Desenhos de estudos

Cristina P Camargo

INTRODUÇÃO

Evidência

DESENHOS DE ESTUDO

Vantagens e desvantagens

PERGUNTA DA PESQUISA E DESENHO D ESTUDO

Selção do estudo mais adequado

Considerações finais

Desenhos de estudo

- Identificação do melhor estudo para responder a pergunta da pesquisa
- Características básicas (Introdução, Método, Resultado, discussão, Conclusão, Referiências)

Introdução

Qual o objetivo do estudo?

Descritivo

Analítico

Quando os desfechos serão coletados?

Retrospectivo.

Prospectivo

Os pacientes serão randomizados?

Observacional

Estudo Clínico Randomizado

COLETA DE DADOS

única

COLETA DE DADOS

Várias vezes

LONGITUDINAL

Desenho do estudo e evidência

Evolução do conhecimento

Características

In vitro
In vivo

Estudos pré clínicos

> Acta Cir Bras. 2019 Feb 28;34(2):e201900202. doi: 10.1590/s0102-8650201900202.

Hyaluronic acid in tobacco-exposed rats. Inflammatory reaction, and duration of effect1

Vantagens

CONHECIMENTO SEGURANÇA E EFICÁCIA ANTES DO USO EM SER HUMANO

Desvantagens

POUCA EVIDÊNCI

Características

Descrição de conduta/ diagnóstico
1-3 casos

Relato de casos

Int J Surg Case Rep. 2020; 73: 332–337.
Published online 2020 Jul 18.
doi: 10.1016/j.ijscr.2020.07.049
PMCID: PMC73939
PMID: 32739

Castleman disease. Interaction with dermatopathy: Cas report

M.L.A. Modolin,[a] C.P. Camargo,[b,*] D.A. Milcheski,[a] W. Cintra, Jr.,[a] R.I. Rocha,[a] G.M. Clivatti,[a] B. Nascimento,[a] and R. Gemperli[c]

Vantagens

DESCRIÇÃO DE DOENÇAS/ CIRURGIAS

Desvantagens

POUCA EVIDÊNCIA

Características

Relatos de tratamento, diagnóstico
3 ou mais casos

Série de casos

Northern Clinics of Istanbul

North Clin Istanb. 2019; 6(2): 171–175.
Published online 2018 Mar 16.
doi: 10.14744/nci.2018.58672

PMCID: PMC6593919
PMID: 31297485

Congenital hiatus hernia: A case series

Didem Baskin Embleton,[1] Ahmet Ali Tuncer,[1] Mehmet Surhan Arda,[2] Huseyin Ilhan,[2] and Salih Cetinkursun[1]

Vantagens

DESCRIÇÃO DE DOENÇAS/ CIRURGIAS
ANALISA VÁRIOS FATORES

Desvantagens

POUCA EVIDÊNCIA
VIESES
SEM GRUPO CONTROLE

Características

Revisão de prontuário
Coleta de dados em um período

Estudo Transversal (cross-sectional)

Contents lists available at ScienceDirect

Brain, Behavior, and Immunity

journal homepage: www.elsevier.com/locate/ybrbi

Letter to the Editor

Depression and anxiety among adolescents during COVID-19: A cross-sectional study

Vantagens

CUSTO BAIXO
RÁPIDO
IDENTIFICAR FATORES PREDITIVOS
PREVALÊNCIA

Desvantagens

VIÉS DE RESPOSTA
VIÉS DE MEMÓRIA
VIÉS DE TEMPO

Características

Doença ------- Fatores (possíveis causas)

Estudo Caso- controle

Características

Doença ------- Fatores (possíveis causas)

Estudo Caso- controle

RESEARCH ARTICLE

Editorial Process: Submission:06/12/2019 Acceptance:11/11/2019

Carcinogen Metabolism Pathway and Tumor Suppressor Gene Polymorphisms and Gallbladder Cancer Risk in North Indians: A Hospital-Based Case-Control Study

Vantagens

EVENTOS RAROS
CUSTO BAIXO
RÁPIDO
DOENÇAS DE REMISSÃO E LATÊNCIA GRANDE

Desvantagens

DIFICULDADE PARA DETERMINAR O GRUPO CONTROLE
INCERTEZA DA RELAÇÃO TEMPORAL(CAUSA E DOENÇA)
VIÉS (A PROPORÇÃO DO GRUPO EXPOSTO E CONTROLE É IRREAL

Características

Estudo longitudinal
Períodos longos dependendo da pergunta da pesquisa
Pode ser retrospectivo ou prospectivo

Estudo Coorte

BMJ Open. 2019 Apr 8;9(4):e026581. doi: 10.1136/bmjopen-2018-026581.

Bidirectional association between migraine and fibromyalgia: retrospective cohort analyses of two populations

Observational Study > Int J Infect Dis. 2021 Aug;109:209-216. doi: 10.1016/j.ijid.2021.07.016.
Epub 2021 Jul 14.

Long-term clinical follow-up of patients suffering from moderate-to-severe COVID-19 infection: a monocentric prospective observational cohort study

Vantagens

INÍCIO DA DOENÇA (TEMPO)
ANALISA VÁRIOS FATORES
EVENTOS FREQUENTES

Desvantagens

CONSOME MUITO TEMPO
EVENTOS RAROS
CARO

Características

Não há randomização ou grupo controle
Segue demais itens de um estudo randomizado

Estudo Quasi-Randomizado


International Journal of
Environmental Research and Public Health

MDPI

Article

Quasi-Randomized Trial of Effects of Perioperative Oral Hygiene Instruction on Inpatients with Heart Diseases Using a Behavioral Six-Step Method

Vantagens

POSSIBILITA ADAPATAR A ÉTICA

Desvantagens

AUSÊNCIA DA RANDOMIZAÇÃO IMPEDE ESTABELECER CAUSA- EFEITO

Características

Previne vieses
Grupo controle e comparador

Estudo Clínico Randomizado

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 FEBRUARY 25, 2021 VOL. 384 NO. 8

