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木下, 栄子

(Degree)
博士（保健学）

(Date of Degree)
2023-03-25

(Date of Publication)
2024-03-01

(Resource Type)
doctoral thesis

(Report Number)
甲第8623号

(URL)
https://hdl.handle.net/20.500.14094/0100482371

博　士　論　文

The influence of self-determination on the social functioning of
long-term day hospitals users with schizophrenia:
A randomized controlled trial
（統合失調症をもつデイホスピタル長期利用者の社会的機能に対する
自己決定の影響：ランダム化比較試験）

令和 5 年 1 月 12 日

神戸大学大学院保健学研究科保健学専攻

Eiko Kinoshita（木下　栄子）

The influence of self-determination on the social functioning of long-term day hospitals users with schizophrenia: A randomized controlled trial

Running title: Self-determination and schizophrenia

Eiko Kinoshita, MS[a*], Takeshi Hashimoto, PhD[b], Ryoji Nishimura, PhD[c], and Kayano Yotsumoto, PhD[d*]

[a] Department of Rehabilitation Science, Kobe University Graduate School of Health Sciences, Japan

[b] Department of Rehabilitation Science, Kobe University Graduate School of Health Sciences, Japan

[c] Medical corporation Keiaikai Fukuma Hospital, Japan

[d] Department of Rehabilitation Science, Kobe University Graduate School of Health Sciences, Japan

＊Corresponding author:

Eiko Kinoshita
Department of Rehabilitation Science, Kobe University Graduate School of Health Sciences, Japan
Tomogaoka 7-10-2, Suma-ku, Kobe 654-0142, Japan
E-mail: ekinosita@stu.kobe-u.ac.jp
Phone: 819073467763

Kayano Yotsumoto
Department of Rehabilitation Science, Kobe University Graduate School of Health Sciences, Japan
Tomogaoka 7-10-2, Suma-ku, Kobe 654-0142, Japan
E-mail: yotumoto@kobe-u.ac.jp
Phone:81787964590

Abstract

Aim: In Japan, day hospitals are a method of rehabilitation for psychiatric disorders, especially for recovering social functioning. Currently, 60% of day hospital users have schizophrenia, the majority of whom are long-term users (for over one year). However, they show no progress in community participation. This study aimed to investigate whether people with schizophrenia who use day hospitals can improve their social functioning and recovery levels, and alleviate psychiatric symptoms, when they engage in self-determination regularly.

Methods: This study employed a multicenter randomized controlled design with a three-month intervention. Participants were divided into two groups. The intervention group (n=24) determined their daily goals in life and attended the day hospitals' programs, while the control group (n=25) only participated in the day hospitals' programs. Participants' social functioning was assessed using the Global Assessment of Functioning (GAF), psychiatric symptoms using the Positive and Negative Syndrome Scale (PANSS), and recovery using the Recovery Assessment Scale (RAS), before and after the intervention.

Results: In the intergroup factors, there were no significant differences in GAF, PANSS, or RAS scores.

Conclusion: The results suggest that participants' regular self-determination of their daily goals did not lead to significantly positive behavior in improving their social functioning. However, the social functioning and psychiatric symptoms of participants in day hospitals improved after three months.

Keywords: Self-determination, Schizophrenia, Day hospital, Long-term, Multicenter study

1. Introduction

Day hospitals were started in the late 1940s by J. Bierer and D. E. Cameron (Goldman, 1990). "Day hospital" is a collective term for acute day hospital care, transitional day care, day treatment programs, and day care centers for mental disabilities (Gelder et al., 2006). A day hospital is an effective alternative to inpatient treatment for people with severe mental disorders (Priebe et al., 2011).

In Japan, these hospitals are one method of rehabilitation for patients with psychiatric disorders, specifically focusing on recovering day hospital users' social functioning (Kayama and Kobayashi, 2010). In other words, day hospitals are a part of outpatient facilities.

