Comment réduire les risques de biais de sélection dans une revue systématique d'interventions comportementales en santé?

international behavioural

trials network

Pr. Gregory Ninot, PhD

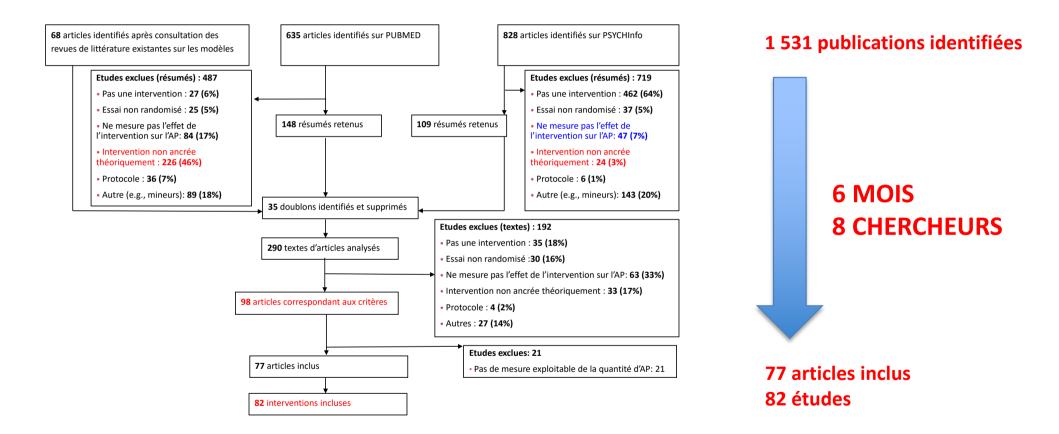
Plateforme CEPS, Université of Montpellier

Montpellier Cancer Institute





Une de nos expériences en la matière



Bernard P, Carayol M, Gourlan M, Boiché J, Romain AJ, Bortolon C, Lareyre O, Ninot G (2017). Moderators of Theory-Based Interventions to Promote Physical Activity in 77 Randomized Controlled Trials. *Health Education and Behavior*, 44(2), 227-35.

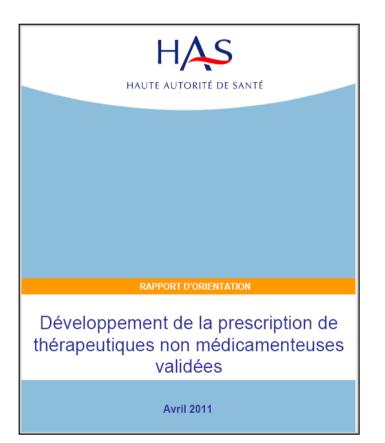


Plan de l'atelier

- 1. Présentation de la Plateforme CEPS
- 2. Introduction
- 3. Définitions
- 4. Objectifs et critères d'inclusion
- 5. Informations à recueillir
- 6. Recherche bibliographique



Prise de conscience des autorités de santé sur les enjeux des INM



- « améliorer le cadre économique et organisationnel ;
- améliorer l'*information* des professionnels de santé et des patients sur les thérapeutiques non médicamenteuses ;
- améliorer l'adhésion des professionnels de santé aux

recommandations sur les thérapeutiques non médicamenteuses ;

• améliorer l'accès à l'offre en matière de thérapeutiques non

médicamenteuses. » (HAS, 2011, p. 52)

HAS (2011)



Les Interventions Non Médicamenteuses (INM) : une nébuleuse





Les Interventions Non Médicamenteuses (INM)

Interventions psychologiques santé	C-O Interventions physiques santé	Interventions nutritionnelles santé	Interventions numériques santé	Autres interventions NM santé
Art Thérapie Education pour la santé Psychothérapie Zoothérapie	Activité physique Hortithérapie Physiothérapie Thérapie manuelle Thermalisme	Complément alimentaire Thérapie nutritionnelle	Objet connecté Thérapie par le jeu vidéo Thérapie par la réalité virtuelle	Objet ergonomique Phytothérapie Thérapie cosmétique Thérapie par les ondes Lithothérapie

Plateforme CEPS (2016)



Les 6 missions de la Plateforme universitaire CEPS jusqu'en 2020

Un objectif opérationnel	Une solution
1. Rapprocher les acteurs de la recherche interventionnelle non médicamenteuse	ICEPS Conference (depuis 2011)
2. Recenser toutes les INM	Ontologie des INM (depuis 2016)
3. Faciliter la recherche bibliographique des études interventionnelles sur les INM	Motrial (depuis 2018)
4. Identifier les chercheurs et les unités de recherche évaluant des INM	NIRI (en 2019)
5. Encourager la réalisation d'études interventionnelles et de surveillance de qualité sur les INM	NISHARE (en 2020)
6. Promouvoir un paradigme d'évaluation et de surveillance des INM après les avoir recensés	Paradigme INM (en 2020)



Randomized

Clinical Trials of

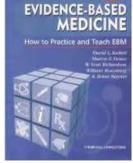
Nonpharmacological Treatments

Pratiques professionnelles de santé fondées sur les preuves



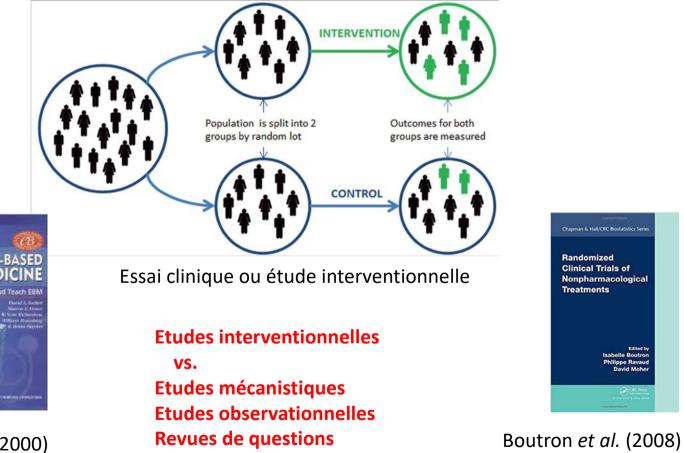
David L. Sackett



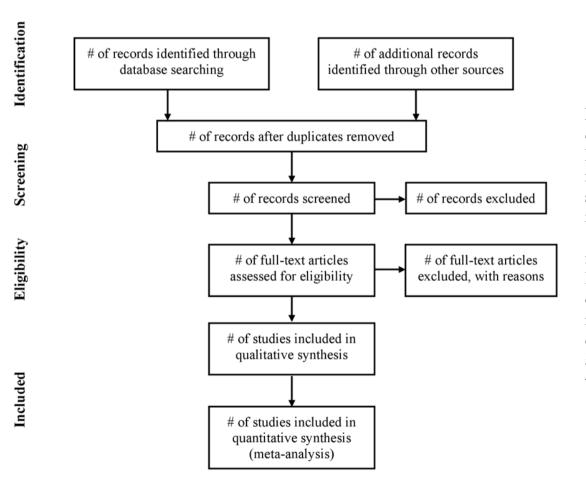


COMP ENVIRON

Sackett et al. (2000)



PRISMA



Explanation. The National Library of Medicine's MEDLINE database is one of the most comprehensive sources of health care information in the world. Like any database, however, its coverage is not complete and varies according to the field. Retrieval from any single database, even by an experienced searcher, may be imperfect, which is why detailed reporting is important within the systematic review.

At a minimum, for each database searched, authors should report the database, platform, or provider (e.g., Ovid, Dialog, PubMed) and the start and end dates for the search of each database. This information lets readers assess the currency of the review, which is important because the publication time-lag outdates the results of some reviews [64]. This information should also make updating more efficient [65]. Authors should also report who developed and conducted the search [66].

Liberati et al. (PLOS Medicine, 2009)





Méthodologies parfaites

Cochrane Handbook for Systematic Reviews of Interventions

Cochrane Book Series

Edited by

Julian PT Higgins and Sally Green

WILEY-BLACKWELL A John Wiley & Sons, Ltd., Publication



Higgins et Green (2008)



Std.

Méthodologies parfaites

	Study or subgroup	Exercise		Control		Mean Difference	Weight	Mean Difference
	,	N	Mean(SD)	N	Mean(SD)	IV,Random,95% Cl		IV,Random,95% CI
Sud Sud Man Man Sudy or subgroup Exercise Control Difference Weight Difference N Man (2D) N Man (2D) Withom (2S) Withom (2S)	Orth 1979	3	7 (6.6)	2	16.5 (2.12)		0.6 %	-1.25 [-3.71, 1.21]
Burnentul 1999 55 8.73 (6.86) 48 7.38 (6.47) 42.% 0.14 [-0.25, 0.52] Burnentul 2007 51 9.2 (6.1) 49 11.1 (?) 42.% 0.29 [-0.68, 0.11]	Pilu 2007	10	8.1 (5.2)	20	16.7 (9.1)	<u> </u>	2.7 %	-1.04 [-1.85, -0.23]
Bitmential 2012a 35 6.4 (5.28) 21 10 (5.24)	Reuter 1984	9	5.1 (4.75)	9	18.56 (7.7)		1.8 %	-2.00 [-3.19, -0.82]
Chi 2008 15 5.8 (238) 12 10.95 (664) 2.7 % -1.02 (1-14, -0.2] Doyne 1987 14 8.18 (527) 11 5.25 (6.3) -2.5 % -1.19 [-2.66, -0.2] Dum-2005 16 0.10 (5.5) 13 14 (49) -2.9 % -0.47 (-1.50, 002)	Schuch 2011	15	5.93 (4.46)		9.45 (3.56)	.	2.7 %	-0.83 [-1.65, -0.01]
Epidein 1986 7 9 (1094) 10 14.3 (7.44) 2.1 % .0.277 [-178, 0.24] Forgy 2088 8 10.8 (9.25) 5 31.62 (102) 1.9 % .0.27 [-140, 0.65] Forgy 208 8 10.8 (9.25) 5 31.62 (102) 1.9 % .0.27 [-140, 0.65]	Setaro 1985	25	62 (6.51)	25	69.88 (3.96)		3.3 %	-1.44 [-2.07, -0.81]
Fermione1987 18 10 (98) 16 8 (7) 32 % 0.21 (.45, 0.05) Gary 2010 20 84 (56) 15 93 (49) 32 % .017 (.04 0.51) Hemistr 2012 10 1.66 (49) 10 2.28 (49) .23 % .027 (.193, 0.65)	Shahidi 2011	20	. (6.2)	20	15.2 (6.1)		3.3 %	-0.65 [-1.29, -0.02]
Hear-Homesr (19) 5 9.8 (6.3) 6 16.2 (8.4) 1.6 % -0.75 [2.00.03] Hoffmar 2010 37 1.6 4 (10.2) 29 2.12 (17) 40.% 0.43 [-0.86,003] Hear-Homesr (198) 54 1.03 (0.94) 8.08 (0.51) 25.% 0.24 [-0.46, 10.1]	Sims 2009	23	15.13 (8.49)	22	20.62 (11.79)		3.4 %	-0.53 [-1.12, 0.07]
Knužben 2007 20 I 12 (4) 18 I 55 (6.1) 33 % 4.083 [-1.49, 0.6] Knagh 2007 48 12.1 (64) 42 10.6 (5.6) 4.1 % 0.25 [-0.17, 0.64]	Singh 1997	17	9.8 (2.4)	15	13.8 (2)	_ 	2.6 %	-1.75 [-2.59, -0.92]
Harmson PBS 24 12.1 (7.) 19 22.8 (1.4)	Singh 2005	18	8.5 (5.5)	19	14.4 (6)		3.1 %	-1.00 [-1.69, -0.31]
Mate-Pereira 2011 19 12.48 (1.74) 10 13.6 (1.34) 2.8 % .0.67 [-1.44, 0.12] Matrie 1988 9 9.46 (2.28) 7 2.1.4 (5.26) 1.4 % 2.39 [-3.76, -1.02] Nablezorn 2005 2.1 1.4 4 (4.12) 2.8 17.5 (422) 3.5 % 0.73 [-1.31, .0.14]	Veale 1992	36	3.94 (2.78)	29	17.79 (10.18)		3.8 %	-0.33 [-0.82, 0.17]
(12) (1) (1) (1) (1) (1) (1) (1) (1) (1) (1	Williams 2008	17	8.37 (5.78)	12	.75 (8.)		2.9 %	-0.48 [-1.23, 0.27]
	Total (95% CI)	711		642		(\cdot)	100.0 %	-0.62 [-0.81, -0.42]
	Heterogeneity: $Tau^2 = 0.19$	$\Theta; Chi^2 = 9$	1.35, df = 34 (P<0.	00001); 2 =	=63%			
Exercice vs. contrôle	Test for overall effect: Z =	6.22 (P < C	.00001)					
Symptômes dépressifs	Test for subgroup difference	es: Not app	blicable					
35 RCT						4 -2 0 2 4		
1353 participants						ours exercise Favours cont		

