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1 **A program centered on smart electrically assisted bicycle outings for rehabilitation after**
2 **breast cancer: a pilot study**

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22 **Abstract**

23 The benefits of physical activity during cancer care and rehabilitation are well established, however
24 introducing and maintaining healthy behaviors in the long-term remains challenging. Technological
25 advances in electrically assisted bicycles and on-board sensors led us to propose an original
26 rehabilitation program combining smart electric bicycle outings with health education.

27 This was a pilot study with physical activity questionnaires and endurance tests to evaluate physical
28 activity following a 6-week program comprising 2 bicycle outings per week in groups of 5 (supervised
29 or not) with briefing and debriefing supplemented by health education sessions.

30 Fourteen post-breast cancer patients participated (median age 52 [IQR 46-55]). A gain of at least 2
31 International Physical Activity Questionnaire points and over 600 MET.min/week was achieved by 9/10
32 (90%; 95%CI[55.5-99.7]) women. The feasibility of the program was clearly demonstrated, with
33 excellent patient adherence (11/12 planned 2h outings per patient).

34 The electric bicycle program strengthened the womens' physiological capacities through personalized
35 levels of electrical assistance made possible by the fine settings of the motorization. This enabled the
36 whole group to achieve the outing objectives together despite very variable levels of deconditioning.
37 The pleasure shared in the group activity and personal empowerment gained should promote long-
38 term maintenance of physical activity.

39 **Keywords:** electrically assisted bicycles; rehabilitation; personal empowerment; long-term physical
40 activity; post-breast cancer

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45 Introduction

46 A recent large cohort study confirmed that any gain in physical activity (PA) increases longevity
47 regardless of the initial level of activity, especially in middle aged adults and patients with cancer [1].
48 Moreover, the value of physical activity in preventing cancer is well known and documented,
49 particularly for breast cancer. Indeed, a 2016 meta-analysis of 38 articles reporting on cohort follow-
50 up showed that the most physically active women significantly decreased their risk of developing
51 breast cancer [2]. Physical activity is also beneficial for patients undergoing treatment and convalescing
52 from breast cancer treatment. In addition, PA seems interesting in tertiary prevention as demonstrated
53 by meta-analysis carried out in 2019 which showed that those breast cancer survivors who were the
54 most physically active had a significantly reduced risk of death [3]. Positive effects include muscle
55 strengthening, better physical condition, less fatigue, better sleep, and improved quality of life [4–7].
56 Reconditioning through supervised exercise has shown its short-term interest for improving all of these
57 criteria. but the data in the literature do not confirm this interest in the long term. However, in daily
58 practice we see that the continued pursuit of PA is difficult to maintain over time, which can partly
59 explain inadequate results in the long term. [8, 9].

60 Encouraging a mindset that includes motivation and self-discipline to maintain healthy behaviors in
61 general, or the adoption of habits and the creation of conditions that help patients to maintain physical
62 activity are concepts that have been well described in the literature [10, 11]. Likewise, the value of
63 health education in promoting lifestyle changes leading to healthier behavior is well documented [12,
64 13]. Health education is all the more effective if it integrates the different aspects of a healthy lifestyle
65 (PA, good nutrition, self-confidence etc.).

66 In this context, it seems necessary to think about collaborative, integrated and contextualized PA with
67 the possibility of post-rehabilitation support in order to increase the chances of maintaining healthy
68 behaviors acquired during rehabilitation [14, 15]. One solution to this is to propose tools that allow
69 group activity that is fun and easy to do in real life conditions. The electric bicycle has promise in
70 meeting these objectives and has already demonstrated its acceptability in patients with chronic
71 diseases [16]. However, its use to promote health requires good control of the level of activity to
72 ensure patient safety. To achieve this, a prototype electrically assisted bicycle (EAB), was specifically
73 developed and tested in a pilot study on healthy subjects, highlighting its accessibility, simplicity and
74 safety of use [17]. The smart electric bicycle incorporates electronics allowing optimal cycling
75 assistance that can be personalized at any time thanks to an original algorithm that is adjustable via a
76 smartphone. In real time the app integrates, analyzes and transmits parameters from the bike (motor

77 power, battery charge, etc.) and from the patient (muscle power, heart rate, pedaling rate) as well as
78 data relating to the outing (altitude difference, route, distance etc.). We hypothesize that by allowing
79 personalization of sessions carried out outdoors in groups, the use of this EAB will promote the
80 maintenance of post-rehabilitation physical activity, and provide empowerment to patients by
81 maintaining the benefits acquired during rehabilitation. The objective of this pilot study was therefore
82 to test, using a before/after design, the effects of a multidisciplinary program on the amount of
83 physical activity undertaken and the physical condition of patients following a course of treatment for
84 breast cancer.

85

86 Materials and methods

87 **Study Design:**

88 Single-center prospective, longitudinal non-randomized pilot study performed in collaboration
89 between the Rocheplane medical center (Audavie foundation), Saint Martin d'Hères, Grenoble Alpes
90 University Hospital and Grenoble Alpes University, France between October 2017 and October 2018.

91 **Population:**

92 Adult post-breast cancer patients, who had followed a 3-week supervised exercise re-training program
93 within the last 6 months. Other inclusion criteria were: ability to use a bicycle for outdoor outings,
94 weight under 125 kg (maximum load for the EAB we used), available for a 4-month follow-up
95 consultation and written consent. The main non-inclusion criteria were: a contraindication to
96 moderate physical activity or cycling (e.g. acute episode of coronary artery disease within the last 2
97 years, locomotor disorder etc.).

