

# Effects of Home-visit Occupational Therapy Using a Management Tool for Daily Life Performance on Severe Mental Illness: A Multicenter Randomized Controlled Trial

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**Keywords:** Activities of daily living, Home-visit, Occupational therapy, Randomized controlled trial, Severe mental illness, Social functioning.

**Aim:** Effective intervention is necessary for improving the social functioning of patients with severe mental illness (SMI). We examined the effects of home-visit occupational therapy (OT) using a Management Tool for Daily Life Performance (MTDLP) that was designed to support patients in completing their desired daily life activities. The control group were treated by home-visit OT without using MTDLP. **Method:** In this multicenter randomized controlled trial, 60 participants included adults aged 18–65 with an ICD-10 diagnosis of F2 (i.e., schizophrenia, schizotypal and delusional disorders) or F3 (i.e., mood [affective] disorders) and who utilized one of the 20 psychiatric outreach teams in Japan. Participants were randomly assigned into two groups: MTDLP ( $n = 29$ ), control ( $n = 31$ ). Home-visit OT was provided to both groups, once a week, for four months. A repeated-measures analysis of variance was conducted to compare changes in participants' social functioning using the Global Assessment of Functioning (GAF) and the Social Functioning Scale (SFS). **Results:** The GAF scores of the MTDLP group improved significantly greater than those of the control group. No significant change in SFS total scores was found between the groups; however, the Employment/Occupation scores (an SFS subscale) of the MTDLP group significantly improved compared to the controls. **Conclusion:** These findings suggest that MTDLP can increase the social functioning of people with SMI more so than controls. Thus, home-visit OT using MTDLP that is intensively focused on the patient's desires and implemented in the real-world environment appears to contribute to improvements in social functioning.

## INTRODUCTION

Severe mental illnesses (SMI), including schizophrenia and mood disorders, rank among the leading mental health causes of the global burden of disease [1] and cause impairments in social functioning [2]. Social functioning, an individual's ability to perform and fulfill normal social roles [3], includes independence, activities of daily living, work, and social relationships [4]. In many cases, people with SMI have small social networks [5] and tend to have sedentary lifestyles [6]. Around two-thirds of people with schizophrenia are unable to fulfill basic social roles [7], and less than 20% hold competitive employment [8]. Therefore, improved social functioning is a key target of psychiatric rehabilitation [9], and can contribute to their community living.

Historically, in Japan, people with SMI have been admitted to psychiatric hospitals because mental health care has been hospital-centered and insufficient support services have made living in the community difficult [10,11]. Recently, the Ministry of Health, Labour and Welfare, Japan announced a policy for promoting said individuals' discharge. Based on this, effective ways to enrich community care for people with SMI have been explored [12]. In many cases, after discharge, people with SMI are referred to psychiatric outreach program by their attending physician. This is provided by nurses, occupational therapists, and social workers. Occupational therapists provide the interventions (i.e., home-visit occupational therapy; OT) that are deemed necessary for community-dwelling people with SMI (e.g., craft work, exercise therapy, medication management, and money management). However, the standards that explain the contents and quality of home-visit OT provided to patients have not been fully established. In addition, the effectiveness of home-visit OT for community-dwelling people with SMI has not been examined. This is because the history of home-visit OT in Japan is relatively new. In contrast, several studies in other countries have suggested that OT practices in the community, which focus on the patients' desires, improve social functioning [13,14,15]. It must be noted that, since most of these studies are

not randomized control trials (RCT), there is no fully established evidence that OT practices in the community improve social functioning.

Therefore, we have used an RCT to examine whether OT practices in the community that focus on people with SMI's desired daily life activities (i.e., an activity that a person needs or wants to do) improve their social functioning. To emphasize their desired daily life activities, we used the Management Tool for Daily Life Performance (MTDLP) and provided home-visit OT. This paper-based MTDLP tool is used to assess desired daily life activities, factors promoting/disturbing said activities, collaborative goal-setting, planning, and intervention [16,17]. We hypothesized that people with SMI will perform various tasks related to their desired daily life activities through home-visit OT using MTDLP. Consequently, their social functioning will improve more than through home-visit OT, which does not use MTDLP. This RCT aimed to reveal the effects of home-visit OT using MTDLP on the social functioning of people with SMI.

