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REVIEW ARTICLE

Does the external nasal dilator strip help in sports activity? A systematic review and meta-analysis

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Abstract

Background Numerous studies have shown that the external nasal dilator (END) increases the cross sectional area of the nasal valve, thereby reducing nasal resistance, transnasal inspiratory pressure, stabilizing the lateral nasal vestibule, and preventing its collapse during final inhalation.

Objectives Our objective was to carry out a systematic review of the literature and meta-analysis on the effects of the END during physical exercise.

Methods After selecting articles in the PubMed, Cochrane Library and EMBASE databases, 624 studies were identified. However, after applying the inclusion and exclusion criteria, 19 articles were considered eligible for review.

Results Those studies included in the meta-analysis, the maximal oxygen uptake (VO_2max.) outcome was assessed in 168 participants in which no statistically significant difference was found, MD (95% CI) = 0.86 [− 0.43, 2.15], $p = 0.19$, and $I^2 = 0\%$. The heart rate (HR) outcome was assessed in 138 participants in which no statistically significant difference was found, MD (95% CI) = 0.02 [− 3.19, 3.22], $p = 0.99$, and $I^2 = 0\%$. The rating of perceived exertion (RPE) outcome was assessed in 92 participants in which no statistically significant difference was found, MD (95% CI) = − 0.12 [− 0.52, 0.28], $p = 0.56$, and $I^2 = 27\%$.

Conclusions The external nasal dilator strip showed no improvement in VO_2max., HR and RPE outcomes in healthy individuals during exercise.

Keywords External nasal dilator · Nasal valve · Nasal resistance · Physical exercise · Performance

Introduction

The anterior portion of the nasal cavities, from the nostril to the nasal valve (NV), is the region of greatest nasal resistance to airflow and of the utmost importance in nasal physiology [1].

Nasal dilators are devices that expand the cross-sectional area of the NV in an attempt to improve airflow. There are several dilators currently available on the market that can act internally or externally in the NV region [2, 3].

Nasal dilators may be recommended for the relief of nasal congestion, allergic reaction, snoring, deviated nasal septum, obstructions that occur in the presence of certain diseases and to improve performance during physical exercise. Given that the END has an impact on maximal oxygen uptake [4–6], reduces nasal airflow resistance [7, 8], delays the onset of breathing through the mouth during aerobic exercise [9], reduces dyspnea and ventilation during exercise [4, 5, 10], among other parameters, it is possible that the dilators affect performance, particularly in aerobic exercise. However, it should be highlighted that although they are used, these devices have limited scientific support and need to be further analyzed regarding their effectiveness [2, 11, 12]. In a recent systematic review aimed at classifying dilators based on their mechanism of action, Kiyohara et al. [2] found a variety of devices available. The external (END)

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and internal (IND) nasal dilators are those that have been studied the most.

The study undertaken by Griffin et al. [4] was one of the first to evaluate the effectiveness of the external nasal dilator in healthy adult athletes. Using a randomized, double-blind, controlled sample with placebo group, a significant drop in the rating of perceived exertion, heart rate, ventilation and maximal oxygen uptake was noted when compared with the placebo group. In addition, acoustic rhinometry was used to measure the area of the NV and, with the END, a significant increase in the NV was observed at rest. On the other hand, studies carried out by Thomas et al. and Overend et al. did not find positive results in healthy adult male and female athletes who used the END [13, 14].

Considering the conflicting data from the research performed, the objective of this study was to undertake a review of the literature to date on the possible effects of the external nasal dilator on performance in physical exercise.

Materials and method

The protocol for this systematic review and meta-analysis followed recommendations from the *Cochrane Collaboration Handbook* and was based on the *Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols* (PRISMA-P) [15, 16]. This systematic review and meta-analysis are registered in the International Register of Systematic Reviews (PROSPERO) under number CRD42019112793 (https://www.crd.york.ac.uk/prospero/). According to the PICO approach, the inclusion criteria were selected by (a) population: adolescent and adult individuals of both sexes aged between 12 and 35 years; (b) intervention: external nasal dilator (Fig. 1); (c) comparison: absence of an external nasal dilator, internal nasal dilator, placebo and medication; (d) outcomes (performance measurements): maximal oxygen uptake (VO_2max.), heart rate (HR) and rating of perceived exertion (RPE).

Eligibility criteria

Only randomized controlled clinical trials (RCTs) and non-randomized controlled clinical trials (NRCTs) were included. The exclusion criteria were: (a) evaluation of the external dilator's effect on sleep, (b) snoring, pregnancy, nasal congestion, any type of neoplasia and individuals with deviated septum, (c) review studies, and (d) summaries of congresses.

Databases and search strategy

The electronic databases MEDLINE (via PubMed), Cochrane Controlled Trials Databases (CENTRAL) and EMBASE were searched with no language or date restrictions. Furthermore, a manual search was undertaken of the references from all the studies included. The following terms and keywords were used with the Boolean operators "AND" and "OR" respecting the specificity of each electronic database: *"nasal obstruction"*, *"nasal blockage"*, *"nasal airway obstruction*", "*external nasal dilator"*, *"external nasal dilator strip"*, "*exercise"*, *"physical exercise"*, *"aerobic exercise", "exercise training"* and *"sports"*.

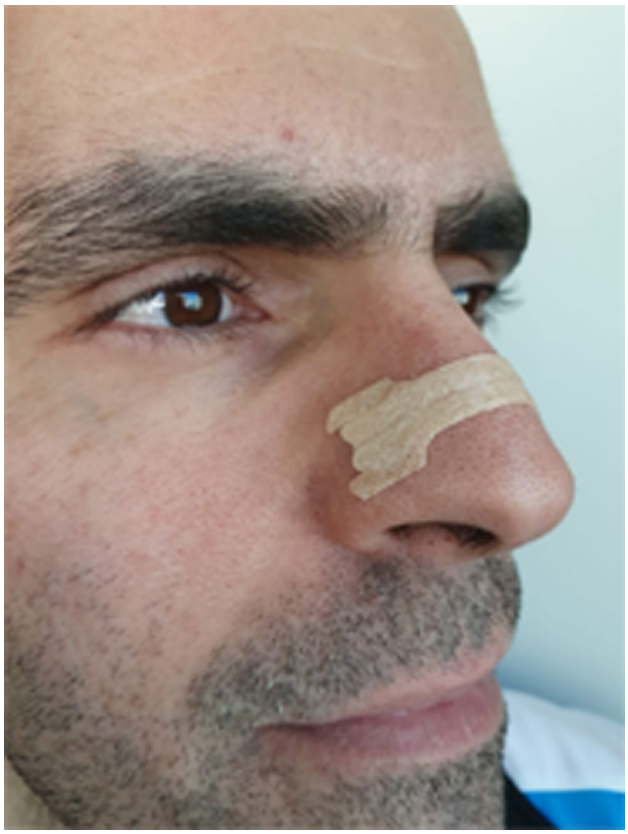

Fig. 1 External nasal dilator

Selection of studies

After excluding duplicate studies, two researchers independently selected the studies according to the eligibility criteria, by first reading the titles and abstracts before then analyzing the texts in full. Disagreements on the inclusion and exclusion of certain studies were resolved by a third researcher.

