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Effects of Cardiovascular Rehabilitation in Children with Congenital Heart Disease: A Systematic Review and Meta-Analysis

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Authors' contributions

This work was carried out in collaboration among all authors. Authors FCN, LMMS and FMCC conceptualized the study, investigation, did funding acquisition, performed the methodology, did validation, visualization, wrote, reviewed and edited the manuscript, helped in project administration, did formal analysis, data curation, software, supervised the study, searched for resources, wrote and prepared the original draft of the manuscript. Author MO did visualization, formal analysis and data curation, wrote, reviewed and edited the manuscript. All authors read and approved the final manuscript.

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ABSTRACT

Background: Home-based physical training is a promising alternative to conventional supervised training for patients with congenital heart disease (CHD). Although the beneficial effects of exercise interventions are well established in patients with CHD, there is still a lack of knowledge about the variety and utility of existing programs.
Aims: Therefore, the aim of this study was to conduct a systematic review and meta-analysis of randomized controlled trials publications on the population of children with CHD, which analyzes outpatient and home cardiopulmonary rehabilitation in children with congenital heart disease.
Study Design: Systematic review and meta-analysis.
Methodology: The searches were carried out in the MEDLINE and PEDro databases. The PICO search strategy was adopted: P (patient) = Child with CHD; I (intervention) = Outpatient rehabilitation and home rehabilitation; C (control) = no activity; O (result) = peak VO2.
Results: Six studies were included in the narrative analysis and all were published in English. RCTs were performed in Canada (n = 2), France (n = 2), Norway (n = 1) and Holland (n = 1). The total number of participants analyzed in all studies was 321 participants (conventional rehabilitation 81 and 63 control; home rehabilitation 98 and 79 control). Regarding gender discrimination, 150 boys and 171 girls were reported. The age range of participants was 6 to 15 years, with most studies reporting mean ages ≤15. A total of six studies involving 578 participants were included. The three studies reporting the peak VO2 at the beginning and after training, which included 144 patients (Rehabilitation 81 patients / Control 63 patients). This comparison was statistically significant 2.81 [0.89, 4.74]; Z = 2.86 (p <0.004) and I2 = 49%. The other three studies reported peak VO2 at baseline and after home rehabilitation, including 177 patients (Reab 98 patients / Control 70 patients). This comparison, however, was not statistically significant (p = 0.66).
Conclusion: The present data suggest that outpatient rehabilitation in children is more effective than home rehabilitation when oxygen consumption analyses is considered.

Keywords: Congenital heart disease; cardiopulmonary rehabilitation.

DEFINITIONS, ACRONYMS, ABBREVIATIONS

ATS : American Thoracic Society;
CHD : Congenital Heart Disease;
ESC/ERC : European Society of Cardiology/European Respiratory Society;
CHF : Congestive heart failure;
BMI : Body mass index;
NYHA : New York Heart Assosication;
OS : Oxidative Stress;
VO2 : Oxygen Consumption;
VO2peak : Maximal oxygen uptake;
WHO : World Health Organization;
HR : Heart rate;
MHR : Maximum Heart Rate.

1. INTRODUCTION

Congenital Heart Disease (CHD) is the most common congenital defect at birth, affecting 8 to 9 per thousand live births (van der Linde et al. 2011). In Europe, approximately 1 million newborns are diagnosed with CHD, according to data from the European Society of Cardiology (van der Linde et al., 2011; Annals of the American Thoracic Society, 2017). Advances in early diagnosis through fetal screening in high-risk groups and the scheduling of deliveries at specialized pediatric cardiology centers have facilitated timely surgical repair (Direção Geral da Saúde 2006, Gharbi & Lacomère 1995, Frederick et al., 1976, Reybrouck et al., 2004; Morrison et al., 2013) and improved survival rates in these patients.

Despite these advancements, most children and adolescents with CHD continue to face restrictions on physical activity, even post-surgery, often growing up in overly protective environments. Physicians and other healthcare professionals frequently recommend limitations on exercise (Reybrouck et al., 2004; Deanfield et al., 2003). There is no consensus on prescribing physical exercise for all types and variants of CHD in pediatric patients (Khairy et al., 2009). Exercise prescriptions are often individualized by the treating cardiologist and may lack standardized parameters, leading to prohibitive or nearly absolute exercise restrictions. This can result in social isolation, stigmatization, and low self-esteem in these children (Duppen et al., 2015).