Cooney et al. (2013, Cochrane)

Std.

Exe Syr 35 13 -0.62 {-0.81, -0,42}



Méthodologistes parfaits

Exercise to reduce depression symptoms post-treatment

-0.82	-0.62	-0.18
(95% CI -1.12 to -0.51)	(95% CI -0.81 to -0.42)	(95% CI -0.47 to 0.11)
28 RCT (17 in the US)	35 RCT (22 in the US)	6 RCT+++ (6 in the US)
		Exercise vs. Control
		Allocation concealment, ITT, blinded outcome
907 participants	1353 participants	464 participants
Exercise for depression (Review) Mod CI, Nodey & Couplet & Couplet A. Mode K, Lado DI.	Cochrane Library Cochrane Database of Systematic Reviews	Cochrane Library Cochrane Database of Systematic Reviews
THE COCHRANE COLLABORATION*	Exercise for depression (Review) Cooney GM, Dwan K, Greig CA, Lawlor DA, Rimer J, Waugh FR, McMurdo M, Mead GE	Exercise for depression (Review) Cooney GM, Dwan K, Greig CA, Lawlor DA, Rimer J, Waugh FR, McMurdo M, Mead GE
Mead <i>et al.</i>	Cooney et al.	Cooney <i>et al.</i>
(2008, Cochrane Reviews)	(2013, Cochrane Reviews)	(2013, Cochrane Reviews)

Essay



Méthodologies perfectibles

OPEN OACCESS Freely available online

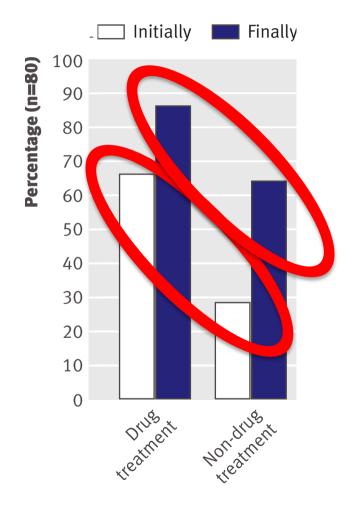
How to Make More Published Research True

John P. A. Ioannidis^{1,2,3,4}*

1 Meta-Research Innovation Center at Stanford (METRICS), Stanford University, Stanford, California, United States of America, 2 Department of Medicine, Stanford Prevention Research Center, Stanford, California, United States of America, 3 Department of Health Research and Policy, Stanford University School of Medicine, Stanford, California, United States of America, 4 Department of Statistics, Stanford University School of Humanities and Sciences, Stanford, California, United States of America Adoption of more appropriate statistical methods [38], standardized definitions and analyses and more stringent thresholds for claiming discoveries or "successes" [39] may decrease false-positive rates in fields that have to-date been too lenient (like epidemiology [40], psychology [41,42], or economics [43]). It may lead them to higher credibility, more akin to that of fields that have traditionally been more rigorous in this regard, like the physical sciences [44].

Ioannidis (2014, Plos Medicine)





"Percentage of studies with sufficient description of treatment initially (based only on the published paper) and after supplementary information was obtained".

Glasziou et al. (2008, British Medical Journal)



Consumer Goods and Services Culture Health promotion Socialization



General Norms



Interventions Comportementales #INM



Quel modèle d'évaluation (CONSORT, ORBIT, MRC, EVOLVE, MOST, AGILE, PROCEED...)?

<section-header> Biomedical Products and Services Object </tr

Evidence of Efficacy and Safety + Approval





PLOS BIOLOGY

COMMUNITY PAGE

Meta-research: Evaluation and Improvement of Research Methods and Practices

John P. A. Ioannidis*, Daniele Fanelli, Debbie Drake Dunne, Steven N. Goodman

Meta-Research Innovation Center at Stanford (METRICS), Stanford University, Stanford, California, United States of America

* jioannid@stanford.edu

Ioannidis et al. (PLOS Medicine, 2015)



Meta-research area	Specific interests (nonexhaustive list)
Methods : "performing research"—study design, methods, statistics, research synthesis, collaboration, and ethics	Biases and questionable practices in conducting research, methods to reduce such biases, meta- analysis, research synthesis, integration of evidence, crossdesign synthesis, collaborative team science and consortia, research integrity and ethics
Reporting : "communicating research"—reporting standards, study registration, disclosing conflicts of interest, information to patients, public, and policy- makers	Biases and questionable practices in reporting, explaining, disseminating and popularizing research, conflicts of interest disclosure and management, study registration and other bias- prevention measures, and methods to monitor and reduce such issues
Reproducibility : "verifying research"—sharing data and methods, repeatability, replicability, reproducibility, and self-correction	Obstacles to sharing data and methods, replication studies, replicability and reproducibility of published research, methods to improve them, effectiveness of correction and self-correction of the literature, and methods to improve them
Evaluation : "evaluating research"—prepublication peer review, postpublication peer review, research funding criteria, and other means of evaluating scientific quality	Effectiveness, costs, and benefits of old and new approaches to peer review and other science assessment methods, and methods to improve them
Incentives : "rewarding research": promotion criteria, rewards, and penalties in research evaluation for individuals, teams, and institutions	Accuracy, effectiveness, costs, and benefits of old and new approaches to ranking and evaluating the performance, quality, value of research, individuals, teams, and institutions



Initiative	Area of work (website)
METHODS	
Cochrane Collaboration	Systematic reviews of health care (cochrane.org)
Campbell Collaboration	Systematic reviews of social science (campbellcollaboration.org)
James Lind Library	Evolution of fair tests of treatment (jameslindlibrary.org)
Society for Clinical Trials	Clinical trials (sctweb.org)
SRSM	Methods for research synthesis (srsm.org)
BioSharing	Standards for biology, natural, and life sciences (biosharing.org)
Human Proteome Project	Collaboration center for proteome (thehpp.org)
NCPRE	Research ethics (ethicscenter.csl.illinois.edu)
REPORTING	
ClinicalTrials.gov	Clinical trials registration (clinicaltrials.gov)
EQUATOR network	Reporting standards for research (equator-network.org)
Sense About Science	Communicating research in public (senseaboutscience.org)
Health News Reviews	Expert review of science news stories (healthnewsreview.org)
REPRODUCIBILITY	
Center for Open Science	Open science in psychology and more (centerforopenscience.org)
BITSS	Transparency in social sciences (bitss.org)
BPS	Best practices in social sciences (bps.stanford.edu)
Political Science Replication	Reproducibility in political science (politicalsciencereplication.com)
YODA	Sharing data from clinical research (yoda.yale.edu)
Neurovault	Data repository for PET and MRI maps (neurovault.org)
OpenfMRI	fMRI data repository (<u>openfmri.org</u>)
NIH repositories, examples:	
dbGAP	Raw data on genotype and phenotype (ncbi.nlm.nih.gov/gap)
GEO	Functional genomics repository (ncbi.nlm.nih.gov/geo)
Science Exchange	Reproducibility checks (validation.scienceexchange.com)
EVALUATION	
Peer Review Congress	Evidence on peer review (peerreviewcongress.org)
Center for Scientific Integrity	Tracking retractions of scientific articles (retractionwatch.com/the-center-for-scientific-integrit
PubMed Commons	Postpublication comments (ncbi.nlm.nih.gov/pubmedcommons)
ArXiv	Preprint article repository (arxiv.org)
ICMJE	Standards for journal publishing (icmje.org)
COPE	Journal publication ethics (publicationethics.org)
PubPeer	Peer comments on research (pubpeer.com)
PEERE	New models for peer review (www.peere.org)
INCENTIVES	
REWARD	Reducing waste and rewarding diligence in research (researchwaste.net)
AAAS	Science policy (aaas.org)
ICSU	International science policy (icsu.org)

Ioannidis et al. (PLOS Medicine, 2015)





BMJ 2017;357:j2490 doi: 10.1136/bmj.j2490 (Published 2017 June 08)

Page 1 of 14

RESEARCH



Evolution of poor reporting and inadequate methods over time in 20 920 randomised controlled trials included in Cochrane reviews: research on research study

Agnes Dechartres *associate professor*¹⁴, Ludovic Trinquart *researcher*¹⁴, Ignacio Atal *data scientist*¹⁴, David Moher *senior scientist*⁵, Kay Dickersin *professor*⁶, Isabelle Boutron *professor*¹⁴, Elodie Perrodeau *statistician*¹³, Douglas G Altman *professor*⁷, Philippe Ravaud *professor*¹⁴⁸



Méthodologies(istes) en progrès constant

Networks



$\label{eq:analytical} \textbf{Annals of Internal Medicine} \quad Research \ \text{and} \ Reporting \ Methods$

CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts

Isabelle Boutron, MD, PhD; Douglas G. Altman, DSc; David Moher, PhD; Kenneth F. Schulz, PhD, MBA; and Philippe Ravaud, MD, PhD, for the CONSORT NPT Group*

Boutron et al. (2017, Annals of Internal Medicine)











Agences

NICE National Institute for Health and Care Excellence









3. Définitions

Etat de l'art = Revue de question = Revue narrative

Revue systématique > Méta-analyse

Transparence, justification de la décision, procéder étape par étape



4. Objectifs et critères d'inclusion

Question initiale

Quel est le niveau d'efficacité d'Interventions Comportementales fondées sur un Modèle Théorique de Changement de Comportement pour promouvoir l'AP à partir d'essais randomisés contrôlés?

