Muscle, Ligaments and Tendons Journal. Basic principles and recommendations in clinical and field science research

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Summary

The design, implementation, evaluation, interpretation and report of research is a key important for the science. The research required minimize the uncertainty, therefore we encourage all authors of respect how much can possible the contents in this official editorial also in order to stimulate interest and debate about constructive change in the use of statistics in our disciplines^{1,2}. Authors are required to confirm that these standards and laws have been adhered to by formally citing this editorial within the methods section of their own manuscript.

KEY WORDS: statistical analysis, case report, experimental approach, design, ethical standard, best practice, sample size, performance indicators, reliability of the measures.

In this editorial, we synthesize the standards and laws into one source for convenience to authors of *Muscle, Ligaments and Tendons Journal* submissions as methodological approach, randomized controlled trials, appropriate statistic for a Best Practice³⁻⁵. Expert groups have also produced statements about how to publish reports of various kinds of medical research⁶: **Interventions (experiments).** *CONSORT:* Consolidated Standards - Reporting Trials^{7,8}. See "consort-state-

ment.org" for statements, explanations, and extensions to abstracts and to studies involving equivalence or noninferiority, clustered randomization, harmful outcomes, nonrandomized designs, and various kinds of intervention. *EQUATOR:* Enhancing the Quality and Transparency Of health Research project aims to help fulfill the potential impact of reporting guidelines on the quality of research "see consort-statement.org".

Observational (non experimental) studies. *STROBE:* Strengthening the Reporting of Observational Studies in Epidemiology^{9,10}. See "strobe-statement.org" for statements and/or explanations, and see "HuGeNet.ca" for extension to gene-association studies.

Diagnostic tests. *STARD:* Standards for Reporting Diagnostic Accuracy^{11,12}.

Meta-analyses. *QUOROM:* Quality of Reporting of Meta-analyses⁸. *MOOSE:* Meta-analysis of Observational Studies in Epidemiology¹³. See also the Cochrane Handbook (at cochrane.org) and guidelines for meta-analysis of diagnostic tests¹⁴ and of gene-association studies (at HuGeNet.ca). *PRISMA:* Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement provides an evidence-based minimum set of items that for reporting systematic reviews and meta-analyses "see consort-statement.org", and is an update and expansion of the *QUOROM* Statement. Although it focuses on randomized trials, the *PRISMA* Statement can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions.

Those points most commonly considered by scientists are summarized below.

 Basic principles. Respect the rights and welfare of participants which must take precedence over all other interests. Ethical review. Before research begins and before amendments are applied, research must be reviewed and approved by an appropriate ethics committee.

We outline the principles of the World Medical Association Declaration of Helsinki¹⁵ and the Institute for Laboratory Animal Research of the National Research Council's Guide for the Care and Use of Laboratory Animals¹⁶. We highlight ethical issues included in national/international law and provide quidance on ethical issues common to Science. Authors who cite this editorial confirm that research using participants was conducted ethically according to the principles line of the Declaration of Helsinki. Consent Informed consent/assent should be provided freely by the participant and should ideally be in writing. If written consent/assent cannot be obtained, or is not appropriate, then oral consent/assent should be formally documented and witnessed. Research that involves children or other populations that cannot consent (e.g. vulner-

- able populations) should seek consent from an appropriate person and assent from the participant.
- The research protocol¹⁷ as Best Practice¹⁸. The study, research design and statistical analysis must be clearly described, justifiable and appropriate. Particularly, each design (for acute or chronic effects) will have to be made a priori of the experiment, while in longitudinal studies will be necessary Control Group in randomized order¹⁹⁻²². Please place your statistical power²³ in the manuscript for the n size used and reliability²⁴ of the dependent measures with Intra-class Correlations Coefficient and $\Delta\%$ (from two trials). Strongly encourage to use ANOVA, rarely may be used ttest²⁵, while Bland and Altman test²⁶ is recommended for assessing agreement between two methods of clinical measurement^{27,28}, besides Factorial Analysis is suggested when subjects are ">100"29.
- The results must be clear and usable by the reader must not duplicate in Table/s and viceversa with Means ± SD, while in the Figure/s are recommended Error bars³⁰.
- Particularly, the purpose of this Editorial is also to foster the terminology accordingly the Systeme International d'Unités that was adopted universally in 1960. Furthermore for Biomechanical³¹ or muscular work³²⁻³⁴ do not use inappropriate words, the human movement should be described for what it is, as well as the use of term "significant"³⁵ should be used with caution. For systematic reviews or meta-analyses, the authors should not normally set limits based on year of publication, and articles in at least two languages should be searched.

