



RCTRaCk Project: RCTs in Rehabilitation Checklist

Trusted evidence.
Informed decisions.
Better health.

Education to research

Research financing

Epidemiologists

Study project

Study conducting
(judgement)

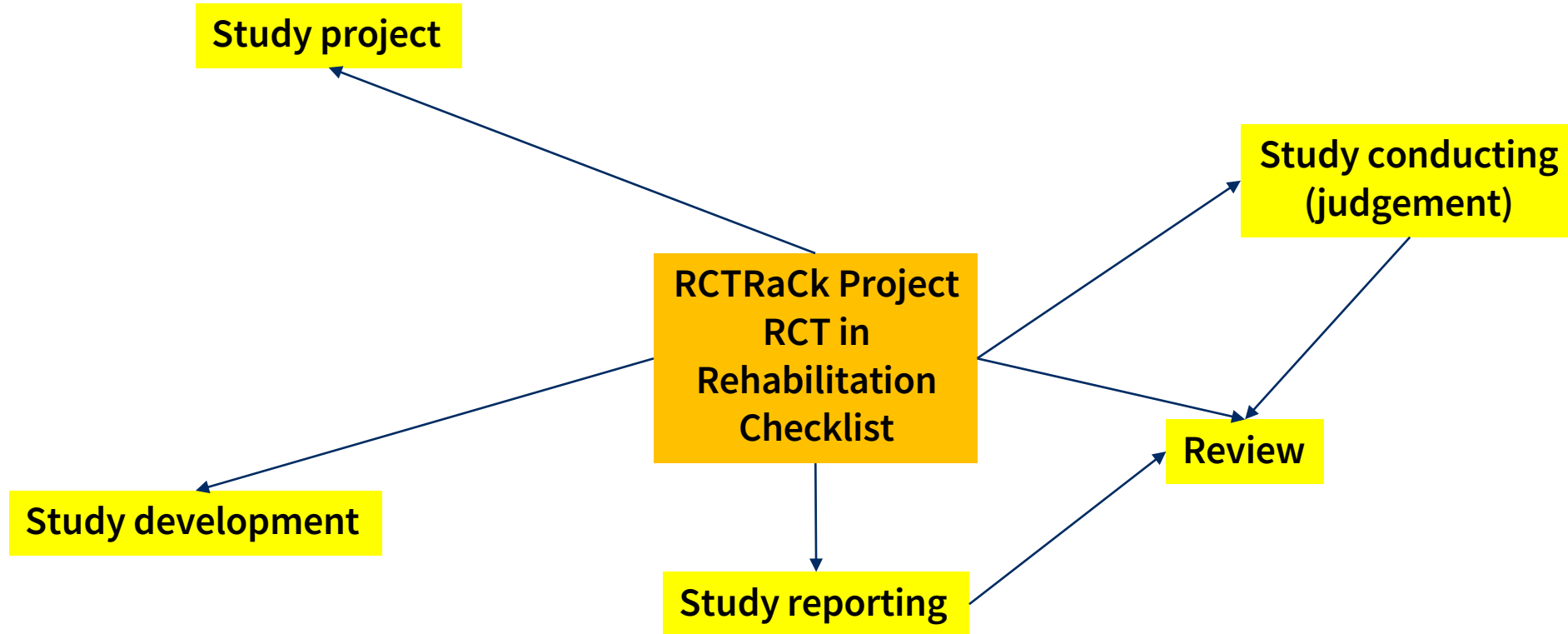
Review

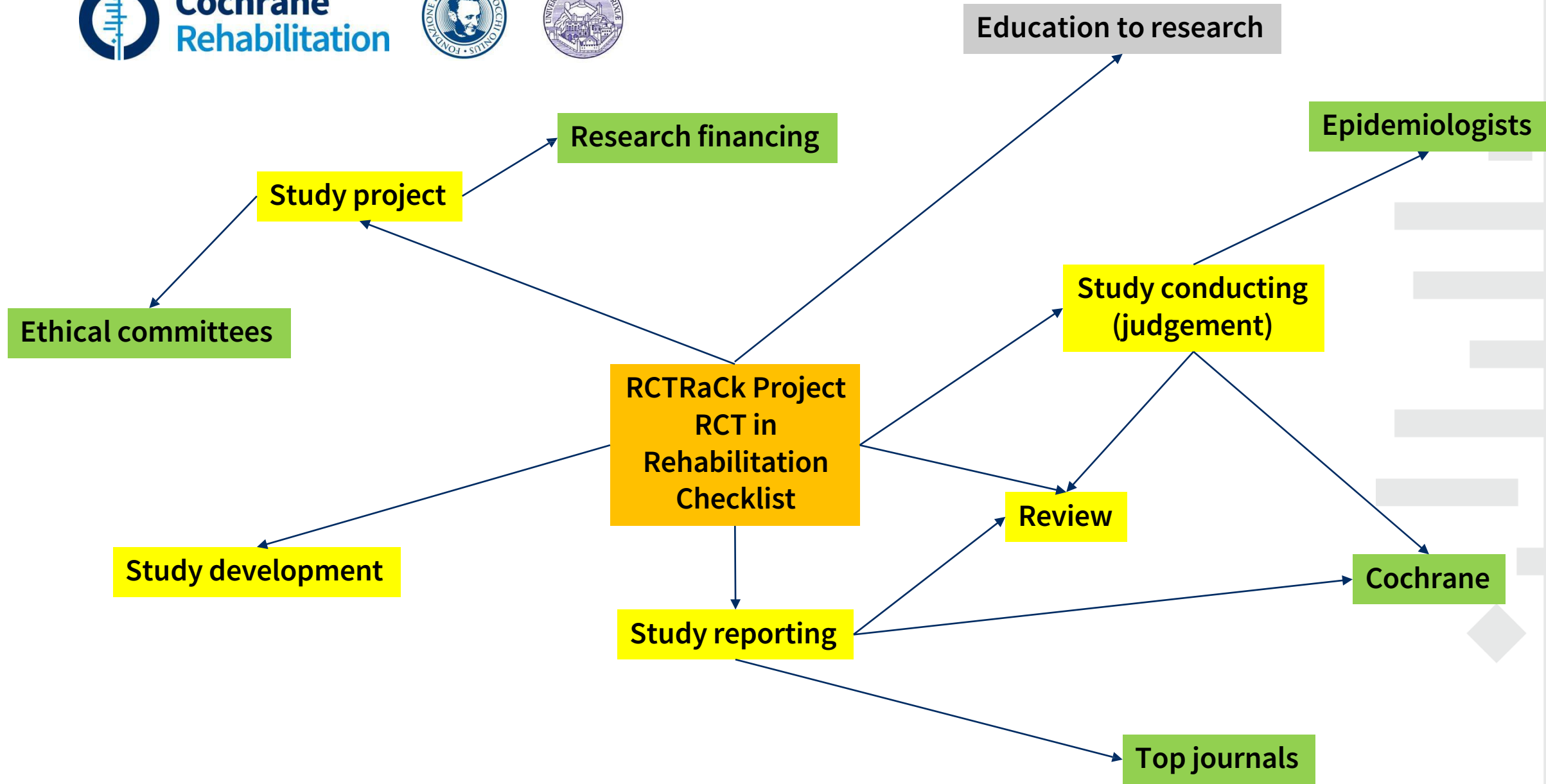
Study development

Study reporting

Cochrane







RCT Rehabilitation Checklist - RCTRaCk

To produce a **checklist of items** to be followed

- in the **reporting** of RCTs in rehabilitation
 - as an **add-on** (not substitution) to the **CONSORT Non-Pharmacological Treatment Studies checklist**
- in the **conduct** and **risk of bias evaluation** of RCTs in rehabilitation
 - as an **add-on** (not substitution) to the **Cochrane Risk of Bias tool**.