Objectifs

(1) Identifier le(s) modèles sociocognitifs efficaces pour augmenter le niveau d'AP à court
(post-intervention) et moyen terme (quelques mois après l'intervention)
(2) Explorer dans quelle mesure certains modérateurs (e.g., qualité de l'implémentation
théorique) sont susceptibles d'expliquer les différences (ou absence de différences) d'efficacité
entre les différents modèles théoriques



5. Informations à recueillir

Critères PICOS

P(opulation) = Adulte (+18), sains et malades

I(intervention) = Interventions de promotion de l'AP sur un modèle théorique

C(ontrol) = *Tout type de groupe contrôle*

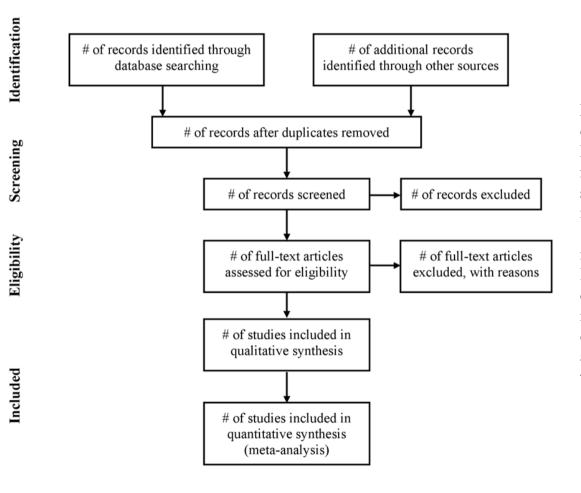
O(outcomes) = *Mesure AP (déclarée ou objective)*

S(tudies) = Essais randomisés contrôlés

Liberati et al. (Journal of Clinical Epidemiology, 2009)



6. Recherche bibliographique



Explanation. The National Library of Medicine's MEDLINE database is one of the most comprehensive sources of health care information in the world. Like any database, however, its coverage is not complete and varies according to the field. Retrieval from any single database, even by an experienced searcher, may be imperfect, which is why detailed reporting is important within the systematic review.

At a minimum, for each database searched, authors should report the database, platform, or provider (e.g., Ovid, Dialog, PubMed) and the start and end dates for the search of each database. This information lets readers assess the currency of the review, which is important because the publication time-lag outdates the results of some reviews [64]. This information should also make updating more efficient [65]. Authors should also report who developed and conducted the search [66].

Liberati et al. (PLOS Medicine, 2009)



6. Recherche bibliographique

February 14, 2018

Updating the PRISMA reporting guideline for systematic reviews and meta-analyses: study

protocol

Matthew J Page¹, Joanne E McKenzie¹, Patrick M Bossuyt², Isabelle Boutron^{3,4,5,6}, Tammy Hoffmann⁷,

Cynthia D Mulrow⁸, Larissa Shamseer⁹, David Moher^{10,11}



6. Recherche bibliographique avec

MOTRIAL www.motrial.fr

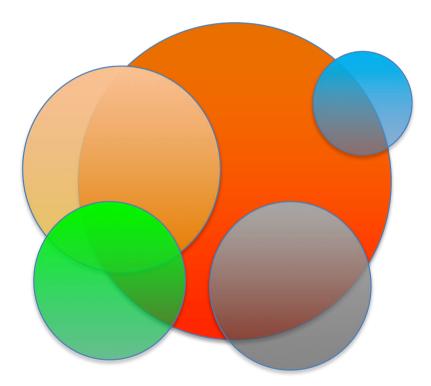
M







Bases de données des registres officiels d'études déclarées

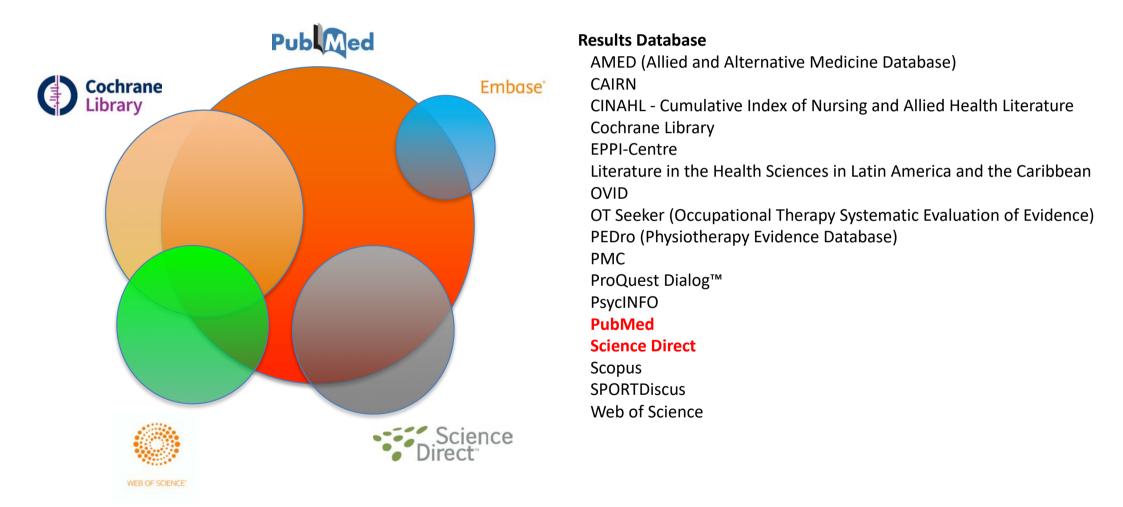


Protocols Database

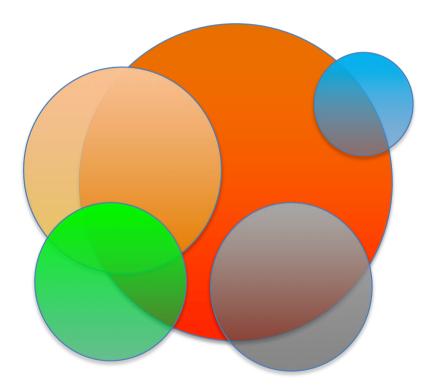
ANSM Chinese Clinical Trial Registry (ChiCTR) ClinicalTrials Cochrane Central Register of Controlled Trials

European Clinical Trials Register (Europe) International Clinical Trials Registry Platform (ICTRP) - WHO ISRCTN registry (BioMed Central, Itd.) UMIN Clinical Trials Registry (UMIN-CTR)



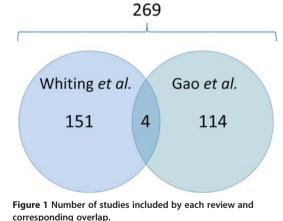






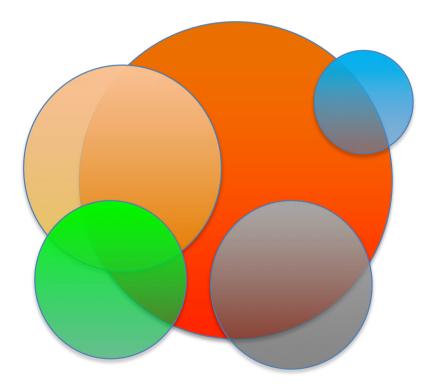
Results Japanese Database JDMC

Results Chinese Database CNKI Chinese Biomedical Literature (CBM) Chinese Medical Current Content (CMCC) VIP WANFANG (China Online Journals)



Cohen et al. (2015, Systematic Reviews)



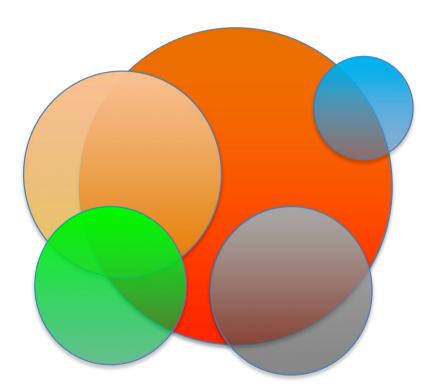


Results from Open Journals

Annals of Saudi Medicine Bangladesh Journal of Pharmacology **Biomedical Imaging and Intervention Journal BMC Health Services Research BMC Medicine BMJ** Open British Medical Journal British Columbia Medical Journal Canadian Medical Association Journal **Dermatology Online Journal** International Journal of Medical Sciences Journal of Clinical Investigation Journal of Postgraduate Medicine The New England Journal of Medicine **Open Heart Open Medicine PLOS Medicine PLOS Neglected Tropical Diseases**

PLOS Neglected Tropical Disease PLOS Pathogens Scientia Pharmaceutica

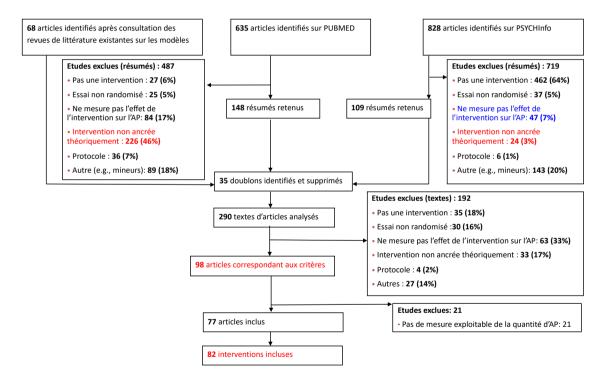




Other ResearchGate GoogleScholar

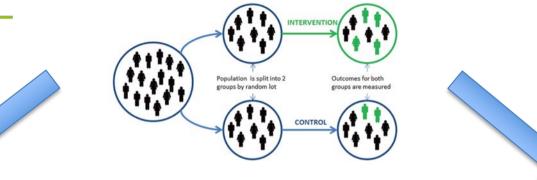


Objectif 1 : diminuer le temps de recherche bibliographique de 6 mois à 6 minutes MOTRIAL



PLATEFORME CEPS

Objectif 2 : obtenir les informations pertinentes de chaque étude clinique sur une INM MOTRIAL



Main publication

For example:

doi: 10.1016/j.rmed.2010.10.002

Ninot G, Moullec G, Picot MC, Jaussent A, Hayot M, Desplan M, Brun JF, Mercier J, Prefaut C. Cost-saving effect of supervised exercise associated to COPD selfmanagement education program. Respir Med. 2011 Mar;105(3):377-85.



Cost-saving effect of supervised exercise associated to COPD self-management education program

G. Ninot a,* , G. Moullec a , M.C. Picot b , A. Jaussent b , M. Hayot c , M. Desplan c , J.F. Brun c , J. Mercier c , C. Prefaut c

¹University Montpellier 1, Laboratory Epsylon, EA-6206 Addictive, Performance and Health Behaviors, 4 Boulevard Henri IV, Montpellier F-34000, France ¹University Montpellier 1, CHU Montpellier, Unité de Rechercher Clinique et Epidémiologie, Montpellier F-34295, France ⁶University Montpellier 1, CHU Montpellier, INSERM ERI25 Muscle and Pathologies, Montpellier F-34295, France

Other publications

Other results, for example: doi: 10.1016/j.rm.2014.10.022 doi: 10.1016/med.2012.10.052 Follow-up, secondary analysis, qualitative...