Dexamethasone in Hospitalized Patients with Covid-19

The RECOVERY Collaborative Group*

Vantagens

CAUSA - EFEITO
CONTROLE DE TODAS AS VARIÁVEIS

Desvantagens

CUSTOS
DEMANDA MUITO TEMPO
TREINAMENTO DA EQUIPE
ÉTICA

Características

Estudo secundário
Aumentar evidência sem por em risco pacientes

Revisão Sistemática

Cochrane Database of Systematic Reviews | Review - Intervention

Botulinum toxin type A for facial wrinkles

Cristina Pires Camargo, Jun Xia, Caroline S Costa, Rolf Gemperli, Maria DC Tatini, Max K Bulsara, Rachel Riera

Vantagens

CAUSA - EFEITO
DEMONSTRA A MELHOR EVIDÊNCIA POSSÍVEL
SEM CUSTO

Desvantagens

DEMANDA MUITO TEMPO
DEPENDE DE ANÁLISE CRÍTICA DO PESQUISADOR
PODE AMPLIFICAR VIESES

Enhancing the QUAlity and Transparency Of health Research

EQUATOR resources in German | Portuguese | Spanish

Search for reporting guidelines

Browse for reporting guidelines by selecting one or more of these drop-downs:

Study type: Please select... and Clinical area: Please select... and Section of report: Please select...

Or search with free text: case report

Search Reporting Guidelines

Start again | Help

Displaying 32 reporting guidelines found.

Key reporting guidelines, shaded green, are displayed first. Show the most recently added records first.

1 The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies

Reporting guidelines for main study types

Randomised trials	CONSORT	Extensions
Observational studies	STROBE	Extensions
Systematic reviews	PRISMA	Extensions
Study protocols	SPIRIT	PRISMA-P
Diagnostic/prognostic studies	STARD	TRIPOD
Case reports	CARE	Extensions
Clinical practice guidelines	AGREE	RIGHT
Qualitative research	SRQR	COREQ
Animal pre-clinical studies	ARRIVE	

CARE case report guidelines

CARE Checklist of information to include when writing a case report

Topic	Item	Checklist item description	Reported on Line
Title	1	The diagnosis or intervention of primary focus followed by the words "case report"	
Key Words	2	2 to 5 key words that identify diagnoses or interventions in this case report, including "case report"	
Abstract (no references)	3a	Introduction: What is unique about this case and what does it add to the scientific literature?	
	3b	Main symptoms and/or important clinical findings	
	3c	The main diagnoses, therapeutic interventions, and outcomes	
	3d	Conclusion—What is the main "take-away" lesson(s) from this case?	
Introduction	4	One or two paragraphs summarizing why this case is unique (**may include references**)	
Patient Information	5a	De-identified patient specific information	
	5b	Primary concerns and symptoms of the patient	
	5c	Medical, family, and psycho-social history including relevant genetic information	
	5d	Relevant past interventions with outcomes	
Clinical Findings	6	Describe significant physical examination (PE) and important clinical findings	
Timeline	7	Historical and current information from this episode of care organized as a timeline	
Diagnostic Assessment	8a	Diagnostic testing (such as PE, laboratory testing, imaging, surveys)	
	8b	Diagnostic challenges (such as access to testing, financial, or cultural)	
	8c	Diagnosis (including other diagnoses considered)	
	8d	Prognosis (such as staging in oncology) where applicable	
Therapeutic Intervention	9a	Types of therapeutic intervention (such as pharmacologic, surgical, preventive, self-care)	
	9b	Administration of therapeutic intervention (such as dosage, strength, duration)	
	9c	Changes in therapeutic intervention (with rationale)	
Follow-up and Outcomes	10a	Clinician and patient-assessed outcomes (if available)	
	10b	Important follow-up diagnostic and other test results	
	10c	Intervention adherence and tolerability (How was this assessed?)	
	10d	Adverse and unanticipated events	
Discussion	11a	A scientific discussion of the strengths AND limitations associated with this case report	
	11b	Discussion of the relevant medical literature **with references**	
	11c	The scientific rationale for any conclusions (including assessment of possible causes)	
	11d	The primary "take-away" lessons of this case report (without references) in a one paragraph conclusion	
Patient Perspective	12	The patient should share their perspective in one to two paragraphs on the treatment(s) they received	
Informed Consent	13	Did the patient give informed consent? Please provide if requested	**Yes** ☐ **No** ☐

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
Outcome data	15*	Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Search for reporting guidelines

