

REVIEW ARTICLE



Inspiratory muscle training on quality of life in individuals with spinal cord injury: A systematic review and meta-analysis

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STUDY DESIGN: Systematic review and meta-analysis.

OBJECTIVES: The objective was to summarize the effectiveness of Inspiratory Muscle Training (IMT) on the quality of life in individuals with Spinal Cord Injury (SCI).

METHODS: An online systematic literature search was conducted in the following databases: PubMed/MEDLINE, PubMed CENTRAL, EMBASE, ISI Web of Science, SciELO, CINAHL/SPORTDiscus, and PsycINFO. Randomized and non-randomized clinical studies investigating the effectiveness of IMT in quality of life were included in the present study. The results used the mean difference and 95% confidence interval for maximal inspiratory pressure (MIP), forced expiratory volume in 1 s (FEV₁), maximal expiratory pressure (MEP), and the standardized mean differences for the quality of life and maximum ventilation volume.

RESULTS: The search found 232 papers, and after the screening, four studies met the inclusion criteria and were included in the meta-analytical procedures ($n = 150$ participants). No changes were demonstrated in the quality of life domains (general health, physical function, mental health, vitality, social function, emotional problem, and pain) after IMT. The IMT provided a considerable effect over the MIP but not on FEV₁ and MEP. Conversely, it was not able to provide changes in any of the quality of life domains. None of the included studies evaluated the IMT effects on the expiratory muscle maximal expiratory pressure.

CONCLUSION: Evidence from studies shows that inspiratory muscle training improves the MIP; however, this effect does not seem to translate to any change in the quality of life or respiratory function outcomes in individuals with SCI.

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INTRODUCTION

Spinal cord injury (SCI) is defined as damage to the spinal cord that results in disturbances to normal sensory, motor, or autonomic function and can affect a patient's physical, psychological, and social well-being [1]. According to National Spinal Cord Injury Statistical Center [2], the most recent estimate of the annual incidence of SCI is approximately 54 cases per one million people, which equals 17,900 cases each year, generating a cost in the first year of about US\$1,163.425 million with high tetraplegia.

Among the physical disturbances caused, respiratory dysfunction resulting from SCI remains a major cause of morbidity, mortality, and economic burden [3]. The extent of dysfunction depends on the injury level and completeness of the injury. Impairment of muscles of respiration post-SCI can lead to an increase in infections in the respiratory system, which can progress to pneumonia and atelectasis [4]. Individuals with disabilities were characterized by difficulty performing everyday activities, feeling tired, having rest and sleep problems, dependence on drugs and pain [5], chronic fatigue, and tiredness [6].

Interventions to improve respiratory dysfunction are highly relevant to this population, reducing respiratory muscle weakness

and possibly increasing lung volumes and exercise tolerance, which can be translated into a sedentary lifestyle reduction and better quality of life (QoL) [4, 7].

The concept of QoL is challenging to define due to its multidimensional nature. The variety of instruments available in the literature makes the psychometric analysis of this context difficult, especially in those following SCI [8]. Equally as important as knowing the clinical impact of pathology is identifying its consequences in daily activities, knowing whether the individual will be able to work and perform the daily activities necessary to fulfill his/her role in different contexts [9], helping to promote not only psychological but also physical health, and well-being after injury [8]. Facing several changes caused by an SCI, individuals are forced to start living in a new condition and commonly experience negative perceptions regarding their QoL, such as suicidal thoughts [10].

The World Health Organization (WHO) [11] states that QoL is the individual's perception of their position in life in the context of the culture and value systems in which they live regarding their goals, expectations, standards, and concerns. However, Dijkers [12] describes a broad and important additional reflection regarding the QoL, separating it into three groups, e.g. QoL as subjective

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well-being, QoL as achievement, and QoL as utility. Given that physical training is known for promoting important and positive changes in health-related QoL, and that inspiratory muscle training (IMT) has been suggested as an alternative or complement to conventional exercise in this population, it is possible that IMT may elicit changes in the QoL of individuals with SCI, with warrants investigation.

IMT is a therapy that involves specific training of respiratory muscles to yield improvements in respiratory muscle strength and function. The studies indicate that IMT has the potential to increase strength, inspiratory muscle resistance, vital capacity, and inspiratory capacity [7, 13–17] in individual SCI. However, although a few studies showed the clinical benefits of several other interventions, such as functional electrical stimulation [18] and short home-based upper-body exercise intervention [19] on QoL, little is known about whether interventions aimed at improving lung function have an impact on the QoL of these individuals. A previous systematic review [7] described possible favorable effects of the IMT intervention on QoL. However, at that time, this study could not conduct a data meta-analysis as the instruments utilized to assess the QoL were different, while alternative therapies to improve respiratory muscles were considered (e.g., singing, normocapnic hyperpnoea).

The specific objective of this study was to determine the effect of the IMT on the QoL of individuals with SCI. The secondary objective was to investigate the effect of IMT on respiratory muscle strength and pulmonary function of individuals with SCI.