Other data, for example: Study protocol, erratum, experience report

Protocol declaration

For example: NCT01167283 ClinicalTrials.gov Identifier

Ethical Committee

For example: n°354903 CPP Sud Méditerranée

Sponsors

For example Programme Hospitalier de Recherche Clinique (PHRC) Etat français

Institution

For example: CHU Montpellier France



Objectif 3 : préciser les contenus des INM évaluées dans les études interventionnelles MOTRIAL

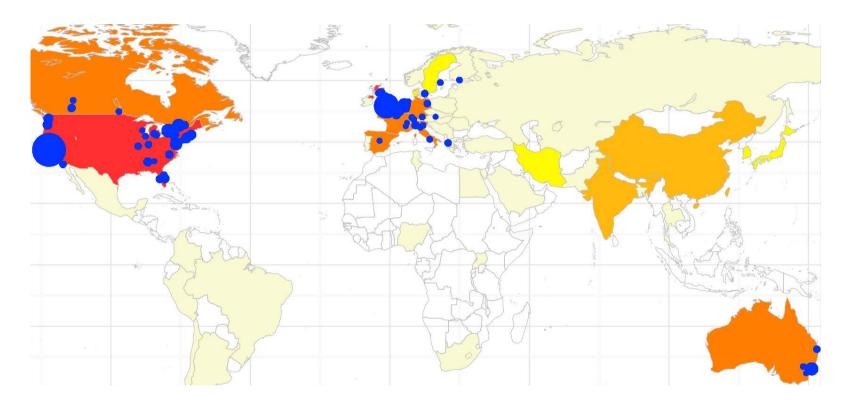
Description d'une INM :

Nom (et synonymes) Contenu (ingrédient, technique, geste) Dose (durée, fréquence, intensité) Modèle théorique explicatif Supervision (formation...)





$\begin{array}{l} \text{Objectif 4: améliorer la justification } \textbf{d'une étude interventionnelle} \\ \textbf{MOTRIAL} \end{array} \end{array} \\$



Ioannidis et al. (PLOS Medicine, 2015)



Accès à MOTRIAL via ORCID (Connecting Research and Researchers)

www.motrial. fr

	Please enter your search te	erms here (in english)	a		
	▼ Filters	1939 95 (BOST)		Registration	n to ORCI
Motrial, q	u'est ce que c'est ?		0 *	OR	Cid
	MO	RIA		Sign into ORCII	D or Register now
				L Personal account	finstitutional account
	A			Sign in with you Email or ID	ur ORCID account
	Académique Gra	atuit Collaboratif		gregory.ninot@umontpellier.fr	
				ORCID password	
				Sign ir Forgotten your password?	nto ORCID



Mots clés NOTRIAL FIND FAVOURITES HISTORY ONTOLOGY STATISTICS ADMIN OR ANGLAIS (ÉTATS-UNIS) FRANÇAIS (FRANCE)

Filters

Provide key words

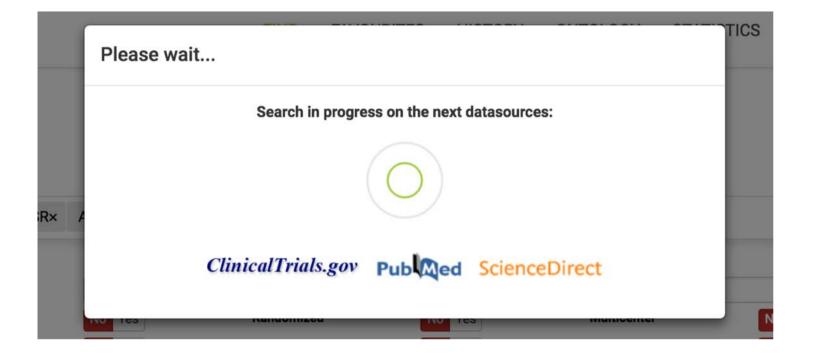


Options méthodologiques

MBSR×	AND Cancer× P	lease enter your search term	ns here (in english)		٩	
	Filters					
Intervention	No Yes	Randomized	No Yes	Multicenter	No Yes	
Follow up	No Yes	Control Group	No Yes	Placebo	No Yes	Select option
Blind study	(\$	Study Purpose			\$
Primary Outcome						(randomization for
Secondary Outcome						
Analysis		\$				example)
Population age	Child No Yes (0-17)	s Adult (18-65)	No Yes	Senior No (66+)	Yes	
Population gender		\$				
Authors						
		\$				



Recherche





Résultat

MOTRIAL | Search results for: MBSR AND Cancer

10 🗘 1 - 9 of 9 m	ssult(s) ▼ Sort Order Descending ♦	Page 1 / 1	Other results : 452 others publications
and the second	ased Stress Reduction in Post-treatment Breast Cancer Patients: Immediate and Sustained Multiple Symptom Clusters	æ	found without having been able to determine their declarations
	ENGACHER Cecile A., ALINAT Carissa B., KIP Kevin E., PATERSON Carly, RAMESAR Sophia, HAN Heather S., ISMAIL-KHAN Roohi, JOHNS IOSCOSO Manolete, BUDHRANI-SHANI Pinky, SHIVERS Steve, COX Charles E., GOODMAN Matthew, PARK Jong	ion-	Associate
Date : Journal name :	1/1/17 Journal of Pain and Symptom Management	>	
	ontrolled pilot trial of mindfulness-based stress reduction compared to psychoeducational sistently fatigued breast and colorectal cancer survivors.	æ 0]0	
	ROWN Linda F, BECK-COON Kathleen, TALIB Tasneem L, MONAHAN Patrick O, GIESLER R Brian, TONG Yan, WILHELM Laura, CARPENTEI ane, WAGNER Christina D, DE GROOT Mary, SCHMIDT Karen, MONCESKI Diane, DANH Marie, ALYEA Jennifer M, MILLER Kathy D, KROEN		
Date :	5/17/16		Results
Journal name :	Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer	*	
	ulness-based stress reduction on somatic symptoms, distress, mindfulness and spiritual omen with breast cancer: Results of a randomized controlled trial.	ß	
	DALTON Susanne Oksbjerg, CHRISTENSEN Jane, ANDERSEN Klaus Kaae, ELSASS Peter, FLYGER Henrik L, PEDERSEN Anne E, SUMBUNDI JENSEN Marianne, JOHANSEN Christoffer	u 📑	
Date :	3/9/15		
Journal name :	Acta oncologica (Stockholm, Sweden)	» ¥	

\$

Results list



B

Exemple d'un rapprochement automatique





Publication:

Mindfulness-Based Stress Reduction in Post-treatment Breast Cancer Patients: Immediate and Sustained Effects Across Multiple Symptom Clusters

Abstract	Breast cancer survivors (BCS) face adverse physical and clusters, distinguishable by prevalence	psychological symptoms, often co	-occurring. Biologic and psychological factors may link symptoms within
Sponsor(s)	N/A	Country	N/A
Journal name	Journal of Pain and Symptom Management	Journal ISSN	08853924
Language	N/A	Date	1/1/17
DOI	Dx.doi.org/10.1016/j.jpainsymman.2016.08.005	ID	S0885392416303335
Authors	REICH Richard R., LENGACHER Cecile A., ALINAT Carissa B., KIP Kevin B SHANI Pinky, SHIVERS Steve, COX Charles E., GOODMAN Matthew, PAR	Statistics for a second state of the second s	N Heather S., ISMAIL-KHAN Roohi, JOHNSON-MALLARD Versie, MOSCOSO Manolete, BUDHRA
Datasources	Publiced ScienceDirect		
Categories			

Declaration:

Mindfulness-Based Stress Reduction (MBSR) Symptom Cluster Trial for Breast Cancer Survivors

 Abstract:
 The purpose of this study among breast cancer survivors is three-fold: (i) to evaluate the efficacy of the MBSR(BC) program in improving psychological and physical symptoms, quality of life and measures of immune function and a stress hormone (cortisol); (ii) to test whether positive effects achieved from the MBSR(BC) program are mediated through changes in mindfulness and fear of recurrence of breast cancer; and (iii) to evaluate whether positive effects achieved from the MBSR(BC) program are modified by specific patient characteristics measured at baseline.

 NTC
 NCT01177124

 Start date
 2/1/09

 Detailed description
 Breast cancer survivors are living longer and may be living with many symptoms incurred from the disease and its treatment. Survivors from 1 to 2 years off treatment report continued fatigue, depression, pain and



Exemple d'un rapprochement manuel

MOTRIAL | Matching page

Date : Journal name :	6/1/18 Hematology/Oncology Clinics of North America	> 30 Declaration(s)
ate :	6/1/18	
ournal name :	Internet Interventions	> 30 Declaration(s)



Sauvergarde dans un dossier personnel

MØ	TRIĄL	FIND	FAVOURITES	HISTORY	ONTOLOGY	STATISTICS	ADMIN	8	ANGLAIS (ĖTATS-UNIS) FRANÇAIS (FRANCE)
MOTRIAL Sear	ch history								
10 🗘 1 - 7 of 7 resu	ult(s) ▼ Sort Order Descending \$								Page 1 / 1
	IBSR AND Cancer kecuted date: 5/24/18 08:11:20						۲		Q
=	ancer AND breast AND exercise kecuted date: 5/22/18 09:53:09						۲		Q

Download queries



Top 50 Journals

1: Gastroenterology 2: The Lancet 3: Journal of Pain and Symptom Management 4: Clinical Nutrition 5: Journal of the American Academy of Dermatology 6: Journal of Ethnopharmacology 7: Archives of Physical Medicine and Rehabilitation 8: Alzheimer's & Dementia 9: Research in Developmental Disabilities 10: American Journal of Obstetrics and Gynecology 11: Social Science & Medicine 12: Bioresource Technology 13: Procedia - Social and Behavioral Sciences 14: Nutrition 15: Microporous and Mesoporous Materials 16: Chest 17: European Journal of Cancer 18: Value in Health 19: Science of The Total Environment 20: Physiotherapy 21: Complementary Therapies in Medicine 22: Chemosphere 23: The Journal of Urology 24: European Psychiatry 25: Annales de Dermatologie et de Vénéréologie 26: Neurobiology of Aging 27: Schizophrenia Research 28: The Journal of Pediatrics 29: Journal of Hazardous Materials 30: Radiotherapy and Oncology 31: Journal of Investigative Dermatology : International Journal of Radiation Oncology*Biology*Physics 33: International Journal of Cardiology 34: Science & Sports 35: Clinical Nutrition Supplements 36: Neuroscience Letters 37: Food Chemistry 38: Journal of the Neurological Sciences 39: Industrial Crops and Products 40: Journal of Psychosomatic Research MOTRIAL 41: Patient Education and Counseling 42: Preventive Medicine 43: Journal of the Academy of Nutrition and Dietetics 44: Kinésithérapie, la Revue 45: Journal of Affective Disorders 46: Journal of the American College of Cardiology www.motrial. fr 47: The Journal of Pain 48: European Journal of Integrative Medicine



Top 50 Authors

1: Michael Heinrich 2: Alain Sarembaud 3: A. Sarembaud 3 (ex aequo): Emeran A. Mayer 4: Wei Wang 5: Michael Camilleri 6: Wei Zhang 7: Leon Chaitow 8: Johnny L. Matson 9: Wei Li 10: Jo-Shu Chang 11: Eduardo Bruera 12: Philip Scheltens 13: Jun Wang 14: Nicholas J. Talley 15: Lin Chang 16: Yan Li 17: Jing Wang 18: Jeff Sigafoos 18 (ex aequo): Tiffany Field 19: Yan Wang 20: Magnus Simren 21: Bernard Poitevin 22: Jing Li 22 (ex aequo): Yan Zhang 23: Lei Zhang 24: Ronald C. Petersen 25: Mark Lebwohl 25 (ex aequo): Jun Li 25 (ex aeguo): William E. Whitehead 26: Bruce D. Naliboff 27: Éliane Frécon Valentin 27 (ex aeguo): Annie Pascal 28: Kaj Blennow 28 (ex aequo): L. Puig 28 (ex aequo): Jing Zhang 29: Jean-Pierre Barral 29 (ex aequo): Alan R. Zinsmeister 29 (ex aequo): Lei Wang 30: Li Li 30 (ex aequo): Ying Wang 31: Clifford R. Jack 31 (ex aequo): Yang Liu 31 (ex aequo): Gerhard Andersson 31 (ex aequo): Alain Croibier 32: Edzard Ernst 32 (ex aequo): Yu Zhang 32 (ex aequo): Jin-Ding Lin





Autres statistiques



Mots clés

Utilisation

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- CARSAT



- SIRIC Montpellier Cancer 🚧 SIRIC
- Institut National du Cancer (INCa)





Motrial en résumé

Le métamoteur de recherche des études évaluant l'efficacité des #INM

Motrial identifie pour chaque étude :

- publication principale (auteurs, titre, résumé, DOI)
- numéro de déclaration au comité d'éthique,
- numéro d'enregistrement du protocole aux autorités compétentes,
- sources de financement,
- nom du promoteur,
- pays de réalisation.

