UNIVERSITÀ DEGLI STUDI
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Scuola di Scienze Mediche e Farmaceutiche

Dipartimento di Neuroscienze, Riabilitazione, Oftalmologia, Genetica e Scienze Materno-Infantili

Master in Riabilitazione dei Disordini Muscoloscheletrici

A.A. 2022/2023

Campus Universitario di Savona

What is the therapeutic quality of exercise programs in chronic low back pain randomized controlled trials assessed by i-CONTENT tool? A meta research study

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Abstract

Background: Exercise therapy is a common intervention recommended for chronic low back pain (cLBP). Although adequate reporting of intervention is crucial to understand and replicate exercise therapy, it does not help clinicians to determine the therapeutic quality. So The international Consensus on Therapeutic Exercise aNd Training (i-CONTENT) tool was developed to assess therapeutic quality of exercise. Therefore, we assessed the therapeutic quality of different exercise interventions by i-CONTENT tool in cLBP RCTs.

Methods: We performed a meta-research study, starting from Cochrane review publication "Exercise therapy for chronic low back pain". We selected a random sample of 100 arms with different type of exercises included (i.e. Core Strengthening, General Strengthening, Stretching, Aerobic exercises, Motor Control, Pilates, McKenzie, Qigong, Yoga, Tai Chi). For each included study's arm, two pairs of independent reviewers assessed the therapeutic quality of exercises applying the i-CONTENT tool.

Results: One hundred arms were included, arising from 67 RCTs. Overall, the majority of exercise were at low risk of ineffectiveness for patient selection (99%), type of exercise (95%), qualified supervisor (81%) and type and timing outcomes (82%), whereas safety of the exercise programs (59%) and adherence of exercise (68%) were mainly scored as probably low risk of ineffectiveness. Dosage of exercises had heterogenous judgements with 25% exercises scoring high-probably high risk of ineffectiveness. Type and timing outcomes was also at high risk of ineffectiveness (18%). Among all exercises, Pilates ranked best in all domains.

Conclusion: Overall, therapeutic quality of exercise in cLBP RCTs assessed by i-CONTENT tool is at low risk of ineffectiveness, although dosage and type and timing outcomes can be at high risk for some exercise types. Pilates seems to be the one with the best therapeutic quality.

1. Introduction

Low back pain is an extremely common symptom that cause activity limitation and participation restriction, with a prevalence in 2017 estimated to be around 577.00 million people[1]. It is the leading global cause of years lived with disability since 1990[1], becoming a public health concern[2].

Exercise therapy is a very common intervention, especially recommended for chronic low back pain (cLBP). Several studies[2–5] have shown that exercise therapy, like motor control exercises, strengthening and endurance exercise, is effective as compared to no treatment and usual care for the treatment of cLBP. However, exercise therapy can be differently prescribed in terms of treatment design (e.g., standard, individualized), dose (duration, frequency, intensity), delivery format (e.g., clinician supervised, group), type (e.g. strengthening, stretching), and combination with other conservative treatments[5]. All of these variables should be clearly and completely reported when describing exercise interventions in randomized controlled trials (RCTs) in order to allow replicability of interventions in clinical practice and research. In recent years, different tools, such as the Consensus on Exercise Reporting Template (CERT)[6] and the Template for Intervention Description and Replication (TIDieR) checklist[7] have been developed to improve the reporting of exercise interventions in rehabilitation research to enhance exercise reproducibility and clinical translation. However, these currently available reporting tools do not interpret the therapeutic quality (i.e., 'the potential effectiveness of a specific intervention given the potential target group of patients') of exercise interventions. To yield optimal effects, the content of an exercise programme should be in line with the latest research, be tailored to the potential of the participants[8] and be of sufficient volume [9,10]. For instance, studies of the dose responsiveness of strength training clearly indicate that strength training programmes produce the greatest increases in muscle strength when the training load is high[10]. So systematic reviews of interventions designed to increase muscle strength should assess whether the training load was adequate. In 2020, The international Consensus on Therapeutic Exercise aNd Training (i-CONTENT) tool[11] was developed for this purpose to assess by a rating tool, instead of a reporting guideline, the risk of ineffectiveness of the exercise purposed and to better identify, appraise and interpret the heterogeneity across RCTs of exercise.

1.1 Objectives

The primary aim of this study was to assess the therapeutic quality of exercise interventions with i-CONTENT tool in cLBP RCTs. The secondary aim was to describe the therapeutic quality of exercise in each exercise types.

2. Methods

2.1 Study design

We performed a meta-research study. Since that the specific reporting checklist is under development[12] , we adapted items from the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) checklist[13] for the reporting of this study.

2.2 Eligibility criteria and information sources

We started from RCTs included in the 2021 Cochrane review publication "Exercise therapy for chronic low back pain"[5] to select a random sample of 100 exercise arms of different type of exercises (i.e. Core Strengthening, General Strengthening, Stretching, Aerobic exercises, Motor Control, Pilates, McKenzie, Qigong, Yoga, Tai Chi). In case of mixed interventions where exercise is combined with other conservative treatments (e.g., drugs, electrotherapy), we excluded the related study's arm if exercise comprised <75% of the treatment (per judgement of the extractor). To ensure consistency of judgments, mixed exercises type (e.g., aerobic plus core strengthening) were excluded.

2.3 Data management

Two reviewers (IG, SB) extracted the following characteristics: author, year of publication, country, sample size, population characteristics (e.g., age, sex), symptom duration, presence of radicular symptoms/leg pain, intervention (e.g., type of exercises, duration of intervention) and outcomes assessed of the related arm.

