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- Patients' preference for exercise setting and its influence on the health benefits gained from exercise-based cardiac rehabilitation. 2 3 4 Author: Lars H Tang<sup>1,2,3</sup>, Selina KikkenborgBerg<sup>1</sup>, Jan Christensen<sup>2,4</sup>, Jannik Lawaetz,<sup>1,2,3</sup> Patrick Doherty<sup>5</sup>, 5 Rod S Taylor<sup>6,7,8</sup>, Henning Langberg<sup>2</sup>, Ann-Dorthe Zwisler<sup>8</sup>. 6 <sup>1</sup>Department of Cardiology, The Heart Centre, Rigshospitalet, Copenhagen University Hospital, 8 Copenhagen, Denmark. 9 <sup>2</sup>CopenRehab, Section of Social Medicine, Department of Public Health, University of Copenhagen, 10 Denmark <sup>3</sup>Bachelor's Degree Program in Physiotherapy, Dept. of Rehabilitation and Nutrition, Faculty of Health and 11 12 Technology, Metropolitan University College, Copenhagen, Denmark. <sup>4</sup>Department of Occupational- and Physiotherapy Therapy, Rigshospitalet, Copenhagen University 13 Hospital, Copenhagen, Denmark 14 <sup>5</sup>Department of Health Sciences, University of York, England 15 <sup>6</sup>Institute of Health Research, University of Exeter Medical School, Exeter, England. 16 <sup>7</sup>National Institute of Public Health, University of Southern Denmark, Copenhagen, Denmark 17 <sup>8</sup>National Centre for Rehabilitation and Palliative Care, University of Southern and Odense University 18 19 Hospital, Denmark 20 "All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented 21 and their discussed interpretation" 22 **Key words:** exercise training, cardiac rehabilitation, exercise setting, patient preference, Heart valve 23 diseases, atrial fibrillation. 24 Corresponding author 25 Lars H Tang: Lars.Hermann.Tang@regionh.dk 26 Word count: 3160 words. 27 Acknowledgement of grant support and any potential conflicts of interest: We acknowledge The Danish 28 Council for Strategic Research, Faculty of Health and Technology at Metropolitan University College and 29 the Association of Danish Physiotherapists for financial support. There were no conflicts of interest. All 30 financial support was provided as non-restricted research grants and the funders have no influence on the 31 trial design, the execution of the trial or the interpretation of the data.
- 32

## 33 Abstract

34 *Objective*:

To assess patient preference for exercise setting and examine if choice of setting influences the long-term
 health benefit of exercise-based cardiac rehabilitation.

37 Methods:

38 Patients participating in a randomised controlled trial following either heart valve surgery, or radiofrequency

39 ablation for atrial fibrillation were given the choice to perform a 12-week exercise programme in either a

40 supervised centre-based, or a self-management home-based setting. Exercise capacity and physical and

41 mental health outcomes were assessed for up to 24 months after hospital discharge. Outcomes between

42 settings were compared using a time x setting interaction using a mixed effects regression model.

- 43 Results:
- 44 Across the 158 included patients, an equivalent proportion preferred to undertake exercise rehabilitation in a
- 45 centre-based setting (55 %, 95% CI: 45% to 63%) compared to a home-based setting (45%, 95% CI: 37% to

46 53%, p=0.233). At baseline, those who preferred a home-based setting reported better physical health (mean

47 difference in physical component score: 5.0, 95 % CI 2.3 to 7.4; p=0.001) and higher exercise capacity

48 (mean between group difference 15.9 watts, 95 % CI 3.7 to 28.1; p=0.011). With the exception the

49 depression score in the Hospital Anxiety and Depression Score (F(3.65), p=0.004), there was no evidence of

50 a significant difference in outcomes between settings.

51 Conclusion:

52 The preference of patients to participate in home-based and centre-based exercise programmes appears to be 53 equivalent and provides similar health benefits. Whilst these findings support that patients should be given 54 the choice between exercise-settings when initiating cardiac rehabilitation, further confirmatory evidence is 55 needed.