## MATERIALS AND METHODS

### Study Design

To compare home-visit OT using MTDLP (intervention) and home-visit OT not using MTDLP (control), a multicenter RCT design was used.

### Participants

**Eligibility criteria.** Eligibility criteria included being an adult aged 18–65 years, having an ICD-10 diagnosis of F2 (i.e., schizophrenia, schizotypal and delusional disorders) or F3 (i.e., mood [affective] disorders) by an attending physician, and having already received or planning to receive the usual home-visit OT (i.e.; not using MTDLP). Exclusion criteria included a diagnosis of severe and moderate mental retardation, dementia, or a substance-use disorder; refusing to participate, being evaluated as unable to give sufficient consent by the attending physician or the director of the psychiatric outreach team, having psychiatric symptoms that were predicted to worsen because of participation, and being unable to complete the pre-test. In addition, the data from individuals who were hospitalized for more than one month during the intervention period were excluded from analysis.

**Sample size.** Based on a sample size calculation by G\* Power version 3.1.9.4., the total sample size needed was 34 participants ( $\alpha$ -error = 0.05, power = 0.80, and  $\eta^2_p$  = 0.06).

### Recruitment

From January to October 2018, information meetings and open announcements about the study were conducted by the first and last authors (M.I & H.T.). The 20 psychiatric outreach teams in Japan, which employ occupational therapists, agreed to participate. The locations of the teams varied and encompassed both rural and urban areas. Patients who received an outreach program from these teams and met the eligibility criteria were given information about the study by their team's staff. This information included an explanatory document that outlined their rights as participants including their ability to withdraw at any time, and the protection of their privacy. If a patient was willing to participate, they provided written consent for participation.

### Randomization

Randomization was conducted by the first author (M.I.) using stratification by psychiatric outreach teams and random computer-generated numbers. Consequently, a participant – the attending occupational therapist pair was allocated into MTDLP or control group. The pairs of participants and therapists were determined by each outreach team prior to the randomization process and were not known to the first author (M.I.). However, the first author was responsible for four participants (MTDLP =2, control = 2) and only had information on them. The occupational therapists were notified of the allocation; however, participants were not.

### Intervention

For both the intervention and control group, one attending occupational therapist per participant provided interventions once a week, for between 30 minutes to 1 hour, for four months (Table I). If the participants' condition was serious, the occupational therapist intervened twice a week, or a pair of professionals comprising the occupational therapist and a nurse visited the participant's home once a week, as per usual crisis management in Japanese psychiatric outreach programs. Cancellations were made up for at a later date.

To practice MTDLP, prior to the intervention, the occupational therapists were recommended to receive a one-day structured training. The training included lectures on the methods to listen to participants' desired daily life activities, to assess participants' states, and to plan rehabilitation programs based on the International Classification of Functioning, Disability, and Health (ICF) codes [18]. Lectures on the methods to complete MTDLP sheets were also included, and exercises were done using simulated cases. However, if an occupational therapist without MTDLP training was assigned into the MTDLP group in the randomization process, the participant – therapist pair was excluded; if not, the therapist was included in this study.

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**Intervention group (MTDLP).** All interventions and related processes were implemented at participants' homes and at the actual performance place utilizing the MTDLP sheets and the following protocols. First, the occupational therapists clarified participants' desired daily life activities by asking them to identify the activities that they needed or wanted to accomplish in their daily lives. Desired daily life activities expressed by the participants were listed on the MTDLP sheets. Second, the occupational therapists evaluated the factors related to the promotion and inhibition of the activities that participants desired using the ICF (e.g., if a participant wants to work; body functions and structures domain; b140: deficit of attention functions etc., activities and participation domain; d220: difficulty undertaking multiple tasks etc., environmental factors domain; e310: can get help from family members, etc.). Third, occupational therapists and participants created a "collaborative goal" to achieve the identified desired daily life activity level based on a shared decision model. Last, occupational therapists implemented a three-step program: 1) a basic program (an approach for body functions and structures domain), 2) an application program (an approach for activity and participation domain, and 3) a social adjustment program (an adaptive approach for environmental factors domain). Participants were explained by the occupational therapist about when and where to engage in the activities, as well as what to do, based on the MTDLP plan. Their family members and other supporters were also asked based on the MTDLP plan to support the participants' desired activities. On the visit day, the occupational therapist made all the necessary environmental adjustments and modifications to the performance. To ensure MTDLP fidelity, occupational therapists received coaching (1–3 times) from an MTDLP-certified instructor during the intervention.