98 **Intervention**

99 The intervention was a series of workshops offering physical activity centered on use of a smart
100 electrically assisted bicycle for health suitable for exercise re-training with a health education
101 dimension. Workshops took place twice a week in groups of 4 to 5 patients supervised by an adapted
102 physical activity (APA) coach, over 6 weeks. Each workshop consisted of:

- 103 - A presentation of the bicycle outing, the route, the purpose of the outing, personalization of
104 the level of electrical assistance and preparation of the equipment (1/2 hour);
- 105 - A 1 to 2 hour EAB outing on secondary roads or cycle paths with or without gradients;
- 106 - Debriefing including opinions on the route, comments on the data recorded during the outing
107 (e.g. elevation climbed, pedaling pace and pressure, level of electric assistance needed, or
108 heart rate) and then a 1 hour health education session on a topic chosen by the participants
109 (see supplementary material);
- 110 - Advice and projects on ways of pursuing physical activity.

111 Before each workshop information was distributed to both the patients and the APA coach to help
112 them prepare for the bicycle outing (see supplementary material items 4 and 5).

113 **The smart electric bicycle for health**

114 The smart electrically assisted bicycle (EAB) used in this study was a prototype (VELIS) developed
115 specifically for health education use by eBikeLabs (Grenoble, France) taking advantage of state-of-the-
116 art technological solutions. This high-performance EAB has a 48V 12Ah battery with a maximum power
117 of 800W. It combines comfort and safety with personalization of electric assistance as required. Its key

118 features for exercise retraining are presented in the supplementary material.

119 Briefly, the smart electric bicycle for health measures, records and provides real-time GPS data (circuit
120 profile (km + elevation gain) and speed), pedaling pace, the pressure applied to the pedals measured
121 by an integrated pressure sensor, the state of the battery and the level of assistance. The level of
122 assistance can be individually adjusted according to the user's capabilities, so as to allow them to keep
123 together with other members of a group. Heart rate parameters were measured with a wrist heart rate
124 monitor integrated in the interface and all of this data could be viewed (on the smartphone) during or
125 after the outing, enabling users to follow their own performance.

126 **Objectives and outcome measures**

127 The main objective of the study was to maintain and extend the benefits gained after 3 weeks of
128 exercise retraining in a rehabilitation center over the longer term, in line with international
129 recommendations on daily physical activity. The primary endpoint was the percentage of patients
130 having reached an equivalent of 150 minutes of moderate physical activity per week, i.e. 600 MET-
131 min/week (international recommendations), evaluated by the French version of the short-form
132 International Physical Activity Questionnaire (IPAQ) [18] at 8 (M2), 12 to 13 (M3), and 17 weeks (M4).
133 Patients who had reached or exceeded 600 MET-min/week at 2 or 3 of the follow-up points (M2, M3
134 and/or M4) were considered as being successes.

135 The secondary objectives were the rate of evolution of physical activity assessed using the IPAQ
136 questionnaire; the feasibility of the bicycle outing program (number of canceled outings, number of
137 incomplete outings, causes of failures according to the APA monitor); the impact of the intervention
138 on physical performance i.e. progression of patient profiles before/after the 6 week course assessed
139 by clinical examination (weight, HR, physio-cardiologic parameters), and the submaximal endurance
140 test (CLET at 80% of maximum aerobic power (MAP), and muscle strength of the upper ("Handgrip"
141 dynamometer) and lower limbs ("Microfet" dynamometer) at M0 and M4.

142 For other secondary objectives any changes were assessed through a series of questionnaires: overall
143 quality of life (EQ5D-3L questionnaire) [19], fatigue (Piper questionnaire) [20], and self-esteem
144 (Rosenberg scale) [21] at M0 and M4. Fatigue and chronic pain were self-assessed by the patient on a
145 scale of 0 to 10 (where 0 = no fatigue or pain and 10 = maximal fatigue or pain imaginable) at M0, M2,
146 M3 and M4. Patient satisfaction with the program was assessed at M4 using a questionnaire developed
147 especially for this study (see online supplement)- The characteristics of each outing and any changes
148 during the program were recorded.

149 **Baseline and follow-up assessments**

150 Before starting the 6 week program of bicycle outings, each patient has a baseline (M0) consultation
151 with the investigating physician of the rehabilitation center that included an endurance test (the
152 Constant-Load Exercise Test, CLET). The CLET was performed on a cycloergometer at 80% of the
153 patient's maximum aerobic power (determined previously during the post-cancer rehabilitation stay).
154 After a 10min warm-up with no load, a load was applied (adapted to the patient) and the stopwatch
155 was triggered when her pedaling frequency reached 70 revolutions/min. The patient was required to
156 maintain this pedaling frequency at constant load throughout the test (usually 12 to 15 min, maximum
157 30 min), and every 5 min the following data were recorded:

- 158 - Heart rate
- 159 - Dyspnea (scored on a Borg scale from 0 to 10)
- 160 - Pain on exertion of the lower limbs (assessed by visual analogue scale of 1 to 10)
- 161 - muscle strength of the upper limbs ("Handgrip" dynamometer)
- 162 - muscle strength of the lower limbs ("Microfet" dynamometer)

163 The test stopped if:

- 164 - the patient was no longer able to maintain the pedaling frequency (70 revolutions/min),
- 165 - heart rate reached maximum heart rate (determined during the pre-inclusion 3 week
166 rehabilitation stay)

167 or the maximum test duration was reached (30 min).

168 Patients had another clinical examination and CLET endurance test at four months (M4).

169

170 **Statistical analysis**

171 Qualitative variables are given in numbers and percentages, and quantitative variables presented as
172 medians with 25% and 75% quartiles. Quantitative variables before and after the intervention (M0 vs.
173 M4) were compared using the Wilcoxon signed rank test. For quantitative variables measured at all
174 four visits M0, M2, M3 and M4), their evolution over time was evaluated by the Skillings-Mack test (a
175 non-parametric ANOVA). For the criteria evaluating the effectiveness of the intervention, only data
176 from patients who had completed at least half of the planned outings was analyzed per protocol (PP).