Data extraction and risk of bias assessment

Data on authorship and year of publication, intervention and comparison, sample, evaluated parameters and results from the selected studies were extracted and organized in Table 1.

Table 1 Characteristics of the included studies

Study	Intervention	Control	*N*	Outcome description	Intervention results	Control results	*p* value
VO_2max							
Trocchio 1995	END: Breath-Right®	Without ND	16 M	VO_2max (ml/kg/min)	END = 43.8±6.5	Control = 44.0 ± 6.7	Between 0.26 – 0.84
Griffin 1997	END/LI and END/HI	Placebo (strip without elastic strips in the center)	30 (20 M and 10 F)	VO_2 (L/min)	END/LI= 1.254 END/HI= 1.861	Placebo/LI = 1.395 Placebo/HI= 2.04	$p < 0.05$
Case 1998	END: Breath-Right®	Placebo and without ND	9 M	VO_2max (ml/kg/min)	END = 48.2 ± 6.1	Control = 48.0 ± 4.4	NR
Chinevere 1999	END: Breath-Right®	Nose (N), Mouth (M), Mouth+Nose (MN), Mouth+Nose+END (MNEND)	10 (4 M and 6 F)	VO_2max (ml/kg/min)	END = 45.8 ± 13.5	*N* = 45.5 ± 10.5, M = 48.1 ± 13.8, MN = 48.4 ± 11.8, MNEND = 50.9 ± 11.1	$p > 0.05$
Baker 1999	END (brand did not mentioned)	Placebo (fake nasal dilator)	10 (3 M and 7 F)	VO_2(L/min)	Not mentioned	Not mentioned	–
O'Kroy 2000	END: Breathe Right®	Placebo and mouth breathing (MB)	15 (5 M and 10 F)	VO_2 (L/min)	END = 3.04 ± 0.94	Placebo = 3.12 ± 1.06 MB = 3.12 ± 1.1	NR
O'Kroy 2001	END: (brand did not mentioned)	Placebo (fake ND)	14 (3 M and 11 F)	Peak VO_2max(mL/kg/min) and 70% VO_2 mL/kg/min	END peak VO_2 = 33.0 ± 6.7 END 70% VO2 = 24.3 ± 4.2	Placebo peak VO_2 = 33.4 ± 6.9 Placebo 70% VO_2 = 23.9 ± 4.6	$p > 0.05$
Tong 2001a	END: (brand did not mentioned)	Without ND	8 M	VO_2max (ml/kg/min)	END = 38.9 ± 3.1	Control = 38.5 ± 2.6	$p > 0.05$ $F_{(2,16)} = 0.52$
Tong 2001b	END: (brand did not mentioned)	Oronasal breathing and Placebo (fake nasal dilator)	9 M	VO_2 (ml/kg/min)	Not mentioned	Not mentioned	$p > 0.05$ $F_{(2,16)} = 0.52$
Thomas 2001	END: Breath-Right®	Placebo (fake nasal dilator) and Without nasal device	14 (8 M and 6 F)	VO_2(ml/kg/min) during recovery from anaerobic exercise	END after 5 minutes = 12.7 ± 3.8 END after 10 minutes = 5.8 ± 1.9	Placebo after 5 minutes = 12.3 ± 3.4 Placebo after 10 minutes = 5.7 ± 1.7 Without END after 5 minutes = 12.9 ± 3.7 Without END after 10 minutes = 5.7 ± 1.6	–
Nespereira 2004	END: Breath-Right®	Without ND	7 M	VO_2 (ml/kg/min) 3 intensities	END intensity 2, 4 and 7, respectively: 1.58, 1.57 and 2.53. (decrease)	NR	$p < 0.05$
Macfarlane and Fong 2004	END: Breath-Right®	Placebo (fake ND) and Without ND	30 M (adolescents)	VO_2max (ml/kg/min)	END improved 3.2% and 2.9% compared to the control condition and placebo, respectively.	NR	$p = 0.037$ (control) and $p = 0.018$ (placebo)

Table 1 (continued)

Study	Intervention	Control	*N*	Outcome description	Intervention results	Control results	*p* value
Nunes 2011	END: Breath-Right®	Placebo (fake ND) and Without ND	9 M	60% VO_2(ml/kg/min)	NR	NR	$p > 0.05$
Dinardi 2013	END: Clear Passage®	Placebo (fake ND)	48 (17 M and 31 F)	VO_2max (ml/kg/min)	END = 53.0 ± 4,2	Placebo = 51.2 ± 5.5	$p = 0.001$
Adams 2017	END: Breath Right®	Turbine® internal ND and Without ND	15 M	W.VO_2(where W is the prescribed wattage for the stage). Standardized warm-up at 30, 50 and 70% of familiarization mean time trial power output	END (W.VO_2) 30% = 53.2 ± 7.8 END (W.VO_2) 50% = 64.2 ± 8.5 END (W.VO_2) 70% = 68.1 ± 7.9	Int. (W.VO_2) 30% = 53.9 ± 5.8; nt. (W.VO_2) 50% = 65.7 ± 5.6; Int. (W.VO_2) 70% = 69.9 ± 3.5 Without ND (W.VO_2) 30% = 53.9 ± 7.2 Without ND (W.VO_2) 50% = 65.3 ± 7.6 Without ND (W.VO_2) 70% = 69.1 ± 6.5	(W.VO_2) 30% = 0.86 (W.VO_2) 50% = 0.67 (W.VO_2) 70% = 0.74
Ottaviano 2017	END: Breath Right®	ND Master-aid Roll-flex® and Without ND	13 (8 M and 5 F)	VO_2max(ml/kg/min) and Nasal VO_2 (ml/kg/min)	END = 55.2 ± 6.6 and 51.0 ± 5.94 (respectively)	Master-aid Roll-flex® = 55.3 ± 7.4 and 51.8 ± 6.8 (respectively) Without ND = 54.3 ± 7.0 and 49.3 ± 6.6 (respectively)	$p = 0.82$ and $p < 0.001$ (respectively)
Dinardi 2017	END: Clear Passage®	Placebo (fake ND)	35 M (adolesc.)	VO_2max(ml/kg/min)	END = 36.1 ± 9.1	Placebo = 34.0 ± 9.2	NR
HR							
Griffin 1997	END/LI and END/HI	Placebo (strip without elastic strips in the center)	30 (20 M and 10 F)	HR (beats/min)	END/LI = 117 END/HI = 145	Placebo/LI = 123 Placebo/HI = 150	LI = 0.06 HI = $p <$ 0.05
Case 1998	END: Breath-Right®	Placebo and without ND	9 M	HR (beats/min)	END = 187 ± 11	Placebo = 181 ± 15 Control = 185 ± 12	NR
Baker 1999	END (brand did not mentioned)	Placebo (fake nasal dilator)	10 (3 M and 7 F)	HR (beats/min)	Not mentioned	Not mentioned	–
Chinevere 1999	END: Breath-Right®	Nose (N), Mouth (M), Mouth+Nose (MN), Mouth+Nose+END (MNEND)	10 (4 M and 6 F)	Maximum HR (beats/min)	END = 185 ± 10	N = 181 ± 9*, M = 192 ± 7, MN = 191 ± 5, MNEND = 191 ± 7	*$p < 0.05$
O'Kroy 2000	END: Breathe Right®	Placebo and mouth breathing (MB)	15 (5 M and 10 F)	HR (beats/min)	Not mentioned	Not mentioned	-

