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Ten-year trajectories of people with mental illness and their families who receive services from multidisciplinary case management and outreach teams: Protocol of a multi-site longitudinal study

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Title

Ten-year trajectories of people with mental illness and their families who receive services from multidisciplinary case management and outreach teams: Protocol of a multi-site longitudinal study

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ABSTRACT

Introduction

Individuals with mental illness and their families often undergo their recovery process in their communities. This study explored the long-term outcome trajectories of individuals and families who received case management services provided by multidisciplinary outreach teams in a community setting. The primary objective of this study was to determine whether improvements in subjective quality of life (QoL) related to personal recovery were linked to enhancements in clinical and societal outcomes, as well as to changes in service intensity.

Methods and analysis

The protocol of this 10-year multi-site cohort study was collaboratively developed with individuals with lived experience of psychiatric disorders who had received services from participating outreach teams, and with family members in Japanese family associations. The participants in the study include patients and their key family members who receive services from 23 participating multidisciplinary outreach teams. The participant recruitment period is set from October 1, 2023, to September 30, 2025. The study will annually evaluate the following outcomes after participants' initial utilisation of services from each team: QoL related to personal recovery, personal agency, feelings of loneliness, well-being, and symptom and functional assessments. The family outcomes encompass QoL, well-being, care burden, and family relationships.

Ethics and dissemination

The study protocol was approved by the ethical committee of the National Center of Neurology and Psychiatry (no. A2023-065). The study findings will be reported in peer-reviewed publications and presented at relevant scientific conferences.

Discussion

This study will delineate the trajectories of several recovery dimensions in patients with mental illness and their families who receive services from 23 multidisciplinary outreach teams across Japan. Specifically, the analyses will shed light on the relationships between changes in several aspects of recovery over time.

Trial registration number

University Hospital Medical Information Network – Clinical Trials Registry (UMIN-CTR), No. UMIN000052275

(295 words)

Keywords

Case management, Cohort study, Multidisciplinary outreach teams: multi-site study, Trajectory

Article summary

Strengths and limitations of this study

The study will examine the long-term trajectories of individuals with mental illness who receive services from 23 multidisciplinary case management and outreach teams.

The study will examine the associations between several aspects of recovery in both individuals with mental illness and their families.

The study will comprehensively assess factors influencing recovery-related quality of life and other patient-reported outcomes over the 10-year study period.

The study's outcome measures were defined in collaboration with people with lived experience of psychiatric disorders who had received case management services from multidisciplinary outreach teams, and with family members in Japanese family associations.

Due to the study design, the effects of particular interventions cannot be identified, but the findings may suggest potentially important factors affecting the recovery process of both patients and their family members.

INTRODUCTION

People with mental illness and their families tend to experience a gradual recovery process that occurs over a long period of time in a community setting. Since pharmacotherapies and psychotherapies often show modest effect sizes in terms of symptom improvement,[1] some individuals require ongoing community-based treatments such as comprehensive case management services.[2] Consequently, a long-term perspective is essential when considering their lives and community care.[3] In this study, case management is defined as a service that includes assessment and care planning, daily support, and family support, all provided by multidisciplinary outreach teams in a community setting.[4]

Mental health research has extensively evaluated various aspects of recovery in individuals with mental illness. These aspects encompass at least three domains, as follows: clinical outcomes (e.g., symptoms and readmission), societal outcomes (e.g., social skills, employment, and housing), and personal recovery. Particularly under the international recovery movement led by patient groups over the past two decades, stakeholders have focused on patients' subjective outcomes. While personal recovery refers to a self-directed life journey[5] and cannot be directly measured, Leamy et al revealed its relevant constructs, including Connectedness, Hope and Optimism, Identity, Meaning in life, and Empowerment (CHIME framework).[6] In this context, subjective and proximate outcomes related to personal recovery, assessed through patient-reported outcome measures (PROMs), have increasingly become important in mental health services research.[7 8]

