



Cochrane
Rehabilitation, Functioning,
and Disability



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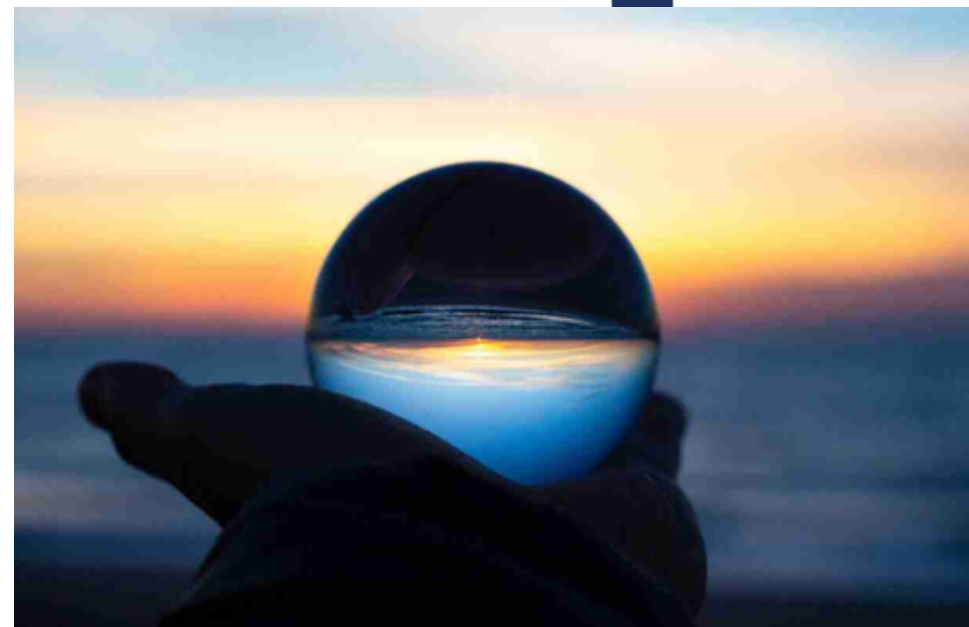
CochraneRehab

The value of evidence for our specialty

Stefano Negrini, MD, PhD

- Director Cochrane Rehabilitation, Functioning and Disability
- University of Milan
- IRCCS Ospedale Galeazzi Sant'Ambrogio Milan

Trusted evidence.
Informed decisions.
Better health.



Disclosures

Director of Cochrane Rehabilitation, Functioning and Disability



Where we are and what's ahead

Introduction

- Evidence Based Medicine and Clinical Practice
- From the **Cochrane Rehabilitation** Field to the **Cochrane Rehabilitation, Functioning and Disability** Thematic Group

The definition of rehabilitation for research purposes and what we can learn from that

Opening the Black Box of rehabilitation: the GUieline for Intervention DEscription in Rehabilitation (GUIDE-Rehab) and its importance also for clinicians

Other study designs for evidence in rehabilitation

Evidence vs Real World Evidence



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Evidence Based Clinical Practice

Are we already there? What's ahead?

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Evidence Based Medicine

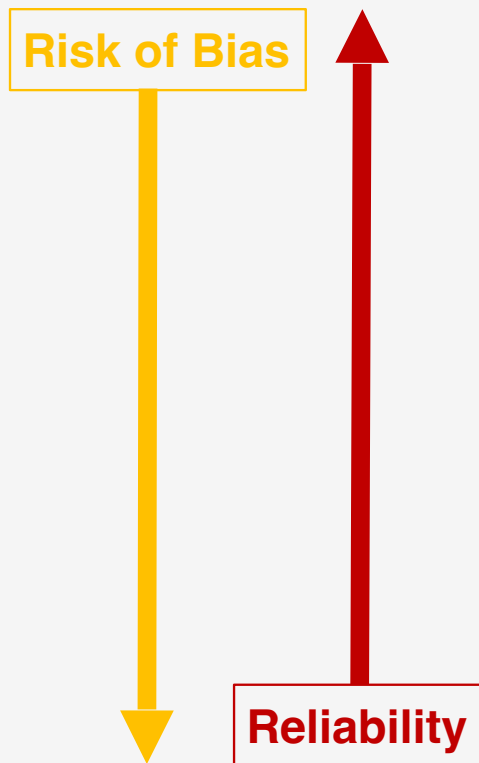
The explicit, conscientious, and judicious use of the current best evidence in making decisions about the care of individual patients (and populations)

Sackett DL et al. Evidence based medicine: what it is and what it isn't.

BMJ 1996; 312:71. doi: <https://doi.org/10.1136/bmj.312.7023.71>



A code to understand the literature



The triad of Evidence Based Clinical Practice

The integration of

- best research evidence
- with clinical expertise
- and patient values



Sackett DL et al. How to practice and teach EBM.
Edinburgh: Churchill Livingstone (2000).

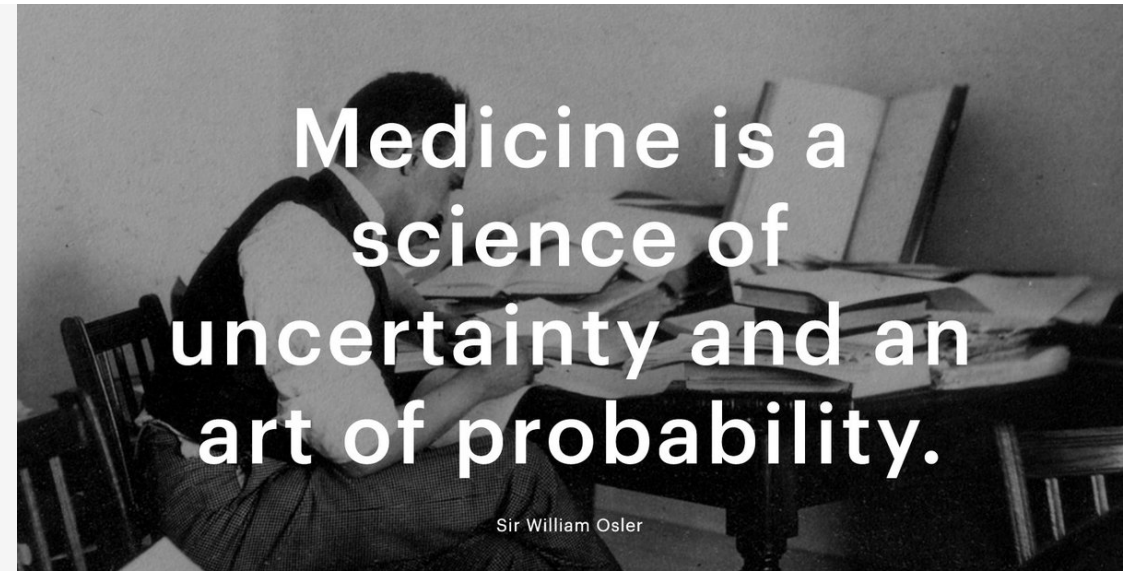
Why we need evidence

Does this intervention work and when?

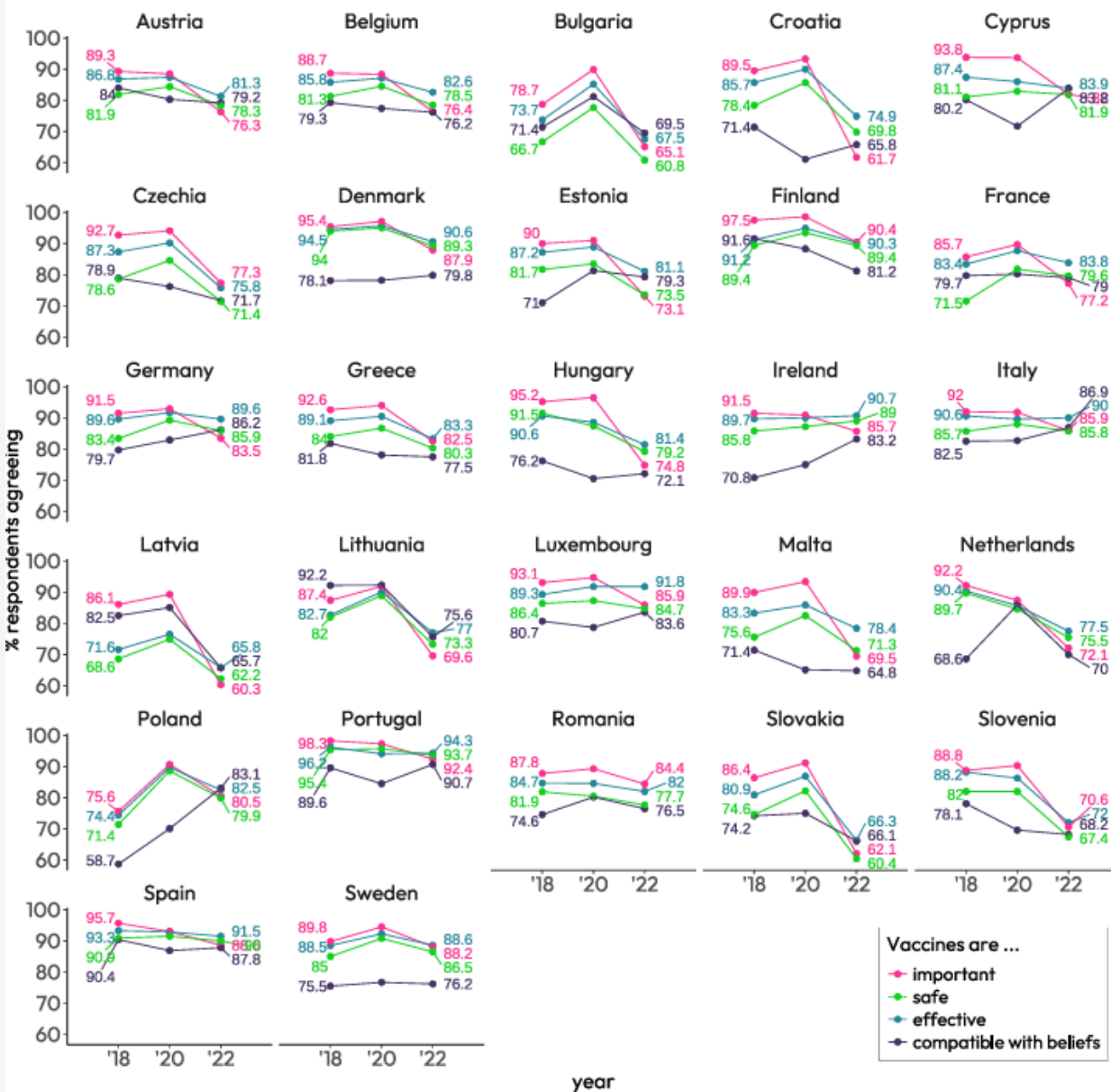
Should it be paid or not?

If yes, for what?