2.4 i-CONTENT tool

The tool was developed by the i-CONTENT working group in 2020[11], which consisted of eight members specialized in sports medicine, exercise therapy, and physiotherapy practice. The aim of the working group was to create a single rating tool that provides recommendations for a transparent assessment of the quality of exercise therapy programmes studied in RCTs, and towards the development of future, higher quality, exercise interventions. The development of the tool followed a four-stage Delphi approach with 49 experts involved reaching consensus that, to yield the potential effectiveness of a therapeutic exercise, the exercise programme should match the patients' problems, should be based on a proven rationale to determine its optimal frequency, intensity, time and type, should be applied by a qualified supervisor, assessed with a proper outcome measure, being safe, and with an adequate therapy adherence. The final tool (Appendix A) comprises seven items: (i) patient selection, (ii) dosage of the exercise programme, (iii) type of exercise programme, (iv) qualified

supervisor, (v) type and timing of outcome assessment, (vi) safety of the exercise programme and (vii) adherence to the exercise programme.

2.5 Application of i-CONTENT tool

For each included study's arm, two pairs of independent reviewers (IG, GC) (SB, GB) were involved in the assessment of the therapeutic quality of exercises applying the i-CONTENT tool[11].

All items were evaluated as "low risk of ineffectiveness" or "high risk of ineffectiveness" of the exercise intervention. If no details on the topic are reported, items were judges as 'probably done' or 'probably not done'. Each evaluation was substantiated by a rationale to support the evaluation. A calibration phase was done on four RCTs on different exercise types. Any disparities were resolved by consensus discussion with another pair of reviewers (TI, SG).

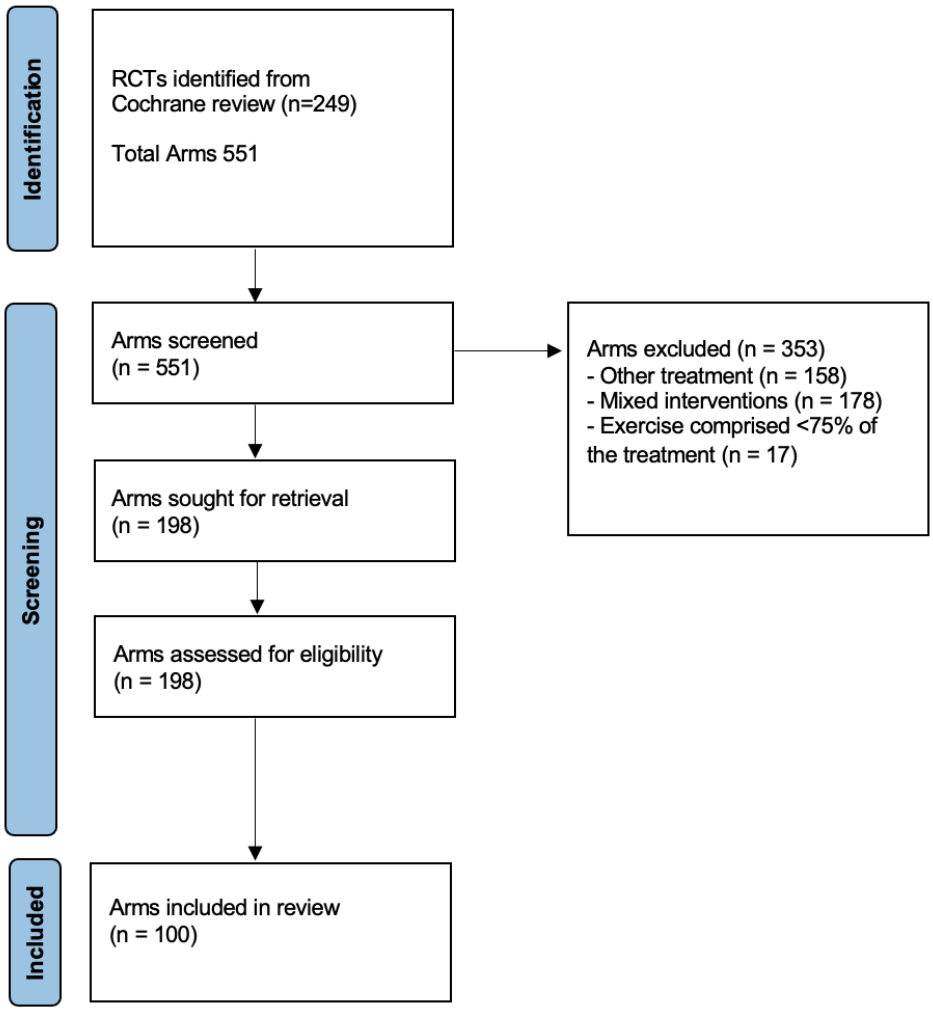
2.6 Statistical analysis

Data are presented descriptively in tabular form as tables and figures. We used descriptive statistics to describe general characteristics of RCTs and the proportion of items assessed as "low risk" or "high risk" of ineffectiveness, "probably done" or "probably not done". We presented results for overall exercises and for each exercise type. All data analyses were performed using STATA.

3. Results

We randomly selected 100 arms from 198 arms. The flow chart of the study selection is reported in figure 1.

Figure 1. *Flow Chart of study selection*



3.1 General characteristics

Overall, the 100 arms included in 67 RCTs were published between 1991 and 2019 (median 2013, IQR 2011 – 2016). The most representative exercise assessed was core strength, with 27 arms assessed. Overall, the 100 arms included 4125 cLBP patients. All general characteristics are reported in table 1.