References

- Maffulli N, Oliva F, Frizziero A. The baby is growing: PubMed Listing for Muscles Ligaments and Tendons Journal. Muscles Ligaments Tendons J 2013; 3(2):58-59.
- Kelberine F. A great day for EFOST. Muscles Ligaments Tendons J 2011: 1(2):40.
- Maffulli N, Bridgman S, Brooks N, Walley GD. Appropriate informed consent, then randomization is the only ethical way! Arthroscopy 2007; 23(2):229-230.
- Maffulli N, Oliva F, Frizziero A. Why I.S.Mu.L.T.? Muscles Ligaments Tendons J 2011; 1(3):67.
- Maffulli N, Oliva F, Frizziero A. Why M.L.T.J.? Muscles Ligaments Tendons J 2011; 1(1):1-2.
- Hopkins WG, Marshall SW, Batterham AM, Hanin J. Progressive statistics for studies in sports medicine and exercise science. Med Sci Sports Exerc 2009; 41(1):3-13.
- Altman DG, Schulz KF, Moher D, et al. The revised CON-SORT statement for reporting randomized trials: explanation and elaboration. Ann Intern Med 2001; 134(8):663-694.
- Moher D, Cook DJ, Eastwood S, Olkin I, Rennie D, Stroup DF. Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. Quality of Reporting of Meta-analyses. Lancet 1999; 354(9193):1896-1900.
- Vandenbroucke JP, von EE, Altman DG, et al. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration. PLoS Med 2007; 4(10):e297.
- 10. von EE, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Van-

- denbroucke JP. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. BMJ 2007; 335(7624):806-808.
- Bossuyt PM, Reitsma JB, Bruns DE, et al. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. BMJ 2003; 326(7379):41-44.
- Bossuyt PM, Reitsma JB, Bruns DE, et al. The STARD statement for reporting studies of diagnostic accuracy: explanation and elaboration. Clin Chem 2003; 49(1):7-18.
- Stroup DF, Berlin JA, Morton SC, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. JAMA 2000; 283(15):2008-2012.
- Irwig L, Tosteson AN, Gatsonis C, et al. Guidelines for metaanalyses evaluating diagnostic tests. Ann Intern Med 1994; 120(8):667-676.
- Declaration of Helsinki. World Medical Association. Available at http://www.wma.net/en/30publications/30ethicsmanual/index html 2013.
- Institute for Laboratory Animal Research NRC. Guide for the Care and Use of Laboratory Animals. Washington, D.C. National Academy Press 1996; 140:2013.
- Graf C, Wager E, Bowman A, Fiack S, Scott-Lichter D, Robinson A. Best Practice Guidelines on Publication Ethics: a publisher's perspective. Int J Clin Pract Suppl 2007; (152):1-26.
- Maffulli N, Oliva F, Frizziero A. I.S.Mu.L.T. Meeting Report. Muscles Ligaments Tendons J 2011; 1(4):118.
- Schulz KF, Grimes DA. Generation of allocation sequences in randomised trials: chance, not choice. Lancet 2002; 359(9305):515-519.
- 20. Wang D, Bakhai A, Maffulli N. A primer for statistical analysis of clinical trials. Arthroscopy 2003; 19(8):874-881.
- Bridgman S, Engebretsen L, Dainty K, Kirkley A, Maffulli N. Practical aspects of randomization and blinding in randomized clinical trials. Arthroscopy 2003; 19(9):1000-1006.
- Bridgman S, Maffulli N. Randomised trials in surgery. Employment of academic and evidence based surgeons and epidemiologists may be the answer. BMJ 2002; 325(7365):658.
- Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods 2007; 39(2):175-191.
- Weir JP. Quantifying test-retest reliability using the intraclass correlation coefficient and the SEM. J Strength Cond Res 2005; 19(1):231-240.
- Cohen J. Statistical power analysis for the behavioral sciences. (2nd ed) Hillsdale, NJ Erlbaum 1988.
- Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986; 1(8476):307-310.
- Rankin G, Stokes M. Reliability of assessment tools in rehabilitation: an illustration of appropriate statistical analyses. Clin Rehabil 1998; 12(3):187-199.
- Padulo J, Ardigo LP. Letter to the Editor concerning "Vertebral rotation in adolescent idiopathic scoliosis calculated by radiograph and back surface analysis-based methods: correlation between the Raimondi method and rasterstereography". Eur Spine J 2013; 22(10):2336-2337.
- Preacher KJ, MacCallum RC. Exploratory factor analysis in behavior genetics research: factor recovery with small sample sizes. Behav Genet 2002; 32(2):153-161.
- Cumming G, Fidler F, Vaux DL. Error bars in experimental biology. J Cell Biol 2007; 177(1):7-11.
- Rodgers MM, Cavanagh PR. Glossary of biomechanical terms, concepts, and units. Phys Ther 1984; 64(12):1886-1902.
- 32. Chamari K, Laffaye G, Ardigo LP, Padulo J. Concentric and eccentric exercise. J Pain 2013; 14(11):1531-1532.

- 33. Padulo J, Laffaye G, Chamari K, Concu A. Concentric and Eccentric: Muscle Contraction or Exercise? Sports Health 2013; 5:306.
- 34. Padulo J, Laffaye G, Chamari K. Concentric and eccentric:
- muscle contraction or exercise? J Ultrasound Med 2013; 32(11):2047-2048.
- 35. Winter E. Use and misuse of the term "significant". J Sports Sci 2008; 26(5):429-430.