**Control group (non-MTDLP).** All interventions were implemented at participants' homes. Occupational therapists assumed participants' needs by having natural conversations without utilizing the MTDLP sheets. The goals for participants of continuous community living were set by the occupational therapist, and the participants were not involved in the goal-setting process. The control group received interventions that occupational therapists deemed necessary for participants' community living. The home-visit OT contents included craft work, exercise therapy, medication management, money management, etc.

**Table I.** Structure of home-visit OT using MTDLP or not using MTDLP

	MTDLP	Control (non-MTDLP)
Using MTDLP sheets	Yes	No
Preliminary training using MTDLP	Yes	Not needed
Listening to a patient talking about the desired daily activity	Yes	Not absolutely necessary
Collaborative goal	Yes	No
Plan which involved the participants and their surrounding people	Yes	No
OT contents	<p>Three-step program to achieve the collaborative goal for participants' desired daily life activity.</p> <p>For example, if a participant wants to work:</p> <p><i>basic program:</i> attention training, etc.;</p> <p><i>application program:</i> practice riding a bus, etc.;</p> <p><i>social adjustment program:</i> preliminary practice at real workplace and assistance of being woken up by family members, etc.</p>	<p>Program that therapists deem necessary for participants' community living.</p> <p>For example, craft work, exercise therapy, medication management, money management, etc.</p>
Coaching to use MTDLP during intervention	Yes (1–3 times)	No
Type	One-on-one (patient on therapist)	One-on-one (patient on therapist)
Duration	4 months	4 months
Frequency	1–2 times a week	1–2 times a week
Session duration	30 min–1 hour	30 min–1 hour
Community setting	Yes	Yes

MTDLP, Management Tool for Daily Life Performance; OT, occupational therapy; therapist, occupational therapist.

### Data Collection

A limited number of outcome measures were chosen in order to maintain engagement with participants who have severe mental illness.

**Demographic and clinical data.** The demographic (e.g., age, gender, education, marital status, and living and work situation) and clinical (e.g., diagnosis, illness duration, number and duration of hospitalizations, antipsychotics' dosage, experience with outreach programs) variables were recorded on a questionnaire specifically designed for this study.

**Social functioning.** The Global Assessment of Functioning (GAF) is the most frequently used scale to measure social functioning in the assessment of schizophrenia [19]. It is a 100-point rating scale that assesses symptoms and psychological, social, and occupational functioning. Scores range from 0–100, and each 10-point

segment is defined in relation to levels of functioning; higher scores indicating better functioning [20]. GAF scores were assessed by medical professionals other than the occupational therapists (e.g., attending physicians or nurses) and who were not involved in the implementation of the study.

We used a Japanese version [21,22] of the Social Functioning Scale (SFS) [4] to assess distinct aspects not captured with the GAF [23]. The SFS is a 79-item scale comprising seven areas of social functioning: social engagement/withdrawal, interpersonal behavior, prosocial activities, recreation, independence-competence (i.e., ability to perform skills necessary for independent living), independence-performance (i.e., performance of skills necessary for independent living), and employment/occupation. A normative average score of 100 was obtained for unemployed people with schizophrenia; a cut-off point of 115 was set, and those scoring below this showed need for clinical interventions [4]. SFS were assessed by their family or caregiver who knew the participants well. Participants who did not have anyone to assess them were assessed through semi-structured interviews conducted by the attending occupational therapists.