Table 1. *General characteristics*

	Arms assessed (n=100)	
Sample of the arms*	35	21 – 50.5
Mean age of the arms*	44	40 – 48,5
Proportion of female*	62,5%	51,75% - 75%
Symptom duration Months*	 72	 30 – 108
Presence Radicular symptoms / leg pain Yes No Some NR	 0 34 30 36	
Duration of intervention*	8	6 – 12
Outcomes^ Pain Disability HrQoL Other	N 91 94 36 50	
Exercises **Aerobic** **Stretching** **Motor Control** **Core Strength** **General Strength** **Yoga** **McKenzie** **Qigong** **Pilates** **Tai Chi**	N 11 10 13 27 10 11 7 3 7 1	

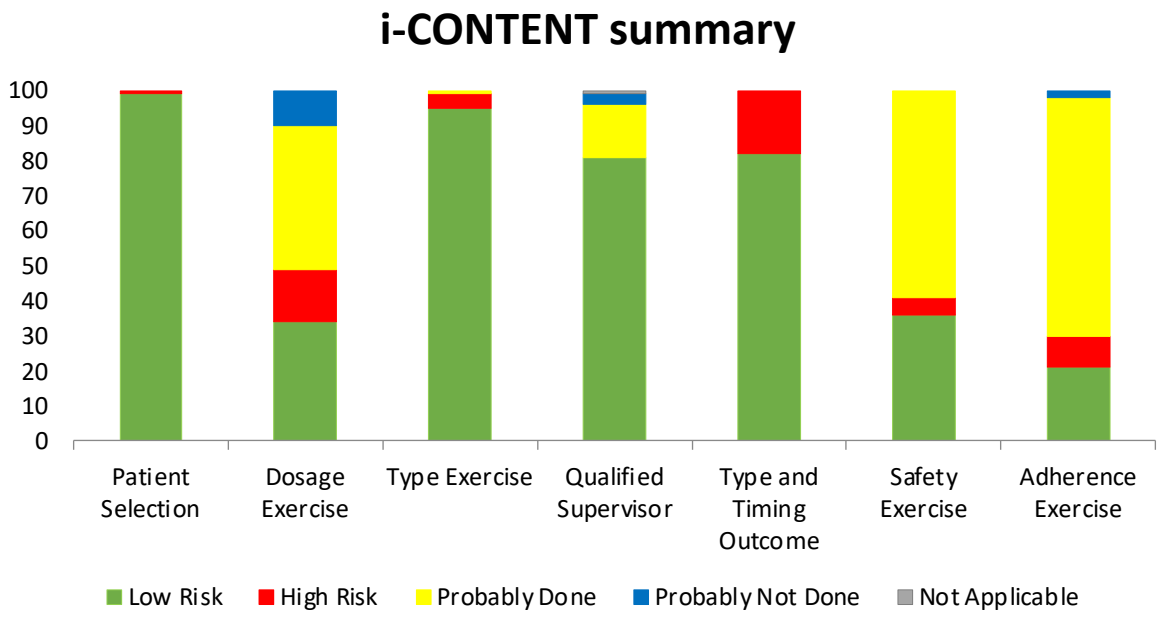
*median and IQR; ^more than one outcome can be reported by each RCT arm

3.2 i-CONTENT assessment

i-CONTENT scores for each study arm are reported in **Appendix 2** and in **Figure 2** as a summary plot. The majority of the exercise were at low risk of ineffectiveness for patient selection (99%), type of exercise (95%), qualified supervisor (81%) and type and timing outcomes (82%). Regarding

dosage of the exercise, a quarter of the arms were assessed at both high risk of ineffectiveness (15%) and as probably not done (10%), with only 34 arms evaluated at low risk. Instead, for type and timing outcomes, high risk was evaluated in 18 arms. The most significant items with no details for judgements were safety of the exercise programs (59%), adherence of exercise (68%) and dosage of exercise (45%), assessed as "probably done".

