





## Trusted evidence. Informed decisions. Better health.

# Cochrane Rehabilitation project: RCTs in Rehabilitation Checklist (RCTRACK)

#### Aim

To produce a checklist of items to be followed in the reporting of RCTs in rehabilitation
To identify areas of methodological research to fill gaps in the actual relevant knowledge









### Education to research

Research financing

Epidemiologists

Study project

Study conducting (judgement)

Review

Study development

Study reporting

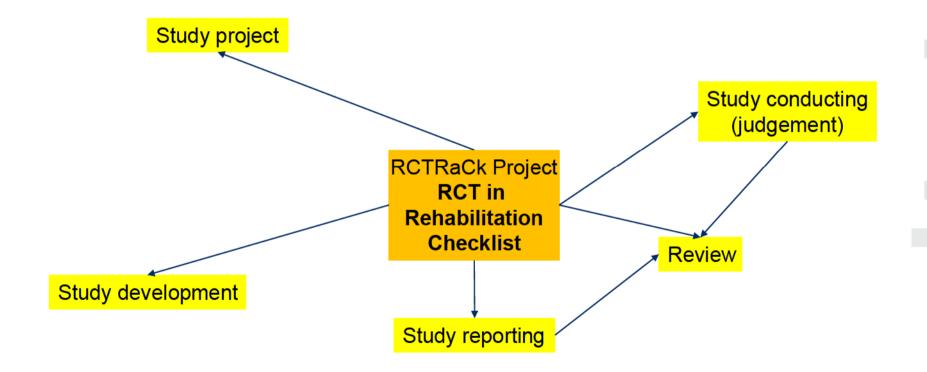
Cochrane

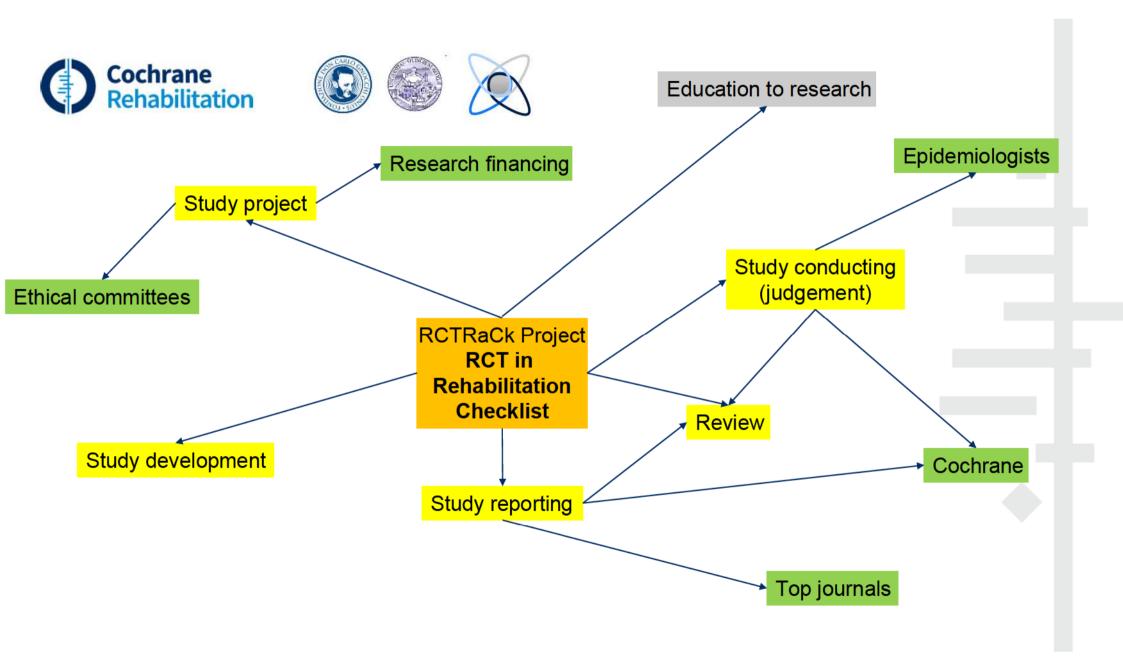




















## **Preparation**



Cochrane Rehabilitation Methodology Meeting @ ISPRM 2018

-EJPRM Special Issue

**Systematic review** on the existing methodological Checklists relevant to rehabilitation

-Armijo-Olivo S et al. Phys Ther 2014; 94(9), 1272-84

Scoping Review on methodological problems in rehabilitation research

-Arienti C et al. submitted

Clinical replicability of rehabilitation interventions in Randomized Controlled

Trials reported in main journals is inadequate

-Negrini S et al. J Clin Epidemiol (2<sup>nd</sup> revision submitted)

**Database** in Cochrane Rehabilitation website of all relevant methodological literature









## 1st Consensus Conference @ Kobe ISPRM 2019

Stefano Negrini (Ita)

Thorsten Meyer (Ger)

Antti Malmivaara (Fin)

Julia Patrick Engkasan (Mal

Walter Roura Frontera (Usa

Allen Heinemann (Usa)