Congenital heart diseases exhibit a broad spectrum of variations and severity, depending

on the type of defect, surgical corrections, residual injuries, and ventricular dysfunction. Clinically, CHD can be categorized based on:

- Pulmonary flow: Hyperflow (e.g., atrial septal defect, ventricular septal defect, total atrioventricular septal defect) or hypoflow (e.g., Tetralogy of Fallot);
- Cyanosis: Cyanotic or acyanotic;
- Ventricular physiology: Biventricular or univentricular (e.g., post-Fontan surgery);
- Complexity: Simple, moderate, or complex, irrespective of surgical correction (Baumgartner et al., 2020).

According to the 2020 ESC Guidelines on Sports Cardiology and Exercise in Patients with Cardiovascular Disease, individuals with CHD should undergo a comprehensive pre-participation evaluation for physical activity. This assessment includes analyses of ventricular function, pulmonary artery pressure, presence of arrhythmias, aortic dilation, resting and exercise oximetry. Cyanotic heart diseases, which are associated with elevated hematocrit levels, hyperviscosity, and exercise intolerance, were not consistently considered in the reviewed studies (Rhodes et al., 2005).

Based on these evaluations and individual preferences, personalized and safe exercise prescriptions can be developed. Studies on patients with CHD suggest that participation in cardiopulmonary rehabilitation programs significantly improves both exercise capacity and psychological well-being. The primary challenge lies in ensuring safe participation in regular physical activity to counteract the negative effects of a sedentary lifestyle.

Exercise interventions have demonstrated improvements in maximum exercise capacity among pediatric CHD patients. A recent systematic review reported an average increase of 8% in VO_2 peak among 621 children with CHD who participated in regular aerobic training programs (European Heart Journal 2020), with no reported adverse events related to exercise. However, results from combined aerobic and resistance training interventions are mixed: some studies reported no significant changes (Duppen et al., 2013), while others observed increases in VO_2peak of up to 19% (Magalhães et al. 2016). For instance, a study noted a 16% increase in VO_2peak following a 12-week exercise program (60-minute sessions twice a week, including 45 minutes of combined aerobic and resistance activities) in 16 children with CHD, with sustained benefits observed 7 months post-program (Brassard et al., 2006).

Malignant arrhythmias and sudden cardiac death are estimated to occur in approximately 1% of CHD patients over a 10-year follow-up. In those with complex lesions, this risk may rise to 10% per decade, with ventricular dysfunction serving as a significant predictor of malignant ventricular arrhythmias. The highest-risk conditions include transposition of the great arteries and a systemic right ventricle after surgical correction, as well as left ventricular obstructions (e.g., aortic stenosis, aortic coarctation). Risk stratification for these patients is based on data from smaller studies, as large-scale clinical trials are lacking (Duppen et al., 2013).

Exercise interventions are generally safe, feasible, and beneficial in children with CHD Magalhães et al., 2016, Brassard et al., 2006), with the exception of patients with heart rhythm disorders (Baumgartner et al., 2020). The patient's cardiologist should be consulted regarding any physical activity or exercise restrictions prior to implementing a program or during its course. Patients with CHD who are on anticoagulant therapy or have implanted devices (e.g., pacemakers) should avoid contact sports. Additionally, exercising in a thermoneutral environment is encouraged to prevent heat-related illnesses and adverse cardiac responses (Opocher et al., 2005; Takken et al., 2012).

Regular clinical assessment of maximal exercise capacity in patients with CHD can be valuable for monitoring disease progression and ensuring adherence to safety guidelines for participation[13]. A maximal cardiopulmonary exercise test offers prognostic value and can also identify impairments in peak exercise performance or the development of abnormal heart rhythms during exercise stress. While references for predicted peak VO_2 values in adults with CHD are available, data for pediatric populations remain limited.

A systematic review is needed to analyze the most effective interventions for face-to-face and home-based cardiopulmonary rehabilitation. Studies often include patients with varying pathological characteristics and a broad age range, which can create confusion by treating children and adults similarly, as well as combining cyanotic, acyanotic, and Fontan

physiologies into a single analysis. Thus, such a systematic review is essential to better evaluate these distinct conditions and assess the outcomes of outpatient and home-based cardiopulmonary rehabilitation in children with congenital heart disease.

