

À quoi penser pour construire un protocole de recherche?

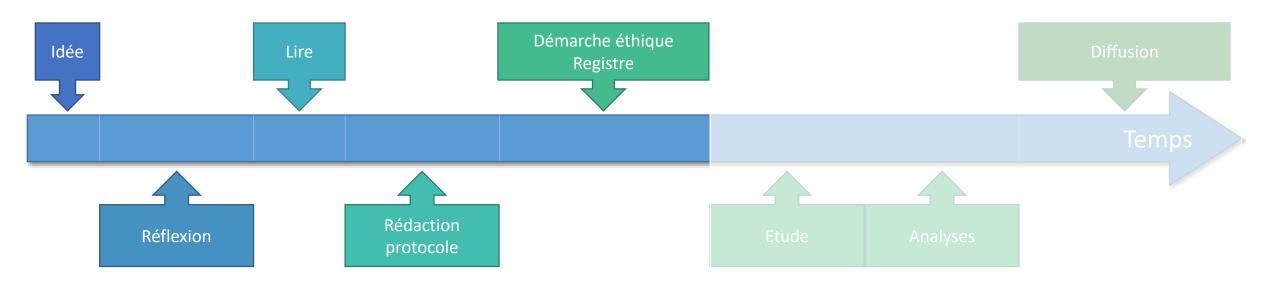
Gregory REYCHLER (Bruxelles)

Thibaud HAASER (Bordeaux)

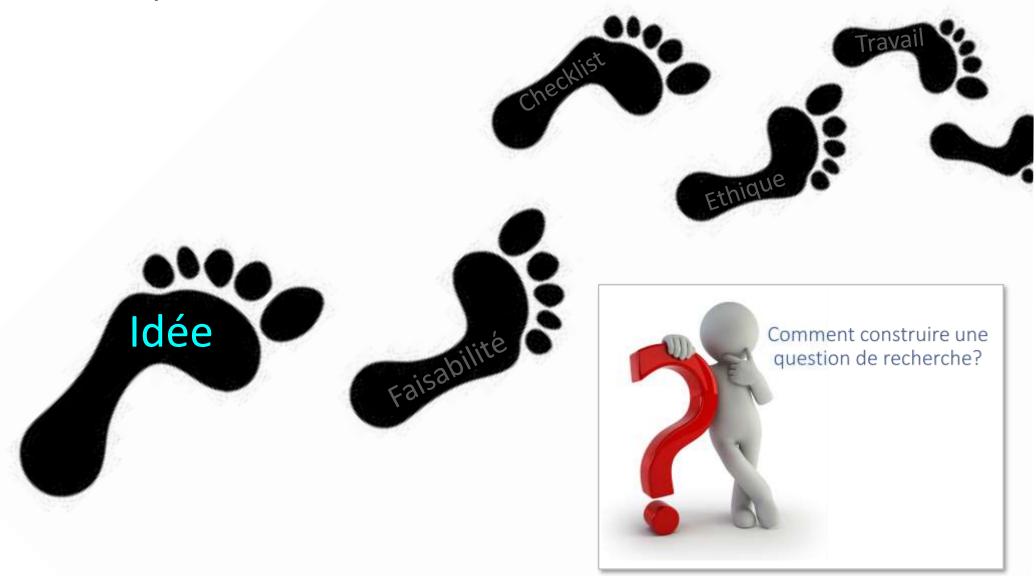




Long processus













Protocole

Taches administratives

Réalisation

Mesures

Analyse

Communication (écrite et c













Exemples...



Randomized Controlled Trial > Respir Med. 2014 Apr;108(4):609-20. doi: 10.1016/j.rmed.2013.12.013. Epub 2014 Jan 2.

Neuromuscular electrical stimulation improves clinical and physiological function in COPD patients

