | 7.2 |  | 8 | 9.9 | 0.772 |
| Between 1 and 5 years | 95 | 38.9 |  | 34 | 42.5 |  | 34 | 41 |  | 27 | 33.3 |
| More than 5 years | 120 | 52.9 |  | 40 | 50 |  | 43 | 51.8 |  | 46 | 56.8 |
|   | n | % |   | n | % |   | n | % |   | n | % | *P-value* |
| Marital status |  |  |  |  |  |  |  |  |  |  |  |  |
| Married | 184 | 73.9 |  | 63 | 75.9 |  | 63 | 75 |  | 58 | 70.7 | 0.722 |
| Not married | 65 | 26.1 |  | 20 | 24.1 |  | 21 | 25 |  | 24 | 29.3 |
| Educational level  |  |  |  |  |  |  |  |  |  |  |  |  |
| Non-universitary | 218 | 87.6 |  | 67 a | 80.7 |  | 81 a,b | 96.4 |  | 70 b | 85.4 | 0.007 |
| Universitary | 31 | 12.4 |  | 16 | 19.3 |  | 3 | 3.6 |  | 12 | 14.6 |
| Occupational status  |  |  |  |  |  |  |  |  |  |  |  |  |
| Working full/part time | 63 | 25.3 |  | 22 | 26.5 |  | 18 | 21.4 |  | 23 | 28 | 0.589 |
| Unemployed/Retired/Housekeeper | 186 | 74.7 |  | 61 | 73.5 |  | 66 | 78.6 |  | 59 | 72 |
| Regular menstruation  |  |  |  |  |  |  |  |  |  |  |  |  |
| Yes | 78 | 31.3 |  | 27 | 32.5 |  | 21 | 25 |  | 30 | 36.6 | 0.263 |
| No | 171 | 68.7 |  | 56 | 67.5 |  | 63 | 75 |  | 52 | 63.4 |
| Analgesics consumption  |  |  |  |  |  |  |  |  |  |  |  |  |
| Yes | 225 | 90.4 |  | 74 | 89.2 |  | 75 | 89.3 |  | 76 | 92.7 | 0.685 |
| No | 24 | 9.6 |  | 9 | 10.8 |  | 9 | 10.7 |  | 6 | 7.3 |
| Antidepressants consumption  |  |  |  |  |  |  |  |  |  |  |  |  |
| Yes | 149 | 59.8 |  | 49 | 59 |  | 52 | 61.9 |  | 48 | 58.5 | 0.892 |
| No | 100 | 40.2 |   | 34 | 41 |   | 32 | 38.1 |   | 34 | 41.5 |
| BMI: Body Mass Index, FIQR: Fibromyalgia Impact Questionnaire, MFI: Multidimensional Fatigue Inventory, PSQI: Pittsburg Sleep Quality Index. Common superscripts indicate significant differences between groups with the same letter† Greater scores indicate worse health status  |





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**Figure 2.** Means of fatigue and sleep quality variables at baseline, at week 24 (after exercise intervention program) and at week 36 (12 weeks after exercise cessation) for each intervention group in intention-to-treat analyses. Greater scores indicate worse health status

MFI: Multidimensional Fatigue Inventory, PSQI: Pittsburgh Sleep Quality Index

\*Significant differences between mean change of land vs. control group

╪ Significant differences between mean change of water vs. control group

┼ Significant differences between mean change of land vs. water group

**Table 2.** Differences in fatigue and sleep quality between groups after 24 weeks of water or land-based exercise: intention to treat analyses