Motrial est :

- gratuit, collaboratif, académique, évolutif



Motrial facilite :

- les revues de littérature,
- les revues systématiques,
- les méta-analyses,
- la justification de nouvelles études.

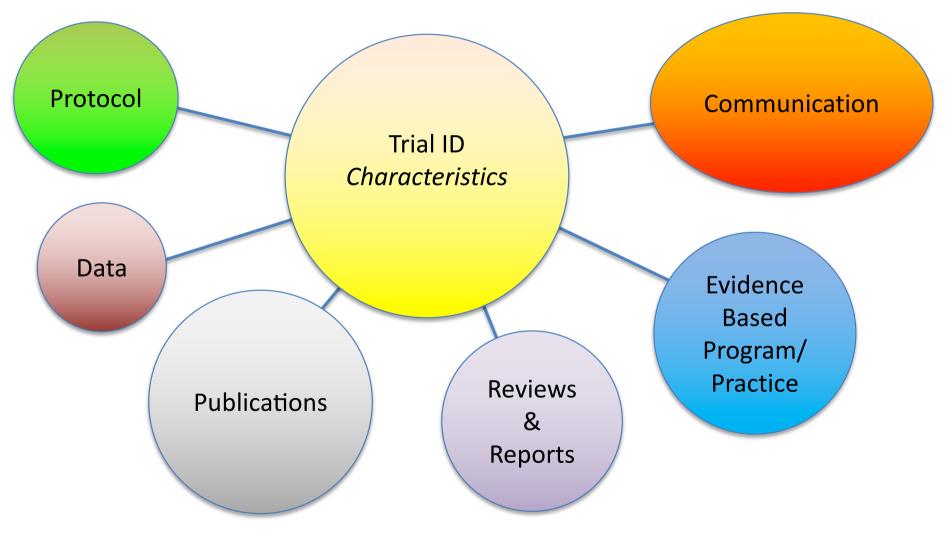
Suggestions :

gregory.ninot@umontpellier.fr





Vers un code et un ID unique d'une étude évaluant une #INM







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Plateforme universitaire Collaborative d'Evaluation des programmes de Prévention et des Soins de support

ues sonis de suppoi

Montpellier, France

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Blog en Santé Blog sur les INM <u>blogensante.fr</u>

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Motrial in Few Words

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Motrial identifies for each behavioral trials:

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- registration protocol number,
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- institution,
- country.

MOTRIAL www.motrial. fr

Motrial for:

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- systematic reviews,
- meta-analyses,
- new trial justification.

New version in progress with DOI addition and new databases

Any comment, suggestion:

gregory.ninot@umontpellier.fr



Information à recueillir

Modèle théorique utilisé

Théorie sociale cognitive, modèle transthéorique, théorie de

l'autodétermination, théorie des comportements planifiés

Population

Age, genre, principale caractéristique (étudiants, diabétiques...)

Caractéristiquesdel'intervention

Méthode de communication (face à face, téléphone, livrets, internet, SMS...), présence d'AP supervisée (oui vs non),

Durée du programme, Nombre total de séances, AP comme critère de jugement principal

Nature de la comparaison

Type de groupe contrôle (pas d'intervention, intervention minimale,

placebo attentionnel, comparaison active)

Outcome

Type d'indicateur d' AP utilisé (e.g., dépense énergétique, durée...), outil utilisé (auto-rapporté vs objectif)



Information à recueillir

Choix de la grille de qualité méthodologique

Boutron, I., Moher, D., Altman, D. G., Schulz, K. F., Ravaud, P., & CONSORT Group. (2008). Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Annals of Internal Medicine, 148(4), 295–309. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/18283207

Des Jarlais, D. C., Lyles, C., & Crepaz, N. (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: the TREND statement. American Journal of Public Health, 94(3), 361–366.

Jackson, N., Waters, E., & Guidelines for Systematic Reviews in Health Promotion and Public Health Taskforce. (2005). Criteria for the systematic review of health promotion and public health interventions. Health Promotion International, 20(4), 367–374. https://doi.org/10.1093/heapro/dai022

Lundh, A., & Gøtzsche, P. C. (2008). Recommendations by Cochrane Review Groups for assessment of the risk of bias in studies. BMC Medical Research Methodology, 8(1), 22. https://doi.org/10.1186/1471-2288-8-22



Information à recueillir

Grille CONSORT

Annals of Internal Medicine Research and Reporting Methods

CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts

Isabelle Boutron, MD, PhD; Douglas G. Altman, DSc; David Moher, PhD; Kenneth F. Schulz, PhD, MBA; and Philippe Ravaud, MD, PhD, for the CONSORT NPT Group*



Les INM : un secteur intermédiaire en pleine expansion

Biens et services de consommation courante



Normes de fabrication





Vérifier et surveiller les bénéfices sur la santé et sur les comportements de santé, l'impact sur la qualité de vie, les risques et l'utilité







Produits et services biomédicaux

Démontrer le service médical rendu (SMR) + autorisation de mise sur le marché (AMM)

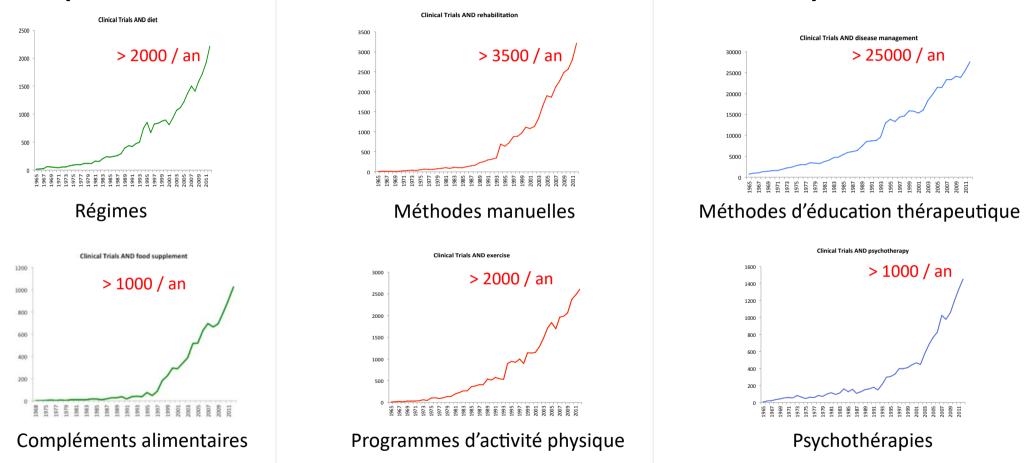


HAS HAUTE AUTORITÉ DE SANTÉ



ICEPS Conference : un congrès scientifique international et un salon sur les INM





Multiplication des études interventionnelles évaluant les INM depuis 2000

2 millions de publications d'études cliniques depuis 1827, dont 73.691 en 2014 (données uniquement de Pubmed)





Permettant leur comparaison dans des méta-analyses

	Study or subgroup	Exercise N	Mean(SD)	Cognitive Therapy N	- Mean(SD)	Std. Mean Difference IV,Random,95% Cl	Weight	Std. Mean Difference IV,Random,95% Cl
	Fremont 1987	15	6.1 (6.6)	16	8 (7.1)	-	16.5 %	-0.27 [-0.98, 0.44]
	Epstein 1986	7	9 (10.94)	9	17.22 (8.45)		7.7 %	-0.81 [-1.85, 0.23]
	Hess-Homeier 1981	5	9.8 (6.93)	6	7.2 (5.03)		5.7 %	0.40 [-0.81, 1.60]
	Klein 1985	14	1.03 (0.94)	4	1.23 (0.84)		15.0 %	-0.22 [-0.96, 0.53]
	Setaro 1985	25	62 (6.51)	25	60.68 (6.2)		26.8 %	0.20 [-0.35, 0.76]
	Fetsch 1979	8	3.63 (7.95)	8	11.63 (5.5)		8.5 %	0.28 [-0.71, 1.26]
	Gary 2010	20	8.4 (5.6)	17	8.2 (6.3)	-	19.8 %	0.03 [-0.61, 0.68]
	Total (95% CI)	94		95		(+)	100.0 %	-0.03 [-0.32, 0.26]
	Heterogeneity: $Tau^2 = 0$.0; Chi ² = 4.	43, df = 6 (P =	0.62); l ² =0.0%		$\mathbf{\nabla}$		
	Test for overall effect: Z	= 0.22 (P =	0.83)					
	Test for subgroup differe	nces: Not ap	plicable					
Exercice vs. TCC							1	
Symptômes dépres	sifs				-4	4 -2 0 2	4	
7 RCT					Favo	ours exercise Favours CB7	Г	
189 participants								

Symptômes dép 7 RCT 189 participants -0.03 {-0.32, 0,26}

Cooney et al. (2013, Cochrane)

Un outil facilitant l'identification des études cliniques évaluant les INM

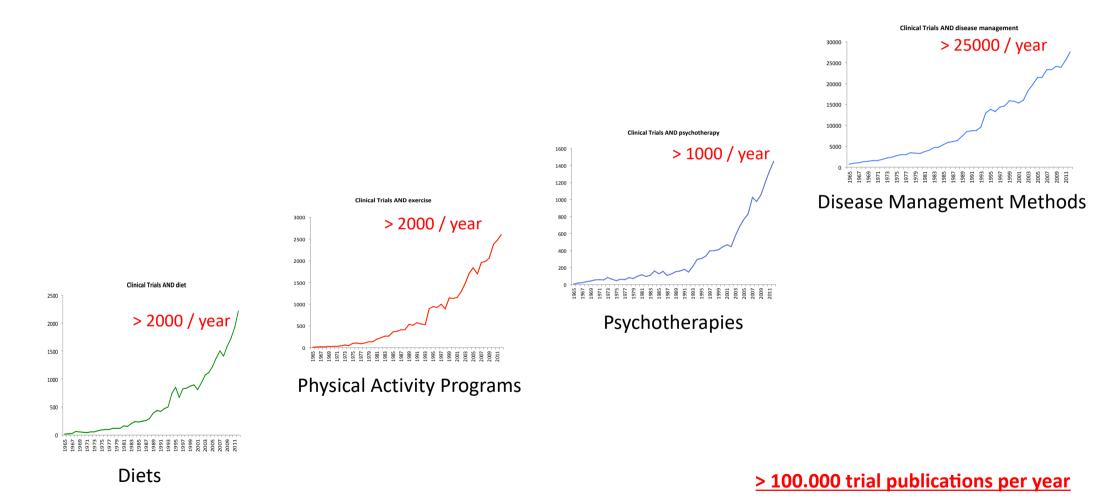
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Objectif 1 : diminuer le temps de recherche bibliographique de 6 mois à 6 minutes