After discharge, day hospitals function as a place where long-term inpatients can spend their daytime, thus minimizing rehospitalization and supporting community living for people with psychiatric disorders (Fukuchi et al., 2015). Currently, 60% of Japanese day hospital users are identified as having schizophrenia (F2 in the International Classification of Diseases and Related Health Problems 10th Revision [ICD-10], 1991), the majority of whom are long-term users (i.e., for over one year; Igarashi and Oki, 2018). Long-term users of day hospitals may find it difficult to stay focused on the purpose of using these facilities, which may result in such users not making progress regarding community participation, such as finding employment and transitioning to community services (Ministry of Health, Labour and Welfare, 2009).

An increase in the number of such users may denote that patients with more severe conditions cannot use day hospitals as a medical resource. Thus, long-term users should focus on the "improvement of social function," the original purpose of day hospital use, and participate in the day hospital programs that fit their individual purpose.

Day hospitals can help patients recover their social functioning. To support independent functioning, social-skills training is one approach for improving the social functioning of people with schizophrenia (Ueno, 2015). In this setting, psychoeducation can be provided to patients and their family members regarding accurate knowledge and information on the recovery process (Ueno, 2015). However, although there are programs designed to help people with mental disorders recover their social functioning, their effects have not been sufficiently examined (Ministry of Health, Labour and Welfare, 2013). In particular, evidence of the effects of treatment in day hospitals has not been determined for long-term users (Ministry of Health, Labour and Welfare, 2009).

Several previous studies have reported on positive behavioral modification in the

field of physical disabilities, provided by incorporating self-determination or a meaningful purpose, for individual patients (Cheng et al., 2018; Kuwaharada et al., 2013; Song and Nam, 2015). Furthermore, Ueda and Tsurumi (2003) emphasize the importance of purpose-oriented rehabilitation based on the right to self-determination. However, people with schizophrenia often have problems with self-determination, including reduced levels of independence following long-term hospitalization (Kobayashi, 2010) and a tendency to unquestioningly follow their therapist (Koda, 2009). Moreover, they have difficulties learning from previous experiences (Hiruta, 2011). Such problems may make it difficult for these individuals to incorporate self-determination and a meaningful purpose into their treatment. However, the importance of self-determination and having a meaningful purpose has recently gained more research attention. If these problems are resolved, positive behavioral modification in individual patients' social functioning can be expected by incorporating self-determination and a meaningful purpose in their treatment, which could in turn lead to possible improvement in their social functioning. Furthermore, self-determination promotes recovery from psychiatric disorders (Kobayashi, 2010).

In addition, as there is a positive correlation between social functioning and psychiatric symptoms (Ikebuchi et al., 1995), improvements in social functioning can be expected to improve psychiatric symptoms. However, to our knowledge, no study has conducted interventions to promote improvement in social functioning through increasing self-determination in long-term users of day hospitals.

In the present study, we hypothesized that, when the self-determination of people with schizophrenia in day hospital programs is promoted consistently, their social functioning, psychiatric symptoms, and recovery levels improve. If this type of intervention is successful in improving social functioning in long-term day hospitals users with schizophrenia, it will be easier to promote their community participation as per their individual needs. Furthermore, a more effective use of day hospitals as medical resources can be expected. In this study, "self-determination" was defined as formulating goals that the patients want to achieve by themselves.

2. Methods
2.1. Study design
This study used a randomized controlled trial design and was conducted at seven facilities in the Fukuoka prefecture in Japan. Participants were randomly assigned to either an intervention group or a control group, and pre- and post-intervention

comparisons were performed in the natural setting of each day hospital.

2.2. Procedure

The day hospital staff members recruited the participants; informed consent was communicated verbally and through a document provided to the participants. Afterwards, the staff gave the participants' administration numbers to the authors. Randomization of the participants into two groups was performed by the authors, who did not have direct contact with the participants.

Participants' sociodemographic characteristics and medical information were collected by day hospital staff members, and all participants' social functioning, psychiatric symptoms, and recovery levels were evaluated at baseline.

In the intervention, the intervention group determined their own goals for their daily lives. They were provided with this intervention in addition to the day hospitals' usual treatment programs during the intervention period. Meanwhile, the control group only participated in the usual treatment programs at the day hospitals.

The staff members confirmed whether the intervention was carried out. They collected data regarding the participants' characteristics before the intervention as the baseline; the same three evaluations were conducted three months after the intervention was started. The study began in December 2016 and was completed in February 2018.

