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Patients' preference for exercise setting and its influence on the health benefits gained from exercise-based cardiac rehabilitation.

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"All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation"

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Abstract

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.

Methods:

Patients participating in a randomised controlled trial following either heart valve surgery, or radiofrequency ablation for atrial fibrillation were given the choice to perform a 12-week exercise programme in either a supervised centre-based, or a self-management home-based setting. Exercise capacity and physical and mental health outcomes were assessed for up to 24 months after hospital discharge. Outcomes between settings were compared using a time x setting interaction using a mixed effects regression model.

Results:

Across the 158 included patients, an equivalent proportion preferred to undertake exercise rehabilitation in a centre-based setting (55 %, 95% CI: 45% to 63%) compared to a home-based setting (45%, 95% CI: 37% to 53%, p=0.233). At baseline, those who preferred a home-based setting reported better physical health (mean difference in physical component score: 5.0, 95 % CI 2.3 to 7.4; p=0.001) and higher exercise capacity (mean between group difference 15.9 watts, 95 % CI 3.7 to 28.1; p=0.011). With the exception the depression score in the Hospital Anxiety and Depression Score (F(3.65), p=0.004), there was no evidence of a significant difference in outcomes between settings.

Conclusion:

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

1. Introduction

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

Patient preference is known to determine whether patients participate in a trial and hypothesised to have positive impact on adherence to interventions and outcomes.[10,11] Evidence from one CR trial showed that half of all patients will choose a home-based rehabilitation programme, when given the choice,[12] which is perhaps surprising given that most CR programmes are delivered in traditional centre-based settings.[6] Qualitative studies report that home-based programmes are preferred by some patients as they align with their everyday life and their employment commitments.[13,14] In contrast, patients preferring social events and the possibility for specific exercise intensity monitoring are more likely to prefer a centre-based setting.[13] 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[15] and its benefits are well documented.[16–19] Based on a systematic 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.[20] Hence, the authors concluded that choice of setting should reflect preference of the individual patient.[10,11] However, this conclusion was based on study designs that randomised patients to either home or centre-based CR and failed to take into account the preference of patients.[20] To our knowledge, only the study by Dalal et al.[12] has offered cardiac patients a 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.

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

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

Once allocated to the intervention groups, patients were then given a choice between a supervised centre-based setting and a self-management home-based programme, thus offering the opportunity to assess the impact of choice.[21,22]

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

2. Method

2.1 Design

Data for this explorative study were pooled across the intervention arms from two CopenHeart parallel group randomised controlled trials. All patients were informed about the trials both verbally and in writing. Written informed consent was also obtained. Both trials were approved by the Data Protection Agency (j.nr. 2007-58-0015) and Regional Ethical Committee (j.nr. H-1-2011-135, j.nr. H-1-2011-157) and have been described in detail elsewhere.[21,22]

2.2 Inclusion criteria

The inclusion criteria in the two trials were: patients who underwent either radiofrequency ablation for atrial fibrillation, or heart valve surgery, age ≥ 18 years, ability to speak and understand Danish, and no musculoskeletal system, or organ disease that would complicate undertaking physical activity.[21,22]

2.3 The intervention

In the intervention group, a 12 week progressive exercise program three times weekly was begun one month after hospital discharge. The program combined 20 minutes of aerobic training with four resistance exercises. The aerobic training was accomplished on a stationary bike with exercise intensity according to exercise-based guidelines in cardiac rehabilitation.[15,23] The resistance training combined both strength and strength-related exercises primarily targeting muscles in the lower extremities. Each single exercise session

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

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

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

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.[21,22] All physical assessments were performed at one month, four months and one year post discharge.

The level of physical activity was self-reported using the International Physical Activity Questionnaire short-form (IPAQ).[24] The physical and mental component scales of the Short-Form 36 (SF-36) questionnaire[25] were used to assess self-reported generic mental health and the level of anxiety and depression were assessed using the Hospital Anxiety and Depression Scale (HADS).[26] These patient reported outcomes were collected 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.[27] Adherence to exercise was categorised into two groups in accordance with the recommendation from Beauchamp et al,[28] i.e. patients participating in ≥75% of the 36 training sessions (i.e., ≥27 sessions) were categorised as 'adherent' and patients participating in <75% of all training sessions as 'non adherent'.

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

2.5 Statistical analyses

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

3. Results

3.1 Trial flow

A total of 177 patients were allocated to the intervention group in the two randomised trials and were included in the current study. An additional patient was included because they had received the intervention, despite being allocated to the control group. Of these 178 patients, 20 patients had post treatment complications, or voluntary withdrawal from the two trials before they were able to select an exercise setting.

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

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.

The results of exercise adherence, based on the individual exercise diary and HR-monitor, were similar between the two settings (p=0.435). Approximately 60% of all patients participated in ≥ 75% of the 36 training session (see Table 1). No adverse events as a consequence to the exercise intervention were reported. Fifteen adverse events were reported but no different were found between the two settings (centre-based settings: 6 events versus home-based setting; 9 events, P=0.218). One patient in both of the two settings reported atrial fibrillation in relation to the exercise intervention. Remaining events were musculoskeletal primarily in the lower extremities.

3.3 Over time differences between the centre and home based setting

Mean physical and patient-reported outcomes over time are shown in Figures 2 and 3 and detailed in e-Tables (appendix A and B). There was evidence of higher HADS depression score in the centre-based group ($F(3.65)$, $p=0.004$) (Figure 3b). No other outcomes differed over time between the two settings. Adjustments for sex, age and diagnosis did not affect the interpretation of these results.

4. Discussion

This study provides important insights into patient's choice for alternative modes for provision in exercise-based CR and the impact that such choice is likely to have. We found an equivalent proportion of patients choose a traditional centre-based setting or a self-management home-based setting, with similar improvements in health benefits in the two settings after two years, with the exception of HADS depression.