METHODS

Protocol and registration

The conduct of this study was based on the Cochrane Handbook for Systematic reviews of interventions [20]. The study protocol was registered with the International Prospective Registry of Systematic Reviews (PROSPERO): CRD42020193778 and the study was reported in line with PRISMA [21].

Eligibility criteria

Participants. We included studies involving people with any level of acquired SCI, both acute and chronic, adult participants aged older than 18 years, both sexes, with a complete or incomplete motor SCI, according to the American Spinal Injury Association Impairment Scale (AIS) grade A, B, C, D or E. Our first proposal was to analyze just individuals with complete injuries, but due to the lack of studies, we decided to include complete and incomplete injuries.

Intervention. Clinical trials of studies that described an IMT intervention and compared with a control group. IMT was considered with a minimum of 4 weeks of training, in which the load was gradually increased, using any respiratory incentive devices with a linear and non-linear load. IMT was the sole intervention difference between the groups.

Control. The control group should not have received IMT training but may have received an active intervention (i.e., education, psychological intervention), or usual medical care alone was considered for inclusion.

Outcomes. We included studies that evaluated the QoL after an IMT protocol in individuals with SCI. The primary outcome was to analyze the QoL, expressed by the change in scores of the assessment methods (validated scale). Secondary outcomes were respiratory muscle strength, which included measures of respiratory muscle strength (maximal inspiratory pressure [MIP] and maximal expiratory pressure [MEP]), expressed as a change in measures of static (i.e., isometric) or dynamic strength between the baseline and post-training/control period.

The other secondary outcome that was analyzed was the pulmonary function, which included measures of 1) forced expiratory volume in one second (FEV₁), expressed as change in the measure of (pulmonary) volume capacity exhaled in the first minute of expiration between baseline and post-training/control period and functional capacity, and 2) maximum ventilation volume (MVV), expressed with the greatest volume of air that the individual could mobilize in one minute with maximum voluntary effort. All the effects were analyzed through outcome changes.

Study designs. Due to the lack of studies in this area, we included all randomized and non-randomized clinical studies that used a validated scale to assess the QoL in individuals with SCI following IMT with an increased device load during the training protocol compared to a control group.

Search methods to identify studies

We did not restrict searches by date, language, or publication status. We searched the following databases: Pubmed/MEDLINE (16 Aug 2020), CENTRAL (16 Aug 2020), EMBASE (16 Aug 2020), ISI Web of Science (16 Aug 2020), Scielo (9 Aug 2020), CINAHL/SPORTdiscus (16 Aug 2020), PsycInfo (16 Aug 2020). A new search was performed on July 12, 2022, and no additional records were found. Appendix 1 lists the search strategies used. Due to the lack of trials in this area, we did not restrict our search by using a filter for Randomized Controlled Trials (RCTs) and sought to identify all types of trials. We reviewed the bibliographies of the trials identified and other reviewers of the subject. We also searched the following trial registries: ClinicalTrials (www.clinicaltrials.gov) (14 June 2020); Australian New Zealand Clinical Trials Registry (www.anzctr.org.au/trialSearch.aspx) (14 June 2020); Controlled Trials meta register (<http://controlled-trials.com>) (14 June 2020) and a new search were performed on July 12, 2022, and no additional records were found. The gray literature was also analyzed.

DATA COLLECTION

Study selection

One review author (LAM) selected trials for inclusion criteria according to scanned eligible titles and abstracts. When a title and abstract could not be excluded, two independent reviewers (LAM and MF) obtained the full-text article and independently screened the article. The disagreements about inclusion studies were resolved by a third review author (GCJ). The software used in this research stage was based on recommendations in the Cochrane Handbook for Systematic Reviews of Interventions [20], the Covidence Systematic Review Software, Veritas Health Innovation, Melbourne, Australia (available at www.covidence.org).

Risk of bias assessment

The Cochrane risk-of-bias tool for randomized trials version 2 (RoB-2) [21] was used in this research. Assessment for individual studies contains the following five domains: randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. In each domain, the reviewers' authors (LAM and MF) made a judgment of low risk of bias, high risk of bias, and some concerns (unclear). If one disagreement occurred, a third review (GCJ) was resolved.

Quality of the evidence

The analysis of the quality of the evidence was carried out by two authors (LAM and MF) using GRADE evidence, which is part of undertaking a Cochrane Review [20], using a desktop version of GRADEpro. GRADE is an established method to rate the quality of evidence with five GRADE considerations: Risk of bias, imprecision, inconsistency, indirectness, and publication bias (Appendix 2: Grading the strength of evidence).