177 In accordance with the guide for calculating the IPAQ score, the questionnaire data were excluded
178 from the primary analysis if the patient answered "I don't know" to at least one of the questions
179 concerning level of physical activity. For criteria assessing the feasibility of the intervention, the data
180 from all included patients were analyzed in intention to treat (ITT). All statistical tests were two sided
181 and performed with an alpha threshold = 0.05. Missing data were not replaced. Statistical analyzes
182 were performed after quality control of the data using Stata software version 15.1.

183 **Sample size**

184 In accordance with the CONSORT extension for pilot and feasibility studies (Eldridge et al. 2016), this
185 study assessed the feasibility of the intervention as well as the magnitude of the effect to be expected
186 in order to plan randomized controlled trials. The number of subjects was therefore not pre-
187 determined by specific hypotheses but by the constraints of the study: number of bikes available and
188 duration of recruitment. Given these constraints, we planned to include 16 patients.

189 **Results**

190 All patients had completed initial curative chemotherapy, the majority had received prophylactic
191 therapy against relapse and all had received follow-up and rehabilitation care (FRC). We included 14
192 women who were divided into 3 groups. All were included in the ITT analyzes, however, two stopped
193 attending workshops before the end of the study, and participated in less than 6 outings on electric
194 bikes. Thus, only 12 patients were included in the PP analyzes (Figure 1). The characteristics of all
195 included patients are presented in Table 1a as are the comparisons between variables recorded at
196 inclusion (M0) and at the last visit (M4). The comparison between variables recorded at inclusion, M2,
197 M3 and M4 are presented in Table 1b. The characteristics of the outings on EAB are shown in Table 2.
198 The themes discussed during the workshops are presented in supplementary Table 3.

199 **Primary endpoint**

200 Twelve women participated in more than 6 outings and filled-in the IPAQ questionnaires at all visits,
201 however, some IPAQ questionnaires could not be analyzed (3 at inclusion, 2 at the following visits)
202 because they were partially incomplete, the patients having answered "I don't know" to the question
203 relating to the duration of physical activity for at least one of the activity levels. The primary endpoint
204 (change in IPAQ score) was calculable for only 10 patients. The goal of at least 2 IPAQ scores after the
205 intervention showing greater than 600 MET min/week was achieved for 9/10 (90%; 95%CI [55.5-99.7])
206 individuals.

207 **Secondary objectives and endpoints**

208 The change in the IPAQ score between inclusion (M0) and post intervention (M2, M3, and M4) is shown
209 in Figure 2 ($p = 0.16$). Concerning feasibility of the program: all 36 planned group outings were
210 completed, although 6 (17%) had to be postponed due to bad weather. Patients participated in 11 [10;
211 12] (median [Q1; Q3]) out of 12 possible outings. In total, of the 168 scheduled individual
212 participations, 138 (82%) individual outings were actually made. Two patients participated in less than
213 6 outings. One patient was scared going downhill. Another had shoulder pain related to problems with
214 her implanted chemotherapy chamber positioned above the clavicle.

215 The comparison between endurance tests performed before and after the EAB program (Table 1a)
216 shows a significant difference in the duration of submaximal endurance (CLET), less pain in the lower
217 limbs, and improvements in upper and lower limb muscle strength. The reduction in the sensation of
218 dyspnea on exertion bordered on significance ($p = 0.08$). The changes in duration and heart rate during
219 the endurance test between inclusion (M0) and M4 are shown in Figure 3.

220 The results of the questionnaires on overall quality of life, fatigue, self-esteem, and pain are presented
221 in Table 1. The differences between M0 and M4 were not significant, although there was a tendency
222 toward better overall quality of life ($p = 0.1$). When asked at M4 if they were able to straightaway easily
223 use the bike, they answered 7 [6; 9] (median [Q1; Q3]) on a scale from 0 (not at all) to 10 (absolutely).
224 Similarly, when asked if they found it easy to use after the start-up learning period, they answered 8
225 [7; 10] (median [Q1; Q3]) on the same scale. Data on the other responses to the questionnaire on
226 patient satisfaction are summarized in Table 1a and in full in the online supplementary material. Details
227 were available for 116 of the 138 outings (84%), either supervised by an APA coach or made
228 independently by a group of patients without a coach (Table 2).

229 Discussion

230 This pilot study proposed an innovative approach based on a complete program of outings on
231 electrically assisted bicycles and a health education program, performed outside the context of
232 institutional health structures allowing a transition between a conventional rehabilitation program and
233 the autonomy needed at the end of “active” medical care. The objectives of this study were to verify
234 the feasibility of setting up such a program, to observe the changes in the amount of physical activity
235 undertaken by the participants and to analyze the evolution of physiological and psychological
236 parameters between M0 and M4.

237

238 Feasibility

239 The program included 12 workshops for each participant (EAB outing plus a discussion around a health
240 theme). A total of 138 EAB outings were carried out, 116 outings recorded an average distance covered
241 of 22km, 2 hours of effort and a gain in elevation of more than 350m per outing. No outing was
242 canceled or shortened but 6 outings had to be postponed for weather reasons for the safety and
243 comfort of participants. The education sessions associated with the EAB outings were all carried out
244 and the participants wished to address various themes ranging from lifestyle, nutrition, the benefits of
245 PA, motivation for PA, treatment interaction, cancer and PA etc.). All these results (Table 2) testify to
246 a real ability to deploy these workshops in real conditions. The conditions for this success lie in the
247 establishment of a quality process and the organization of training time for the study team.

248 The parameters collected during the study (HR, power developed by the motor and by the cyclist,
249 pedaling frequency, GPS data, etc.) were available for 84% of the outings performed. For the purpose
250 of further research this is very encouraging.