Our findings suggest that there is no difference in patients' outcome between centre and home-based CR with the exception of a small difference in HADS depression. This result of no difference between the two settings is in accord with Dalal et al, who previously investigated the influence of self-preferred setting in CR.[12] However, where Dalal and colleagues offered a different intervention in the a centre-based setting compared to the home-based setting (i.e. either hospital-based rehabilitation classes over eight to ten weeks, or a self-help package of six weeks duration supported by a nurse), we offered the same structured exercise intervention based upon CR guidelines in the two settings. Despite the variation between studies, they both 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.[20] 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.[10,11] 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[30] and Jolly et [al31,32] 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.[33,34]

The proportion of patients who preferred a home-based setting in this study may seem high. However, Dalal et al[12] 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[12] 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.[13,14] Furthermore, patients with higher income appear to choose a home-based CR programme.[35] The results of this study strengthen the current evidence by offering further insight into the patient characteristics, suggesting that patients with better physical condition and health prefer the home-based setting.

4.1 Strength and limitations

An important strength in the present study is the possibility for patients to undertake the exercise intervention in a centre-based environment located closer to home as routinely offered in everyday clinical practice. A single-centre design would have influenced the preference for the exercise intervention, due to longer distances to the centre-based training location.[36] An additional strength is the exploration of long-term effects between exercise settings (24 months) where evidence is sparse. Nonetheless, our findings need to be interpreted with caution. Firstly, as this is an explorative study it only allow us to express trends in the data.[37] Given the explorative design and the relative low number of patients, post hoc analysis were not performed to explore variation between two time points (e.g. differences in settings from 1 month to 4 months). Secondly, being a non-randomised study with allocation based upon patients' preference to either a home, or a centre-based setting, selection bias or confounding is likely to occur when comparing the outcomes between the two settings. We considered this by adjusting for important potential confounders, i.e. age, gender, diagnosis. In addition, we found no baseline difference in employment status, marital status, disease severity or HADS depression or anxiety scores. Nevertheless, given the non-randomised nature of the comparison in this study we recognise that other unmeasured psychosocial factors may have confounded our 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[38] have reported that elderly (≥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.[39]

5. Conclusion

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

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7. Conflict of interest

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

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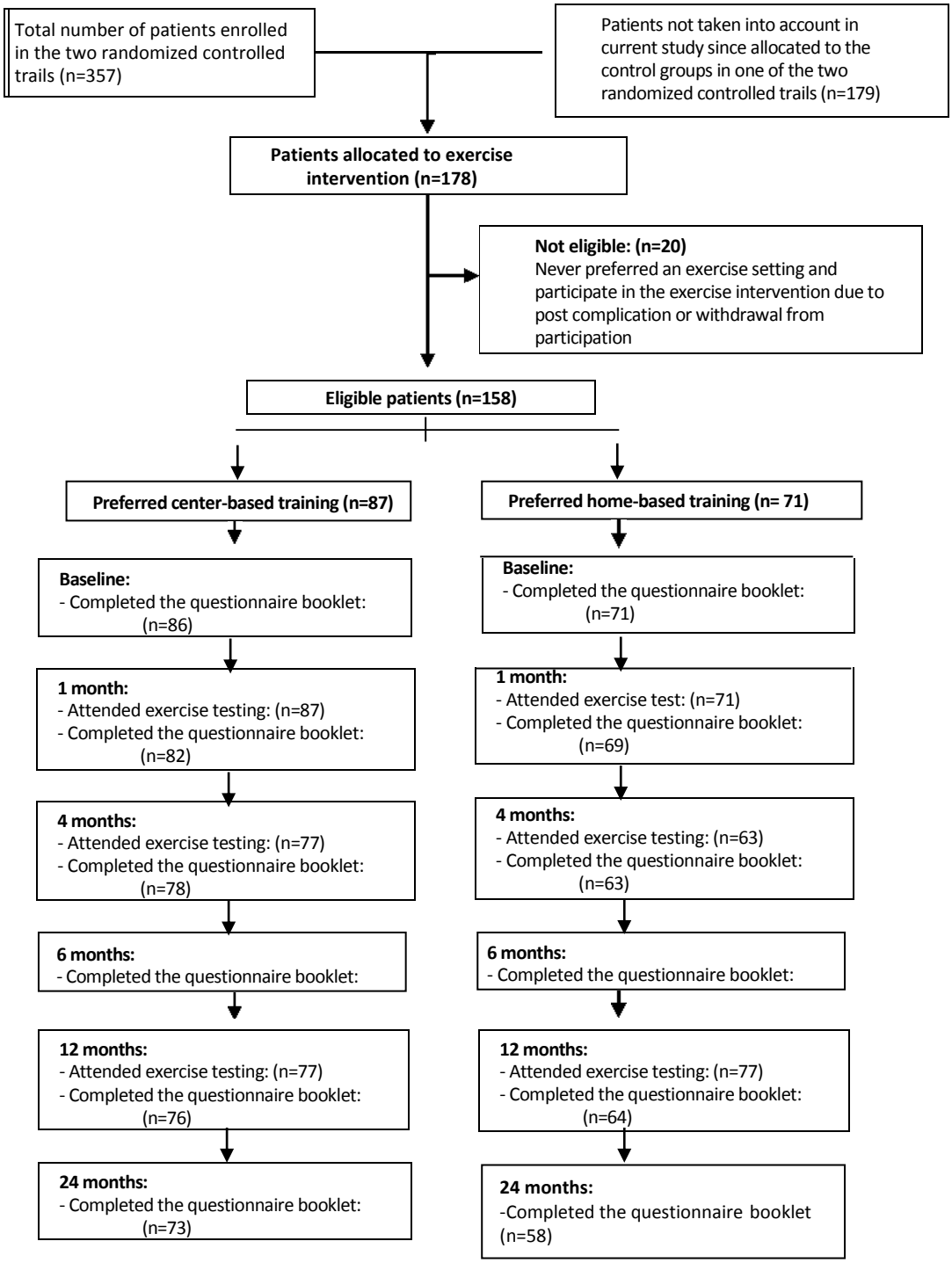
384 **Figure legend:**

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

386 booklet throughout the study period



389 **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

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Insert figure 2a here

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

Figure citations:

HADS and IPAQ is presented as median and Interquartile range.