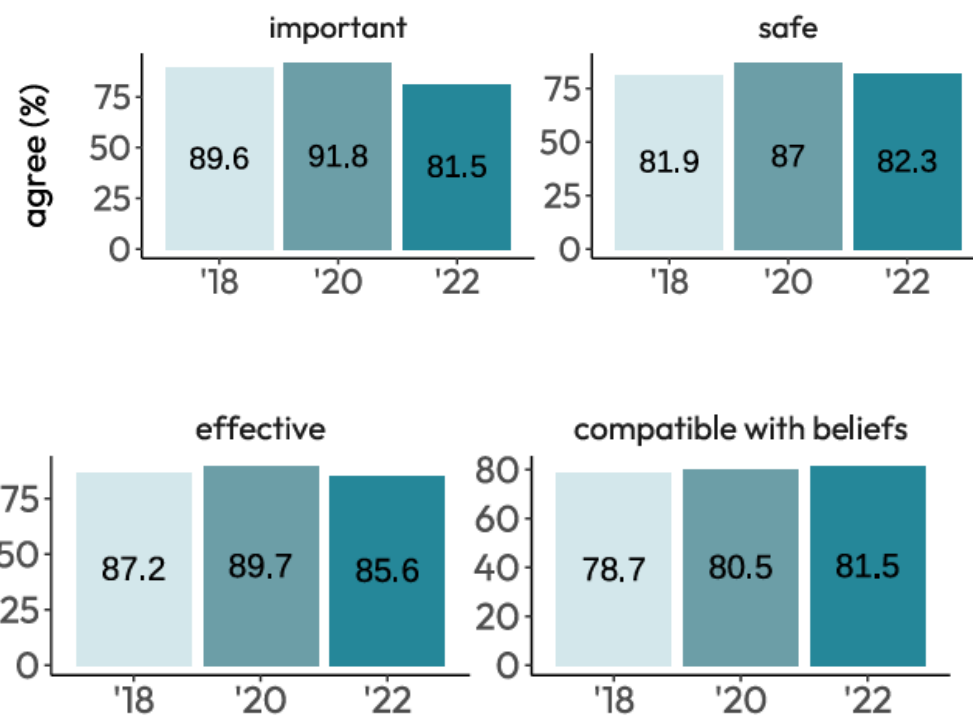
Medicine is an art based on science



General vaccine confidence



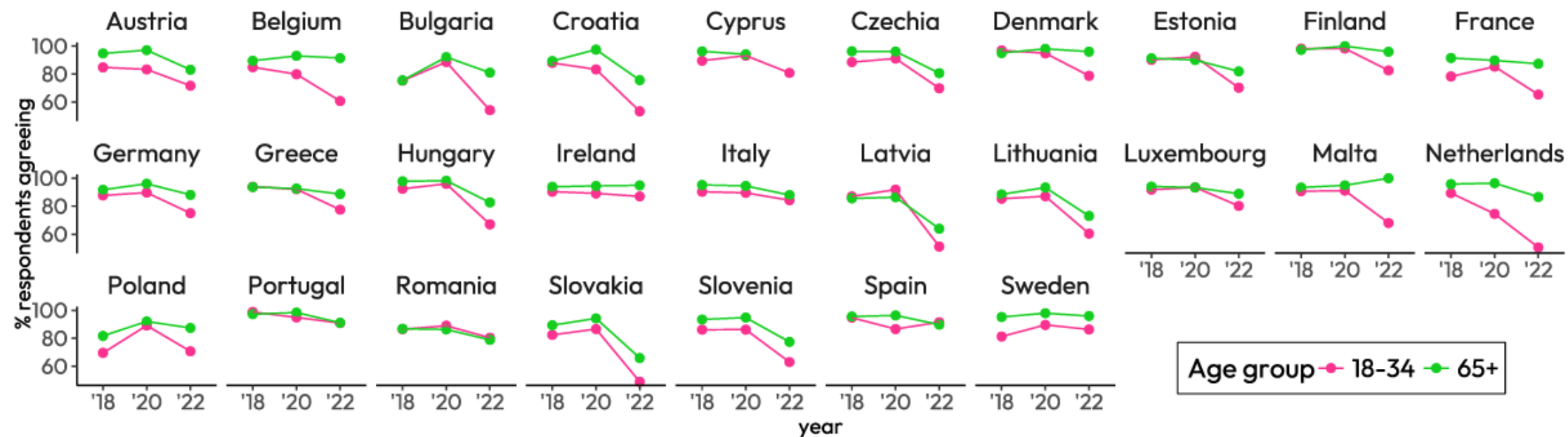
Vaccines are ...



State of Vaccine Confidence in the European Union

2022

Vaccines are important



State of Vaccine
Confidence in the
European Union

2022

Flat Earth believers

15% United States
7% Brasil
10% Italy
Germany?



~~Flat Earth~~ surfing championship?
championship

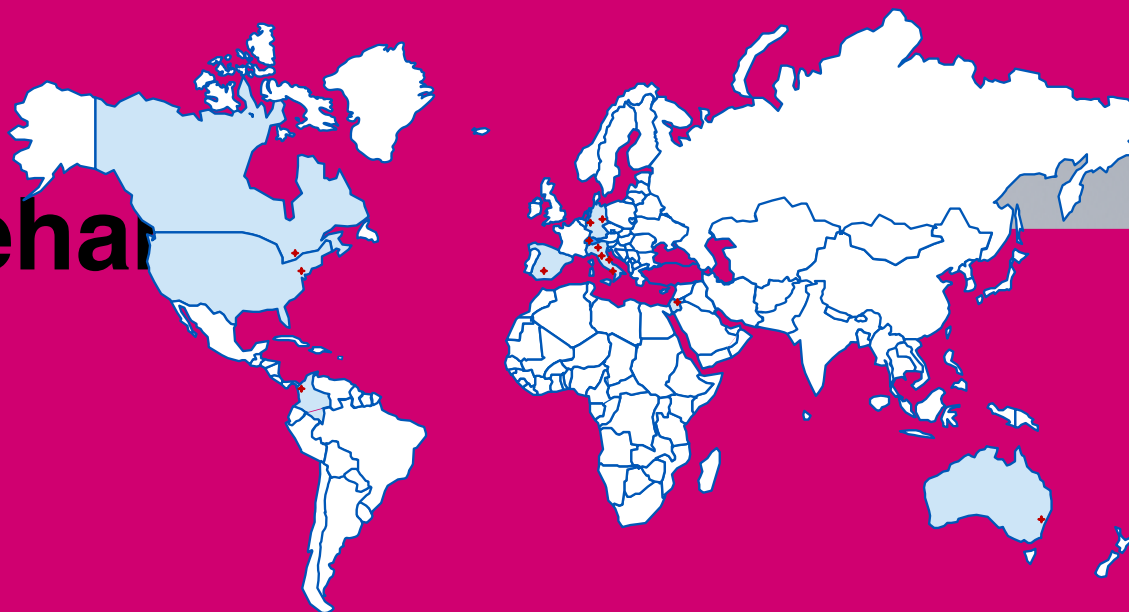


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Cochrane Rehabilitation, Functioning, and Disability

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Cochrane Rehabilitation Field (2016): a bridge

Knowledge Translation - Methodology

Cochrane



Rehabilitation
stakeholders

Knowledge Translation

Comprehensive **website**

Monthly **newsletter** (n=73, to 1748 emails, to...)

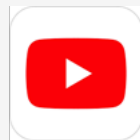
All available **social media** channels (14.000 followers)

Educational activities (webinars, workshops, posters and lectures,...)

Scientific papers (including Cochrane corners - 199 in 14 journals), and lectures at scientific meetings

Blogshots

eBook with an index based on a prioritisation exercise, and for which we are currently revising methodology and format, evolving to overviews of CSRs using a mapping synthesis.



Blogshots

English: 137

Translations in 14 languages

Total: 576



**Cochrane
Rehabilitation**

Exercise therapy for treatment of acute non-specific low back pain



For people with acute non-specific low back pain, it is uncertain if exercise therapy has an effect on pain and on functional status, compared to sham/placebo treatment or to no treatment, at short term (very low-certainty evidence).



There is not enough information about harms.



Cochrane review (published in August 2023); 23 studies (2674 people with acute non-specific low back pain) comparing effects of exercise therapy on pain and functional status to sham/placebo treatment or to no treatment.



**Cochrane
Rehabilitation**

Massage for neck pain



For people with acute, subacute or chronic neck pain, massage may make little to no difference in pain, function-disability and health-related quality of life compared to placebo at up to 12 weeks of follow-up (low-certainty evidence).




There was not enough information about harms.




Cochrane review (published in February 2024); 33 studies (1994 people with acute, subacute or chronic neck pain) comparing massage to sham or placebo, no treatment or wait-list, or massage as an adjuvant treatment.




Blogshots – translations with Geographic groups

**Cochrane Rehabilitation**

Rehabilitación luego de cirugía para la lesión de tendones flexores de la mano

**Cochrane Iberoamérica**



En personas que tuvieron cirugía para lesiones tendinosas de la mano, es incierto si un régimen de ejercicios pasivos controlados más flexión activa temprana hace alguna diferencia en la funcionalidad del paciente o en el rango de movilidad articular de los dedos cuando se comparó con un régimen de ejercicios pasivos controlados, entre el sexto al decimosegundo mes de seguimiento (certeza de la evidencia muy baja).


Es incierto (certeza de la evidencia muy baja) si un régimen de ejercicio activo reduce la pérdida del rango de movilidad (<25% de lo normal) comparado con un régimen de inmovilización entre los meses 12 a 36 de seguimiento; también es incierto si hacer ejercicio con una ortosis versus ejercicios pasivos controlados usando bandas de tracción elástica tiene alguno de estos efectos: 1.) hacer alguna diferencia en la funcionalidad (autodirigida) o 2.) mejorar el rango de movilidad activo a los 12 meses de seguimiento.

Es incierto si las intervenciones de rehabilitación pos operatoria (IRPO) (aquí reportadas) son responsables de eventos adversos (padecer uno o más eventos adversos o requerir cirugía).


Revisión de Cochrane que comparó alguna o ninguna IRPO, control o placebo, u otra IRPO. Revisión de Cochrane (publicada en enero de 2021); 17 estudios con 1108 personas luego de cirugía para lesión de tendones flexores de la mano.


rehabilitation.cochrane.org | @CochraneRehab traducido por el Grupo de Rehabilitación en Salud - Universidad de Antioquia [Colombia] | <http://bit.ly/RehabCD012479>



**Cochrane Rehabilitation**

Reabilitação cardíaca baseada no exercício para adultos com angina estável

**Cochrane Portugal**



Em pessoas com angina estável, estamos incertos acerca dos efeitos da reabilitação cardíaca baseada no exercício na mortalidade, morbidade, internamentos hospitalares relacionados com o sistema cardiovascular, eventos adversos, qualidade de vida relacionada com a saúde e capacidade dos indivíduos para regressarem ao trabalho. A reabilitação cardíaca baseada no exercício pode resultar num aumento reduzido da capacidade de exercício. **EVIDENCE GAP**

Revisão Cochrane; 7 estudos com 581 adultos com angina estável, comparando reabilitação cardíaca vs. cuidados habituais.

Revisão Cochrane por: Cochrane Heart

rehabilitation.cochrane.org | @CochraneRehab | #CochraneEvidence <http://bit.ly/AnginaRehab>

Special Projects



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Evidence About and Contacts Resources News & Events **Special Projects**

Special Projects

- ◆ Ongoing special projects
- ◆ Completed special projects



Ebook website

On this page are the ongoing and completed projects of Cochrane Rehabilitation:

- [Ongoing special projects](#)
- [Completed special projects](#)



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Publications

Here are listed the **Cochrane Rehabilitation publications**, from newest to oldest:

2024

Arienti C, Lazzarini SG, Zaina F, Cordani C, Minozzi S, Kiekens C, Negrini S. **Lumbar braces and other assistive devices for treatment of chronic low back pain.** Cochrane Database Syst Rev. 2024 Jul 8;7:CD015492. doi: 10.1002/14651858.CD015492. PMID: 38973783. [PubMed link](#)

Levack WM, Gross DP, Martin RA, Every-Palmer S, Kiekens C, Cordani C, Negrini S; Participants in the 5th Cochrane Rehabilitation Methodological Meeting. **Designing studies and reviews to produce informative, trustworthy evidence about complex interventions in rehabilitation: a narrative review and commentary.** Eur J Phys Rehabil Med. 2024 Jun 26. doi: 10.23736/S1973-9087.24.08459-4. Epub ahead of print. PMID: 38922317. [PubMed link](#) - [Full-text link](#)

Del Furia MJ, Arienti C, Cattadori G, Di Marco S, Kiekens C. **Overview of Cochrane Systematic Reviews on Interventions for Rehabilitation in People with Ischemic Heart Disease: A Mapping Synthesis.** Journal of Clinical Medicine. 2024; 13(13):3662. <https://doi.org/10.3390/jcm13133662>. [Full-text link](#)

Liguori S, Moretti A, Toro G, Arienti C, Patrini M, Kiekens C, Negrini S, Iolascon G, Gimigliano F. **Overview of Cochrane Systematic Reviews for Rehabilitation Interventions in Individuals with Upper Limb Fractures: A Mapping Synthesis.** Medicina. 2024; 60(3):469. <https://doi.org/10.3390/medicina60030469>. [Link](#)

<https://futurecochrane.org/>



Why are these changes happening? Support & training events Key projects News New production model FAQs Funders Co


COCHRANE HAS CHANGED.