251 **Amount of physical activity**

252 For our primary endpoint, 9 out of 10 patients reached the threshold defined as the primary endpoint
253 (achievement of 600 MET.min in 2 of the 3 IPAQs at M2, M3 and/or M4). This apparently good result
254 is unfortunately difficult to interpret since, in the IPAQ at inclusion, 6 out of 9 patients had already
255 reached this success criterion. Two points should be mentioned, first of all our results show that the
256 endpoint chosen in this study was not demanding enough. In fact, the patients included were much
257 more active than we had imagined and the threshold defining success should therefore have been set
258 higher. Secondly, the IPAQ questionnaire, in accordance with its analysis guide, does not allow a score
259 to be counted when a participant answered "I don't know" to one of the items. This reduced the
260 number of interpretable scores despite the collection of 12 completed questionnaires for each
261 evaluation. However, if we analyze the evolution of the amount of PA undertaken by the participants,
262 figure 2 seems to show an increase between M0 and M2 ($p = 0.05$ in post hoc analysis) then a decrease
263 with a final score at M4 greater than that at inclusion. The intervention took place between M0 and
264 M2, and the physical activity carried out during the EAB outings was not counted. Despite almost
265 doubling the mean amount of PA between M0 and M4, the small number of subjects and the significant
266 variability did not allow a significant difference to be demonstrated.

267

268 **Physiological parameters**

269 Our results show that the mean duration of CLET achieved after the EAB program was significantly
270 improved and mean dyspnea on exertion (Borg scale) seems lower, at the limit of statistical
271 significance. Figure 3 allows a more detailed interpretation of these results. We see that 6 patients
272 upheld the 30 min (maximum duration of the test) from inclusion. At M4, these 6 patients maintained
273 their level of performance but with a lower average heart rate, which reflects an improvement in their
274 capacities. The other 6 patients all managed to increase their exercise time, and therefore their
275 capacity. Maximum strength in the upper and lower limbs also increased significantly between M0 and
276 M4. These results, obtained for physiological parameters and that could be clinically meaningful, must
277 be interpreted with caution and the observed effects cannot necessarily be attributed to the program
278 (EAB outings + health education) since we lacked a control group. The study design did not meet the
279 accepted criteria (a randomized trial) for an evaluation of efficacy, but nevertheless demonstrated the
280 feasibility of such a program and measured the effect size. The magnitude of the effect sizes obtained

281 can be compared with those observed in the literature for similar patients and similar parameters but
282 different activities. For example, a randomized controlled trial of progressive twice-weekly weight
283 lifting in 141 breast cancer survivors with stable arm lymphedema showed that the intervention group
284 increased their IPAQ from 1954 to 2397 at 1 year [22]. The gain in our study appears to be greater,
285 reaching an equivalent level at the end of the program. Another feasibility study that included 14
286 women with metastatic breast cancer, randomized to either a control group or an 8-week home-based
287 physical activity intervention comprising twice weekly supervised resistance training and an
288 unsupervised walking program [23] showed an inter-group difference for the intervention of about 2
289 kg for the leg strength, which is much lower than what we obtained, and the total IPAQ difference was
290 966 at 8 weeks and 767 at 16 weeks, which is also considerably less than the difference observed in
291 our study (1177 MET-min-week⁻¹). The good performance of our patients may have been due to the
292 fact that they had already attended a medically supervised 3-week rehabilitation course at the center.
293 Studies of interventions to maintain physical activity during and beyond the transition to normal
294 everyday life are rare. Our results confirm the relevance of this approach and that of the specific
295 criteria used to assess the subjects' physical condition and justify an evaluation of the effect of the
296 intervention in randomized controlled studies in the field of cancer and/or chronic diseases. For
297 individuals with disabilities or chronic disease unable to use an EAB, e-trike cycling has recently been
298 proposed as a low intensity activity [24].

299

300 **Psychological parameters**

301 Our results show that quality of life and self-esteem were not significantly affected by the intervention.
302 It is possible that here again the lack of statistical power explains this result. Nevertheless, there was
303 a trend ($p = 0.11$) towards improvement in quality of life, despite the very generic nature of the EQ5D.
304 Some patients found the Rosenberg self-esteem auto-questionnaire difficult to understand with errors
305 in the answers detected during discussions after the database had been locked. This questionnaire is
306 not specific to PA, and it is recognized that the different dimensions of self-esteem are quite
307 independent of each other, which perhaps explains in part the apparent lack in modification of the
308 self-esteem score.

309

310 **Adherence and continuation of physical activity**

311 The literature seems to show that the first factor necessary for maintaining physical activity over the
312 long term is intrinsic motivation [25–27]. The results of the patient satisfaction questionnaire were
313 unequivocal and showed real pleasure in the activity practiced. Electrically assisted cycling reduces the

314 risk of stigma and extrinsic social comparisons by homogenizing the speed within the group despite
315 differences in physical condition. This had already been observed in the proof of concept study with
316 healthy volunteers [17] and seems to be true for patients in this study. The study design gave patients
317 the possibility of making independent EAB outings. The program support team was present to manage
318 the technical aspects of the outings, but the initiative, planning and outing were left to the group.
319 These independent outings (13 in total) are very similar to the supervised ones in terms of duration,
320 number of kilometers and elevation (Table 2). This demonstrates the patient empowerment capacity
321 of such a program, but also the acceptance and ease of use of the EAB, and the adherence of patients
322 to the proposed activity.

323 There is agreement in the literature that the expansion of an individual's social environment
324 encourages the maintenance of a new behavior [10,11]. This is reflected by the fact that at the end of
325 our study the patients created a social club "LES ROCHEPLANEUSES" to promote social ties and
326 encourage physical activity for women recovering from breast cancer. Although this was not an initial
327 goal of this study, this development indicates the creation and anchoring of habits that offer hope for
328 lasting changes in lifestyle.