SF-36 is presented as mean and the standard deviation.

P-values represent the test for time x setting interaction adjusted for adjusted for sex, age, and diagnosis

Insert figure 3a here

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404 **Tables**
405

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%)	
IIII	2	(2%)	1	(1%)	
The Charlson comorbidity index					
0	79	(91%)	69	(97%)	0.187
≥1	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

˜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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Figure(s)
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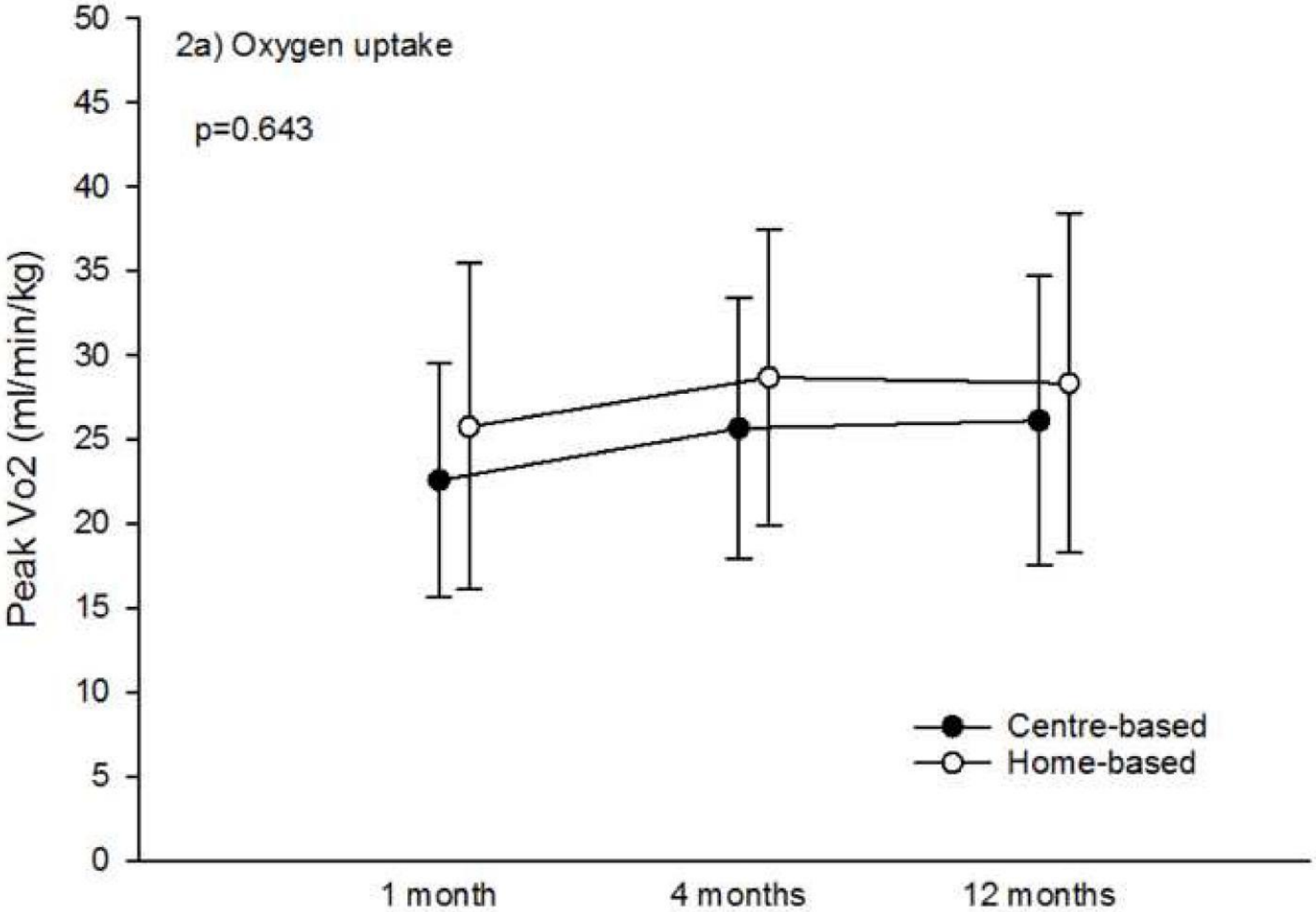

