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5	Effect of a high-intensity short-duration cycling elevation training mask on $\dot{VO}_{2max}$ and
6	anaerobic power. A randomized controlled trial.
7	
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18	Abstract
19	This study investigated the effect of high-intensity interval training (HIIT) cycling elevation
20	training mask (ETM) in moderately trained participants on both aerobic ( $\dot{VO}_{2max}$ ) and anaerobic
21	power performance. Sixteen participants, five females (25.8 $\pm$ 7.6 years) and eleven males
22	$(22.2 \pm 3.5 \text{ years})$ took part in this randomized controlled trial. Participants were assigned to
23	the experimental group (ETM, $n = 8$ participants) wearing an ETM or the control group (CON,
24	$n=8$ participants) without the ETM. $\dot{\textit{V}}O_{2max}$ was determined during a standardized protocol
25	using Cortex Metalyzer-3B on a cycle ergometer. Peak and average power were calculated a
26	30-second Wingate test. Participants completed 4-weeks (two sessions a week) of high-
27	intensity cycle training. Each training session consisting of 4 separate bouts of 4-minutes of
28	high-intensity cycling exercise. After the training period, ETM reported an increment in $\dot{VO}_{2max}$
29	(effect size ( $d$ ) = 1.19), peak power ( $d$ = 0.77), and average power ( $d$ = 0.76). CON reported
30	an increment only in $\dot{V}O_{2max}$ (d = 1.00). No-between group differences were found in any
31	parameter (ANCOVA), therefore the two protocols should be considered equally effective. In
32	conclusion, this study reported that both HIIT protocols significantly enhance $\dot{V}O_{2max}$ in a very
33	short training period (4 weeks).
34	

#### 35 Key words: Training, Aerobic fitness, Performance, Environmental physiology, Sports

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#### 37

## 38 INTRODUCTION

The use of altitude and intermittent hypoxic training have received substantial attention in the research literature, primarily due to their effectiveness in generating performance gains from very short exercise bouts (1–3). Both simulated and genuine altitude training at moderate (2,000-3,000 m) to high elevations (3,000-4,500 m) are known to result in improvements in both central and peripheral adaptations that increase  $O_2$  delivery and utilization (4–6), and that high-intensity interval training (HIIT) in hypoxia can be more effective than other training modes (*e.g.*, intermittent hypoxic exposure during rest) (7).

46

47 There are several different types of altitude training, including live-low train-high (LLTH), 48 whereby an athlete will train in hypoxic hypobaric conditions and take rest in normoxic and 49 normobaric conditions (8). Whilst other methods of altitude training exist, including live-high 50 train-low (LHTL) and live-high train-high, they all aim to make use of reduced partial pressure 51 of oxygen  $(ppO_2)$  to enhance the physiological adaptations seen with aerobic endurance 52 training. However, many athletes will struggle to incorporate altitude training into their 53 programme due to the cost of simulated hypobaric chambers, and/or the cost and time 54 constraints of travel to real moderate to high altitude environments. According to earlier 55 research, in order to gain the benefits of hypoxic training an athlete would need to remain at 56 moderate to high altitude for  $\sim 2$  to 3 weeks (5,9,10). However, this is not always practical so 57 there are techniques designed to mimic the LLTH protocol of hypoxic exposure, including 58 hypoxia tents and the more recent development of the elevation training mask (ETM).

59

60 The ETM covers the nose and mouth, restricting the amount of air, and so hypothetically O<sub>2</sub>, 61 an athlete can inspire using adjustable vents (11). Manufacturers of these ETM's claim that by 62 using this hypoxic training technique alongside bouts of HIIT, athletes can achieve the same 63 beneficial adaptations over shorter exercise durations without the cost of more elaborate 64 simulated altitude apparatus, or the cost and time constrains of travel to moderate to high altitude environments. There currently exists very limited research that investigate the efficacy 65 66 of ETM's (11–13). Existing research used training durations ranging from 6 to 7 weeks. 67 However, we know that 4 weeks are usually sufficient to elicit physiological adaptations and maximal aerobic power ( $\dot{V}O_{2max}$ ) and peak power performance improvements using normoxic 68