2. METHODOLOGY

2.1 Eligibility Criteria

This systematic review examines randomized controlled trials (RCTs) conducted to assess the effects of cardiopulmonary rehabilitation and home-based cardiopulmonary rehabilitation in children with congenital heart disease (CHD). The study was developed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The criteria for including studies in this review are detailed below.

PICO Framework: P: Children with congenital heart disease; I: Outpatient rehabilitation; C: Home rehabilitation; O: Oxygen consumption (VO_2).

2.2 Types of Studies

This review included RCTs involving children with CHD who were allocated to cardiopulmonary or home-based rehabilitation programs or to a control group, as specified in the Cochrane Review guidelines.

2.3 Type of Participants

Inclusion criteria were:

- Children under 15 years of age diagnosed with CHD.
- Studies involving children and/or adolescents post-CHD surgery assigned to an exercise group.
- Included CHD pathologies: Tetralogy of Fallot, transposition of the great arteries (Senning/Mustard procedure), atrial septal defect, pulmonary valve atresia, ventricular septal defect, right ventricular outflow tract obstruction, aortic stenosis, coarctation of the aorta, truncus arteriosus, hypoplastic left heart syndrome, tricuspid atresia, double outlet right ventricle, double inlet left ventricle, single ventricle (post-Fontan surgery).
- Studies including patients participating in cardiopulmonary rehabilitation (aerobic training) or home-based rehabilitation for a minimum of 10 weeks.

The primary outcome for meta-analysis was peak oxygen consumption (VO_2peak), measured in $mL \cdot kg^{-1} \cdot min^{-1}$, evaluated before and after the intervention.

2.4 Type of Interventions

Interventions included aerobic exercises meeting the following criteria:

1. Duration of at least 20 minutes per session.
2. Performed at least twice a week.
3. Minimum intervention period of 3 weeks.

Control groups (CG) included no intervention or associated interventions.

Exercise groups followed an aerobic program with these parameters:

1. At least 30 minutes per session.
2. Conducted at least twice weekly.

Studies comparing exercise groups to healthy control groups were excluded.

2.5 Types of Outcome Measures

The primary outcome measure evaluated was VO_2peak ($mL \cdot kg^{-1} \cdot min^{-1}$).

2.6 Exclusion Criteria

The following were excluded:

- Abstracts, conference presentations, posters, letters to the editor, book chapters, or unpublished articles.
- Retrospective studies.
- Studies lacking published baseline data or where VO_2peak was not used as a primary or secondary outcome.
- Studies comparing the primary intervention (cardiopulmonary or home rehabilitation) to healthy or untrained control groups.

2.7 Research Methods to Identify Studies

Potential studies were identified by a systematic review librarian. A systematic search was conducted in Medline (Ovid, 1989–April 2021), Cochrane Central Register of Controlled Trials, CINAHL, and the PEDro database without date restrictions.

The search strategy combined Medical Subject Headings (MeSH) terms from the United States National Library of Medicine (NLM) and free-text terms for key concepts (intervention and population), with filters limiting results to clinical trials (Phase I–IV), RCTs, and systematic reviews. No language restrictions were applied. Reference lists of identified articles were screened for additional studies.

All identified articles were independently reviewed and assessed for methodological quality by three reviewers (FN, LMMS, and FC). Searches for published articles continued through April 2024.

2.8 Search Terms

Intervention strategy:

- "Exercise training" [Mesh] OR "aerobic training" OR "rehabilitation" OR "physical training" OR "exercise program".

Population strategy:

- "Congenital Heart Disease" [Mesh] OR "children" OR "child".

2.9 Quality Assessment

The methodological quality of included studies was assessed to ensure the robustness of findings and reliability of conclusions.

In the article quantification phase, the reviewers kept their scores confidential. The quality of RCTs was assessed using the Pedro scale (Physiotherapy Evidence Base Database) to evaluate the likelihood of bias in articles. Items assessed included: eligibility criteria, random allocation, concealed allocation, baseline similarity, subject blinding, therapist blinding, evaluator blinding, follow-up completeness, intention-to-treat analysis, statistical comparisons between groups, and point and variability estimates. The eligibility criterion (first item) is not included in the total score because it pertains to external validity. The total score ranges from 0 to 10, with higher scores indicating greater methodological quality. Articles with a score of 6 or higher are considered high quality, while those with a score below 6 are classified as lower quality. The Cochrane Handbook for Systematic Reviews of Interventions was used to assess the quality of included studies, focusing on risk of bias.

