

# Association between the transtheoretical model approach and sustained intradialytic pedaling exercise

# A retrospective cohort study

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# Abstract

The transtheoretical model (TTM) is a promising approach to the promotion of behavior change, but it remains to be established whether there is an association between the TTM approach and intradialytic exercise among patients on hemodialysis (HD) with low motivation to exercise in a real-world setting.

This retrospective cohort study, conducted in a regional hospital in Japan, included adult outpatients receiving HD 3 times per week who had never participated in intradialytic pedaling exercise despite the encouragement of the HD personnel. Patients were divided into 2 groups according to HD weekday. Patients undergoing HD on Tuesday, Thursday, and Saturday were encouraged by the HD unit team to exercise during HD based on the TTM (exposure group) and those receiving HD on Monday, Wednesday, and Friday were encouraged to exercise as usual (control group). The primary outcome was sustained intradialytic exercise using a leg ergometer, defined as a total of 72 sessions of 30-minute pedaling exercise (duration of at least 6 months).

Overall, 85 patients were included in the analysis (mean age:  $67.1 \pm 11.9$  years, 22% female). Of 33 patients in the exposure group, 10 (30%) maintained intradialytic exercise, compared with 2 of 52 patients (4%) in the control group. Log-binomial regression models with stabilized inverse probability of treatment weighting showed a significant association between the TTM approach and sustained intradialytic exercise (adjusted risk ratio 9.23 [95% confidence interval 2.13–40.00]). There were no exercise-related cardiovascular events.

Among patients with low motivation to exercise during HD, use of the TTM approach in clinical practice was associated with sustained intradialytic exercise compared with usual care.

**Abbreviations:** 95% CI = 95% confidence interval, ESKD = end-stage kidney disease, HD = hemodialysis, Mon-Wed-Fri = Monday, Wednesday, and Friday, TTM = transtheoretical model, Tue-Thu-Sat = Tuesday, Thursday, and Saturday.

Keywords: dialysis, intradialytic exercise, multidisciplinary team, physical activity, transtheoretical model

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The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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## 1. Introduction

Physical activity is associated with lower all-cause and causespecific mortality<sup>[1,2]</sup>; therefore, promotion of physical activity is a public health priority. The gap between evidence for and practice of physical activity is particularly noticeable in patients with end-stage kidney disease (ESKD) undergoing dialysis. Patients treated with dialysis are less active than healthy sedentary individuals<sup>[3]</sup> and their physical inactivity is strongly associated with mortality.<sup>[4,5]</sup> Meta-analyses suggest that intradialytic exercise, which is commonly provided for patients receiving dialysis,<sup>[6]</sup> can improve hemodialysis (HD) efficacy,<sup>[7,8]</sup> exercise capacity,<sup>[7-12]</sup> blood pressure,<sup>[8]</sup> and quality of life.<sup>[7-10]</sup> The Kidney Disease Outcomes Quality Initiative guidelines for patients on dialysis recommend that "the goal for activity should be for cardiovascular exercise at a moderate intensity for 30 minutes most, if not all, days per week."<sup>[13]</sup> However, only 36.9% of patients undergoing HD exercise more than once a week.<sup>[14]</sup> More efforts are needed to close the evidence-practice gap in physical activity in these patients.

It is not easy for HD personnel to effectively promote regular exercise for patients receiving HD. Although most patients on HD acknowledge that exercise would be beneficial, only 25% are able to exercise without any difficulty.<sup>[15]</sup> There are several barriers that hinder patients on HD from participating in exercise, such as fatigue on dialysis and nondialysis days, shortness of breath, and weakness.<sup>[15–17]</sup> Moreover, nephrologists and HD personnel do not regularly provide exercise counseling to their patients because it has low priority in their workload.<sup>[18,19]</sup> This means many patients are unaware of the type of exercise that is appropriate for them.<sup>[15]</sup> Therefore, an effective approach to successfully overcome such barriers and promote patient participation in exercise is urgently required.