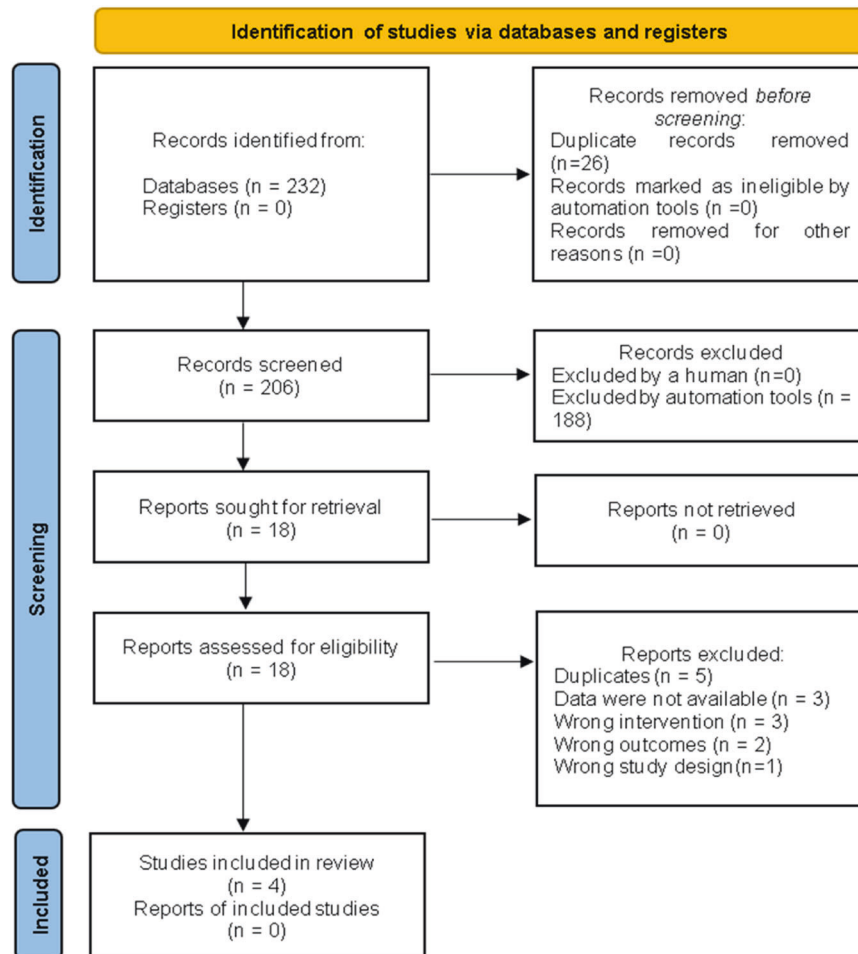


Fig. 1 PRISMA statement 2020 flow diagram for systematic reviews, which included searches of databases and registers only.

Data extraction

For each included study, a review (LAM) documented the following information using the Software Review Manager (RevMan 5) (based on recommendations in the Cochrane Handbook for Systematic Reviews of Interventions) [22]: study design, individual characteristics (age, number, AIS classification, gender). We resolved any disagreement by discussion and contacted the author to obtain data or information if necessary. A third review author (GCJ) resolved disagreements if they existed. Both review authors independently conducted the data analysis.

DATA SYNTHESIS

Statistical analysis

After the studies inclusion, one review (LAM) documented the data: study design, protocol characteristics: groups, number of participants in each group, mean and standard deviation (SD) for each outcome (including unit of measurement and interpretation of scores) at Software Review Manager 5.4 (RevMan). Two other reviewers (MF and GCJ) checked this data. The authors used different rating scales to analyze the QoL and MVV.

Heterogeneity

The I^2 statistic examines the percentage of total variation across RCTs due to heterogeneity rather than chance. We used a fixed-effect model when the statistical homogeneity ($I^2 < 50\%$) calculated 95% confidence intervals (CI) for each effect size estimate. For substantial heterogeneity, random-effect models were used to adjust between-study variance ($I^2 > 50\%$) [20]. We

also used visual inspection of the forest plots to assess heterogeneity.

Data synthesis

We calculated the Standard Mean Difference (SMD) and 95% CIs for QoL and MVV because the authors used different metrics for the same outcome. MIP and FEV₁ were analyzed in the trials using the same measurement; then, we calculated the Mean Difference (MD) and 95% CIs.

Subgroup analysis

Due to the lack of studies and the small number of trials available for systematic reviews, a subgroup analysis was not possible.

RESULTS

Flow of studies through the review

The search found 232 papers, and 26 were duplicates. A total of 206 studies were screened, but 188 were irrelevant. Moreover, 18 full-text studies were assessed for eligibility, but 14 were excluded (5 duplicates, 3 pieces of wrong data not available, 3 wrong interventions, 2 wrong outcomes, and 1 wrong study design). Only 4 studies met the inclusion criteria. We present a PRISMA diagram [21] in Fig. 1.

Characteristics of included studies

Design. Data from 4 eligible studies are shown in Table 1. One author [23] carried out two different analyses with IMT; due to this, there are 5 studies in Table 1. A total of 150 participants were studied, 91 had complete tetraplegia, 47 had incomplete tetraplegia,

Table 1. Characteristics of studies.