Frane Grubisic (Cro)

Carlotte Kiekens (Bel)

William Levack (Nzl)

Wendy Machalich

eck (Usa)

Aydan Oral (Tur)

Melissa Selb (Swi)

Gerold Stucki (Swi)

Will Taylor (Nzl)

Susan Armijo-Olivo (Can)

Chiara Arienti (Ita)









## **Topics under evaluation**

Working group	Leader(s)
Patient selection (population)	Thorsten Mayer, Psy (Ger)
Blinding	Allen Heineman, Psy (Usa)
Treatment group	John Whyte, MD (Usa)
Control group & co-interventions	William Levack, PT (Nzl)
Attrition, follow up and protocol deviation	Susan Armijo-Olivo, PT (Can) Wendy Machalicek, BCBA (Usa)
Outcomes	Pierre Coté, DC (Can)
Statistical analysis and appropriate randomization	Dinesh Kumbhare, MD (Can)
Generalities on research (research question, effectiveness, etc)	Chiara Arienti, DO, MSc (Ita)









## RCTRACK production

### Consensus Conference 2020 @ ISPRM Orlando

- RCTRaCk Executive Committee and Chief-Editor of the Special issue (Tbd)
- Technical Working Groups reporting: systematic/scoping reviews
- Definition of the preliminary items to be kept in the draft RCTRaCk

### Consensus procedure through Delphi Rounds (3/4 rounds)

- Cochrane Advisory Board, Rehabilitation Journals Chief-Editors
- Representatives of
  - Scientific Societies
  - -groups dealing with evidence and methodology in rehabilitation
  - -PEDrO, TIDIeR, CERT
  - Cochrane methods groups
  - -Patients groups
- Authors







## State of research in rehabilitation

Trusted evidence. Informed decisions. Better health.











Analytical, Diagnostic and Therapeutic Techniques and Equipment Category
Therapeutics

Patient Care

Continuity of Patient Care

**Aftercare** 

#### ▶ Rehabilitation

Activities of Daily Living

Animal Assisted Therapy

**Equine-Assisted Therapy** 

Art Therapy

<u>Bibliotherapy</u>

Cardiac Rehabilitation

Correction of Hearing Impairment

Communication Methods, Total

Lipreading

Manual Communication +

Dance Therapy

Early Ambulation

Exercise Therapy

Motion Therapy, Continuous Passive

Muscle Stretching Exercises

Plyometric Exercise

Resistance Training

Music Therapy

Neurological Rehabilitation

Stroke Rehabilitation

Occupational Therapy

Recreation Therapy

Rehabilitation of Speech and Language Disorders

Language Therapy

Myofunctional Therapy

Speech Therapy

Speech, Alaryngeal +

Voice Training

Rehabilitation, Vocational

Telerehabilitation

Negrini S. Steady growth seen for research in physical and rehabilitation medicine: where our specialty is now and where we are going. Eur J Phys Rehabil Med. 2012 Dec;48(4):543-8.









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Steady growth of research

	Population	2000	2011	Change
PRM	PubMed	0.7%	1.5%	+114%
United States PRM	Country	1.7%	1.6%	+111%
United Kingdom PRM	Country	1.9%	1.7%	+113%
Germany PRM	Country	1.7%	1.1%	+150%
Canada PRM	Country	2.5%	1.9%	+128%
Australia PRM	Country	3.4%	1.8%	+195%
Italy PRM	Country	1.9%	0.9%	+207%
Netherlands PRM	Country	2.8%	1.8%	+155%
Japan PRM	Country	0.8%	0.6%	+138%
Sweden PRM	Country	3.4%	2.5%	+135%
France PRM	Country	1.2%	0.9%	+132%

Negrini S. Steady growth seen for research in physical and rehabilitation medicine: where our specialty is now and where we are going. Eur J Phys Rehabil Med. 2012 Dec;48(4):543-8.





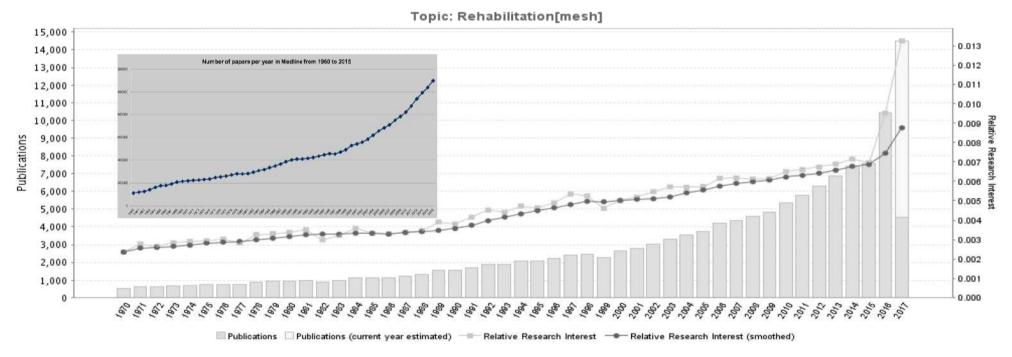




## Research interest in Rehabilitation is growing

Search: Rehabilitation [Mesh]

Source: www.gopubmed.org



Negrini S. Steady growth seen for research in physical and rehabilitation medicine: where our specialty is now and where we are going. Eur J Phys Rehabil Med. 2012 Dec;48(4):543-8.