Several studies have examined PROMs and clinical outcomes. For instance, meta-analyses have demonstrated that PROM-based personal recovery is associated with clinical,

functional, and societal recovery.[9 10] Furthermore, a recent 4-year longitudinal study indicated a potential correlation between stable symptomatic remission and self-reported quality of life (QoL) in people who had experienced an initial psychotic episode.[11] Given that personal recovery encompasses various facets and represents a long-term individual journey,[6 12] research with even longer follow-up durations and repeat assessments that include not only a QoL measure but also other PROMs could offer deeper insights into recovery trajectories and the interrelations among different recovery aspects. A notable example is a Danish 10-year cohort study currently conducting repeat assessments of multiple outcomes in people with psychotic disorders.[13] On the other hand, recovery is not a concept focused only on schizophrenia or psychotic disorders.[14 15] Moreover, the recovery process is influenced by cultural factors. For instance, in Japan, interactions with familiar persons are deemed particularly significant among people with mental illness, and loneliness and a lack of connectedness may be more serious issues in the recovery process in a Japanese context.[16] Consequently, there is a keen anticipation for evidence on long-term recovery trajectories related to diverse diagnoses and community service settings.

With regard to community care, case management has emerged as a leading evidence-based practice for supporting individuals with mental illness after deinstitutionalisation. In particular, assertive community treatment (ACT) and intensive case management (ICM) are well-known case management models in which a multidisciplinary outreach team provides frequent, comprehensive services to people with very severe mental illness.[17 18] Two reviews, one by Cochrane, have demonstrated that ACT and ICM effectively reduced the duration of hospital stays for 2 years of follow-up, especially among individuals with severe mental illness who have experienced prolonged hospitalisations.[19 20] Another meta-analysis highlighted the potential effects of ACT and ICM in reducing psychiatric symptoms and family burden, and enhancing social functioning and family satisfaction.[21] Japanese studies have also shown similar benefits of ACT. [22-25] Furthermore, a recent meta-analysis, with an average intervention duration of 16 months, concluded that non-intensive case management yielded small but significant improvements in psychiatric symptoms and QoL.[26] This suggests that case management services across multiple countries have a tangible short-term impact on various aspects of recovery in people with severe mental illness.

Despite a substantial body of literature, the long-term trajectories of individuals receiving case management by multidisciplinary outreach teams remain underexplored. First, while at least six studies with over 5 years of follow-up, including a Japanese trial, have investigated primarily clinical outcomes such as readmission rates among ACT participants, the results have been mixed.[27-33] Two of these studies also measured societal outcomes and QoL,[30 33] yet the range of outcomes assessed may be considered limited. Second, previous long-term studies have often focused on ACT, which typically targets people with schizophrenia and bipolar disorder.[27-31] In real-world community care settings, case management services are frequently provided to individuals diagnosed with a diverse range of mental illnesses,[4 34-36] yet data on long-term trajectories encompassing a variety of diagnoses are scarce. Third, assessment of family outcomes appears to be lacking. Whereas case management has been shown to potentially have short-term effects on reducing family burden,[21 24] studies have seldom addressed long-term outcomes related not only to family members' burdens but also to their QoL and well-being.[27-31] Fourth, although personal recovery does not necessarily equate to graduation from community mental health services,[37] the intensity of case management services is likely to decrease over time.[38 39] Despite the aforementioned findings, few studies have examined the long-term relationship between the service provision process and subjective outcomes.[13, 33] In summary, although existing long-term studies offer promising evidence, further research is required on the long-term trajectories of people with mental illness and their families within the context of case management services.

In a national context, Japan has undergone a significant transition from inpatient to community mental health care since the early 2000s.[40, 41] Indeed, the current community mental health system in Japan encompasses a range of services that include visiting nurses, non-multiciliary team services, brokering case management services, sheltered workshops, employment services, and housing services. Additionally, the average length of psychiatric hospital stays has decreased from about 500 days in 1990 to approximately 270 days in 2018.[42] These policy changes have led to an increased utilisation of community services among people with mental illness.[43, 44] In this context, multidisciplinary outreach teams provide case management services not only for people with schizophrenia and bipolar disorder, but also for those with diverse mental illness diagnoses and a wide variety of medical and social needs. In some areas, multidisciplinary outreach teams adjusted the ACT model to provide case management services corresponding to their own national and local care systems.[45] In other words, such teams may contribute to community development by treating people with unmet needs. However, since Japan recently launched mental health reforms, information on the long-term outcomes of individuals who require ongoing community care is still limited. This underscores the critical need for empirical evidence regarding the trajectories of individuals with mental illness who receive case management from multidisciplinary outreach teams.