Study Year Design	Subjects		ASIA		Intervention		Outcomes Measure
	Intervention N	Control	Intervention AIS	Control	Intervention Device	Control	
	Sex: M/F		Tetraplegia		Training Load		
	Age: mean (SD) / Y		Paraplegia		Sessions per week		
					Duration of sessions		
					Number of sessions		
					Training time		
Mueller et al. 2013 Randomized Clinical Trial	8 6/2 35.2 (12.7)	8 6/2 41.6 (17)	AIS A Tetraplegia	AIS A Tetraplegia	Respift S less than 80% maximal inspiratory power 10 min 4x per week 32 supervised training 8 weeks	Voldyne 5000 NS 10 min 16 times (30–40 s) 32 supervise training 8 weeks	QoL (SF-12) MIP FEV ₁ MVV
Postma et al. 2014 Randomized Clinical Trial	19 18/1 47.1 (14.1)	21 17/4 16.6 (14.9)	AIS A AIS B AIS C AIS D Tetraplegia Paraplegia	AIS A AIS B AIS C AIS D Tetraplegia Paraplegia	Threshold Training was 60% MIP 7 sets of 2 min 5x a week 8 weeks	NS	QoL (SF-36) MIP FEV ₁ MVV
Litchke et al. 2012 Non- randomized Clinical Trial	8 NS NS	8 NS NS	NS Tetraplegia	NS Tetraplegia	Power Lung Begin at level 1 3 sets of 10 breathing cycles 3 times per day 9 weeks	NS	QoL (SF-36v2)
Litchke et al. 2012 Non- randomized Clinical Trial	8 NS NS	8 NS NS	NS Tetraplegia	NS Tetraplegia	Expand-a-Lung Begin at level 1 10 breathing cycles (10–20 s) 3 times per day 9 weeks	NS	QoL (SF-36v2)
Boswell-Ruys et al. 2020 Randomized Clinical Trial	30 30/0 51.5 (14.3)	32 28/4 55.7 (14.9)	AIS A AIS B AIS C Tetraplegia	AIS A AIS B AIS C Tetraplegia	Threshold Training was 30% MIP increased each week Three to five sets of 12 breaths Twice a day, 5 days a week 6 weeks	Threshold Modified pressure valve permanently open Three to five sets of 12 breaths Twice a daily, 5 days a week 6 weeks	QoL (SF-36wwt) MIP VEF ₁

AIS American Impairment Scale, FEV₁ Forced expiratory volume in one second, MVV Maximum ventilation volume, MIP Maximal inspiratory pressure, QoL Quality of life, NS Not specified.

9 had complete paraplegia, 1 had incomplete paraplegia, 1 had spastic cerebral palsy, and 1 had congenital upper and lower limb deformities. One hundred and twenty-seven participants were male. Four RCTs investigated the effect of IMT on QoL. They used different scales for the study: An adapted Short-Form (SF)-12 quality of life questionnaire [24], a 36-Item Short-Form Health questionnaire (SF-36) [25], a 36-item Medical Outcome Study Short-Form Health Survey Version 2.0 (MOS SF-36 v2) [23], Short-Form Health Survey: walk/wheel (SF36 ww) [26].

Interventions

One study analyzed the effect of IMT on MIP using the Threshold booster, with an initial load of 30% of MIP, increasing the load weekly, using 3–5 sets of 12 breaths, twice a day, 5 days a week,

for 6 weeks [26]. Litchke [23] analyzed two different techniques: one with a Power Lung device, starting at level 1, 3 sets of 10 breathing cycles, 3 times a day for 9 weeks. Another technique was with an Expand-a-lung device, starting at level 1, 10 breathing cycles (10–20 s), 3 times per day for 9 weeks. Postma [25] analyzed with a Threshold device, was 60% MIP, 7 sets of 2 min, 5 times a week for 8 weeks. Using a Respift S device, Mueller [24] analyzed less than 80% MIP, 10 min, 4 times per week, 32 supervised training for 8 weeks. Three studies used the same measurement for analyzing FEV₁ after IMT using the same American Thoracic Society protocol but different devices for this measurement [23, 25, 26] and two studies analyzed the effect of IMT on MVV with the same protocol and different devices [23, 25]. See the characteristics of studies in Table 1.