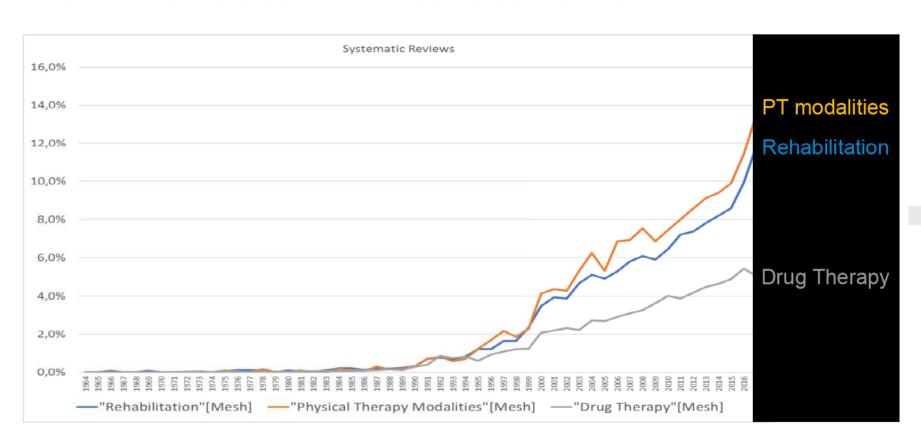






Negrini S, Levack W, Gimigliano F, Arienti C, Villafañe JH, Kiekens C. The struggle for evidence in physical and rehabilitation medicine: publication rate of randomized controlled trials and systematic reviews is growing more than in other therapeutic fields. Am J Phys Med Rehabil. 2018 Oct 1. doi: 10.1097/PHM.0000000000001058.

### Relative research interest: SRs





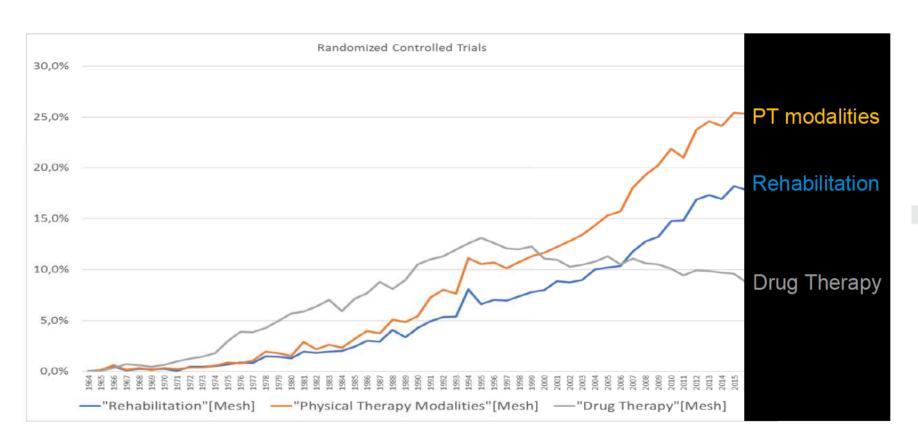






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## Relative research interest: RCTs











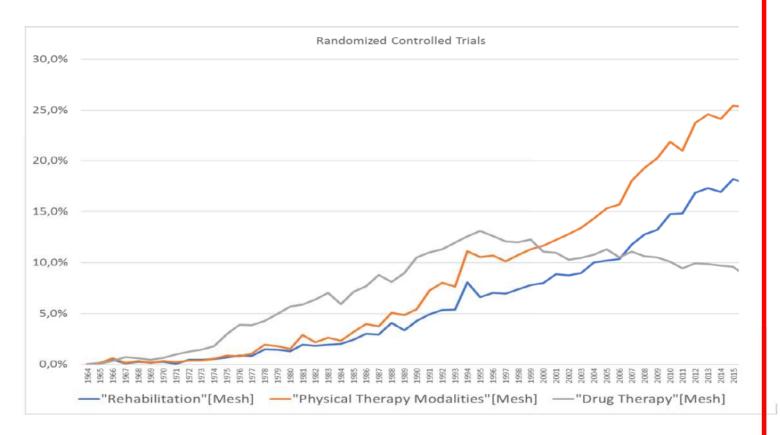
Analytical, Diagnostic and Therapeutic Techniques and Equipment Category
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## What is Rehabilitation [Mesh]?