2.3. Participants

It was necessary for the participants to meet the following inclusion criteria:
1) Having used the day hospitals' facilities in a prefecture for more than one year.
2) Having a diagnosis of schizophrenia, as defined by the ICD-10.
3) Being aged between 18 and 65 years.
4) Participating in the day hospital programs more than twice a week regularly.
5) Agreeing to participate in this study.

Patients were excluded if they were unable to sufficiently consent to the study or if their condition was expected to be aggravated by participating.

2.4. Evaluation and measures
2.4.1. Social functioning

The Global Assessment of Functioning scale (GAF; Ministry of Health, Labour and Welfare, 2003) rates psychological, social, and occupational functioning on a scale from 1 ("continuously dangerous to oneself or others") to 100 ("superior

functioning") and has well-established reliability and validity. Day hospital staff members assessed participants' social functioning using this scale. At the beginning of the study, staff members and authors discussed the GAF measurements and reached general agreement. The GAF assessment could not be administered blindly, as staff members needed to ensure that the participants had performed the intervention.

2.4.2. Psychiatric symptoms

The Positive and Negative Syndrome Scale (PANSS) comprises 30 items in total, including subscales of positive, negative, and general symptoms. The symptom severity of each item is distributed across seven phases, ranging from 1 ("absent") to 7 ("extreme"). The scale was used by the physicians at the day hospitals to evaluate participants' psychiatric symptoms. Each physician ensured inter-rater reliability by previous use or using training DVDs. The physicians were unaware whether the participants were assigned to the intervention or control group.

2.4.3. Recovery

The Japanese version of the Recovery Assessment Scale (RAS; Chiba, 2008) comprises 24 items evaluating the personal subjective recovery process, rated on a five-point scale ranging from 1 ("completely disagree") to 5 ("completely agree"); higher scores indicate higher levels of recovery. The RAS was used in a self-administered form for participants to assess their own recovery.

2.5. Data collection

Data were collected at baseline by the staff members and included participant characteristics such as age, gender, education, work experience, duration of illness, total length of admission, number of admissions, presence of intellectual disability, age at first participation in the day hospital, period of use of the day hospital, frequency of using the day hospital weekly, medication, and number of housemates.

2.6. Concrete intervention methods

In addition to the usual treatment program, participants in the intervention group were offered an intervention involving regular self-determination of their goals. On the first day of the week, the participants thought of their goals for the daily-life area for the week and wrote them on their individual sheets, along with the area which they fell under in Figure 1. When it was difficult for them to think of daily goals, they wrote down their goals in reference to the set examples of the

seven areas provided to them.

2.7. Intervention content

We considered the characteristics of schizophrenia and adjusted the intervention accordingly. The adjusted content was as follows:

1) Self-determination within a limited range

When people with schizophrenia face an ambiguous situation, they tend to become confused and become unable to act coherently (Hiruta, 2011; Ishitani, 1997). Therefore, to avoid causing them confusion, we limited the scope of self-determination to behavioral goals related to their daily life situations. Moreover, we prepared a list with concrete examples of daily goals as a reference.

2) Self-determination without others' interference

Even if people with schizophrenia are encouraged to engage in self-determination, they tend to make decisions following the expectations of their therapists (Koda, 2009). Thus, we required staff members not to reject, modify, or make suggestions regarding the goals for daily life determined by the participants. This enabled the participants to engage in self-determination following their own intentions without interference from others.

3) Accumulation of experiences

People with schizophrenia often have difficulty learning from experience, and it is not easy for them to change their social behavioral patterns (Hiruta, 2011). Therefore, it is necessary to repeatedly use the same approach with them for modifying their behavior (Hiruta, 2011; Tajima et al., 1967; Yokoyama, 2005). Thus, the participants set self-determined goals once a week for three months (12 times in total) to experience self-determination regularly.