Table 1 (continued)

Study	Intervention	Control	*N*	Outcome description	Intervention results	Control results	*p* value
Overend 2000	END: Breath Right®	Without ND (control)	19 M	HR (beats/min) in 3 conditions: 1) the transition between walking and jogging, 2) the time when the subject indicated the desire to remove the mouthguard and 3) volitional fatigue.	END HR 1) = 135 ± 14 END HR 2) = 175 ± 16 END HR 3) = 189 ± 8	Control HR 1) = 132 ± 13 Control HR 2) = 171 ± 17 Control HR 3) = 187 ± 9	NR
Thomas 2001	END: Breath-Right®	Placebo (fake nasal dilator) and Without nasal device	14 (8 M and 6 F)	HR (beats/min)	END after 5 minutes = 109.6 ± 29.6 END after 10 minutes = 91.2 ± 24.9	Placebo after 5 minutes = 109.5 ± 29.1 Placebo after 10 minutes = 93.3 ± 25.2 Without END after 5 minutes = 109.7 ± 28.7 Without END after 10 minutes = 92.4 ± 23.9	–
Bourdin 2002	END: Breath-Right®	Without ND and no nasal ventilation (using a nose clip)	10 M	HR (beats/min)	END = 173 ± 8	Without ND = 173 ± 7 Nose clip = 172 ± 7	$p = 0.99$
Nespereira 2004	END: Breath-Right®	Without ND	7 M	HR (beats/min) 3 intensities	END intensity 4 and 7, respectively: 6.7 and 5.09 (increase); END intensity 2: 1.36 (decrease)	NR	$p > 0.05$
Nunes 2011	END: Breath-Right®	Placebo (fake ND) and Without ND	9 M	HR (beats/min)	NR	NR	$p > 0.05$
Dinardi 2013	END: Clear Passage®	Placebo (fake ND)	48 (17 M and 31 F) (adolescents)	HR after activity HR% (beats/min) HR percentage increase after completing the activity.	END before = 77 ± 40 END after = 159 ± 24	Placebo before = 68 ± 40 Placebo after = 168 ± 21	$p = 0.128$ $p = 0.015$
Adams 2017	END: Breath Right®	Turbine® internal ND and Without ND	15 M	Mean HR (beats/min) standardized warm-up at 30, 50 and 70% of familiarization mean time trial power output	END 30% = 97 ± 9 END 50% = 114 ± 12 END 70% = 127 ± 10	Int. 30% = 100 ± 18 Int. 50% = 117 ± 19 Int. 70% = 130 ± 13 Without ND 30% = 100 ± 22 Without ND 50% = 115 ± 16 Without ND 70% = 126 ± 8	HR 30% = 0.74; HR 50% = 0.75; HR 70% = 0.26

Table 1 (continued)

Study	Intervention	Control	*N*	Outcome description	Intervention results	Control results	*p* value
Ottaviano 2017	END: Breath Right®	ND Master-aid Roll-flex® and Without ND	13 (8 M and 5 F)	HR (beats/min)	END = 181.1 ± 10	Master-aid Roll-flex® = 178.7 ± 13.9 Without ND = 179.2 ± 12.4	$p = 0.96$
RPE							
Griffin 1997	END/LI and END/HI	Placebo (strip without elastic strips in the center)	30 (20 M and 10 F)	RPE (Borg - 20)	END/LI = 10.9; END/HI = 13.4	Placebo/LI = 11.5; Placebo/HI = 14.3	$p = 0.03$
Baker 1999	END (brand did not mentioned)	Placebo (fake nasal dilator)	10 (3 M and 7 F)	RPE (Borg - 20)	Not mentioned	Not mentioned	–
O'Kroy 2000	END: Breathe Right®	Placebo and mouth breathing (MB)	15 (5 M and 10 F)	RPE (Borg – 20 and Borg - 10)	END (Borg – 20) = 18.9 ± 1.22 END (Borg – 10) = 9.13 ± 1.2	Placebo (Borg – 20) = 18.9 ± 1.33 Placebo (Borg – 10) = 9.3 ± 1.2 MB (Borg – 20) = 18.8 ± 1.78 MB (Borg – 10) = 9.1 ±1.58	NR
Tong 2001a	END: (brand did not mentioned)	Without ND	8 M	RPE (Borg – 20 and Borg - 10)	END (Borg – 20) = 16.9 ± 1.1 END (Borg – 10) = 7.4 ± 1.0	Control (Borg – 20) = 17.7 ± 0.7 Control (Borg – 10) = 8.1 ± 0.6	$p < 0.05$ $p < 0.05$
Tong 2001b	END: (brand did not mentioned)	Oronasal breathing and Placebo (fake ND)	9 M	RPE (Borg – 20 and Borg - 10) (at exhaustion)	END (Borg – 20) = 19.4 ± 0.4 END (Borg – 10) = 8.6 ± 0.9	Placebo (Borg – 20) = 19.6 ± 0.4 Placebo (Borg – 10) = 9.6 ± 0.4 Control (Borg – 20) = 19.6 ± 0.3 Control (Borg – 10) = 8.4 ± 0.8	$p > 0.05$ $F_{(2,16)} = 0.125$ $p > 0.05$ $F_{(2,16)} = 3.29$
Bourdin 2002	END: Breath-Right®	Without ND and no nasal ventilation (using a nose clip)	10 M	RPE (Borg - 20)	END = 11.8 ± 1.9	Without NR= 12.1 ± 1.7 Nose clip = 13.2 ± 0.8	$p = 0.18$
Macfarlane and Fong 2004	END: Breath-Right®	Placebo (fake ND) and Without ND	30 M (adolescents)	RPE (Borg - 10) long-term anaerobic power (LAnP) and peak aerobic performance (AeP)	NR (Study only described values in %)	NR (Study only described values in %)	NR
Nunes 2011	END: Breath-Right®	Placebo (fake ND) and Without ND	9 M	RPE (Borg - 20)	NR	NR	$p > 0.05$