To identify **areas of methodological research** to fill gaps in the actual relevant knowledge – toward a constant development of the RCTRaCk



Preparation

Cochrane Rehabilitation **Methodology Meeting @ ISPRM 2018**

- Special Issue. Eur J Phys Rehabil Med. 2019 Jun;55(3): 319-410

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 Arch Phys Med Rehabil. 2021;102(8):1614-1622.e14.

Clinical replicability of rehabilitation interventions in Randomized Controlled Trials reported in main journals is inadequate

- Negrini S, et al. J Clin Epidemiol. 2019;114:108-117

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 Machalicheck (Usa)

Aydan Oral (Tur)

Melissa Selb (Swi)

Gerold Stucki (Swi)

Will Taylor (Nzl)

Susan Armijo-Olivo (Can)

Chiara Arienti (Ita)

RCTRaCk Executive Committee

Stefano Negrini (Ita)

Allen Heinemann (Usa)

Gert Kwakkel (Ned)

Wendy Machalicheck (Usa)

Antti Malmivaara (Fin)

Thorsten Meyer (Ger)

Gerold Stucki (Swi)

Susan Armijo-Olivo (Can)

Chiara Arienti (Ita)

Invited

- Walter Roura Frontera (Usa)

- Carlotte Kiekens (Bel)

- William Levack (Nzl)

- Will Taylor (Nzl)

Management

- Michele Patrini

- Stefano Giuseppe Lazzarini

- Roberta Bettinsoli



Topics to be focused

1. Patient selection (population)
2. Blinding
3. Treatment group
4. Control group & co-interventions
5. Attrition, follow up and protocol deviation
6. Outcomes
7. *[Statistical analysis]*
8. *[Generalities on research (design, question, effectiveness)]*
9. *[Appropriate randomization]*

Thorsten Mayer, Cecile Roe

Allen Heineman

John Whyte

William Levack

Wendy Machalicek, Susan Armijo-Olivo

Chiara Arienti

Technical Working Groups

Aim: identification of the item(s) to be added to the CONSORT Non-Pharmacological Treatments Guideline in the RCTRaCk checklist

Composition: Responsible and the team he/she will chose

- **Methods**

- **Systematic/scoping review** on the identified topic OUTSIDE the world of rehabilitation
- Proposal of the preliminary item(s) for the **draft version of the RCTRaCk**

- **Results**

- Presentation at the **Orlando 2020 Consensus Meeting** for general discussion
- **Publication** of the systematic/scoping review



Consensus Conference 2020 @ ISPRM Orlando

Participants

- RCTRaCk Executive Committee
- Chief-Editor of the Special issue (Tbd)

Technical Working Groups reporting:

- Presentation of systematic/scoping reviews
- Proposal of preliminary item(s) and relevant description

Definition of the preliminary items to be kept in the **draft RCTRaCk**



Consensus participants

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 of

- Papers on **methodology** in rehabilitation
- **Cochrane Reviews** relevant to rehabilitation
- **RCTs** published in rehabilitation journals



Delphi Rounds

Agreement/disagreement/ suggestions about the addition of 16 new items and 13 additional explanations to the CONSORT 2010

Thresholds

- >80% agreement: accept
- 40-80%: equipoise – further round
- <40% disagreement: reject



Delphi Rounds

First round: **refinement of items and descriptions**

- Suggestions and possible approval

Second round: **further refinement of items and descriptions**

- New version and approval

Third round: **final approval**

- Final approval

Agreement reached at the 1° round



RCTTRACK new items-explanations

16 new items to be added to the original CONSORT

- 1 in title section,
- 3 in the background section,
- 8 in the methods section,
- 4 in the results section

13 new additional explanations to existing CONSORT items that added further information or contextualized the item to the rehabilitation field.

- 1 in title section,
- 1 in the background section,
- 9 in the methods section,
- 2 in the results section

Final products

Publication

- Major medical/epidemiological journal
- Co-publication in all adhering rehabilitation journals

Manual

- Special issue of a rehabilitation journal

Presentations

- Main meetings worldwide by member of the Executive Committee

