European Journal of Physical and Rehabilitation Medicine 2022 August;58(4):520-9
DOI: 10.23736/S1973-9087.22.07413-5

SYSTEMATIC REVIEW

A systematic review opens the black box of "usual care" in stroke rehabilitation control groups and finds a black hole

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ABSTRACT

INTRODUCTION: In experimental trials, new methods are tested against the "best" or "usual" care. To appraise control group (CG) interventions provided as "usual care," we focused on stroke as a leading cause of disability demanding rehabilitation as a complex intervention.
EVIDENCE ACQUISITION: For this methodological appraisal, we conducted a systematic review of RCTs without timespan limitation. The PICO included stroke survivors, rehabilitation, control group intervention, lower limb function. To assess the risk of bias, we used the Cochrane risk of bias tool (RoB). We identified the terminology describing the CG Program (CGP), performed a knowledge synthesis and conducted a frequency analysis of provided interventions.
EVIDENCE SYNTHESIS: We included 155 publications. 13.6% of the articles did not describe the CG, and 11.6% indicated only the professionals involved. In the remaining 116 studies, three studies provided an intervention according to specific guidelines, 106 different "usual care" CGPs were detected, with nine proposed twice and two between four and five times. The most adopted terminology to state "usual care" was "conventional physiotherapy."
CONCLUSIONS: This study shows that usual care in CG does not actually exist, as both specific terminology and consistency within CGP contents are missing. Reporting guidelines should give better assistance on this issue. These results should be verified in other fields.

(*Cite this article as:* Arienti S, Buraschi R, Pollet J, Lazzarini SG, Cordani C, Negrini S, *et al*. A systematic review opens the black box of "usual care" in stroke rehabilitation control groups and finds a black hole. Eur J Phys Rehabil Med 2022;58:520-9. DOI: 10.23736/S1973-9087.22.07413-5)

KEY WORDS: Control groups; Systematic review; Stroke rehabilitation; Lower extremity.

Introduction

The Declaration of Helsinki (1964) states that the "benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods."[1] In many fields of medicine, the 'best current therapy' is not simple to identify, and many practices reported as "standard" have never been actually validated in clinical trials. In 1998, the term "usual care" was introduced, in particular for pragmatic trials,[2] to determine whether a new intervention could improve current practice in comparison with a more accepted "standard care" control group. The control group is supposed to receive the care usually administered to patients in daily clinical practice.[3] Since then, the term "usual care" has become commonly used, but researchers have different opinions about its meaning since it may reflect the standards of each single clinic and may encompass a wide variety of control interventions.[4] Consequently, when designing and reporting a trial with

a "usual care" control group, authors may apply different methods or interventions.[5] The choice of "usual care" should be based on the available guidelines.[6] However, reporting guidelines often do not cover the specific requirements for describing the composition and management of a "usual care" control group, and the variation in treatments for control patients can make trial results difficult to interpret and generalize.[7, 8] Since there is an ethical need to compare new treatments to the best available standard of care, it is even more important to understand what "usual care" stands for.[9] As "usual care" obviously varies across, and even within, the different medical specialties, it is impossible to perform a complete review of the term and contents across medicine. For this reason, an approach based on some specific clinical fields can be considered.[3]

In February 2017, the World Health Organization launched "Rehabilitation 2030: a call for action,"[10] proposing rehabilitation as a key health strategy for the 21st century.[11] The rationale is based upon the gradual and continuous increase of chronicity and disability due to ageing, increased survival following trauma and disease and an increase in non-communicable diseases.[12] Hence, there is a worldwide need in health systems to improve research in this specific area.[13] Physical and rehabilitation medicine (PRM) is the primary medical specialty dealing with rehabilitation.[14] PRM is a young specialty,[15] which typically proposes complex multidisciplinary interventions[16] based on outcomes like disability and quality of life.[17] In clinical and research protocols, complex multidisciplinary interventions require precise descriptions, usually provided for the intervention group in contrast to the complexity of the control group program (CPG) that is often simply summarized by adopting "usual care" as an umbrella term. Outcomes like disability and quality of life depends on multiple factors, of which one single intervention can be a single feature, but not the whole. In real life, these outcomes could be focused by complex interventions where the studied intervention is only one part added to the "usual care." As a result, these features amplify some of the issues related to the concept of "usual care," and rehabilitation, in particular, represents an extremely appropriate field to investigate these concerns.[18]

To have a proper and relevant case in point for assessing usual care in rehabilitation, we decided to focus on stroke rehabilitation and, specifically, on one of its primary aims such as lower limb recovery. Stroke is a worldwide leading cause of adult disability, and the number of people living with the consequences of stroke continues to rise.[19] Stroke rehabilitation has shown not only to be effective but also cost-effective,[20] being one of the areas in rehabilitation where more research is performed, with a big amount of data available compared to the other fields of rehabilitation.[21] Recovery of lower limb function after stroke is one of the most important aims of the rehabilitation process and significantly impacts patients' residual disability.[22] It is consequently a relevant research topic with broad interest beyond the world of PRM itself.

Based on the aforementioned assumptions, we decided to focus our attention on stroke rehabilitation, specifically on the recovery of lower limb function, to more thoroughly understand what 'usual care' represents in this specific area and which kind of interventions it encompasses, considering the heterogeneity of rehabilitation interventions that may be included in the rehabilitation program of the control group.[23] Therefore, the aim of the present study was to categorize "usual care" within the control group rehabilitation programs that are included in clinical trials, specifically, by identifying the types and number of interventions provided, checking similarities and differences among the different programs, and highlighting the terminology used.