#### 58 1. Introduction

59 Over recent years, cardiac rehabilitation (CR) has expanded from simple, single centre programmes into 60 large comprehensive programmes offering centre based and "home-based" delivery options.<sup>1–3</sup> Home-based 61 programmes are widely ranging from self-management programmes without any supervision to tele-62 monitored supervised programmes. These can be delivered either in the patients' home, or in a local non-63 hospital location.<sup>4,5</sup> Common to the expansions of alternative CR settings is an attempt to tailor CR towards 64 the preferences of a broader group of patients<sup>1,2,4</sup> and, by doing so, tackle the very low uptake and adherence 65 rate that globally is reported in CR.<sup>6–9</sup>

66 Patient preference is known to determine whether patients participate in a trial and hypothesised to have positive impact on adherence to interventions and outcomes.<sup>10,11</sup> Evidence from one CR trial showed that 67 68 half of all patients will choose a home-based rehabilitation programme, when given the choice,<sup>12</sup> which is perhaps surprising given that most CR programmes are delivered in traditional centre-based settings.<sup>6</sup> 69 70 Qualitative studies report that home-based programmes are preferred by some patients as they align with their everyday life and their employment commitments.<sup>13,14</sup> In contrast, patients preferring social events and 71 the possibility for specific exercise intensity monitoring are more likely to prefer a centre-based setting.<sup>13</sup> 72 73 These findings emphasise that it is unlikely that a single standardised CR model will fit all patients. Physical exercise is a key element in CR<sup>15</sup> and its benefits are well documented.<sup>16–19</sup> Based on a systematic 74 75 review of the studies investigating exercise-based CR, Taylor and colleagues found similar health benefits between centre-based and home-based interventions, at similar costs.<sup>20</sup> Hence, the authors concluded that 76 77 choice of setting should reflect preference of the individual patient.<sup>10,11</sup> However, this conclusion was based 78 on study designs that randomised patients to either home or centre-based CR and failed to take into account the preference of patients.<sup>20</sup> To our knowledge, only the study by Dalal et al.<sup>12</sup> has offered cardiac patients a 79

choice between centre-based rehabilitation classes over eight to ten weeks, or a home-based self-help
package of six weeks duration. The results showed no difference in patient outcomes. More evidence is,
therefore, needed in order to validate the benefits and consequence of allowing patients a choice between
settings for CR.

84 The CopenHeart trials were designed to investigate the effect of a similar comprehensive CR programme
85 across cardiac diagnoses, including atrial fibrillation and valve disease. Patients were randomised to either

86 usual care or a programme consisting of physical exercise training and psycho-education.

88 Once allocated to the intervention groups, patients were then given a choice between a supervised centre-

89 based setting and a self-management home-based programme, thus offering the opportunity to assess the

90 impact of choice.<sup>21,22</sup>

91 The aims of this study were to assess if the choice of a CR exercise programme delivered either as a

92 traditional rehabilitation program in a supervised centre-based setting, or in a self-management home-based

setting would: 1) be equally preferred by patients and 2) provide similar patient health benefits over 24
months.

### 95 2. Method

## 96 2.1 Design

97 Data for this explorative study were pooled across the intervention arms from two CopenHeart parallel

98 group randomised controlled trials. All patients were informed about the trials both verbally

100 and in writing. Written informed consent was also obtained. Both trials were approved by the Data

101 Protection Agency (j.nr. 2007-58-0015) and Regional Ethical Committee (j.nr. H-1-2011-135, j.nr. H-1-

102 2011-157) and have been described in detail elsewhere.<sup>21,22</sup>

103 2.2 Inclusion criteria

104 The inclusion criteria in the two trials were: patients who underwent either radiofrequency ablation for atrial

105 fibrillation, or heart valve surgery, age  $\geq$  18 years, ability to speak and understand Danish, and no

106 musculoskeletal system, or organ disease that would complicate undertaking physical activity.<sup>21,22</sup>