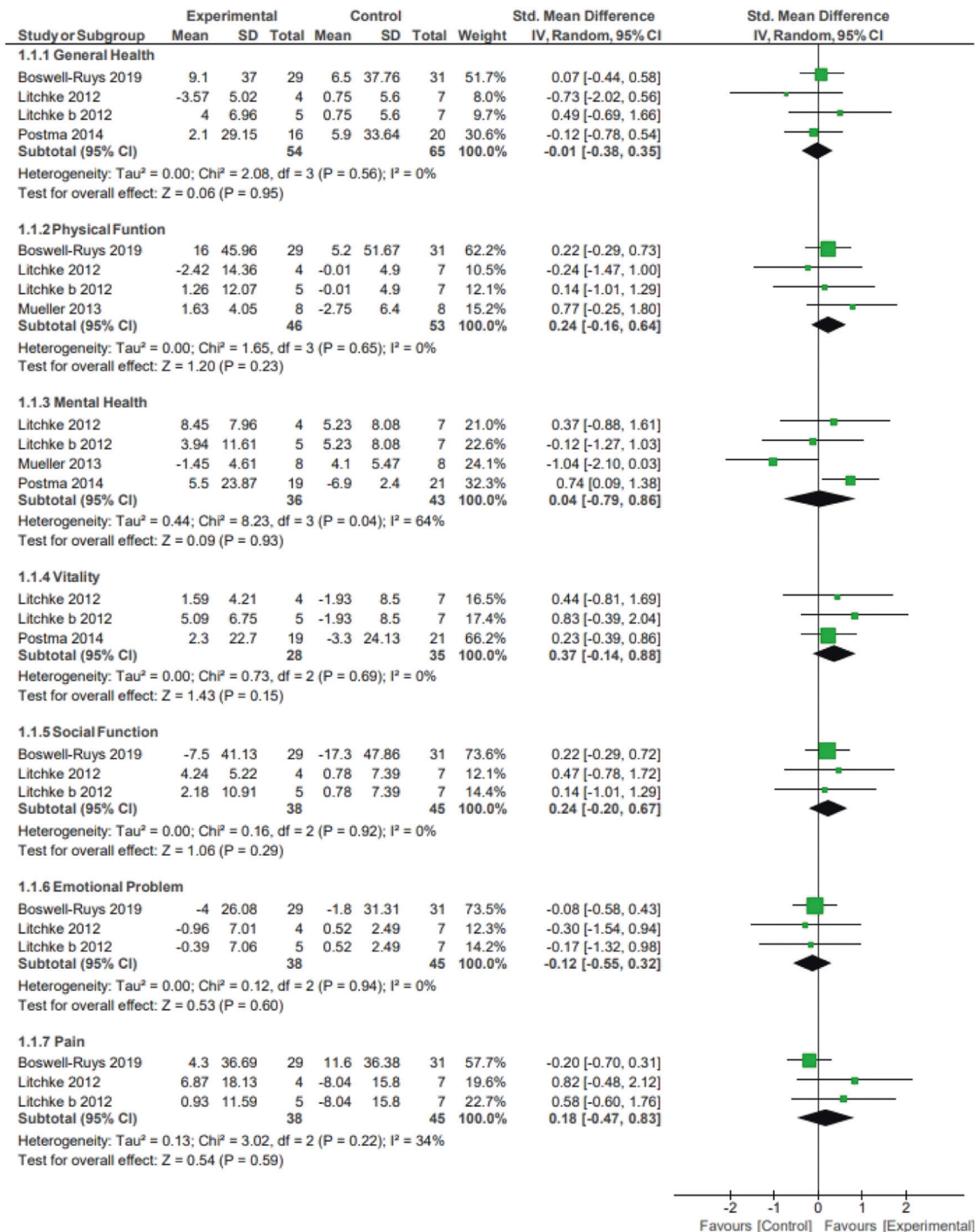


Fig. 2 Forest Plot of Quality of life.

Outcomes

Quality of life. We divided the QoL by domain because the authors used different questionnaires. All the questionnaires were derivatives by SF-36, Litchke et al. [23], used SF-12, Postma et al. [25], used SF-36, Mueller et al. [24], used SF-36v2 and Boswell-Ruys et al. [26], used SF-36 ww. The domains analyzed were general health, physical function, mental health, vitality, social function, emotional problem, and pain. The results were expressed with SMD.

We did not observe changes in the QoL domains after IMT (Fig. 2).

Pulmonary function and respiratory muscle strength

Forced expiratory volume in 1 s. Three authors [24–26] ($N = 60$) analyzed this variable after IMT, the results were expressed with MD, but the data did not show a significant difference (MD = 0.16; 95% CI, -0.16 to 0.49; $P > 0.05$) (Fig. 3).

Maximum ventilation volume. Two authors [24, 25] ($N = 29$) analyzed this variable in our studies. The results were expressed with MD. The data did not show a significant change in maximum ventilation volume after IMT (MD = 0.11; 95% CI, -0.42 to 0.64; $P > 0.05$) (Fig. 3).

