

# Opening the **black box** of “usual care” and finding a **black hole**

## A numerical systematic review on the RCTs' “usual care” control groups in stroke rehabilitation

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### Background and aims

Ethically, new therapies should be tested against the “best” or, if not defined, “usual” care according to current Guidelines. In non-pharmacological fields “usual care” is a recognized, but not well defined issue. We focused on stroke rehabilitation as a case-study because: stroke is a leading cause of disability; rehabilitation is based on multiprofessional complex interventions; rehabilitation need is increasing, due to growth of chronicity and disability (World Health Organization). Our aim was to numerically appraise stroke rehabilitation “usual care” interventions and compare high to low quality randomized controlled trials (RCTs).

### Methods

Systematic review of RCTs (2006-16). Inclusion criteria: stroke survivors; intervention: rehabilitation; control: rehabilitative “usual care”; outcome: lower limb function. We rated low- or high-quality studies using the Cochrane ‘risk of bias’ tool. We identified the terminology used to describe the Control Group Intervention (CGI), performed a knowledge synthesis process and a frequency analysis to sort heterogeneity through the itemized identification of the CGI contents. The two quality trials groups have then been compared.

### Results

We included 86 publications (23% at low risk of bias). Nine per cent did not describe the CGI; in the others we identified 64 different interventions: 53 proposed only once, with a maximum of 3 similar in 3 papers. Most repeated interventions (gait and balance) were proposed in 52% and 51% of papers, respectively; 4 interventions reached more than 30%, the remaining less than 15%. Results did not differ by RCTs quality.

### Conclusion

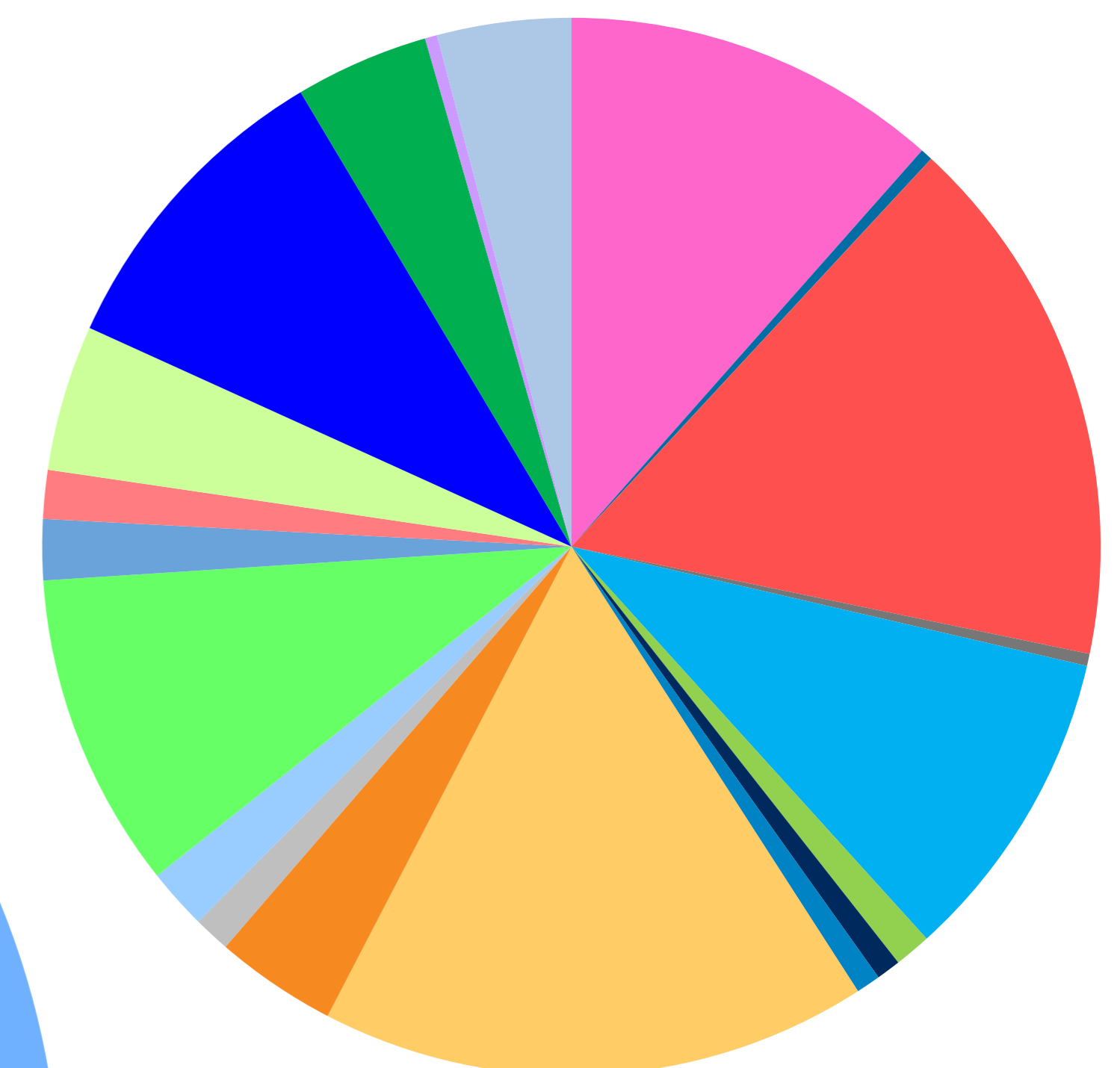
This case-study has numerically shown that the term “usual care” in CGI is inadequately used; methodological quality of papers does not avoid these problems; terminology for interventions is missing. These results should be verified in other fields, with this or other methodologies. Nevertheless, they are probably generalizable, since they involve many authors, reviewers, field-specific and generalist journals. Reporting guidelines should probably give better expert guidance also on this issue.