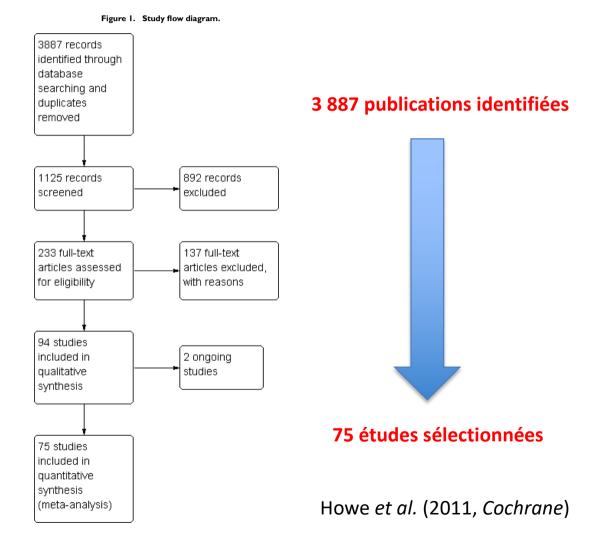
Electronic searches

We searched the Cochrane Bone, Joint and Muscle Trauma Group Specialised Register (January 2011), the Cochrane Central Register of Controlled Trials (*The Cochrane Library* 2011, Issue 1), MEDLINE (1966 to 1st Feb 2011), EMBASE (1980 to 1st Feb 2011), PEDro - The Physiotherapy Evidence Database (accessed 27th Jan 2011), OTseeker - The Occupational Therapy Systematic Evaluation of Evidence Database (accessed 18th Jan 2011), CINAHL - Cumulative Index to Nursing and Allied Health Literature (from 1982 to 21st Jan 2011) and AMED - Allied and Complementary Medicine Database (from 1985 to Jan 2011). No language restrictions were applied.

In MEDLINE (Ovid Web), the first two phases of the optimal trial search strategy (Robinson 2002) were combined with one subject specific search and the less precise third phase of the optimal trial search strategy was combined with a more precise subject specific search (Appendix 1). Search strategies are also shown in Appendix 1 for *The Cochrane Library*, CINAHL, EMBASE, AMED, PEDro, and OTseeker.

Searching other resources

Further studies were identified by contact with institutions, experts in the field and reference lists of articles.





Objectif 2 : obtenir les informations pertinentes de chaque étude clinique sur une INM



John P. A. Ioannidis^{1,2,3,4}*

1 Meta-Research Innovation Center at Stanford (METRICS), Stanford University, Stanford, California, United States of America, 2 Department of Medicine, Stanford Prevention Research Center, Stanford, California, United States of America, 3 Department of Health Research and Policy, Stanford University School of Medicine, Stanford, California, United States of America, 4 Department of Statistics, Stanford University School of Humanities and Sciences, Stanford, California, United States of America Adoption of more appropriate statistical methods [38], standardized definitions and analyses and more stringent thresholds for claiming discoveries or "successes" [39] may decrease false-positive rates in fields that have to-date been too lenient (like epidemiology [40], psychology [41,42], or economics [43]). It may lead them to higher credibility, more akin to that of fields that have traditionally been more rigorous in this regard, like the physical sciences [44].

Ioannidis (2015, Plos Medicine)













Objectif 2 : obtenir les informations pertinentes de chaque étude clinique sur une INM

INTERVENTIO

Population is solit into 2 Outcomes for both groups by random lot groups are measured CONTROL

Publication principale de l'essai

Par exemple:

doi: 10.1016/j.rmed.2010.10.002

Ninot G, Moullec G, Picot MC, Jaussent A, Hayot M, Desplan M, Brun JF, Mercier J, Prefaut C. Cost-saving effect of supervised exercise associated to COPD selfmanagement education program. Respir Med. 2011 Mar;105(3):377-85.

Déclaration du protocole

Par exemple: NCT01167283 ClinicalTrials.gov Identifier

Comité d'éthique

Par exemple: n°354903 CPP Sud Méditerranée

Cost-saving effect of supervised exercise associated to COPD self-management education program

G. Ninot ^{a,*}, G. Moullec ^a, M.C. Picot ^b, A. Jaussent ^b, M. Hayot ^c, M. Desplan ^c, J.F. Brun^c, J. Mercier^c, C. Prefaut^c

ersity Montpellier 1, Laboratory Epylion, EA-806 Addictive, Performance and Health Behaviors, 4 Boulevard N., Montpellier F-34000, France ersity Montpellier I, CHU Montpellier, Unité de Recherche Clinique et Epidémiologie, Montpellier F-3405, France ersity Montpellier 1, CHU Montpellier, INSERM ER05 Muscle and Pathologies, Montpellier F-3405, France

Autres publications sur l'essai

Par exemple: doi: 10.1016/j.rm.2014.10.022 doi: 10.1016/med.2012.10.052

Financeur

Par exemple Programme Hospitalier de Recherche Clinique (PHRC) Etat français

Promoteur

Par exemple: **CHU Montpellier** France

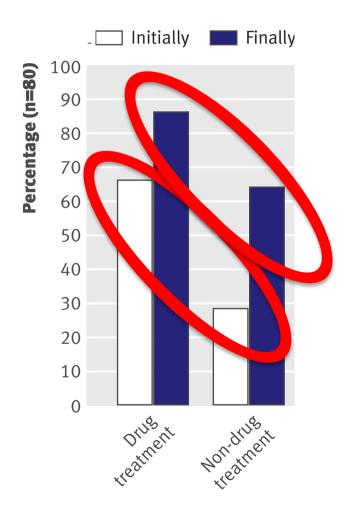








Objectif 3 : préciser les contenus des INM évaluées dans les études interventionnelles



Des INM insuffisamment décrites dans les publications

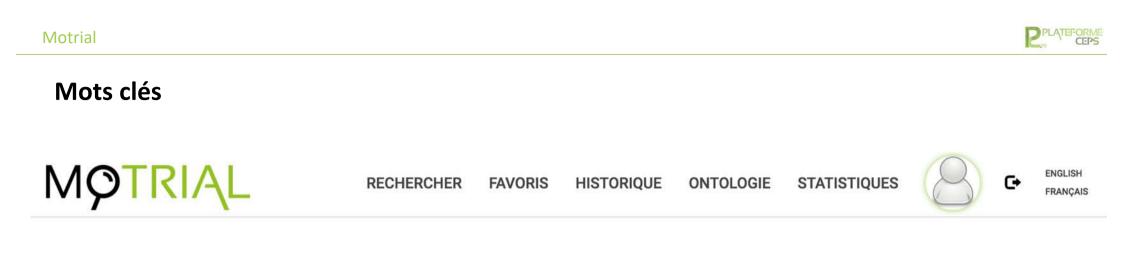
"Percentage of studies with sufficient description of treatment initially (based only on the published paper) and after supplementary information was obtained".

Glasziou et al. (2008, British Medical Journal)



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	acupuncture	
Filters		

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Choix méthodologiques MOTRIAL ENGLISH **RECHERCHER** FAVORIS HISTORIQUE ONTOLOGIE STATISTIQUES ADMIN FRANCAIS cancer× AND \$ Physical Activi...× Saisissez les termes de votre recherche Q **Filtres** Intervention Contrôlée No Yes Randomisé No Yes Multicentrique No Yes **Sélectionner des options** No Yes No Yes Suivi Groupe de contrôle No Yes Placebo Objectif de l'étude Étude aveugle \$ \$ **Résultat principal** méthodologiques (par Résultat secondaire Analyse \$ exemple la randomisation) Âge de la population Enfant Adulte No Yes No Yes Sénior No Yes (0-17) (18-65) (66+) Sexe de la population \$ Auteurs Pays \$ Date jj/mm/aaaa Nom de la revue Organisation





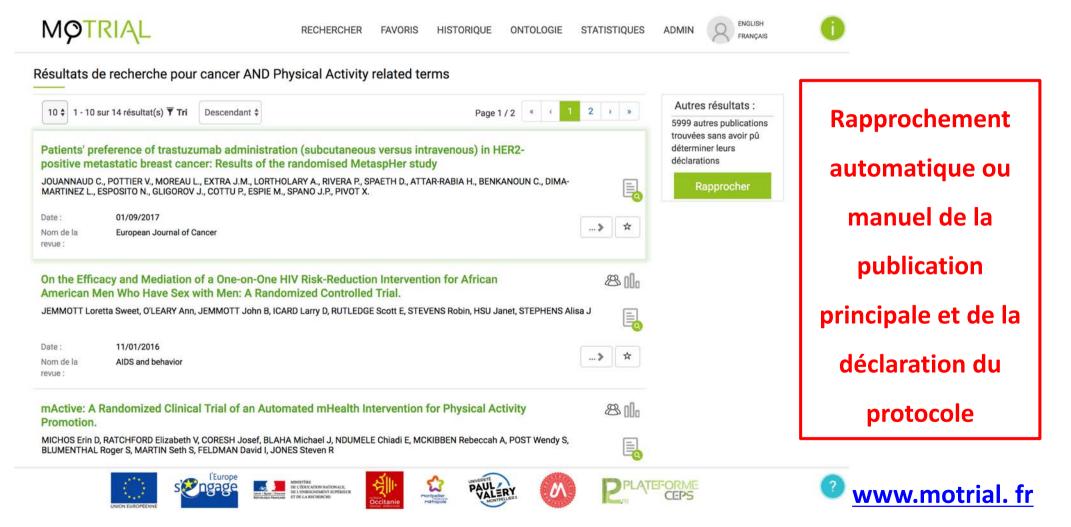


Recherche sur les bases de données partenaires

	R	echerche en cours sur les s	ources de données	suivantes:		
		C	\mathbf{O}			
cancer×	ClinicalT	rials.gov @ PLOS		Seienee Direct	٩	
Intervention	Cunical	PLOS	ONE PUD	ScienceDirect		
Contrôlée	No res	Nanuumise	NOTYES	maineentridee	No Yes	
Suivi Étude aveugle	No Yes	Groupe de contrôle	No Yes Objectif de l'étude	Placebo	No Yes	
Résultat principal		\$	objectil de l'étude			+
Résultat secondaire						_
Analyse		\$				
Âge de la population	Enfant No Yes (0-17)		No Yes	Sénior No (66+)	Yes	
Sexe de la population		\$				
Auteurs						
Pays		\$				
Date	jj/mm/aaaa					
Nom de la revue						
Organisation						