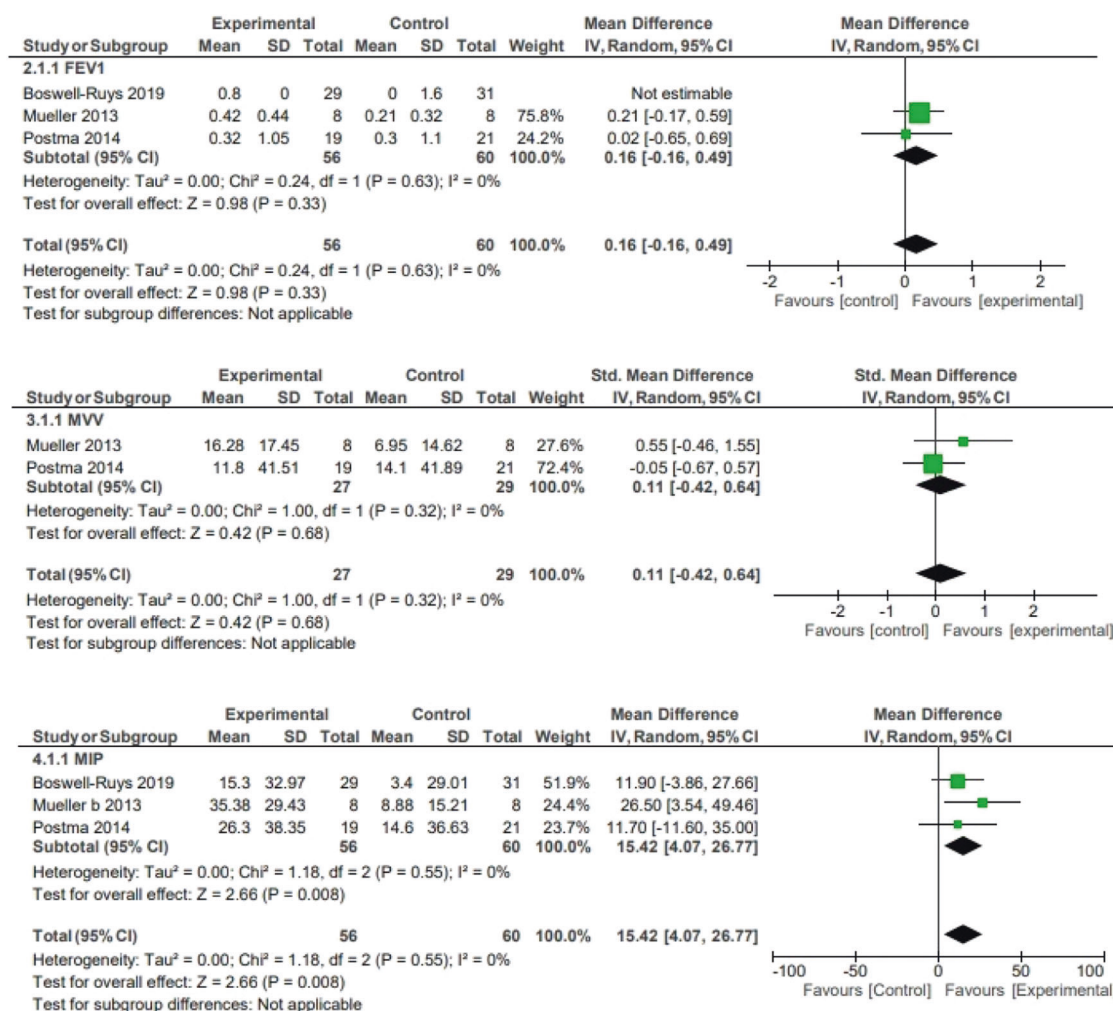


Fig. 3 Forest plot of pulmonary function and respiratory muscle strength. FEV₁ Forced ventilation volume in 1 s. MVV Maximal ventilatory pressure, MIP Maximal inspiratory pressure.

Maximal inspiratory pressure. Three authors [24–26] (N = 60) analyzed maximal inspiratory pressure. The results were expressed with MD. The findings showed a significant change in this analysis, with a big overall effect, after IMT expressing in 15,42 cmH₂O increase in inspiratory muscle strength (MD = 15.42; 95% CI, 4.07 to 26.77; P < 0.05) (Fig. 3).

Maximal expiratory pressure. We did not find any articles on MEP.

Risk of bias in included studies

Two independent authors (LAM, MF) assessed the risk of bias using the Cochrane Risk of Bias tool version 2 [RoB2] [21] of the four RCTs included. We resolved all disagreements after a consensus meeting. Figure 4 presents the risk of bias percentage of the author's judgments and an overview of the risk of bias scores on the author's judgments. All studies randomized the participants. One study used intention to treat intervention assignment and did not show the risk of bias [26]. Two studies showed some concerns: bias due to deviations from intended interventions, missing outcome data, randomization process, deviations from intended interventions, missing outcome data arising from the randomization process for all outcomes [24], in general bias due to deviations from intended interventions and missing outcome data for all secondary outcome, not to the QoL [25]. One study [23] had a high risk of bias because the allocation of these studies is unclear.

We did not detect any other potential risks of bias.