69 environment HIIT (2,14). And to date ETM research has used varying types of training 70 prescription to elicit aerobic and anaerobic improvements. As an example, Biggs et al. (2017) 71 used a protocol of 4 sessions per week for 6-weeks, running at 80% of heart rate reserve and 72 found improvements, *e.g.* in  $\dot{V}O_{2max}$  (ES = 0.61). However, this study did not found a significant 73 difference between the experimental protocol and control group, which could be related to the 74 running bouts of the exercise that were only 90-second long (13). Recent meta-analyses suggest 75 that HIIT in normoxic environments is most effective when protocols use bouts of over 2-76 minutes (standardized mean difference = 0.65-1.07, p < 0.05) (15). Both Pocari et al. (2017) 77 and Bellovary et al. (2019) defined intensity using a percentage of peak power obtained during pre-testing (11,16). Whilst this was adjusted as the participants adapted to the protocol, using 78 79 a percentage of peak heart rate is thought to be the most effective way to define intensities to see greater results from HIIT training in normoxic environments (17,18). Finally, Warren et al. 80 81 (2017) had to rely on incredibly varied exercise stimuli, with training sessions ranging from 82 sprints to bodyweight circuits and physical therapy sessions with male-only U.S. Marine 83 Reserve Officers (19).

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Therefore, the aim of this study is to investigate the effect of a HIIT short-duration cycling ETM in both male and female moderately trained subjects, for both aerobic and anaerobic power performance. The study will use a controlled training prescription that is widely recommended and evidenced for HIIT based physiological adaptation and performance improvements (15,17). We hypothesized that HIIT will lead to improvements in both aerobic and anaerobic power in both ETM and non-ETM (CON) groups, however, the authors did not have *a priori* between groups hypothesis.

92

## 93 METHODS

## 94 *Participants*

Five female ( $25.8 \pm 7.6$  years;  $166 \pm 4$  cm;  $76.2 \pm 8.3$  kg) and eleven male ( $22.2 \pm 3.5$  years; 178.8 ± 7.6 cm;  $81.0 \pm 17.6$  kg) participants volunteered to take part in this study. ETM group and CON group had the following parameters:  $22.6 \pm 3.9$  years,  $173 \pm 7$  cm;  $77.3 \pm 7.9$  kg, and 24.1 ± 5.8 years,  $176 \pm 10$  cm;  $81.0 \pm 9.1$  kg. After receiving University ethics approval (University of Suffolk, Ipswich, UK), and prior to any data collection sessions, all participants received written explanation of all study procedures, were offered an opportunity ask questions 101 of the research team, completed a PARQ and subsequently provided written informed consent.

- 102 All study procedures conformed to the guidelines set by the 2013 Declaration of Helsinki.
- 103

# 104 *Procedures*

105 The current study was designed to examine the effect of 4 weeks of cycling ETM on  $\dot{V}O_{2max}$ 106 and peak power. The primary outcome of this study was the  $\dot{V}O_{2max}$  while anaerobic power 107 parameters were identified as secondary outcomes. This study used a randomized controlled 108 trial design (RCT). Randomization was performed according to a computer-generated 109 sequence. Participants were randomly assigned to one of two groups: one group (ETM, n = 8participants) performed all training sessions whilst wearing an ETM (FDBRO Workout Fitness 110 111 Mask, Henzhenshi Longhuaxinqu Guangshidianzichang, China), and the Control (CON, n = 8 participants) performed all training sessions without the ETM. The ETM's were set at the mid-112 113 point of air restriction for all sessions, which this FDBRO model claimed to be "3X Height: 114 2000 meters".

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116 In this investigation, the statistical power of the sample was calculated a priori to verify that a 117 power of 0.80 was respected. A sample size of 16 (using intention to treat analysis to avoid a 118 decrement in participants) reported a power = 0.84 based on p < 0.05 and f = 0.4. Fourteen 119 participants completed the study, whereas two participants of the control (CON) dropped out 120 because of personal problems not related to the protocol. Sixteen participants (including the 121 drop out) were considered in the final statistical analysis (intention to treat analysis) (20). 122 Figure 1 reported CONSORT diagram showing participants through each stage of this RCT 123 (21).