There is growing evidence that behavioral counseling, which aims to increase knowledge, motivation, and skills for behavior change, is useful in promoting healthy diet and physical activity.<sup>[20]</sup> The transtheoretical model (TTM) is a promising approach to lifestyle modifications such as exercise, healthy diet, and smoking cessation.<sup>[21–25]</sup> This approach has been used in the field of dialysis to promote better self-management, including exercise.<sup>[26–29]</sup> To date, only 1 randomized controlled trial has reported a substantial effect of the TTM approach on sustained intradialytic exercise.<sup>[26]</sup> However, the study included relatively younger patients with low comorbidity, a sample not very representative of most patients on dialysis.<sup>[30]</sup> Therefore, little is known about the effect of the TTM approach on exercise among patients on HD who do not engage in intradialytic exercise, despite recommendations by HD personnel in a real-world setting.

In the present study, we aimed to retrospectively evaluate the TTM approach as a quality improvement activity at our dialysis unit. We examined the effect of this approach on sustainable intradialytic exercise among patients with low motivation to engage in such exercise. We hypothesized that application of the TTM approach in clinical practice would be associated with sustained exercise during HD compared with usual care.

#### 2. Methods

# 2.1. Study design and setting

This retrospective cohort study was conducted at Saku Central Hospital, one of the largest hospitals in eastern Nagano

Prefecture, Japan.<sup>[31]</sup> Although no full-time transplant surgeons and infectious disease physicians have ever worked in this facility,<sup>[32]</sup> it is the only hospital in the area where patients with ESKD can receive living-donor kidney transplantation.<sup>[33]</sup> There are 46 beds and 5 full-time nephrologists in the dialysis unit.

A multidisciplinary team approach has been used to improve the quality of dialysis care in the facility.<sup>[34]</sup> To promote selfmanagement such as medication, dietary and fluid restriction, and exercise,<sup>[35]</sup> the team comprises nephrologists, dialysis nurses, clinical engineers, a physical therapist, nutritionists, care workers, and administrative personnel. However, although the team has successfully promoted several self-management behaviors, this has not included exercise.

The team members regularly encouraged patients to participate in pedaling exercise using simple words of encouragement, after the introduction of 2 mobile leg ergometers (escargot PBE-100 (2), MEISEI Corporation, Tokyo, Japan) into the dialysis unit in 2009. Although several patients started pedaling exercise in line with team recommendations, almost all of these patients discontinued the exercise after several months; subsequently, the patients seldom used the leg ergometers. Thus, a quality improvement activity to incorporate intradialytic exercise into the routine dialysis care of patients in our dialysis unit was required.

We followed the STrengthening the Reporting of OBservational Studies in Epidemiology guidelines in reporting our results.<sup>[36]</sup> All study procedures were approved by the institutional review boards of Saku Central Hospital Group (#R202006-17). Informed consent was not required owing to the retrospective nature of the study.

#### 2.2. Study subjects

Participants were adult outpatients (aged  $\geq$ 20 years) receiving maintenance HD who had never participated in intradialytic exercise, despite the encouragement of the HD personnel. The other inclusion criterion was that patients were undergoing HD 3 times per week (Monday, Wednesday, and Friday [Mon-Wed-Fri] or Tuesday, Thursday, and Saturday [Tue-Thu-Sat]) at the facility's dialysis unit as of October 1, 2015. The exclusion criteria were as follows: unstable angina pectoris, severe valvular disease, heart failure (New York Heart Association classes III and IV), fatal arrhythmia, lower limb amputation, musculoskeletal symptoms, and severe cognitive impairment.

# 2.3. Comparison groups

Patients were divided into 2 groups according to HD day of the week. Patients undergoing HD on Mon-Wed-Fri were allocated to the control group; those undergoing HD on Tue-Thu-Sat were in the exposure group. We were able to perform this comparison for 2 reasons: first, 5 nephrologists provided care to patients on a designated weekday in the dialysis unit. Thus, nephrologists who cared for patients undergoing HD on Mon-Wed-Fri did not see patients on Tue-Thu-Sat and vice versa. Second, the attending nephrologist (M Murakami) for patients on Thursday introduced the TTM approach into the routine dialysis care of patients based on previous evidence<sup>[22–25]</sup> and his experience.<sup>[37]</sup> The remaining 4 nephrologists, however, did not participate in the approach owing to lack of time. Except for these 4 physicians, the multidisciplinary team was the same on each day.<sup>[38]</sup> As a result, only patients on Tue-Thu-Sat received the TTM approach.