To address the evidence gap, we launched a new project, called the "10-year

October/April Follow-up Evaluation of Multidisciplinary Community Outreach Services study (OCTAP-10)". The overarching aim of this project is to describe the changes in outcome measures related to subjective, clinical, and societal outcomes among individuals with mental illness and their families who have received case management services from multidisciplinary outreach teams over a decade-long follow-up period. The study is designed to explore various aspects of the recovery process, and aims to uncover PROM-related mechanisms and factors associated with personal recovery in a community care setting. Specifically, the primary objective of this study is to determine whether improvements in subjective QoL scores are linked to enhancements in clinical and societal outcomes, as well as changes in service intensity. Secondary objectives involve examining the relationships between other subjective outcome measures (such as subjective personal agency, loneliness, and well-being) and clinical, societal, or service intensity outcomes over time. The third objective is to examine the correlation between patients' QoL scores and family members' QoL or burdens over time.

[Fig 1 about here]

METHODS AND ANALYSIS

Overall design, settings, and public involvement

A 10-year multi-site cohort study is planned. The study protocol has been collaboratively designed by an array of stakeholders, including researchers, service providers, individuals with lived experience of psychiatric disorders who had received case management services from multidisciplinary outreach teams (with two such individuals serving as co-authors), and family members in Japanese family associations. In particular, to improve the feasibility of this study, the project teams jointly established recruitment methods and selected appropriate outcome measures and timings of assessments over the course of several meetings. The participants in the study include patients who newly received services from participating multidisciplinary outreach teams and their key family members. The participant recruitment period is set from October 1, 2023, to September 30, 2025. The study will annually evaluate participants' outcomes following their initial utilisation of services from each team.

In collaboration with the Japanese Association of Community Mental Health Outreach Services (https://www.outreach-net.or.jp/), the study recruited multidisciplinary outreach teams comprising professionals from at least three different occupations, such as psychiatrists, social workers, nurses, psychologists, occupational therapists, and peer supporters. This collaboration led to the participation of 23 teams across Japan. The geographic distribution of these teams is illustrated in Figure 1, and their characteristics are presented in Table 1. As of October, 2023, the mean number of staff members on each participating team was 9.0 (SD = 4.6), and the mean caseload per staff member was 11.9 (SD = 5.7). Among the 23 teams, the average number of patients who were contacted at least twice in the past 6 months was 72.8 (SD = 46.3). Of those, an average of 70.3 patients (SD = 45.9) were contacted as outpatients the last three times. Of these, an average of 70.3 (SD = 45.9) had their last three contacts not at the outreach team's office, but rather in the patient's home or nearby, such as in a coffee shop space, supermarket, or community center. We provided multiple briefings and training sessions to participating teams prior to the start of the study. This study was registered in the University Hospital Medical Information Network – Clinical Trials Registry (UMIN-CTR, No. UMIN000052275), and was approved by the ethical committee of the National Center of Neurology and Psychiatry (No. A2023-065).

[Table 1 about here]

Eligibility criteria of service users

Eligible participants are 1) patients aged 55 or younger, 2) those diagnosed with mental and behavioural disorders (F00–F90) according to the International Classification of Diseases 10th Revision (ICD-10), and 3) those who are newly receiving services from the participating teams during the recruitment period. The exclusion criteria are as follows: 1) inability of staff members on each team to explain the study due to the severity of the patient's illness; 2) only temporary registration with each team for use of services; and 3) anticipation that the patient will be difficult to track for personal reasons, such as relocation to a distant location. Upon registration of a potential participant with each participating team, trained case managers or team psychiatrists assess the patient's eligibility.