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Water vs Control |  | Land vs Control |  | Water vs Land |  |
|  | Mean difference | SE | (95% CI) | *P* | *d* | Mean difference | SE | (95% CI) | *P* | *d* | Mean difference | SE | (95% CI) | *P* | *d* |
| MFI General Fatigue | **-0.8** | **0.3** | **-1.4** | **-0.1** | **0.012** | **0.4** | -0.6 | 0.3 | -1.3 | 0.0 | 0.060 |  | -0.1 | 0.3 | -0.8 | 0.5 | 0.999 |  |
| MFI Physical Fatigue | -0.7 | 0.3 | -1.5 | 0.1 | 0.100 |  | **-0.9** | **0.3** | **-1.7** | **-0.1** | **0.020** | **0.4** | 0.2 | 0.3 | -0.6 | 1.0 | 0.999 |  |
| MFI Reduced Activity | -1.0 | 0.5 | -2.2 | 0.3 | 0.189 |  | -0.8 | 0.5 | -2.0 | 0.4 | 0.381 |  | -0.2 | 0.5 | -1.4 | 1.1 | 0.999 |  |
| MFI Reduced Motivation | 0.0 | 0.4 | -1.0 | 1.0 | 0.999 |  | 0.3 | 0.4 | -0.7 | 1.4 | 0.999 |  | -0.3 | 0.4 | -1.4 | 0.7 | 0.999 |  |
| MFI Mental Fatigue | -0.1 | 0.3 | -0.8 | 0.5 | 0.999 |  | 0.1 | 0.3 | -0.5 | 0.7 | 0.999 |  | -0.2 | 0.3 | -0.9 | 0.4 | 0.978 |  |
| PSQI Subjective sleep quality | **-0.2** | **0.1** | **-0.4** | **0.0** | **0.030** | **0.4** | 0.1 | 0.1 | -0.1 | 0.3 | 0.867 |  | **-0.3** | **0.1** | **-0.5** | **-0.1** | **0.001** | **0.5** |
| PSQI Sleep latency | -0.2 | 0.1 | -0.5 | 0.0 | 0.147 |  | 0.0 | 0.1 | -0.2 | 0.3 | 0.999 |  | **-0.3** | **0.1** | **-0.5** | **0.0** | **0.046** | **0.3** |
| PSQI Sleep duration | 0.0 | 0.1 | -0.3 | 0.2 | 0.999 |  | 0.2 | 0.1 | -0.1 | 0.4 | 0.236 |  | -0.2 | 0.1 | -0.4 | 0.0 | 0.144 |  |
| PSQI Sleep efficiency | -0.2 | 0.1 | -0.5 | 0.1 | 0.545 |  | 0.0 | 0.1 | -0.3 | 0.3 | 0.999 |  | -0.2 | 0.1 | -0.5 | 0.1 | 0.602 |  |
| PSQI Sleep disturbances | -0.1 | 0.1 | -0.3 | 0.0 | 0.115 |  | -0.1 | 0.1 | -0.2 | 0.1 | 0.999 |  | -0.1 | 0.1 | -0.3 | 0.1 | 0.792 |  |
| PSQI Sleep medication  | **-0.5** | **0.1** | **-0.9** | **-0.2** | **<0.001** | **0.7** | **-0.4** | **0.1** | **-0.8** | **-0.1** | **0.005** | **0.4** | -0.1 | 0.1 | -0.4 | 0.2 | 0.999 |  |
| PSQI Daytime dysfunction | **-0.3** | **0.1** | **-0.5** | **-0.1** | **0.004** | **0.5** | -0.1 | 0.1 | -0.4 | 0.1 | 0.291 |  | -0.1 | 0.1 | -0.3 | 0.1 | 0.358 |  |
| PSQI Sleep quality global score | **-1.6** | **0.4** | **-2.7** | **-0.6** | **0.001** | **0.6** | -0.5 | 0.4 | -1.5 | 0.6 | 0.920 |  | **-1.2** | **0.4** | **-2.2** | **-0.1** | **0.023** | **0.4** |

Data is presented as estimated mean difference between groups, standard error (SE) and 95% confidence interval (CI). *P* values obtained from post-hoc Bonferroni corrections from the linear mixed repeated measures analyses. Missing values were imputed using multiple imputation by chained equations. CI: Confidence Interval; MFI: Multidimensional Fatigue Inventory. PSQI: Pittsburg Sleep Quality Index.