Figure 2. *i-CONTENT summary*

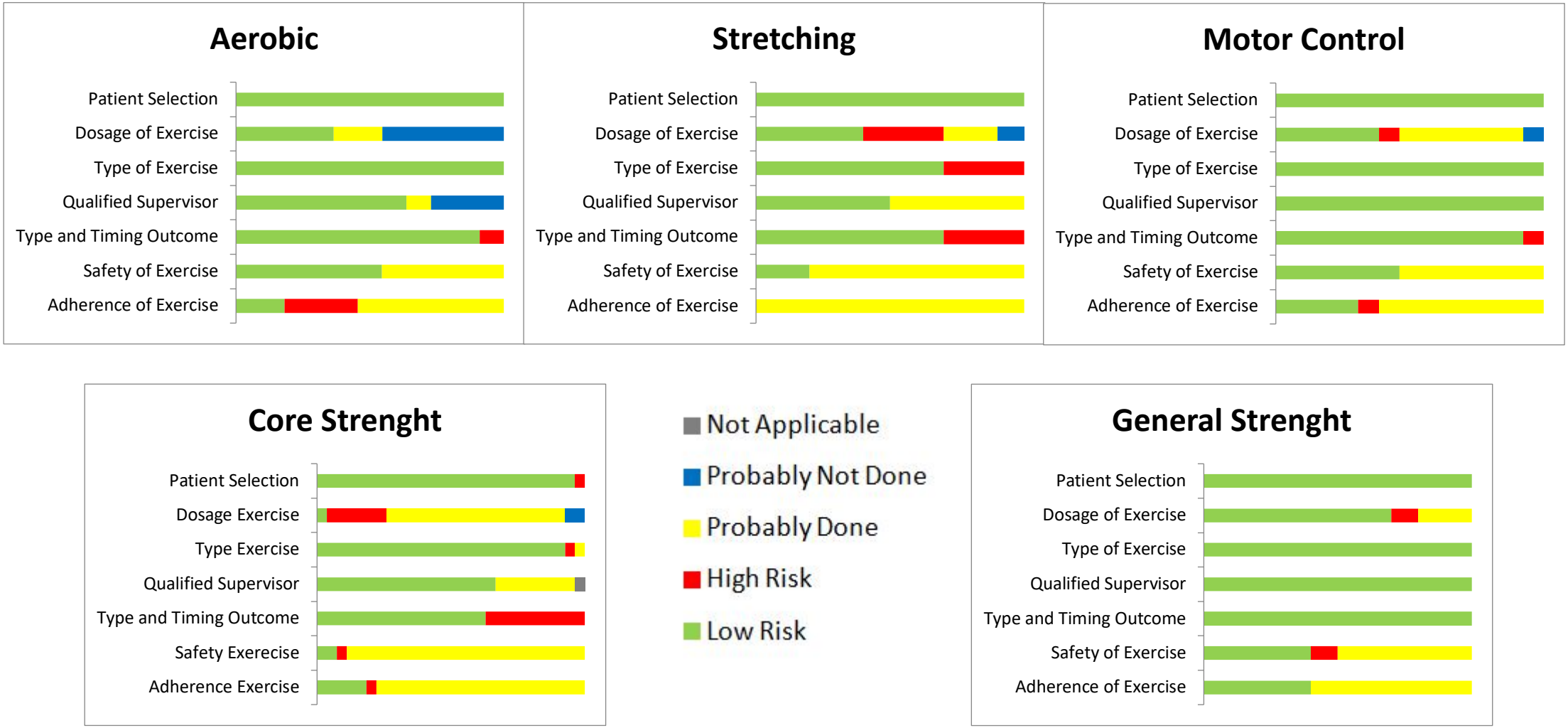


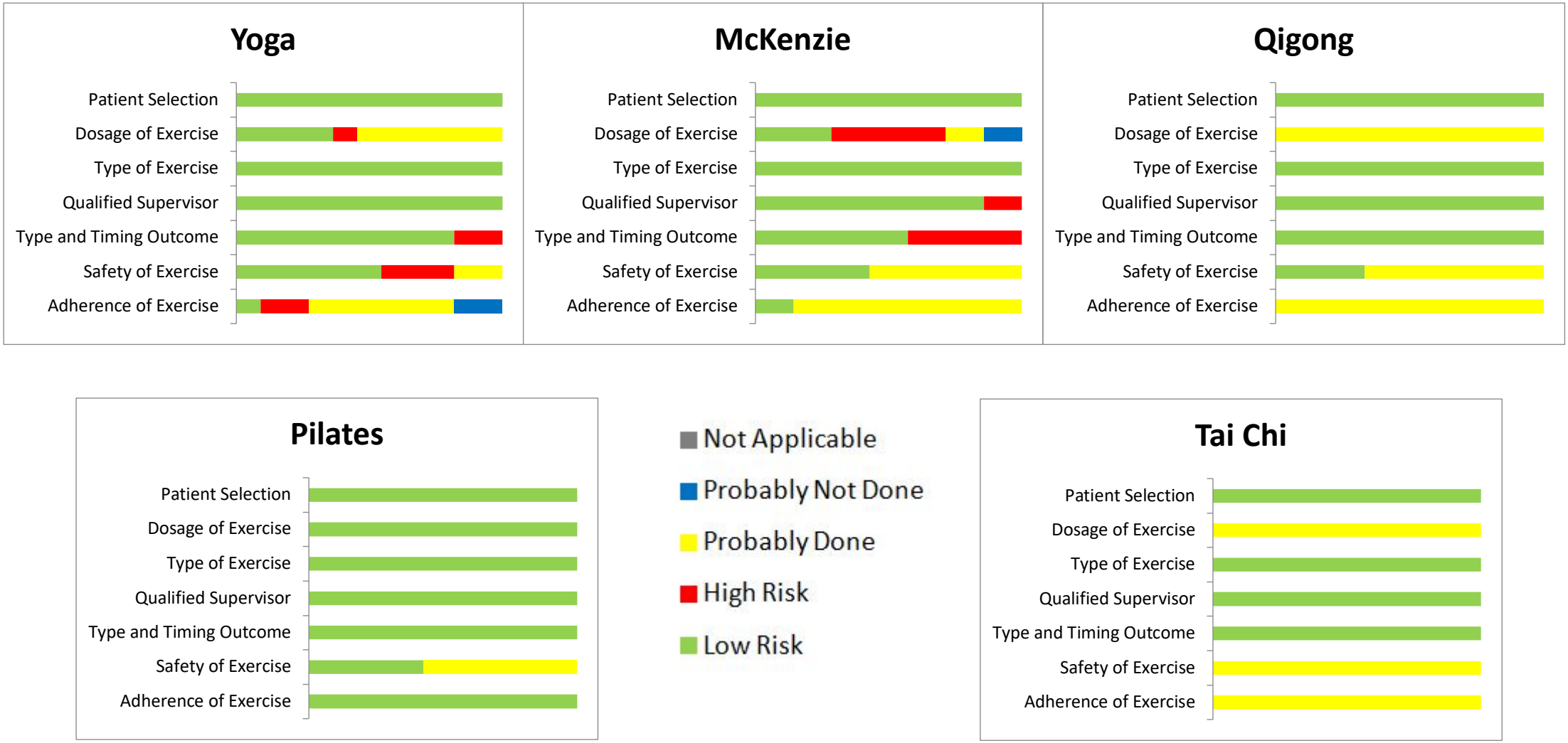
3.3 i-CONTENT assessment by exercise type

As shown in **Figure 3**, we stratified i-CONTENT assessments for each exercise type. Patient selection was evaluated as low risk of ineffectiveness in all exercises, excepted for one (Core Strength). The dosage of exercise was judged at high risk of ineffectiveness, especially in the McKenzie group (42%), in the Stretching group (30%), in the Yoga group (25%), in the Core Strenght group (22%) and in the General Strenght group (10%). Overall, the type of exercise (form in which the exercise is provided) was mainly assessed as low risk, except in the Stretching group (30%) and in the Core Strength group (4%). Qualified supervisor was most assessed as probably done. In the Pilates group, as well as in the Yoga, Tai Chi and Qigong it was always evaluated as low risk. The type and timing outcomes were most at high risk of ineffectiveness in the McKenzie group (42%), in the Stretching group (30%) and in the Yoga group (18%). The safety of exercise was most evaluated as probably done. In the Yoga group (27%), in the Core Strength group (4%) and in the General Strength group (10%) it was assessed as high risk. Also the adherence of exercise was most evaluated as probably

done. In the Aerobic group (27%), in the Yoga group (18%), in the Motor Control group (8%) and in the Core Strength group (4%) it was assessed as high risk. Tai Chi group consisted of only one study (Hall 2011) and it was assessed with probably done in dosage of exercise, safety of exercise and adherence of exercise.