#### Rehabilitation

Activities of Daily Living

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Analytical, Diagnostic and Therapeutic Techniques and Equipment Category Therapeutics

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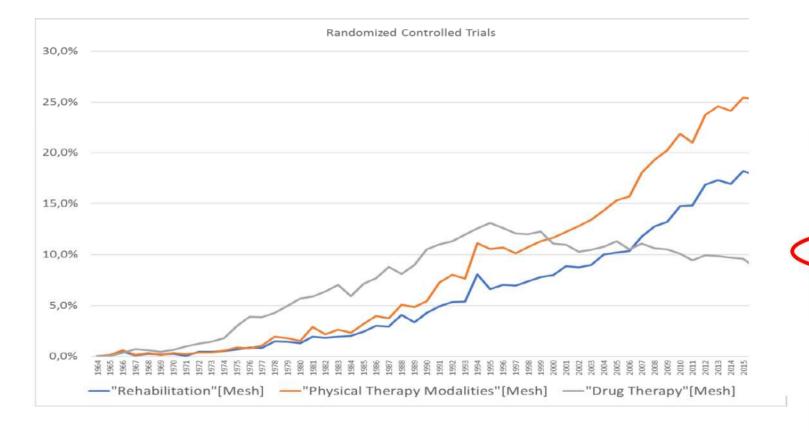
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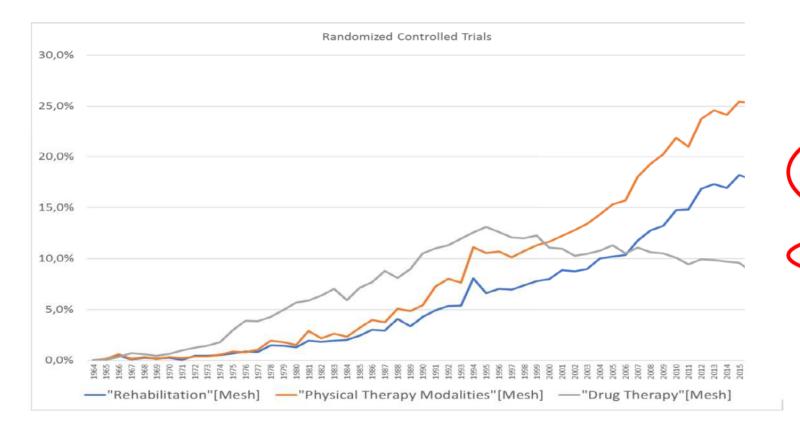
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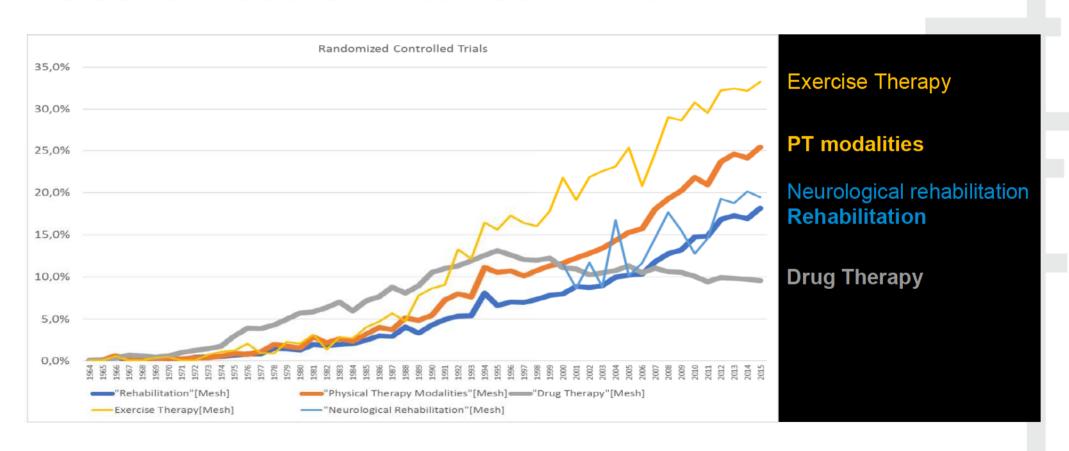






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### Relative research interest: RCTs











# Cochrane Rehabilitation project: prioritisation of future Cochrane Reviews

#### Aim

To identify the current research gaps in Cochrane Review production and define the priorities for research among these gaps

Trusted evidence.
Informed decisions.
Better health.









13 Chapters: Rehabilitation approach to health conditions	Paragraph s	Review s
Musculoskeletal	24	294
Neurological	28	246
Pain	16	134
Cardiovascular and Pulmonary	4	79
Internal medicine	9	4
Cancer- Organ Transplant and Immune-compromised	6	34
Pelvic floor	7	42
Psychiatric	6	20
Sport medicine	1	5
Pediatric	5	74
Geriatric	6	55
Rehabilitation management	8	47
General prophylaxis approach using rehabilitation	6	25









## Methodology

First Delphi Round: Identification of the priorities

does the number of reviews correspond to the importance of the topic?

**Second Delphi Round** (under way): identification of the final list of priorities

which list is the best?