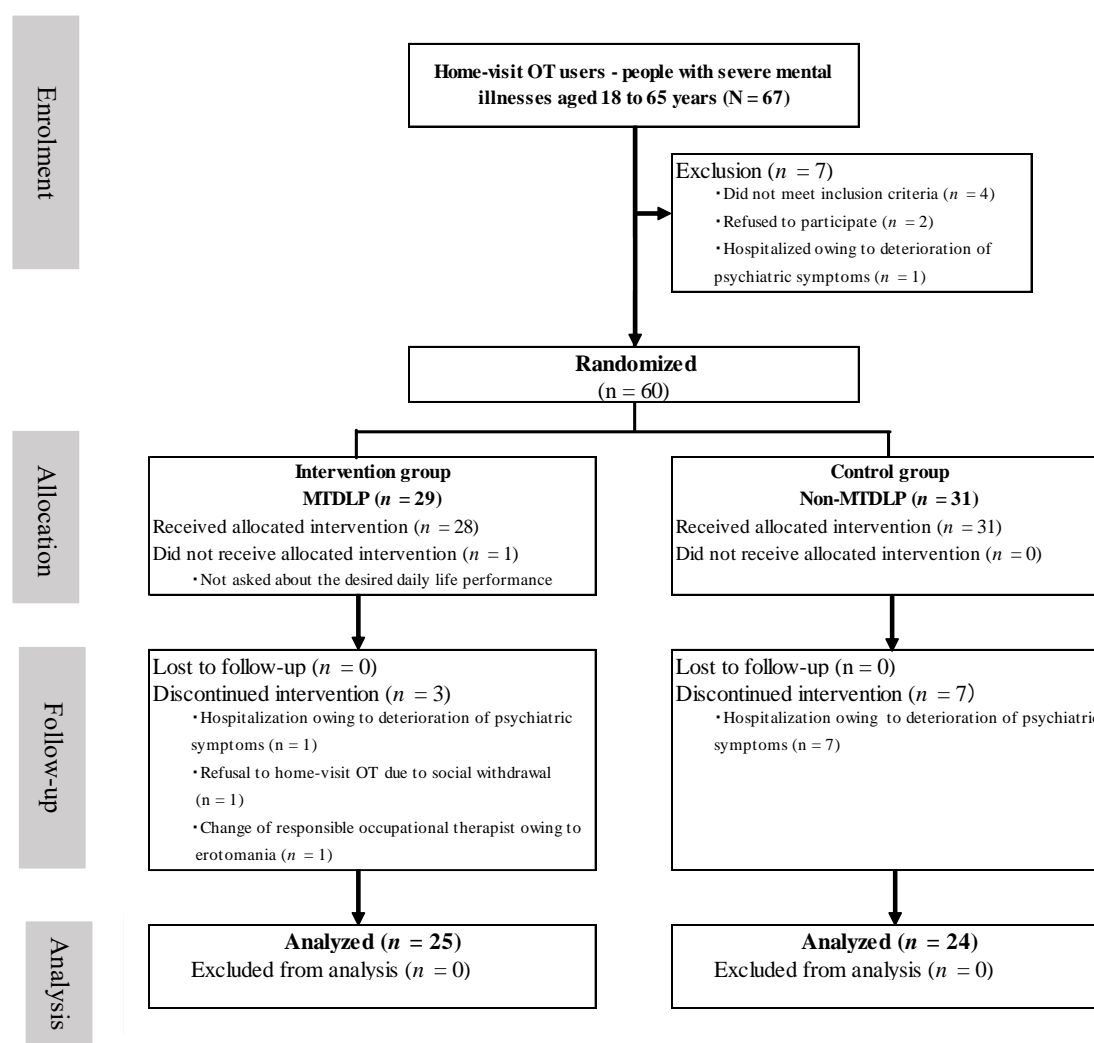


Figure 1. Flow diagram of the randomized control trial using CONSORT guidelines (2010)

### Statistical analysis

To compare participants' characteristics at baseline and between groups, we used Student *t*-tests for parametric data, Mann-Whitney tests for non-parametric data, and Fisher's exact test to evaluate the ratio differences. Next, to examine the effects of the intervention, a repeated-measures analysis of variance (ANOVA) with Time (i.e., from pre-test to post-test) and Group (i.e., MTDLP or control) was conducted. Partial  $\eta^2$  was calculated to provide an estimate of the intervention effect size. An effect size of 0.01 was considered small, 0.06 was medium, and 0.14 was large [24,25]. Data were analyzed using IBM SPSS Statistics v.25.

