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Evidence-based health: mathematical strategies for translating scientific findings into routine clinical care

André Pontes-Silva[1]*

Currently, in the health area, several experimental studies (investigating an intervention versus placebo/control) attempt to demonstrate the relevance of outcomes through statistically significant results[1]. However, statistical significance (i.e., p<0.05) does not indicate clinical relevance (Figure 1)[2,3]. In fact, it is possible to find a statistically significant result with no clinical relevance, just as it is possible to find a statistically significant result with clinical relevance[4].

A challenge in longitudinal studies (e.g., clinical trials) is the difficulty in translating numbers (outcome) into something applicable to the clinical context (real world) because the p-value (<0.05 or >0.05) only indicates statistical significance[5,6], in which interpretation only translates a hypothesis test governed by a previously defined probability of error alpha (H0 versus H1)[7]. The language of health is biostatistics[8,9], but patients are not numbers[10]. Therefore, numerical conclusions should be translated into applicability to routine clinical care[11]. As such, science should be combined with clinical context so that patients could receive optimal treatment[12]. How to solve it? It could be done simply by evaluating the clinical relevance of the results[10].

One way to verify the clinical relevance of results is through health economic evaluations[13], effect size assessments[14], or estimates of minimal clinically important differences and minimal detectable change[15]. I suggest that new studies describe Cohen's effect size[14,16] (e.g., d-value or w-value). Cohen's d can be used to assess effect sizes when comparing two means (0.2=small effect, 0.5=moderate effect, and 0.8=large effect)[17] and the Cohen's w can be used to assess effect sizes using a chi-squared test (0.1=small effect, 0.3=moderate effect, and 0.5=large effect)[18].

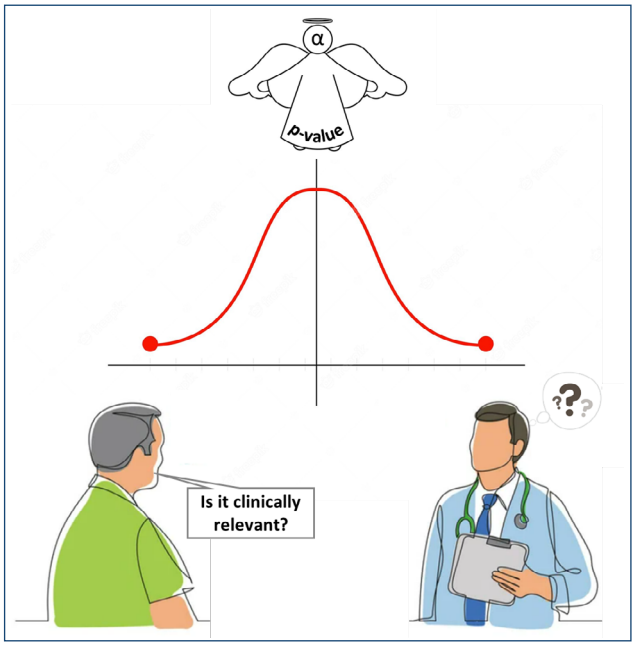

Figure 1. Statistical significance (i.e., p≤0.05) does not show clinical relevance.

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[1]Universidade Federal de São Carlos, Physical Therapy Department, Physical Therapy Post-Graduate Program – São Carlos (SP), Brazil.
*Corresponding author: contato.andrepsilva@gmail.com

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