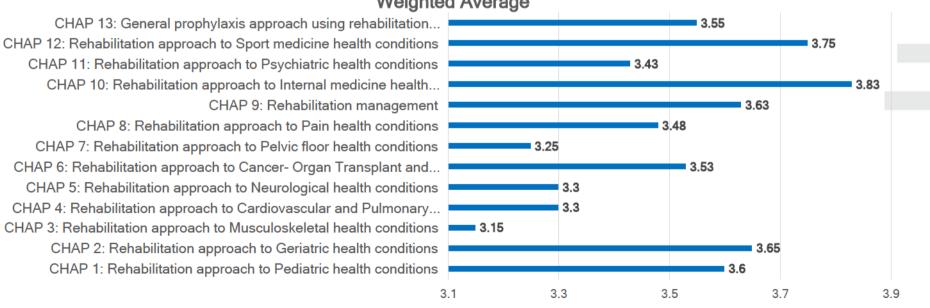




## **Fourth Survey**

According to the number of Cochrane Systematic Reviews and Protocols that have already been produced on every chapter, please rate how important is the need to produce more reviews for each chapter.

Weighted Average





TOT. This list of priorities has been achieved comparing all the previous lists and averaging the level of priority that each Paragraph received in the previous lists (3 points for priorities level 1 - 2 points for priorities level 2 and 1 point for priorities level 3)

					the previous lists (3 points for priorities level 1 - 2 points for p	rioriues
					level 2 and 1 point for priorities level 3)	
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					or 9.5. Intervention protocols treatment (0)	
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					r 8.12. Pain in older people (0)	2
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					E5.15. Neurogenic Bladder (2)	1
					vi 1.4. Physical Activity in children with reduced function or disabilities (2)	1
					ie 12.1. Muscle injuries in sports (1)	1
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	and Disability (1	\			117.4. Sexuality and Disability (1)	1
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					et 1.2. Musculoskeletal health conditions (7)	
					el 6.5. Transplant Rehabilitation (0)	
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				neurological patie		
					ti 5.21. Venticular Diseases and Ventigo (1)	0
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	on and rehabilitati	on of pulmonary as			nc4 3. Presention and rehabilitation of pulmonary aspiration (1)	
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		1.3. Pediatric by		1.3. Pediatric syn		
		5.25 Myelgice	5.28 Myelini e	cephalomyelitis/C	h 5.28. Mystgic encephalomysitis/Chronic Fangue Syndrome (ME/CFS) (2)	
				11.5. Mourning pr	o 11.5. Mouning process after loss of health (0)	
				7.2. Fecal incontin	x 7.2. Fecal incontinente (3)	
			9.4. Vocational	and professional re	e.9.4. Vocational and professional rehabilitation (12)	
					s 9.6. Education of patients, relatives and caregivers (7)	
					n 9.7. Ottoosis, prothesis, devices and technical aids (20)	0
			10.2. HIV (0)		(0.2. HIV (0)	









## 14 priorities #1

10.1. Rehabilitation of patients with burns (0)	3
9.5. Intervention protocols treatment (0)	3
9.8. Goal setting in rehabilitation (2)	2,8
5.2. Spinal Cord Injury (5)	2,4
10.8. Obesity (1)	2,4
13.4. Rehabilitation as Secondary prevention in stroke (2)	2,4
2.5. Independence and technical aids in the elderly (3)	2,4
5.14. Neurogenic Bowel (0)	2,2
8.12. Pain in older people (0)	2,2
3.3. Compression Fractures of the Spine (0)	2
9.2. Rehabilitation Setting (0)	2
6.3. Palliative care (0)	2
9.1. Rehabilitation assessment strategies (3)	2
13.1. Prevention of obesity with rehabilitation interventions (1)	2









## 16 priorities #2

2.3. Depression (1)	1,8
8.15. Adverse effects of pain management (0)	1,8
5.15. Neurogenic Bladder (2)	1,6
1.4. Physical Activity in children with reduced function or disabilities (2)	1,6
12.1. Muscle injuries in sports (1)	1,4
3.16. Polytrauma (0)	1,4
13.6. Physical Activity in the Prevention of Chronic Disease (6)	1,4
4.4. Deconditioning (4)	1,2
7.4. Sexuality and Disability (1)	1,2
2.1. Geriatric Frailty Syndrome (4)	1,2
8.9. Complex regional pain syndrome (CRPS) (3)	1,2
3.21. Amputation (3)	1
1.2. Musculoskeletal health conditions (7)	1
6.5. Transplant Rehabilitation (0)	1
9.3. Rehabilitation Team (3)	1
10.9. Metabolic syndrome (0)	1









## 16 priorities #3

11.2. Functional neurological disorders (1)	0,8
13.5. Biomechanical evaluation for prevention of chronic pain (1)	0,8
13.3. Sport injury prevention with rehabilitation intervention (3)	0,6
5.12. Nutrition in neurological patients (1)	0,6
5.21. Vestibular Diseases and Vertigo (1)	0,6
8.10. Psychological pain components and Post-traumatic stress (2)	0,6
4.3. Prevention and rehabilitation of pulmonary aspiration (1)	0,6
5.17. Spasticity (10)	0,6
1.3. Pediatric syndromes (2)	0,4
5.28. Myalgic encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) (2)	0,4
11.5. Mourning process after loss of health (0)	0,4
7.2. Fecal incontinence (3)	0,4
9.4. Vocational and professional rehabilitation (12)	0,4
9.6. Education of patients, relatives and caregivers (7)	0,4
9.7. Orthosis, prothesis, devices and technical aids (20)	0,4
10.2. HIV (0)	0,4







# Cochrane Rehabilitation project (with WHO): Best Evidence for Rehabilitation (be4rehab)

#### Aim

To identify the best evidence in rehabilitation to develop the WHO Package of Rehabilitation Interventions

Trusted evidence. Informed decisions. Better health.