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### Ethical Considerations

This study was approved by the Ethics Committee of Kobe University Graduate School of Health Sciences (approval number 661-2), Japanese Association of Occupational Therapists (approval number 2017-1216). This study is registered in the University Hospital Medical Information Network Clinical Trials Registry (no. UMIN000031695). Written informed consent was obtained from participants prior to their inclusion in the study.

## RESULTS

### Participants

Figure 1 illustrates the participant flow. A total of 60 participants received the intervention in this study. No significant difference was observed in the drop-out ratios between the MTDLP (3/28) and the control group (7/31) ( $p = 0.194$ ; Fisher's exact test), while the hospitalization ratios during follow-up periods showed a

**Table II.** Participants' baseline characteristics (N = 49)

	MTDLP ( <i>n</i> = 25)		Control ( <i>n</i> = 24)		<i>p</i>
	n (%) or mean (SD)		n (%) or mean (SD)		
Age (years) <sup>a</sup>	46.7	(12.5)	50.5	(10.2)	0.259
Gender (%)					0.393
Male	12	(48.0)	15	(62.5)	
Female	13	(52.0)	9	(37.5)	
Diagnosis (%)					1.000
Schizophrenia	18	(72.0)	18	(75.0)	
Schizoaffective disorder	2	(8.0)	2	(8.3)	
Mood disorder	5	(20.0)	4	(16.7)	
Illness duration (years) <sup>b</sup>	21.1	(13.4)	22.1	(11.0)	0.542
Hospitalization duration (days) <sup>b</sup>	703.1	(946.8)	567.8	(916.2)	0.534
Hospitalization number (time) <sup>b</sup>	3.6	(4.5)	2.9	(2.3)	0.951
Antipsychotic dosage (mg/day) <sup>b</sup>					
Chlorpromazine	582.2	(502.2)	643.5	(641.1)	0.912
Imipramine	29.0	(90.9)	6.3	(21.2)	0.399
Education (%)					0.342
Junior high school	8	(32.0)	4	(16.7)	
Senior high school	13	(52.0)	12	(50.0)	
Vocational school/junior college	2	(8.0)	2	(8.3)	
College or above	2	(8.0)	6	(25.0)	
Marital status (%)					0.837
Single	16	(64.0)	16	(66.7)	
Separated/divorced	4	(16.0)	5	(20.8)	
Married	5	(20.0)	3	(12.5)	
Living situation (%)					0.208
Alone	8	(32.0)	12	(50.0)	
With family	16	(64.0)	9	(37.5)	
Group home	1	(4.0)	3	(12.5)	
Work situation (%)					1.000
No employment	20	(80.0)	20	(83.3)	
Employment transfer support	1	(4.0)	0	(0.0)	
Supported employment workshop	4	(16.0)	4	(16.7)	
Experience with outreach service (%)					0.609
New user	3	(12.0)	1	(4.2)	
Ongoing user	22	(88.0)	23	(95.8)	

MTDLP, Management Tool for Daily Life Performance; SD, standard deviation.

a, Student *t*-test; b, Mann-Whitney test; Other, Fisher's exact test.

significant difference between the two groups (MTDLP, 1/28; control, 7/31,  $p = 0.037$ ; Fisher’s exact test). The data from 49 participants were analyzed (MTDLP,  $n = 25$ ; control,  $n = 24$ ), and participants’ characteristics did not significantly differ between the two groups (Table II). At baseline, three participants of the MTDLP group and two participants of the control group needed home-visit OT twice a week or a pair visit from professionals comprising the attending occupational therapist and a nurse in the team per week; it is worth noting that no significant difference in the intensive visit rate was found between the two groups ( $p = 0.520$ ; Fisher’s exact test).

**Occupational Therapists**

The 29 occupational therapists joined this study and received MTDLP training. However, one occupational therapist did not receive training in MTDLP. In the randomized process, this therapist–participant pair was assigned to the control group, so this pair was not excluded from this study. Meanwhile, two occupational therapists were excluded from this study because they had been paired with participants who had met the exclusion criteria. As a result, 27 occupational therapists intervened in the MTDLP group and/or control group. While 14 therapists intervened in both the groups, the remaining 13 therapists did so in either one of the two. The number of participants that each therapist was in charge of was not significant between the two groups (MTDLP; mean = 1.25, SD = 0.72, control; mean = 1.14, SD = 0.46,  $p = 0.899$ ; Mann-Whitney test). Further, there was no difference in the number of years of clinical experience for the occupational therapists between the MTDLP (mean = 12.76, SD = 5.63) and the control group (mean = 13.21, SD = 4.91) ( $p = 0.768$ ; Student t-test).