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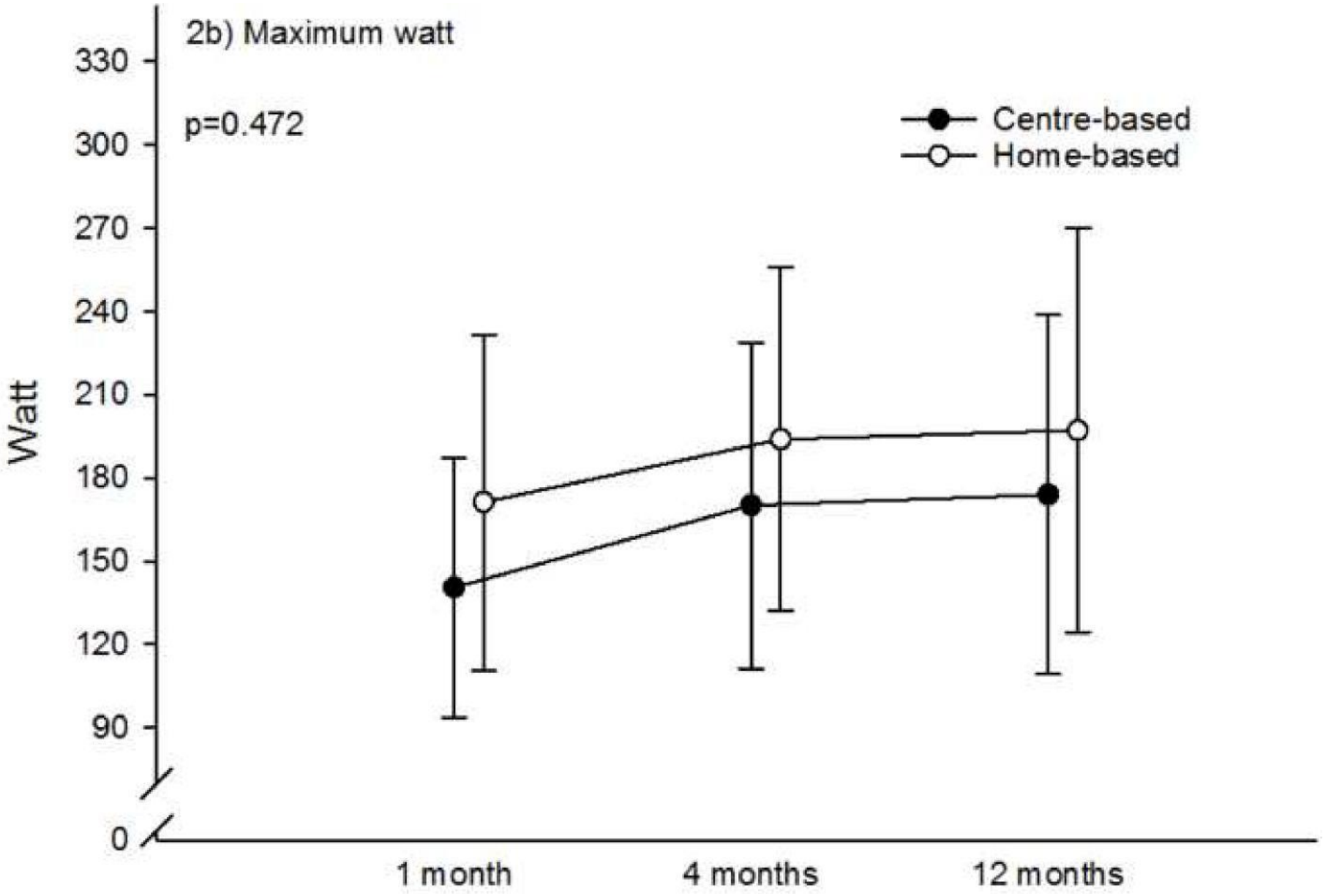

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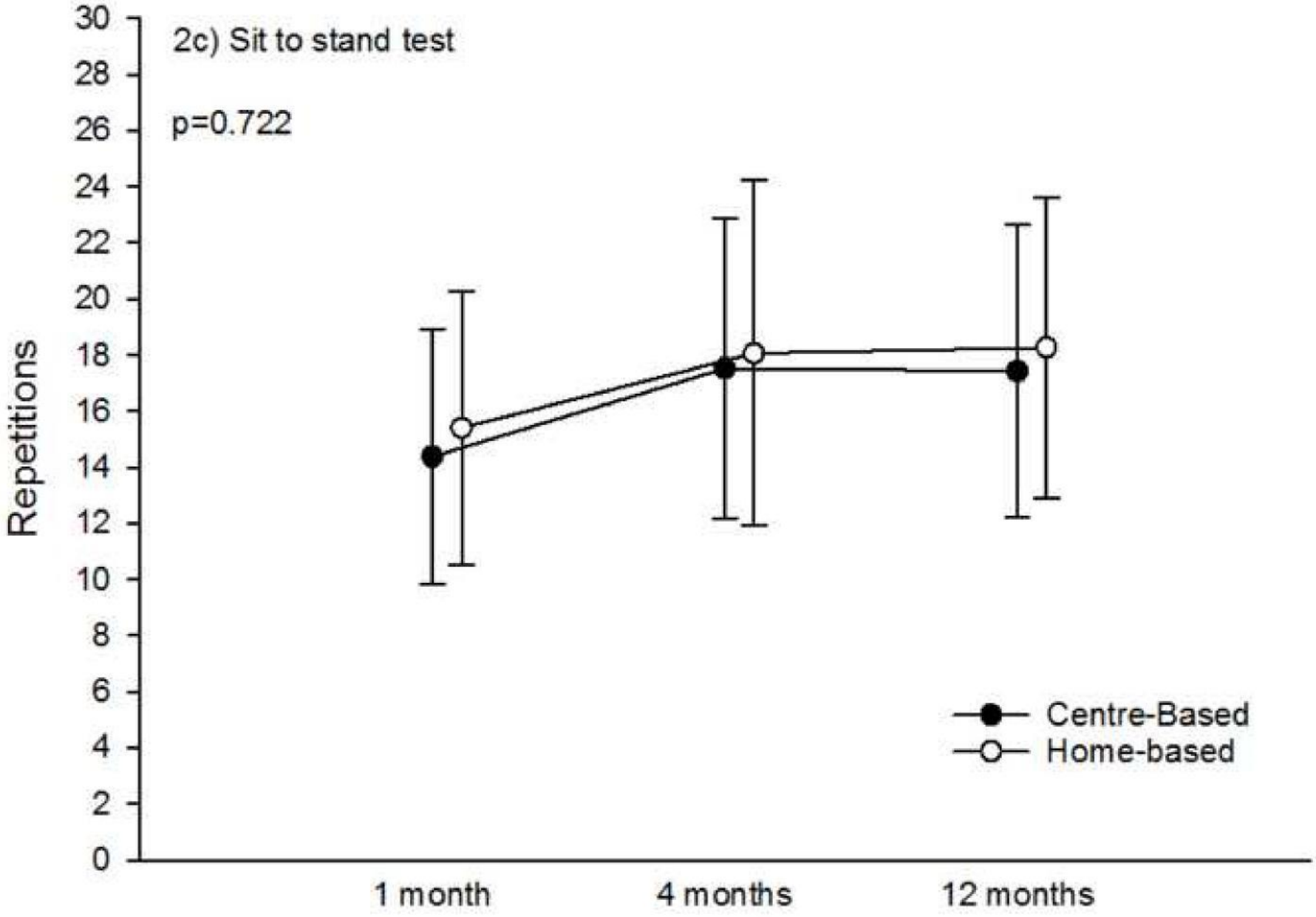