Use your browser's Back button to return to your search results

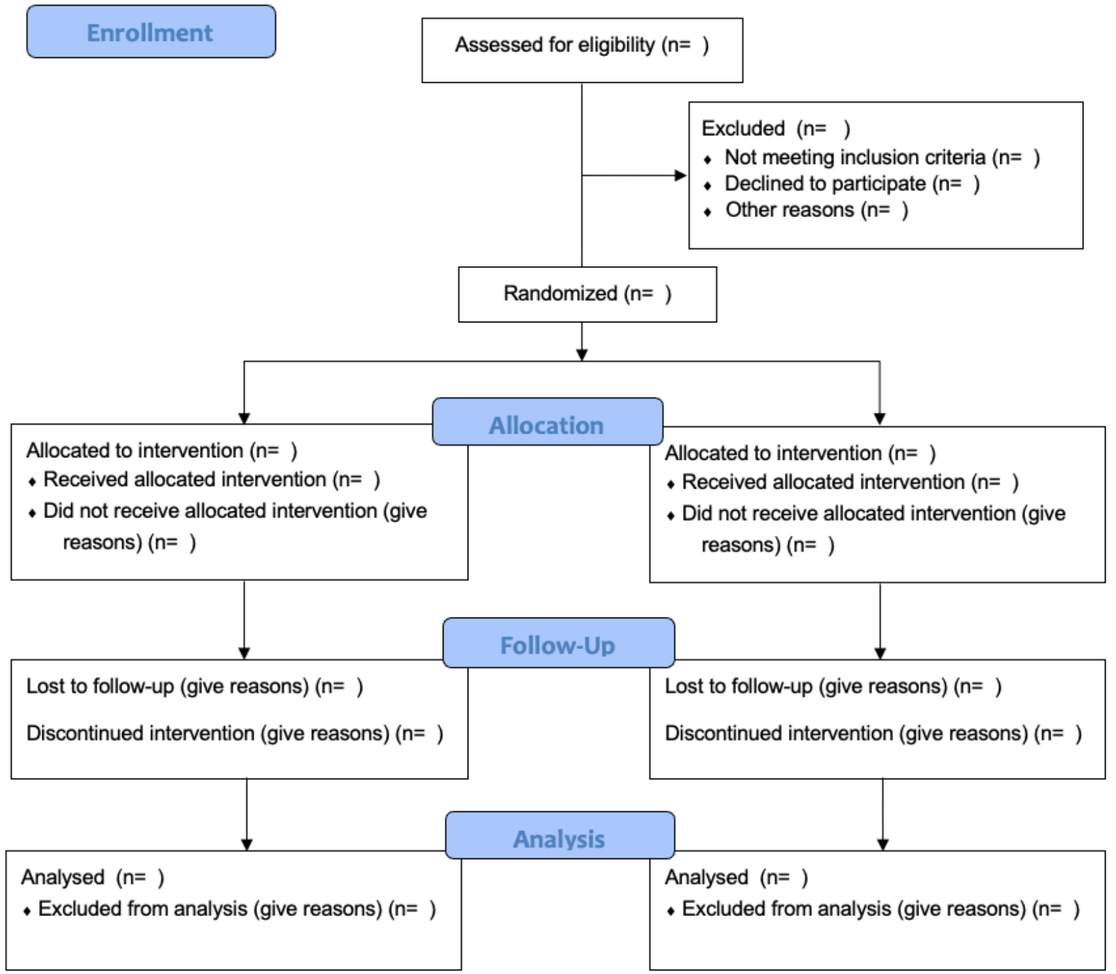
The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies

Reporting guideline provided for? (i.e. exactly what the authors state in the paper)	Observational studies in epidemiology (cohort, case-control studies, cross-sectional studies)
	STROBE checklist: combined Word / PDF
	STROBE checklist: cohort studies Word / PDF

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 objectives	2a	Scientific background and explanation of rationale	
	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	
Interventions	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 generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), 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 Flow Diagram



SPIRIT CHECKLIST

Title

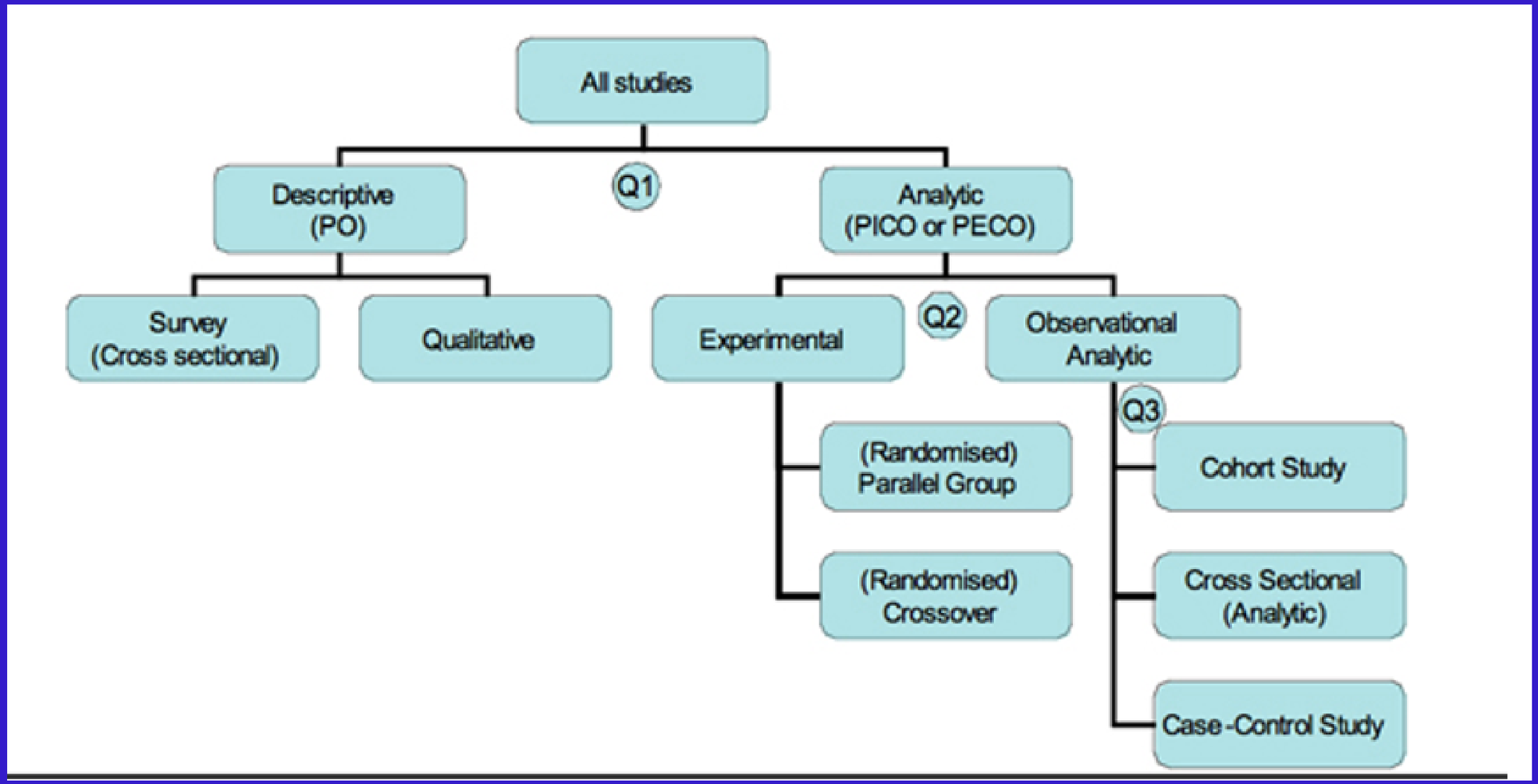
Item 1: Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym.