**2.3.1.** Usual care (control group). Patients in the control group were encouraged by the team members to participate in intradialytic exercise, which was consistent with usual procedure before this study. Patients also regularly received an information pamphlet on the benefits of exercise and a simple recommendation for exercise during HD (usual care). The recommendation was not based on behavioral change theories.

**2.3.2. TTM approach (exposure group).** In addition to usual care, patients in the exposure group received monthly or bimonthly motivation to engage in intradialytic exercise based on the TTM. The TTM approach, conducted as a quality improvement activity, was incorporated into the usual care of patients on HD to foster the culture of exercise, as described below.

**2.3.3. Preparation of the TTM approach.** The TTM approach used in the dialysis unit was prepared using 3 steps (Table 1).<sup>[39]</sup> First, the team members shared evidence supporting our new approach to develop the knowledge and skills to assist patients. Second, the roles of members were determined to reduce their burden of exercise support (personnel workload).<sup>[40]</sup> Finally, after several months of preparation, the members implemented the TTM approach in the dialysis unit on October 1, 2015.

**2.3.4. TTM-based approach.** The TTM posits that health behavior change involves progression through 5 different stages of behavioral change: precontemplation, contemplation, preparation, action, and maintenance (Fig. 1).<sup>[21]</sup> Individuals are categorized into one of these stages, which reflect their intention to change their behavior. The remaining core constructs of the TTM are processes of change, decisional balance (pros and cons), and self-efficacy. Processes of change represent activities that individuals engage in when they try to modify their cognition and behavior. The decisional balance includes the perceived benefits and barriers of behavior change. Self-efficacy refers to the level of individual confidence in maintaining the desired behavior change.

The TTM approach provides a feasible method of categorizing an individual's current stage of behavioral change. In this study, team members shared information about the readiness of each patient for intradialytic exercise via a conference. To help patients to successfully progress through these strategies, the nephrologist provided stage-matched motivational advice (Table 1).<sup>[41]</sup> Team members then helped patients to assess and balance the benefits and barriers of exercise, and encouraged the establishment of the self-efficacy and confidence required for behavior change.

#### 2.4. Intradialytic pedaling exercise

The intradialytic exercise was performed 3 times a week during the first 3 hours of HD. Each exercise session comprised a warmup phase of stretching exercise and then pedaling exercise for up to 60 minutes on the bed. The exercise was performed under the careful observation of the team (except for the physical therapist), who provided assistance. Patients were encouraged to gradually increase the pedaling time from 10 minutes to 30 minutes or more per HD treatment, at a perceived exertion rating of 1 to 13 on Borg Scale.<sup>[42]</sup> All exercise sessions were monitored and both intradialytic exercise and exercise-related adverse events for each session were recorded by HD personnel.

Because there is no health insurance reimbursement for intradialytic exercise in Japan, the physical therapist did not directly assist patients in the pedaling exercise. Instead, the physical therapist instructed the team on how to set up the exercise equipment on the dialysis bed and how to help patients perform the exercise, and gave professional advice to the team members before the implementation of the TTM approach. Moreover, the team members could consult the physical therapist as needed.

#### 2.5. Study outcomes

The primary outcome was sustained intradialytic exercise for 6 months (at least 72 exercise sessions during follow-up).<sup>[21]</sup> If a patient pedaled for at least 30 minutes per HD session, regardless of speed, we counted this as 1 intradialytic exercise.<sup>[13,40]</sup> The secondary outcomes were participation in intradialytic exercise and major adverse cardiovascular events. We defined participation in intradialytic exercise sessions during follow-up (at least 30 minutes per HD session). Major adverse cardiovascular events were defined as hospital admission for cardiovascular disease during intradialytic exercise.