**Contents and Achievement of the collaborative goals**

The contents of the collaborative goals in the MTDLP group are shown in Table III. This was categorized as follows: work ( $n = 10$ , 40%), health management ( $n = 6$ , 24%), housework ( $n = 4$ , 16%), and other ( $n = 5$ , 20%). Regarding the achievement of the collaborative goals, for instance, “work,” one participant was engaged in competitive employment, and four in supported employment (i.e., opportunities for work and productive activities, as well as training and support to improve work capacity). In contrast, the attending occupational therapists in control group did not ask about the participants’ goal achievement because they did not set collaborative goals.

**Table III.** The collaborative goals for desired daily life activities in the MTDLP group ( $n = 25$ )

Category ( $n$ )	Goals
Work (10)	<ul style="list-style-type: none"> <li>• Working at the supported employment workshop twice a week</li> <li>• Searching for a job at the public employment security office</li> <li>• Selling the lace-knits that I made online</li> </ul>
Health management (6)	<ul style="list-style-type: none"> <li>• Attending the psychiatric day treatment program more than twice a week</li> <li>• Continuing my diet and exercise to improve my diabetes</li> </ul>
Housework (4)	<ul style="list-style-type: none"> <li>• Cooking independently</li> </ul>
Outing (2)	<ul style="list-style-type: none"> <li>• Going shopping and to the dentist</li> </ul>
Leisure (1)	<ul style="list-style-type: none"> <li>• Independently operate the remote control at karaoke</li> </ul>
Money management (1)	<ul style="list-style-type: none"> <li>• Budgeting to spend money on leisure with my friends</li> </ul>
Appearance (1)	<ul style="list-style-type: none"> <li>• Dieting to be fashionable</li> </ul>

MTDLP, Management Tool for Daily Life Performance.

The collaborative goals for the patients' desired activities were set in the MTDLP group.

**Intervention Effects**

Table IV shows the results of the repeated-measures ANOVA examining the intervention effects on the GAF and SFS. From pre- to post-intervention, both groups showed higher scores on the GAF, with a significant Time effect ( $F(1, 47) = 17.79, p < 0.001, \eta^2_p = 0.28$ ). Moreover, the GAF scores of the MTDLP group significantly improved as compared to the control group; the Time  $\times$  Group interaction was significant, showing a medium-sized effect ( $F(1, 47) = 5.92, p = 0.019, \eta^2_p = 0.11$ ).

No significant effect was observed in SFS total scores. We found a significant medium-sized Group effect in the interpersonal behavior/communication subscale scores ( $F(1, 47) = 6.78, p = 0.012, \eta^2_p = 0.13$ ); however, there was no significant Time  $\times$  Group interaction that influenced interpersonal behavior/communication

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**Table IV.** Analysis of the effect of Group and Time on outcome measures