To maintain our hard-earned place as one of the world's most trusted health evidence producers, Cochrane is changing how we do things and a lot has already happened.

Please take a look at the information on this site to find out more, including [FAQs](#) and the [latest news](#).

In 2023, Cochrane made significant strides towards the future by evolving and enhancing its systems.


SCROLL



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Our evidence About us Join Cochrane News and jobs Cochrane Library ▶

Cochrane Evidence Synthesis and Methods ▶



Cochrane announces new scientific strategy

Latest Cochrane evidence

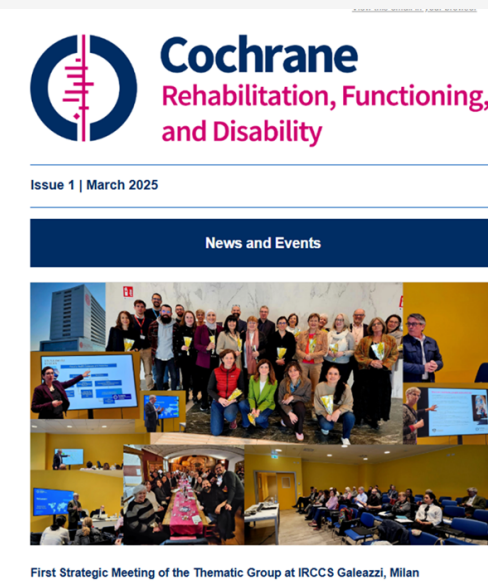
Does galantamine help people with dementia due to Alzheimer's disease and people with mild
Updated: 5 November 2024

Does taking statins prevent blood clots from forming in the veins of people who have not
Published: 5 November 2024

Is there a difference in outcome when a surgeon makes a single cut rather than several cuts to
Updated: 5 November 2024

2016 2024

The Cochrane Field: Cochrane Rehabilitation The Cochrane Thematic Group Cochrane Rehabilitation, Functioning & Disability



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John Walsh Centre for Rehabilitation Research, University of Sydney	Lisa Harvey
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The George Washington University	L. Susan Wieland
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University Hospital Cologne	Sascha Köpke
University of Campania Luigi Vanvitelli	Francesca Gimigliano
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University of Jordan	Rawan AlHeresh
University of Lucerne	Carla Sabariego

Team



Meet the team
Cochrane
Rehabilitation, Functioning,
and Disability



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Marianna Capecci



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Maria Grazia Celani



Vice Chair
Cristina García-Muñoz



Vice Chair
Joanne Ginsky



Vice Chair
Stefano Lazzarini



Vice Chair
Sara Liguori



Vice Chair
Ana-Maria Posada Borrero



Vice Chair
Ziad Hawamdeh



Cochrane
Rehabilitation, Functioning,
and Disability

VISION



Our vision is a world where the **best available evidence** informs **rehabilitation, treatment, and health policy and systems decisions** regarding the **health and functioning** of people experiencing disability.



Cochrane

Rehabilitation, Functioning,
and Disability

Our mission is to support the improvement of the health and functioning of people experiencing disability with a **global perspective across professions, culture, language and economic resources** by:

- **enhancing evidence production and synthesis**, particularly in rehabilitation, and by **introducing functioning as the third health indicator**, alongside mortality and morbidity;
- **facilitating evidence implementation** through knowledge translation, including education and training;
- **promoting evidence-based practices** integrating evidence with professional expertise and patient values.

Mission



Cochrane

Rehabilitation, Functioning,
and Disability

Working groups

- ✓ Cochrane internal affairs
-  Dissemination and knowledge translation
-  Education
-  Equity, Diversity and Inclusion
-  Financing and resources
-  Methods
-  Strategic partnerships
-  ~~Strategic partnerships~~
Functioning

Websites

<https://rehabilitation.cochrane.org/>

<https://www.cochrane.org/about-us/who-we-are/our-groups/rehabilitation-functioning-and-disability>

Email: cochranerehab@unimi.it



Cochrane

Rehabilitation, Functioning,
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Cochrane Rehabilitation Methodological Meetings

1. Paris 2018 (EJPRM) 10 papers
2. Kobe 2019 (AJPM&R) 6 papers
3. Milan 2020 (EJPRM) 6 papers
4. Orlando 2020 (AJPM&R, APM&R, EJPRM) 12 papers
5. Milan 2023 (EJPRM) 10 papers



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Cochrane

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Evidence & rehab

What is rehabilitation?

What's new and what's ahead

Trusted evidence.
Informed decisions.
Better health.



What is rehabilitation

The term “rehabilitation” is used in fields ranging from architecture to correctional facilities to health.

In health it can refer to various aspects

- one of the five **core strategies** for achieving and maintaining population health, alongside promotion, prevention, treatment, and palliation;
- an essential **service** for universal health coverage;
- a **field** that encompasses multiple rehabilitation professionals, including physical and rehabilitation medicine physicians and other medical specialists
- a specific **intervention**.



SPECIAL ARTICLE

Rehabilitation definition for research purposes. A global stakeholders' initiative by Cochrane Rehabilitation

Stefano NEGRINI ^{1, 2}, Melissa SELB ^{3, 4}, Carlote KIEKENS ^{5 *},
Alex TODHUNTER-BROWN ⁶, Chiara ARIENTI ⁷, Gerold STUCKI ^{3, 4, 8},
Thorsten MEYER ⁹, 3rd Cochrane Rehabilitation Methodology Meeting participants[‡]

¹Department of Biomedical, Surgical and Dental Sciences, University "La Statale," Milan, Italy; ²IRCCS Istituto Ortopedico Galeazzi, Milan, Italy; ³Swiss Paraplegic Research, Nottwil, Switzerland; ⁴Swiss Paraplegic Research, Nottwil, Switzerland; ⁵Nursing Midwifery and Allied Health Professions, Fondazione Don Carlo Gnocchi, Milan, Italy; ⁶Department of Public Health, Bielefeld University, Germany

[‡]Members are listed at the end of the paper

ORIGINAL RESEARCH ARTICLE

Rehabilitation Definition for Research Purposes A Global Stakeholders' Initiative by Cochrane Rehabilitation

Stefano Negrini, MD, Melissa Selb, MSc, Carlote Kiekens, MD, Alex Todhunter-Brown, PhD, BSc(Hons), Chiara Arienti, MSc, PhD, DO, Gerold Stucki, MD, MS, Thorsten Meyer, PhD, and 3rd Cochrane Rehabilitation Methodology Meeting participants

Objective: Since its foundation, Cochrane Rehabilitation has faced challenges with rehabilitation definitions because existing definitions did not indicate what rehabilitation includes and what it excludes. We aimed to develop a comprehensive and shared rehabilitation definition for research purposes to: (1) support the conduct of primary studies and systematic reviews and (2) identify relevant systematic reviews for knowledge translation purposes.

Design: We performed a multimodal study including seven preliminary research and discussion papers, four Consensus Meetings, and three Delphi rounds with 80 rehabilitation stakeholders. The Delphi Study aimed to obtain agreement and refine and complete the items composing the definition and meanings of rehabilitation. These stakeholders covered 5 continents, representing 11 global and continental rehabilitation organizations, 11 scientific journals, 4 Cochrane Networks, and 3 Cochrane Groups and included invited experts and representatives of rehabilitation stakeholders.

What Is Known

- Existing rehabilitation definitions do not indicate what rehabilitation includes and what it excludes, leading to methodological heterogeneity in both primary and secondary scientific literature.

What Is New

- This publication proposes a rehabilitation definition for research purposes, supported by a broad agreement among global stakeholders. This definition provides explicit criteria to define rehabilitation and allows to improve rehabilitation research by standardizing the description of interventions.

Rehabilitation Definition for Research Purposes. A Global Stakeholders' Initiative by Cochrane Rehabilitation

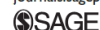
Stefano Negrini, MD^{1,2}, Melissa Selb, MSc^{3,4}, Carlote Kiekens, MD⁵, Alex Todhunter-Brown, PhD, BSc⁶, Chiara Arienti, MSc, PhD, DO⁷, Gerold Stucki, MD, MS^{3,4,8}, Thorsten Meyer, PhD⁹, and 3rd Cochrane Rehabilitation Methodology Meeting participants[‡]



Neurorehabilitation and
Neural Repair
2022, Vol. 36(7) 405-414
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Methods

Design: **mixed methods study** including:

- 7 preliminary research and discussion papers,
- 3 Delphi surveys
- 4 Consensus meetings

80 rehabilitation stakeholders from the 5 continents:

- 11 global and continental rehabilitation organizations (scientific and professional societies),
- 11 scientific journals,
- 4 Cochrane Networks
- 3 Cochrane Groups,
- invited experts,
- representatives of low middle-income countries (LMICs) and consumers.

The definition (PICO + ICF)

In a health care context rehabilitation is a

(intervention - general)

- multimodal person-centered collaborative process

(intervention - specific)

- including interventions targeting a person's capacity (by addressing body structures, functions, and activities/participation) and/or contextual factors related to performance

(outcome)

- with the goal of optimizing functioning

(population)

- of persons with health conditions currently experiencing disability or likely to experience disability, or persons with disability

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European Journal of Physical and Rehabilitation Medicine 2022 June;58(3):333-41
DOI: 10.23736/S1973-9087.22.07509-8

SPECIAL ARTICLE

Rehabilitation definition for research purposes. A global stakeholders' initiative by Cochrane Rehabilitation

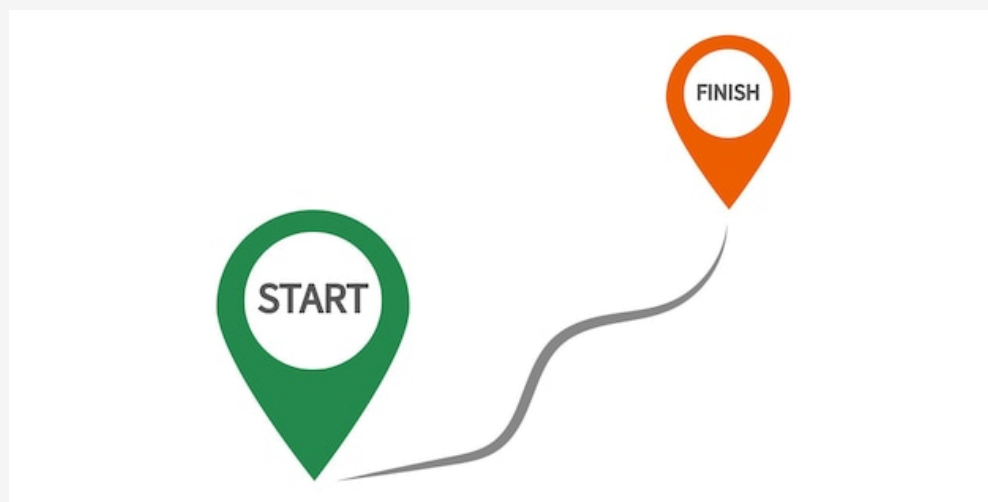
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[†]Members are listed at the end of the paper

Process (Intervention – general)

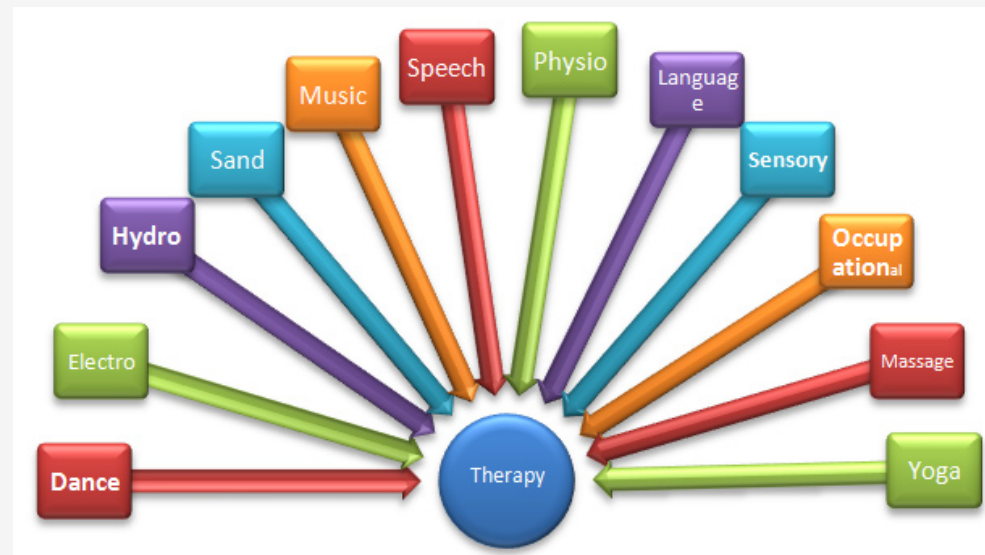
The process includes one or more consecutive rehabilitation cycles (assessment including goal setting, assignment, interventions, evaluation and repetition if needed) until the optimisation of functioning - commonly referred to as the Rehab-Cycle.