Table 1 (continued)

Study	Intervention	Control	*N*	Outcome description	Intervention results	Control results	*p* value
Adams 2017	END: Breath Right®	Turbine® internal ND and Without ND	15 M	RPE (Borg - 20); Standard warm-up at 30, 50, 70% of familiarization mean time trial power output	END 30% = 8 ± 1; END 50% = 10 ± 1; END 70% = 12 ± 1	Int. 30% = 8 ± 1 Int. 50% = 10 ± 1 Int. 70% = 12 ± 1 Without ND 30% = 8 ± 1 Without ND 50% = 10 ± 1 Without ND 70% = 11 ± 2	RPE 30%: $p = 0.87$; RPE 50%: $p = 0.48$; RPE 70%: $p = 0.14$
Dinardi 2017	END: Clear Passage®	Placebo (fake ND)	35 M (adolescents)	RPE (Borg - 20)	END = 7.2 ± 1	Placebo = 7.5 ± 1.2	NR

END external nasal dilator, *ND* nasal device, *LI* Low-intensity, *HI* high-intensity, *NR* not related, *Int.* internal, *M* male, *F* female, *Min* minutes, VO_2max maximal oxygen uptake, *HR* heart rate; *RPE* ratings perceptual effort

As the study designs were similar (cross-over study), this item was not included in the table.

Risk of bias assessment was also carried out independently by two researchers and any inconsistencies were resolved by a third researcher. We used the Cochrane Collaboration risk assessment tool for randomized clinical trials, Revman software (Review Manager 5.3). This is composed of seven areas that must be evaluated: generation of random sequence, allocation concealment, blinding of participants and professionals, incomplete outcomes, report of outcome and other sources of bias [15]. The study was considered high-risk if it demonstrated a high-risk of bias in at least one of the evaluated criteria (randomization, allocation concealment, blinding).

Summary measures, approach to synthesis and analysis

Quantitative data syntheses (meta-analysis) was performed using the random effects model of Review Manager Software 5.*3 (Cochrane Community, Haymarket, London*, UK) for the following outcomes: VO_2max., HR and RPE. Data were pooled using a mean difference (MD) for continuous variables with a 95% confidence interval. Analysis with an $I^2 > 40\%$ and a p value of chi-square test < 0.10 were considered significant heterogeneity.

Sensitivity analyses were performed to investigate the causes of any heterogeneity, excluding a study each time and recorded the changes in I^2 and p values.

Results

Selection of studies

Initially 624 articles were identified. After the titles and abstracts were read, duplicate studies and those that did not meet the eligibility criteria were excluded. Of these, 19 studies that matched the proposed theme of the review were selected. The flowchart for the article selection process and the results of identification, screening, eligibility and included studies is shown in Fig. 2.

Study characteristics

Maximal oxygen uptake (VO_2max)

A total of 17 studies evaluated VO_2max [4–6, 10, 13, 17–19, 21–27, 29, 31], of which three indirectly assessed VO_2max [5, 6, 18] in adolescents who regularly practice physical exercise. One of the studies directly assessed trained cyclists [29], others used triathletes [17, 31], and a fourth was assessed VO_2max during recovery