To ensure greater transparency regarding the methodological quality of studies chosen for this systematic review, four items were extracted from the CONSORT statement: trial registration, funding, sample size calculation, and the naming of a primary outcome.

2.10 Data Analysis

The data were processed according to the Cochrane Handbook for Systematic Reviews of Interventions, 2008. Results were presented as continuous data, including averages for each intervention and control group, standard deviations for each group, and the number of participants for whom results were recorded.

Standard deviation was calculated for each study using the change scoring method. Heterogeneity between studies was assessed both qualitatively (by comparing study characteristics) and quantitatively (using the chi-square test for heterogeneity and the I^2 statistic). Additionally, a funnel plot of the standard mean difference was used qualitatively to assess heterogeneity when more than two studies were analyzed. Where appropriate, results from included studies were combined for an overall estimate of treatment effect. A fixed-effect model meta-analysis was used, based on qualitative assessment of low risk of bias and low heterogeneity. All analyses were conducted using Review Manager Version 5.2.

3. RESULTS AND DISCUSSION

The initial research identified 1,017 studies related to physical training in patients with congenital heart disease, of which 9 were considered potentially relevant and retrieved for detailed analysis. Only 6 studies were ultimately included for relevant results and comparison in this meta-analysis. Of these, 3 studies examined cardiopulmonary rehabilitation, and 3 studies focused on home-based care, all evaluating the VO_2 outcome (Fig. 1).

3.1 Quality of Studies

The PEDro scale was used to analyze the quality of the studies. Six studies were independently scored by two authors (FN and LMMS), and discrepancies were discussed and resolved. Of the 6 studies, 5 (90%) were of good quality and 1 (10%) was of medium quality (Fig. 2).