124

125

# \*\*\*Please, Figure 1 here \*\*\*

126

127 All participants completed familiarization sessions for all study procedures, at least 48 hours 128 prior to any data collection sessions. All participants had been participating in low volume, 129 moderate intensity, mixed-mode (e.g., cycling, running) exercise for at least 3 months prior to 130 participating in this study. All were non-smokers and not taking any regular medication. 131 Participants were requested to maintain normal dietary behaviors, and normal low volume, 132 moderate intensity exercise training outside of prescribed study sessions. We controlled for 133 potential diurnal variation in test results by completing all post-intervention tests within 1-hour 134 of the pre-intervention test time of day.

135

Pre-Intervention Baseline Tests: Following anthropometric measurements participants 136 completed a maximal aerobic power,  $\dot{V}O_{2max}$  test. Breath-by-breath cardiopulmonary data were 137 138 collected using a Cortex Metalyzer 3B (Cortex Biophysik GmbH, Leipzig, Germany) and an 139 ergometer (Sport Excalibur lode, Groningen, Netherland) was used to administer the exercise 140 protocol. Cycle power started at 25W, and increased by 25W every 60-seconds until volitional 141 fatigue, or when VO<sub>2</sub> had plateaued despite increases in exercise intensity with a respiratory exchange ratio greater than 1.05 (22). Peak heart rate (HR<sub>peak</sub>) was determined from this  $\dot{V}O_{2max}$ 142 143 test, to be used for training prescription described below, using a synced Polar T-31 coded 144 transmitter (Polar Electro, Kempele, Finland) (23). 145 24-hours later, following a 5-minute warm-up on the Wattbike Trainer cycle ergometer (Wattbike, Nottingham, UK), participants completed a 30-second maximal effort Wingate test 146 147 on the same cycle ergometer, separated by 5-minutes of active recovery. The Wingate test has 148 been established as an effective tool in measuring both muscular power and anaerobic capacity 149 in a 30-second time period (24). Peak power (Ppower) and average power (Apower) were 150 calculated. The test was repeated after 5-minutes of active recovery to calculate the test-retest 151 reliability.

152

153 Training Sessions: Participants then completed 4-weeks (two sessions a week) of high 154 intensity cycle training using Wattbike cycle ergometer; training commenced within 1-week of 155 the completion of the pre-intervention baseline tests. Each training session consisting of 4 156 separate bouts of 4-minutes of high intensity cycling exercise from 90% to 95% HR<sub>peak</sub> 157 determined from the baseline  $\dot{V}O_{2max}$  test. Each 4-minute bout was separated by 3-minutes of 158 active recovery at 70% HR<sub>peak</sub> (2). The researchers involved in this study monitored the intensity of the cycling exercise and gave verbal feedback to the participants in order to 159 160 maintain the appropriate intensity. The training sessions were identical for both training groups, 161 apart from one group wore an ETM, and CON did not, for all of the 8 training sessions in total. 162

*Post-Intervention Tests:* All procedures described in the pre-intervention baseline test section
were repeated, between 48-hours and 1-week, following the final training session.

165

166 Statistical Analyses

167 The Shapiro-Wilk test was used to determine whether data were normally distributed. Data
168 were presented as mean ± standard deviation (SD). Test-retest reliability (two-way mixed