2.8. Statistical methods

We examined whether any sociodemographic differences existed between the intervention and control groups. Age, duration of illness, total length of admission, number of admissions, age at first participation in the day hospital, period of use of the day hospital, weekly frequency of day hospital use, medication, and number of housemates were compared between the groups using an unpaired t-test. Gender differences were examined using Pearson's chi-square test, while differences in education, work experience, and intellectual disability were assessed using Fisher's exact test. Two-factor repeated-measures analysis of variance (two-way ANOVA) was conducted to test the effects of interactions, time, and group on the participants' GAF, total PANSS, and RAS scores. Further multiple

comparisons were performed using the Bonferroni method if a main effect and no interaction were confirmed (Tsushima, 2011).

All analyses were carried out using SPSS version 28 for Windows software. The level of significance was 5%.

3. Results

The Consolidated Standards of Reporting Trials for this study are shown in Figure 2. Of the 66 potentially eligible participants, 57 were included in the study sample; 6 did not meet the inclusion criteria, and 3 declined to participate. Subsequently, 29 were randomly allocated to the intervention group and 28 to the control group.

At baseline, a total of three participants dropped out.

In the intervention group, one participant was admitted to the hospital. In the control group, one participant was in poor physical condition, and one participant did not participate regularly.

During the intervention period, two people dropped out. One participant in the intervention group was absent for a long time because of family circumstances and one in the control group was admitted to the hospital. Three months later, a total of three participants dropped out or were excluded from the analysis, as one in the intervention group was admitted to the hospital, and two required too many interventions. Thus, 24 patients in the intervention group and 25 in the control group participated for the full study period, and their data were included for analysis.

The baseline characteristics of the participants are shown in Table 1, and the results of the two-way ANOVA for each rating scale are shown in Table 2. GAF scores for the two groups revealed that there was no statistically significant difference in the main effect for intergroup (F =.12, p =.73), and the effect size was small (η^2<.01). There was no interaction (F < 0.01, p = .990), and the effect size was small (η^2<.001). However, a statistically significant main effect was observed for the time factor (F = 8.82, p <.005), and the effect size was large (η^2 =.158).

The total PANSS scores for the two groups indicated that there was no statistically significant difference in the main effect for intergroup (F = 0.44, p =.510), and the effect size was small (η^2<.01). There was no interaction (F < 0.01, p =.95), and the effect size was small (η^2 <.001). However, a statistically significant main effect was observed in the time factor (F = 9.48, p <.004), and the effect size was large (η^2 =.168).

The RAS scores demonstrated that there were no statistically significant

differences in the main effects or interactions (F = 3.28, p =.077) for the intergroup factor (F = 0.76, p =.390) and time factor (F = 1.75, p =.190).

As no interaction between GAF scores and total PANSS scores was observed, and a main effect of the time factor was observed, we performed a post-hoc comparison for the intervention and control groups. Post-intervention GAF scores in the intervention group were significantly higher than baseline (p =.030) and did not differ in the control group (p =.064). Furthermore, both the intervention and control groups had statistically significantly lower post-intervention PANSS scores compared with baseline scores (p =.044, p =.036, respectively).

4. Discussion

This study investigated whether regularly engaging in self-determination improves social functioning, psychiatric symptoms, and recovery levels for people with schizophrenia who participate in psychiatric day hospitals. A two-way ANOVA was performed on GAF, total PANSS, and RAS scores using two factors: group and time. GAF and total PANSS scores indicated a main effect of the time factor alone, with no main effects or interactions between groups for either score. Furthermore, RAS scores revealed no main effect of the group or time factors. The between-group factors presented no main effects, indicating that the intervention had no effect on social functioning, psychiatric symptoms, or recovery. Multiple comparisons of GAF scores showed a significant increase in scores for the intervention group alone, and the intervention resulted in a slight improvement in social functioning. It would be reasonable to assume that the intervention effect was too small for the length of the participants' day hospital use. Therefore the possibility that the intervention improves social functioning cannot be ruled out.

The intervention had no effect on the total PANSS score, but a main effect of the time factor was observed. Multiple comparisons revealed that the total PANSS score decreased significantly in both the intervention and control groups. This finding indicated that the psychiatric symptoms of the participants in this study improved regardless of the intervention. These outcomes may be due to the natural course of recovery or the therapeutic effect of the day hospital.

