

## **Statistical Analysis Plan (SAP) Phase II**

### **Trial- 19833163- Claudio Merkier (LSBU)**

Performance outcome measures will be analysed by using SPSS by including the 95% confidence interval ( $p < 0.05$ ) and 80% power sample size calculations.

#### **Participants:**

- Intervention group (Master Athletes aged 60+): MA1, MA2, ....MA15
- Control group (Adults aged 60+): CO1, CO2, ... C015

#### **Demographics for each group:**

Mean, median or mode (?) With their standard deviation (SD), median absolute difference (MAD) or inter-quartile range (?).

- Age
- Gender
- Weight
- Height
- Sports (Discipline)
- Achieved highest winning level

<https://www.thepowerof10.info/athletes/athleteslookup.aspx>

- Geographical training region
- Years of training/competing
- Push off leg (Dominant)

**Primary outcome variables:**

1. MVICM R PF peak
2. MVICM L PF peak
3. MVICM B PF peak
4. MVICM B PF (L) peak
5. MVICM B PF (R) peak
6. RMSE AMSS1
7. RMSE AMSS2
8. RMSE AMSF1
9. RMSE AMSF2

References for the primary outcomes	
PRE1	1 <sup>st</sup> Measurements taken at baseline
PRE2	2 <sup>nd</sup> Measurements taken for control (within subject)
POST	3 <sup>rd</sup> Measurements taken for intervention group
PRE3	3 <sup>rd</sup> Measurements taken for control group
Parameters	
MVICM R PF peak [Nm]	Maximum voluntary isometric contraction moment of Right plantar flexor muscles peak measurement result
MVICM L PF peak [Nm]	Same MVICM for left PF
MVICM B PF peak [Nm]	Same MVICM for both PF
MVICM B PF (L) peak [Nm]	Same for both but measurement the left PF
MVICM B PF (R) peak [Nm]	Same for both but measurement the right PF
RMSE AMSS1[%]	Root mean square error for accuracy motor skill slow delay first trial (60 secs)
RMSE AMSS2 [%]	Same AMSS second trial
RMSE AMSF1 [%]	RMSE for AMS fast delay first trial (15 secs)
RMSE AMSF2 [%]	Same AMSF second trial

**Statistical tests for the Primary outcomes****1. Within subjects (dependent groups) comparison:**

Parameters will be analysed by using the “dependent t-test for paired samples” for the estimated difference in mean change.

1.1 PRE1 vs PRE2 (MA)

1.2 PRE1 vs PRE2 (CO)

1.3 PRE1 vs POST (MA)

1.4 PRE1 vs PRE3 (CO)

1.5 PRE2 vs POST (MA)

1.6 PRE2 vs PRE3 (CO)

If a significant mean difference is encountered for any of the comparison above an effect size (Cohen’s d) will be calculated.

**2. Between groups (independent groups) COs vs MAs comparison:**

Parameters will be analysed by using the “unpaired t-test” for the estimated difference in mean change.

2.1. PRE1-PRE2 (CO) vs PRE1-PRE2 (MA)

2.2. PRE1-PRE3 (CO) vs PRE1-POST (MA)

2.3. PRE2-PRE3 (CO) vs PRE2-POST (MA)

If a significant mean difference is encountered for any of the comparison above an effect size (Cohen’s d) will be calculated.

**Categorical statistics for secondary outcomes:**

1. Global anticipated effects (GAE) of chiropractic care on primary outcomes (before care was provided)
2. Global perceived effects (GPE) of chiropractic care on primary outcomes (after care was provided)

GAE and GPE will be measured using a 7-points scale score:

Worse than ever (-3); Much worsened(-2); Slightly worse (-1)

Not changed/Don't know (0)

Slightly better (+1); Much better (+2); Best than ever (+3)