Evidence acquisition

Study design

We conducted a methodological study focused on control groups of Randomized Clinical Trials (RCTs) that evaluated the effectiveness of stroke rehabilitation interventions on lower limb function. The protocol was registered on PROSPERO (N°CRD42019111539).

Search strategy

The systematic database search and article selection were performed by three independent investigators, blinded to each other. According to the Patient, Intervention, Comparison/control, Outcomes (PICO) framework, we used the following keywords (customized for each database): "stroke," "rehabilitation," "intervention," "physical therapy," "physiotherapy," "lower limbs," "lower extremities." No language filters were used for the search strategy. The search was performed by the information specialist (SGL) on the 26th of March 2020 in the following databases: EMBASE, PubMed (MEDLINE), PEDro, Cochrane Central Register of Controlled Trials, Web of Science, Scopus and CINAHL, retrieving articles without timespan limitation. The detailed search strategy is reported in Table I.

TABLE I.—*Search strategy.*

Database	Search strategy
MEDLINE (Pubmed)	1. ((“Stroke”[Mesh] AND “Rehabilitation”[Mesh]) AND “Lower Extremity”[Mesh]) AND (“Randomized Controlled Trials as Topic”[Mesh] OR Randomized Controlled Trial[ptyp]) AND “humans”[MeSH Terms] 2. stroke AND (rehabilitation OR rehabilit* OR “physical therapy” OR (physical AND therap*) OR physiotherap*) AND ((lower AND (extremit* OR limb*)) OR leg*) AND (“randomized controlled trial” OR “RCT” OR “randomized clinical trial” OR random*) 3. #1 OR #2
PEDro	stroke rehab* lower limb AND “clinical trial” [Method]
Cochrane Central Register of Controlled Trials	stroke AND (rehab* OR physiotherap* OR (physical AND therap*)) AND ((lower AND (extremit* OR limb*)) OR leg*) in Title Abstract Keyword - in Trials (Word variations have been searched)
EMBASE	(‘stroke patient’/exp OR ‘stroke patient*’ OR ‘stroke’/exp OR stroke) AND (‘rehabilitation medicine’ OR rehab* OR ‘physiotherapy’/exp OR ‘physiotherapy’ OR physiotherap* OR ‘physical therap*’ OR (physical AND therap*)) AND (‘lower limb’/exp OR ‘lower limb’ OR (lower AND (extremit* OR limb*)) OR leg*) AND [randomized controlled trial]/lim AND [humans]/lim
Web of Science	(((TS=(stroke AND (rehab* OR physiotherap* OR (physical AND therap*)) AND ((lower AND (extremit* OR limb*)) OR leg*) AND (“randomized controlled trial” OR “RCT” OR “randomized clinical trial” OR random*)) OR TI=(stroke AND (rehab* OR physiotherap* OR (physical AND therap*)) AND ((lower AND (extremit* OR limb*)) OR leg*) AND (“randomized controlled trial” OR “RCT” OR “randomized clinical trial” OR random*))))) AND DOCUMENT TYPES: (Article) Timespan: All years. Indexes: SCI-EXPANDED. SSCI. A&HCI. CPCI-S. CPCI-SSH. ESCI.
Scopus	TITLE-ABS-KEY (stroke AND (rehab* OR physiotherap* OR (physical AND therap*)) AND ((lower AND (extremit* OR limb*)) OR leg*) AND (“randomized controlled trial” OR “RCT” OR “randomized clinical trial” OR random*)) AND (LIMIT-TO (DOCTYPE . “ar”)) AND (LIMIT-TO (EXACTKEYWORD . “Human”) OR LIMIT-TO (EXACTKEYWORD . “Randomized Controlled Trial”))
CINAHL	stroke AND (rehab* OR physiotherap* OR (physical AND therap*)) AND (((lower AND (extremit* OR limb*)) OR leg*)) AND ((“randomized controlled trial” OR “RCT” OR “randomized clinical trial” OR random*))

Selection criteria

Three reviewers (J.P., R.B., and S.G.L.) independently reviewed the records identified in the search and assessed the full texts. The inclusion criteria are described below.

Type of studies

We included RCTs (as defined by the Authors of the papers) assessing the effectiveness of stroke rehabilitation for lower limb function recovery, written in English language. Protocols, pilot studies, congress abstracts and secondary analysis papers were excluded.

Type of participants

We included RCTs that had enrolled adult participants (age >18 years) with a clinical diagnosis of ischemic or hemorrhagic stroke in accordance with the WHO definition: acute (event occurrence within the first month), subacute (event occurrence between one and six months), and chronic (more than six months after stroke occurrence).[24, 25] We excluded RCTs with participants who had diseases other than stroke with possible impact on balance (*e.g*., Parkinson’s disease, cerebral traumas, multiple sclerosis, medications, ear infections and other infections, benign paroxysmal positional vertigo or positional vertigo, labyrinthitis, Ménière’s disease, vestibular neuritis, perilymph fistula, mal de debarquement syndrome, arthritis and eye muscle imbalance).

Type of rehabilitation interventions

All rehabilitation interventions that were focused on improving physical functioning and reducing motor impairment were included. We excluded non-rehabilitation interventions, such as surgery and/or pharmacological treatments. We did not place any restrictions on the setting in which the interventions were delivered, or on the timing of the interventions (*i.e*. stage of recovery or length of time post-stroke).