Multimodal (Intervention – general)

Application of

- more than one intervention or
- one intervention with more than one component



Person-centered (Intervention – general)

Interventions are

- selected and tailored to an individual's needs and engagement,
- building on and strengthening the resources of the person,
- taking into account the person's values, preferences and contextual factors



Collaborative (Intervention – general)

Participation of

- the person(s) **providing** the interventions and
- the person(s) **engaged** in rehabilitation.

The degree of participation and the participants vary according to the

- health condition(s),
- rehabilitation phase (acute, post-acute, chronic), and
- contextual factors, including setting(s) (inpatient, outpatient, home, community).

Participation of the person(s) engaged in rehabilitation can be absent at early stages but must gradually develop during the individual continuum of care (rehabilitation process).



Intervention - specific

specific

Capacity (by addressing body structures, functions, and activities/participation)

- What a person can do with limited or no influence of environmental factors

Contextual factors related to performance

- Contextual factors include
 - personal (that influence how the individual experiences disability) and
 - environmental (the physical, social and attitudinal environment in which people live and conduct their lives) factors
- that influence performance (what a person with a health condition does in their usual environment)

Outcome

Optimising

- Improving or maintaining or limiting decline (changing trajectory in terms of deceleration and/or duration) in comparison to the expected (natural) course

Functioning

- Functioning is an umbrella term for body structures and functions, activities and participation



Population



Persons with health conditions: Health conditions include illnesses, injuries and also physiological changes (for example, associated with ageing or pregnancy) that affect health and functioning

- **Currently experiencing disability:** Persons with an impairment(s), activity limitation(s) or participation restriction(s) with potential for resolution of the condition or improvement of functioning
- **Likely to experience disability:** Probability of disability due to worsening of the health condition or contextual factors, and with a potential for prevention or reduction
- **Persons with disability:** Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others (United Nations Convention on the Rights of Persons with Disabilities - UNCRPD), with a potential to avoid or limit decline or optimise functioning

Multimodal



Process



Process



ne
on, Functioning,
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Person-centred



Collaborative



Consequences of avoiding circular arguments like rehabilitation is what rehabilitation professionals do

1. **Not all of what is done by rehabilitation professionals is rehabilitation:** they can propose
 1. **Stand-alone** single interventions
 - Usually performed within the rehabilitation process
 - Not usually performed within the rehabilitation process
 2. Multimodal interventions but **without process/personalization/collaboration**
2. **Rehabilitation can also be practiced by others who are not rehabilitation professionals**

Rehabilitation is a complex intervention

What makes an intervention complex

Intervention characteristics

- **Multiple components**
- **Multiple people involved**
- **Multiple settings**
- **Multiple outcome targets**
- **Required behaviour change**
 - Knowledge and skills of health professional
 - Ability and engagement of patient or other stakeholders (e.g. family)

Context characteristics:

- **Interaction between intervention and context**
- **Influence of context over interventions**



How to study a complex intervention

RESEARCH METHODS AND REPORTING

OPEN ACCESS

Check for updates

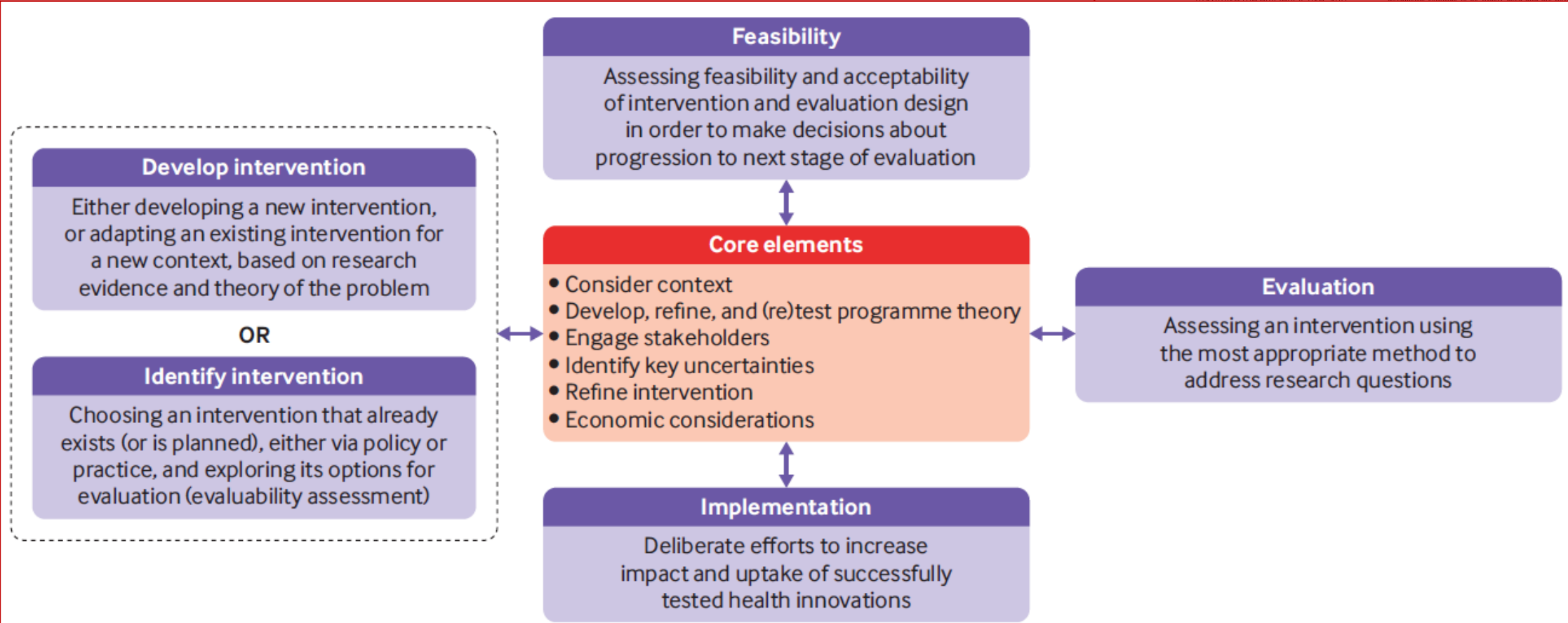
A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance

Kathryn Skivington,¹ Lynsay Matthews,¹ Sharon Anne Simpson,¹ Peter Craig,¹ Janis Baird,² Jane M Blazeby,³ Kathleen Anne Boyd,⁴ Neil Craig,⁵ David P French,⁶ Emma McIntosh,⁴ Mark Petticrew,⁷ Jo Rycroft-Malone,⁸ Martin White,⁹ Laurence Moore¹

For numbered affiliations see end of the article.
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Cite this as: BMJ 2021;374:n2064.
<http://dx.doi.org/10.1136/bmj.n2064>
Accepted: 9 August 2021

The UK Medical Research Council's widely used guidance for developing and evaluating complex interventions has been replaced by a new framework, commissioned jointly by the Medical Research Council and the National Institute for Health Research, which takes account of recent developments in theory and methods and the need to maximise the efficiency, use, and

Complex interventions are commonly used in the health and social care services, public health practice, and other areas of social and economic policy that have consequences for health. Such interventions are delivered and evaluated at different levels, from individual to societal levels. Examples include a new surgical procedure, the redesign of a healthcare programme, and a change in welfare policy. The UK Medical Research Council (MRC) published a framework for researchers and research funders on developing and evaluating complex interventions in 2000 and revised guidance in 2006.^{1,2} Although these documents continue to be widely used and are now



Long-term consequences of a definition

It can bring **clarity**, structure, and progress to a field or discussion

It also carries the risk of oversimplification, **rigidity**, and controversy.

Impacts:

- Understanding
- Research and Policy
- Societal and Cultural Effects
- Education
- Institutional and Discursive Lock-In
- Potential for Conflict or Re-Evaluation

Importance of definitions in rehabilitation

From the **ICIDH** (1980)

- Impairment
- Disability
- Handicap

From the **ICF** (2001)

- Functioning
- Health condition
- Contextual factors
- Capacity
- Performance



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Opening the Black Box of rehabilitation

The GUieline for Intervention DEscription
in Rehabilitation (GUIDE-Rehab)

Trusted evidence.
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Better health.



The usual therapy «black box»

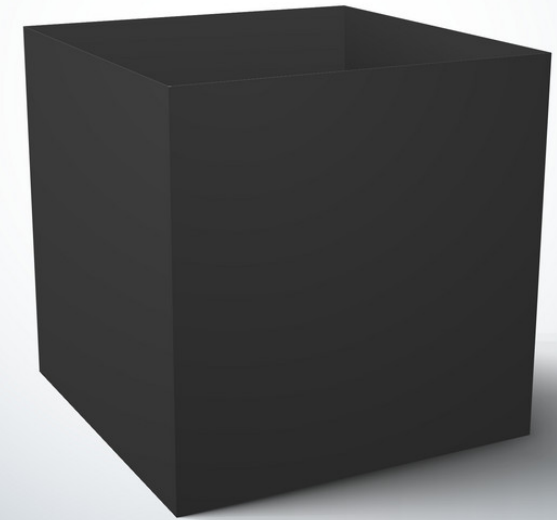
Methods

- Systematic Review
- **Control group description**
- Rehabilitation RCTs
- **Lower limb after stroke**
- No time limitations

Results

- 155 papers (out of 4850)
- **2% provided an intervention according to specific guidelines**
- **7% proposed at least twice the same “usual care” (1.3% between four and five times)**
- 25% of the articles did not describe the Control Group (11.6% indicated the professionals involved)
- 68% proposed different "usual cares"

**BLACK
BOX**



It is not «black box», but a «black hole»

TABLE IV.—Adjectives and nouns utilized within the articles.