## Cochrane Rehabilitation WHO Rehabilitation 2030: a call for action



Rehabilitation is essential in addressing the full scope of health needs of a population: **ensure healthy lives and promote well-being for all at all ages**.

Health systems need to be equipped to provide services that optimize functioning in light of impairments, injuries or health conditions, acute or chronic

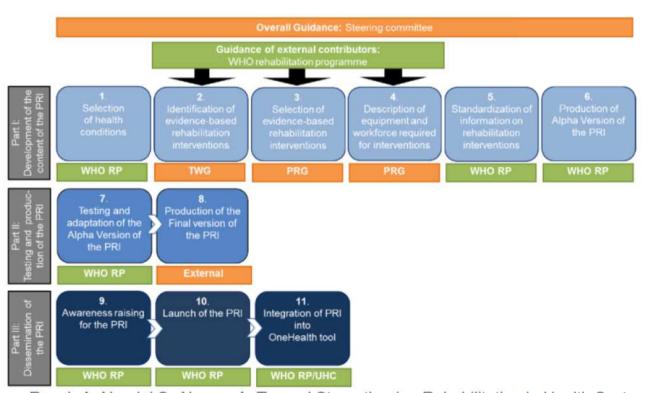
The benefits of rehabilitation are realized beyond the health sector.

Rehabilitation must be integrated into national health plans and budgets. Current epidemiological trends, demographic shifts and expanded access to health care make scaling up rehabilitation services imperative for health systems in the 21st century.



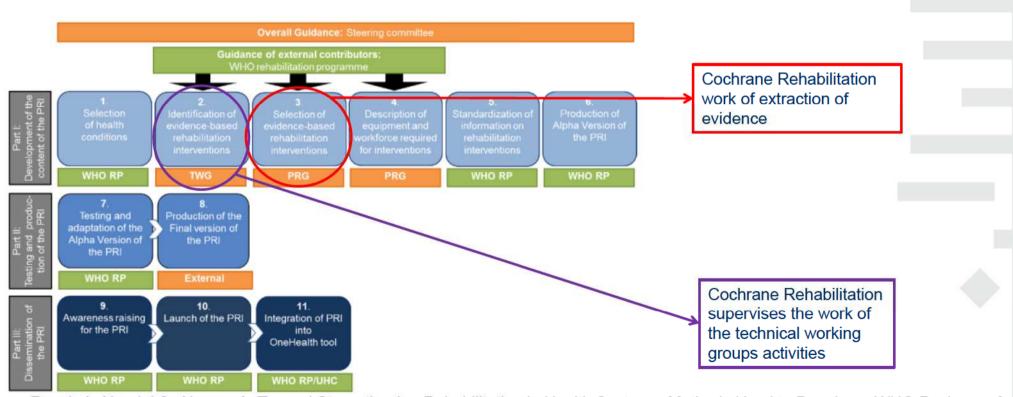


## Cochrane Rehabilitation WHO Package of Rehabilitation Interventions (PRI)



Rauch A, Negrini S, Alarcos A. Toward Strengthening Rehabilitation in Health Systems: Methods Used to Develop a WHO Package of Rehabilitation Interventions. Arch Phys Med Rehabil. 2019 Nov;100(11):2205-2211.

## Cochrane Rehabilitation WHO Package of Rehabilitation Interventions (PRI)



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be4rehab: Best Evidence for Rehabilitation

Data from selected **best Guidelines (expertise and evidence)** and from **Cochrane Reviews (evidence)** on 20 health conditions to produce the Minimum Package of Rehabilitation Interventions for Ministries of Health

#### Cochrane rehabilitation role:

- co-responsible of the methodology
- recruitment and methodological overview of 10 out of 20 existing review groups
- Extraction of the best available evidence from Cochrane Systematic Reviews

Rauch A, Negrini S, Alarcos A. Toward Strengthening Rehabilitation in Health Systems: Methods Used to Develop a WHO Package of Rehabilitation Interventions. Arch Phys Med Rehabil. 2019 Nov;100(11):2205-2211.







**Knowledge translation efforts of Cochrane Rehabilitation** 

Trusted evidence.
Informed decisions.
Better health.