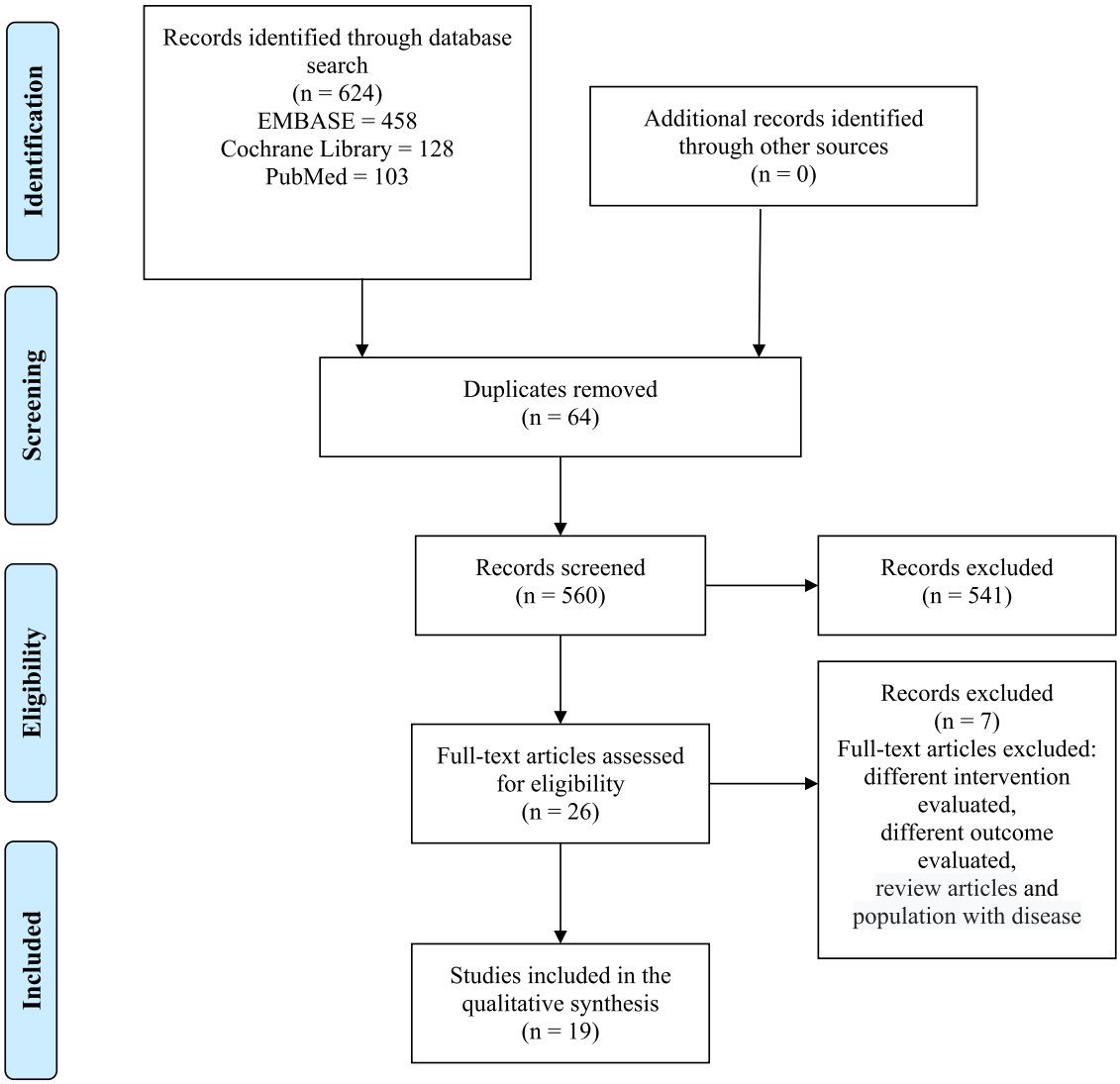

Fig. 2 The flowchart for the article selection process

from anaerobic exercise [13]. A significant difference in VO_2max when using the END was noted in five studies only, whereby one evaluated male triathletes [17], three studied adolescents of both sexes who regularly practice exercise [5, 6, 18], and one study was on adult men and women (the study did not describe the training level of the volunteers) [4]. The use of a placebo END was reported in ten studies [5, 6, 13, 18, 19, 23–27] and in the others it was compared with the absence of the END [4, 10, 17, 21, 22, 29, 31]. Eight studies evaluated men and women [4, 5, 13, 22, 24, 26, 27, 31] and the others only assessed men. Other variables such as ventilation, respiratory rate, peak nasal inspiratory flow, respiratory exchange ratio, heart rate, and rating of perceived exertion were also jointly evaluated with VO_2max.

Heart rate (HR)

Thirteen studies evaluated heart rate (HR) in men and women [4, 5, 13, 14, 17, 22–26, 28, 29, 31]. Of these, one evaluated triathlete men [17], one assessed adult male trained cyclists [29], and one investigated male and female adolescents who regularly practice physical exercise [5]. The other studies did not describe the training level of the sample. A significant difference in HR while using the END was noted in only two of the studies [4, 5]: one was carried out on male and female adults (the study did not describe the training level of the volunteers); another was on male and female adolescents who regularly practice exercise. Most of the investigations compared the END

with the placebo device (seven studies) [5, 13, 23–27] and the rest concentrated on the absence of the END.

Rating of perceived exertion (RPE)

Certain studies classified RPE as subjective perception of respiratory exertion (SPRE). In total, ten studies [4, 6, 10, 18, 19, 24–26, 28, 29] evaluated this variable and five showed less perception of exertion with the END [4, 6, 10, 18, 19]. Only two studies evaluated adolescents who regularly practiced exercise: one study assessed Chinese adolescents [18], and another investigated Brazilian teenagers [6]. Results were similar, that is, participants using the END executed the task with less exertion. Four studies evaluated RPE in women [4, 22, 24, 26], three of which did not demonstrate significant changes with the use of the END [22, 24, 26].

Studies or data included on meta-analysis

Nine studies were included in the meta-analysis that evaluated VO_2max.[5, 6, 21–23, 22, 23, 26, 31]. The VO_2max. outcome was assessed in 168 participants in which no statistically significant difference was found, MD (95% CI) = 0.86 [− 0,43, 2.15], $p = 0.19$, and $I^2 = 0\%$ (Fig. 3).

Eight studies were included in the meta-analysis that evaluated HR [5, 13, 14, 22, 23, 28, 29, 31]. The HR outcome was assessed in 138 participants in which no statistically significant difference was found, MD (95% CI) = 0.02 [− 3.19, 3.22], $p = 0.99$, and $I^2 = 0\%$ (Fig. 4).

Six studies were included in the meta-analysis that evaluated RPE [6, 10, 19, 26, 28, 29]. The RPE outcome was assessed in 92 participants in which no statistically significant difference was found, MD (95% CI) = − 0.12 [− 0.52, 0.28], $p = 0.56$, and $I^2 = 27\%$ (Fig. 4).

In the sensitivity analysis, excluding one study at a time did not change the direction and significance of the outcomes.

Effects of END on maximal oxygen uptake (VO_2max)

Two experimental situations (with and without END) were tested in the study by Griffin et al. [4]. A decrease in VO_2 was observed in healthy adults after a low exercise protocol and high intensity. Dinardi et al. [5] observed a significant difference in VO_2max. in adolescents who used the END and placebo. Macfarlane and Fong [18] also studied adolescents with END. An improvement of 3.2% was reported and 2.9% in aerobic performance compared to the control condition and placebo, respectively. Using a maximum characteristic test, Dinardi et al. [6] observed a significant difference in VO_2max. in healthy adolescents who played soccer regularly. Tong et al. [10] did not observe significant changes in VO_2 in men submitted to 30 series of 20 s each, when compared with and without the END. Thomas et al. [13] did not observe significant changes in VO_2 in 14 individuals (8 men and 6 women) regarding the effectiveness of END in recovery after anaerobic exercise. In the study of Nespereira et al. [17], the use of END resulted in a small but significant reduction in VO_2 in three different intensities, compared to the non-use of END in male triathletes. Using a protocol of

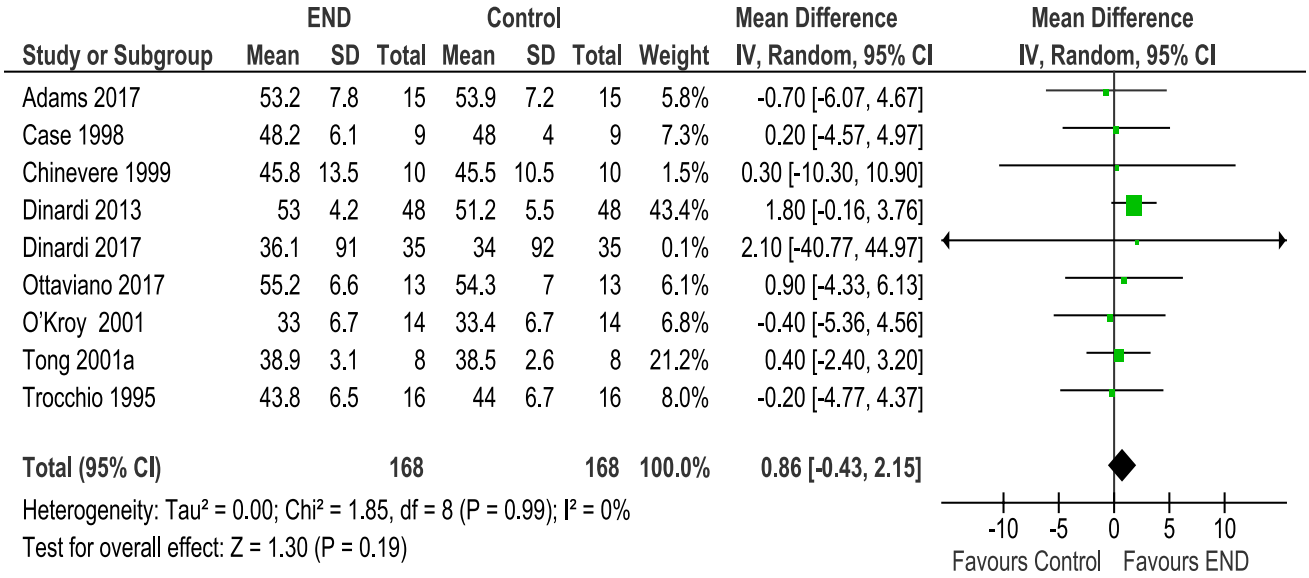

Fig. 3 VO_2max (END vs control). *END* external nasal dilator, *IV* inverse variance, *CI* confidence interval, *SD* standart deviation