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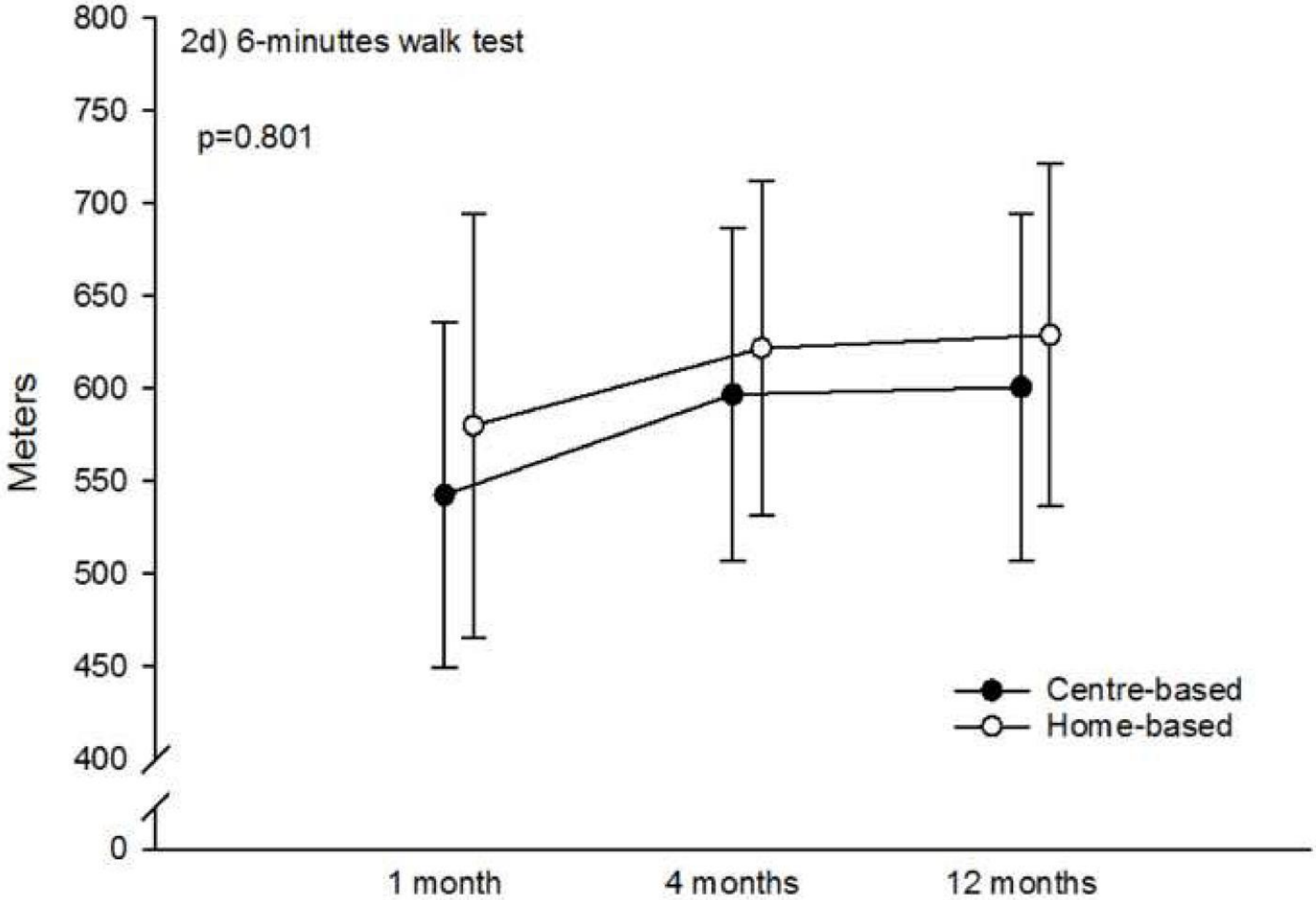