Example

> "A Multi-center, Investigator-blinded, Randomized, 12-month, Parallel-group, Non-inferiority Study to Compare the Efficacy of 1.6 to 2.4 g Asacol® Therapy QD [*once daily*] Versus Divided Dose (BID) in the Maintenance of Remission of Ulcerative Colitis." [19]

Explanation

The title provides an important means of trial identification. A succinct description that conveys the topic (study population, interventions), acronym (if any), and basic study design – including the method of intervention allocation (e.g., parallel-group randomised trial; single-group trial) – will facilitate retrieval from literature or Internet searches and rapid judgment of relevance.[20] It can also be helpful to include the trial framework (e.g.,


All studies
Q1
Descriptive
(PO)
Analytic
(PICO or PECO)
Survey
(Cross sectional)
Qualitative
Experimental
Q2
Observational
Analytic
Q3
(Randomised)
Parallel Group
(Randomised)
Crossover
Cohort Study
Cross Sectional
(Analytic)
Case-Control Study

Características

Superioridade
equivalênecia
Não -inferioridade

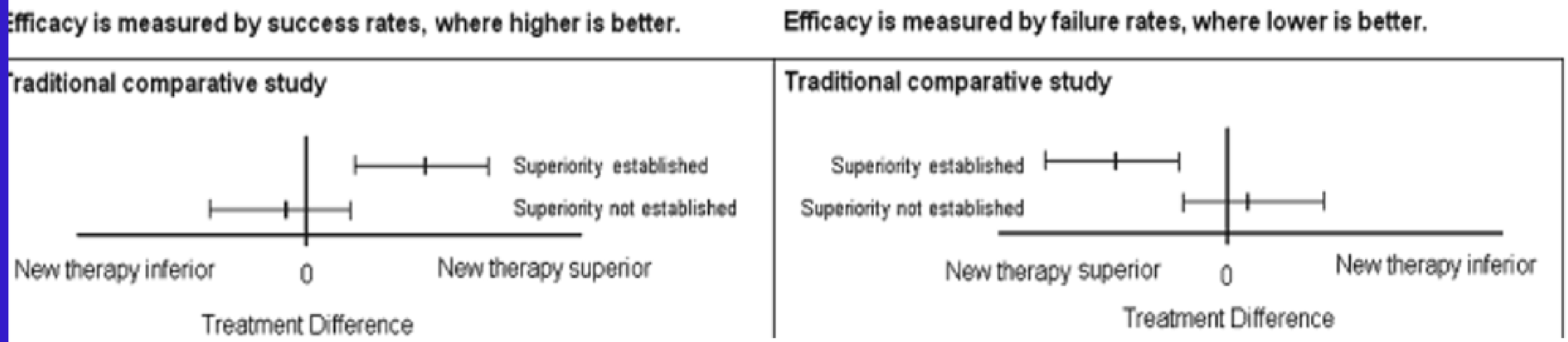
Estudo Analítico

Table 1. Hypotheses Associated with the Different Types of Studies when Comparing a New Therapy Against a Current Therapy with Respect to Efficacy

Type of study	Null hypotheses	Research hypothesis
Traditional comparative	There is no difference between the therapies	There is a difference between the therapies
Equivalence	The therapies are not equivalent	The new therapy is equivalent to current therapy
Noninferiority	The new therapy is inferior to the current therapy	The new therapy is not inferior to the current therapy