Résultat de la recherche des publications et des déclarations d'études





	Publication	11						
Actions :	mActive: A Rand	domized Clinical Trial of an Automated mH	lealth Intervention for Physic	cal Activity Promot	ion.			
+ Liste résultats		to 69 years at an ambulatory cardiology center i during a blinded run-in (week 1), in phase I (wee interface. In phase II (weeks 4 to 5), we random individual encouragement and fostering feedba	ks 2 to 3), we randomized 2:1 to un ized unblinded participants 1:1 to s	unblinded versus blinde smart texts versus no	d tracking. Unblinding a texts. Smart texts provi	llowed continuous a ded smartphone-del	access to act livered coach	tivity data through a smart ning 3 times/day aimed at
		steps/day goal. Forty-eight outpatients (46% wo Daily activity data capture was 97.4%. The phas [CI], -580 to 2628; P=0.21). In phase II, participar 3376 (95% CI, 1951 to 4801; P<0.001). An auton tracking technologies as facilitators in need of t	omen, 21% nonwhite) enrolled with e I change in activity was nonsigni nts receiving texts increased their mated tracking-texting intervention	h a mean±SD age of 58 hificantly higher in unbli daily steps over those n increased physical ac	nded participants versu not receiving texts by 2 tivity with, but not with	dex of 31±6 kg/m(2) s blinded controls b 534 (95% Cl, 1318 to but, the texting comp), and baselin by 1024 daily o 3750; P<0.0	steps (95% confidence inte 001) and over blinded cont
	Sponsor(s)	steps/day goal. Forty-eight outpatients (46% wo Daily activity data capture was 97.4%. The phas [CI], -580 to 2628; P=0.21). In phase II, participal 3376 (95% CI, 1951 to 4801; P<0.001). An auton	omen, 21% nonwhite) enrolled with e I change in activity was nonsigni nts receiving texts increased their mated tracking-texting intervention	h a mean±SD age of 58 hificantly higher in unbli daily steps over those n increased physical ac	nded participants versu not receiving texts by 2 tivity with, but not with	dex of 31±6 kg/m(2) s blinded controls b 534 (95% Cl, 1318 to but, the texting comp), and baselin by 1024 daily o 3750; P<0.0	steps (95% confidence inte 001) and over blinded cont
	Sponsor(s) Nom de la revue	steps/day goal. Forty-eight outpatients (46% wo Daily activity data capture was 97.4%. The phas [CI], -580 to 2628; P=0.21). In phase II, participar 3376 (95% CI, 1951 to 4801; P<0.001). An auton tracking technologies as facilitators in need of t	omen, 21% nonwhite) enrolled with e I change in activity was nonsigni nts receiving texts increased their mated tracking-texting intervention	h a mean±SD age of 58 hificantly higher in unbli daily steps over those n increased physical ac b://ClinicalTrials.gov/. U	nded participants versu not receiving texts by 2 tivity with, but not with Inique identifier: NCT01	dex of 31±6 kg/m(2) s blinded controls b 534 (95% Cl, 1318 to but, the texting comp), and baselin by 1024 daily o 3750; P<0.0	steps (95% confidence inte 001) and over blinded cont
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Déclaration:

mActive: A Blinded, Randomized mHealth Trial of Digital Activity Tracking and Smart Texting to Promote Physical Activity

Abstract: Despite their importance, health-related behaviors are hard to change. Among behaviors, physical activity is associated with protection from multiple diseases. People who are physically active have lower risk for heart disease, stroke, type 2 diabetes, depression, and some cancers with associated dose-dependent reductions in cardiovascular and all-cause mortality. However, most US adults do not meet CDC physical activity guidelines. Sedentary work behavior in industrialized nations is likely a contributor to this problem. Current low-technology strategies for encouraging lifestyle change are disappointingly ineffective and are highly resource intensive. Systematic reviews of the literature show mixed evidence for using activity trackers (i.e., pedometers) and a limited body of evidence for text messaging in preventive health care. However, prior studies have not integrated digital activity tracking with mobile phone text messaging feedback. Given 91% of adults in the United States now use a mobile phone, and 56% a smartphone, this represents a potentially widely applicable avenue for therapeutic intervention. There is growing interest in leveraging mobile health (mHealth) technologies to improve health behaviors in the general population. The investigators propose to conduct a blinded, randomized mHealth trial of digital activity tracking and smart texting to promote physical activity. NTC

NCT01917812



80h



Enregistrement dans un dossier personnel exportable

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PLATEFORME CEPS

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Production de statistiques

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Top 50 des revues scientifiques	
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Parcours des princeps	Top 50 des revues scientifiques
	1: Contemporary clinical triats 2: Annales d'endocrinologie 3: PLoS ONE 4: 4: 5: Zhongguo zhen jiu = Chinese acupuncture & moxbusstion 6: PLOS ONE 7: The Lancet 2: 8: Sleep Medicine 9: Chest 9: 10: Evidence-based complementary and alternative medicine 9: Chest 9: 11: Gastroenterology 7: 12: Complementary Threapies In Medicine 13: Deutsche Zeitschrift für Akupunktur 4: 14: PloS one 15: Journal of ethnopharmacology 4: 16: BNC complementary and alternative medicine 17: Osteopathische Medizina 16: PLOS one 16: PLOS one 16: PLOS one 16: PLOS one 16: DNC omplementary and alternative medicine 17: Osteopathische Medizina 17: Osteopathische Medizina 18: Zhen di van jiu = Acupuncture research 19: Journal of Chinas gemateria medica 20: Journal of Affective Disorders 20: Deutscharger and Affective Disorders 20: Deutscharger and
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Motrial en résumé

Le métamoteur de recherche des études évaluant l'efficacité des INM

Motrial identifie pour chaque étude :

- la publication principale (auteurs, titre, résumé,
- référence bibliographique complète, DOI),
- le numéro de déclaration au comité d'éthique,
- le numéro d'enregistrement du protocole aux autorités compétentes,
- les sources de financement,
- le nom du promoteur,
- le pays de réalisation.



Motrial facilite :

- les revues de littérature,
- les revues systématiques,
- les méta-analyses,
- la justification de nouvelles études.

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Une méta-analyse : un long (3 ans) travail d'équipe multidisciplinaire

Health Psychology Review, 2015 http://dx.doi.org/10.1080/17437199.2014.981777



Efficacy of theory-based interventions to promote physical activity. A meta-analysis of randomised controlled trials

M. Gourlan^{a,b,c}*, P. Bernard^{a,b}, C. Bortolon^{a,b}, A. J. Romain^{a,b,d}, O. Lareyre^{a,b,c}, M. Carayol^{a,b,e}, G. Ninot^{a,b} and J. Boiché^{a,b}





Activités physiques et santé

"Pour"







Expertise Collective

"Contre"

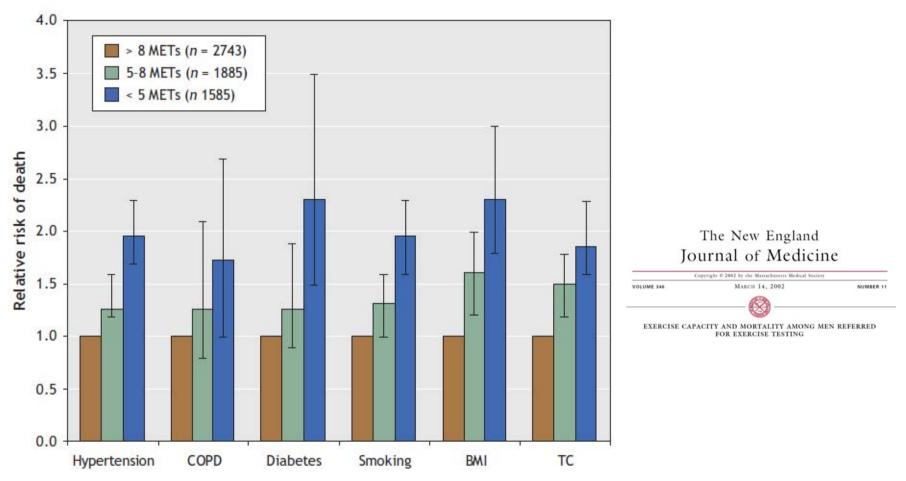


"Whenever I feel the urge to exercise, I sit down and wait until the urge passes"





Activités physique et santé



Myers (2002, NEJM)



Solutions de promotion de la santé







Ministère de la Santé et des Solidarités Ministère délégué à la Sécurité Sociale, aux Personnes âgées, aux Personnes handicapées et à la Famille Ministère de la Jeunesse, des Sports et de la Vie associative

PLAN NATIONAL **"BIEN VIEILLIR"** 2007 - 2009

Programme National Nutrition Santé (PNNS) (2001-2005; 2006-2010; 2011-2015) Plan Obésité (2010-2013) Plan Bien Vieillir (2007-2009)

2,5 h d'intensité modérée par semaine pour l'adulte sain

Activité physique cumulable par des séquences d'au moins 10 minutes d'activité sportive, de déplacement, d'activité professionnelle ou de la vie quotidienne



Objectifs opérationnels de la méta-analyse

- identifier le(s) modèle(s) socio-cognitif(s) le(s) plus efficace(s) pour augmenter le niveau d'activité physique à court (i.e., post-intervention) et moyen terme (i.e., quelques mois après l'intervention)

- comparer les interventions s'appuyant sur un ou plusieurs modèles

 explorer le rôle de deux modérateurs qualité méthodologique selon critères CONSORT pour les thérapies non médicamenteuses Boutron et al. (2008, AIM) qualité d'implémentation théorique (*Theory Coding Sheme*) Michie et Prestwich (2010, HP)

Critères d'inclusion

- action de prévention primaire visant à augmenter le niveau d'activité physique
- intervention basée sur un modèle théorique (explicitement mentionné, justifiant l'intervention)
- intervention ciblée sur des adultes
- essai randomisé contrôlé
- mesure du niveau d'AP des participants (dépense énergétique, nombre de pas et/ou questionnaire)



Modèle d'équation de recherche sur Pubmed et PsychInfo jusqu'au 15 mai 2013 et MESH

« Randomized controlled trial »

AND

"Exercise" OR "Exercise Therapy" OR "Exercise Movement Techniques" OR "Physical activity" OR "Resistance Training" OR "Muscle Stretching Exercises" OR "Breathing Exercises" OR "Sports" OR "Motor Activity" OR "Relaxation" OR "Physical Fitness"

AND

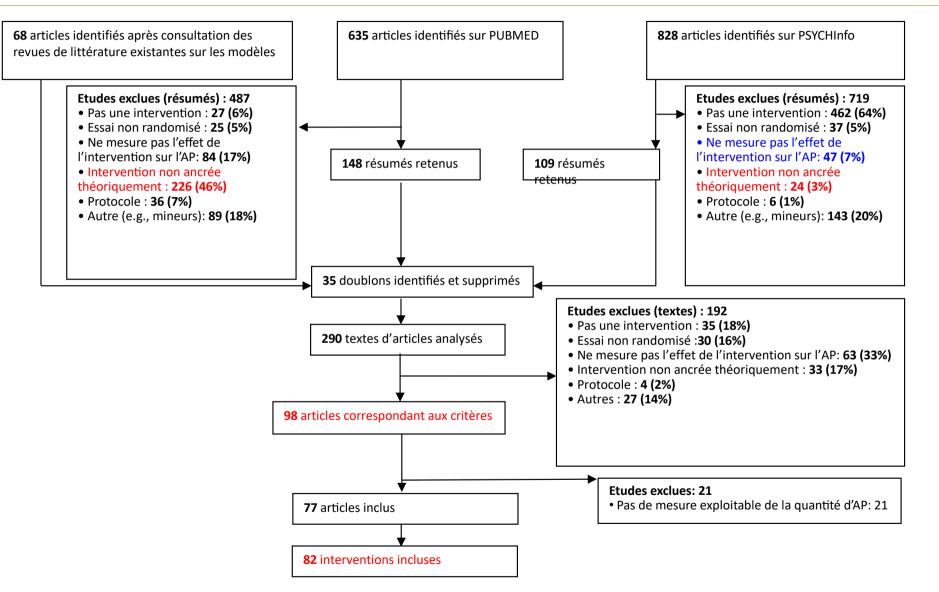
« Intervention » OR « Program » OR « Treatment » OR « Promotion » OR « Management »