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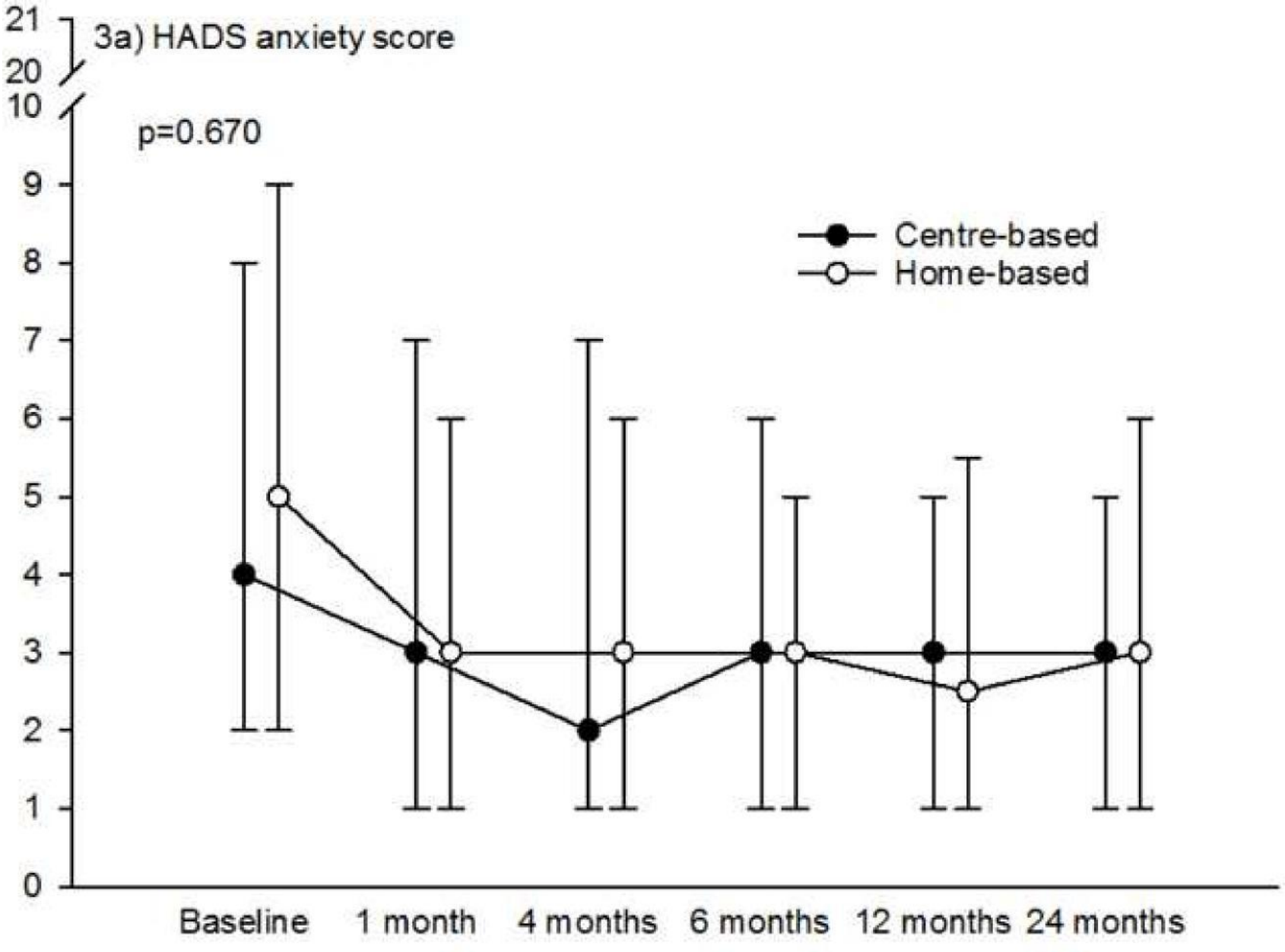

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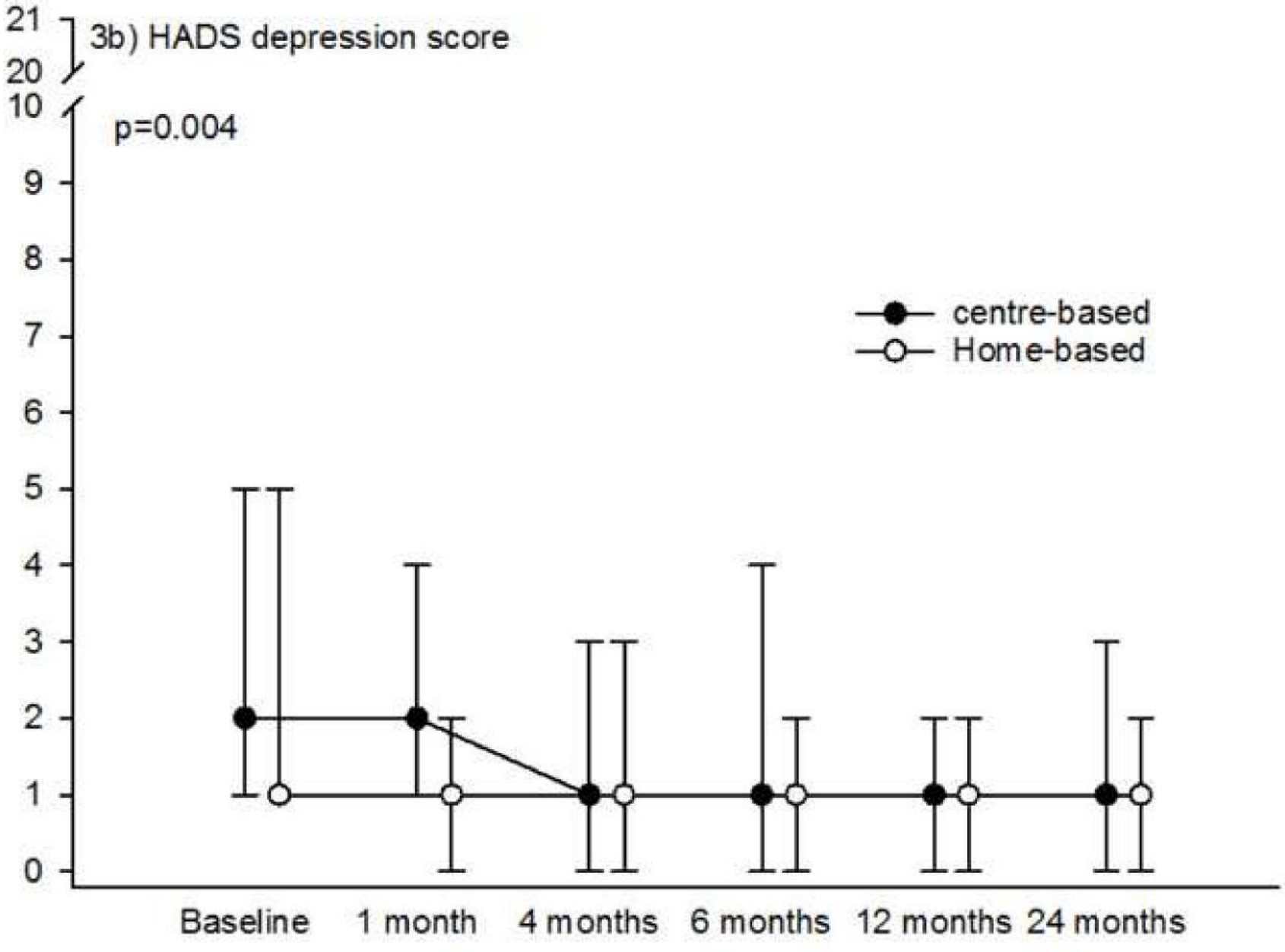