Type of control interventions

Any control interventions labelled as “usual care,” or in a form semantically referable to that concept, were included.

Type of outcome measures

All outcome measures referring to disability (*i.e*., independence in activities of daily living, motor function, balance, gait) and length of hospital stay, were included.

Assessment of the risk of bias in the included studies

Three review authors (J.P., R.B. and S.G.L.) independently assessed the risk of bias of the included studies using the Cochrane Risk of Bias tool.[26] Disagreements were solved through discussion between the reviewers. We assessed the following domains: sequence generation; allocation concealment; blinding of participants, personnel and outcome assessors; incomplete outcome data; selective outcome reporting; baseline imbalances; and other bias issues (namely, any other source of bias able to change the magnitude of the effect). In this review we added "baseline imbalances" as a source of bias, referring to a non-balancing of characteristics between groups at baseline and a sample size calculation not expressly described. Studies were rated as low, high or unclear risk of bias for each domain, according to the criteria used in the Cochrane Risk of Bias tool.[26]

Statistical analysis

We first identified the type of CGP proposed in each trial and, subsequently, we grouped the different types of CGP through a terminological analysis.[27] Frequency analysis was performed to numerically explain the contents of the CGP and the terminology utilized within each included paper. The specific contents composing each CGP were extracted and grouped according to the temporal classification of stroke onset, specifically, we have extracted data concerning the individual contents of physical therapy intervention, while for rehabilitative interventions other than physical therapy, we have simply recorded their presence within CGP (*e.g.* occupational therapy). The terminology used to identify the CGP was highlighted: from each paper we extracted all the definitions used to label the "usual care" within CGP, then we listed all nouns and adjectives retrieved. We also looked at how many times the "usual care" treatment terminology was defined in different ways within single papers.

Evidence synthesis

The search strategy initially yielded 2338 publications from which, after selection, 155 publications were eventually included and analyzed (Figure 1). The characteristics of the selected studies are reported in Supplementary Digital Material 1 (Supplementary Table I). The content of all control group rehabilitation programs is offered in Supplementary Digital Material 2 (Supplementary Table II), and a complete listing of the studies is provided in Supplementary Digital Material 3 (Supplementary Table III).

Out of the 155 included studies, the CGP was administered according to specific guidelines for stroke rehabilitation in only three of them,[28-30] of which two came

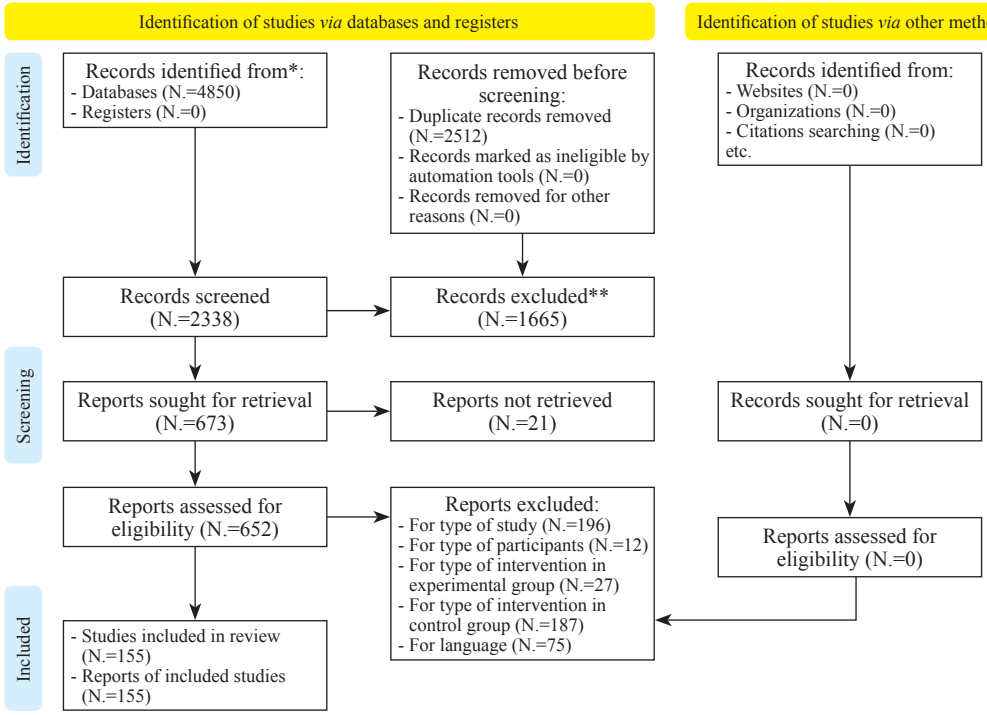

Figure 1.—PRISMA flow diagram.
*Consider, if feasible to do so, reporting the number of records indentified from each database or register searched (rather than the total number across all data)
**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

TABLE II.—*Control group rehabilitation program.*

Repetitions	%	Control group rehabilitation program
5	3.23%	Activity of Daily Living (OT) + Bobath/NDT
4	2.58%	Bobath/NDT
2	1.29%	Balance + Gait (Overground) + Strengthening + Stretching
2	1.29%	Bobath/NDT + Gait (Overground) + Sensory stimulation (Proprioception)
2	1.29%	Stretching
2	1.29%	Bobath/NDT + Motor Learning
2	1.29%	Gait (Overground) + Strengthening + Stretching
2	1.29%	Gait (Overground) + Stretching
2	1.29%	No treatment
2	1.29%	Bobath/NDT + ROM increasing + Stretching
2	1.29%	ROM increasing + Strengthening
1	0.65%	89 other CGP Programs

from the same investigation group. In 39 articles (25.2%), the CGP contents were not specified. In particular, in 18 articles (11.6%), the description of the protocol used was not accurate and only an indication of the professionals involved (*e.g.* physiotherapist, occupational therapist) was provided. In 21 articles (13.6%), no information about the "usual care" into CGP was reported. In the 116 papers that specified the control interventions, 106 different "usual care" CGP were detected: 89 programs were present only once, nine programs were identified twice, one program was present in four studies, and finally, one program was present in five different RCTs (the highest number of repetitions of the same CGP among all the articles) (Table II).