# 2.6. Follow-up

Follow-up started on October 1, 2015, and ended on the earliest date of death, change of kidney replacement therapy, dialysis unit transfer, or April 30, 2017 (a maximum of 18 months), because in May 2017, patients attending Mon-Wed-Fri HD sessions were also offered encouragement based on the TTM approach. If the patients maintained intradialytic exercise but did not reach 6 months owing to death or loss to follow-up, this was counted as only participation in intradialytic exercise.

#### 2.7. Data sources

The baseline clinical characteristics of each participant were obtained from the electronic and paper medical records as of October 1, 2015. Laboratory data were obtained from regular blood tests on October 5 (Mon) and 6 (Tue) for patients receiving HD on Mon-Wed-Fri and those on Tue-Thu-Sat, respectively. Data on intradialytic exercise were obtained from exercise recording sheets. Two authors (M Murakami and MT) independently collected all data to ensure the accuracy and completeness of the data.

#### 2.8. Statistical analysis

Data for all patients were included in the main analysis, except those who died or were lost to follow-up during the study period. We did not use any imputation procedures because there was no missing data. We described the patient baseline characteristics using frequencies and percentages for categorical variables and means ( $\pm$  standard deviations) or medians (interquartile ranges) for continuous variables. We used Fisher exact test to compare the categorical variables between the 2 groups. To compare scores on continuous variables, we used Student *t* test for normally distributed data and the Mann–Whitney *U* test for skewed data.

Log-binomial regression models with stabilized inverse probability of treatment weighting were performed to estimate risk ratios and 95% confidence intervals (95% CI), to examine the association between the TTM approach and sustainable intradialytic exercise. In addition to the log-binomial regression

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	Component	Detail	Dialysis personnel in charge
1	Preparation of the transtheoretical model approach	<ol> <li>Suggestion: implementation of the transtheoretical model approach</li> <li>Update of the evidence: learning and sharing knowledge about intradialytic exercise and the transtheoretical model approach</li> </ol>	Nephrologist All members*
		<ol> <li>Reinforcement of knowledge: instruction and professional advice in how to set up the leg ergometer on the dialysis bed and assist patients to perform intradialytic exercise</li> </ol>	Physical therapist
2	Determination of roles	Reduction of personnel burden: consideration of reducing the burden of medical personnel such as dialysis nurses and clinical engineers	All members
3	Transtheoretical model approach (progression to action stage) <sup>†</sup>	<ol> <li>Continuation of usual care<sup>‡</sup>: delivery of the information pamphlet on the benefits of exercise</li> </ol>	Dialysis nurse, clinical engineer, and care worker
		<ol> <li>Information sharing: sharing the information about each patient's readiness for intradialytic exercise via a conference</li> </ol>	All members
		3) Stage-matched approach	Nephrologist
		3-1) Precontemplation stage	
		Processes of change: consciousness-raising, social liberation, and helping relationships	
		Decisional balance <sup>§</sup> : pros $<<$ cons	
		Self-efficacy: lowest self-efficacy	
		3-2) Contemplation stage	
		Processes of change: consciousness-raising, social liberation, dramatic relief, and self-reevaluation	
		Decisional balance: pros < cons	
		Self-efficacy: promoting self-efficacy	
		3-3) Preparation stage	
		Processes of change: consciousness-raising, dramatic relief, self- reevaluation, and self-liberation	
		Decisional balance: pros $\leq$ cons	
		Self-efficacy: promoting self-efficacy	
4	Start of intradialytic exercise	1) Set up of the bed ergometer <sup><math>\ddagger</math></sup>	Dialysis nurse, clinical engineer, and care worker
		2) Monitoring of vital signs throughout each session <sup><math>\ddagger</math></sup>	Dialysis nurse and clinical engineer
		3) Recording of intradialytic time and adverse events $^{\ddagger}$	Dialysis nurse and clinical engineer
		4) Management of exercise recording sheet	Administrative personnel
		5) Sharing of exercise situation and feedback from each patient	All members
		6) Discussion about improving team approach	All members
5	Transtheoretical model approach (progression from action stage to maintenance stage) <sup>†</sup>	1) Stage-matched approach	Nephrologist
		1-1) Action stage	
		Processes of change: helping relationships, environmental reevaluation, counter conditioning, reinforcement management, self-liberation, and stimulus control	
		$D_{O}$	
		Decisional balance. $pros > cons$	
		2) Flothouldt of self-efficacy in our approach	(Patient)
		2-7) Analytic of a sear of the exercise sheet and relevation for	All members
		natient's effort if the natient completed the above-mentioned sheet	
		2-3) Provision of a graph sheet showing average mileage per month	Clinical engineer