107 2.3 The intervention

108 In the intervention group, a 12 week progressive exercise program three times weekly was begun one month

- 109 after hospital discharge. The program combined 20 minutes of aerobic training with four resistance
- 110 exercises. The aerobic training was accomplished on a stationary bike with exercise intensity according to
- 111 exercise-based guidelines in cardiac rehabilitation.<sup>15,23</sup> The resistance training combined both strength and
- 112 strength-related exercises primarily targeting muscles in the lower extremities. Each single exercise session

113 was described in detail in an individual training diary given to patients, along with a heart monitor (Polar 114 Electro, Finland), when introduced to the exercise programme. All patients undertook the first training 115 session in the same tertiary centre hospital (Department of Cardiology). Thereafter, patients continued their 116 programme in one of two settings in accordance to patient preference: either a supervised centre-based 117 setting either at the tertiary hospital, at a local hospital or healthcare centre (across 29 certified collaborating 118 training locations where all personnel were educated and certified in delivering the exercise training 119 intervention), or as a self-management home-based programme performed either at home, or in a local 120 fitness centre with no additional staff supervision.

121 In both exercise setting, all patients were encouraged to perform moderate physical activity of 30 minutes a 122 day during the intervention period. In addition, all patients received one of five psycho-educational 123 consecutive nurse consultations every four to six weeks, during the first six months after discharge. All 124 consultations started within the first month following discharge and were performed either at the same 125 tertiary centre hospital, or by phone.

126 After the 12 weeks intervention period, patients were encouraged to continue exercising by themselves and 127 follow the clinical recommendations of 30 minutes physical activity each day.

### 128 2.4 Outcome assessment

We utilised all physical and mental outcomes common to both trials. Physical capacity was measured objectively using a maximum cardiopulmonary exercise test using a ramp protocol on an ergometer bicycle.
Further with a six-minute walk test and a Sit-to-Stand (STS) test. Details of these test are described elsewhere.<sup>21,22</sup> All physical assessments were performed at one month, four months and one year post discharge.

134 The level of physical activity was self-reported using the International Physical Activity Questionnaire short-

135 form (IPAQ).<sup>24</sup> The physical and mental component scales of the Short-Form 36 (SF-36) questionnaire<sup>25</sup>

136 were used to assess self-reported generic mental health and the level of anxiety and depression were assessed

137 using the Hospital Anxiety and Depression Scale (HADS).<sup>26</sup> These patient reported outcomes were collected

138 at baseline, one, four, six 12 and 24 months after hospital discharge.

Adherence to each exercise session was assessed using a patient training diary and data from the heart rate monitors worn during exercise.<sup>27</sup> Adherence to exercise was categorised into two groups in accordance with the recommendation from Beauchamp et al,<sup>28</sup> i.e. patients participating in 275% of the 36 training sessions (i.e., 227 sessions) were categorised as 'adherent' and patients participating in <75% of all training sessions as 'non adherent'.

144 We assessed disease-specific symptoms using the "New York Heart Association (NYHA) class Functional
145 Classification' in patients following heart valve surgery, or with a "European Heart Rhythm Association
146 (EHRA) score indicating atrial fibrillation related symptoms' in patients who underwent an ablation for
147 atrial fibrillation. Level of comorbidity at baseline was calculated using the Charlson comorbidity index.<sup>29</sup>

## 148 2.5 Statistical analyses

149 An independent two-sample t-test, or a Chi-square test was used to explore differences in patient 150 demographic, medical condition, exercise adherence and adverse events between the centre and home 151 settings. A one sample binomial test was used to compare the proportion of patients who preferred one 154 setting more than the other. We used a linear mixed effects regression model, adjusted for sex, age, and 155 diagnosis, to compare outcome differences at baseline. This same mixed effect model was used to compare 156 outcome differences over time between the two settings by introducing a time x setting interaction. All 157 models were run with and without adjustment for sex, age, and diagnosis. Level of statistical significant was 158 expressed as a p<0.05. All statistical analyses were performed using the software SAS Enterprise Guide 5.1 159 (SAS Institute Inc., Cary, NC, USA).