Table III shows the distribution of specific interventions

TABLE III.—*Contents of all control group rehabilitation programs.*

Contents	General (N.=155)		Acute (N.=64)		Subacute (N.=82)		Chronic (N.=69)	
	N.	%	N.	%	N.	%	N.	%
Gait	61	39.35%	21	32.81%	38	46.34%	34	49.28%
Overground	59	38.06%	20	31.25%	37	45.12%	34	49.28%
Treadmill	8	5.16%	4	6.25%	5	6.10%	3	4.35%
Balance	60	38.71%	25	39.06%	35	42.68%	28	40.58%
Standing training	35	22.58%	16	25.00%	19	23.17%	14	20.29%
Sit to Stand activity	22	14.19%	13	20.31%	14	17.07%	6	8.70%
Trunk control	20	12.90%	9	14.06%	11	13.41%	8	11.59%
Stairs/obstacles	10	6.45%	2	3.13%	5	6.10%	6	8.70%
Concepts/methods/specific intervention	53	34.19%	20	31.25%	27	32.93%	20	28.99%
Bobath/NDT	44	28.39%	16	25.00%	21	25.61%	17	24.64%
PNF	7	4.52%	1	1.56%	3	3.66%	6	8.70%
Neuromuscular facilitation techniques	9	5.81%	3	4.69%	7	8.54%	3	4.35%
Motor Learning	7	4.52%	2	3.13%	3	3.66%	3	4.35%
Brunnstrom	6	3.87%	1	1.56%	5	6.10%	3	4.35%
Motor control	3	1.94%	2	3.13%	2	2.44%	1	1.45%
Rood	1	0.65%	1	1.56%	1	1.22%	0	0.00%
Strengthening	49	31.61%	24	37.50%	29	35.37%	21	30.43%
Activity of daily living (OT)	47	30.32%	23	35.94%	28	34.15%	13	18.84%
Not specified	39	25.16%	19	29.69%	21	25.61%	14	20.29%
Intervention	21	13.55%	11	17.19%	10	12.20%	11	15.94%
Contents	18	11.61%	8	12.50%	11	13.41%	3	4.35%
ROM increasing	37	23.87%	18	28.13%	21	25.61%	17	24.64%
Stretching	33	21.29%	12	18.75%	14	17.07%	18	26.09%
Speech language therapy	16	10.32%	9	14.06%	12	14.63%	3	4.35%
Functional retraining/training	13	8.39%	6	9.38%	6	7.32%	7	10.14%
Electrical stimulation	9	5.81%	2	3.13%	4	4.88%	5	7.25%
Proprioception stimulation	7	4.52%	2	3.13%	3	3.66%	4	5.80%
Spasticity	6	3.87%	2	3.13%	3	3.66%	3	4.35%
Transfers activity	3	1.94%	1	1.56%	3	3.66%	2	2.90%
Walking devices	3	1.94%	1	1.56%	1	1.22%	2	2.90%
Aerobic training	2	1.29%	1	1.56%	1	1.22%	1	1.45%
Cycling	2	1.29%	2	3.13%	1	1.22%	0	0.00%
Neurophysiological exercises	2	1.29%	2	3.13%	1	1.22%	1	1.45%
No treatment	2	1.29%	1	1.56%	1	1.22%	1	1.45%
Cognitive training	1	0.65%	1	1.56%	0	0.00%	0	0.00%
Massage	1	0.65%	1	1.56%	0	0.00%	0	0.00%
Physical agents therapy	1	0.65%	0	0.00%	1	1.22%	0	0.00%
Swallowing Training	1	0.65%	1	1.56%	0	0.00%	0	0.00%

inside all CGPs, as total and also divided by the phase of stroke (acute/subacute/chronic).

As expected, most of interventions for lower limb recovery after stroke focused on gait (39.4%) and balance (38.7%); occupational therapy was reported in 30.3% of the papers examined.

While in 81% of the RCTs the definition of the CGP did not change throughout the single articles, two papers used four different terms to address the same CGP (*e.g.*, CGP was defined in the text of a single study as "regular physical therapy," "conventional rehabilitation," "conventional PT gait training," and "conventional treatment").[31] Similarly, four papers adopted three different definitions, and 24 papers used two different definitions. We identified 13 different adjectives used to refer to the concept of "usual care." Out of them, "conventional" resulted as the most frequent term (49%), followed by "standard" (12%) (Table IV). It is worth noting that it could happen to detect multiple adjectives in the same paper or even in the same sentence. With regards to the 42 nouns utilized for the treatment description, 'physical therapy/physiotherapy' was the most common (32%) followed by "care" (9%) (Table IV).

