The black hole within the black box: a numerical systematic review on "usual care" control groups in stroke rehabilitation RCTs

Stefano Negrini[1], Chiara Arienti[2], Riccardo Buraschi[2], Joel Pollet[2], Massimiliano Gobbo[1]

[1]University of Brescia, Italy; [2]IRCCS Fondazione Don Carlo Gnocchi.

Abstract

Introduction. Ethically, in every experimental trial new method should be tested against the 'best' or, if not defined, the 'usual' care according to current Guidelines. To understand the latter, we focused on stroke rehabilitation as a case in point because stroke is a leading cause of disability and rehabilitation is a complex intervention whose need is increasing due to growth of chronicity and disability (World Health Organization). Our aim was to appraise stroke rehabilitation interventions provided as "usual care" and the terminology used, comparing high to low quality randomised-controlled trials (RCTs).

Methods. Systematic review of RCTs (2006-16). Inclusion criteria were as follows: stroke survivor patients, intervention, rehabilitation, control: rehabilitative "usual care", outcome: lower limb function. We used the Cochrane 'risk of bias' tool, rating studies as low or high quality. We identified the terminology used to describe the Control Group Rehabilitation Program (CGP), performed a knowledge synthesis process and conducted a frequency analysis to sort the heterogeneity through the itemised identification of the CGP contents. Two quality groups of studies (high-low risk of bias) have been compared.

Results. We included 86 publications (23% low-risk of bias). Nine per cent of articles did not describe the CGP. In the remaining 78, we identified 64 interventions: 53 were proposed once, 8 were proposed twice and 3 were proposed in 3 papers. Two interventions (gait and balance) were proposed in 52% and 51% of papers, respectively. Results did not differ in the two RCT quality groups.

Conclusion. This case study on stroke rehabilitation has shown that the term 'usual care' in CGP is not adequately used: a good terminology to define interventions is missing and respecting CONSORT checklists does not avoid these problems. These results are clear, and involve authors, reviewers and both field-specific and generalist journals. Nevertheless, they should be verified by future studies in other fields, with this or other methodologies. Reporting guidelines should probably give better expert guidance on this issue.

Patient or healthcare consumer involvement. Not applicable.

Relevance to diversity. The research addressed to authors, reviewers and both field-specific and generalist journals and how to improve the definition and the description of the term "usual care", as control intervention.