#	Adjective	N.	%	#	Noun	N.	%
1	Conventional	96	49.23%	1	Physical therapy/physiotherapy	63	32.14%
2	Standard	23	11.79%	2	Care	18	9.18%
3	Routine	22	11.28%	3	Rehabilitation	17	8.67%
4	Usual	17	8.72%	4	Therapy	17	8.67%
5	General	10	5.13%	5	Rehabilitation program/programs/programme	9	4.59%
6	Regular	10	5.13%	6	Rehabilitation therapy	7	3.57%
7	Traditional	8	4.10%	7	Training	6	3.06%
8	Basic	3	1.54%	8	Treatment	6	3.06%
9	Common	1	0.51%	9	Rehabilitation training	4	2.04%
10	Comprehensive	1	0.51%	10	Rehabilitation treatment	4	2.04%
11	Daily	1	0.51%	11	Stroke rehabilitation	4	2.04%
12	Functional	1	0.51%	12	Stroke rehabilitation program/programme	4	2.04%
13	Standardized	1	0.51%	13	Exercise program	3	1.53%
				14	Physical therapy/physiotherapy program/programme	3	1.53%
				15	Exercise therapy	2	1.02%
				16	Outpatient rehabilitation	2	1.02%
				17	Rehabilitation techniques	2	1.02%
				18	Care physiotherapy	1	0.51%
				19	Gait training program	1	0.51%
				20	Hemiplegia rehabilitation therapy	1	0.51%
				21	Inpatient rehabilitation therapy	1	0.51%
				22	Inpatient stroke rehabilitation program	1	0.51%
				23	Intervention	1	0.51%
				24	Motor therapy	1	0.51%
				25	Multidisciplinary rehabilitation program	1	0.51%
				26	Multidisciplinary stroke rehabilitation	1	0.51%
				27	Neurological care	1	0.51%
				28	Neurorehabilitation	1	0.51%
				29	Nursing model	1	0.51%
				30	Outpatient physical therapy	1	0.51%
				31	Physical therapy care	1	0.51%
				32	Physical therapy exercises	1	0.51%
				33	Physiotherapy based on clinical practice guidelines for stroke patients	1	0.51%
				34	Physiotherapy protocol	1	0.51%
				35	PT gait training	1	0.51%
				36	Rehabilitation care	1	0.51%
				37	Stroke physical therapy	1	0.51%
				38	Stroke rehabilitation care	1	0.51%
				39	Stroke rehabilitation therapy	1	0.51%
				40	Therapeutic program	1	0.51%
				41	Treatment exercise program	1	0.51%
				42	Treatment methods	1	0.51%
Total		194	100%			195	100%

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European Journal of Physical and Rehabilitation Medicine 2022 August;58(4):520-9
DOI: 10.23736/S1973-9087.22.07413-5

SYSTEMATIC REVIEW

A systematic review opens the black box of “usual care” in stroke rehabilitation control groups and finds a black hole

Chiara ARIENTI ¹, Riccardo BURASCHI ^{1 *}, Joel POLLET ¹, Stefano G. LAZZARINI ¹,
Claudio CORDANI ², Stefano NEGRINI ^{2,3}, Massimiliano GOBBO ⁴


¹IRCCS Fondazione Don Carlo Gnocchi, Milan, Italy; ²IRCCS Istituto Ortopedico Galeazzi, Milan, Italy; ³Department of Biomedical, Surgical and Dental Sciences, La Statale University, Milan, Italy; ⁴Department of Clinical and Experimental Sciences, University of Brescia, Brescia, Italy




Let's open the box!



Reporting Guidelines



Enhancing the QUALity and Transparency Of health Research


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CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

Reporting guideline provided for?
(i.e. exactly what the authors state in the paper)

Parallel group randomised trials


Please note that the CONSORT website is currently unavailable. To access the checklists via the original published paper please follow the PubMed links in the full bibliographic reference section of this web page. Or via the GoodReports website at <https://www.goodreports.org/reporting-checklists/consort/>

[CONSORT checklist \(Word\)](#) [CONSORT flow diagram \(Word\)](#)



Reporting guidelines for main study types

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



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Rehabilitation, Functioning, and Disability

Methods

EQUATOR Network's guidance

Design: **mixed methods study** including

- 21 preliminary research and discussion papers,
- 1 Delphi survey: **69 global experts**
- 2 Consensus meetings

Starting points

- TIDieR,
- Rehabilitation Treatment Specification System,
- Cochrane Rehabilitation definition of rehabilitation for research purposes.

Large piloting

- 17 journals' chief editors,
- 7 clinical groups,
- 8 international meetings' participants

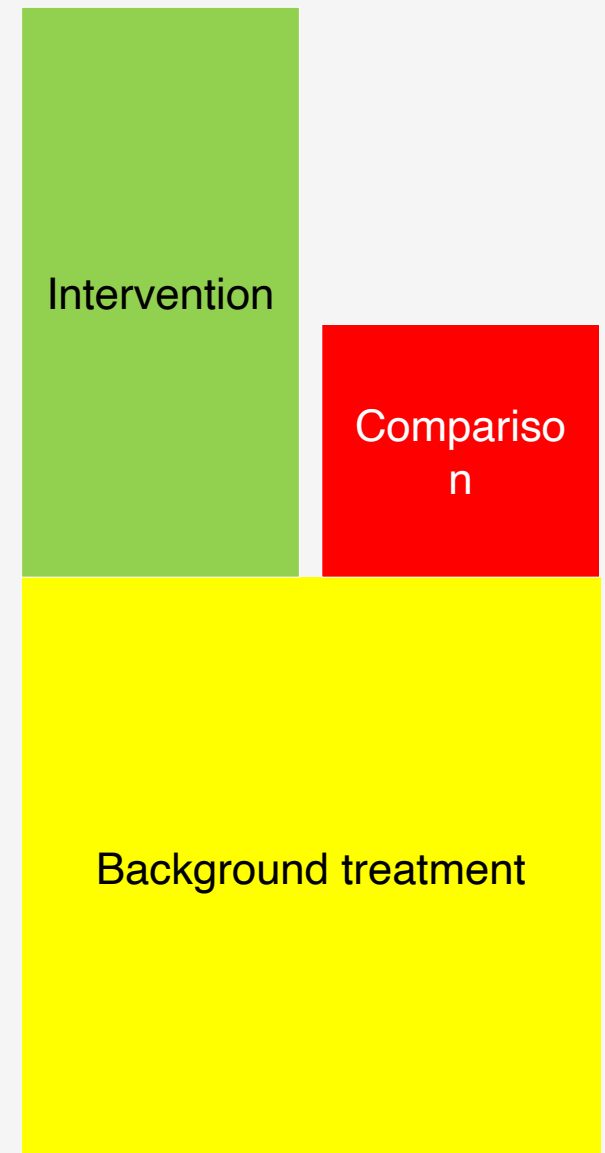
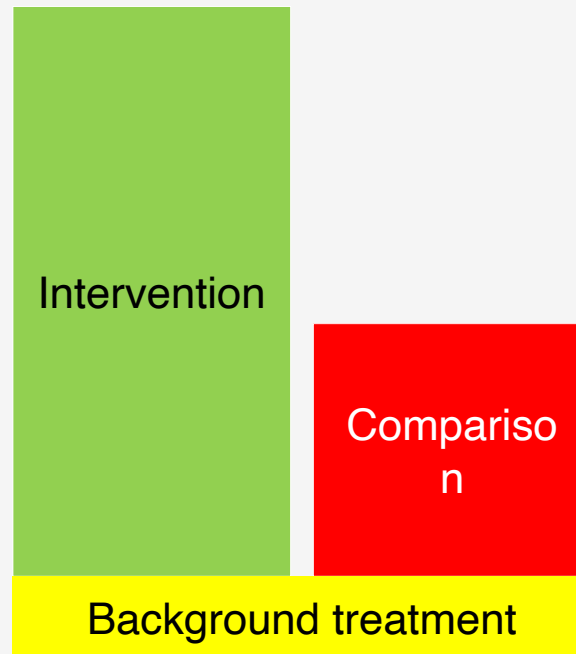
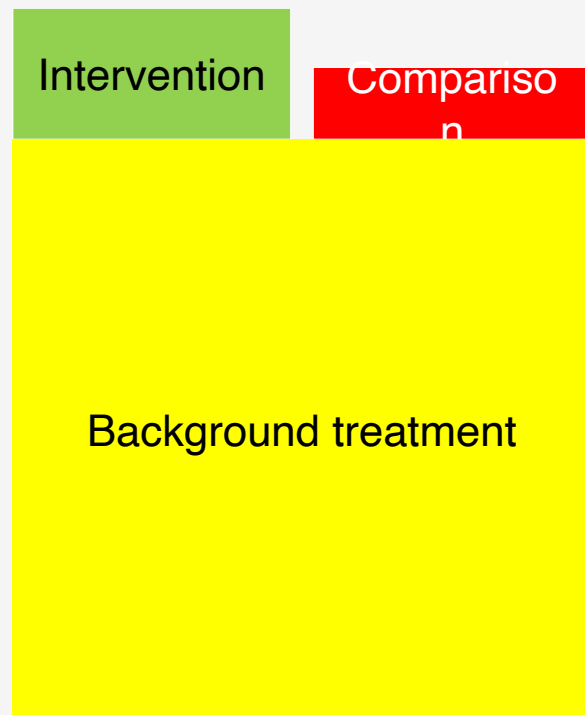
GUIDE-Rehab items

	ITEM
	Abstract, introduction and title
1	Intervention type
	Material and Methods
2	Intervention theory
3	Intervention targets
4	Intervention components
5	Intervention rationale
6	Intervention ingredients and quantity
7	Tailoring
8	Quantity changes
9	Treatment fidelity optimisation and assessment

	ITEM
1	Comparator rationale
0	
1	Comparator description
1	
1	Sham comparator
2	
1	Background treatment
3	
	Results
1	Program modifications and fidelity
4	
	Discussion
1	Comparator, background treatment and

Background treatment

All interventions provided to all study participants (intervention and comparison)



Intervention

Intervention components

Intervention

Intervention theory

Interventions target (needs a measurable outcome)	Intervention component 1	Component theory
Interventions target (needs a measurable outcome)	Intervention component 2	Component theory
Interventions target (needs a measurable outcome)	Intervention component N	Component theory

Intervention ingredients			
Active ingredient 1	Quantity	Tailoring	Quantity changes
Active ingredient 2	Quantity	Tailoring	Quantity changes
Active ingredient N	Quantity	Tailoring	Quantity changes
Active ingredient 1	Quantity	Tailoring	Quantity changes
Active ingredient 2	Quantity	Tailoring	Quantity changes
Active ingredient N	Quantity	Tailoring	Quantity changes
Active ingredient 1	Quantity	Tailoring	Quantity changes
Active ingredient 2	Quantity	Tailoring	Quantity changes
Active ingredient N	Quantity	Tailoring	Quantity changes

To reduce complexity and confounders, we usually perform research on single interventions

