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The Building Blocks of Good Clinical Evidence

(1) Explicitly defined research question, population, and endpoints; (2) Randomized treatment allocation and intention-to-treat analysis; (3) Participants and outcomes assessors blind to treatment allocation; (4) Use of a valid health measurement (quality of life) instrument; (5) Power and sample size determined *a priori*; (6) Statistical analyses compatible with type and distribution of the data; (7) Point estimate and 95% confidence interval reported (From Turlick MA, Kushner D, Stock D. J Am Podiatri Med Assoc 93:392-398, 2003.

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Describe members of the investigational team in regard to their participation in the study: (1) If they served as outcome assessors. (2) If they performed an intervention. (3) If they abstracted data from medical records, in the case of a retrospective study.

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Explicitly describe the intervention in any investigation.

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Thoroughly describe all novel interventions, notable variations on standard procedures, decision points related to an intervention, and adjunct procedures.

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Clearly state if outcomes were based on physical examination, chart review, telephone interview, questionnaire, radiographic films, or some other method.

Consider for analysis any variable that you consider to be important in regard to the treatment of patients, as it pertains to the investigation

"Hard" endpoints such as analytical measurements, clinical and microbiology laboratory results, and other specific measurements are preferred to "soft" endpoints. If "soft" endpoints such as quality of life (QOL) or foot-related QOL are used, it is preferred that health measurement instruments that have been previously shown to be reliable and provide valid information be used.
A health measurement instrument is not in and of itself valid, although the information gained from the use of the health measurement instrument should be used. QOL instruments should be specific to the foot and ankle (e.g., ACFAS, AOFAS, Bristol Foot Score, Foot Function Index).

Describe an investigator-derived questionnaire in terms of reliability and validity if such testing was undertaken by the investigators or if the questionnaire has been described in a previous publication.

For scales that rank categories (e.g., mild, moderate, severe), use an aggregate score. For measurements of pain, the 10-cm visual analog scale (VAS) is recommended.

Statistical Methods

Clearly describe the statistical plan. Include, at minimum, descriptive and inferential statistical analyses. Ideally, also include univariate and multiple variable statistical analyses.

In the descriptive statistical analysis, define parameters such as the measure of central tendency (mean or median average) and measures of dispersion (standard deviation or range).

Select the parameter, as well as the statistical test, based on the type and distribution of data.

Continuous numeric data that are normally distributed are suitable for representation using the mean and standard deviation and may be analyzed using mean-based statistical tests such as Student’s t test.

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Use univariate analyses to describe the association of independent variables with the outcome of interest (dependent variable). Use multiple variable analyses to describe the association of all of the clinically important variables with the outcome of interest.

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Additional references that may be useful in regard to the description of the methods and the presentation of a statistical plan include:


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**Level 1:** Testing of established diagnostic criteria in series of consecutive patients with universally applied “gold” standard; Systematic review of Level 1 studies. **Level 2:** Development of diagnostic criteria in series of consecutive patients with universally applied “gold” standard; Systematic review of Level 2 studies. **Level 3:** Study of nonconsecutive patients without consistently applied “gold” standard; Systematic review of Level 3 studies. **Level 4:** Case-control study; Poor reference standard. **Level 5:** Expert opinion.

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