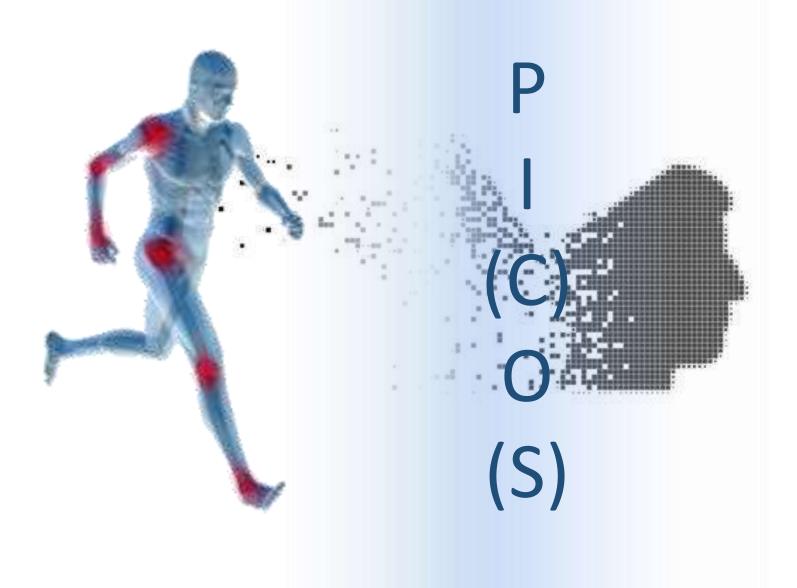
Case Reports > Neurorehabil Neural Repair. 2000;14(1):73-6. doi: 10.1177/154596830001400109.

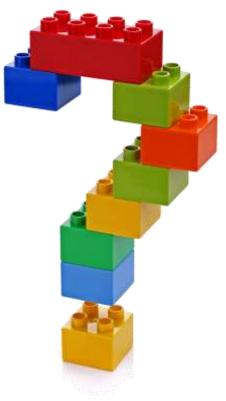
Doing it with mirrors: a case study of a novel approach to neurorehabilitation

> Chest. 1993 Jan;103(1):174-82. doi: 10.1378/chest.103.1.174.

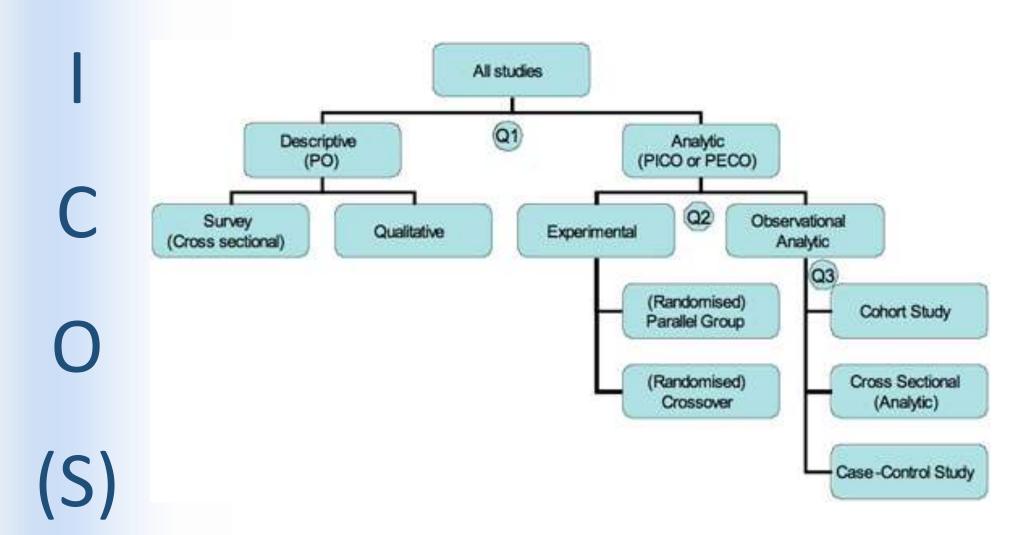
Intermittent positive pressure ventilation via the mouth as an alternative to tracheostomy for 257 ventilator users