### **Different audiences**



## Consumers and the public

Those seeking health care, their families and carers, and the public



#### **Practitioners**

of health care including clinicians and public health practitioners



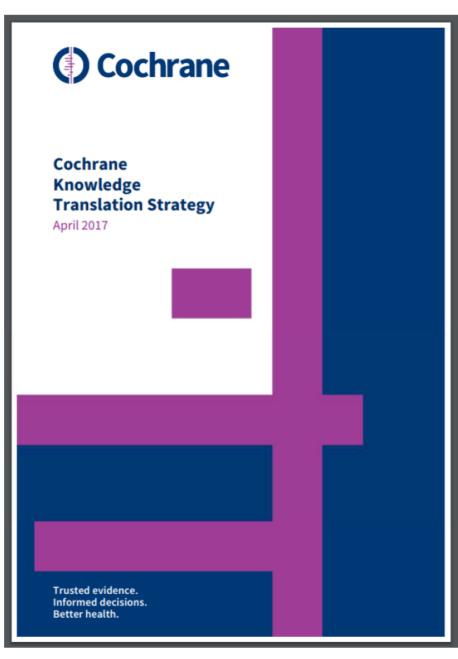
#### Policy-makers & healthcare managers

making decisions about health policy within all levels of management



#### Researchers & Research Funders

who need information regarding important gaps in the evidence



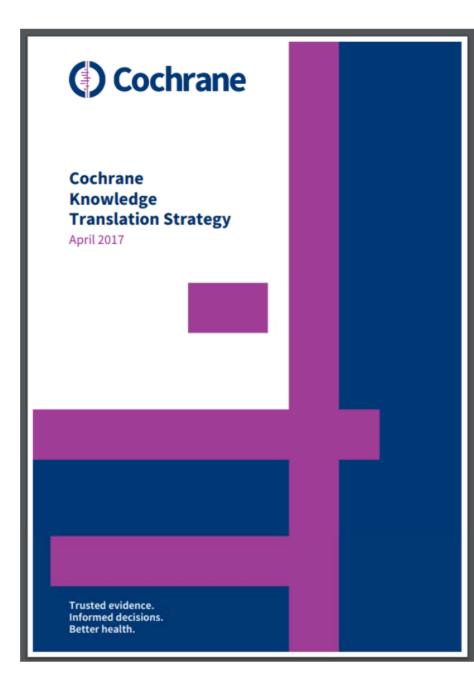


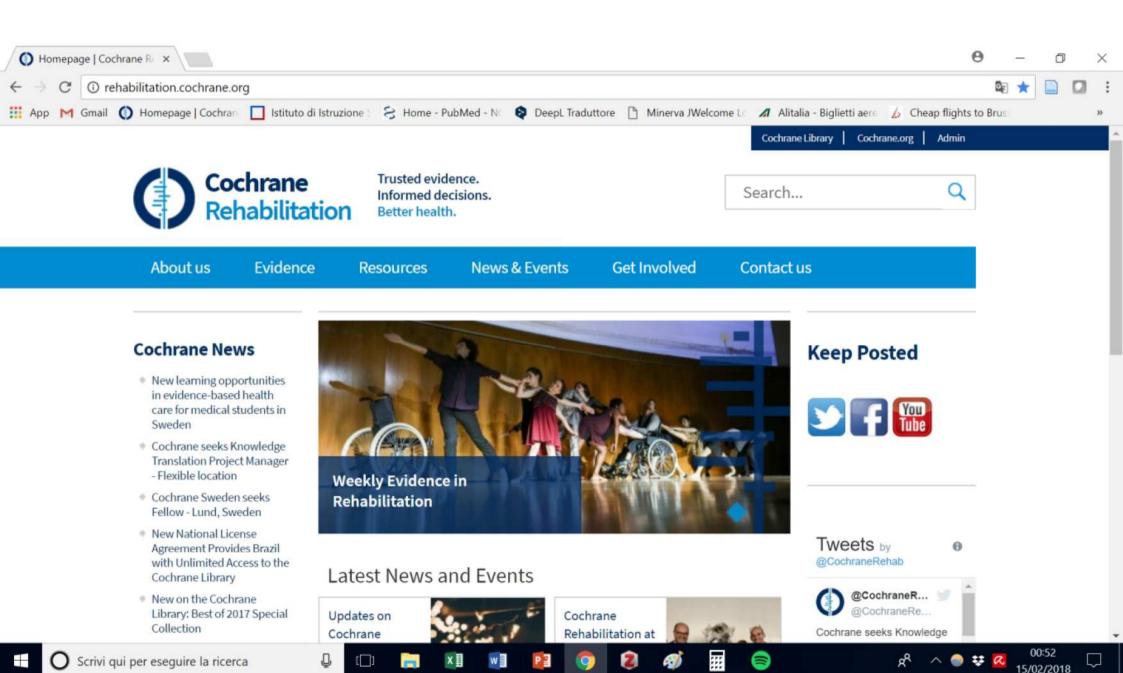


















Some other future solutions for EBM in rehabilitation

Trusted evidence.
Informed decisions.
Better health.