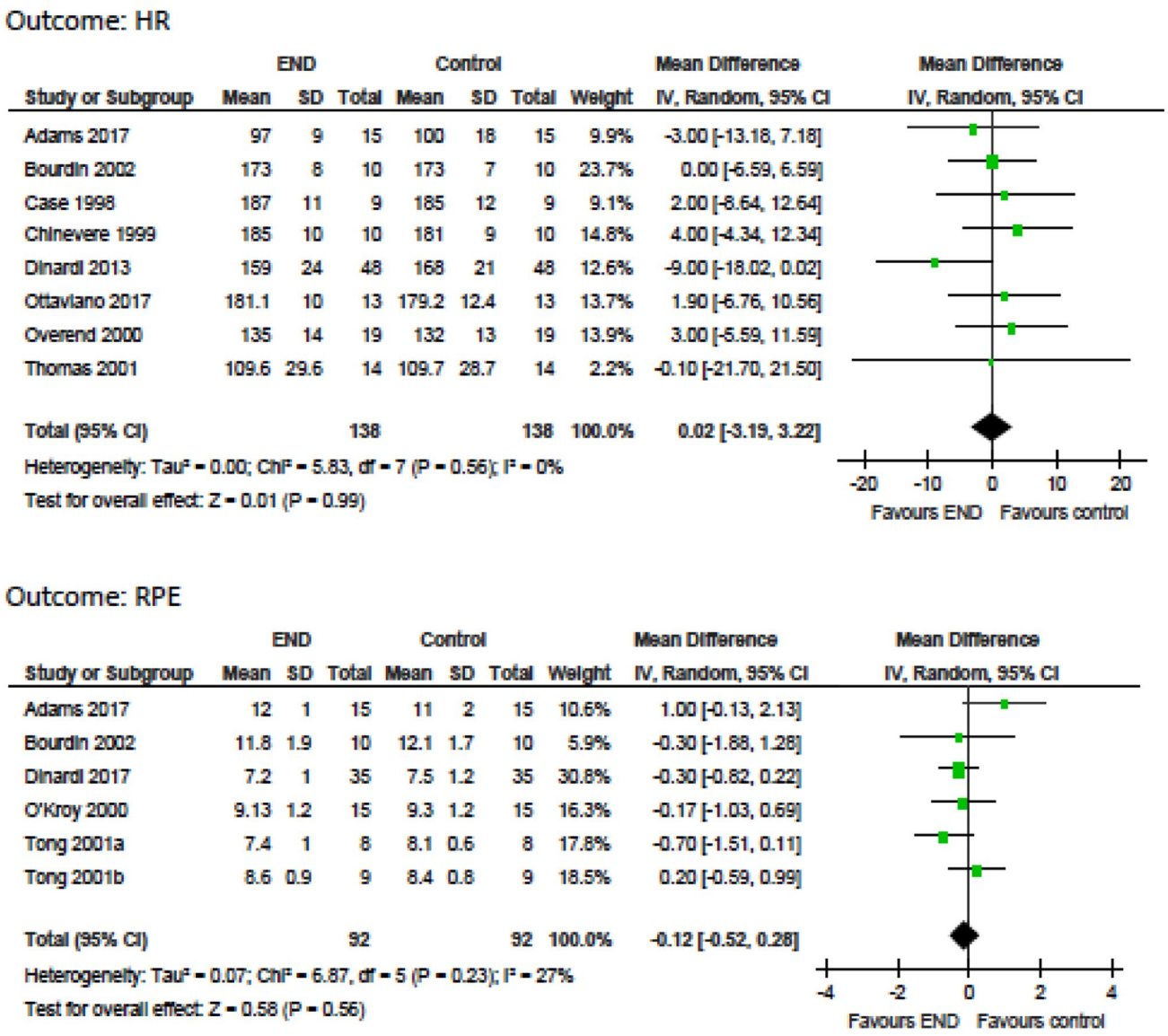

Fig. 4 HR and RPE (END vs control). *END* external nasal dilator, *IV* inverse variance, *CI* confidence interval, *SD* standart deviation, *HR* heart rate, *RPE* rating of perceived exertion

moderate intensity in nine men, Tong et al. [19] observed no difference in VO_2 between the conditions tested. Trocchio et al. [21] observed no significant difference in VO_2max. when adult athletes used the END compared to not using it. Chinevere et al. [22] evaluated ten adults (four men and six women) in a maximum treadmill test in five experimental conditions. When using the END, there was no difference between the conditions. Case et al. [23] evaluated the performance of nine men at running intervals and observed that there was no difference in VO_2max. Baker et al. [24] also they did not observe improvement in the aerobic performance in ten adults (seven women and three men) when they used the END, compared to the placebo. In the study conducted by Nunes et al. [25], there was no performance improvement (VO_2) in nine adults who used the END evaluated on an ergometer cycle, compared to placebo and not using the device. Data from O'kroy's [26] study demonstrate no significant difference on VO_2max. measurements with the END compared to the placebo test and in the oral condition (nose clip) in 15 healthy adults (10 women and 5 men). Subsequently O'kroy et al. [27] also did not observe significant difference when the individuals used the END, compared to the placebo. Adams et al. [29] observed no significant difference in the average movement economy using the END compared to an internal device and without the END. Ottaviano et al. [31] used three experimental situations (with nasal dilator Breath Right®, nasal dilator Master-aid Roll-flex® and without nasal device) to evaluate 13 adult triathletes (8

men and 5 women) regarding the effectiveness of the END. Considering the VO_2max. between the three situations, no significant difference was observed. When individuals breathed only through their nose, VO_2max. nasal proved to be significantly higher when dilators were used.