Eligibility criteria of family members

For family members, we set two eligibility criteria: 1) resides with the patient participating in the study, lives in close proximity to the patient's home, or frequently visits the patient's home; and 2) is a key person within the family. Family members with suspected or confirmed dementia or other relevant conditions that impede their ability to provide informed consent are excluded from the study. If a participating family member passes away during the 10-year study period, we will not recruit an alternate family member to take their place.

Recruitment procedures

This study utilises a two-stage recruitment process. The initial stage involves an opt-out method to ensure participants have the opportunity to decline participation. All participating teams display an official poster that informs participants about the use of observational data from their service and medical records. The National Center of Neurology and Psychiatry also makes this information available on its website. When a new patient is enrolled in each participating team, a trained case manager or team psychiatrist evaluates the patient's eligibility. In the absence of refusal by eligible patients, trained case managers gather data on observer-rated outcome measures, including symptom and function scales, as well as other characteristics including health and societal information such as living situation and employment statues. Following the enrolment of patient participants in the initial stage, trained case managers provide them with a detailed explanation of the study in the second stage, encompassing its aims and ethical considerations. After each individual provides consent, they are asked to complete all the PROMs. In a parallel process, case managers also present a detailed overview of the study to a key family member of the patient participant. If this family member voluntarily agrees to participate, they are subsequently asked to fill out the PROMs specifically designed for family participants.

[Fig 2 about here]

Timing of data collection

A case manager evaluation and an initial survey that includes PROMs for both patients and their families will be carried out at the commencement of services for eligible participants (i.e., upon their enrolment in the study). This initial data collection will serve as the baseline assessment for the study (T0). Subsequent follow-up assessments (T1 to T10) will be carried out annually, in October for individuals who registered between July and December, and in April for those who registered between January and June. For the 1-year follow-up assessment (T1), a gap of up to 3 months may occur in the timing of follow-up. Considering the 10-year duration of this follow-up study, minimising the case managers' burden is essential. Consequently, after consultation with the participating teams, it was determined to be viable and practical to schedule follow-up assessments twice each year (in October and April). Figure 2 details the schedule for these assessments. Even if patient participants graduate from their involvement with each participating team, case managers maintain contact with them and continue ongoing data collection.

[Table 2 and 3 about here]

Research measures and variables

The measures used at each time point in this study are detailed in Tables 2 and 3. They were selected on the basis of an internationally recommended set of outcome measures for psychotic disorders and through discussion with multiple stakeholders.

PROMs for patients

For patients, the study utilises five PROMs at all time points. These include the following: the Recovering Quality of Life 10-item version (ReQoL-10) as the primary outcome measure;[46] the five-item Subjective and Personal Agency scale (SPA-5);[47] the University of California, Los Angeles loneliness scale – short form, 10-item version (UCAL-LS-SF-10);[48 49] the single-item well-being measure;[50] and the Patient Health Questionnaire 2-item version (PHQ-2).[51-53]

The ReQoL-10, serving as a shorter version of the 20-item ReQoL, comprises 10 items with scores ranging from 0 to 40.[46] The Japanese translation and back-translation of the ReQoL-10 were conducted by Oxford University Innovation (https://innovation.ox.ac.uk/). The authors confirmed the accuracy of translations.[54] A higher score indicates a better QoL related to personal recovery. The SPA-5 is designed to measure personal agency in people with severe mental illness, and encompasses five items. The scale originated in Japan and was developed through collaboration between researchers and people with schizophrenia.[47] Its overall score ranges from 5 to 25, with higher scores reflecting a stronger sense of personal agency in community life. The UCLA-LS-SF-10 assesses subjective feelings of loneliness and social isolation. While the original UCLA-LS consists of 20 items,[48] a Japanese study validated a 10-item short form (scoring range 10–40), with higher scores indicating greater feelings of loneliness.[49] The single-item well-being measure asks, "Overall, how satisfied are you with life as a whole these days?" using a 0–10 scale, where 0 means "Not at all" and 10 means "Completely". This measure, suggested by VanderWeele et al.[50] is also employed in a Japanese government survey to quickly evaluate an individual's well-being.[55] The PHQ-2 is a self-rated tool for depression screening, and is based on the Diagnostic and Statistical Manual of Mental Disorders.[51-53] The PHQ has several versions; however, this study employs the two-item version to minimise participant burden.[53] The scoring range for the PHQ-2 is 0 to 6, with higher scores indicating more severe depressive symptoms.