169 model) was assessed using an intraclass correlation coefficient (ICC) and interpreted as 170 follows: ICC > 0.9 = excellent; 0.9 > ICC > 0.8 = good; 0.8 > ICC > 0.7 = acceptable; 0.7 >171 ICC > 0.6 = questionable; 0.6 > ICC > 0.5 = poor; ICC < 0.5 = unacceptable (25). Smallest172 worthwhile change (SWC) calculated as 0.2 multiplied by the between-subject SD was 173 reported. Intention to treat analysis was adopted (every participant was considered in the final 174 analysis) (26). Levene's test was used to verify the equality of variance. Two-Ways analysis 175 of variance (ANOVA) was used to detect possible time\*group interactions. Between-Group 176 differences was also analyzed using the analysis of covariance (ANCOVA) using baseline 177 values as covariate. Delta difference were reported with 95% confidence intervals (CI) were 178 also reported. Significance was set at p < 0.05 and reported to indicate the strength of the 179 evidence. The Cohen's *d* effect size was calculated and interpreted as follows: < 0.20: *trivial*, 0.20–0.59: *small*, 0.60–1.19: *moderate*, 1.20–1.99: *large*, and > 2.00 *very large* (27). Data were 180 181 analyzed using JASP software (version 0.9.2; JASP, Amsterdam, The Netherlands). 182 **RESULTS** 183 184 The following test-retest reliability scores were found between the familiarization and baseline session:  $\dot{V}O_{2max}$  test was ICC = 0.963, *excellent*, SWC = 1.3 ml·kg<sup>-1</sup> min<sup>-1</sup>; Ppower test was ICC 185 186 = 0.921, excellent, SWC = 44.7 W; Apower was ICC = 0.945, excellent, SWC = 25.0 W. 187 188 Time\*Group interactions was not found for any test such as  $\dot{VO}_{2max}$  test (F = 0.105, p = 0.750), Prover test (F = 0.658, p = 0.429), and Apower (F = 0.023, p = 0.882). 189 190 191 \*\*\*Please, Figure 2 here, Figure 3 and Figure 4 here\*\*\* 192 193 ETM comparisons between baseline and follow-up as well as CON comparisons between 194 baseline and follow-up were reported in Table 1. 195 \*\*\*Please, Table 1 here\*\*\* 196 197 198 ANOVA between-groups (ETM vs CON) analysis did not reported differences for VO<sub>2max</sub> test 199 (F = 0.048, p = 0.829), Ppower test (F = 0.450, p = 0.834), Apower (F = 0.030, p = 0.864). 200 ANCOVA between-groups (ETM vs CON) analysis did not reported differences for  $\dot{V}O_{2max}$ 201 test (F = 0.071, p = 0.794), Ppower test (F = 0.683, p = 0.421), Apower (F = 0.037, p = 0.850). 202

#### 203 **DISCUSSION**

204 The aims of this study were to evaluate the effect of 4 weeks (two sessions per week) ETM vs. 205 CON cycling training on  $\dot{V}O_{2max}$  and power parameters. After 4 weeks of training, ETM reported significant improvements in  $\dot{VO}_{2max}$ , Ppower, and Apower, while CON reported 206 207 significant improvements only in  $\dot{V}O_{2max}$  (Figure 2, Figure 3, and Figure 4). These findings 208 were in agreement with original authors' hypothesis. Instead, between-group analysis (ETM 209 vs CON training) did not report any significant difference. This study reported that both HIIT 210 methods significantly enhance  $\dot{V}O_{2max}$  in a very short training period but ETM can also 211 significantly enhance Ppower and Apower. However, this study does not show a significant 212 between-groups difference and therefore the two training protocols should be considered 213 equally effective.