329

330 **Limitations and perspectives**

331 This was a single center pilot study and the number of participants was limited by the number of smart
332 EAB and the availability of the APA coach. Physical activity was assessed using a patient questionnaire
333 (by telephone at the intermediate time points M2 and M3). While participants underwent a clinical
334 examination and endurance tests not all details of their medical history were collected, particularly
335 comorbidities and the possibility of chemotherapy-induced peripheral neuropathy (CIPN) in these
336 breast cancer survivors. Nevertheless, our study provides a rationale for randomized controlled studies
337 in the field of cancer rehabilitation or for chronic disease. Indeed two randomized comparative studies
338 are currently recruiting, one on fibromyalgia (FIBROVELIS NCT04318054), and another for overweight
339 diabetics (DIABEOTHERMES, NCT03912623) as well as a third non-randomized comparative study on
340 pre-habilitation before major surgery (PAPRIKA NCT NTC04190719).

341

342 **Conclusion**

343 Smart electrically assisted bicycle outings in small groups show promise as a means of encouraging
344 breast cancer survivors to continue to pursue physical activity in the transition from rehabilitation to
345 autonomy and normal everyday life. Indeed, the feasibility and adherence of participants to such a

346 program was confirmed and the results on the evolution of physiological parameters showed an
347 interesting magnitude of effect. The transition phase between supervised medical care and autonomy
348 remains a delicate phase for patients [15] and the program proposed here could provide an interesting
349 solution allowing gradual empowerment thanks to personalized support.

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358 **Author Contributions**

359 **Sophie Rey-Barth:** Conceptualization, Writing - Original Draft; **Nicolas Pinsault:** Conceptualization,
360 Supervision, Writing - Original Draft; **Hugo Terrisse:** Formal analysis, Visualization, Writing - Review &
361 Editing; **Claire Eychenne:** Project administration, Investigation; Data Curation: Writing - Review &
362 Editing **Carole Rolland:** Project administration: Investigation, Writing - Review & Editing; **Alison Foote:**
363 Visualization, Writing - Original Draft, Writing - Review & Editing; **Catherine Guyot:** Supervision,
364 Investigation, Writing - Review & Editing; **Jean-Luc Bosson:** Conceptualization, Methodology,
365 Supervision, Formal analysis, Writing - Original Draft.

366 **Conflict of interest.**

367 None of the authors have a conflict of interest to declare.

368

369 **Ethics and Regulatory Requirements**

370 The protocol received approval from the South Mediterranean Ethics Committee (Committee de
371 Protection des Personnes, CPP) on September 13, 2017 and full authorization from the French National
372 Commission for Informatics and Freedoms on October 17, 2017. The National Agency for the Safety of
373 Medicines and Health Products (ANSM) was informed on August 28, 2017, and the protocol was
374 registered on the clinical trial.gov website (NCT03340857).

375

376

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465 Figure Legends

466 **Figure 1. Study Flow Diagram**

467 IPAQ: International Physical Activity Questionnaire used to determine the MET; CLET: Constant-Load

468 Exercise Test; VAS: self-assessed pain and fatigue on a scale of 1 to 10; CE: Clinical examination

469 Other questionnaires: EQ5D quality of life, Piper Fatigue Scale,

470

471 **Figure 2. Evolution in Physical activity assessed using the International Physical Activity**

472 **Questionnaire (IPAQ)**

473 Considering only the 12 patients who had completed the program and included in this analysis $p=0.16$

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475

476 **Figure 3. Duration of Constant-Load Exercise Test (CLET) and heart rate at baseline (M0) and at M4**

477 Top: CLET duration in minutes at M0 and M4. Six patients achieved the maximum duration at M0 and

478 M4: solid bold line for all 6 patients.

479 For heart rate, due to an interaction according to whether the maximum duration of the endurance

480 test was reached at baseline ($n = 6$), or not ($n = 6$), the change in heart rate is shown for two

481 subgroups:

482 Bottom-left: Heart rate at M0 and M4 during CLET, for patients who had the maximum duration at

483 baseline.

484 Lower right: Heart rate at M0 and M4 during CLET, for patients who had not achieved the maximum

485 duration at M0.

486

487 **Table 1. Patient characteristics and results**488 **Table 1a. Variables measured at baseline and/or at M4 only**

Variable	Baseline (M0)	M4	p
Demographic Characteristics			
Sex (female), n (%)	14 (100)	-	-
Age (years)	52 [46 - 55]	-	-
Height (cm)	165 [161 - 168]	-	-
IPAQ >= 600 MET.minutes, at baseline, n (%)	6 (67%)	-	-
Physical Activity			
At least 2/3 IPAQ scores post-intervention ≥ 600 MET.minute, n (%)	-	9 (90%)	-
Clinical examination			
Weight (kg)	71.5 [63.9 - 80.0]	70.5 [63.5 - 81.0]	0.63
Body Mass Index (kg/m ²)	26.7 [25.7 - 29.2]	26.6 [25.2 - 29.2]	0.63
Systolic Blood Pressure (mmHg)	117.0 [110.0 - 122.5]	117.0 [108.5 - 127.5]	0.46
Diastolic Blood Pressure (mmHg)	70.0 [70.0 - 80.0]	78.5 [70.0 - 84.0]	0.01
Heart Rate (bpm)	77.0 [72.5 - 90.5]	79.5 [70.0 - 84.5]	0.46
Physical tests			
CLET : Duration (min)	27.5 [13.5 - 30.0]	30.0 [24.0 - 30.0]	0.02
CLET : Heart Rate (bpm)	150.0 [140.5 - 160.5]	146.0 [132.0 - 158.0]	0.58
CLET : Borg scale	4.0 [3.0 - 4.5]	3.0 [2.0 - 4.5]	0.08
CLET : VAS for leg pain*	4.0 [2.0 - 5.5]	2.5 [1.5 - 4.0]	<0.01
Handgrip R (kg)	25.0 [21.5 - 28.5]	28.5 [23.5 - 31.0]	0.02
Handgrip L (kg)	23.1 [20.0 - 26.5]	27.0 [24.0 - 28.5]	0.03
Microfet	25.9 [20.9 - 28.4]	29.5 [28.4 - 31.5]	<0.01
Questionnaires			
EQ5D	0.80 [0.77 - 0.94]	0.89 [0.80 - 0.91]	0.11
Piper Fatigue Scale	4.4 [2.9 - 5.2]	4.1 [1.9 - 5.6]	0.75
Rosenberg self-esteem scale	33 [27 - 35]	32 [28 - 39]	0.39
Summary of responses to the Participant Satisfaction Questionnaire		Score out of 10	
Did you enjoy the workshops?	-	9 [8 - 10]	-
Would you like to participate in similar EAB workshops if we offered them	-	10 [8 - 10]	-
How did you find the debriefing after the bicycle outing?	-	8 [7 - 9]	-
Were you able to use the bike easily straightaway?	-	7 [6 - 9]	-
After the start-up period, did you find the use of the electrically assisted bike easy?	-	8 [7 - 10]	-
Did you notice any progression over the weeks of the program?	-	9 [7 - 10]	-
Did you find the safety of the outings to be sufficient?	-	8 [5 - 10]	-
Would you recommend the EAB workshops to a friend in the same situation as you?	-	10 [9 - 10]	-
Have you continued to practice a physical activity after the end of the EAB workshops?	-	10 [7 - 10]	-