\* The team comprised nephrologists, dialysis nurses, clinical engineers, a physical therapist, nutritionists, care workers, and administrative personnel.

<sup>†</sup> Consciousness raising, efforts by the patient to seek new information and to gain understanding and feedback about sedentary lifestyles; social liberation, awareness, availability, and acceptance by the patient of alternative, problem-free lifestyles in society; helping relationships, trusting, accepting, and using the support of caring others during attempts to change the sedentary lifestyle; dramatic relief, affective aspects of behavior change, often including emotional experiences related to sedentary lifestyles; self-reevaluation, emotional and cognitive reappraisal of values by the patient about the sedentary lifestyle; environmental reevaluation, consideration and assessment by the patient of how the sedentary lifestyle; affects the physical and social environments; counter conditioning, substitution of alternative behaviors for the sedentary lifestyle; reinforcement management, changing the contingencies that control the sedentary lifestyle; self-liberation, the patient's choice and commitment to change the sedentary lifestyle; stimulus control, control of situations and other causes that trigger the sedentary lifestyle; decisional balance, result of weighing the pros and cons of intradialytic exercise; self-efficacy, the extent to which the patient feels confident that he or she can maintain intradialytic exercise.

<sup>‡</sup> This approach was also provided to the patients in the control group.

<sup>§</sup> Decisional balance means the balance between the perceived benefits and barriers of intradialytic exercise.



models, we used the propensity score method to provide less biased estimates in this small cohort, with fewer outcome events per adjustment covariate.<sup>[43]</sup> First, we calculated the propensity score using a logistic regression model adjusted for age (as a continuous variable), sex, cause of ESKD (diabetes or others), and mobility (independent or assisted) at baseline, following previous studies.<sup>[14,44]</sup> Then, the propensity scores were incorporated as stabilized inverse probability of treatment weighting in the log-binomial regression models to balance for potential confounders.<sup>[45]</sup> Finally, we calculated standardized differences to assess the balance of the above-mentioned confounding factors between the 2 groups. An absolute standardized difference of <10% was defined as indicative of good balance.<sup>[46]</sup>

We performed a sensitivity analysis for the primary outcome to examine the robustness of our main results using the same statistical analysis as above. This analysis was performed for patients who died or were lost to follow-up during the study period by assuming a worst-case scenario. The worst-case scenario meant that those patients participated in intradialytic exercise for 6 months in the control group and not in the exposure group. We set the control group as the reference throughout the analysis. All statistical tests were 2-sided, with P < .05 considered statistically significant, and were performed using STATA version 15.0 (STATA Corporation, College Station, TX).

# 3. Results

#### 3.1. Patients

As shown in Figure 2, 107 adult patients received HD 3 times per week at the start of the study period. Of the 91 eligible patients, 6 patients who died or were lost to follow-up were excluded from the main analysis (exposure group=33, control group=52). Overall, the mean $\pm$  standard deviation age was  $67.1 \pm 11.9$  years, and 19 (22%) participants were women. Diabetes was the most



common cause of ESKD (n = 39; 46%), and 16% of patients were unable to walk without a supporting device at the time of the study. There were no significant differences between the 2 groups at baseline (Table 2). Although patients in the exposure group were slightly older than those in the control group, this difference was not significant.