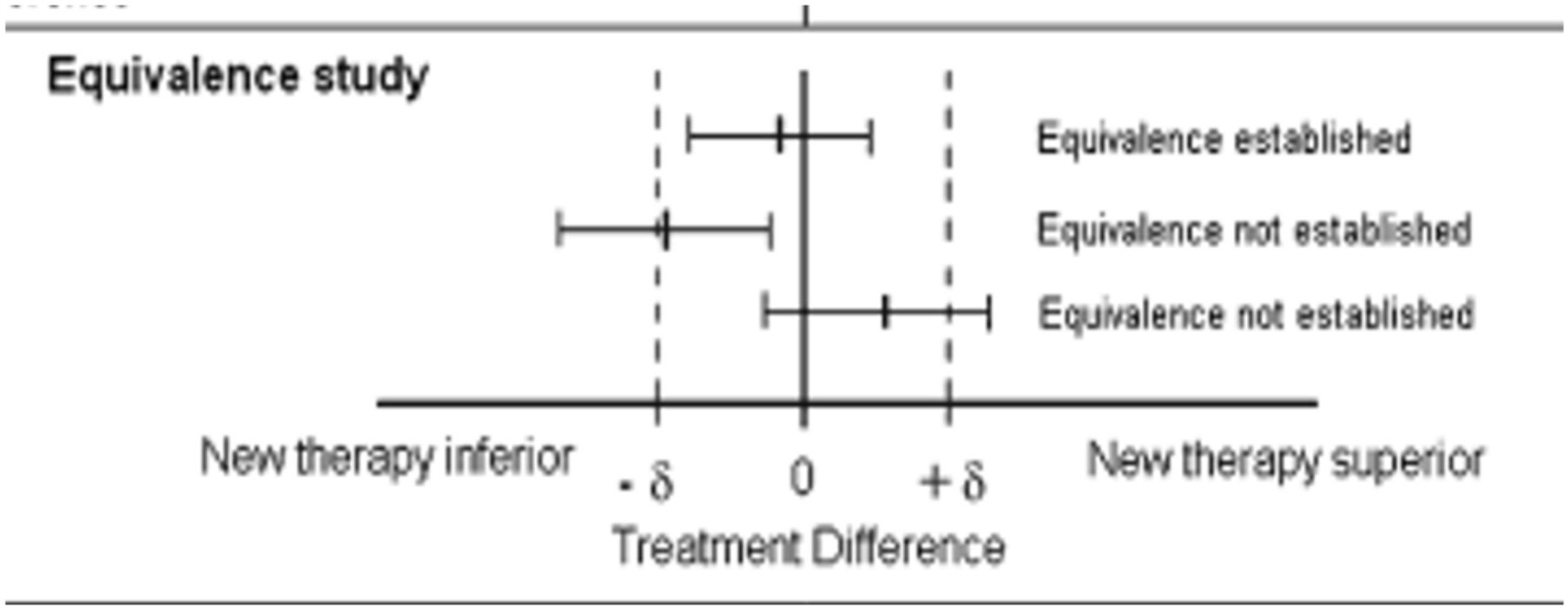
Walker, E., & Nowacki, A. S. (2011). Understanding Equivalence and Noninferiority Testing. Journal of General Internal Medicine, 26(2), 192–196

Superioridade



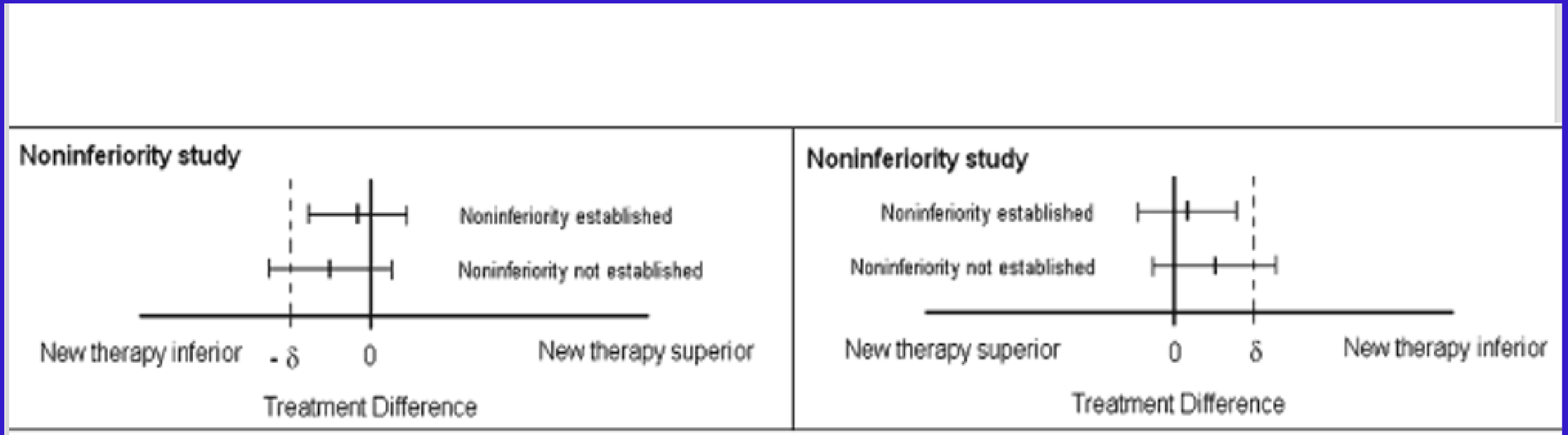
Walker, E., & Nowacki, A. S. (2011). Understanding Equivalence and Noninferiority Testing. Journal of General Internal Medicine, 26(2), 192–196.

Equivalência

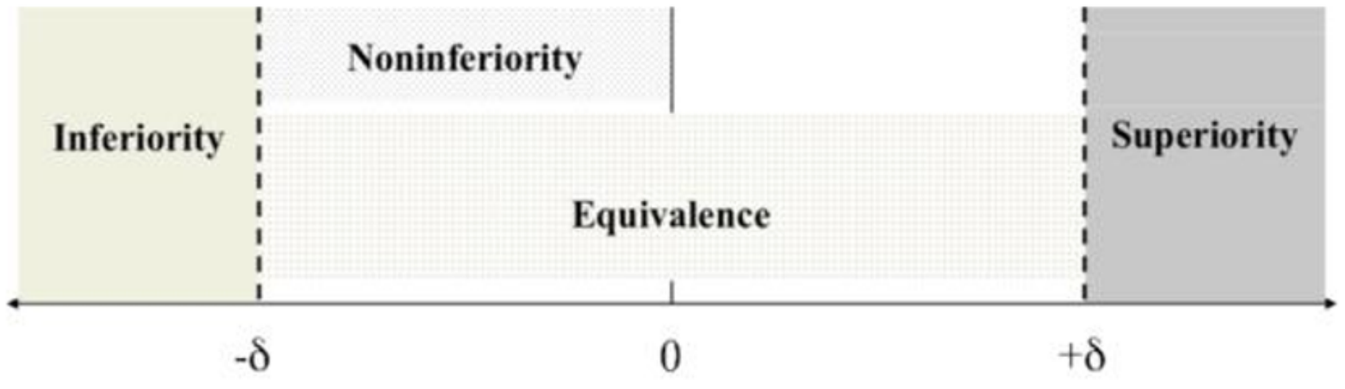


Walker, E., & Nowacki, A. S. (2011). Understanding Equivalence and Noninferiority Testing. Journal of General Internal Medicine, 26(2), 192–196.