TABLE IV.—*Adjectives and nouns utilized within the articles.*

#	Adjective	N.	%	#	Noun	N.	%
1	Conventional	96	49.23%	1	Physical therapy/physiotherapy	63	32.14%
2	Standard	23	11.79%	2	Care	18	9.18%
3	Routine	22	11.28%	3	Rehabilitation	17	8.67%
4	Usual	17	8.72%	4	Therapy	17	8.67%
5	General	10	5.13%	5	Rehabilitation program/programs/programme	9	4.59%
6	Regular	10	5.13%	6	Rehabilitation therapy	7	3.57%
7	Traditional	8	4.10%	7	Training	6	3.06%
8	Basic	3	1.54%	8	Treatment	6	3.06%
9	Common	1	0.51%	9	Rehabilitation training	4	2.04%
10	Comprehensive	1	0.51%	10	Rehabilitation treatment	4	2.04%
11	Daily	1	0.51%	11	Stroke rehabilitation	4	2.04%
12	Functional	1	0.51%	12	Stroke rehabilitation program/programme	4	2.04%
13	Standardized	1	0.51%	13	Exercise program	3	1.53%
				14	Physical therapy/physiotherapy program/programme	3	1.53%
				15	Exercise therapy	2	1.02%
				16	Outpatient rehabilitation	2	1.02%
				17	Rehabilitation techniques	2	1.02%
				18	Care physiotherapy	1	0.51%
				19	Gait training program	1	0.51%
				20	Hemiplegia rehabilitation therapy	1	0.51%
				21	Inpatient rehabilitation therapy	1	0.51%
				22	Inpatient stroke rehabilitation program	1	0.51%
				23	Intervention	1	0.51%
				24	Motor therapy	1	0.51%
				25	Multidisciplinary rehabilitation program	1	0.51%
				26	Multidisciplinary stroke rehabilitation	1	0.51%
				27	Neurological care	1	0.51%
				28	Neurorehabilitation	1	0.51%
				29	Nursing model	1	0.51%
				30	Outpatient physical therapy	1	0.51%
				31	Physical therapy care	1	0.51%
				32	Physical therapy exercises	1	0.51%
				33	Physiotherapy based on clinical practice guidelines for stroke patients	1	0.51%
				34	Physiotherapy protocol	1	0.51%
				35	PT gait training	1	0.51%
				36	Rehabilitation care	1	0.51%
				37	Stroke physical therapy	1	0.51%
				38	Stroke rehabilitation care	1	0.51%
				39	Stroke rehabilitation therapy	1	0.51%
				40	Therapeutic program	1	0.51%
				41	Treatment exercise program	1	0.51%
				42	Treatment methods	1	0.51%
	Total	194	100%			195	100%

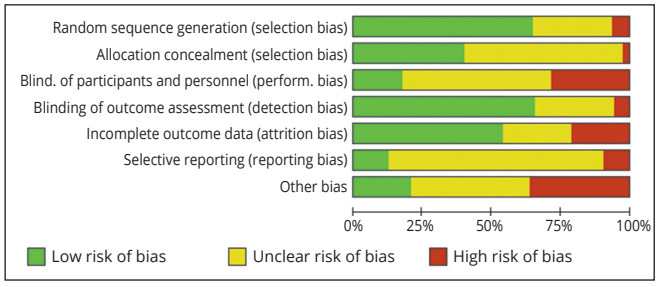

Figure 2.—Graph of the risk of bias of the included studies.

Risk of bias of the included studies

The graph of the risk of bias is reported in Figure 2, and the summary of the risk of bias assessment is reported in Supplementary Digital Material 4 (Supplementary Figure 1). The risk of bias evaluation reported the following judgments.

Sequence generation (selection bias)

One hundred studies (64.5%) were judged as having a low risk of selection bias as the random sequence generation was adequately described. Forty-five studies (29.0%) with no information about the randomization process were rated as having an unclear risk of bias. Ten studies (6.5%) reported a non-random component in the sequence generation and were judged as having a high risk of bias. The latter studies may be considered as quasi-RCTs; nevertheless, we decided to include also these studies in our analysis since the sequence generation (although affecting the quality of these RCTs characterized by a high risk of bias) was not primarily involved in the definition of the CGP which, instead, was our leading purpose.

Allocation

Sixty-two studies (40.0%) were judged as having a low risk of selection bias due to allocation to treatment groups. Eighty-nine studies (57.4%) with no information about the allocation concealment were rated as having an unclear risk of bias. Four studies (2.6%) were considered to have a high risk of selection bias because the allocation of treatment was not concealed.

Blinding

Twenty-seven studies (17.4%) were judged as having a low risk of performance bias due to the blinding of participants and experimenters. Eighty-four studies (54.2%) that provided no information about blinding of participants and experimenters were rated as having an unclear risk of bias. Forty-four studies (28.4%) were rated as having a high risk of bias as participants and experimenters were aware of the intervention (in some cases the blinding was not possible due to the nature of the interventions themselves).

One hundred and one studies (65.2%) stated that the outcome assessors were blinded and were judged as having a low risk of bias. Forty-five studies (29.0%) did not specify if the outcome assessors were blinded and were rated as having an unclear risk of bias. The outcome assessors were not blinded in nine studies (5.8%), which were judged as having a high risk of bias.

Incomplete outcome data

Eighty-three studies (53.5%) were judged as having a low risk of bias due to the incomplete outcome data. Thirty-nine studies (25.2%) provided insufficient information and were rated as having an unclear risk of bias. Thirty-three studies (21.3%) were rated as having a high risk of attrition bias.