Grading the strength of evidence

The evidence is current to July 12, 2022. The grading of the strength of evidence is shown in Appendix 2.

DISCUSSION

This is the first systematic review with meta-analysis assessing the IMT effects on the QoL and other main respiratory parameters in individuals with SCI. Despite the benefits of the IMT intervention on inspiratory muscle strength and respiratory parameters, its effect was not translated to a better QoL. In general, all studies showed a low risk of bias. Just two judgments showed high risk for overall bias and randomization process. The certainty of evidence was very low for most of the analysis, and moderate for domains of QoL, except for mental health and pain.

Our study is unique because we evaluated the QoL in individuals with SCI not only adopting the rigorous method to conduct a systematic review, which permeated a detailed evaluation using the format PICO and COVIDENCE for screening and extraction data but also using more appropriate tools for assessing the risk of bias (ROB-2 tool) and the certainty of the evidence (GRADE method). This approach minimized the risk of obscure discoveries and interpretations.

The IMT is consecrated in the literature due to its efficacy in individuals with SCI [7]; however, we examined the effect of the IMT in the QoL through a systematic review with a meta-analysis

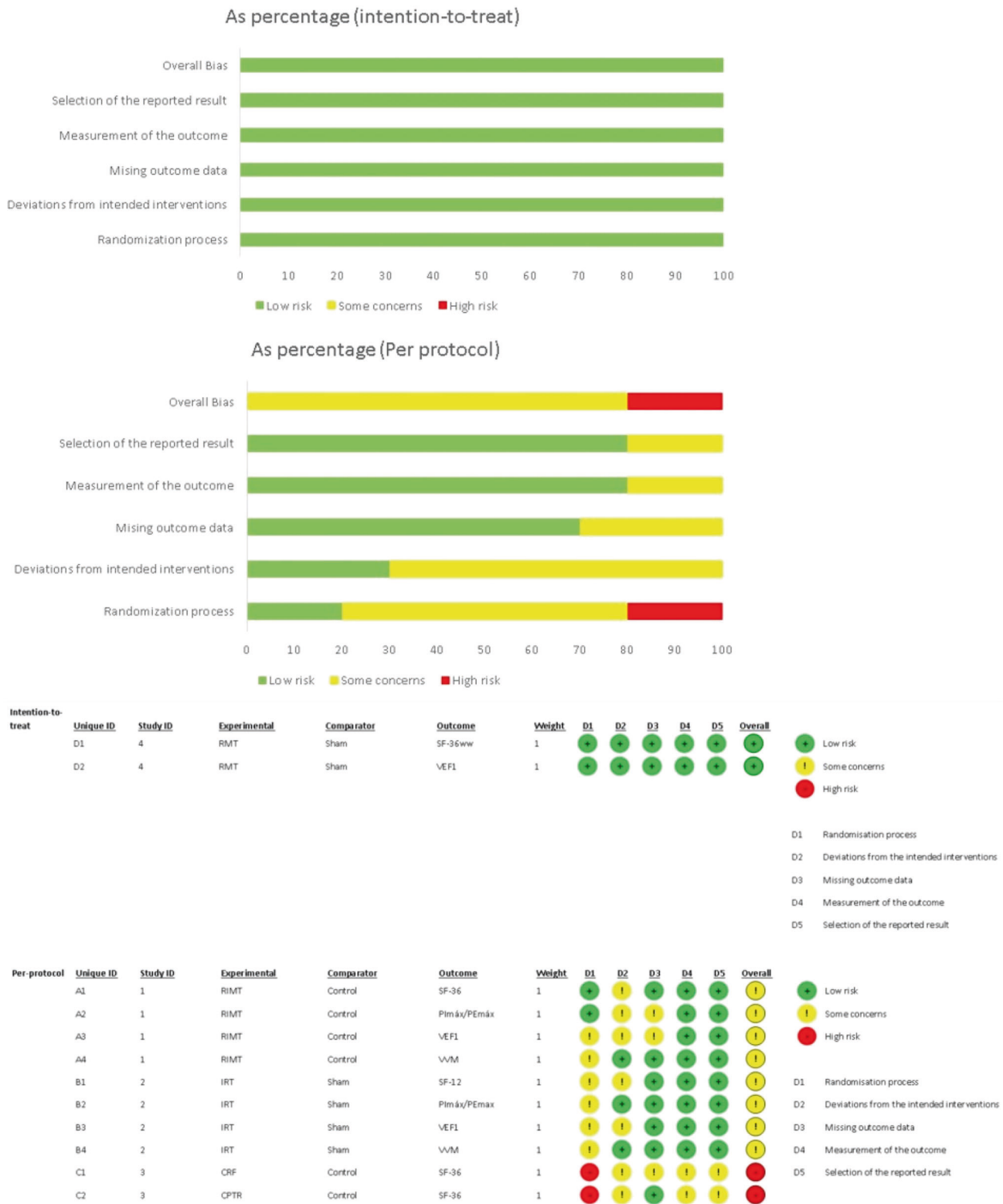


Fig. 4 Risk of bias graph: review authors’ judgments about each Risk of bias, and an overview of the Risk of bias scores: Review authors’ judgments. Study A: Postma, 2014. Study B: Mueller, 2013. Study C: Litchke, 2012. Study D: Boswell-Ruys, 2020.

procedure. A common complication resulting from an SCI is the weakness of the respiratory muscles, especially in individuals with tetraplegia, which increases the risk of pulmonary infections such as pneumonia, higher mortality, and risk of hospitalizations [26]. In the study by Boswell-Ruys et al. [26], despite encountering a small

increase in QoL after the IMT, the respiratory symptoms improved significantly.