Não-inferioridade



Walker, E., & Nowacki, A. S. (2011). Understanding Equivalence and Noninferiority Testing. Journal of General Internal Medicine, 26(2), 192–196.



(Experimental Treatment – Standard Treatment)

δ = pre-specified margin of equivalence/noninferiority

The two-sided 95% confidence interval of the difference between treatments is less than the non-inferiority margin: fail to claim noninferiority of new treatment.

The confidence interval is greater than the non-inferiority margin: claim noninferiority of new treatment.

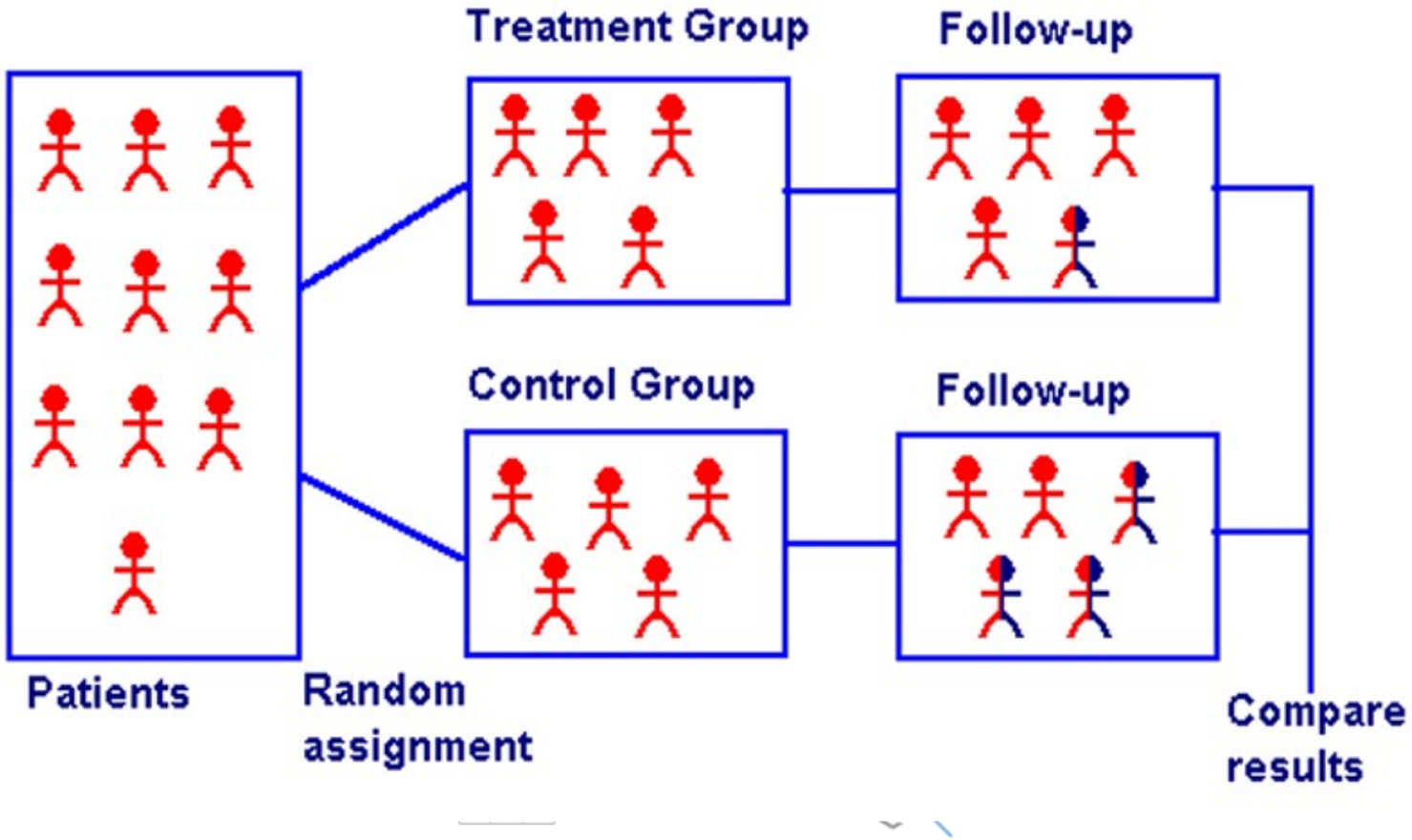
The confidence interval is greater than than the non-inferiority margin and less than the non-superiority margin: claim equivalence of new treatment.