Observer-rated outcome measures for patients

The study uses two clinical and social outcome measures rated by trained case managers. Symptom assessment is performed using the Clinical Global Impression scales, encompassing the CGI-S (Severity) and CGI-I (Improvement) measures.[56 57] Both scales are rated on a 7-point scale, with responses ranging from 1 (Normal or Very much improved) to 7 (Among the most severely ill or Very much worse). The CGI-S will be utilised at all time points, but the CGI-I will be excluded at the baseline assessment (T0) due to the nature of the scale. Another staff-rated evaluation is the 12-item version (short-form) of the World Health Organization Disability Assessment Schedule 2.0 (WHODAS), which is designed to assess social functioning and community activities among participants.[58] Although WHODAS is available in a 36-item version, research within a Japanese community mental health care setting has demonstrated a high correlation between the total scores of the 12- and 36-item versions.[59] The scoring for the 12-item WHODAS ranges from 0 to 100, with higher scores indicating increased difficulty in community living.

Other health, social, and service exposure variables for patients

Case managers will gather the following participant information from medical records at each assessment point: living status (such as living with family or alone), family structure, employment or educational status, hospitalisation history and duration, and medication adherence status (categorised as No prescription, Unknown medication status, Taking medication but irregularly, or Taking medication as prescribed). Additionally, the Charlson Comorbidity Index (CCI) will be used to rate participants' physical health. The CCI evaluates the severity and number of comorbidities on the basis of the ICD.[60 61] With regard to service and treatment variables, the use of particular medications (e.g., antipsychotic drugs, clozapine, and long-acting injections) and of social or medical services other than the participating teams are investigated at every assessment point. Beginning with the 1-year follow-up assessment (T1), the study will also evaluate the frequency of visiting services provided monthly to each participant. Additionally, it will examine the provision of specific services such as peer support, family psychoeducation, and cognitive behavioural therapy offered by the participating teams.

Outcome measures and service intensity evaluations for family members

Similar to the patient participants, family members participating in the study will complete the ReQoL-10 [46] and single-item well-being measure.[50] Additionally, two validated family-reported outcome measures are employed: the eight-item Zarit Burden Index (ZBI-8)[62] and the Family Questionnaire (FQ).[63 64] The ZBI-8, a shortened version of the original 22-item ZBI, assesses the burden of family care.[65 66] Its validation, including factor validity and high internal consistency, was confirmed in a Japanese study.[62] The overall ZBI-8 score ranges from 0 to 40, with higher scores indicating a greater burden of family care. The FQ, comprising 20 items, evaluates family relationships and emotional attitudes towards other family members with mental illness.[63] Its overall score ranges from 20 to 80, with higher scores reflecting more negative emotional responses by the family towards the patient. The Japanese FQ's convergent validity, concurrent validity, and test–retest reliability have been confirmed in a previous study.[64] We also created the following two original questions on living and economic conditions: "How have you felt about your finances during the past year?" with response options ranging from 0 (very distressed) to 4 (very comfortable), and "What is your primary income?" with options including labour income, asset management, pension, or other. Regarding service intensity, case managers will document the number of services per month provided to the family throughout the follow-up period (Table 4).

[Table 4 about here]

Sample size consideration

We have established a maximum enrolment limit of 20 patient participants for each team, given the research burden on each team and the feasibility of this study. With 23 teams participating, the theoretical maximum number of participants is set at 460 each for patient participants and family participants. However, given that some teams may enrol fewer than 10 new patients annually and that some patient participants may live alone, we anticipated that the actual number of participants will be around 200 to 300. Given that not all patient participants live with their family members, the number of family participants is expected to be below 200.