«Usual care» in (stroke) rehabilitation does not exist and the term should not be used

Methodological checklists do not avoid this problem

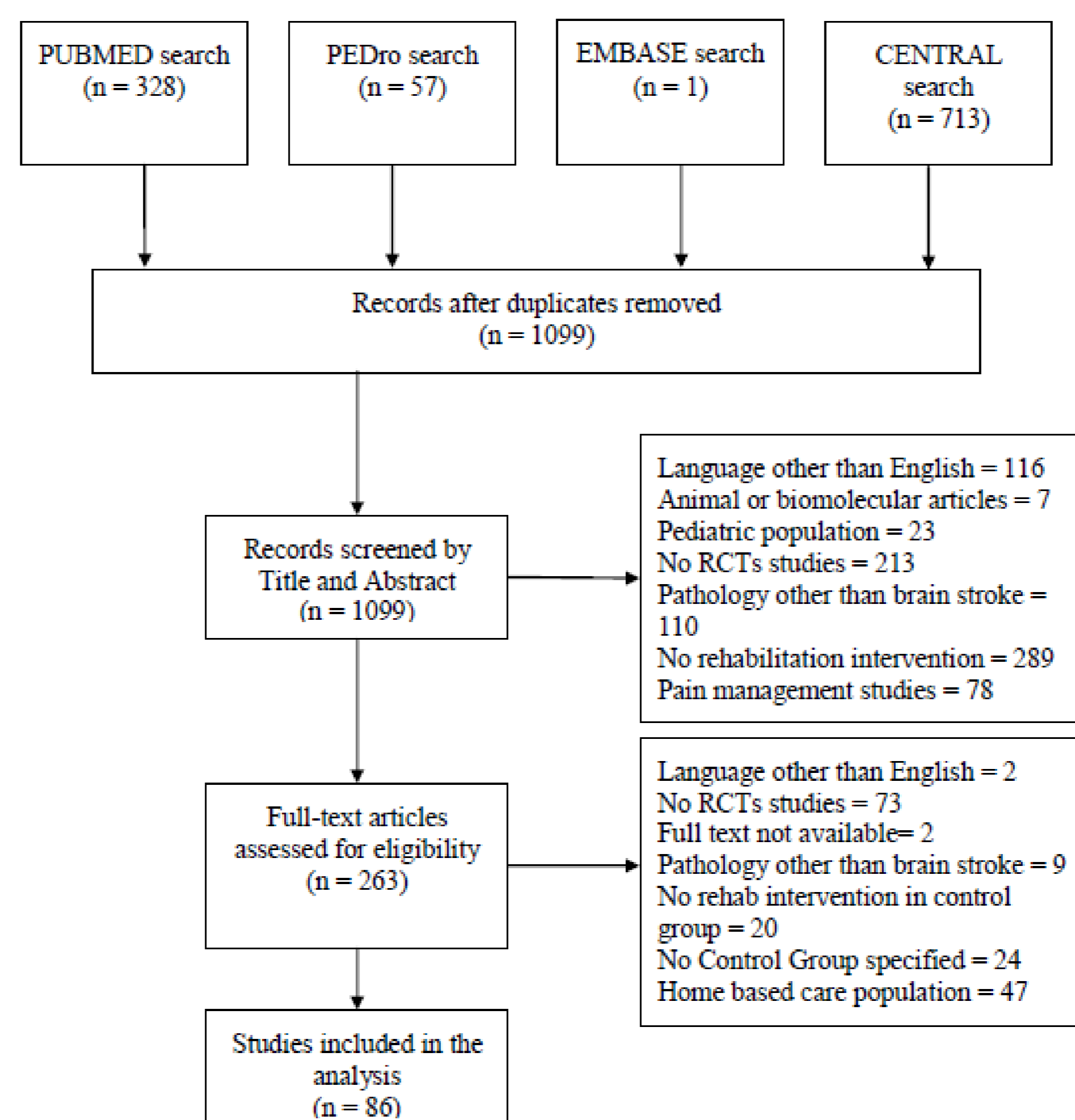
Terminology to group treatments is inadequate

Control Groups Interventions



- Activity of Daily Live (OT)
- Aerobic training
- Balance
- Breathing exercise
- Concepts / Methods / Specific intervention
- Cycling
- Educational
- Electrical stimulation
- Gait
- Interventions not specified
- Physical Agents Therapy
- Placebo / Sham intervention
- RoM
- Sensory stimulation
- Spasticity
- Speech Language
- Strengthening
- Stretching
- Swallowing Training
- Treadmill Cardio

PRISMA Diagram



Adjective TAG Cloud