#### 3.2. Primary outcome

Overall, 10 of 33 patients (30%) in the exposure group continued to exercise during HD sessions for at least 6 months, compared with 2 of 52 patients (4%) in the control group (crude risk ratio for the exposure group 7.88 [95% CI 1.84–33.73]; P < .001) (Table 3). The result remained the same after multivariate analysis (adjusted risk ratio 9.23 [95% CI 2.13–40.00]; P = .003). We confirmed that the absolute standardized differences of the above-mentioned potential confounders were <10% (age -2.8%, sex 5.2%, cause of ESKD -1.0%, and mobility 1.6%).

The results of the sensitivity analysis remained unchanged. The worst-case sensitivity analysis, which assumed that the 5 patients in the control group who died or were transferred to another hospital had continued to exercise for 6 months, yielded consistent results (adjusted risk ratio 2.88 [95% CI 1.20–6.94]; P=.018).

#### 3.3. Secondary outcomes

Patients in the exposure group were significantly more likely to participate in intradialytic exercise than those in the control group (36% vs 4%; adjusted risk ratio 10.84 [95% CI 2.56–45.94]; P=.001). Of the 12 patients who participated in intradialytic exercise in the exposure group, 1 stopped exercising at 1 month after starting exercise because of backache, and 1 patient stopped at 1.5 months because of lack of motivation. No major cardiovascular events related to the exercise occurred during the 18 months of the study.

#### 4. Discussion

This retrospective cohort study examined the effect of the TTM approach on intradialytic pedaling exercise among patients who did not participate in such exercise during HD, despite the encouragement of the multidisciplinary team members (ie, patients with low motivation to exercise). In this real-world setting, we found that a much higher proportion of patients in the TTM exposure group engaged in and safely maintained intradialytic exercise for more than 6 months compared with patients receiving usual care.

We found a significant relationship between application of the TTM approach in clinical practice and sustained intradialytic Table 2

Baseline characteristics of patients receiving maintenance hemodialysis.

	Exposure group (n=33)	Control group (n=52)	P value
Age, mean $\pm$ SD, yr	69.2±12.0	$65.8 \pm 11.9$	.21
Female sex, n (%)	6 (18)	13 (25)	.46
BMI, median (IQR), kg/m <sup>2</sup>	22.7 (19.6–24.6)	21.9 (20.0-24.9)	.94
Cause of end-stage kidney disease, n (%)			.22
Diabetes	16 (48)	23 (44)	
Chronic glomerulonephritis	5 (15)	16 (31)	
Nephrosclerosis	3 (9)	1 (2)	
Others	9 (27)	12 (23)	
Dialysis duration, median (IQR), yr	5.3 (2.8–12.9)	5.6 (1.9–14.9)	.85
Comorbidity, n (%)			
Hypertension	30 (91)	50 (96)	.32
Stroke	6 (18)	12 (23)	.59
Coronary artery disease	5 (15)	9 (17)	.79
Peripheral artery disease	3 (9)	6 (12)	.72
Mobility, n (%)			.73
Independent	27 (82)	44 (85)	
Assisted	6 (18)	8 (15)	
Regular exercise (at least once a wk), n (%)	11 (33)	15 (29)	.66
Blood test			
Urea clearance (single pool Kt/V), mean $\pm$ SD	$1.43 \pm 0.32$	$1.43 \pm 0.30$	.96
Hemoglobin, median (IQR), g/dL	10.8 (10.2–11.4)	11.3 (10.5–11.9)	.22
Albumin, median (IQR), g/dL	3.8 (3.6–3.9)	3.8 (3.5–3.9)	.86

BMI = body mass index, IQR = interquartile range, SD = standard deviation.