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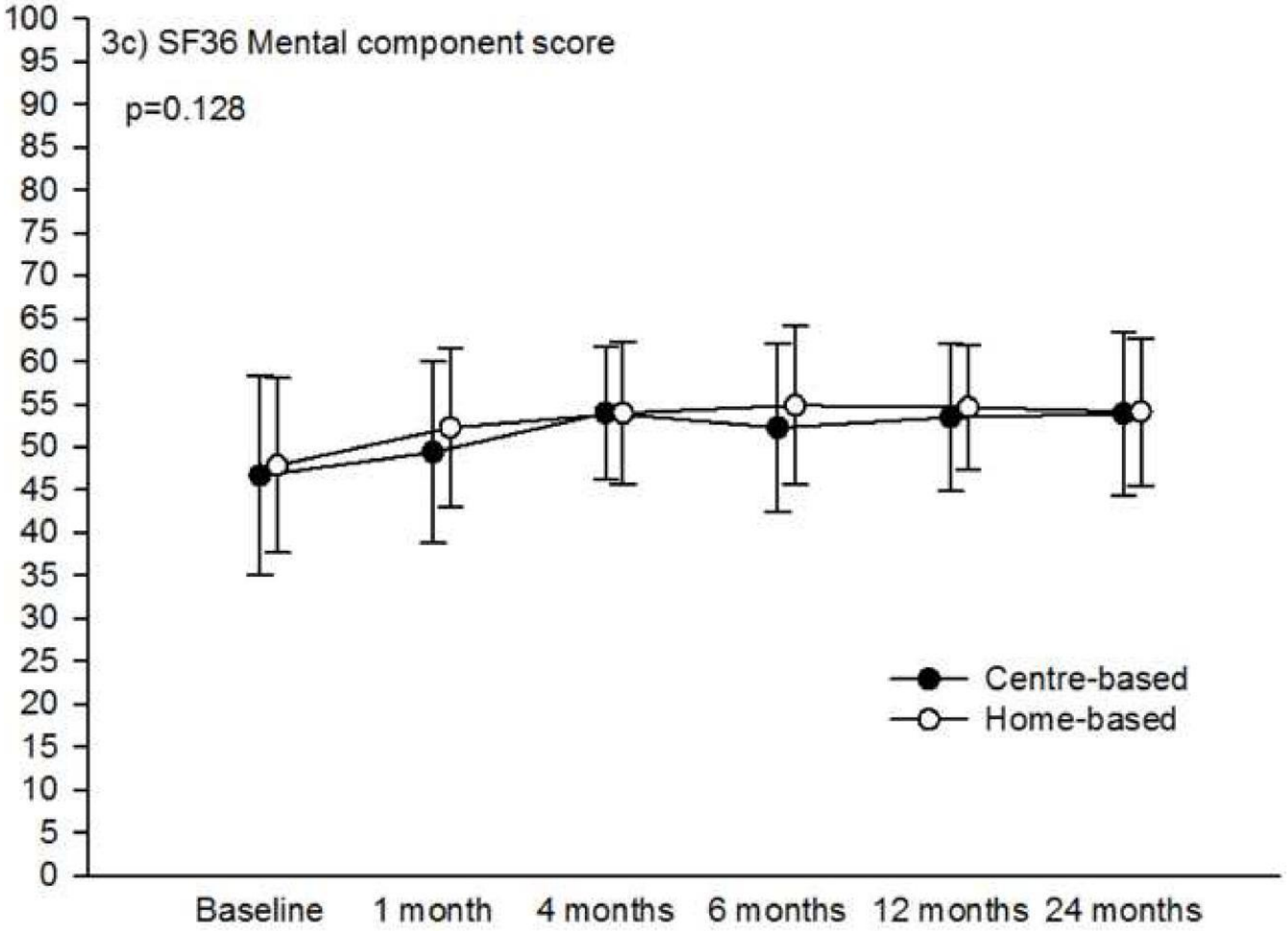