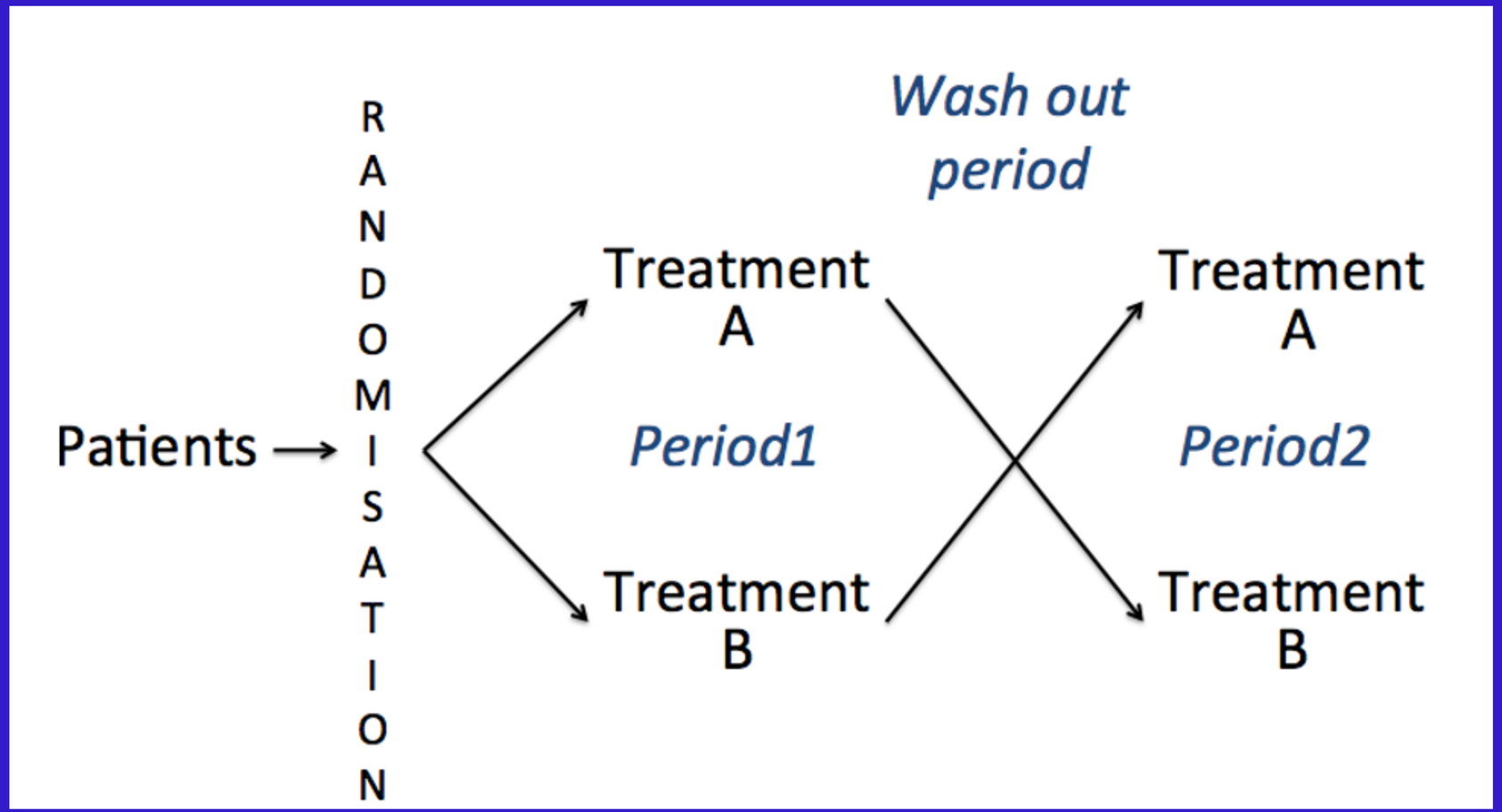
Greene, C. J., Morland, L. A., Durkalski, V. L., & Frueh, B. C. (2008). Noninferiority and Equivalence Designs: Issues and Implications for Mental Health Research. Journal of Traumatic Stress, 21(5), 433–439.