Scientific research concerning the QoL in SCI is available in the literature [5, 9, 12, 19, 23, 25], however, psychometric variability is a factor that may hinder robust interpretations [8]. Generally,

respondents do not distinguish between health and functional limitation, and this becomes evident when we think about QoL assessment through the subjective well-being domain, proposed by Dijkers [12], which is related to cognitive and affective issues. In this perspective, the changes that occur in the respiratory system after IMT, even causing systemic physiological repercussions, may not be perceived as a direct effect on general QoL, but only when asked about perceptions on respiratory function.

In addition to the well-being domain, other domains must also be taken into account for a comprehensive analysis of the QoL according to Dijkers [12], as well as the achievement and the utility dimension. Achievement dimension can be interpreted by the survival of individuals with SCI injury after IMT, reflecting in the reduction of hospitalizations and reduction in the risk of pneumonia, while the utility dimension, a limited measure in the context of SCI [8, 12], can be analyzed through disability-adjusted life years. At this moment, we still do not have robust data that can infer the real size of the IMT effect in these dimensions [7].

Other components were also studied to assess the QoL in individuals with SCI, with inconclusive effects, such as pharmacological and non-pharmacological intervention in chronic pain management [27] and body weight training without load, in the depression symptoms and behavioral mechanisms. Better scores in psychological stress and pain have been documented after more intense physical training. The authors emphasize that greater exercise adherence improves QoL scores [28]. Muller et al. [24], recommend motivating individuals to achieve the highest training intensity in each session, as it appears to be an important stimulus for effective training shown by the high effect size on the physical component assessed by the SF-12. All these aspects can be justified by requiring the individual's participation in activities, as they require minimal skills, which are impaired after an SCI; therefore, the importance of specific training programs in this population is growing.

We analyze other respiratory variables, including MVV, FEV₁, and MIP. The studies showed significant differences only for MIP, while the FEV₁ and MVV had no improvements after IMT, similar to a previous study [16]. The mean initial MIP of the studies included in this review was 59.1 cmH₂O with an increment at the end expressed through this meta-analysis in 15cmH₂O. Studies have shown that individuals with greater inspiratory weakness could achieve more gains in inspiratory muscle strength after undergoing rehabilitation protocols than those without weakness [16, 17].

The high level of injury and the individuals' complete injuries included in this review may be another factor to be considered for not showing gains in QoL after IMT. These individuals have no innervation in the upper abdomen, which is irreversible to complete SCI and makes it difficult to perform more elaborate activities. Except for one author [25], the others [23, 24, 26] analyzed domains of physical function, without considerable gains in QoL. The mean duration of the protocols was 7.66 weeks, and the authors used different devices and training loads. These data draw attention to the extent to which this improvement can be reflected in this population, and there are still no well-established parameters in the literature.

This study has limitations, namely the few references in the literature, which may not reflect the reality of this population, and the significant heterogeneity among the protocols, which makes it challenging to identify adequate protocol characteristics.

Future studies with better methodological quality would help to elucidate the potential benefits and safety of the IMT intervention in SCI individuals. Due to the lack of studies and the small number of trials available for systematic reviews, the subgroup analysis was not possible.

CONCLUSION

IMT showed significant gains in inspiratory strength muscles and respiratory parameters in SCI individuals; however, this

modification does not sufficiently translate to a better QoL. The risk of bias of the studies included in this overall was low and the certainty of evidence ranged from very low to moderate. Further studies assessing the impact of IMT on the QoL are needed.

DATA AVAILABILITY

All data generated or analyzed during the current study are included in this article and the Supplementary information files.

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AUTHOR CONTRIBUTIONS

LAM was responsible for designing the review protocol, screening potentially eligible studies, extracting data, meta-analysis, writing the data, creating the table of results and figures, and writing the article. MFF was responsible for extracting and interpreting data and contributing to the writing of the article. GCJ was responsible for designing the review protocol, resolving discrepancies between authors, interpreting the data, and reviewing the writing of the article. GRC and WRM were responsible for assisting in the elaboration of the protocol, assisting in the meta-analysis, interpreting the results, and reviewing the writing of the article. GFBC

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COMPETING INTERESTS

The authors declare no competing interests.

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