Question de départ





P -> STUDY DESIGN











Rationnel



Connaissances



Collaboration

Rationnel



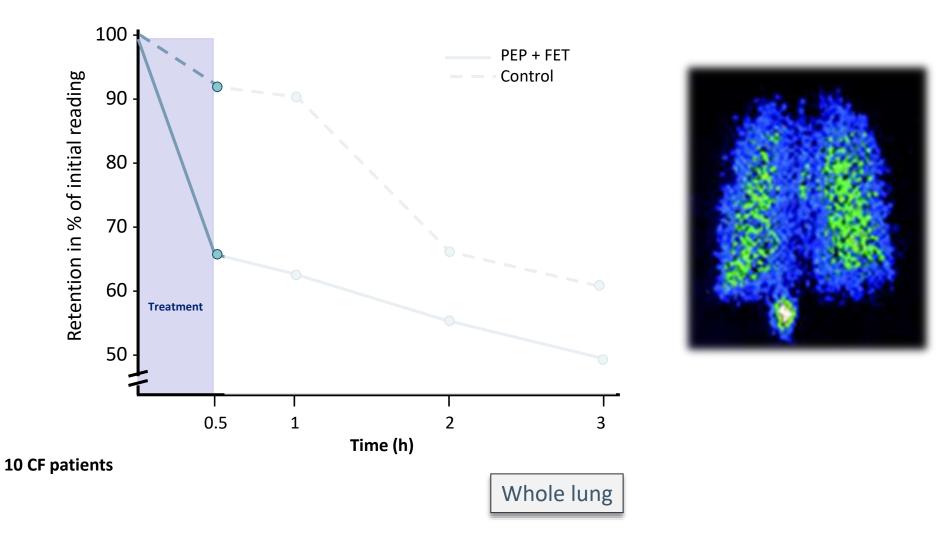


Connaissances

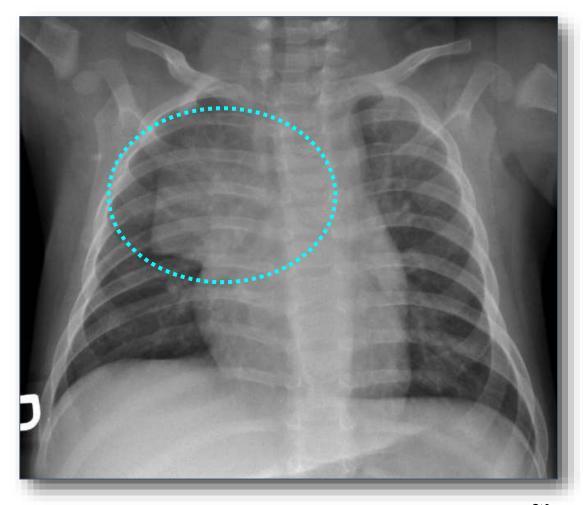
- Physiopathologie
- Outils d'évaluation
 - Propriétés
 - Utilisation



Connaissances: exemples...



Connaissances: exemples...



 $\ll\ldots$ We see only what we look for, and we recognize only what we know \ldots »



Search

Advanced

PubMed® comprises more than 35 million citations for biomedical literature from MEDLINE, life science journals, and online books. Citations may include links to full text content from PubMed Central and publisher web sites.