Education

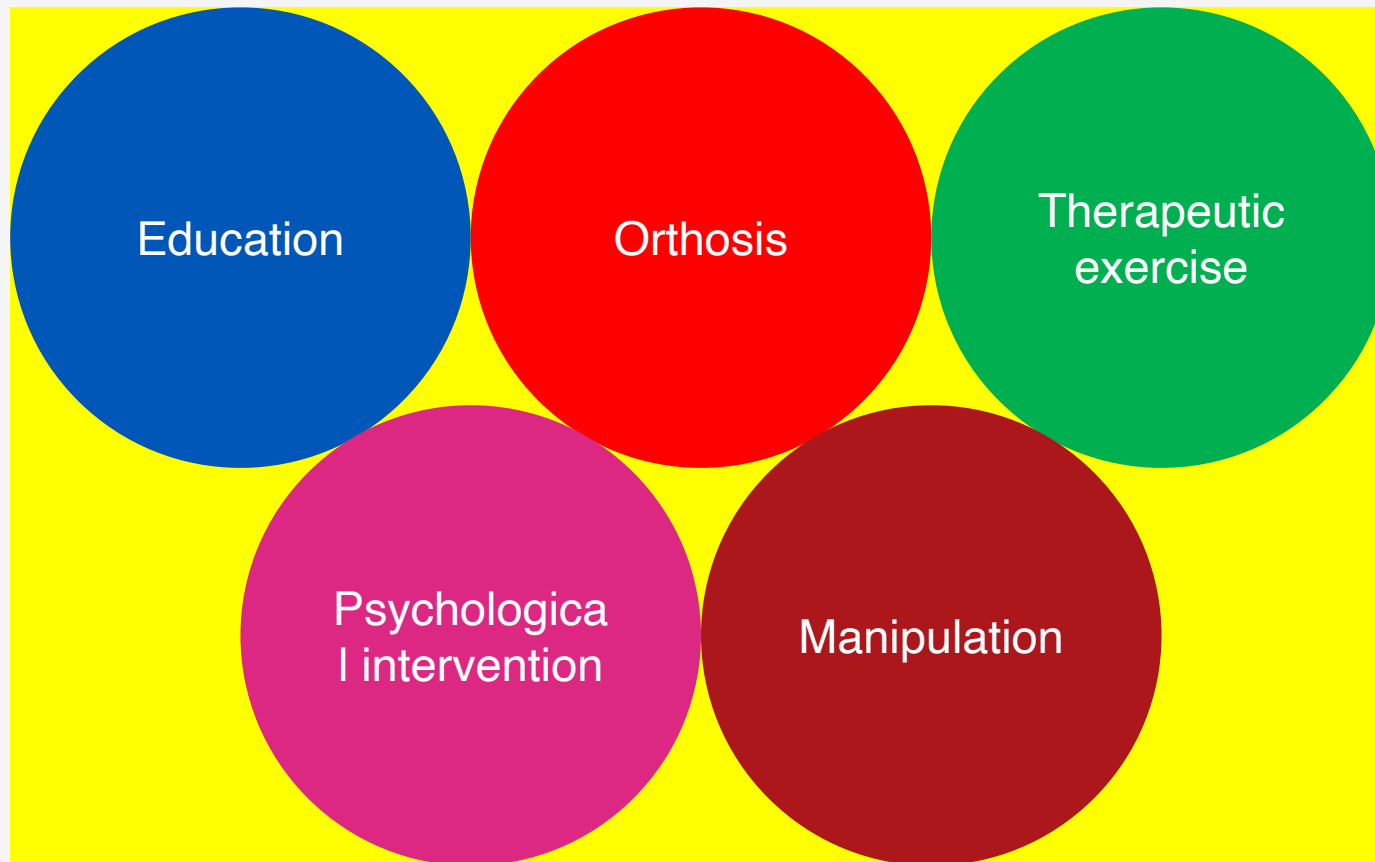
Orthosis

Therapeutic
exercise

Psychological
intervention

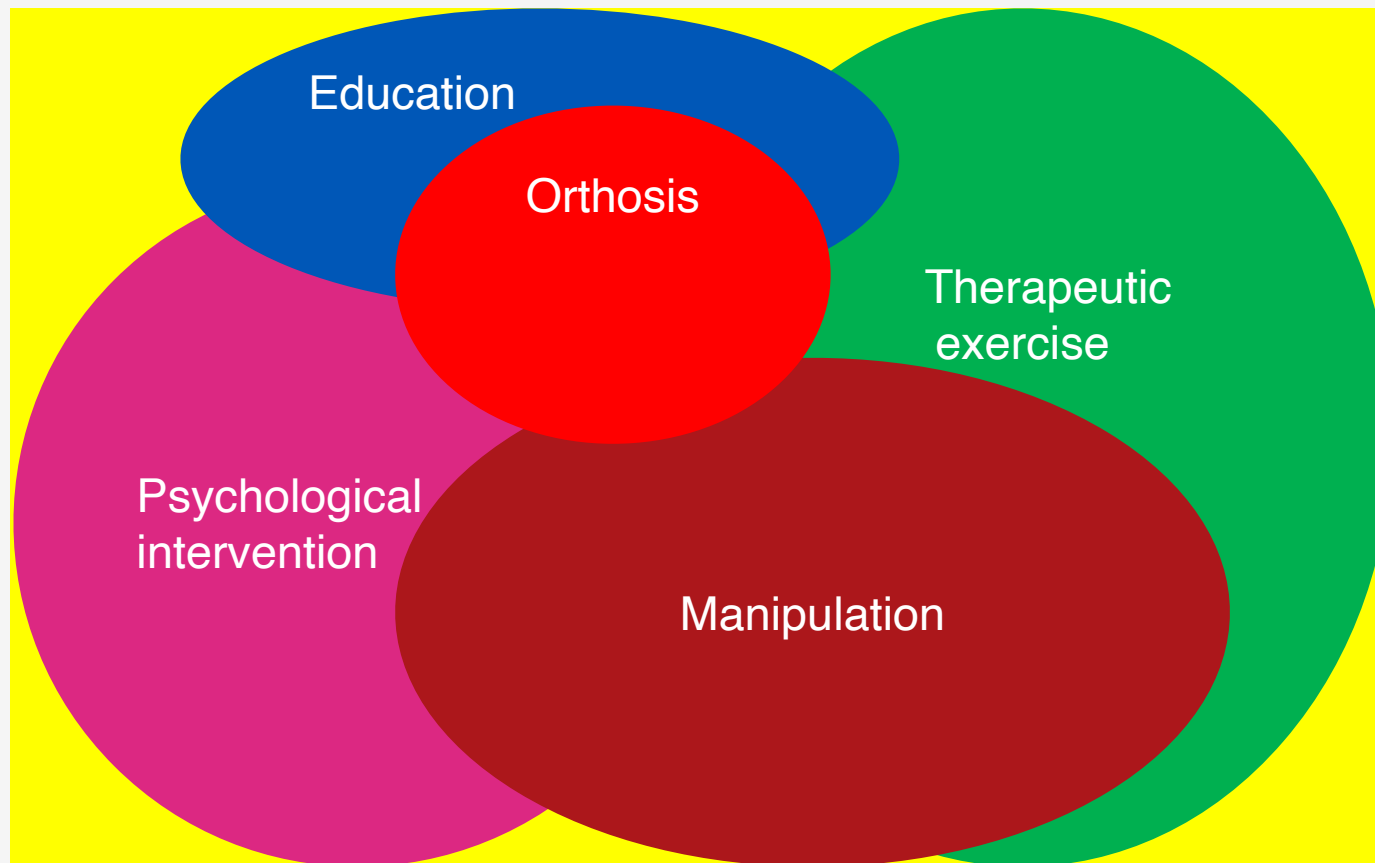
Manipulation

While research is usually done on single interventions,
complex interventions **are NOT** the sum of single interventions

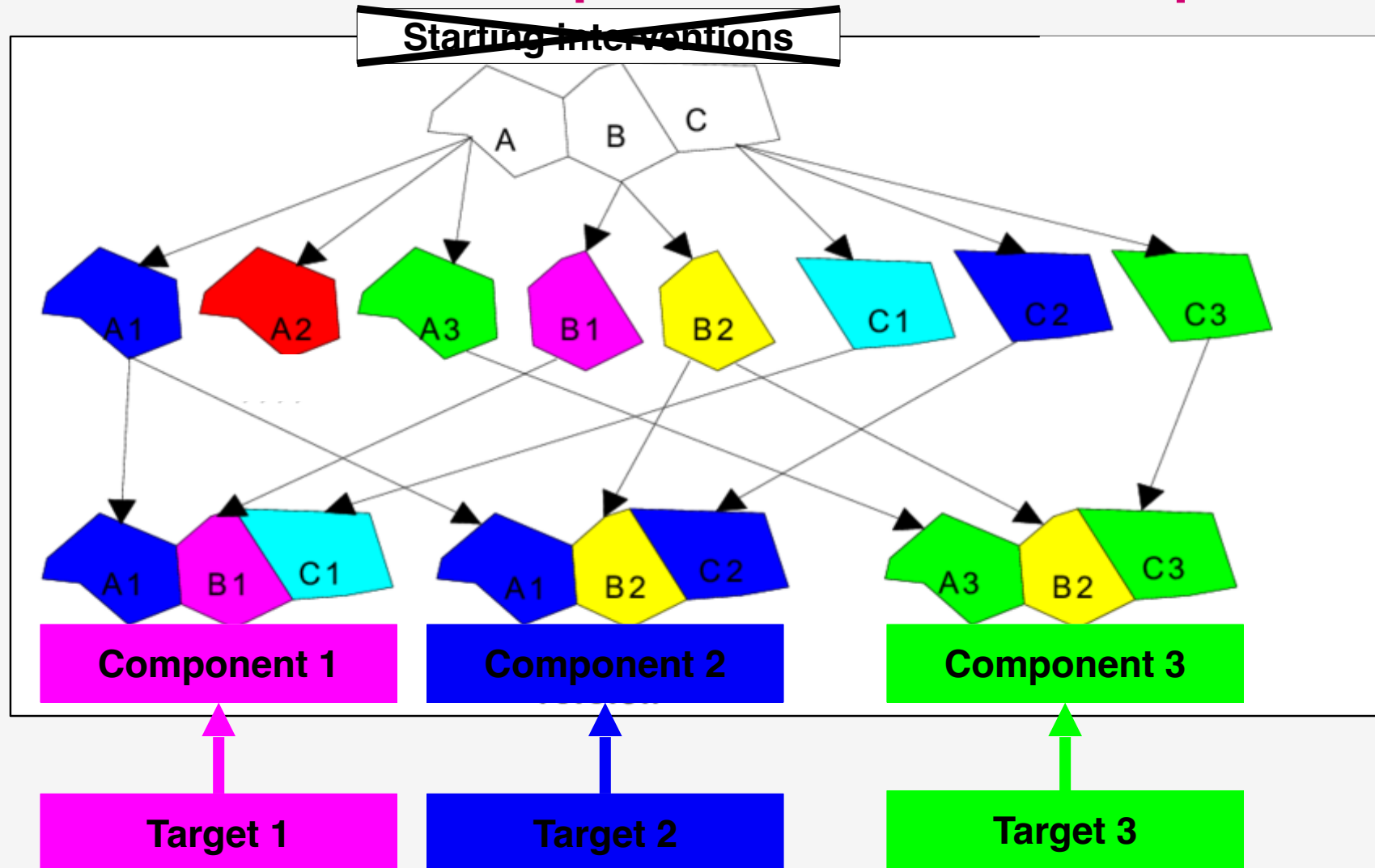


In the «real world» clinical life

Complex interventions **are** an **interaction** between single interventions



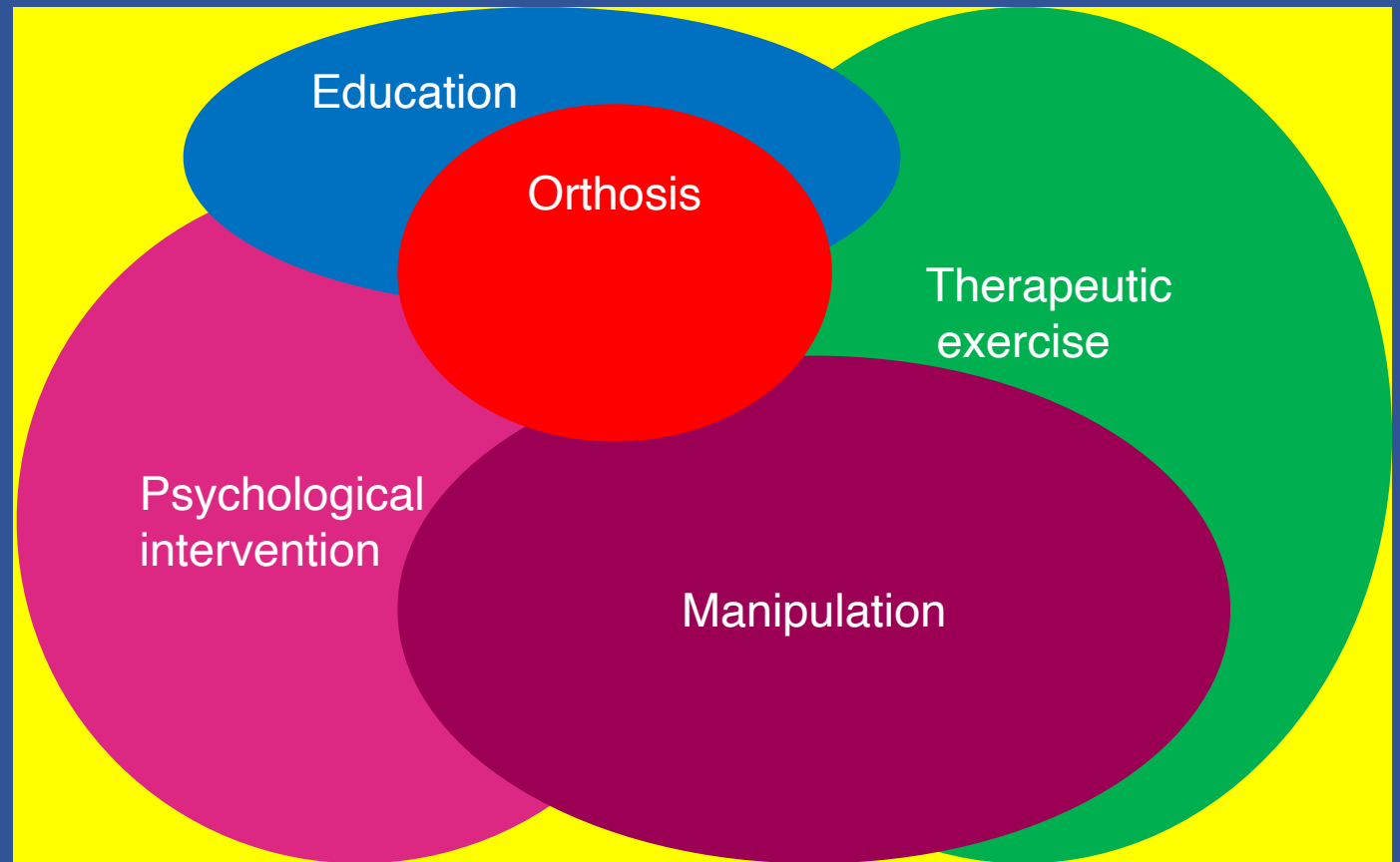
GUIDE-Rehab proposes to unpack the simple interventions and repack them in the complex intervention



Intervention

Intervention

Intervention
theory



BRACING rehabilitation treatment

It includes:

- Brace
- Exercises
- Cognitive-behavioural and psychological approach
- Sport activities
- Adapted therapeutic environment

Intervention theory

Braces mechanically immediately improve the pathological curve and change the asymmetrical compression of the vertebrae. Their use till bone maturity possibly allows vertebrae corrective remodelling. Maximal correction is achieved in the first months of treatment - the remaining treatment focuses on keeping the correction.