214

215 The use of altitude and intermittent hypoxic training have reported effectiveness in generating performance gains using short-term protocols (1-3). In particular, HIIT in hypoxia can be very 216 217 effective to stimulate both central and peripheral adaptations such as O<sub>2</sub> delivery and utilization 218 (5,7). The advantages of altitude training to induce physiological adaptations are well reported 219 (8). To take advantage of this type of training, athletes would need to remain at moderate to 220 high altitude for ~2 to 3 weeks (5,9), but this is not always possible. Nowadays, many athletes 221 may struggle to incorporate proper altitude training into their programmes for geographical 222 reasons (lack of adequate altitude locations nearby), cost and time constraints of travel to the 223 appropriate altitude environments, and because of the cost of simulated hypobaric chambers. 224 Therefore, ETM, which is a popular and relatively inexpensive method, may be a valid 225 alternative to real hypoxic altitude training (11). Recently, it has been suggested that healthy 226 adults may be required to perform a high-intensity exercise with an ETM to simulate a hypoxic 227 environment (28), but future research is needed to determine whether repeated exposure to this 228 condition provides similar benefits as altitude training. According to previous research, to 229 obtain some benefits following HIIT, participants should perform at least 2 sessions per week 230 at an intensity of around 90-95% HR<sub>peak</sub> (17,18). The ETM group reported after only 4 weeks 231 of training a *moderate* increment in  $\dot{V}O_{2max}$ , Ppower, and Apower, while the CON group 232 reported a *moderate* improvement only in  $\dot{V}O_{2max}$ . Such aerobic and anaerobic improvements 233 were practically meaningful because they were greater than the respective SWCs (of these 234 tests). The ETM group reported a positive increment in VO<sub>2max</sub> of 2.9 ml·kg<sup>-1</sup>·min<sup>-1</sup>, Ppower test of 84.2 W, and Apower of 38.0 W, and the respective SWCs were 1.3 mlkg<sup>-1</sup>min<sup>-1</sup>, 44.7 235 W, and 25.0 W. This was also the case for the CON group, which reported a practically 236

meaningful increment in  $\dot{V}O_{2max}$  of 3.3 ml·kg<sup>-1</sup>·min<sup>-1</sup> that was bigger than its SWC (1.3 ml·kg<sup>-1</sup>·min<sup>-1</sup>). These findings highlight the capacity of a short-duration HIIT protocol to generate meaningful variation in  $\dot{V}O_{2max}$ , however, the ETM protocol reported additional anaerobic power benefits compared to CON after the training period, which could be explained by the ETM-based physiological adaptations (*e.g.*, glycolytic activity, PCr resynthesis rate, increased reliance on anaerobic metabolism) (29).

243

244 As previously reported, the rationale for the use of ETM is related to the capacity of this 245 instrument to cover the nose and mouth causing a restriction in the amount of air, and so 246 hypothetically O<sub>2</sub>, that an athlete can inspire (11). Previous research reported that ETM can 247 cause a pronounced increase in oxyhemoglobin and total hemoglobin vs. control condition 248 (30). Other research reported that ETM causes modest hypoxemia and limited discomfort (31). 249 Up to now, manufacturers have claimed that by the combination of hypoxic training technique 250 such as ETM and HIIT, athletes may achieve similar adaptations that can be obtained at high 251 altitude environments or greater benefits than training without O<sub>2</sub> restriction (*i.e.*, hypoxia). 252 This could be particularly useful and practical for athletes because they could obtain equivalent 253 physiological adaptations without the burden of more elaborate simulated altitude apparatus, 254 or the cost and time constraints of travel to moderate to high altitude environments. However, 255 the current evidence about the validity of ETM is very limited. In particular, this is true for 256 short-duration HIIT (4 weeks), where previous research focused its attention to longer training 257 protocols of ranging from 6 to 7 weeks (12,13). Previous research reported that 4 weeks of 258 HIIT should be enough to obtain some physiological adaptations in moderately trained 259 participants (14), therefore this training duration was implemented in the current protocol with 260 a training frequency of 2 sessions a week. As reported above, significant *moderate* time effects 261 were found in all tests in the ETM group after 4 weeks of training, therefore the data of the 262 present study further support the existing evidence for the use of short-term HIIT in eliciting 263 positive effects relevant to moderately trained participants. The findings of this study are 264 especially interesting because they show for the first time that the combination of HIIT and 265 ETM can be beneficial as a short-duration protocol and this is particularly important for athletes 266 that have limited available training time due to travel and schedule restrictions These results 267 could be also applied to athletes of other sports (e.g. team sports) who may need to improve both aerobic and anaerobic power quickly and do not have enough time for extensive moderate-268 269 intensity protocols because of congested match schedules or the need for tactical and technical 270 skills training (32,33). Additionally, the combination of HIIT and ETM may be a useful new

training strategy to obtain both aerobic and anaerobic adaptations as well as marginal gains inperformance for professional athletes.

