

UE 7.4 - MÉTHODOLOGIE D'ANALYSE D'ARTICLES

CM5: Study design, Result checking &
Randomised controlled trials

NOTIONS DE CONCEPTION : L'AVEUGLE

Eviter les biais

Du participant

Du chercheur

3 niveaux

Simple participant **ou** chercheur

Double participant **et** chercheur

Triple participant **et** chercheurs

NOTIONS DE CONCEPTION : BRAS

Séparation selon traitements

Types

- Expérimental

- Comparaison active

- Placébo

- Factice

- Sans intervention

NOTIONS DE CONCEPTION : ATTRIBUTION

Distribution aléatoire ou non aléatoire

Randomisation

A priori

Par blocs permutés

Par strates - en fonction des caractéristiques des patients

A posteriori

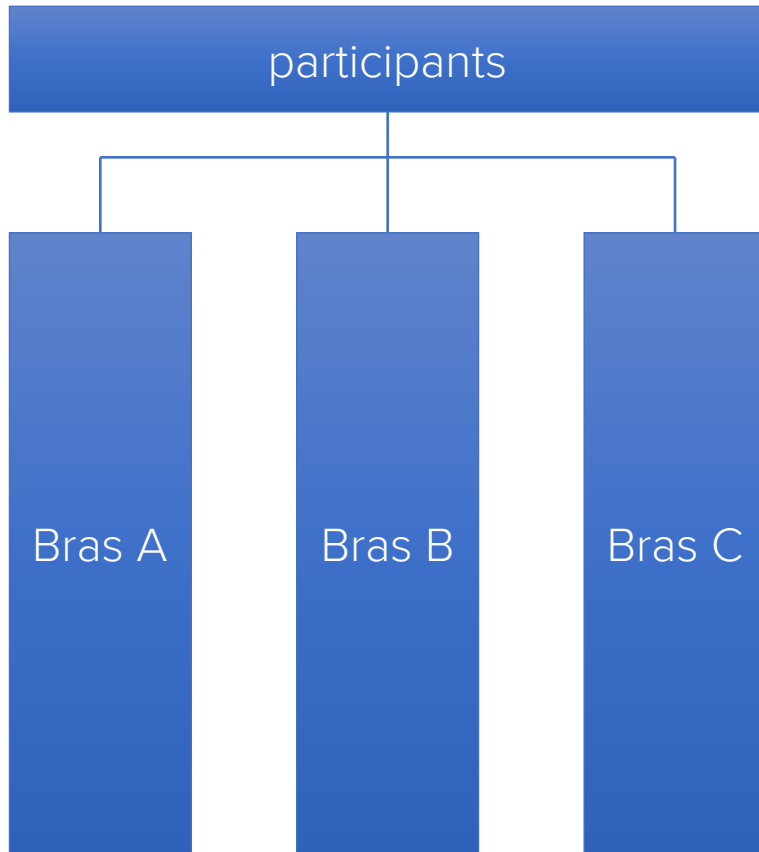
Adaptive – tient compte des attributions qui précèdent

Minimisée – adaptive par strates

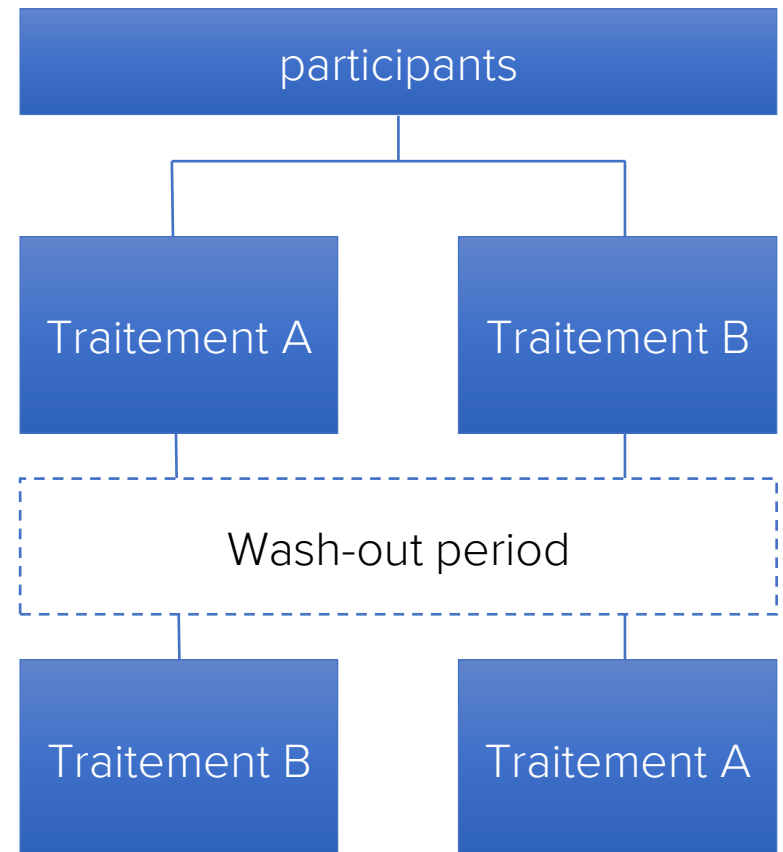
Gagnant renforcé – efficacité précédente prise en compte