AND

« Self determination theory » OR « Autonomous motivation » OR « Controlled motivation » OR « Self determined motivation » OR « Non self determined motivation » OR « Intrinsic motivation » OR « Extrinsic motivation » OR « Basic psychological needs » OR « Autonomy support » OR « Psychological needs support »

Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement - PICOS (Liberati et al., 2009, Plos Med)

Flow chart de la revue systématique



PLATEFORME CEPS



Participants = 19 357 (dont 10 574 groupes intervention et 8 783 groupes contrôle)

Age moyen = 48,4 (ET = 13,9) Mixte = 62 (75%), 18 (23%) exclusivement féminin et 2 (2%) exclusivement masculin Sédentaires = 18 Travailleurs = 7 Etudiants = 5 Personnes âgées = 5 Femmes enceintes (ou période postnatal) = 3 Diabétiques (type 1 ou 2) = 10 Obèses ou en surpoids = 7 Patients atteints de cancer = 5 Patients atteints de maladies chroniques « diverses » (e.g., hypertension, cardiopathies) = 11 Populations « spécifiques » (e.g., adultes dont au moins un parent a un diabète, femmes en

surpoids d'origine latine à faible revenu et rencontrant des problèmes d'acculturation) = 13



Interventions incluses = 82

- Transtheoretical model (TTM) = 31
- Social cognitive theory (SCT) = 16
- Planned Behavior theory (PBT) = 8
- Self-determination theory (SDT) = 5
- Protection motivation theory (PMT) = 1

- 1 théorie = 61
- 2 théories = 14 (dont 2 sans TTM)
- 3 à 5 théories = 7 (dont 0 sans TTM)

Présence de séances d'activité physiques supervisées

- 14 (16%)

Durée de l'intervention

- Critère non applicable (n = 17) / critère applicable (n = 67) : 24,0 semaines

Nombre total de séances

- Critère non applicable (n = 28) / critère applicable (n = 56) : 13,6 séances

Fréquence des séances

- Critère non applicable (n= 28) / critère applicable (n = 56) : 1,1 séance par semaine

Les interventions



1 mode d'intervention (n = 44) (52%)

- Face à Face (n = 18)
- Brochures (n = 12)
- Site internet (n = 9)
- Messages « Informatique/internet » (n = 4)
- Podcast (n = 1)

2 modes d'intervention (n= 28)

- Face à face + Téléphone (n = 14)
- Face à face + Brochures (n= 5)
- Téléphone + Site internet (n = 3)
- Téléphone + Brochure (n = 2), Face à face + Site internet (n = 2)
- Site internet + Brochure (n= 1), Messages « informatique/internet » + Fiches AP (n = 1)

3 modes d'intervention (n = 10)

- Face à face + Téléphone + Site internet (n = 4)
- Face à face + Brochures + Site internet (n = 2)
- Face à face + téléphone + Brochure (n = 1), Face à face + Téléphone + SMS (n = 1), Site internet + Téléphone + Brochure (n = 1), Site internet + Vidéos + Brochures (n = 1)

4 modes d'intervention (n = 1)

• Face à face + Téléphone + Messages « Informatique/internet » + Brochures

5 modes d'intervention (n = 1)

• Face à face + Téléphone + Brochures + Vidéos + Cassettes audio



Activité physique = critère de jugement principal

- oui = 74 (89%)
- non = 10 (11%)

Nature de la comparaison entre groupe intervention et groupe contrôle

- aucune intervention = 18 (22%)
- intervention minimale = 36 (44%)
- intervention alternative = 13 (15%)
- intervention temps de contact = 17 (19%)

Mesure de l'activité physique

- auto-rapportée = 70 (83%)
- auto-rapportée + objective = 11 (13%)
- objective = 3 (4%)

Indicateur de l'activité physique

- durée = 46 (55%) / dépense énergétique = 22 (26%) / score (index) = 14 (17%) / counts = 2 (2%)



Suivi

- oui = 20 (24%)
- non = 64 (76%)

Nature de la comparaison entre groupe intervention et groupe contrôle

- suivi 1 = +3 mois après intervention
- suivi 2 = +4 mois après intervention (n = 4)
- suivi 3 = +5 ans après intervention (n = 1)



Critères CONSORT (Boutron et al., 2008)	Oui	Non	Non applic
Participants (Eligibility criteria for participants and the settings and locations where the data were collected)	81 (96%)	3 (4%)	
Interventions (Precise details of both the experimental treatment and comparator)	70 (83%)	14 (17%)	
Interventions standardized (interventions were standardized)	64 (76%)	20 (24%)	
Objectives (Specific objectives and hypotheses (critere jugement principal))	74 (88%)	10 (12%)	
Sample size (How sample size was determined When applicable, details of whether and how the clustering by care providers or centers was addressed)	41 (49%)	43 (51%)	
Randomization (Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification) When applicable, how care providers were allocated to each trial group)	50 (60%)	34 (40%)	
Blinding (Whether or not those administering co-interventions were blinded to group assignment)	24 (29%)	57 (67%)	3 (4%)
Participant flow chart (for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome)	57 (68%)	27 (32%)	
Care providers (care providers or centers performing the intervention in each group and the number of patients treated by each care provider)	35 (42%)	27 (32%)	22 (26%)
Baseline data (When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group)	59 (70%)	25 (30%)	
Numbers analyzed (Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; state the results in absolute numbers when feasible (e.g., 10/20, not 50%)).	31 (37%)	53 (63%)	

Nombre moyen de critères remplis par les interventions: 5,77 (ET = 2,71)



Critères (theory coding scheme) Michie et Prestwich (2010)	Oui	Non
Construct mentioned (Evidence that the psychological construct relates to (correlates/predicts/causes) behaviour should be presented within the introduction or method (rather than the Discussion))	73 (87%)	11 (13%)
Theory used to select recipients for the intervention (Participants were screened/selected based on achieving a particular score/level on a theory-relevant construct/predictor)	19 (23%)	65 (77%)
Theory used to develop intervention techniques (The intervention is explicitly based on a theory or predictor or combination of theories or predictors)	78 (93%)	6 (7%)
Theory used to tailor intervention techniques to recipients (The intervention differs for different sub-groups that vary on a psychological construct (e.g., stage of change) or predictor at baseline)	32 (38%)	52 (62%)
All intervention techniques are explicitly linked to at least one theory-relevant construct (Each intervention technique is explicitly linked to at least one theory-relevant construct/predictor)	29 (35%)	55 (65%)
At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct (At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct)	34 (40%)	50 (60%)
Group of techniques are linked to a group of constructs/ predictors (A cluster of techniques is linked to a cluster of constructs)	34 (40%)	50 (60%)
All theory-relevant constructs are explicitly linked to at least one intervention technique (Every theoretical construct within a stated theory, or every stated predictor, is linked to at least one intervention technique)	21 (25%)	63 (75%)
At least one, but not all, of the theory relevant constructs are explicitly linked to at least one intervention technique (At least one, but not all, of the theoretical constructs within a stated theory or at least one, but not all, of the stated predictors are linked to at least one intervention technique)	47 (56%)	37 (44%)
Theory-relevant constructs are measured ((a) At least one construct of theory mentioned in relation to the intervention is measured POST-INTERVENTION, b) At least one construct of theory mentioned in relation to the intervention is measured PRE AND POST-INTERVENTION)	60 (71%)	24 (29%)

Nombre moyen de critères remplis par les interventions: 4,29 (ET = 2,33)



Comparaison inter-théories mesures (avant – après)

- Effet significatif (faible) : Cohen's *d* (82 interventions) = 0.31 (95% CI [0.24, 0.37])
 Hétérogénéité significative : Q = 348.52, p < .001, l² = 76.85%
- Pas de différences significatives entre les théories : Qb = 5,26 (p > .05)

Théories		d [95% Cl]	2	Qw	Qb
					5.26
Self determination theory	5	0.61 [0.32, 0.89]	51.28	8.21	
Social cognitive theory	16	0.42 [0.28, 0.56]	42.89	26.26*	
Transtheoretical model	31	0.31 [0.20, 0.42]	80.13	151.01***	
Theory of planned behavior	8	0.26 (0.03, 0.48]	83.22	41.72***	

Effet significatif monothéorie > multi-théories : Qb = 4,03 (p < .05)</p>

Théorie	Nombre d' interventions	d	IC 95%
1 théorie	60	0.35	0.26-0.43
Combinée	21	0.21	0.11-0.32



Sur le plan théorique

- Self determination theory, social cognitive theory, transtheoretical model, theory of planned behavior efficace pour augmenter le niveau d'AP (= Prestwich et al., 2014, HP)

=> overlaps théoriques des modèles socio-cognitifs (Gourlan et al., 2015)

- Monothéorie > Multi = Prestwich et al. (2014, HP) et ≠ Glanz et Bishop (2010, ARPH)

=> techniques de changement de comportement (Michie et al., 2013, ABM)

Mais

- 50% des études basées sur le modèle trans-théorique de Prochaska et al. (2009, HP) => raisons ?
- 46% des études recensées par Pubmed sans interventions ancrées théoriquement => théorie utile ?
- 47% des études recensées par Psychinfo sans mesure de l'effet => processus ou intervention ?



Bibliographie

Borenstein, M., Hedges, L. V., Higgins, J. P. T., & Rothstein, H. (2011). Introduction to Meta-Analysis. Chichester, United Kingdom: Wiley. Cooper, H. M. (2017). Research synthesis and meta-analysis : a step- by-step approach (5th ed.). Thousand Oaks, CA: Sage Publications.

Lipsey, M. W., & Wilson, D. B. (2001). Practical meta-analysis. Thousand Oaks, CA: Sage Publications.



Solution d'une intervention en prévention primaire pour augmenter la pratique d'AP

Intervention visant un changement durable de comportements Intervention basée sur un modèle théorique (e.g., Glanz & Bishop, 2010, ARPH; Nigg & Paxton, 2008, book; Biddle et al., 2014, PM)

Principaux modèles théoriques (Glanz & Bishop, 2010; Nigg & Paxton, 2008)

Health Belief Model (HBM: Rosenstock, 1974, HEM) Social Cognitive Theory (SCT: Bandura, 1997, book) Transtheoretical Model (TTM: Prochaska et, 2009, book) Theory of Planned Behaviour (TPB: Ajzen, 1991, OBHDP) Self-Determination Theory (SDT: Deci et Ryan, 2000, PI) Protection Motivation Theory (PMT: Rogers, 1983, book) Health Action Process Approach (HAPA: Schwarzer, 1992, book)

Certains modèles plus efficaces que d'autres pour augmenter la dose d'activité physique?