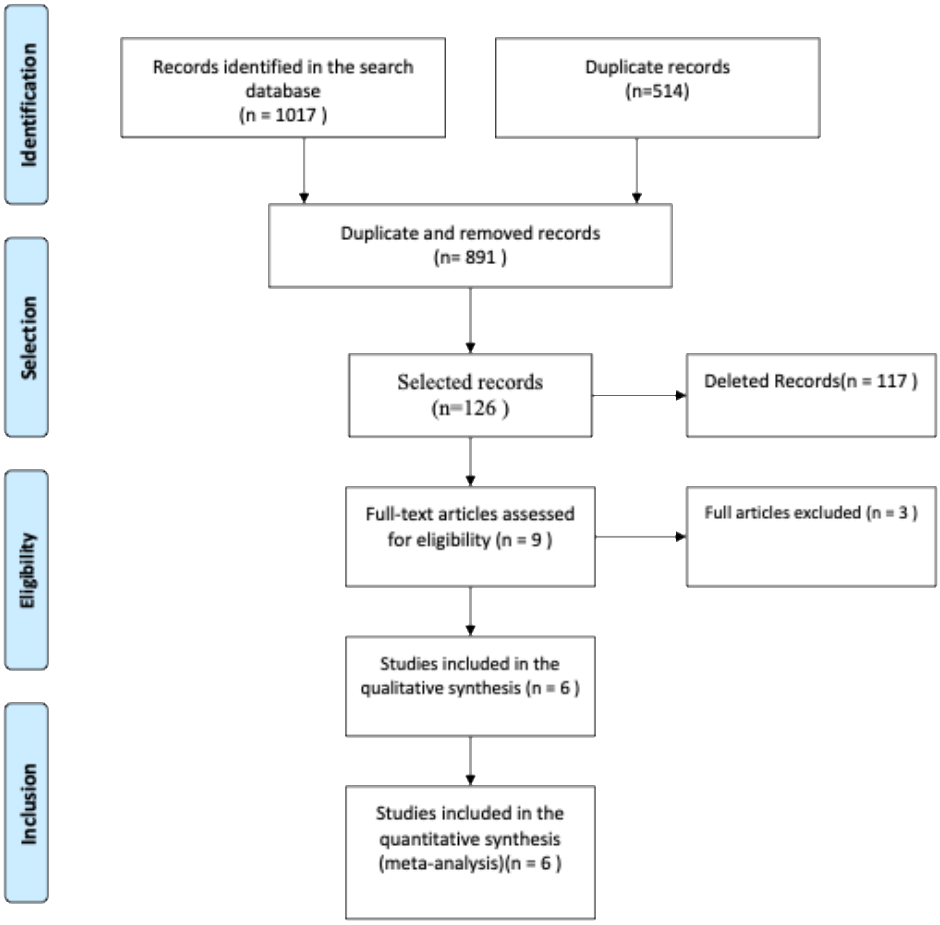

Fig. 1. Flow chart of PRISMA analysis

3.2 Characteristics of the Studies

Fig. 3 shows the 3 studies reporting the peak VO2 at the beginning and after training, which included 144 patients (Reab 81 patients / Control 63 patients). This comparison was statistically significant 2.81 [0.89, 4.74]; Z = 2.86 (p <0.004) and I2 = 49%. Fig. 4 shows three studies reporting the peak VO2 at the beginning and after home rehabilitation, including 177 patients (Reab 98 patients / Control 70 patients). This comparison was not statistically significant (p = 0.66).

This systematic review assessed that exercise interventions for patients with CHD performed in both home and outpatient settings are viable, safe, and improve functional outcomes. The studies included in our review evaluated exercise programs for populations with diverse physiological conditions: patients in the postoperative period of interatrial communication have physiologically normal hearts and were compared with individuals experiencing severe cardiopathies, many of whom have residual lesions, such as Transposition of the Great Arteries in the postoperative period of Senning and Mustard, Tetralogy of Fallot, and even Fontan physiology (univentricular hearts, with systemic venous return connected to the lungs). In the postoperative period of congenital heart diseases, the presence of residual lesions, such as pulmonary insufficiency in Tetralogy of Fallot, obstructions in pulmonary or systemic outflow (e.g., degree of aortic stenosis), use and type of medication, and especially ventricular dysfunctions are crucial for assessing exercise capacity and the risk associated with physical activity.

The risk stratification proposed by the ESC Guidelines on sports cardiology and exercise in patients with cardiovascular disease 22 provides a comprehensive and safe approach to prescribing physical exercises, their type, and intensity for adults with congenital heart disease. Standardizing exercise types and intensities allows for a more accurate assessment of the

real benefits of rehabilitation in these complex patients, offering a broader, safer, and more universal prescription. The diversity of protocols in studies, particularly when considering home rehabilitation protocols, may contribute to significant heterogeneity in results, in addition to the differences in the studied populations.

Six studies were included in the narrative analysis, and all were published in English. RCTs were performed in Canada (n = 2), France (n = 2), Norway (n = 1) and Holland (n = 1).

The total number of participants analyzed in all studies was 321 participants (conventional rehabilitation 81 and 63 control; home rehabilitation 98 and 79 control). Regarding gender discrimination, 150 boys and 171 girls were reported. The age range of the participants was 6 to 15 years, with most studies reporting mean ages ≤15 years (Table 1).

The duration of the intervention ranged from 6 to 24 weeks, with three studies reporting data for 12 weeks, one study reporting data for 10 weeks, one study reporting data for 20 weeks, and one study reporting data for 24 weeks (Table 1).

The frequency of training used during the intervention ranged from 1 to 3 days / week. Two studies performed the intervention 3 days/week and 2 studies performed the intervention 2 days/week and 2 once a week (Table 1).

Of the four studies described (aerobic training), 2 reported exercises (Table 1).

A meta-analysis was performed to analyze the peak VO2 in conventional and home rehabilitation. Forest plots graphs for changes in peak VO2 between interventions in patients with CHD are shown in Figs. 3 to 4.