The results of this study differed from previous reports that have not found evidence of the therapeutic effects of day hospitals for patients in the chronic phase of their disease (Ministry of Health, Labour and Welfare, 2009). Some studies have reported that the use of psychiatric day hospitals improved psychiatric symptoms, with an average of 9 to 46 months of day hospital use

(Someya; 1986, Takano; 1995, Kawanori; 2010). This study's participants were in the chronic phase of schizophrenia, and had been using the day hospitals for an average of 87.4 months, which was longer than in previous studies. However, their psychiatric symptoms improved over the 3-month period. The differences in change with and without a day hospital should be examined.

According to a survey of approximately 20,000 people in Japan, 60% of day hospital users have been diagnosed with schizophrenia (F2 in ICD-10) and 78% have been using day hospitals for more than a year (Igarashi and Oki, 2018). The participants in this study were patients with schizophrenia who had used day hospitals for over a year and were therefore, considered to be a representative sample of Japanese day hospital users.

In this study, 86% of participants completed the survey. The number of dropouts was the same in both groups, and there was no significant difference in the reasons for dropping out between the groups. Therefore, the intervention was considered non-invasive for the participants in the intervention group. Since the intervention is simple and easy-to-implement, it may be considered for long-term users because it requires no staff involvement and the users themselves set and record their own goals on a regular basis.

4.1. Limitations

This study had some limitations. As this survey was conducted in one prefecture in Japan, there may have been regional bias. In addition, the desired sample size could not be reached, as there were only seven psychiatric day hospitals that had collaborators who met the inclusion criteria and agreed to participate in this study. To reduce the burden of participation in each facility and allow as many facilities as possible to participate, the intervention period was set to three months; therefore, it was too short a time to accurately determine changes in social functioning or recovery. Although we provided examples of concrete goals based on the opinions of day hospital staff, we could not verify whether the interventions were based on the participants' values. Additionally, intention-to-treat and sensitivity analysis of the dropouts is necessary.

Future studies should verify the effectiveness of the intervention by expanding the target areas, lengthening the intervention period, increasing the number of participants, and examining interventions such as goal selection methods based on participants' values.

Acknowledgments

Funding

Conflict of interest

The authors declare no conflicts of interest associated with this manuscript.

CRediT authorship contribution statement

Eiko Kinoshita and Kayano Yotsumoto designed the study and oversaw its implementation. Eiko Kinoshita and Ryoji Nishimura collected the data, and Eiko Kinoshita, Kayano Yotsumoto and Takeshi Hashimoto analyzed and interpreted the data. Eiko Kinoshita and Kayano Yotsumoto wrote the text. All authors contributed to reviewing and providing critical input to the manuscript and have approved the final manuscript.

Ethical approval

The study was approved by the Kobe University Graduate School of Health Science, Health Science Ethics Committee and the Ethics Committee of the hospitals.

Patient consent statement

This study received written consent from the participants.

Clinical trial registration

This study was registered with the University Hospital Medical Care Information Network Research Center (UMIN; https://www.umin.ac.jp/).

Data availability statement

N/A

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Figure Legends

Figure 1. Areas of daily life activities

The two figures show the first and second pages of the "Areas of daily life activities." When the participants wrote down the areas that fitted their goal on the goal sheet, they chose one from seven of the listed areas on Page 1. When it was difficult for them to think of any daily goals, they wrote down their goals in reference to the set examples of the seven areas provided to them. Page 2 shows examples of concrete goals for the area of health management. These were developed based on input from authors and day hospital professionals.

Figure 2. CONSORT diagram

Consolidated Standards of Reporting Trials for this study. Of the 66 eligible participants, 57 were included in the study sample. Subsequently, 29 were randomly allocated to the intervention group and 28 to the control group. Three months later, 24 patients in the intervention group and 25 in the control group had participated for the full study period, and their data were included for analysis.