Exercises and gradual brace weaning (to gradually adapt the trunk and spine to doffing without losing correction) play a major role in maintaining the results. Gradual brace weaning also provides a rewarding system (brace reduction at each consultation) to keep compliance. Exercises also reduce the braces side-effects, including reduction of the anti-gravity neuromuscular trunk capacity and spine rigidity. Exercises also increase the patient's counter-scoliosis neuromotor capacity (reduction of the postural collapse on the deformity).

A **cognitive-behavioural approach, motivational tools, adapted therapeutic environment and psychological support** help keeping well-being and quality of life and allow patients to achieve the best adherence possible.

Physical activities (and sports) potentiate the other treatments' effects and have psychological value.

Intervention

Intervention components

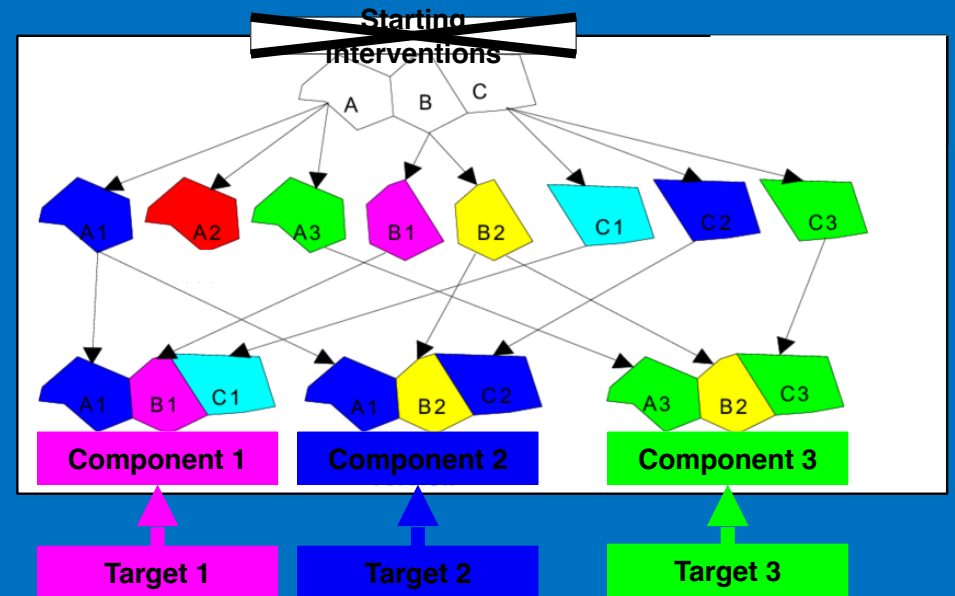
Interventions
target (needs a
measurable
outcome)

**Intervention
component 1**

**Component
theory**

Intervention

Intervention
theory



Targets, components and measures

Spinal three-dimensional osteo-ligamentous deformity

- Interventions to reduce scoliosis: maximal possible reduction
 - Difference in Cobb angle between pre-brace and in-brace radiographs

Spine support system (neuro-musculo-skeletal and ligamentous)

- Interventions to stabilise scoliosis: maintenance of the achieved correction
 - Difference in Cobb angle between out-of-brace and the pre-brace radiographs

Trunk deformity

- Interventions to improve aesthetics
 - Trunk Aesthetic Clinical Evaluation (TRACE) index

Restrictive pulmonary syndrome and aerobic capacity

- Interventions to prevent the restrictive syndrome and improve aerobic capacity
 - Vital capacity and VO2 max

Adherence to treatment

- Interventions to increase compliance
 - Brace compliancemeters (sensors)

Appropriate psychological development during growth, well-being and quality of life

- Interventions to allow appropriate psychological development during growth, well-being and quality of life
 - ISYQOL and SRS-22 questionnaires

Intervention

Intervention components

Interventions target (needs a measurable outcome)

Intervention component 1

Component theory

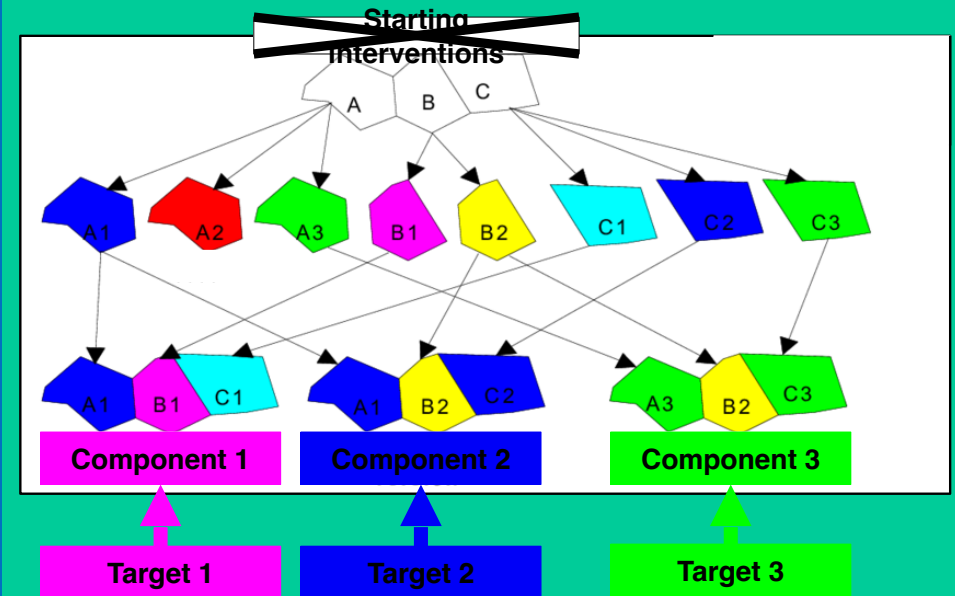
Intervention ingredients

Active ingredient 1

Quantity

Tailoring

Quantity changes



Interventions to stabilise scoliosis: maintenance of the achieved correction

Prolonged **brace** wearing

Constant daily use of the brace

Gradual brace weaning

Active self-correction without external aids (including without the brace) taught by an expert physiotherapist

Stability **exercises** without the brace taught by an expert physiotherapist

Introduction of self-correction in everyday activities without the brace

Sports/Physical activity

Intervention

Intervention components

Intervention

Intervention theory

Interventions target (needs a measurable outcome)	Intervention component 1	Component theory
Interventions target (needs a measurable outcome)	Intervention component 2	Component theory
Interventions target (needs a measurable outcome)	Intervention component N	Component theory

Intervention ingredients			
Active ingredient 1	Quantity	Tailoring	Quantity changes
Active ingredient 2	Quantity	Tailoring	Quantity changes
Active ingredient N	Quantity	Tailoring	Quantity changes
Active ingredient 1	Quantity	Tailoring	Quantity changes
Active ingredient 2	Quantity	Tailoring	Quantity changes
Active ingredient N	Quantity	Tailoring	Quantity changes
Active ingredient 1	Quantity	Tailoring	Quantity changes
Active ingredient 2	Quantity	Tailoring	Quantity changes
Active ingredient N	Quantity	Tailoring	Quantity changes

What is the advantage?

You measure each component and check its efficacy

Spinal three-dimensional osteo-ligamentous deformity

- Interventions to reduce scoliosis: maximal possible reduction
 - Difference in Cobb angle between pre-brace and in-brace radiographs

Spine support system (neuro-musculo-skeletal and ligamentous)

- Interventions to stabilise scoliosis: maintenance of the achieved correction
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Appropriate psychological development during growth, well-being and quality of life

- Interventions to allow appropriate psychological development during growth, well-being and quality of life
 - ISYQOL and SRS-22 questionnaires

GUideline for Intervention DEscription in Rehabilitation (GUIDE-Rehab)

**Opening the black-box will revolutionize
the way we are studying and
implementing rehabilitation interventions**



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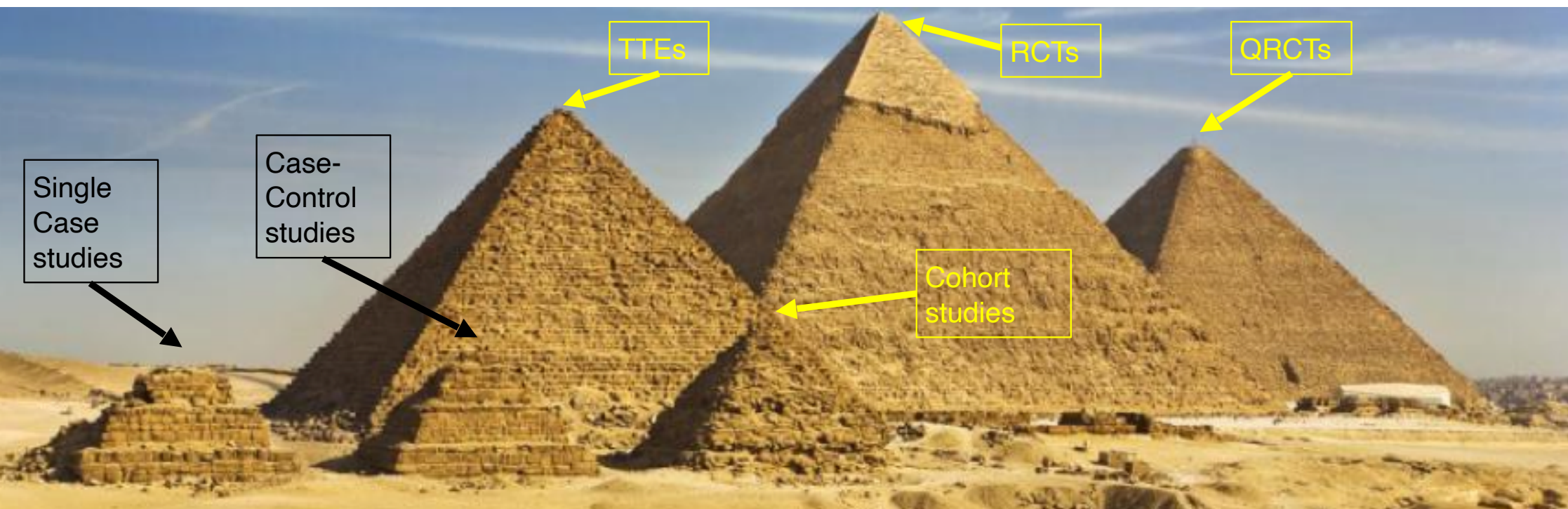


Other study designs for evidence in rehabilitation

Trusted evidence.
Informed decisions.
Better health.