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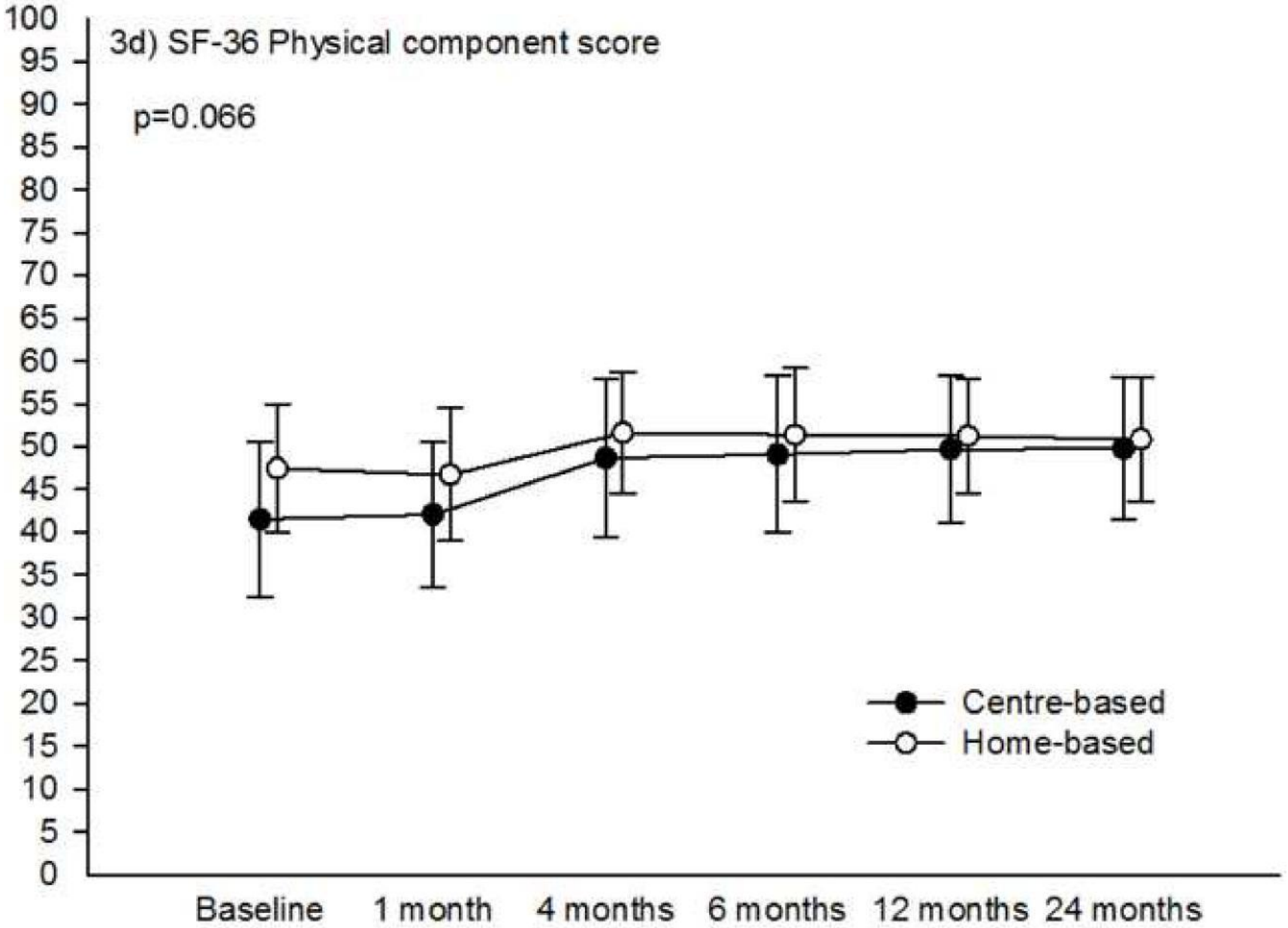

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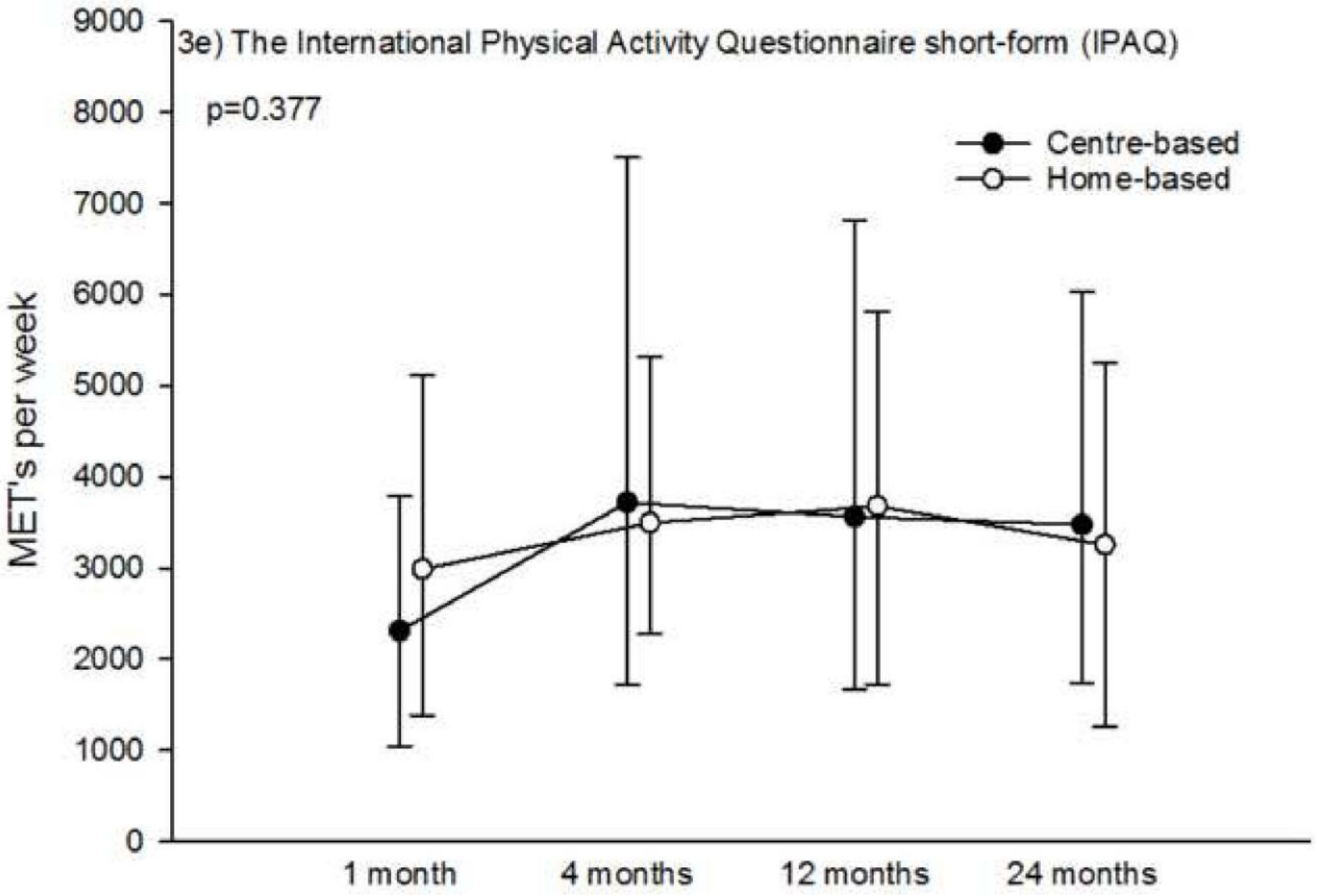

e-component

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