Cruzado

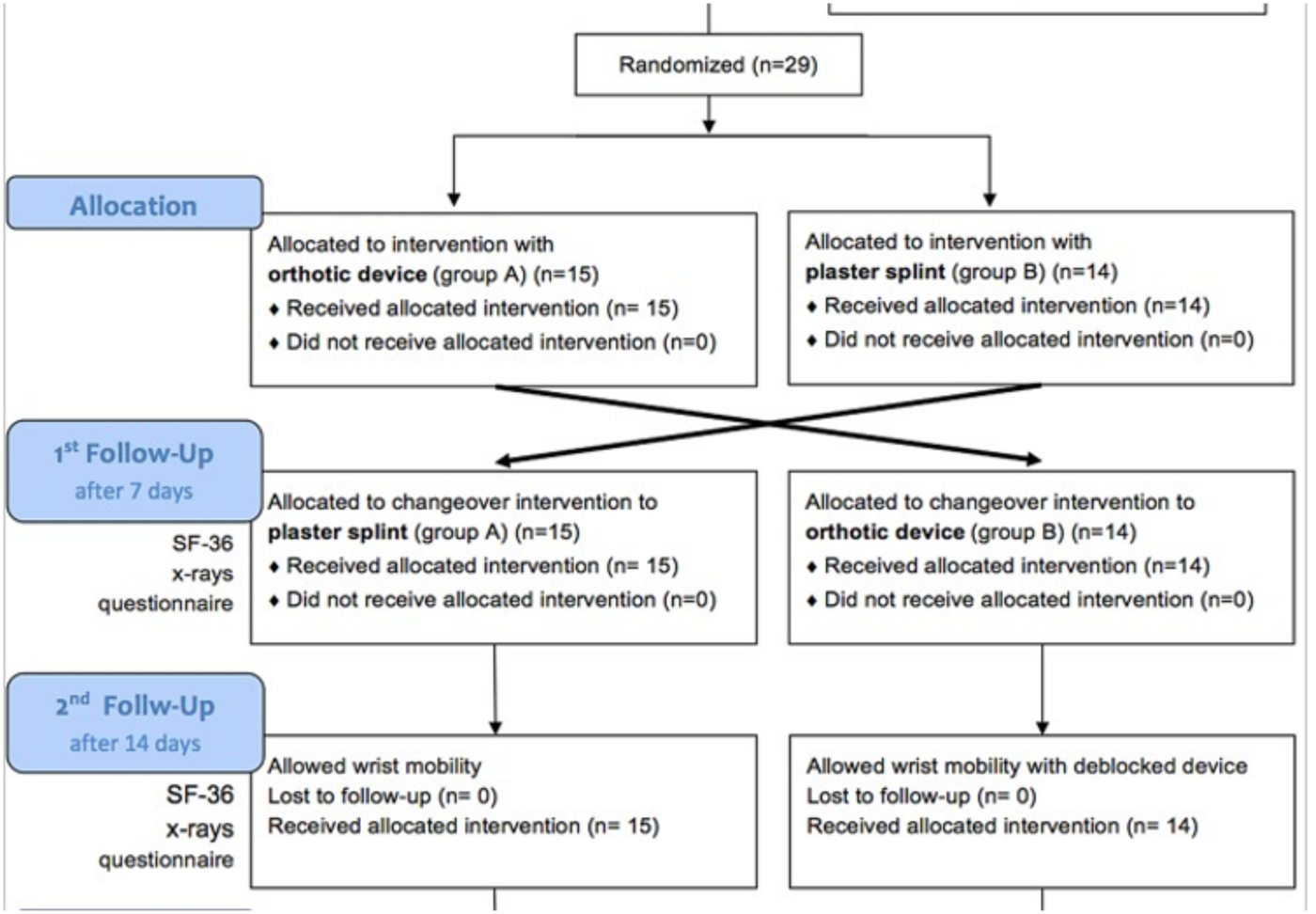
Paralelos

Fatorial

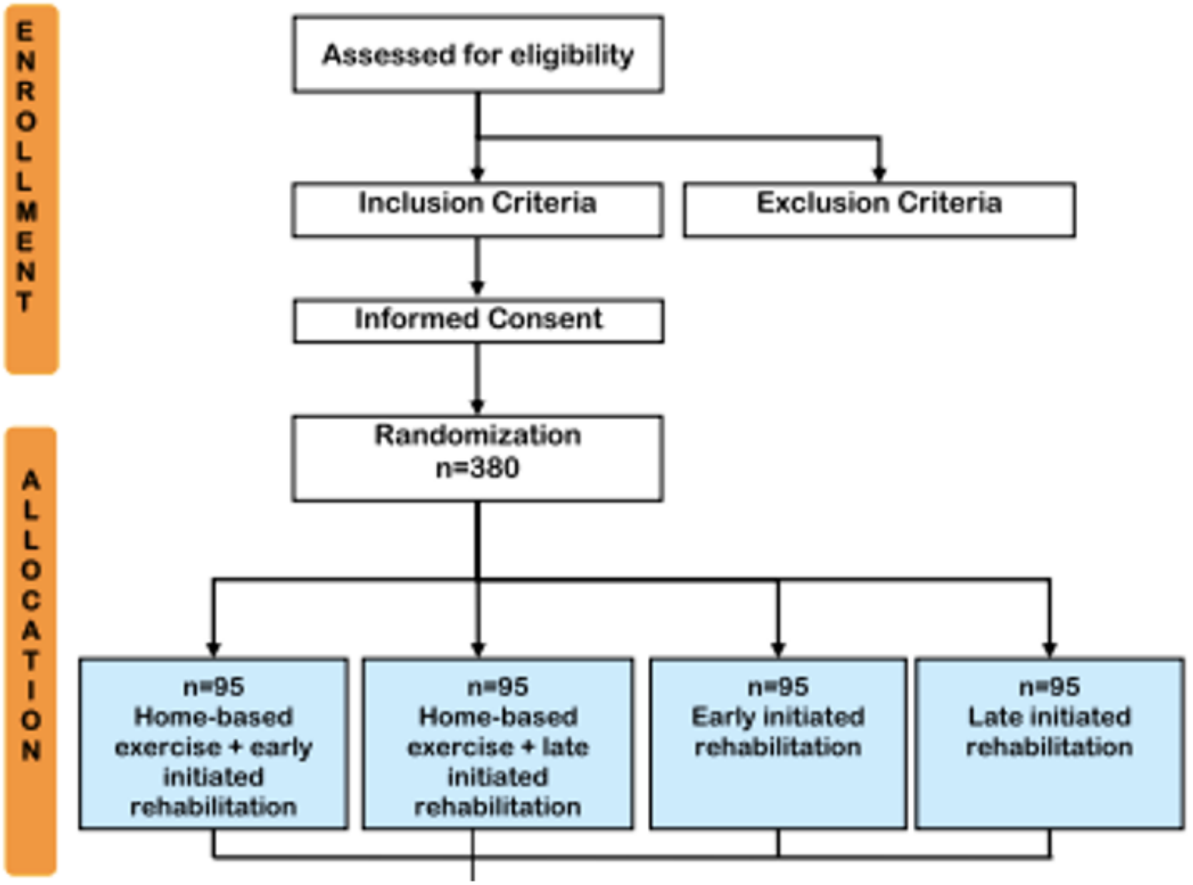

Treatment Group
Follow-up
Control Group
Follow-up
Patients
Random assignment
Compare results


Wash out
period
Patients
RANDOMISATION
Treatment
A
Treatment
B
Period1
Treatment
A
Treatment
B
Period2

Cross over



Stuby, F. M.et al.. (2015). Early Functional Postoperative Therapy of Distal Radius Fracture with a Dynamic Orthosis: Results of a Prospective Randomized Cross-Over Comparative Study. PLoS ONE, 10(3), e0117720.



Sommer, M. S.et al. (2014). Perioperative rehabilitation in operation for lung cancer (PROLUCA) – rationale and design. BMC Cancer, 14, 404.

Study design	Advanatges	Disadvantages
Parallel	Cause - effect	Expensive
Cross-over	The patient is his own control All patients receive the intervention	Wash-out period Adherence Carry over effect
Factorial	Study two or more factors Study the interaction	Less statistical power If interaction exist_ misleading results
Cluster	Study regions, schools	Complexity

Estudo Clínico Pragmático

Estudo clinico randomizado - expert

Cook et al. rials. 2015 May 30;16:241

Conclusões

O MELHOR DESENHO DO ESTUDO É AQUELE QUE RESPONDE A SUA PERGUNTA DA PESQUISA

CONSIDERAR

Vantagens e desvantagens

TREINAMENTO