The multiple Pyramids of Evidence in PRM



5th Cochrane Rehabilitation Methodological Meeting

Observational study designs

- IDEAL Framework
- Target Trial Emulation

Single Case Experimental Designs (SCEDs)

Randomised Controlled Trials (RCTs)

Qualitative studies

Complex intervention studies

Health services research studies





EDITORIAL

COCHRANE REHABILITATION CORNER 5th COCHRANE REHABILITATION METHODOLOGICAL MEETING

Improving the quality of evidence production in rehabilitation Results of the 5th Cochrane Rehabilitation Methodological Meeting

Stefano NEGRINI ^{1,2}, Carlotta KIEKENS ², William M. LEVACK ³, Thorsten MEYER-FEIL ⁴,
Chiara ARIENTI ^{5 *}, Pierre CÔTÉ ⁶, Participants in the 5th Cochrane Rehabilitation Methodological Meeting ‡

Arienti C, Armijo-Olivo S, Ferriero G, Feys P, Hoogeboom T, Kiekens C, Lazzarini SG, Minozzi S, Negrini S, Oral A, Pollini E, Puljak L, Todhunter-Brown A, Walshe M; Participants in the 5th Cochrane Rehabilitation Methodological Meeting. **The**

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epidemiological studies. Eur J Phys Rehabil Med. 2024 Feb;60(1):135-144. doi: 10.23736/S1973-9087.23.08310-7. Epub 2023 Dec 12. PMID: 38088137. [PubMed link](#)

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[PubMed link](#)

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Machalicek W, Gross DP, Armijo-Olivo S, Ferriero G, Kiekens C, Martin R, Walshe M, Negrini S; 5th Cochrane Rehabilitation Methodological Meeting participants.

The role of single case experimental designs in evidence creation in rehabilitation. Eur J Phys Rehabil Med. 2024 Oct 7. doi: 10.23736/S1973-9087.24.08713-6. Epub ahead of print. PMID: 39374052. [PubMed link](#)

- Qualitative research
- IDEAL Framework

Table of evidence production in rehabilitation

	Single intervention		Rehabilitation process
	Stand-alone	Within a complex intervention (rehab?)	
Hypothesis Generating studies	IDEAL Rehab Framework	Complex interventions MRC framework	
Hypothesis Checking studies (evidence)			
Rare situations (rare diseases, very expensive therapies, non-responders)	Single Case Experimental Designs	<ul style="list-style-type: none">Qualitative studies on contextprogramme theorystakeholdersuncertaintiesintervention refinementeconomic considerations	
RCTs not feasible (absent equipoise, costs, urgency, funding priorities, long term outcomes)	Target Trial Emulation		
Absent/rare/contradictory RCTs	RCT		
Absent/rare/contradictory Systematic Reviews	Systematic Review		
Implementation studies			

Other study designs for rehabilitation

**Rehabilitation research is mostly clinical,
but we need tools to implement strong
research methodologies and expand our
perspectives to HPSR**



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Evidence versus Real World Evidence

Trusted evidence.
Informed decisions.
Better health.



Observational Health Data Sciences and Informatics

Single center studies are limited by bias, lack of generalizability and variability, and inability to study rare conditions

Multicenter observational research could address many of those concerns; however, there are numerous **barriers** including regulatory issues, lack of common terminology, and variable data set structures.

The OHDSI uses the **Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM)** to standardize health care data into a **common language**, enabling consistent and reliable analysis.

Extensive suite of open-source tools for all research stages, from data extraction to statistical modelling

By **keeping sensitive data local** and only sharing summary statistics, OHDSI ensures compliance with privacy regulations while allowing for large-scale analyses.



[Topics](#)[More](#)[Categories](#)[General](#)[Implementers](#)[Developers](#)[Researchers](#)[CDM Builders](#)[All categories](#)[Tags](#)[cdm](#)[atlas](#)[vocabularies](#)[patientprediction](#)[webapi](#)

Observational Health Data Sciences and Informatics (OHDSI, pronounced “Odyssey”) is an international community of stakeholders committed to bringing out the value of health data through large-scale analytics. **If you are a new member-- Welcome! Tell us a bit about yourself on the General forum and let us know how we can help.** Learn more at www.ohdsi.org



New workgroup rehabilitation

General



Esther_Janssen

Dec 2023

Dear OHDSI colleagues,

If you are interested in working in rehabilitation¹ related research in the OHDSI community, please follow up here. We are interested in building a community working on data driven research in rehabilitation care. You can find a description of the working group and it's aims below. So please join us and let's work together!

Background

An increasing wealth of data on rehabilitation healthcare and a person's functioning is becoming available. These data are largely still unstructured and unavailable for large-scale analysis. Leveraging these data for international research can further personalize evidence-based rehabilitation care, for instance, by developing person-centered prediction and/or stratification models. However, there are major barriers to overcome before rehabilitation data can be used for big data analyses. The challenges stem from considerable heterogeneity within rehabilitation

Dec 2023

1 / 17

Dec 2023

Dec 2024

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Effects of Bracing in Adolescents with Idiopathic Scoliosis

Stuart L. Weinstein, M.D., Lori A. Dolan, Ph.D., James G. Wright, M.D., M.P.H., and Matthew B. Dobbs, M.D.

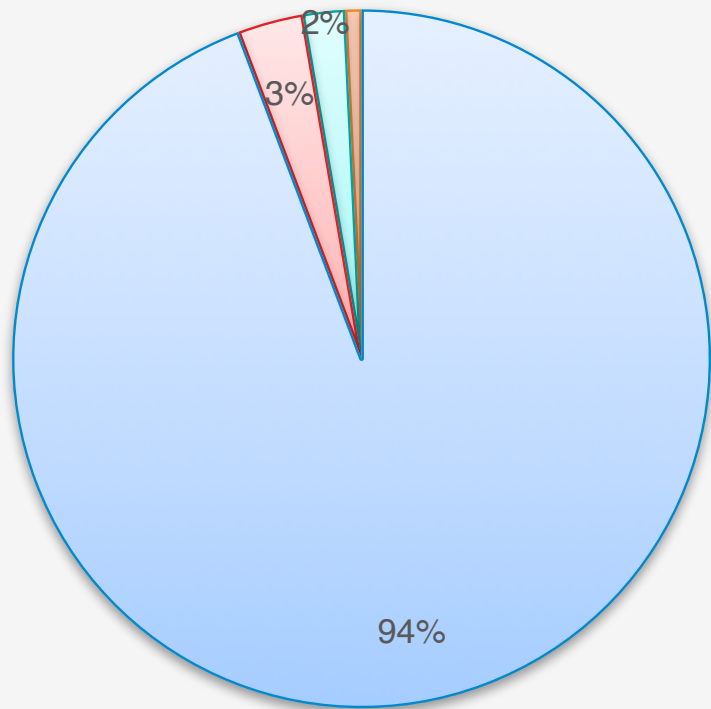
Journal of Clinical Medicine

Article

A Pragmatic Benchmarking Study of an Evidence-Based Personalised Approach in 1938 Adolescents with High-Risk Idiopathic Scoliosis

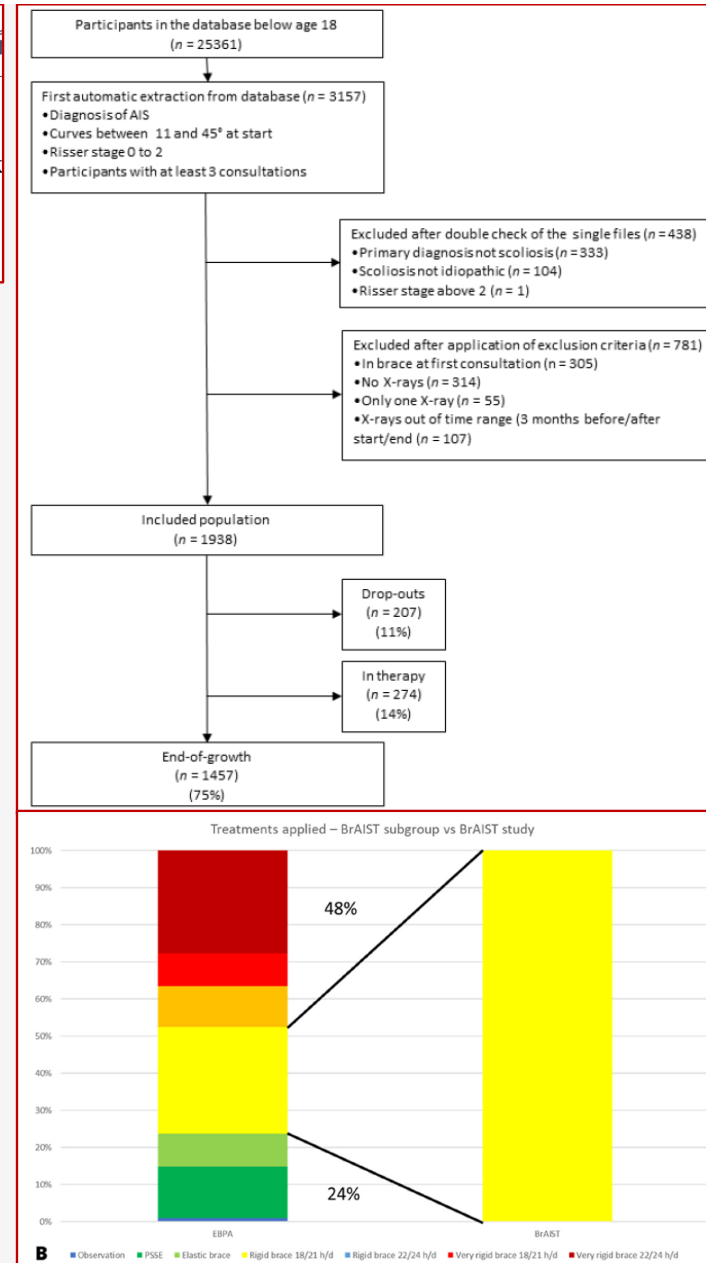
Stefano Negrini ^{1,2}, Sabrina Donzelli ³, Francesco Negrini ^{2,*}, Chiara Arienti ⁴, Fabio Zaina ³ and Koen Peers ^{5,6}

RCT vs real life



- Not studied
- Included in RCTs
- Included in bracing RCT
- Treated as in the RCT

Negrini S, Donzelli S, Negrini F, Arienti C, Zaina F, Peers K. **A Pragmatic Benchmarking Study of an Evidence-Based Personalised Approach in 1938 Adolescents with High-Risk Idiopathic Scoliosis.** J Clin Med. 2021 Oct 28;10(21):5020. doi: 10.3390/jcm10215020.



Artificial Intelligence and Big Data



Evidence vs Real World Evidence

There is no contradiction, they will both survive and provide different highly relevant information



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Take home messages

1. Is Evidence the future?
 - This is not granted at all, and we shall work for that as clinicians and scientists
2. The Rehabilitation definition and GUIDE-Rehab
 - We don't know how, but the future will be different because now we have a precise definitionEvidence vs Real World Evidence
3. Other study designs for rehabilitation
 - Rehabilitation research is mostly clinical, but we need tools to implement strong research methodologies and expand our perspectives to HPSR
4. Evidence vs Real World Evidence
 - There is no contradiction, both will survive and provide different relevant information



Cochrane

Rehabilitation, Functioning,
and Disability

European Organization for University Physical and Rehabilitation Medicine (**UniPRM**)

Call for **founding members**

- **Full** Professors of PRM – Grade A
- **Associate** Professors of PRM - Grade B
- **Prospective** Professors of PRM - Grade C
- University-affiliated Academics in PRM

UniversityPRM@gmail.com

UniPRM founding Executive: Negrini S, de Boissezon X, Gimigliano F, Arokoski J, Groleger Sršen K, Rummens F, Stam H, Stucki G, Picelli

UniPRM Founding Council: 38 countries – see map





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Rehabilitation, Functioning,
and Disability

Thank you!

Trusted evidence.
Informed decisions.
Better health.