Figure 3. *i-CONTENT by exercise type*




Yoga
Patient Selection
Dosage of Exercise
Type of Exercise
Qualified Supervisor
Type and Timing Outcome
Safety of Exercise
Adherence of Exercise
McKenzie
Patient Selection
Dosage of Exercise
Type of Exercise
Qualified Supervisor
Type and Timing Outcome
Safety of Exercise
Adherence of Exercise
Qigong
Patient Selection
Dosage of Exercise
Type of Exercise
Qualified Supervisor
Type and Timing Outcome
Safety of Exercise
Adherence of Exercise
Pilates
Patient Selection
Dosage of Exercise
Type of Exercise
Qualified Supervisor
Type and Timing Outcome
Safety of Exercise
Adherence of Exercise
Not Applicable
Probably Not Done
Probably Done
High Risk
Low Risk
Tai Chi
Patient Selection
Dosage of Exercise
Type of Exercise
Qualified Supervisor
Type and Timing Outcome
Safety of Exercise
Adherence of Exercise

4. Discussion

4.1 Summary

We analyzed a sample of 100 study's arms starting from Cochrane review publication "Exercise therapy for chronic low back pain"[5].
Overall, most exercises were at low risk of ineffectiveness for patient selection, type of exercise, qualified supervisor and type and timing outcomes.

Considering patient selection and type of exercise, a previous study[14] found that various exercise training approaches are effective for treating cLBP, so any patient with cLBP could underwent different type of exercise. However, among all types of exercises, recent network meta-analysis[1514] found that Pilates, core strength and mind-body disciplines (e.g., Yoga, Tai Chi, Qigong) were most effective for pain and disability compared to aerobic training, stretching and McKenzie. This can find rationale in our results, with Pilates having the highest therapeutic quality in each item whereas stretching and McKenzie the lowest.

We judged low risk also for qualified supervisor, as most of provided exercise were delivered by physiotherapist or specialized operators (e.g, Pilates). It's crucial that supervisors competences match to the goals and the content of the programme, and therefore not having a proper qualification could undermine the quality of the proposed exercise.

Even if the majority of arms were at low risk in type and timing outcome, we need to underline that some of them (18%) were judged at high risk. It's imperative assessing outcomes included in the core outcome set[16] with a be valid and responsive measurement tool should, deployed at the right moment in time[11]. Patients who presented with cLBP improved markedly in the first six weeks[17]. So we considered that the shortest follow up should be at least at 4 weeks post intervention, considering the time window where the expected effect would most likely take place.

Dosage of exercises was assessed with heterogenous judgements with a quarter of exercises having high-probably high risk of ineffectiveness. The dosage of exercise is a crucial element for the therapeutic quality of interventions. Currently, there is no consensus about the optimal dose for exercise in cLBP. Clinicians should aim to gradually increase exercise intensity using the Frequency, Intensity, Time and Timing (FITT) principle[18], applying a progressive overload. Some studies[19,20] reported higher intensity training can improve pain and function. Gordon et al[21] reported moderate intensity aerobic exercise (40%–60% heart rate reserve) should be promoted for cLBP rehabilitation.

For instance, Niederer[22] found that a training duration of 20 to 30 minutes, three or five times a week, for at least six weeks, elicits the largest impact on the effect sizes on both pain and disability of core strength interventions.

Safety of the exercise programs and adherence of exercise were mainly scored as probably low risk of ineffectiveness because studies reported insufficient information to judge them.
Davidson[23] reported that 60,9% of the studies do not assess or measure adherence. As a confirmation, we found that most arms included in our study (68%) do not report adherence. Adherence is defined in several terms and many studies measured this item using different approaches. Hawley-Hague[24] discussed the different cut-off points and measurements for various concepts related to participation in a class or program. These concepts include completion (retention), attendance, duration, and intensity.
As well, adverse events are poorly reported. An overview of Cochrane Reviews[25] on adults with chronic pain shown that only 25% of the studies included (61/246) have reported on adverse events. However, we considered the majority of exercises being safe, as it is already known from the literature[26].

4.2 Comparison with previous studies

Even if it is amply demonstrated how effective exercise is in the treatment of cLBP, no study has ever investigated the therapeutic quality of proposed interventions. Davidson[23] focused on reporting quality of exercises for low back pain showing that it was typically poor assessed by TIDieR and the CERT checklist. Considering the assessment of therapeutic quality in other musculoskeletal field, Burton[27] applied i-CONTENT tool in lower limb tendinopathy, considering the tool as a reporting tool instead of a rating tool of the therapeutic quality. Wagemans[26] assessed therapeutic quality of exercise program in lateral ankle sprain, finding that there was a good therapeutic quality, although type and timing outcome was the most at "high risk of ineffectiveness", while dosage was the most assessed with "probably done", like our study.

4.3 Strength and limitations

To our knowledge, this meta-research study is the first assessing therapeutic quality by i-CONTENT tool in cLBP. We assessed 100 different exercise arms, developing instructions for raters before starting the assessment to increase the consistency of ratings, especially for "dosage of exercise". However, some limitations should be acknowledged. We randomly selected 100 arms belonging to 67 RCTs, with 32 multi-arms RCTs. However, arms in a multi-arm study are correlated and not

independent. In fact, the therapeutic quality of exercises in the same multi-arm RCT could have been influenced by the reporting quality of that trial. In addition, type and timing outcome item was rated with the same judgement since it is at study level.

Lastly, we are aware that the therapeutic quality can be influenced by the quality of reporting. We did not assess studies by TIDIER checklist to compare the therapeutic quality and the quality of reporting. However, we had the possibility to use the "probably done" assessment in case of missing information. This was the case for dosage of exercise (41%), qualified supervisor (15%), safety (59%) and adherence of exercise (68%).