NOTIONS DE CONCEPTION : CROISEMENT

Parallèle



Croisé



$A+B = B+A ?$

NOTIONS DE CONCEPTION : CLUSTER RANDOMIZATION

- Attribution en fonction d'un groupe pas de l'individu
- Permet
 - d'évaluer une intervention où l'impact concerne le système plutôt que l'individu
 - d'éviter la contamination
- Exemple : Essai de deux stratégies de perte de poids



AUTRES APPROCHES DE CLASSIFICATION DES ÉTUDES

Par méthodologie

Observation

Intervention

Par objectif (réf. NIH)

Prévention

Dépistage

Diagnostic

Traitement

Qualité de vie

Accès étendu – tt non-approuvé

Avant maladie



Début de maladie



Maladie chronique
ou avancée

MÉTHODES ITÉRATIVES

DESIGN ADAPTATIF

Stratégie d'optimisation

Evaluations régulières

➤ Modifications

1. Dosage
2. Taille d'échantillon
3. Traitement
4. Critères d'inclusion
5. Traitements associés

RECHERCHE TRANSLATIONNELLE

1. **Développer** un traitement ou une intervention.
(recherche fondamentale)
2. **Tester** l'efficacité
(recherche clinique)
3. **Diffuser** le plus largement possible

VÉRIFICATION DE RÉSULTATS

Test-retest

Comparaison des résultats d'un même test après un laps de temps

Inter-rater reliability

Comparaison des résultats à un même test de deux évaluateurs différents

Spécificité

Bonne identification des vrais négatifs, peu de faux positifs

Sensibilité

Bonne Identification des vrais positifs, peu de faux négatifs

The Truth

		Has the disease	Does not have the disease	
Test Score:	Positive	True Positives (TP) a	False Positives (FP) b	$PPV = \frac{TP}{TP + FP}$
	Negative	c False Negatives (FN)	d True Negatives (TN)	

<p>Sensitivity</p> $\frac{TP}{TP + FN}$ <p>Or,</p> $\frac{a}{a + c}$	<p>Specificity</p> $\frac{TN}{TN + FP}$ $\frac{d}{d + b}$
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TESTS POST-HOC

Réduction ou élimination des erreurs, notamment de type I

Nombreuses méthodes statistiques

Scheffé, Tukey, Bonferroni, Dunn, Fischer's LSD, Newman-Keuls, Dunnett's...

Choix dépendra de la nature des données et du test initial

L'ESSAI (OU ÉTUDE) RANDOMISÉ CONTROLÉ

Une référence (gold standard)

Méthode rigoureuse pour identifier une relation cause-effet entre un traitement et un résultat

Méthode de **randomisation** choisie au besoin

Groupe de **contrôle** ou de comparaison

Aveugle utilisé lorsque c'est possible

L'ÉTUDE RANDOMISÉE CONTROLÉE

+

Niveau de preuve le plus élevé
pour évaluer un traitement

Meilleure démonstration de lien
cause à effet

La randomisation limite l'influence
des facteurs de confusion
potentiels

Pas de doute sur la chronologie

Permet les études en aveugle et
ainsi limite certains biais

Peut mesurer incidence et
résultats multiples

–

Problèmes éthiques pour
l'attribution.

Coûteux et long.

Peu efficace pour une
pathologie rare ou un effet
retardé.

Generalisabilité – les
participants peuvent être plus
enclins à adhérer au traitement
que la population plus large.

TABLEAU COMPARATIF

PMC full text: [Can J Hosp Pharm. 2014 Sep-Oct; 67\(5\): 366–372.](#)
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Table 1.

Limitations of Randomized Clinical Trials (RCTs) Potentially Addressed by Cohort and Case–Control Studies

Limitation of RCT [*]	Complementary Aspect of Cohort and Case–Control Studies
Use of a strict study protocol that is often not representative of typical care	Usually representative of settings of routine medical care
Exclusion of key patient populations, such as children, pregnant women, and elderly people	May focus on vulnerable and under-represented populations
Limited sample size	May include large number of patients, especially if secondary data sources are used, thereby allowing rare events to be detected
Short duration	May follow patients for long periods of time (e.g., years)
Evaluation of irrelevant treatment comparisons	May compare several relevant therapies
Outcomes measured may not be important to the patient (e.g., surrogate end points)	May include any outcome that is measurable within the data source
High cost	Relatively low cost

^{*}These limitations apply to typical RCTs. Designing more pragmatic RCTs would also overcome many these limitations.

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ANALYSE DE LA MÉTHODOLOGIE D'UNE ÉTUDE CONTROLÉE RANDOMISÉE : SURE 2016

1. Does the study address a clearly focused question/hypothesis ?

Population/Problem?

Intervention?

Comparator/control?

Outcomes?

Can you identify the primary outcome?

2. Was the population randomised?

If YES, were appropriate methods used?