Effects of END on heart rate (HR)

Griffin et al. [4] observed a reduction in HR in healthy adults after a low exercise protocol and high intensity. Dinardi et al. [5] observed in adolescents athletes who used END compared to placebo, a drop in HR after the cardiorespiratory test. Thomas et al. [13] did not observe significant changes in HR in 14 individuals (8 men and 6 women) regarding the effectiveness of END in recovery after anaerobic exercise. Overend et al. [14] evaluated HR in 19 healthy adults using mouthguards during two experimental situations (END and without END) in a treadmill exercise protocol. There was no positive effect of END on HR at the following levels of the test used: (1) transition between walking and running, (2) time when the participant wished to remove the mouthguard, (3) moment of fatigue. In the study by Nespereira et al. [17] the use of END did not result in significant differences in HR when using END compared to not using it in three different intensities in the protocol used. Chinevere et al. [22] evaluated ten adults (four men and six women) in a maximum treadmill test in five experimental conditions (nose, nose + END, mouth, mouth + nose, mouth + nose + END). Maximum heart rate was significantly lower only in the "nose" condition, compared to the other conditions. Case et al. [23] evaluated the performance of nine men at running intervals and observed that there was no difference in HR between the conditions analyzed. Baker et al. [24] found no improvement in the aerobic performance in ten adults (seven women and three men) when they used the END, compared to the placebo. In the study conducted by Nunes et al. [25], HR was not affected in nine adults who used the END evaluated on an ergometer cycle, compared to placebo and not using the device. Data from the O'kroy's [26] study demonstrate that HR did not show a significant difference in the END test compared to placebo and mouth condition (nose clip) in 15 healthy adults (10 women and 5 men). Bourdin et al. [28] did not observe differences in ten male triathletes after comparing the END with no nasal ventilation (close clip) and without the END. Adams et al. [29] observed no significant difference in the mean HR using the END compared to an internal device and without the END. Ottaviano et al. [31] used three experimental situations (with external nasal dilator Breath Right®, nasal dilator Master-aid Roll-flex® e without nasal device) to evaluate 13 adult triathletes (8 men and 5 women) regarding the effectiveness of the END. Considering the HR between the three situations, no significant difference was observed.

Effects of END on rating of perceived exertion (RPE)

Griffin et al. [4] observed a reduction in RPE in healthy adults after a low exercise protocol and high intensity. Baker et al. [24] and Nunes et al. [25] showed no significant difference when the participants used the END compared to the placebo. Both studies did not present the data from the RPE. Data from the O'kroy's [26] study demonstrate that RPE did not show a significant difference in the END test compared to placebo and mouth condition (nose clip) in 15 healthy adults (10 women and 5 men). On the other hand, Tong et al. [10] observed a significant difference in RPE when eight men used the END compared to the absence of the device. Bourdin et al. [28] did not observe differences in ten male triathletes after comparing the END with no nasal ventilation (close clip) and without the END. Dinardi et al. [6] observed a significant difference in RPE in adolescents who used the END and placebo. Macfarlane and Fong [18] also evaluated adolescents with END. The breathing effort perceived by the subjects was significantly lower in the ENDs condition compared to the control after both the long-term anaerobic power (LAnP) and peak aerobic performance (AeP) tests, while the placebo had no significant impact on the subjects RPE during these two tests. Using a protocol of moderate intensity in nine men, Tong et al. [19] observed no difference in RPE (Borg-20 and Borg-10) (at exhaustion) between the conditions tested. Adams et al. [29] observed no significant difference in the RPE using the END compared to an internal device and without the END.

Risk of bias in included studies

Reliability for evaluators measuring bias risk was verified by the *kappa* statistic (0.81). Of the 19 RCT studies included in this systematic review and meta-analysis, the bias risk assessment revealed that most studies (18 studies) demonstrated a high risk of bias or uncertain risk (Fig. 5). Only one study had a low risk of bias [6].

Discussion

To the best of our knowledge, this is the first systematic review of the literature and meta-analysis that has evaluated the effects of the external nasal dilator on performance in physical exercise. Of the 19 studies included in this review, 8 demonstrated an improvement in one or more of the performance parameters during physical exercise for healthy adolescents or adults of both sexes using the external nasal dilator [4–6, 10, 14, 17–19]. In one of these studies, where a positive impact was noted for END usage in physical exercise, the sample was comprised of healthy male adolescents and those with allergic rhinitis [6].

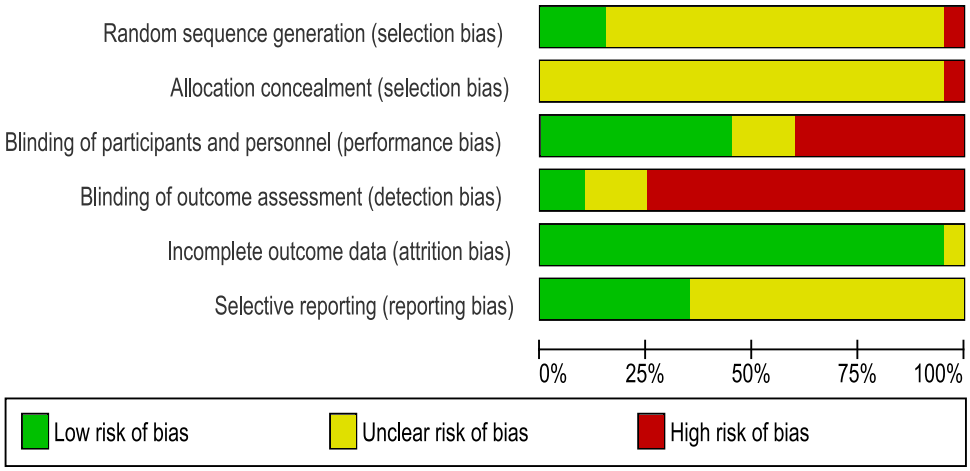

Fig. 5 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

Despite these findings, through studies included in the meta-analysis, the external nasal dilator showed no improvement on VO_2max, HR and RPE results in healthy individuals during exercise.

Numerous studies have shown that the END increases the cross-sectional area of the nasal valve, reduces nasal resistance, transnasal inspiratory pressure, stabilizing the lateral nasal vestibule, and preventing its collapse during final inhalation [4, 6–8, 20]. Specifically in relation to performance during physical exercise, several investigations provide contradictory results. In a study by Seto-Poon et al., it was noted that after progressive stages of exercise lasting 1 min on a cycle ergometer at a rate of 60 rpm, there was a delay in the start of the switching point from nasal to oronasal breathing in healthy adults (four men and five women), that is, the END prolonged the duration of nasal breathing during exercise and lessened inspiratory nasal resistance at rest in seven volunteers ($p < 0.01$), assessed with rhinomanometry [9]. In view of this evidence that the END delays the onset of oral breathing during exercise, favoring output and nasal function, several studies have been conducted with the aim of verifying its effectiveness in physical exercise. Tong et al. evaluated the effect of the END on nine trained men when practicing aerobic exercise of moderate intensity (75% of VO_2max), randomized in oronasal, nasal breathing with the END and placebo condition [10]. It was concluded that nostril dilation when using the END resulted in an increase in nasal ventilation capacity, in physical exercise maintained at 75% of VO_2max and reduced the perceived magnitude of respiratory exertion during exercise [10].