4.4 Implications for clinical practice

Tools such as the i-CONTENT tool enable clinicals and researchers to assess the therapeutic quality of studies. If the therapeutic quality of the proposed exercise is not adequate, there is a risk of ineffectiveness. Through this judgment it is possible to establish whether that exercise can be effective and adequate to that patient. Our study reveals that the "dosage" and the "type and timing outcome" in some exercise types can be at greater risk for some exercises, so careful evaluation is recommended, when interpreting results from these RCTs. The lack of a sound rationale for the dosage of the exercise therapy programme may result in underdosing or overdosing.

4.5 Implications for research

Future studies should assess the inter-rater reliability of the tool as well as which item can be the proxy of overall therapeutic quality. Some improvements can be performed in i-CONTENT tool to objectify assessments. For example, we found that patient selection and type of exercise were strictly similar. In addition, further information on how rating dosage in case of no agreement in the literature are needed. Recently, advanced statistical techniques for network meta-analysis have been proposed to facilitate the identification of the best treatment and dose to produce relevant and clinically meaningful results for patients, clinicians and decision makers[28]. Furthermore, knowing the therapeutic quality of interventions could be useful for systematic review authors to interpret findings (e.g., sensitivity analysis on high risk of ineffectiveness studies).

5. Conclusion

Therapeutic quality of exercise is essential for evaluating effectiveness of interventions. Exercises for chronic low back pain seem to be of good therapeutic quality, although dosage and type and timing outcomes can be at high risk for some exercise types. Pilates seems to be the exercise with the best therapeutic quality. Tools such as the i-CONTENT tool need to be implemented in clinical practice, in order to allow clinicians to replicate high therapeutic quality exercises.

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Appendix A. *Checklist i-CONTENT tool*

	"Low risk" of ineffectiveness	**"High risk" of ineffectiveness**	If not details Probably (done)	on the topic Probably not (done)	Support for judgement
Patient selection	❑ The purpose of the exercise therapy program matches the patients' problems (directly or through a plausible causative relationship).	❑ The purpose of the exercise therapy program does not match the patients' problems.	❑	❑	
Dosage of the Exercise program	❑ The investigators applied a plausible or proven rationale* to determine the 'Frequency', 'Intensity', and 'Time' of the exercise program, matching the purpose of the exercise intervention.	❑ The investigators did not use a plausible or proven rationale*, did not match the rationale with the purpose of the exercise program, or did not match the rationale and the 'Frequency', 'Intensity', and 'Time' of the exercise program.	❑	❑	
Type of the Exercise program	❑ The investigators applied a plausible or proven rationale* to determine the 'Type' of exercise, defined as the form in which the exercise is provided, and the investigators matched the 'Type' of the exercise therapy program with the purpose of the exercise therapy program.	❑ The investigators did not use a plausible or proven rationale* or did not match the 'Type' of the exercise program with the purpose of the exercise therapy program.	❑	❑	
Qualified Supervisor (if applicable)	❑ The supervisors of the exercise therapy program are experienced with the targeted patient population and sufficiently skilled in providing the proposed exercise program.	❑ The supervisors of the exercise therapy program are inexperienced with the patient population or insufficiently skilled to provide the exercise program	❑	❑	
Type and Timing of Outcome Assessment	❑ The investigators used one or more valid and responsive performance-based outcome measure(s) which reflect the goals and purpose of the exercise program to assess the effectiveness exercise therapy program. The measurements have taken place within the time window where the expected effect would most likely take place.	❑ The investigators use a non- validated performance measure as primary outcome measure to assess the effect of the therapeutic intervention.	❑	❑	
Safety of the Exercise Program	❑ The number and severity of the exercise- related adverse events in the study are in line with the expected number of adverse events for similar exercise programs in similar populations.	❑ The number and severity of the exercise related adverse events are substantially higher than what would be expected.	❑	❑	
Adherence to the Exercise Program	❑ The intended exercise dosing was achieved, based on relevant information regarding to exercise adherence (i.e., the number of sessions attended, the number of exercises performed, and whether or not the intended exercise dosage was reached).	❑ The level of exercise adherence of patients to the exercise therapy program was insufficient to assume the intended exercise dosing was achieved.	❑	❑	

Appendix B. *i- CONTENT assessment for each included studies*

Author	Year	Type of exercise	Patient Selection	Dosage of Exercise	Type of Exercise	Qualified Supervisor	Type and Timing Outcome	Safety of Exercise	Adherence of Exercise
Akodu	2017	Core Strength	Low Risk	Probably Done	Probably Done	Probably Done	Low Risk	Probably Done	Probably Done
Akodu	2017	Stretching	Low Risk	High Risk	High Risk	Probably Done	Low Risk	Probably Done	Probably Done
Akthar	2017	Core Strength	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Andrusaitis	2011	Core Strength	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Andrusaitis	2011	Motor Control	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Arab	2016	McKenzie	Low Risk	High Risk	Low Risk	Low Risk	High Risk	Low Risk	Probably Done
Bellido-Fernandez	2018	Core Strength	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Bentsen	1997	Core Strength	Low Risk	Probably Done	Low Risk	Probably Done	High Risk	Probably Done	High Risk
Bentsen	1997	Core Strength	Low Risk	Probably Done	Low Risk	Not Applicable	High Risk	Probably Done	Probably Done
Bid	2017	McKenzie	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Blodt	2015	Qigong	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Bramberg	2017	Yoga	Low Risk	Low Risk	Low Risk	Low Risk	High Risk	Probably Done	Probably Done
Bramberg	2017	Core Strength	Low Risk	Probably Done	Low Risk	Low Risk	High Risk	Probably Done	Probably Done
Bronfort	2011	General Strength	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Chung	2018	Core Strength	Low Risk	Probably Done	Low Risk	Probably Done	Low Risk	Probably Done	Probably Done
Cortell-Tormo	2018	General Strength	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Costa	2009	Motor Control	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Cruz Diaz	2017	Pilates	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Cruz Diaz	2017	Pilates	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Cuesta Vargas	2012	Aerobic	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Da luz	2014	Pilates	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Da luz	2014	Pilates	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Dufour	2010	Core Strength	High Risk	High Risk	High Risk	Low Risk	Low Risk	High Risk	Probably Done
Elnaggar	1991	Core Strength	Low Risk	High Risk	Low Risk	Probably Done	Low Risk	Probably Done	Probably Done
Elnaggar	1991	McKenzie	Low Risk	High Risk	Low Risk	Probably Done	Low Risk	Probably Done	Probably Done
Farajzadeh	2017	Core Strength	Low Risk	Probably Done	Low Risk	Probably Done	Low Risk	Probably Done	Probably Done
Ferreira	2007	Motor Control	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done

