Editorial

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Dear Readers,

It is with great pleasure that I write the third editorial of Pró-Fono, 2010. In this Editorial, I would like to present, within the evidence based practice paradigm, a new concept to us, Clinical Trial. The idea of a clinical trial is based on the need - humanist and financial - the testing of new therapies or procedures that present more promising results than those obtained by traditional practices.A clinical trial is a planned experiment that has a purpose to evaluate the efficacy of a procedure. Efficacy is the extension to which a specific procedure results in the benefit in a determined circumstance.

In the case of a treatment, efficacy is assessed when comparing the obtained results in a group of individuals who were treated with the test procedure with the results obtained in a group of individuals who were submitted to a control treatment. For this, the participants of the study are: assessed, treated and receive follow-up for a certain period of time.Two key concepts are: protocols and quality indicators of the study.

The protocol is a plan or a collection of steps that will be followed throughout the clinical trial. The plan/ collection of steps is carefully delineated to preserve the health of the participants, as well as to preserve identity secrecy. The protocol describes the participants' inclusion and exclusion criteria; sets a testing Schedule; describes the adopted procedures and the extension of the study. The participants are carefully followed in order to guarantee their well being. Quality indicators of the study are: design of the research, reduction or elimination of possible interferences of the researcher's opinion (bias) about

the study; sample randomization; presence of a control group; application of standardized and quantifiable tests; statistical analyses and precision of results.

Clinical trials are divided into four sequential phases:

. Phase 1 - it is the testing of a procedure in a small group of individuals to assess safety , methodology and the possible adverse effects;
. Phase 2 - it is the expansion of the procedure to a bigger group of individuals, validating the effectiveness of the proposal. Participants are set in a study and in a control group;
. Phase 3 - it involves the application of the procedure to a wide group of people in order to confirm effectiveness, monitoring of the adverse effects and comparison of the new treatment to the other existing proposals. This phase exists to validate the results obtained in the previous phases;
. Phase 4 - it involves the replication of the procedures with the purpose of testing its viability in different populations and also to assess the long-term effects.

Clinical trials produce results that can be:

. Positive - when the trial proves that the effect of the new procedure is superior to that produced by traditional procedures;
. Non-inferior - when the trial proves the equivalence between the new and traditional procedures;
. Negative - when the trial proves that the effect of the new procedure is inferior to that produced by traditional procedures;
. Inconclusive - when the trial does not prove its effect.

A clinical trial is not an isolated entity Each trial should be considered as a stage in the process of generating knowledge. Proof studies are indispensable - replication of the study by other research groups - to confirm results. Clinical practice also does not change by the effect of a single trial. Practice changes based on a body of evidence given by several studies, by professional expertise and considering patients' perception.

Scientific and social relevance of clinical trials in Speech-Language and Hearing Sciences is the generation of solid knowledge for the constitution of a relevant science and for a practice that is applied in a responsible and judicious manner.

Regards, Claudia.