Reporting of trial design, sample size calculation, statistical methods and results

1. **Methods**:
   a. Include details of study design and how important relevant elements of design were accomplished. For example: In a clinical trial, were the subjects and outcome assessors blinded to treatment assignment; how was allocation to groups achieved; how was allocation concealment achieved?
   b. If the paper is a report of a comparative clinical trial, indicate the trial registry number (see MSF).
   c. Include a statement as to the method by which the sample size was determined including the assumptions used in any calculation.
   d. Include a list of all outcomes you intended to assess.
   e. Include a statement of all statistical tests used and how data will be presented (e.g., "*Data will be presented as mean±standard deviation with range, where appropriate*").
   f. Any *a priori* choice of threshold for statistical significance should be described.
   g. Seeking advice from a biostatistician at the initial planning stage of a study can be advantageous.

2. **Choice of statistical methods**:
   a. Include a justification for the use of a parametric test. What is the basis for the assumption of normality?
   b. It is not acceptable to use parametric testing for a clearly non-normal distribution (e.g. a bimodal distribution).

3. **Testing for differences in multiple variables or at multiple time points**:
   a. When testing multiple variables, authors should use one of the Bonferroni or similar corrections for Type I error probability (alpha).
   b. If testing at multiple time points in the same subjects, authors should use appropriate repeated-measure methods.
   c. Authors should not model multiple collinear independent variables.

4. **Absolute and relative differences**:
   a. In general, the journal prefers the direct comparison of outcomes between groups in a comparative study, e.g., the chance of wound healing was 20% greater in the group that received HBOT (20% with sham versus 40% with HBOT, 95% CI for the difference 15% to 25%). Authors should avoid comparing the magnitude of change in each group as a measure of the impact of any (therapeutic) intervention, e.g., percentage increase or e.g., the pain score decreased significantly in the HBOT group (4 points, $P = 0.04$), but not in the sham group (3 points, $P = 0.06$).

5. **Presentation of results**:
   a. Results should be as clearly and simply stated as possible. Care should be taken that the non-specialist reader should understand the result.
   b. Differences between groups should include an estimate of the difference between groups as well as the confidence interval of that estimate (usually 95% CI). At this time the journal recommends the additional presentation of *P*-values as a measure of the statistical importance of the result.
   c. Any findings to be presented as trends (below the threshold for outright statistical significance) must be clearly described as such and cautiously (conservatively) discussed.

6. **Interpretation of findings**:
   a. The findings detailed in the results section of the submission should be interpreted in the discussion section.
   b. Interpretation will include the clinical and/or scientific implications of the results and the implications for future research. Authors should note both the clinical or practical importance and statistical significance when interpreting results.
   c. Care should be taken not to 'over-state' marginal results or those where there is a substantial threat of bias. NOTE: A substantial possibility of bias exists for any comparison between groups that was not achieved through a randomized trial of the highest methodological rigour.
   d. Limitations text should be fully developed as a separate section in the discussion to establish the most valid context for the findings and to help direct future research.