E.g. : random number tables, opaque envelopes

Note: The following methods are not appropriate: alternating participants coin toss, birth dates, record numbers, days of the week

3. Was allocation to intervention or comparator groups concealed?

Is it possible for those allocating to know which group they are allocating people to?

As above, methods such as alternating participants coin toss, birth dates, record numbers, days of the week will not allow appropriate allocation concealment.

4. Were participants/investigators blinded to group allocation?

If NO, was assessment of outcomes blinded?

5. Were interventions (and comparisons) well described and appropriate?

Aside from the intervention, were the groups treated equally?

Was exposure to intervention and comparison adequate?

Was contamination acceptably low?

6. Was ethical approval sought and received?

Do the authors report this?

7. Was a trial protocol published?

Was a protocol published in a journal or clinical trial registry before participants were recruited?

If a protocol is available, are the outcomes reported in the paper listed in the protocol?

8. Were the groups similar at the start of the trial?

Are baseline characteristics provided and discussed (eg age, sex, social class, life style etc.)?

Are any differences >10%?

9. Was the sample size sufficient?

Were there enough participants?

Was there a power calculation? If YES, for which outcome?

Were there sufficient participants?

10. Were participants properly accounted for?

Was follow-up $\geq 80\%$?

Were patients analysed in the groups to which they were randomised?

Was an Intention to Treat analysis conducted?

Was the follow-up period long enough?

11. Data analysis

Are the statistical methods well described?

Consider: How missing data was handled; were potential sources of bias (confounding factors) controlled for; How loss to follow-up was addressed.

12. Results

Were outcome measures reliable?
(e.g. objective or subjective measures)

Were all outcome measurements complete?

Were all important outcomes assessed?

Are the authors' conclusions adequately supported by the results?

13. Is any sponsorship/conflict of interest reported?

14. Finally...consider:

Did the authors identify any limitations?

15. Coherence

Are the conclusions the same in the abstract and the full text?

UN MODÈLE D'ANALYSE : COUGHLAN ET AL. (2007)

Section one – elements influencing the believability of the research

Writing style

*Is the report well written – concise, grammatically correct, avoid the use of jargon?
Is it well laid out and organised?*

Author

Do the researcher(s) qualifications/positions indicate a degree of knowledge in this particular field?

Report title

Is the title clear, accurate and unambiguous?

Abstract

Does the abstract offer a clear overview of the study, including the research problem, sample, methodology, findings and recommendations?

CITED BY : FOTHERGILL, A., AND A. LIPP. "A GUIDE TO CRITIQUING A RESEARCH PAPER ON CLINICAL SUPERVISION: ENHANCING SKILLS FOR PRACTICE." JOURNAL OF PSYCHIATRIC AND MENTAL HEALTH NURSING (2014)

Section two – elements influencing the robustness of the research

Purpose/research problem

Is the purpose of the study/research problem clearly identified?

Logical consistency

Does the research report follow the steps of the research process in a logical manner? Do these steps naturally flow and are the links clear?

Literature review

Is the review logically organised? Does it offer a balanced critical analysis of the literature? Is the majority of the literature of recent origin? Is it mainly from primary sources and of an empirical nature?

Theoretical framework

Has a conceptual or theoretical framework been identified? Is the framework adequately described? Is the framework appropriate?

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Aims/objectives/research question/hypotheses

Have aims and objectives, a research question or hypothesis been identified? If so are they clearly stated? Do they reflect the information presented in the literature review?

Sample

Has the target population been clearly identified? How was the sample selected? Was it a probability or non-probability sample? Is it of adequate size? Are the inclusion/exclusion criteria clearly identified?

Ethical considerations

Were the participants fully informed about the nature of the research? Was the autonomy/confidentiality of the participants guaranteed? Were the participants protected from harm? Was ethical permission granted for the study?

Operational definitions

Are all the terms, theories and concepts mentioned in the study clearly defined?

CITED BY : FOTHERGILL, A., AND A. LIPP. "A GUIDE TO CRITIQUING A RESEARCH PAPER ON CLINICAL SUPERVISION: ENHANCING SKILLS FOR PRACTICE." JOURNAL OF PSYCHIATRIC AND MENTAL HEALTH NURSING (2014)

Methodology

Is the research design clearly identified? Has the data gathering instrument been described? Is the instrument appropriate? How was it developed? Were reliability and validity testing undertaken and the results discussed? Was a pilot study undertaken?

Data analysis/results

What type of data and statistical analysis was undertaken? Was it appropriate? How many of the sample participated? Significance of the findings?

Discussion

Are the findings linked back to the literature review? If a hypothesis was identified was it supported? Were the strengths and limitations of the study including generalizability discussed? Was a recommendation for further research made?

References

Were all the books, journals and other media alluded to in the study accurately referenced?

APPLICATION

Article 3 – RCT

Maughan, A. L., Lunskey, Y., Lake, J., Mills, J. S., Fung, K., Steel, L., & Weiss, J. A. (2023). Parent, child, and family outcomes following Acceptance And Commitment Therapy for parents of autistic children: A randomized controlled trial. *Autism*, 13623613231172241.