In a study by Griffin et al., there was a reduction in VO_2max noted in 30 healthy athletes evaluated at 2 intensities on the cycle ergometer (100 W and 150 W) when utilizing the END [4]. Participants were randomized using a double-blind, controlled design and a control group. Studying a pediatric population, Macfarlane and Fong randomized 30 healthy male Chinese students, with mean age of 15.2 years, in 6 equal groups, analyzing 3 conditions: END, placebo and control [18]. There was no significant difference in experimental situations with anaerobic characteristics. However, regarding aerobic performance, the END demonstrated a significant increase of 3.2% ($p = 0.037$) and 2.9% ($p = 0.018$) compared to the control condition and placebo, respectively. In addition, there was an improvement in the subjective sensation of exertion compared to the placebo ($p = 0.048$) and the control ($p = 0.016$). Notwithstanding the methodological differences, studies such as Thomas et al., Trocchio et al., Chinevere et al., Case et al., Baker et al., Nunes et al., O'Kroy, O'Kroy et al., Bourdin et al., Adams et al. did not demonstrate differences between the experimental and placebo conditions during physical exercise when using the END on healthy individuals [13, 21–29].

It is worth highlighting that most investigations evaluated the effects of the END in tests with aerobic characteristics. The use of the END in high-level sports has become common due to its absence from the World Anti-Doping Agency (WADA) list, since the expected and proven effects are not prohibited [30]. Along these lines, Bourdin et al. evaluated ten randomized male triathletes in three experimental conditions: normal nasal ventilation, no nasal ventilation (nose clip used) and END usage [28]. The study revealed that changes in nasal ventilation when using the END did not have an impact on heart rate or the rate of perceived exertion of the triathletes, when running five minutes at 80% of the maximum aerobic condition. Recently, Dinardi et al. evaluated 65 adolescents who regularly played football [6]. Of these, 35 were healthy and 30 had allergic rhinitis. It was noted that use of the END significantly increased nasal patency and aerobic capacity both in healthy adolescent athletes and those with allergic rhinitis. Moreover, a significant reduction in nasal resistance was noted, assessed by rhinomanometry [6]. In a previous study, this same group of researchers noted that in a track race test, adolescent athletes using the END, as opposed to the placebo, showed

an improvement in VO_2max (53.0 ± 4.2 mL/kg^{-1}/min^{-1} and 51.2 ± 5.5 mL/kg^{-1}/min^{-1}, respectively) ($p < 0.05$), a drop in heart rate after the cardio-respiratory test (END = 159 beats/min and placebo = 168 beats/min) ($p = 0.015$); improvement in nasal patency measured by the peak nasal inspiratory flow (PNIF) (123 ± 38L/min and 117 ± 35L/min, respectively) and reduction of dyspnea evaluated by the visual analog scale (VAS) ($p < 0.05$) [5].

With the hypothesis that the END would facilitate the distribution of oxygen to the body and prevent fatigue of the respiratory muscles, O'Kroy et al. applied two maximum tests on a cycle ergometer to 14 healthy untrained adults with the aim of proving this theory [27]. Parameters such as VO_2max, ventilation, tidal volume, respiratory rate, among others, were assessed and there was no difference noted between the experimental and placebo conditions, during exercise. In a previous study, O'Kroy evaluated ten healthy women and five healthy men under the parameters of VO_2max, maximum ventilation and maximum work rate (rating of perceived exertion and dyspnea) [26]. The volunteers completed the three tests on a cycle ergometer until fatigue set in, in a random manner for three experimental situations (control, END and placebo). This investigation concluded that the END did not improve performance, as evaluated through direct measurements of aerobic capacity. Furthermore, the subject measurements of exertion and dyspnea did not have an impact on physical exercise with the use of the END. A study conducted by Tong et al. assessed the work of the ventilatory muscles in eight healthy, untrained adults during intermittent exercise [19]. The training workload proposed corresponded to 30 series of 20 s each and a 40 s interval at the end of each series on the cycle ergometer. In seven of the eight individuals, a greater average initial power was noted in the tests where the END was used, compared to the control ($p < 0.05$) and lower subjective perception of exertion and breathing ($p < 0.05$). There was no impact on the ventilatory responses and VO_2max in both experimental situations. The use of the END may have resulted in an absence of fatigue in the ventilatory muscles, leading to an increase in initial power for the exercise and a reduction in the perceived magnitude of respiratory exertion. Recently, Ottaviano et al. evaluated 13 healthy triathletes (8 men and 5 women) in 3 experimental situations (2 different brands of END and without the END) [31]. A progressive treadmill test was applied, where volunteers were told to breathe predominantly through the nose. There was no significant difference in the VO_2max variable, evaluated by direct method, in the three experimental conditions. On the other hand, in the nasal VO_2max and in the nasal breathing time, there was a significant improvement when the nasal dilators were used ($p < 0.001$ and $p = 0.015$, respectively). Using a randomized crossover design, Adams et al., submitted 15 trained cyclists to a 20 km test, in 3 experimental situations (Breathe Right® external nasal dilator, Turbine® internal nasal dilator and no dilator) [29]. The use of nasal dilators, regardless of the mechanism (internal or external), did not have an impact on the performance of the healthy trained cyclists. The authors suggest that the effectiveness of these devices in a competitive sporting environment should be questioned.

Limitations

The inherent limitations in this systematic review and meta-analysis are the low number of studies and the lower quality of published studies evaluating nasal dilators in the physical exercise. The majority of the included studies presented high risk of bias and small samples, with no placebo, mostly healthy individuals and a wide variety of tests utilized. More high quality studies should be conducted to provide robust evidence and to clarify the effects of external nasal dilator during physical exercise in healthy persons.

Conclusion

Although the external nasal dilator is a low-cost, low-risk device, free from any regulatory restrictions by the World Anti-Doping Agency (WADA), this systematic review and meta-analysis found no improvement in VO_2max, HR and RPE results in healthy individuals during exercise.

Author contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by RRD, CHSF, GSS, VEAS, CCI and CRA. The first draft of the manuscript was written by RRD and CHSF and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Compliance with ethical standards

Conflict of interest The author(s) declare that they have no conflicts of interest to declare.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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