Table 1. Characteristics of the participants

	Intervention group (n＝24)		Control group (n=25)		p-value
	n(%)	Mean±SD	n(%)	Mean±SD	
Age(years)		50.83±10.06		46.16±10.12	0.11
Sex					0.68
male/female	18/6		20/5		
Education					0.39
Junior high school	3		1		
High school	14		17		
Technical school	3		4		
Technical college	0		1		
Junior college	0		1		
University	4		1		
Work experience (%)	21(87.5)		23(92.0)		0.48
Duration of illness (months)		242.25±143.54		225.24±130.63	0.67
Total length of admissions (months)		26.83±30.48		29.4±55.23	0.84
Number of admissions		3.42±2.54		2.68±2.36	0.30
Intellectual disability (%)	2(8.3)		2(8.0)		0.68
Age at first participation of day hospital (years)		42.92±11.58		39.32±10.74	0.27
Period of use of day hospital (months)		92.46±83.63		82.6±68.42	0.65
Frequency of day hospital use (days/week)		4.25±0.90		3.88±1.13	0.21
Medication (CPZ equiv, mg/day)		504.79±352.35		700.15±556.55	0.15
Number of housemates		1.08±1.02		1.00±1.23	0.80

Pearson's chi-square test ($p < 0.05$) for gender.

Fisher's exact test ($p < 0.05$) for education, working experience, and intellectual disability.

Non paired t-test ($p < 0.05$) for other items.

The items of work experience and intellectual disability show the ratio.

Medication and the number of the housemates are data at baseline.

Table 2. GAF, PANSS, and RAS scores in the intervention and control groups

	Intervention group (n=24)	Control group (n= 25)		F	p	η^2
	Mean±SD	Mean±SD				
GAF						
T1	59.91±11.70	61.08±11.21	F(group)	0.12	.730	.003
			F(interaction)	<0.01	.990	<.001
T2	61.33±13.14	62.48±10.44	F(time)	8.82	<.005	.158
PANSS						
T1	66.38±24.85	70.56±19.74	F(group)	0.44	.510	.009
			F(interaction)	<0.01	.950	<.001
T2	64.29±24.56	68.56±19.85	F(time)	9.48	<.004	.168
RAS						
T1	87.43±13.20	81.625±11.77	F(group)	0.76	.390	.017
			F(interaction)	3.28	.077	.068
T2	86.74±14.41	86.08±14.99	F(time)	1.75	.190	.040

GAF: Global Assessment of Functioning Scale. PANSS: Positive and Negative Syndrome Scale (total score).

RAS: Japanese version of the Recovery Assessment Scale.

T1: baseline, T2: post-intervention.

Analysis were conducted using a two-way repeated-measures ANOVA.

Areas of daily life activities

Area of daily life	Content	Page
Health management	Management of medication, health condition, and nutrition	2
Daily life performance	Performance of tasks, such as eating, bathing, shopping, and cleaning	3
Daily life management	Management of money and other valuables	4
Social interaction	Interaction with friends and colleagues in the workplace	5
Study/Work	Continuing school, returning to school or work, and employment	6
Resource utilization	Using public facilities and transportation	7
Leisure activity	Rest, hobby, and amusement	7

Health management
Example of concrete goals
◎I go to the hospital regularly. ◎I keep taking medication. ◎I wake up in the morning and go to bed at night. ◎I manage my physical and nutritional condition. *I eat well balanced meals.* *I don't overeat my favorite food.※* *I take a rest when I feel tired.*

※ *e.g., alcohol, coffee, chocolate.*

Figure 1. Area list of daily life activities

Enrollment

Assessed for eligibility (n=66)

Excluded (n=9)
♦ Did not meet inclusion criteria (n=6)
♦ Declined to participate (n=3)

Randomized (n=57)

Allocation

Allocated to intervention group (n=29)
♦ Received allocated intervention (n=28)
♦ Did not receive allocated intervention
  - reason: hospital admission (n=1)

Allocated to control group (n=28)
♦ Received treatment as usual (n=26)
♦ Did not receive treatment as usual
  -reason: poor physical condition (n=1)
  -reason: did not participate regularly (n=1)

Follow-Up

Lost to follow-up (with reason) (n=1)
Discontinued intervention; reason: long absence (n=1)

Lost to follow-up (with reason) (n=1)
Discontinued intervention; reason: admission (n=1)