Selective reporting

Nineteen studies (12.3%) had a registered or published trial protocol where all the primary outcomes have been reported in a pre-specified way and were therefore judged as having a low risk of bias. Most of the studies (one hundred and twenty-one studies – 78.0%) had no trial protocol and were rated as having an unclear risk of bias. Fifteen studies (9.7%) showed discrepancies between the trial protocol and the publication and were judged as having a high risk of bias.

Other potential sources of bias

In thirty-two studies (20.6%) no other potential sources of bias were identified and they were judged as having a low risk of bias. Sixty-seven studies (43.2%) were rated as having unclear risk of bias. Other potential sources of bias were identified in fifty-six studies (36.1%), that were judged as having a high risk of bias.

Discussion

This paper assesses the concerns related to the "usual care" control group in stroke rehabilitation as a case in point for complex interventions. We found that CGPs in RCTs for lower limb function rehabilitation are heterogeneous amongst but also within papers. As "usual care" emerged to be not a standard, it is consequently impossible to reliably understand and compare the effectiveness of experimental treatments that are tested against "usual care" con-

trol groups. More precisely, the same experimental treatment could be effective when compared/added to a single treatment but not significantly effective when compared/added to a sum of different treatments. If these alternatives are masked under the single term 'usual care', the understanding of the efficacy and, all the more reason, the effectiveness of that treatment might be remarkably impaired.

Main findings

Overall, the paper shows the limits and problems consequent to using the term 'usual care' as a description for the control group intervention. The absence of a standard drove all the authors to cover different therapies under this term, with a wide variety of the interventions included in the rehabilitation programs, which, in some cases, were not adequately described. Indeed, 2% of the studies referred their intervention to a guideline, and 25% presented an inadequate and insufficient description of the control group interventions. The aim of this paper was to clarify what "usual care" is, also in terms of how it is reported by authors in their articles. In this perspective, we have included in the analysis of the "usual care" control group also those articles reporting "no treatment," or articles where the intervention proposed was not specified, or those articles that partially specified the usual care program by describing only the professionals involved. Further, the risk of bias evaluation highlighted many domains as "unclear" because relevant details, such as the method of concealment, the protocol registration, and the blinding of participants and experimenters were not provided, contributing to the general poor description of the studies, in addition to the defective reporting of the interventions. A scarce description of the interventions is frequent in rehabilitation research,[32, 33] which strongly limits the clinical replicability and the generalizability of the results.[34-36] The difficulty of designing appropriate control interventions is related to many factors: 1) the absence of a specific intervention taxonomy; 2) the poor description of dosage, frequency, control program ingredients, and its different components; 3) the lack of a satisfactory control establishment, a sort of criterion standard, that can raise similar expectations and that can involve equivalent associated experimental activities.[37] These factors seem even more relevant for the control group interventions, because they can create difficulties in choosing a reasonable and realistic outcome measure and it is not always obvious which interventions or mediating variables should be measured and what effects is the intervention expected to have on the desired outcomes. These issues are spread among all the studies included in this review, from the oldest to the more recent, from journals without impact factor to the top medical journals.

Comparison with other studies

Rehabilitation can be seen as a complex intervention due to its multidisciplinary and multi-professional team approach based on multimodal treatments. Defining a complex intervention means describing its active ingredients and the specific ways in which these ingredients are conveyed.[38] While rehabilitation can be considered as a complex intervention, it has also been described as a process. Splitting the effects of individual interventions and their multiple interactions is an analytical and statistical challenge that should start from a standard nomenclature.[39] Without classifying, it is impossible to know the parts whose effects should be measured and possibly finally evaluate the effectiveness of the whole and what each part adds.[40] The great diversity of rehabilitation settings, populations, and targeted treatment outcomes, contribute to the lack of a uniform definition of interventions.[41] Since the proven efficacy of interventions drives evidence-based decision-making in clinical practice,[40, 42] rehabilitation will grow only solving the issue raised by this review. In particular, it is important to highlight once more that only three studies over the 155 included (1.9%) clearly stated that their conventional intervention was designed according to clinical guidelines. The standardization of terminology, and the precise definition of 'usual' and 'standard' care, when adopted as the control condition, is a prerequisite for improving the evaluation of research evidence. The lack of well-defined definitions, semantic contents and descriptions make the black box[43, 44] become a black hole, confounding any obtained result.

Strengths and limitations of the study

The main limitations of the study include: the focus on a single field, although this is a way to provide a specific description of the phenomenon; the present study did not address the effects of the "usual care" interventions provided by the included records, not being our primary aim; the study might have language bias as only papers written in English were included in the analysis.

Conclusions and interpretation of available data

This study raises two main issues. The first is that some papers have been published before the development of the CONSORT checklist and this confirms that the adoption

of checklists is mandatory to improve the general quality of research methodology. Second, the issue of improving the definition of "standard of care" for CGP and the need to create a common terminology in stroke rehabilitation. As reported previously,[34] it also raises the issue that the existing reporting guidelines do not focus specifically on the 'usual care' problem. In this view, the need for the development of specific guidelines for the reporting in RCTs in the rehabilitation field, adopting clear and standard terminology, is urgent. Cochrane Rehabilitation started an important initiative, the Randomized Controlled Trials Rehabilitation Checklist (RCTRACK) project to produce a specific reporting guideline in rehabilitation.[45] At present, a shared "usual care plane" does not exist and the only way to proceed according to the best methodology is to design the "usual care" intervention according to best available clinical guidelines. In this way, further quantitative study, like meta-epidemiological studies would be needed to evaluate the influence of control intervention on the effects of rehabilitation interventions in this area, also extending the analysis to upper limb function.