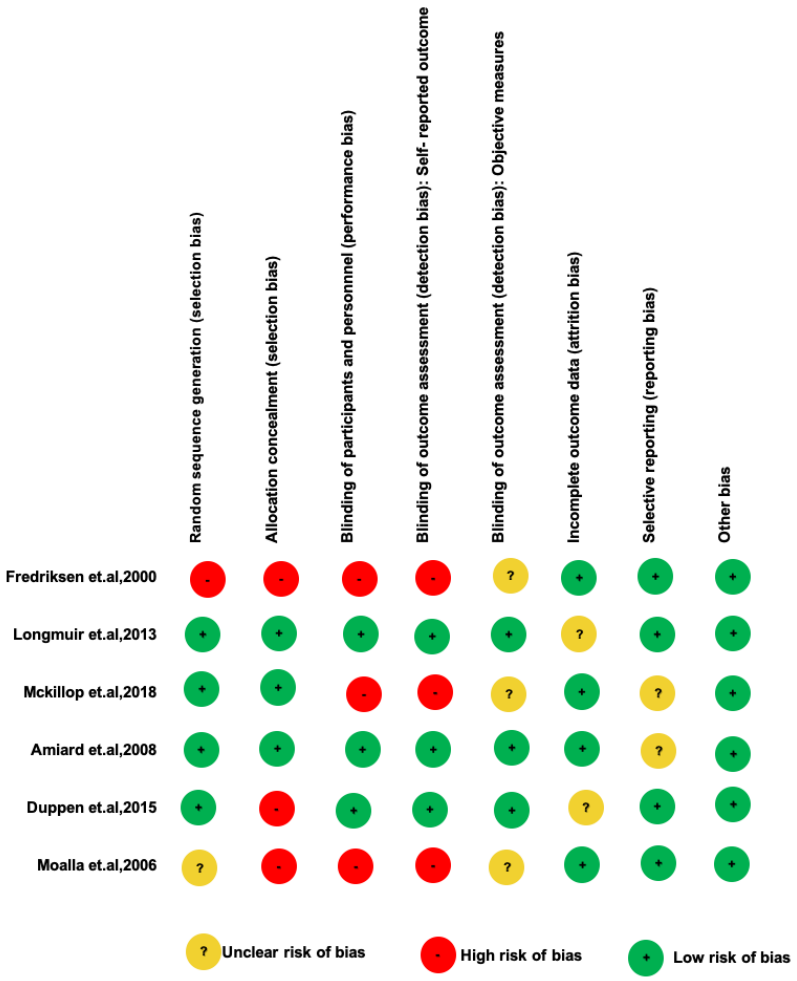

Fig. 2. Bias analysis

Table 1. Characteristics of the included studies: clinical, demographic, and description of the intervention

Authors	Population Classification.	N	Age (years)	Inverting Description			Measures studied
				Kind (Frequency/Modality/Intensity)	Frequency (Days/Weeks)	Protocol (Weeks)	
Amiard, et al 2008	3 single ventricle Atresia Valvular with intact septum 5 tretalogia de fallot 5 tga 5 cia	Intervention (13)	13.8±2.1	Aerobic training - 45 min	3 sessions/week.	10 weeks	VO2
		Control (10)	13.7±2.3	Usual activity			
Duppen et al., 2015	TOF / Fontain	Intervention (53)	15±3	Continuous aerobic exercises (40 min) and arm exercises (10 min)	1sessions/week.	12 weeks	VO2
		Control (37)	16±3	Normal activity			
Moalla et al., 2006	T4F, CIA, TGA, Pulmonary Atresia	Intervention (10)	13±1.4	Aerobic interval training 10/5 min for 45 minutes	3 sessions/week.	12 weeks	VO2
		Control (8)	12.8±1.3	Normal activity			
Fredriksen et al., 2000	TGA, CIV, CIA, T4F, RV outlet obstruction and single ventricle	Intervention (55)	12.4±1.5	Varied aerobic training	2 sessions/week.	20 weeks	VO2
		Control (38)	12.4±1.5	Normal activity			
McKillopet al., 2018	CIV, CIA, aortic stenosis, coarctation of the aorta, T4F, TGA, Pulmonary Atresia, Truncus Arteriosus Hypoplasia of the LV,	Intervention (18)	15.3±1.5	Playful Activities (With phone call)	2 sessions/week.	12 weeks	VO2
		Control (18)	14.5±1.5	Playful activities (no phone call			
Longmuir et al., 2013	Tricuspid atresia, Pulmonary atresia, Double RV outlet, LV hypoplasia, Dual EV entry lane	Intervention (30)	8±6 am	Recreational activities (1 hour and a half per week)	1 session/week.	24 weeks	VO2
		Control (31)	9.3±1.3	Educational Program			