	Time	MTDLP ( <i>n</i> = 25)		Control ( <i>n</i> = 24)		Time effect			Group effect			Time × Group effect		
		Mean	(SD)	Mean	(SD)	<i>F</i> ( <i>df</i> = 1,47)	<i>P</i>	$\eta^2_p$	<i>F</i> ( <i>df</i> = 1,47)	<i>P</i>	$\eta^2_p$	<i>F</i> ( <i>df</i> = 1,47)	<i>P</i>	$\eta^2_p$
GAF	Pre	48.24	(15.14)	52.08	(16.71)	<b>17.79</b>	<b>&lt;0.001</b>	<b>0.28</b>	<0.01	0.992	<0.01	<b>5.92</b>	<b>0.019</b>	<b>0.11</b>
	Post	58.64	(13.62)	54.88	(16.26)									
SFS total scores	Pre	99.52	(28.68)	98.17	(16.15)	0.73	0.397	0.02	0.44	0.510	0.01	3.69	0.061	0.07
	Post	104.08	(29.35)	96.42	(20.48)									
Social engagement/withdrawal	Pre	9.76	(2.11)	8.83	(2.63)	0.54	0.468	0.01	3.88	0.055	0.08	1.02	0.318	0.02
	Post	9.84	(2.10)	8.33	(2.66)									
Interpersonal behavior/communication	Pre	6.92	(2.71)	5.42	(3.11)	<0.01	0.976	<0.01	<b>6.78</b>	<b>0.012</b>	<b>0.13</b>	1.23	0.273	0.03
	Post	7.36	(2.60)	5.00	(3.27)									
Independence-performance	Pre	22.96	(7.51)	25.67	(4.39)	1.06	0.309	0.02	0.91	0.345	0.02	3.61	0.064	0.07
	Post	24.64	(7.55)	25.17	(4.72)									
Independence-competence	Pre	25.56	(8.41)	29.71	(4.15)	0.45	0.506	0.01	3.14	0.083	0.06	1.54	0.222	0.03
	Post	26.68	(8.57)	29.38	(6.02)									
Recreation	Pre	19.52	(7.34)	18.00	(4.60)	0.21	0.649	<0.01	1.26	0.267	0.03	0.54	0.466	0.01
	Post	20.24	(7.68)	17.83	(5.65)									
Prosocial activities	Pre	10.60	(7.72)	6.92	(4.81)	<0.01	0.959	<0.01	3.79	0.057	0.08	0.57	0.456	0.01
	Post	10.20	(7.09)	7.38	(4.27)									
Employment/occupation	Pre	4.20	(3.45)	3.63	(3.39)	1.18	0.284	0.02	1.52	0.223	0.03	<b>4.66</b>	<b>0.036</b>	<b>0.09</b>
	Post	5.08	(3.35)	3.33	(3.51)									

Repeated-measures analysis of variance; MTDLP, Management Tool for Daily Life Performance; GAF, Global Assessment of Functioning (Japanese Version); SFS, Social Functioning Scale (Japanese Version); Bold = *p* < 0.050.

subscale scores. Significant medium-sized effect of the Time  $\times$  Group interaction were observed in the employment/occupation subscale scores ( $F(1, 47) = 4.66, p = 0.036, \eta^2_p = 0.09$ ). After the intervention, the mean scores of the MTDLP group increased but that of the control group decreased.

## DISCUSSION

We examined the social functioning effect of people with SMI by home-visit OT using the MTDLP. We verified the presence of significant differences in the effectiveness of the MTDLP compared to the control group, over four months on the social functioning improvement of individuals with SMI. A previous meta-analysis on social functioning [2] reported, that minimum follow-up times of 12 months for schizophrenia and 6 months for depression are recommended. Therefore, as a study duration of four months is a relatively short time frame to observe clinically meaningful change, improvements in social functioning for those with SMI within four months support the strength of the intervention effect. Our results suggest that the following three points were effective in improving social functioning.

First, we focused on participants' desired daily life activities by using MTDLP. Participants' desired daily life activities may be intrinsically motivated. Intrinsic motivation refers to behaviors that individuals engage in for the pleasure and satisfaction derived from performing them because they produce feelings of competency and self-determination [26]. In the MTDLP group, 40% of participants desired "work," and employment/occupation subscale scores significantly increased after the intervention. A previous study [27] revealed that intrinsic motivation could directly promote psychosocial functioning, although, no specific strategy for incorporating it into treatment is known in community settings. Therefore, we provided evidence that the MTDLP's intervention strategies, supporting participants in performing the desired daily life activities, could promote intrinsic motivated performance gains and improve social functioning. In contrast, the control group supported participants' community living, but did not focus strongly on their desired daily life activities. This led participants to become passive and they found it more difficult to involve themselves in home-visit OT.

Second, we revealed the value of setting collaborative goals. Collaborative goal-setting has a positive effect on the outcomes of rehabilitation [28]. As mentioned above, in the MTDLP group, participants' desire to work coincided with the intervention effect of employment/occupation subscale scores. This result indicated that occupational therapists could effectively set collaborative goals focusing on participants' intrinsically motivated activities using MTDLP sheets. In the control group, the goals were set by occupational therapists. However, in many cases, there are differences in the contents of the therapist-set goals and collaborative goals [29]. Our results suggest that the positive involvement of participants in the goal-setting process promotes their performance and yields positive effects on social functioning.