References

1. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA 2013;310:2191–4.

2. Roland M, Torgerson DJ. What are pragmatic trials? BMJ 1998;316:285.

3. Smelt AF, van der Weele GM, Blom JW, Gussekloo J, Assendelft WJ. How usual is usual care in pragmatic intervention studies in primary care? An overview of recent trials. Br J Gen Pract 2010;60:e305–18.

4. Thompson BT, Schoenfeld D. Usual care as the control group in clinical trials of nonpharmacologic interventions. Proc Am Thorac Soc 2007;4:577–82.

5. Ford I, Norrie J. Pragmatic Trials. N Engl J Med 2016;375:454–63.

6. Moher D, Schulz KF, Altman D; CONSORT Group. The CONSORT Statement: revised recommendations for improving the quality of reports of parallel-group randomized trials 2001. Explore (NY) 2005;1:40–5.

7. Puffer S, Torgerson D, Watson J. Evidence for risk of bias in cluster randomised trials: review of recent trials published in three general medical journals. BMJ 2003;327:785–9.

8. Mant D. The problem with usual care. Br J Gen Pract 2008;58:755–6.

9. Takala J. Better conduct of clinical trials: the control group in critical care trials. Crit Care Med 2009;37(Suppl):S80–90.

10. World Health Organization. Rehabilitation 2030: A Call for Action; 2017 [Internet]. Available from: https://cdn.who.int/media/docs/default-source/documents/health-topics/rehabilitation/call-for-action/rehab2030meetingreport_plain_text_version.pdf?sfvrsn=891ff06f_5 [cited 2022, May 26].

11. World Health Organization. Rehabilitation: key for health in the 21st century; 2017 [Internet]. Available from: https://cdn.who.int/media/docs/default-source/documents/health-topics/rehabilitation/call-for-action/keyforhealth21stcentury.pdf?sfvrsn=43cebb7_5 [cited 2022, May 26].

12. World Health Organization. The need to scale up rehabilitation; 2017 [Internet]. Available from: https://www.who.int/docs/default-source/documents/health-topics/rehabilitation/call-for-action/need-to-scale-up-rehab-july2018.pdf?sfvrsn=f627c34c_5 [cited 2022, May 26].

13. Krug E, Cieza A. Strengthening health systems to provide rehabilitation services. Bull World Health Organ 2017;95:167.

14. European Physical and Rehabilitation Medicine Bodies Alliance. White Book on Physical and Rehabilitation Medicine (PRM) in Europe. Chapter 1. Definitions and concepts of PRM. Eur J Phys Rehabil Med 2018;54:156–65.

15. European Physical and Rehabilitation Medicine Bodies Alliance. White Book on Physical and Rehabilitation Medicine (PRM) in Europe. Chapter 4. History of the specialty: where PRM comes from. Eur J Phys Rehabil Med 2018;54:186–97.

16. European Physical and Rehabilitation Medicine Bodies Alliance. White Book on Physical and Rehabilitation Medicine (PRM) in Europe. Chapter 3. A primary medical specialty: the fundamentals of PRM. Eur J Phys Rehabil Med 2018;54:177–85.

17. European Physical and Rehabilitation Medicine Bodies Alliance. White Book on Physical and Rehabilitation Medicine (PRM) in Europe. Chapter 7. The clinical field of competence: PRM in practice. Eur J Phys Rehabil Med 2018;54:230–60.

18. Negrini S, Arienti C, Kiekens C. Usual care: the big but unmanaged problem of rehabilitation evidence. Lancet 2020;395:337.

19. Murray CJ, Barber RM, Foreman KJ, Abbasoglu Ozgoren A, Abd-Allah F, Abera SF, *et al.*; GBD 2013 DALYs and HALE Collaborators. Global, regional, and national disability-adjusted life years (DALYs) for 306 diseases and injuries and healthy life expectancy (HALE) for 188 countries, 1990-2013: quantifying the epidemiological transition. Lancet 2015;386:2145–91.

20. Lloyd M, Skelton DA, Mead GE, Williams B, van Wijck F. Physical fitness interventions for nonambulatory stroke survivors: A mixed-methods systematic review and meta-analysis. Brain Behav 2018;8:e01000.

21. Levack WM, Rathore FA, Pollet J, Negrini S. One in 11 Cochrane Reviews Are on Rehabilitation Interventions, According to Pragmatic Inclusion Criteria Developed by Cochrane Rehabilitation. Arch Phys Med Rehabil 2019;100:1492–8.

22. Harris JE, Eng JJ. Goal Priorities Identified through Client-Centred Measurement in Individuals with Chronic Stroke. Physiother Can 2004;56:171–6.

23. Arienti C, Armijo-Olivo S, Minozzi S, Tjosvold L, Lazzarini SG, Patrini M, *et al.* Methodological Issues in Rehabilitation Research: A Scoping Review. Arch Phys Med Rehabil 2021;102:1614–1622.e14.

24. Hart T, Tsaousides T, Zanca JM, Whyte J, Packel A, Ferraro M, *et al.* Toward a theory-driven classification of rehabilitation treatments. Arch Phys Med Rehabil 2014;95(Suppl):S33–44.e2.

25. Teasell R, Rice D, Richardson M, Campbell N, Madady M, Hussein N, *et al.* The next revolution in stroke care. Expert Rev Neurother 2014;14:1307–14.

26. Higgins JP, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, *et al.*; Cochrane Bias Methods Group; Cochrane Statistical Methods Group. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ 2011;343:d5928.