Franca	2012	Motor Control	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Franca	2012	Stretching	Low Risk	Low Risk	High Risk	Low Risk	Low Risk	Probably Done	Probably Done
Garcia	2013	McKenzie	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Garcia	2017	McKenzie	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Groessl	2017	Yoga	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Guastala	2016	Stretching	Low Risk	Low Risk	Low Risk	Probably Done	Low Risk	Probably Done	Probably Done
Guastala	2016	Stretching	Low Risk	High Risk	High Risk	Probably Done	Low Risk	Probably Done	Probably Done
Hall	2011	Tai Chi	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Halliday	2016	McKenzie	Low Risk	Probably Done	Low Risk	Low Risk	High Risk	Probably Done	Probably Done
Halliday	2016	Core Strength	Low Risk	Probably Done	Low Risk	Low Risk	High Risk	Probably Done	Probably Done
Hartvigsen	2010	Aerobic	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Hartvigsen	2010	Aerobic	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Henry	2014	Motor Control	Low Risk	Probably Done	Low Risk	Low Risk	High Risk	Low Risk	Probably Done
Highland	2018	Yoga	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Iversen	2018	General Strenght	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done	High Risk
Kader	2012	Motor Control	Low Risk	Probably done	Low Risk	Low Risk	Low Risk	Probably done	Probably Done
Keane	2017	Stretching	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably done	Probably Done
Kendall	2015	Core Strenght	Low Risk	Probably Not Done	Low Risk	Low Risk	High Risk	Probably Done	Low Risk
Kendall	2015	Core Strenght	Low Risk	Probably Not Done	Low Risk	Low Risk	High Risk	Probably Done	Low Risk
Krein	2013	Aerobic	Low Risk	Probably Not Done	Low Risk	Probably Not Done	Low Risk	Low Risk	Low Risk
Little	2008	Aerobic	Low Risk	Probably Not Done	Low Risk	Probably Not Done	Low Risk	Low Risk	Probably Done
Little	2008	Aerobic	Low Risk	Probably Not Done	Low Risk	Probably Not Done	Low Risk	Low Risk	High Risk
Lomond	2014	General Strenght	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Probably Done	Low Risk
Lomond	2014	Motor Control	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Probably Done	Low Risk
Macedo	2012	Motor Control	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Marshall	2013	Pilates	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably done	Low Risk
Marshall	2013	Aerobic	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably done	High Risk
McDonough	2013	Aerobic	Low Risk	Probably Not Done	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Michaelson	2016	General Strength	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done

Michaelson	2016	Motor Control	Low Risk	Probably Not Done	Low Risk	Low Risk	Low Risk	Low Risk	High Risk
Miller	2005	Core Strength	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Miller	2005	McKenzie	Low Risk	Probably Not Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Miyamoto	2013	Pilates	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Phattharasupharerk	2019	Qigong	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Puntumetakul	2013	Core Strength	Low Risk	Probably Done	Low Risk	Probably Done	High Risk	Probably Done	Probably Done
Puntumetakul	2013	Stretching	Low Risk	High Risk	Low Risk	Probably Done	High Risk	Probably Done	Probably Done
Rasmussen-Barr	2009	Core Strength	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Low Risk
Rasmussen-Barr	2009	Aerobic	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done	High Risk
Rhee	2012	Core Strength	Low Risk	Probably Done	Low Risk	Probably Done	Low Risk	Probably Done	Probably Done
Risch	1993	Core Strength	Low Risk	Probably Done	Low Risk	Probably Done	High Risk	Probably Done	Probably Done
Salamat	2017	Core Strength	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Salamat	2017	Motor Control	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Saner	2016	Motor Control	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Saner	2016	General Strenght	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Saper	2013	Yoga	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	High Risk	High Risk
Saper	2013	Yoga	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	High Risk	High Risk
Saper	2017	Yoga	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	Probably Not Done
Segal-Snir	2016	Stretching	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Sherman	2005	Yoga	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Sherman	2005	Stretching	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Sherman	2011	Yoga	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	High Risk	Probably Not Done
Shnayderman	2013	Aerobic	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Shnayderman	2013	General Strength	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Smith	2011	Core Strength	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Smith	2011	Core Strength	Low Risk	High Risk	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Sung	2013	Core Strength	Low Risk	High Risk	Low Risk	Low Risk	High Risk	Probably Done	Probably Done
Sung	2013	Stretching	Low Risk	Probably Done	Low Risk	Low Risk	High Risk	Probably Done	Probably Done
Tekur	2012	Yoga	Low Risk	High Risk	Low Risk	Low Risk	High Risk	Low Risk	Probably Done
Teut	2016	Yoga	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done	Low Risk