273

274 Despite the positive effects reported by both groups following this short-term HIIT, this study 275 does not report any significant difference between ETM and CON in  $\dot{VO}_{2max}$  test (p = 0.794), 276 Ppower test (p = 0.421), and Apower (p = 0.850), therefore this RCT cannot demonstrate that 277 ETM represents a superior method to obtain aerobic and anaerobic performance enhancements 278 in moderately active participants. These results may be explained by the short duration of the 279 protocol, which consisted of only 4 weeks (8 sessions) of training. In our opinion, a longer 280 training protocol ranging from 8 to 12 weeks may be more suitable to find between-groups 281 differences, therefore future studies could investigate the effects and the differences of HIIT 282 when performed with and without ETM. Authors explain the current non-significant results 283 because the two cycling protocols were identical in design and therefore can have induced 284 similar physiological adaptations. However, the ETM group reported both Ppower and Apower 285 moderate improvements following the training protocol but CON did not, for this reason, we 286 believe that further research is needed to verify the results reported in this study using a longer 287 training protocol duration, which could be a more suitable to observe physiological differences 288 between ETM and CON training.

289

290 This study is not without limitations, first, a relatively low sample size was enrolled in this 291 study. Despite this sample was calculated *a priory* obtaining an adequate power (0.84), a larger 292 sample size could have offered a better chance to find between-groups differences and could 293 have helped to better understand the time-related physiological adaptations. In order to mitigate 294 this limitation, authors adopted a robust design such as a RCT (following CONSORT 295 guidelines) and an intention to treat analysis to account for dropouts. Second, a short-duration 296 HIIT protocol was used, which could have limited the time to obtain physiological adaptations 297 and could have masked the differences between ETM and CON. However, previous research 298 reported that 4 weeks of HIIT are sufficient to find some aerobic and anaerobic adaptations, 299 which have been confirmed by the current study. Therefore, future research should verify and 300 further explore the findings of this study using a longer training protocol. Third, in this study 301 the ETM's were set at the mid-point of air restriction for all sessions, but different settings may 302 be more effective, therefore future studies could investigate how different ETM settings can 303 affect training adaptations. Lastly, this study enrolled a sample of moderately trained 304 participants and therefore the current results should be applied to this type of population. Future

studies could replicate this protocol with amateur and professional cyclists or different sports
 populations in order to verify the benefits of the combination of HIIT and ETM.

307

## 308 Conclusions

309 This study supports the previous knowledge that short-duration (4 weeks) HIIT performed 310 twice a week can elicit physiological adaptations in moderately trained participants. The 311 combination of HIIT and ETM guarantee *moderate* positive improvements in  $\dot{V}O_{2max}$ , Ppower, and Apower, while CON reported significant improvements only in  $\dot{V}O_{2max}$ . However, this 312 313 RCT did not find significant differences between ETM and CON, therefore the two protocols 314 should be considered equally effective. Future research is needed to verify the superiority of 315 ETM vs. CON using longer HIIT duration. Practitioners could utilize the findings of this study 316 for designing short-term HIIT-ETM protocols, which can be particularly important for athletes 317 that have limited training time availability due to travel and schedule restrictions, or for 318 obtaining aerobic and anaerobic adaptations and marginal performance gains in professional 319 athletes.

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443	
444	
445	Figure 1
446	CONSORT diagram showing the flow of participants through each stage of a randomized
447	controlled trial. ETM = Elevation training mask; CON = Control.
448	
449	Figure 2
450	Time effect following ETM and CON training compared to baseline. $\dot{V}O_{2max}$ = maximal
451	aerobic power; ETM = Elevation training mask; CON = Control; *: p < 0.05 = pre-post
452	analysis.
453	
454	Figure 3
455	Time effect on peak power following ETM and CON training compared to baseline. ETM =
456	Elevation training mask; $CON = Control$ ; *: $p < 0.05 = pre-post analysis$ .
457	
458	Figure 4
459	Time effect on average power following ETM and CON training compared to baseline. ETM
460	= Elevation training mask; CON = Control; #: p = 0.051 = pre-post analysis