## 160 3. Results

#### 161 3.1 Trial flow

162 A total of 177 patients were allocated to the intervention group in the two randomised trials and were

163 included in the current study. An additional patient was included because they had received the intervention,

- 164 despite being allocated to the control group. Of these 178 patients, 20 patients had post treatment
- 165 complications, or voluntary withdrawal from the two trials before they were able to select an exercise setting.

166 Therefore, the results of 158 participating patients were analysed. There was no difference in preference for 167 the settings, i.e. centre-based setting was preferred by 55% (95% CI 45% to 63%)) versus 45% (95% CI 37% 168 to 53%), who preferred a home-based setting (p=0.233) (See Figure 1 for study flow). One patient was 169 reported to switch from a centre-based setting and into a home-based setting during the exercise period. This 170 patient was analysed as a centre-based participant as 2/3rds of their exercise intervention was accomplished 171 in a healthcare centre. In the centre-based setting, 64 (74%) patients attended all three test sessions and 68 172 (78%) answered their questionnaire booklet, at all times points during the study period. In comparison, these 173 numbers were 60 (85%) patients attended all three test sessions and 57 (78%) answered their questionnaire 174 booklet at all times points during the study period in the home-based setting.

### 175 3.2 Patient characteristics

Baseline characteristics by settings are reported in Table 1. Patients who underwent heart valve surgery more often preferred a centre-based setting and vice versa for patients' that underwent an ablation (p=0.002). No other baseline demographic was found to be significantly different.

The adjusted mixed model showed better physical performance and health at baseline in patients who preferred a home-based setting expressed by increased maximum watt level during bicycle testing (mean difference 15.9 (95 % CI 3.7-28.1; p=0.011) and increased SF-36 physical component scale score (mean difference 5.0 (95 % CI 2.3-7.6; p=0.001)). No other outcome variables were found to be different at baseline between the two settings.

184 The results of exercise adherence, based on the individual exercise diary and HR-monitor, were similar

185 between the two settings (p=0.435). Approximately 60% of all patients participated in  $\geq$  75% of the 36

186 training session (see Table 1). No adverse events as a consequence to the exercise intervention were

187 reported. Fifteen adverse events were reported but no different were found between the two settings (centre-

188 based settings: 6 events versus home-based setting; 9 events, P=0.218). One patient in both of the two

189 settings reported atrial fibrillation in relation to the exercise intervention. Remaining events were

190 musculoskeletal primarily in the lower extremities.

191 3.3 Over time differences between the centre and home based setting

192 Mean physical and patient-reported outcomes over time are shown in Figures 2 and 3 and detailed in e-

193 Tables (appendix A and B). There was evidence of higher HADS depression score in the centre-based group

194 (F(3.65), p=0.004) (Figure 3b). No other outcomes differed over time between the two settings. Adjustments

195 for sex, age and diagnosis did not affect the interpretation of these results.

## 196 4. Discussion

197 This study provides important insights into patient's choice for alternative modes for provision in exercise-

198 based CR and the impact that such choice is likely to have. We found an equivalent proportion of patients

199 choose a traditional centre-based setting or a self-management home-based setting, with similar

200 improvements in health benefits in the two settings after two years, with the exception of HADS depression.

201 Our findings suggest that there is no difference in patients' outcome between centre and home-based CR 202 with the exception of a small difference in HADS depression. This result of no difference between the two 203 settings is in accord with Dalal et al, who previously investigated the influence of self-preferred setting in 204 CR.<sup>12</sup> However, where Dalal and colleagues offered a different intervention in the a centre-based setting 205 compared to the home-based setting (i.e. either hospital-based rehabilitation classes over eight to ten weeks, 206 or a self-help package of six weeks duration supported by a nurse), we offered the same structured exercise 207 intervention based upon CR guidelines in the two settings. Despite the variation between studies, they both 208 suggest that patients can prefer a CR setting and archive similar health benefits.