**Table 3.** Differences in fatigue and sleep quality between groups 12 weeks after water or land-based exercise cessation: intention to treat analyses

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Water vs Control |  | Land vs Control |  | Water vs Land |  |
|  | Mean difference | SE | (95% CI) | *P* | *d* | Mean difference | SE | (95% CI) | *P* | *d* | Mean difference | SE | (95% CI) | *P* | *d* |
| MFI General Fatigue | -0.4 | 0.3 | -1.0 | 0.3 | 0.575 |   | 0.1 | 0.3 | -0.6 | 0.7 | 0.999 |   | -0.4 | 0.3 | -1.1 | 0.2 | 0.387 |  |
| MFI Physical Fatigue | -0.3 | 0.3 | -1.1 | 0.5 | 0.999 |   | -0.4 | 0.3 | -1.1 | 0.4 | 0.822 |   | 0.0 | 0.3 | -0.8 | 0.7 | 0.999 |  |
| MFI Reduced Activity | -0.5 | 0.5 | -1.7 | 0.8 | 0.999 |   | 0.2 | 0.5 | -1.1 | 1.4 | 0.999 |   | -0.6 | 0.5 | -1.9 | 0.6 | 0.687 |  |
| MFI Reduced Motivation | 0.2 | 0.4 | -0.8 | 1.3 | 0.999 |   | 0.1 | 0.4 | -0.9 | 1.2 | 0.999 |   | 0.1 | 0.4 | -0.9 | 1.1 | 0.999 |  |
| MFI Mental Fatigue | -0.3 | 0.2 | -0.9 | 0.3 | 0.794 |   | -0.2 | 0.2 | -0.8 | 0.4 | 0.999 |   | -0.1 | 0.2 | -0.7 | 0.5 | 0.999 |  |
| PSQI Subjective sleep quality | -0.1 | 0.1 | -0.3 | 0.1 | 0.703 |   | 0.0 | 0.1 | -0.2 | 0.2 | 0.999 |   | -0.1 | 0.1 | -0.3 | 0.1 | 0.309 |  |
| PSQI Sleep latency | -0.2 | 0.1 | -0.5 | 0.0 | 0.097 |   | 0.0 | 0.1 | -0.2 | 0.3 | 0.999 |   | -0.2 | 0.1 | -0.5 | 0.0 | 0.052 |  |
| PSQI Sleep duration | 0.1 | 0.1 | -0.1 | 0.3 | 0.714 |   | **0.3** | **0.1** | **0.0** | **0.5** | **0.022** | 0.4 | -0.1 | 0.1 | -0.4 | 0.1 | 0.381 |  |
| PSQI Sleep efficiency | 0.0 | 0.1 | -0.3 | 0.3 | 0.999 |   | 0.1 | 0.1 | -0.2 | 0.4 | 0.999 |   | -0.1 | 0.1 | -0.4 | 0.2 | 0.999 |  |
| PSQI Sleep disturbances | -0.1 | 0.1 | -0.3 | 0.1 | 0.530 |   | 0.0 | 0.1 | -0.2 | 0.1 | 0.999 |   | -0.1 | 0.1 | -0.2 | 0.1 | 0.981 |  |
| PSQI Sleep medication  | **0.4** | **0.1** | **-0.7** | **0.0** | **0.023** | 0.4 | **0.3** | **0.1** | **-0.7** | **0.0** | **0.035** | 0.4 | 0.0 | 0.1 | -0.3 | 0.3 | 0.999 |  |
| PSQI Daytime dysfunction | -0.1 | 0.1 | -0.3 | 0.1 | 0.999 |   | 0.0 | 0.1 | -0.2 | 0.2 | 0.999 |   | -0.1 | 0.1 | -0.3 | 0.1 | 0.999 |  |
| PSQI Sleep quality global score | -0.8 | 0.4 | -1.8 | 0.2 | 0.194 |   | 0.2 | 0.4 | -0.9 | 1.2 | 0.999 |   | -1.0 | 0.4 | -2.0 | 0.1 | 0.070 |  |

Data is presented as estimated mean difference between groups, standard error (SE) and 95% confidence interval (CI). *P* values obtained from post-hoc Bonferroni corrections from the linear mixed repeated measures analyses. Missing values were imputed using multiple imputation by chained equations. CI: Confidence Interval; MFI: Multidimensional Fatigue Inventory. PSQI: Pittsburg Sleep Quality Index.