489 Results are presented as median [Q1 - Q3], unless specified otherwise. IPAQ: International Physical
 490 Activity Questionnaire; CLET: Constant-Load Exercise Test.

491 *The visual analog scale (VAS) for leg pain ranged from 0 to 10 and was not graduated:: 0 = "no pain"
492 and 10 = "maximum pain imaginable"
493

494 **Table 1b. Variables measured at baseline, M2, M3 and M4**

Variable	Baseline (M0)	M2	M3	M4	p
IPAQ score (MET.minutes)	1074 [570 - 3891]	3183 [2895 ; 6132]	2136 [1638 ; 4434]	2251 [885 - 4271]	0.16
VAS fatigue	3.5 [2.6 - 4.1]	3.1 [2.5 ; 5.6]	3.0 [1.7 ; 4.2]	2.8 [2.1 - 3.2]	0.45
VAS pain	2.1 [0.5 - 3.1]	1.5 [0.7 ; 1.9]	2.7 [0.9 ; 3.4]	1.9 [1.2 - 4.0]	0.53

495 Results are presented as median [Q1 - Q3]. IPAQ: International Physical Activity Questionnaire.

496 VAS: Visual Analog Scale ranging from 0 to 10, not graduated: for pain VAS: 0 = "no pain" and 10 =

497 "maximum pain imaginable" * for fatigue VAS: 0 = "no fatigue" and 10 = "maximum imaginable

498 fatigue"

499 The data at M2 (8 weeks) and M3 (13 weeks) were collected by telephone interview.

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504 **Table 2. Characteristics of outings on smart electrically assisted bicycles (median [Q1 - Q3])**

	Guided (with APA coach)	Self-Guided	Total
Number of outings	102	13	116
Duration (min)	122 [99 - 135]	121 [108 - 204]	122 [100 - 135]
Length (km)	21 [17 - 27]	24 [21 - 24]	22 [17 - 27]
Gain in Elevation (m)	358 [194 - 642]	363 [306 - 751]	361 [202 - 647]
Mean Heart Rate (bpm)	112 [100 - 126]	105 [88 - 120]	111 [100 - 126]
Mean Pedaling Frequency (rpm)	57 [52 - 61]	53 [48 - 57]	56 [52 - 61]
Mean Human Power (W)	80 [62 - 103]	72 [67 - 99]	77 [63 - 103]

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Figure Legends

Figure 1. Study Flow Diagram

IPAQ: International Physical Activity Questionnaire used to determine the MET; CLET: Constant-Load Exercise Test; VAS: self-assessed pain and fatigue on a scale of 1 to 10; CE: Clinical examination
Other questionnaires: EQ5D quality of life, Piper Fatigue Scale,

Figure 2. Evolution in Physical activity assessed using the International Physical Activity Questionnaire (IPAQ)

Considering only the 12 patients who had completed the program and included in this analysis $p=0.16$

Figure 3. Duration of Constant-Load Exercise Test (CLET) and heart rate at baseline (M0) and at M4