Based on evidence from randomised control trials, it is suggested that the exercise setting should reflect patients' preference.<sup>20</sup> Randomisation to exercise settings will reduce types of systematic bias between setting but can result in eliminating motivational variables, such as preference to a specific setting.<sup>10,11</sup> Thus, our paper is the first to investigate if same structured exercise intervention performed in a home-based setting will provide comparable clinical benefits to those in a centre-based setting, when choice of setting reflects the preference of the individual patient.

Evidence investigating the long-term effects in CR ( $\geq$  1 year follow up) across CR settings is sparse. Similar to our findings, Marchionni et al<sup>30</sup> and Jolly et <sup>al31,32</sup> report no difference in patient outcomes between home and centre-based settings after 14 months and, 12 and 24 months respectively. In contrast, Smith and colleagues report better maintenance of patient benefits and higher physical activity in those who have been allocated to home-based programs after one and six years.<sup>33,34</sup> The proportion of patients who preferred a home-based setting in this study may seem high. However, Dalal et al<sup>12</sup> reported slightly higher percentage of patients (57% of 126 patients) preferring a home-based CR program compared to centre-based.

Our study shows that diagnosis may affect preferences in CR as patients who underwent heart valve replacement preferred traditional centre-based setting and patients who underwent ablation for atrial fibrillation preferred home-based CR. Dalal et al<sup>12</sup> reported that patients with acute myocardial infarction had a higher preference to perform a self-management CR manual at home. In addition, qualitative studies show that a home-based setting is preferred by patients who would appreciate a programme that can be incorporated into their everyday life, or by patients who find participating in traditional CR restrictive.<sup>13,14</sup> Furthermore, patients with higher income appear to choose a home-based CR programme.<sup>35</sup> The results of this study strengthen the current evidence by offering further insight into the patient characteristics,

231 suggesting that patients with better physical condition and health prefer the home-based setting.

## 232 4.1 Strength and limitations

233 An important strength in the present study is the possibility for patients to undertake the exercise intervention 234 in a centre-based environment located closer to home as routinely offered in everyday clinical practice. A 235 single-centre design would have influenced the preference for the exercise intervention, due to longer 236 distances to the centre-based training location.<sup>36</sup> An additional strength is the exploration of long-term effects 237 between exercise settings (24 months) where evidence is sparse. Nonetheless, our findings need to be 238 interpreted with caution. Firstly, as this is an explorative study it only allow us to express trends in the data.<sup>37</sup> 239 Given the explorative design and the relative low number of patients, post hoc analysis were not performed 240 to explore variation between two time points (e.g. differences in settings from 1 month to 4 months). 241 Secondly, being a non-randomised study with allocation based upon patients' preference to either a home, or 242 a centre-based setting, selection bias or confounding is likely to occur when comparing the outcomes 243 between the two settings. We considered this by adjusting for important potential confounders, i.e. age, 244 gender, diagnosis. In addition, we found no baseline difference in employment status, marital status, disease 245 severity or HADS depression or anxiety scores. Nevertheless, given the non-randomised nature of the 246 comparison in this study we recognise that other unmeasured psychosocial factors may have confounded our 247 results. Thirdly, the data used in this study were taken from two randomised controlled trials not designed

for the purpose of this paper. Thus, only the follow-up assessments and outcomes common for both trials
were included for analysis (e.g., objective measures of physical capacity were not obtained at 24 months and
measurement of disease-specific quality of life was excluded).

