**Participant Flow**

**Assessed, met the inclusion criteria and were eligible for the study**

**(n=445)**

**(n=445)**

**Eligible participants who consented to take part in the Study**

**(n=81)**

Randomisation to either **control** or **experimental** group

**(n=81)**

**Allocated to Control Group.** Back to Fitness Programme (BTFP)

**(n=40)**

**Allocated to Experimental Group:** Spinal Rehabilitation Programme (SRP)

**(n=41)**

**Received allocated intervention**

**(n=28, 68%)**

**Intervention attrition**

**(n=13, 32%)**

**Lost to follow-up at 6 months**

**(n=18, 44%)**

**Received allocated intervention**

**(n=26, 65%)**

**Intervention attrition**

**(n=14, 35%)**

**Lost to follow-up at 6 months**

**(n=14, 35%)**

**Analysed post programme (n=26, 65%)**

**Analysis at 6 months (n= 12, 30%)**

**Overall drop-out (n=28, 70%)**

**Analysed post programme (n= 28, 68%)**

**Analysis at 6 months (n=10, 24%)**

**Overall drop-out (n=31, 76%)**

**Baseline Characteristics**

**Table 1: Baseline characteristics of the two treatment groups**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Baseline characteristic | Programme | | All Patients  (N=81) | P-value |
| SRP  (N=41) | BTFP  (N=40) |
| Age, mean ± SD  n | 46.4 ± 12.1  41 | 43.3 ± 12.7  40 | 44.9 ± 12.4  81 | 0.25 |
| Sex, n (%)  Male  Female | 15 (36.6%)  26 (63.4%) | 16 (40%)  24 (60%) | 31 (38.3%)  50 (61.7%) | 0.75 |
| Duration of symptoms, median (P25, P75)  n | 36 (11, 72)  41 | 21.5 (10, 72)  40 | 24 (10, 72)  81 | 0.30 |
| Start Back Tool, n (%)  Low  Medium  High | 16 (39.0%)  9 (22.0%)  16 (39.0%) | 19 (47.5%)  13 (32.5%)  8 (20.0%) | 35 (43.2%)  22 (27.2%)  24 (29.6%) | 0.16 |
| Employment, n (%)  Working  Non-working | 20 (48.8%)  21 (51.2%) | 32 (80.0%)  8 (20.0%) | 52 (64.2%)  29 (35.8%) | 0.003 |
| FRI\*, mean ± SD  n | 54.0 ± 23.2  34 | 48.2 ± 13.7  31 | 51.2 ± 19.4  65 | 0.23 |
| EQ-5D\*, median (P25, P75)  n | 0.48 (0.30, 0.68)  33 | 0.59 (0.53, 0.69)  31 | 0.57 (0.35, 0.69)  64 | 0.048 |
| NPRS\*, mean ± SD  n | 5.09 ± 2.75  33 | 4.91 ± 1.34  30 | 5.00 ± 2.18  63 | 0.74 |
| EQ-VAS\*, median (P25, P75)  n | 50.0 (30.0, 80.0)  33 | 62.5 (50.0, 70.0)  30 | 60.0 (40.0, 80.0)  63 | 0.20 |

P25 is defined as the 25th percentile and P75 is defined as the 75th percentile; SD = standard deviation, SRP = spinal rehabilitation programme, BTFP = Back to Fitness programme

\*Primary Outcome Measures

**Outcome measures**

Primary Outcome Measures

**Table 2: Pre versus Post-Programme/Follow-up for SRP patients (n=28)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcome |  | | Raw mean difference (95% CI)  (Post/Follow-up minus Pre) | P-value |
| Pre  Raw mean (95% CI) | Post/Follow-up  Raw mean (95% CI) |
| FRI pre versus post-programme (n=28) | 51.9 (42.9, 61.0) | 40.3 (30.9, 49.7) | -11.6 (-17.5, -5.7) | 0.0004 |
| FRI pre versus 6-month follow-up (n=10) | 49.6 (35.2, 63.9) | 38.8 (18.4, 59.2) | -10.8 (-22.9, 1.3) | 0.07 |
| EQ-5D pre versus post-programme (n=28) | 0.47 (0.35, 0.58) | 0.55 (0.44, 0.67) | 0.08 (0.02, 0.16) | 0.02 |
| EQ-5D 6-month follow-up (n=10) | 0.46 (0.20, 0.71) | 0.56 (0.29, 0.84) | 0.10 (0.01, 0.20) | 0.04 |
| NPRS post-programme (n=28) | 4.94 (3.88, 6.00) | 3.88 (2.89, 4.86) | -1.06 (-2.08, -0.05) | 0.04 |
| NPRS 6-month follow-up (n=10) | 4.92 (2.66, 7.17) | 3.63 (1.54, 5.72) | -1.28 (-3.20, 0.64) | 0.17 |
| EQ-VAS post-programme (n=28) | 56.4 (46.0, 66.8) | 63.1 (53.9, 72.3) | 6.7 (-4.5, 17.8) | 0.22 |
| EQ-VAS 6-month follow-up (n=10) | 56.0 (33.3, 78.7) | 65.5 (46.3, 84.7) | 10.3 (-13.9, 32.9) | 0.38 |

**Table 3: Pre versus Post-Programme/Follow-up for BTFP patients (n=26)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcome |  | | Raw mean difference (95% CI)  (Post/Follow-up minus Pre) | P-value |
| Pre  Raw mean (95% CI) | Post/Follow-up  Raw mean (95% CI) |
| FRI pre versus post-programme (n=26) | 49.7 (44.2, 55.1) | 42.7 (37.0, 48.3) | -7.0 (-12.6, -1.3) | 0.02 |
| FRI pre versus 6-month follow-up (n=12) | 54.8 (47.4, 62.2) | 42.6 (28.4, 56.8) | -12.1 (-26.8, 2.5) | 0.10 |
| EQ-5D pre versus post-programme (n=26) | 0.59 (0.53, 0.66) | 0.65 (0.59, 0.71) | 0.06 (-0.02, 0.13) | 0.14 |
| EQ-5D 6-month follow-up (n=12) | 0.60 (0.47, 0.72) | 0.54 (0.38, 0.71) | -0.05 (-0.23, 0.12) | 0.52 |
| NPRS post-programme (n=26) | 5.04 (4.54, 5.54) | 4.32 (3.63, 5.01) | -0.72 (-1.29, -0.15) | 0.02 |
| NPRS 6-month follow-up (n=12) | 5.43 (4.71, 6.15) | 4.23 (2.74, 5.73) | -1.20 (-2.35, -0.04) | 0.04 |
| EQ-VAS post-programme (n=26) | 61.7 (55.3, 68.2) | 67.3 (59.6, 75.0) | 5.6 (-2.2, 13.4) | 0.15 |
| EQ-VAS 6-month follow-up (n=12) | 58.3 (47.1, 69.6) | 65.6 (51.0, 80.1) | 7.3 (-6.5, 21.0) | 0.27 |

Secondary Outcome Measures

**Table 4: Outcome: PSRS (n=54)**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Programme | | P-value |
| SRP  (N=28) | BTFP  (N=26) |
| Median (P25, P75) | 20.0 (17.4, 21.5) | 19.0 (15.0, 21.0) | 0.19 |

P25 is defined as the 25th percentile and P75 is defined as the 75th percentile

**Adverse events**

There were no adverse events associated with this trial.