27. Arienti C, Patrini M, Pollock A, Lazzarini SG, Oral A, Negrini S. A comparison and synthesis of rehabilitation definitions used by consumers (Google), major Stakeholders (survey) and researchers (Cochrane Systematic Reviews): a terminological analysis. Eur J Phys Rehabil Med 2020;56:682–9.

28. Nikamp CD, van der Palen J, Hermens HJ, Rietman JS, Buurke JH. The influence of early or delayed provision of ankle-foot orthoses on pelvis, hip and knee kinematics in patients with sub-acute stroke: A randomized controlled trial. Gait Posture 2018;63:260–7.

29. Nikamp CD, Hobbelink MS, van der Palen J, Hermens HJ, Rietman JS, Buurke JH. A randomized controlled trial on providing ankle-foot orthoses in patients with (sub-)acute stroke: short-term kinematic and spatiotemporal effects and effects of timing. Gait Posture 2017;55:15–22.

30. Chen L, Fang J, Ma R, Gu X, Chen L, Li J, *et al*. Additional effects of acupuncture on early comprehensive rehabilitation in patients with mild to moderate acute ischemic stroke: a multicenter randomized controlled trial. BMC Complement Altern Med 2016;16:226.

31. Tong RK, Ng MF, Li LS. Effectiveness of gait training using an electromechanical gait trainer, with and without functional electric stimulation, in subacute stroke: a randomized controlled trial. Arch Phys Med Rehabil 2006;87:1298–304.

32. Armijo-Olivo S, Saltaji H, da Costa BR, Fuentes J, Ha C, Cummings GG. What is the influence of randomisation sequence generation and allocation concealment on treatment effects of physical therapy trials? A meta-epidemiological study. BMJ Open 2015;5:e008562.

33. Armijo-Olivo S, Fuentes J, da Costa BR, Saltaji H, Ha C, Cummings GG. Blinding in Physical Therapy Trials and Its Association with Treatment Effects: A Meta-epidemiological Study. Am J Phys Med Rehabil 2017;96:34–44.

34. Armijo-Olivo S, Cummings GG, Fuentes J, Saltaji H, Ha C, Chisholm A, *et al.* Identifying items to assess methodological quality in physical therapy trials: a factor analysis. Phys Ther 2014;94:1272–84.

35. Negrini S, Arienti C, Pollet J, Engkasan JP, Francisco GE, Frontera WR, *et al.*; REREP study participants. Clinical replicability of rehabilitation interventions in randomized controlled trials reported in main journals is inadequate. J Clin Epidemiol 2019;114:108–17.

36. Arienti C, Lazzarini SG, Patrini M, Puljak L, Pollock A, Negrini S. The Structure of Research Questions in Randomized Controlled Trials in the Rehabilitation Field: A Methodological Study. Am J Phys Med Rehabil 2021;100:29–33.

37. Dijkers MP. Reporting on interventions: issues and guidelines for rehabilitation researchers. Arch Phys Med Rehabil 2015;96:1170–80.

38. Hart T. Treatment definition in complex rehabilitation interventions. Neuropsychol Rehabil 2009;19:824–40.

39. Hoenig H, Lee J, Stineman M. Conceptual overview of frameworks for measuring quality in rehabilitation. Top Stroke Rehabil 2010;17:239–51.

40. Dejong G, Horn SD, Gassaway JA, Slavin MD, Dijkers MP. Toward a taxonomy of rehabilitation interventions: using an inductive approach to examine the "black box" of rehabilitation. Arch Phys Med Rehabil 2004;85:678–86.

41. Strasser DC, Falconer JA, Stevens AB, Uomoto JM, Herrin J, Bowen SE, *et al.* Team training and stroke rehabilitation outcomes: a cluster randomized trial. Arch Phys Med Rehabil 2008;89:10–5.

42. Pollock A, Baer G, Campbell P, Choo PL, Forster A, Morris J, *et al.* Physical rehabilitation approaches for the recovery of function and mobility following stroke. Cochrane Database Syst Rev 2014;(4):CD001920.

43. Whyte J, Hart T. It's more than a black box; it's a Russian doll: defining rehabilitation treatments. Am J Phys Med Rehabil 2003;82:639–52.

44. Dijkers MP. An End to the Black Box of Rehabilitation? Arch Phys Med Rehabil 2019;100:144–5.

45. Negrini S, Armijo-Olivo S, Patrini M, Frontera WR, Heinemann AW, Machalicek W, *et al.*; RCTRACK Promoters. The Randomized Controlled Trials Rehabilitation Checklist: Methodology of Development of a Reporting Guideline Specific to Rehabilitation. Am J Phys Med Rehabil 2020;99:210–5.

Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

Funding.—This work was supported and funded by the Italian Ministry of Health – Ricerca corrente 2021.

Authors' contributions.—Chiara Arienti: drafting, critical revision of the article. Riccardo Buraschi and Joel Pollet: drafting, data collection, data analysis and interpretation, critical revision of the article. Stefano G. Lazzarini: data collection, data analysis and interpretation, critical revision of the article. Claudio Cordani: critical revision of the article. Stefano Negrini and Massimiliano Gobbo: conception and design of the work, data interpretation, critical revision of the article. All authors read and approved the final version of the manuscript.

History.—Article first published online: May 30, 2022. - Manuscript accepted: May 25, 2022. - Manuscript revised: May 5, 2022. - Manuscript received: December 22, 2021.

Supplementary data.—For supplementary materials, please see the HTML version of this article at www.minervamedica.it