Finally, data are limited to patients who had undergone either heart valve surgery or treatment for atrial fibrillation. Thus, the results may not be generalisable to all cardiac diagnoses. In addition our patient group was somewhat younger compared to other CR patient groups. However, Oerkild et al<sup>38</sup> have reported that elderly ( $\geq$ 65 years) patients with coronary heart disease also experience similar effects when participating in CR in a home-based setting compared to a centre-based setting. Still, we acknowledge that age could impact the results of this study, especially in relation to patients choice of exercise setting.<sup>39</sup>

#### 260 5. Conclusion

261 This study investigated patients' preference for undertaking a 12-week CR programme delivered in either a 262 supervised centre-based setting, or a self-management home-based setting and how this impacted on long-263 term health benefits. Whilst we found that, on average, both settings were preferred equally among 264 participants, it is noted, that the preference of individual patients are likely to be influenced by their 265 diagnosis and physical condition. Despite these potential differences in the preference of individual patients, 266 similar health benefits are achieved in both settings. Our results support future tailoring of CR programmes 267 towards patients' needs and preferences. Further research is needed to inform the implementation of patient-268 preferred approaches to cardiac rehabilitation.

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277 procedures.

# 278 **7. Conflict of interest**

279 The authors report no relationships that could be construed as a conflict of interest.

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383

## 384 Figure legend:

385 Figure 1: The exact numbers of patients that attended exercise testing and answered the questionnaire

386 booklet throughout the study period



- **Figure 2:** Physical test outcomes presented over time and divided between the two exercise settings.
- 390 *Figure citations:*
- 391 Data is presented as mean and the standard deviation.
- 392 P-values represent the test for time x setting interaction adjusted for adjusted for sex, age, and diagnosis
- 393
- 394

Insert figure 2a here

Insert figure 2b here

Insert figure 2c here

Insert figure 2d here

395 Figure 3: Patient reported outcomes by the Hospital Anxiety and Depression Scale (HADS), The short-form
396 36 (SF-36) and the International Physical Activity Questionnaire short-form (IPAQ) presented separately for
397 the two exercise settings over time.

398 Figure citations:

- 399 HADS and IPAQ is presented as median and Interquartile range.
- 400 SF-36 is presented as mean and the standard deviation.
- 401 P-values represent the test for time x setting interaction adjusted for adjusted for sex, age, and diagnosis
- 402
- 403

Insert figure 3a here

Insert figure 3b here

Insert figure 3c here

Insert figure 3d here

Insert figure 3e here

# 404 **Tables** 405

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Table 1: Patients demographic, medical condition and exercise adherence compared between settings

		Centre-based (n=87)		Home-based (n=71)	
Demographic data	n	Mean (±SD)	n	Mean (±SD)	p-
Age	87	62.0 (10.3)	71	58.9 (9.8)	0.058
BMI	87	25.9 (4.2)	71	26.1 (4.2)	0.725
Sex (Female/Male)	23/64		17/54		0.720
Employment status		(%)		(%)	
Employed	42	(48%)	37	(52%)	0.631
Unemployed	45	(52%)	34	(48%)	
Marital status					
Living alone	14	(16%)	13	(18%)	0.713
Living with a partner	73	(84%)	58	(82%)	
Patient type					
Radiofrequency ablation	43	(49%)	52	(73%)	0.002
Valve replacement	44	(51%)	19	(27%)	
NYHA/EHRA class*					
I	41	(47%)	25	(35%)	0.163
II	32	(37%)	26	(37%)	
III	12	(14%)	19	(27%)	
1111	2	(2%)	1	(1%)	
The Charlson comorbidity index					
0	79	(91%)	69	(97%)	0.187
21	8	(9%)	2	(3%)	
Medical Records					
Warfarin	71	(82%)	58	(82%)	0.990
B-Blockers	32	(37%)	39	(55%)	0.023
Calcium antagonists	23	(26%)	10	(14%)	0.057
Statin	34	(39%)	14	(20%)	0.009
Exercise adherence					
Participating in ≥27 exercise sessions	46	(56%)	40	(63%)	0.435

<sup>~</sup>Fischer Exact test

NYHA/EHRA class :The New York Heart Association (NYHA) Functional Classification/ European Heart Rhythm Association (EHRA) score of atrial fibrillation related symptoms

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e-component Click here to download e-component: Appendix A.doc e-component Click here to download e-component: Appendix B.doc