exercise among patients on HD with low motivation to exercise; this relationship was stronger than expected. There are 2 possible explanations for this finding. First, the TTM approach may strengthen the multidisciplinary team approach that was already incorporated into standard dialysis care for patients at the beginning of the study.<sup>[47]</sup> It has been reported that intradialytic exercise is a low priority in the HD personnel workflow, and initiating exercise at the busiest time for HD personnel is a barrier to personnel participation.<sup>[48]</sup> However, using a combination of the TTM approach and the multidisciplinary team approach, care workers and administrative personnel in the team seemed to adopt an important role in successfully reducing the burden of other medical personnel; for example, by setting up the exercise equipment, managing the records of each patient who participated in the exercise, and/or effective communication with these patients. Second, through the above-mentioned quality improvement activity, the culture of intradialytic exercise was gradually promoted in the dialysis unit.<sup>[39]</sup> As the number of patients who maintained exercise increased, team members became delighted with patients' participation and took a more active approach to

patients than before. In fact, qualitative studies have shown that the perspectives and values toward exercise of HD personnel are influential in encouraging patients to exercise.<sup>[48]</sup>

This study has several strengths. To our knowledge, this is the first study to report an association between TTM and exercise in a sample that included only patients with low motivation to exercise (despite regular exercise counseling by HD personnel). Compared with previous studies on the TTM approach and intradialytic exercise,<sup>[26,29]</sup> our study included patients who were older and had more comorbidities. In fact, 16% of patients in our study were unable to walk without a supporting device, reflecting the real-world setting.<sup>[30]</sup> This is noteworthy, because beneficial effects of regular exercise have also been reported for physically disabled patients on HD with a high mortality risk.<sup>[14]</sup> Another strength of the present study is that the retrospective cohort study design meant that a possible Hawthorne effect (for both groups) was avoided.<sup>[49]</sup> It is therefore likely that the findings accurately represent the effect of the TTM approach on intradialytic exercise.

This study has several limitations that should be acknowledged. First, of the 91 patients, 6 (7%) died or were lost to follow-

# Table 3

Association between transtheoretical model approach and outcomes.

		Control group (n=52), n (%)	Risk ratio <sup>*</sup>			
Outcomes	Exposure group (n=33), n (%)		Crude	P value	Adjusted <sup>†</sup>	P value
Primary outcome						
Sustained intradialytic exercise	10 (30)	2 (4)	7.88 (1.84-33.73)	<.001	9.23 (2.13-40.00)	.003
Secondary outcomes						
Start of intradialytic exercise	12 (36)	2 (4)	9.45 (2.26-39.59)	<.001	10.84 (2.56-45.94)	.001
Major adverse cardiovascular events	0	0	-	-	-	-

\* Log-binomial regression models with stabilized inverse probability of treatment weighting were used.

<sup>†</sup> Adjusted for age, sex, cause of end-stage kidney disease (diabetes or others), and mobility (independent or assisted).

up during the study period. However, the worst-case scenario results remained unchanged. Second, team members (except for the attending nephrologist for Thursday patients) may also have motivated patients in the control group to participate in intradialytic exercise. Although this might have affected the results, contamination between the 2 groups would not result in overestimation of the effect. Third, as this approach was integrated into routine practice, we did not assess the clinical benefits of intradialytic exercise, such as physical function, body composition, and quality of life among patients on HD. However, completion of an exercise program is associated with lower risk of cardiovascular events among patients on HD.<sup>[50]</sup> Fourth, we acknowledge that the potential for residual bias owing to unmeasured confounding factors, such as readiness for intradialytic exercise in the control group and depression in both groups, remains. Fifth, our outcomes may not be independent owing to exercise contagion.<sup>[51]</sup> However, both groups experienced similar situations. Finally, study participants were selected from only 1 dialysis facility, which limits the generalizability of these findings to patients on HD in Japan. Additional studies with large samples from multiple centers are needed to confirm the effect of the TTM approach on sustainable exercise.

In conclusion, among patients who declined to exercise despite the advice offered, application of the TTM approach in routine practice was associated with increased exercise during HD compared with simple recommendations by the HD personnel. These findings from a real-world setting suggest that, with a multidisciplinary dialysis unit team, the TTM approach encouraged patients with low motivation to safely participate in intradialytic exercise and maintain this exercise over 6 months. This evidence-based approach may have the potential to narrow the gap between clinical evidence and practice regarding physical activity in the field of dialysis.

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