Analysis

Analyzed (n=24)
♦ Excluded from analysis (with reason) (n=3)
  - reason: admission (n=1)
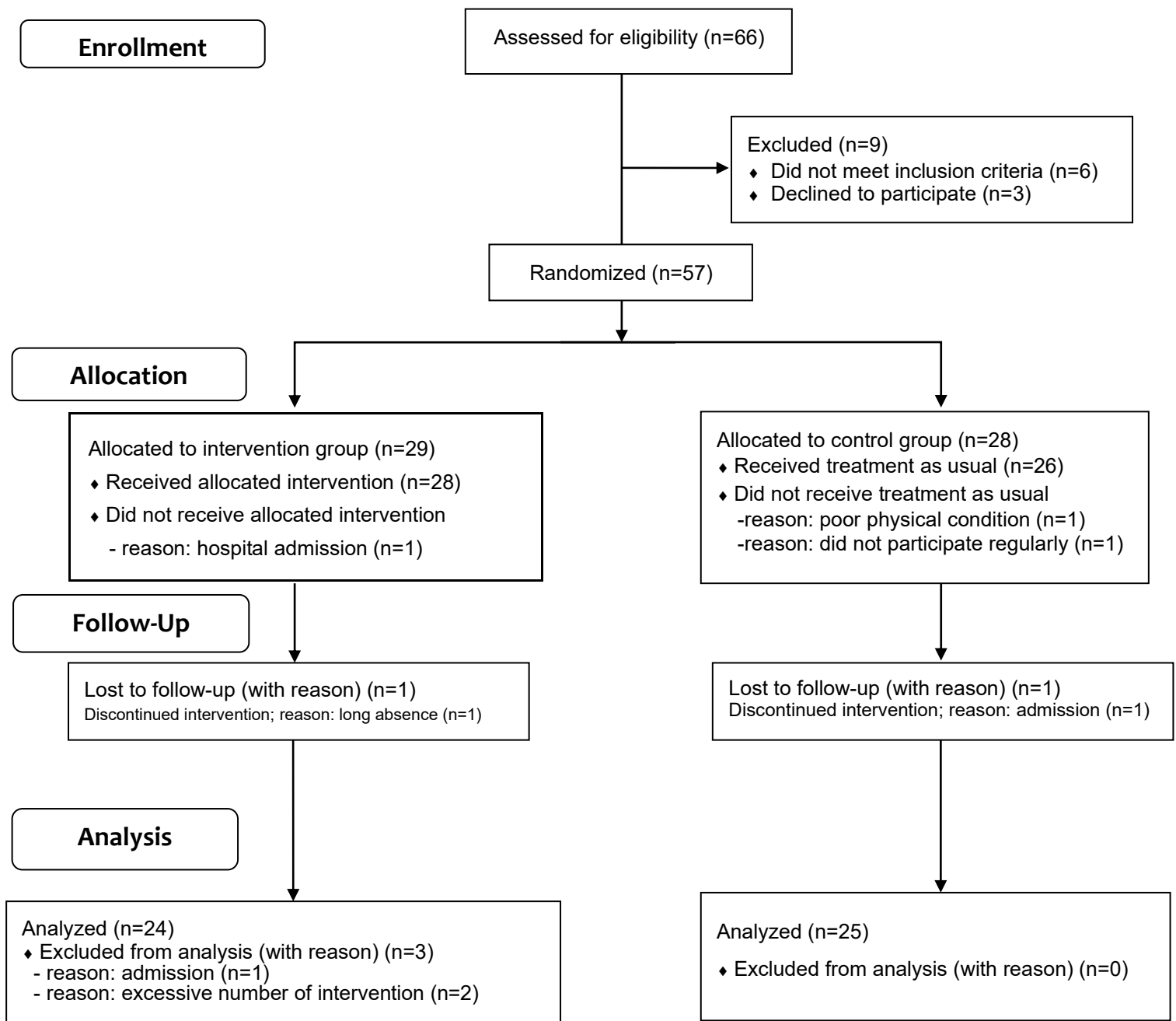 - reason: excessive number of intervention (n=2)

Analyzed (n=25)
♦ Excluded from analysis (with reason) (n=0)

Figure 2. CONSORT diagram