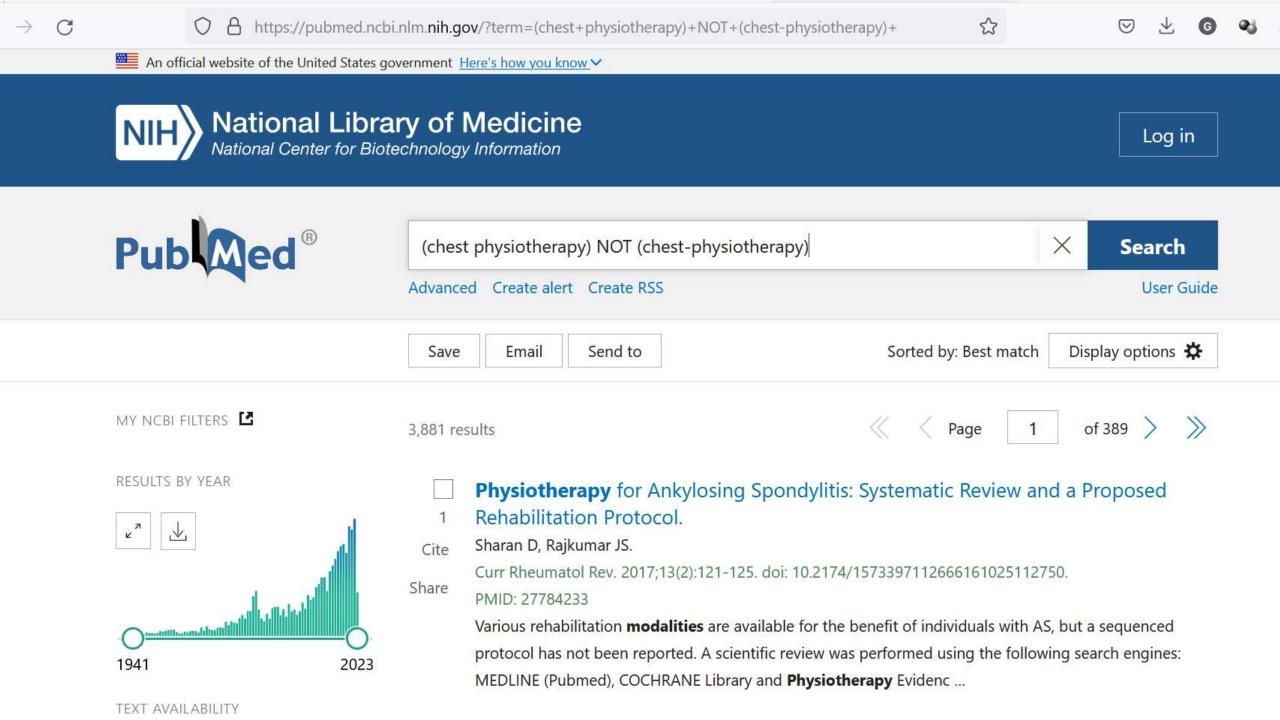


History and Search Details

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Search	Actions	Details	Query	Results	Time
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#3	•••	>	Search: chest physiotherapy	4,868	04:24:51
#7	•••	>	Search: (chest physiotherapy) NOT (chest-physiotherapy)	3,881	04:23:42

Showing 1 to 3 of 3 entries

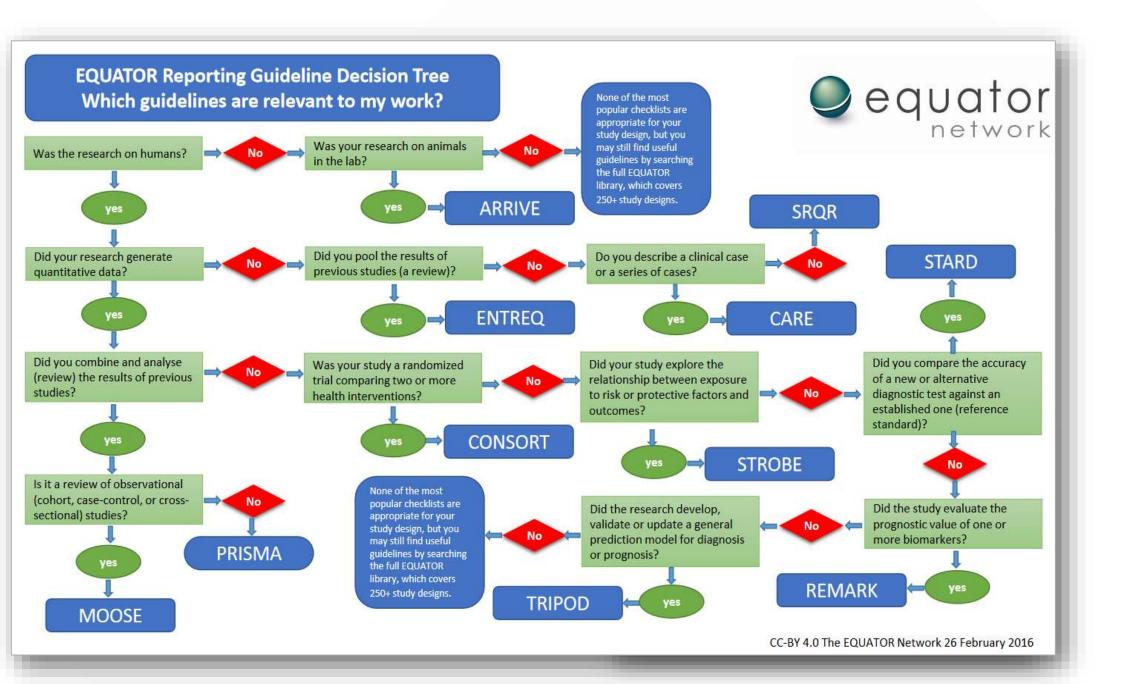














CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and	2a	Scientific background and explanation of rationale	
objectives	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
nterventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	_ 11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

CONSORT 2010 checklist

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

^{*}We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

CONSORT 2010 checklist Page 2

PEDro scale

1	eligibility criteria were specified	no □ yes □	whore:
1.	engionity enteria were specified	iio d yes d	where.
2.	subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no □ yes □	where:
3.	allocation was concealed	no □ yes □	where:
4.	the groups were similar at baseline regarding the most important prognostic indicators	no □ yes □	where:
5.	there was blinding of all subjects	no 🗆 yes 🗅	where:
6.	there was blinding of all therapists who administered the therapy	no □ yes □	where:
7.	there was blinding of all assessors who measured at least one key outcome	no □ yes □	where:
8.	measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no □ yes □	where:
9.	all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no □ yes □	where:
10.	the results of between-group statistical comparisons are reported for at least of key outcome	no 🗆 yes 🗖	where:
11.	the study provides both point measures and measures of variability for at least one key outcome	no □ yes □	