# Cochrane Rehabilitation What else can we do to face these challenges?

There is a general «agreement» that rehabilitation has low evidence

- We are struggling to produce sound (and meaningful) research
- In reality, we are not missing methodologically sound research (RCTs)
- But this good research does not relieve us: we still feel that we are missing evidence

Probably we are stuck by the RCT gold standard, that is not the best methodological approach due to the intrinsic limitation of rehabilitation:

- Rehabilitation process
- Black box











## What else can we do to face these challenges?

There is a general «agreement» that rehabilitation has low evidence

- We are struggling to produce sound (and meaningful) research
- In reality, we are not missing methodologically sound research (RCTs)
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Probably we are stuck by the RCT gold standard, that is not the best methodological approach due to the intrinsic limitation of rehabilitation:

- Rehabilitation process
- Black box

It's time to think out of the box!











Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

BMJ VOLUME 327 20-27 DECEMBER 2003 bmjcom

### The Parachute Systematic Review of RCTs

**Objectives.** To determine whether parachutes are effective in preventing major trauma related to gravitational challenge.

Material and Methods. <u>Design</u>: Systematic review of RCTs. <u>Data sources</u>: Medline, Web of Science, Embase, and the Cochrane Library databases; appropriate internet sites and citation lists. <u>Study selection</u>: Studies showing the effects of using a parachute during free fall. <u>Main outcome measure</u>: Death or major trauma, defined as an injury severity score > 15.

**Results.** We were unable to identify any randomised controlled trials of parachute intervention.

**Conclusions.** As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials.

Parachiste use to prevent deads and major transmarehead to gravitational challenge; systematic review of rarichmenic customics controlled trials.

However, the state of the s

Smith GCS. Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials











### **Equipoise**

The ethics of clinical research requires equipoise – a state of genuine uncertainty ... regarding the comparative therapeutic merits of each arm in a trial...

- Individual level
- Expert medical community



Let's imagine gait rehabilitation for stroke

Is an RCT about making the patient walk like a parachute RCT?

Would an ethical committee consider unethical a control group without treatment?

- Yes!
- Rehabilitation in this topic has evidence without RCTs

What are not parachutes (ethical committees would allow the studies)?

- Who makes him walk?
- How he/she makes him walk?
- How we increase the recovery speed?
- How we reduce inherent costs?

# Parachute Evidence Based Ethical List in rehabilitation

#### What is this?

- A proposal to systematically list all rehabilitation treatments that
  - -are like parachutes,
  - -would be unethical to stop providing,
  - -do not need any scientific study to prove their evidence

#### Methods

- Consensus procedures
- Partners

#### Limits

Conflict of interest (?): but, who else if not us ?



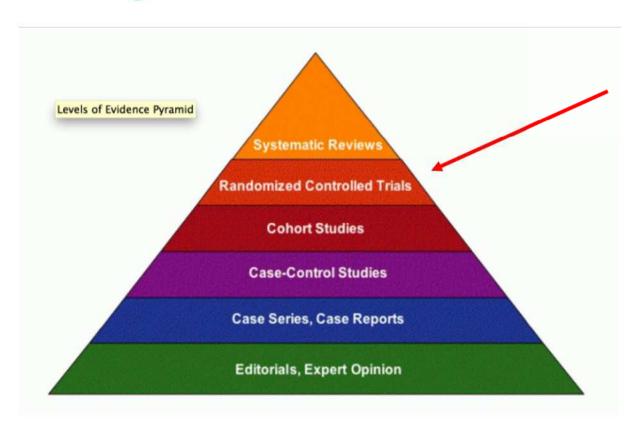








# **The Pyramid of Evidence**











# 2. The Pyramids of Evidence in rehabilitation

Task of Cochrane Rehabilitation







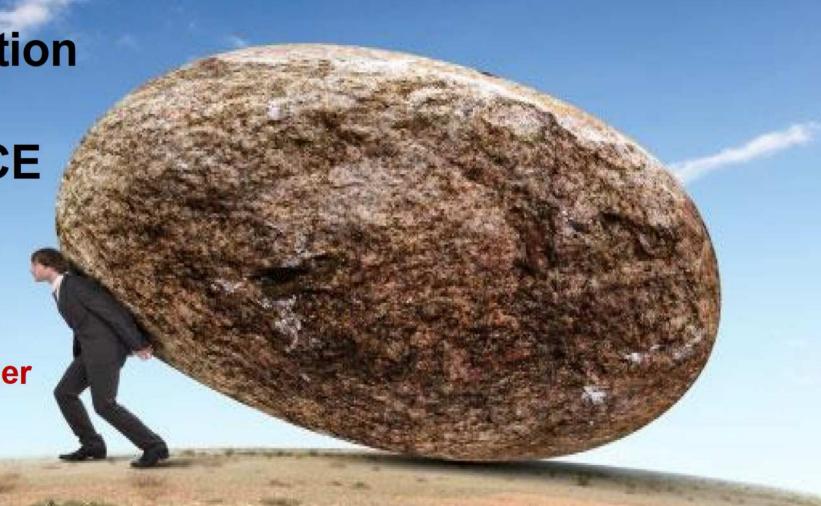








A constant boulder on rehabilitation shoulders





















# Thank you!

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