Teut	2016	Qigong	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Low Risk
Tillbrook	2011	Yoga	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Tritilanunt	2001	Stretching	Low Risk	Probably Not Done	Low Risk	Probably Done	High Risk	Probably Done	Probably Done
Tritilanunt	2001	Aerobic	Low Risk	Probably Not Done	Low Risk	Probably Done	High Risk	Probably Done	Probably Done
Ulger	2017	Core Strength	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Unsgard-Tondel	2010	Motor Control	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Unsgard-Tondel	2010	Core Strength	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Unsgard-Tondel	2010	General Strength	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Low Risk	High Risk
Vincent	2014	General Strength	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	High Risk	Low Risk
Vincent	2014	Core Strength	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk
Wajswelner	2012	Pilates	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Wajswelner	2012	General Strength	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Low Risk	Probably Done
Xueqiang	2012	Core Strength	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done
Xueqiang	2012	Motor Control	Low Risk	Probably Done	Low Risk	Low Risk	Low Risk	Probably Done	Probably Done

Protocol of the study

What is the therapeutic quality of exercise programs in chronic low back pain randomized controlled trials assessed by i-CONTENT tool? A meta research study

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1. Introduction

Low back pain is an extremely common symptom that cause activity limitation and participation restriction, with a prevalence in 2017 estimated to be around 577.00 million people[1]. It is the leading global cause of years lived with disability since 1990[1], becoming a public health concern[2].

Exercise therapy is a very common intervention, especially recommended for chronic low back pain (cLBP). Several studies[2–5] have shown that exercise therapy, like motor control exercises, strengthening and endurance exercise, is effective as compared to no treatment and usual care for the treatment of cLBP. However, exercise therapy can be differently prescribed in terms of treatment design (e.g., standard, individualised), dose (duration, frequency, intensity), delivery format (e.g., clinician supervised, group), type (e.g. strengthening, stretching), and combination with other conservative treatments[5]. All of these variables should be clearly and completely reported when describing exercise interventions in randomized controlled trials (RCTs) in order to allow replicability of interventions in clinical practice and research. In recent years, different tools, such as the Consensus on Exercise Reporting Template (CERT)[6] and the Template for Intervention Description and Replication (TIDieR) checklist[7] have been developed to improve the reporting of exercise interventions in rehabilitation research to enhance exercise reproducibility and clinical translation. However, these currently available reporting tools do not interpret the therapeutic quality (i.e., 'the potential effectiveness of a specific intervention given the potential target group of patients') of exercise interventions. To yield optimal effects, the content of an exercise programme should be in line with the latest research, be tailored to the potential of the participants[8] and be of sufficient volume [9,10]. For instance, studies of the dose responsiveness of strength training clearly indicate that strength training programmes produce the greatest increases in muscle strength when the training load is high[10]. So systematic reviews of interventions designed to increase muscle strength should assess whether the training load was adequate. In 2020, The international Consensus on Therapeutic Exercise aNd Training (i-CONTENT) tool[11] was developed for this purpose to assess by a rating tool, instead of a reporting guideline, the risk of ineffectiveness of the exercise purposed and to better identify, appraise and interpret the heterogeneity across RCTs of exercise.

1.2 Objectives

The primary aim of this study will be to assess the therapeutic quality of exercise interventions with i-CONTENT tool in cLBP RCTs. The secondary aim will be to describe the therapeutic quality of exercise in each exercise types.

2. Methods

Study design

We will perform a meta-research study. Since that the specific reporting checklist is under development[12], we will adapt items from the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) checklist[13] for the reporting of this study.

2.1 Eligibility criteria and information sources

We will start from RCTs included in the 2021 Cochrane review publication "Exercise therapy for chronic low back pain"[5] to select a random sample of 100 exercise arms of different type of exercises (e.g, core strengthening, general strengthening, motor control, stretching, aerobic exercises, pilates, McKenzie, Qigong, Tai Chi, yoga). In case of mixed interventions where exercise is combined with other conservative treatments (e.g. drugs, electrotherapy), we will exclude the related study's arm if exercise comprised <75% of the treatment (per judgement of the extractor). To ensure consistency of judgments, mixed exercises type (e.g. aerobic plus core strengthening) will be excluded.

2.2 Data management

Two reviewers (IG, SB) will extract the following characteristics: author, year of publication, country, sample size of the arms, population characteristics (e.g., age, sex), symptom duration (e.g., mean months), presence of radicular symptoms/leg pain, intervention (e.g., type of exercises, frequency, intensity), comparison and outcomes assessed.

2.3 Application of the i-CONTENT tool

According to the i-CONTENT tool[11], to yield the potential effectiveness of a therapeutic exercise, the exercise programme should match the patients' problems, should be based on a proven rationale to determine its optimal frequency, intensity, time and type, should be applied by a qualified supervisor, assessed with a proper outcome measure, being safe, and with an adequate therapy adherence.

For each included study's arm, two pairs of independent reviewers (IG, GC) (SB, GB) will be involved in the assessment of the therapeutic quality of exercises applying the i-CONTENT tool[11]. The sample will be divided in four subsets (**Table 1**). They will independently assess seven items: (i) patient selection, (ii) dosage of the exercise programme, (iii) type of exercise programme, (iv) qualified supervisor, (v) type and timing of outcome assessment, (vi) safety of the exercise programme and (vii) adherence to the exercise programme.

All items will be evaluated as “low risk of ineffectiveness”) or “high risk of ineffectiveness” of the exercise intervention. If no details on the topic will be reported, items will be judges as ‘probably done’ or ‘probably not done’. Each evaluation will be substantiated by a rationale to support the evaluation. A calibration phase will be done on four RCTs on different exercise type. Any disparities were resolved by consensus discussion with another pair of reviewers (TI, SG).
The full checklist along with instructions used by reviewers for judgements is reported in **Appendix A** and **B.**

Table 1.

	Set A (25%)	Set B (25%)	Set C (25%)	Set D (25%)
Rater 1	X			x
Rater 2	x	X		
Rater 3		x	X	
Rater 4			x	X

Statistical analysis

Data will be presented descriptively in tabular form as tables and figures. We will use descriptive statistics to describe the proportion of items assessed as “low risk” or “high risk” of ineffectiveness, “probably done” or “probably not done”. We will present results for overall exercise and for each exercise types. All data analyses will be performed using STATA.

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