Third, the MTDLP implemented in this study was a well-planned, real-world intervention. The occupational therapists in the MTDLP group evaluated the promotion or hindering factors that might influence target performance based on the ICF [18] levels of "body functions and structures," "activities and participation," and "environmental factors." Moreover, based on this evaluation the occupational therapists created a series of plans which involved both participants and their surrounding people; this is to enable participants to perform the desired daily life activities. A person's real-world performance could be affected by both individual factors (e.g., functional capacity, intrinsic motivation) and environmental factors (e.g., social prompts, physical environment) [7]. Therefore, the results suggest that the elements in the home-visit OT using MTDLP—enhancing motivation, practicing in the actual environment, involving surrounding people, and adjusting the environment—are all essential to improve social functioning.

It is noteworthy that the drop-out ratios during the follow-up periods were not different between the groups; in addition, the hospitalization ratios of the MTDLP group were significantly lower than those of the control group. When combined, our study findings suggest that home-visit OT using MTDLP is feasible and can help people with SMI to continue and develop their life in the community through improvement in social functioning. The imminent clinical challenge in SMI research, such as that related to schizophrenia, is to develop comprehensive treatment modules individually tailored to the time-variable needs of patients [30]. A previous study [31] revealed that an individualized OT program for psychiatric inpatients reduced rehospitalization. Thus, individualized and customized OT seems to be beneficial for their community living. Home-visit OT using MTDLP is an individually tailored intervention and can be implemented using the MTDLP sheets. The use of MTDLP can cover the minimum criteria required for effective OT. This leads to the standardization of occupational therapy independent of the therapist's individual skills.

There were some limitations in this study. First, participants may have recognized their group membership, and if they were receiving the intervention, as the MTDLP group used specialty sheets. Second, we focused on the improvement of social functioning, so we did not conduct an evaluation of the psychiatric symptoms. As our previous study [11] has shown, patients' desired activities may improve psychiatric symptoms. Thus, future



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studies should verify whether home-visit OT using MTDLP improves not only social functioning but also psychiatric symptoms. Finally, this study was conducted with a relatively short intervention period of four months. A longer intervention may produce greater impacts on participants' social functioning. In the future, a long-term follow-up study should be conducted.

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### CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare.

### APPENDIX

The OTR (the psychiatric outreach teams) that joined this study included: Keiji Shiratori (Visiting Nurse Station Cocoroccle); Nami Funatsu, Kanako Asari (Shukokai home-visit nursing station "Wing"); Tomoki Yonezawa, Sachie Shimazu, Ryu Nomura (Ujioubaku-Hospital /Eijinkai Visiting Nursing Station Oubaku); Kouji Nakai, Noriko Uejima (Healthcare Corporations Kounoike-kai Akitsukounoike Hospital); Hidenori Kawai, Taku Ooya, Kenta Okii (Kibouya home-visit nursing station); Akihito Dodo (Visiting Nursing Station Inaho); Mai Tanaka (Houmonkango station "fureai" Hannan hospital); Kilchoon Cho, Natsumi Murata (Home Nursing Station Satuki-kan "Satsuki House"); Takamitsu Shimamoto (Senogawa Medical Corporation Visiting nursing station Visite); Hisanori Ohata (Hyogo Mental Health Center); Yuuko Fukada (Nagaoka Health Care Center, "Nagaoka Hospital"); Hirokazu Saitou (Visiting nursing station Arimakougen); Mai Ikuta, Naoko Miyazaki (Warai Home Nursing Station); Shigeki Tatsumi (Home Nursing Station "KEYAKI"); Nana Mori (Psychiatric home-visit nursing care uninet machikado); Yuuta Matsumoto (Muromachi home-visit nursing station); Miharu Nojima (Home Visiting Station Clover); Masashi Takeda (Visiting Nursing Station Hiraku); Teruhiro Asakura (Visiting Nursing Station Musubu); Seizou Ono (Visiting nursing station Relife inokuchi).

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