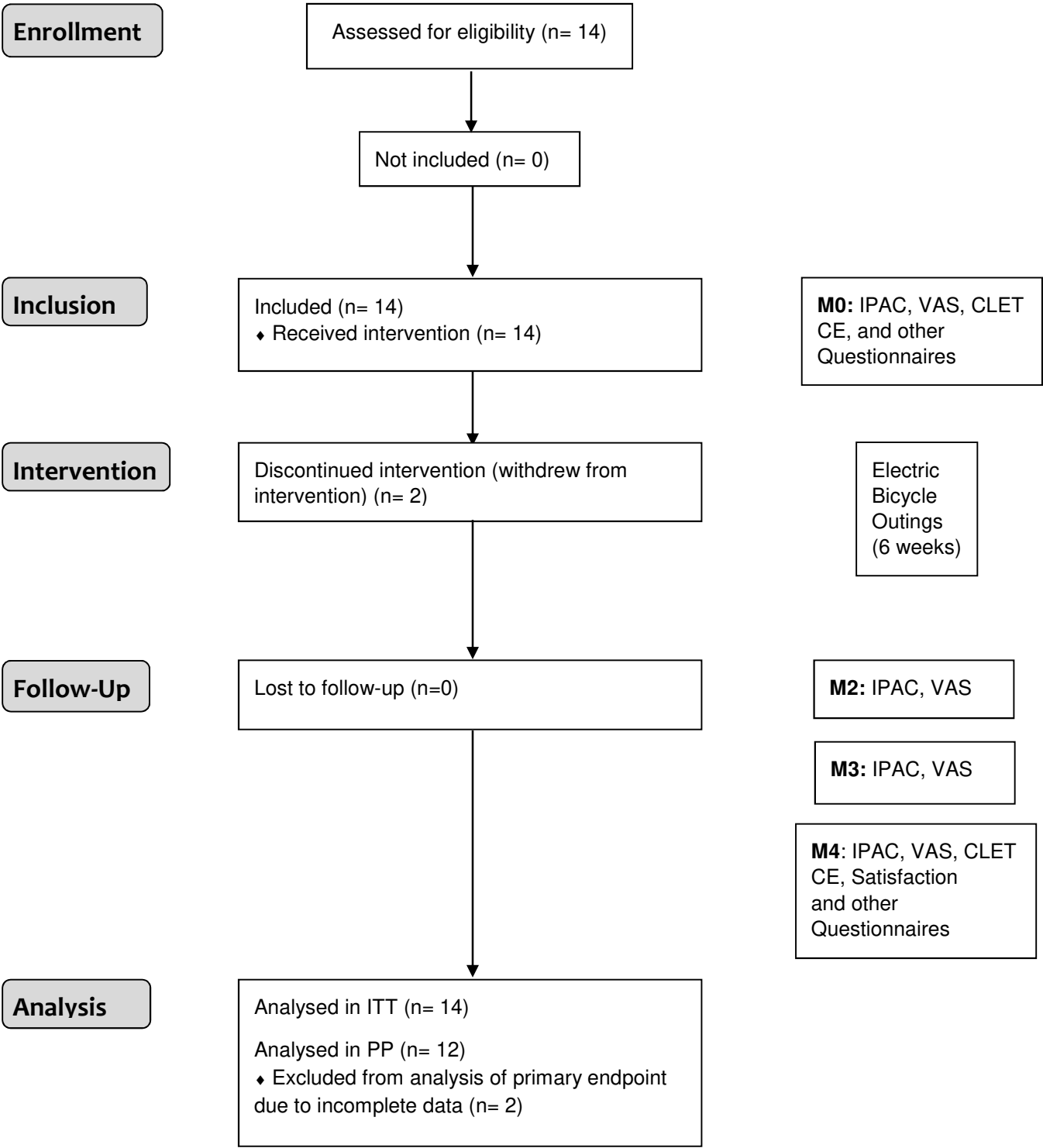
Top: CLET duration in minutes at M0 and M4. Six patients achieved the maximum duration at M0 and M4: solid bold line for all 6 patients.

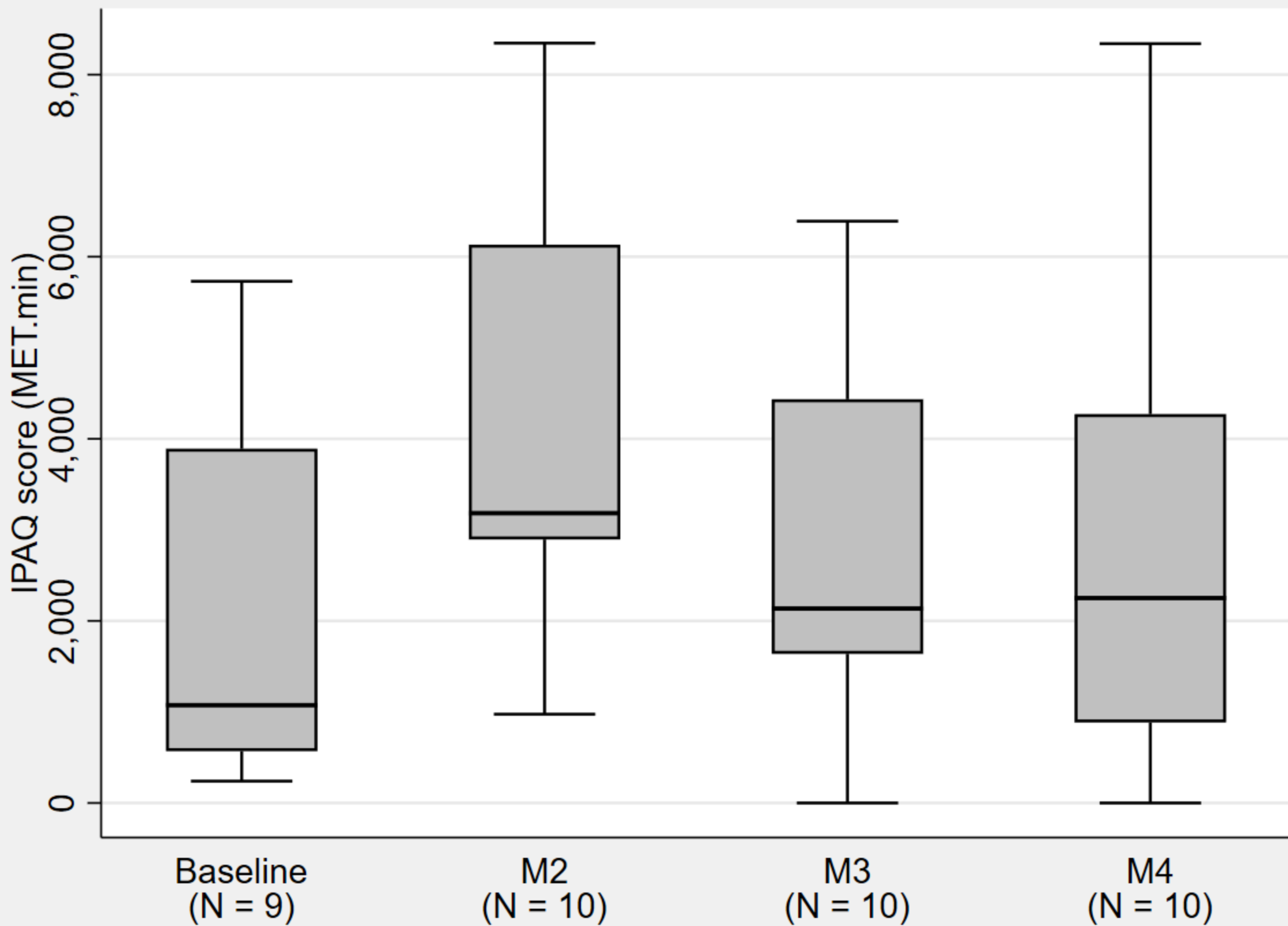
For heart rate, due to an interaction according to whether the maximum duration of the endurance test was reached at baseline ($n = 6$), or not ($n = 6$), the change in heart rate is shown for two subgroups:

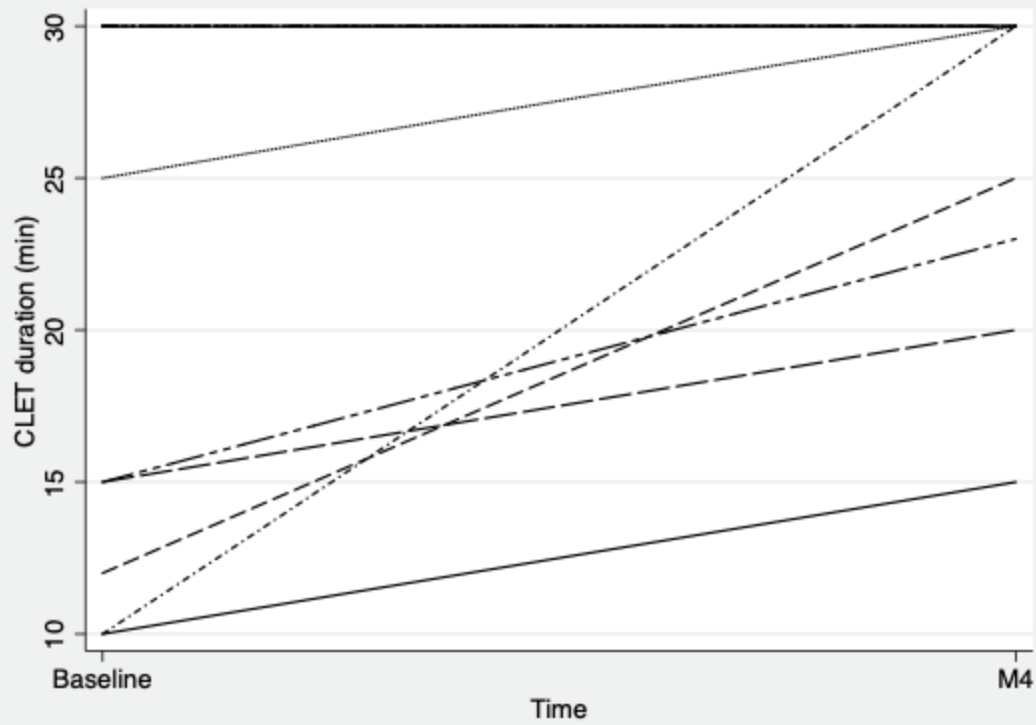
Bottom-left: Heart rate at M0 and M4 during CLET, for patients who had the maximum duration at baseline.

Lower right: Heart rate at M0 and M4 during CLET, for patients who had not achieved the maximum duration at M0.

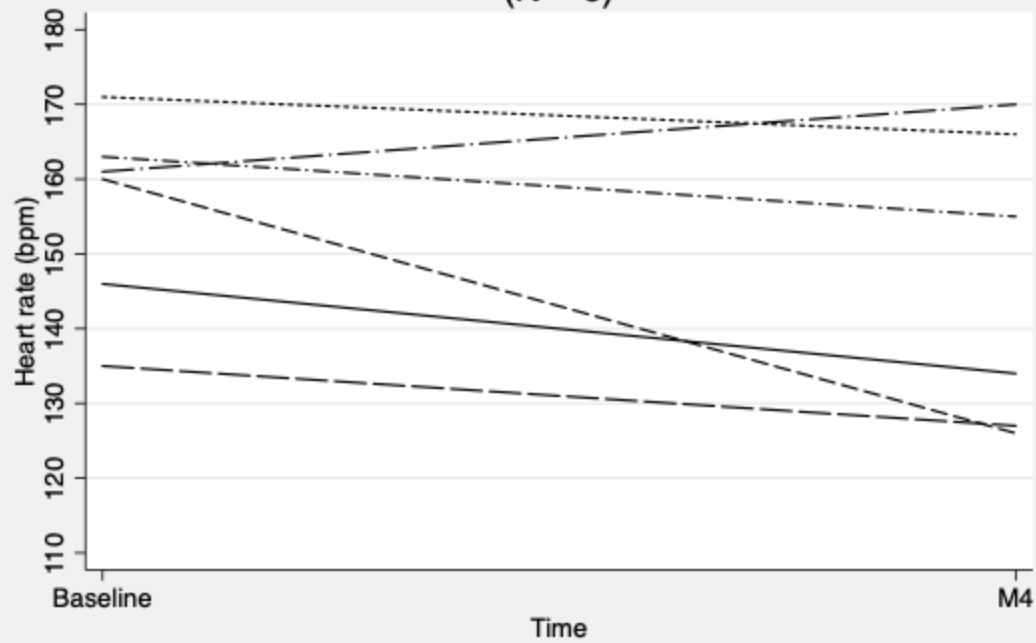
Figure 1. Study Flow Diagram with timeline







Baseline duration = 30 minutes
(N = 6)



Baseline duration < 30 minutes
(N = 6)