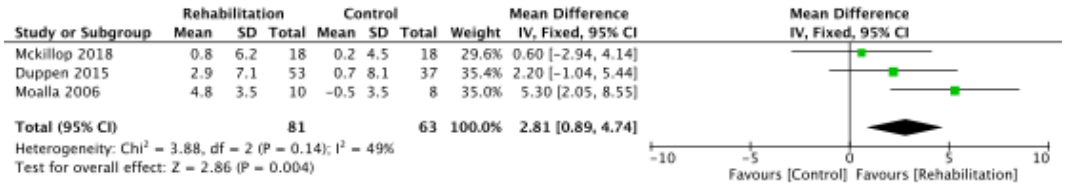

Fig. 3. Shows the 3 studies reporting the peak VO2

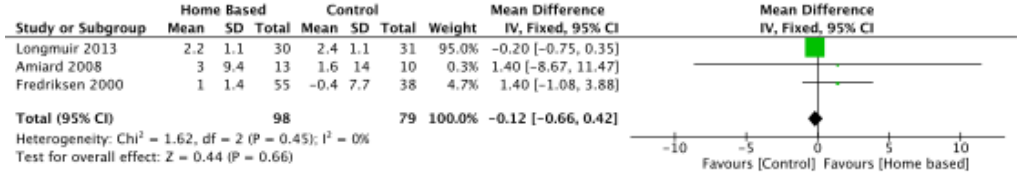

Fig. 4. Shows three studies reporting the peak VO2 at the beginning and after home rehabilitation

Regarding the population, children undergoing outpatient rehabilitation demonstrated improved oxygen consumption, though with different interventions. This highlights the importance of clinical and randomized trials for specific populations and age groups, with defined protocols, to ensure better safety and conditioning.

Considering the spectrum of congenital heart diseases, their residual lesions, and specific characteristics, further studies will be necessary, potentially separated by pathology and those features described above, to demonstrate the real benefit of cardiopulmonary rehabilitation in each population, as well as its safety and type of intervention (Duppen et al., 2015; 2013).

Cardiopulmonary rehabilitation in an outpatient setting proved to be more beneficial than home-based rehabilitation, which showed no significant improvement in VO_2. This suggests a possible need for trained professionals to accompany home rehabilitation activities, ensuring uniformity and safety for both patients and their families during physical exercise. Home rehabilitation requires more thorough evaluation through clinical trials that control the intensity, frequency, and safety of patients (McBride et al. 2007, Elisberg et al. 1953). Tele-rehabilitation could serve as a valuable tool for conducting more precise and safe intervention protocols, where patients are monitored by health professionals, such as physiotherapists. In the current context of the Coronavirus pandemic, this approach, combined with remote monitoring devices (telerehabilitation), presents an extremely promising option.

In addition to the well-known benefits of exercise for the general population, physical activity for children with congenital heart disease represents the beginning of an active and functional life, providing safety for the patient, family, and professionals involved in education (Duppen et al., 2015; 2013; Akamagwuna & Badaly 2019).

The stigma associated with congenital heart disease often includes overprotection, insecurity, and almost absolute restriction of physical activity, isolating these children in school, extracurricular activities, recreational activities, and social life (Opocher et al. 2005). A well-structured cardiopulmonary rehabilitation program, which provides safe parameters for prescribing supervised or recreational activities, is essential for integrating approximately one percent of the world population with congenital heart disease into real society, enabling them to become active, productive citizens.

4. CONCLUSION

There are several strengths in our review. To date, this meta-analysis represents the most up-to-date research on outpatient and home rehabilitation specifically in children with CHD, showing improvements in oxygen consumption as previously established, particularly in outpatient aerobic training outcomes, while home care requires further investigation. Additionally, we employ a conservative approach when calculating standard deviations. Furthermore, our research question on outpatient and home rehabilitation in children has not been adequately addressed by previous reviews. Therefore, this systematic review and meta-analysis was necessary to address the significant gaps in cardiopulmonary rehabilitation for patients with congenital heart disease.

5. LIMITATION OF THE STUDY

Our study was limited by constraints including geographic diversity and the absence of a standardized definition for normal and recreational activities.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declares that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc.) and text-to-image generators have been used during the writing or editing of this manuscript.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Aqui estão as referências formatadas no estilo do exemplo fornecido:

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