Data analysis

Descriptive statistics

Descriptive summary statistics will be calculated for each variable. These values will be presented as means, standard deviations, medians, interquartile ranges, frequencies, and proportions as appropriate.

Research objectives

For the primary objective, generalised mixed models with repeated measures (MMRM) will be performed to investigate factors influencing changes in the ReQoL-10 score over time, with this score serving as the dependent variable. Key independent variables will include the CGI-S, the WHODAS, and service intensity. We may also include various demographic and social variables such as age, sex, diagnosis, employment, and living status. Additionally, the variable representing the team will be incorporated as a random effect. For the secondary objective, we will conduct the MMRM again, but instead of using the ReQol-10 score as the dependent variable, we will use the SPA-5, UCAL-LS-SF-10, or single-item well-being score. For the third objective, MMRM will also be performed to compare the ReQoL-10 between patients and family members. However, a decade hence, should new statistical modelling techniques be recommended for the analysis of longitudinal data, we may consider employing these methods as an alternative to MMRM. Missing values will be dealt with accordingly.

DISCUSSION

This study will delineate the trajectories of several recovery types in patients with mental illness and their families who receive services from 23 multidisciplinary outreach teams across Japan. Specifically, the analyses will shed light on the relationships between changes in subjective QoL and other PROMs related to personal recovery and other recovery dimensions over time. Although this study does not employ a randomised controlled trial design, and thus cannot definitively ascertain the effects of interventions, it potentially allows for the identification of factors influencing the trajectories of subjective outcomes in patients and their families who receive services from multidisciplinary outreach teams. Such insights could significantly contribute to the development of future effective interventions in community care settings and to determining the outcome measures that should be routinely assessed in clinical settings.

The strengths of this study are twofold. First, the participants in this study include family members in addition to patients. Given that multidisciplinary outreach teams typically extend case management services to family members, evaluating their long-term subjective outcome trajectories promises to yield valuable insights. Second, the study protocol was developed collaboratively with service providers, individuals with lived experience of psychiatric disorders, and family members. This collaboration was particularly crucial in selecting outcome measures, taking into account the collaborators' interests and the participants' burden.

However, we recognise at least three study limitations. The first pertains to sample size.

Despite the participation of 23 multidisciplinary outreach teams, the annual number of new patients in each team may be limited. Even with the planned 2-year recruitment period, the participant count might be smaller than anticipated. The second limitation concerns the consent process and the collection of PROM data. Although the study employs a two-stage recruitment strategy, acquiring PROM data necessitates obtaining consent directly from the participants. Given that patients often face challenges when commencing services provided by multidisciplinary outreach teams, such as relationship-building difficulties or severe symptoms, it may not be feasible to seek their consent for participation in the research, and consequently, for completing PROMs, particularly at baseline. Third, this study does not evaluate or control the detailed service quality of the participating teams. While organisational structures are examined, such as caseload numbers per case manager and others shown in Table 1, and the MMRM analysis accounts for the team variable as a random effect, the study does not provide evidence on the relationship between each team's service quality and the outcomes.

Despite the potential methodological limitations, this study covers multiple variables related to the community lives of people with mental illness. Collecting information for certain variables, particularly PROMs, can pose challenges, especially in retrospective or national database studies. As such, the insights derived from this study will be invaluable in comprehending the recovery processes of patients within their community settings.

ETHICS and DISSEMINATION

The ethical considerations of the current study, including the informed consent process and patient privacy measures, are based on ethics guidelines for medical research in Japan. The study protocol has been approved by the ethical committee of the National Center of Neurology and Psychiatry (No. A2023-065). The study findings will be reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement[67] in peer-reviewed publications, and presented at relevant scientific conferences. We will also ask an organisation involving patients and families to help disseminate the study findings.

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Figure title and legend

Figure 1. Locations of the 23 participating teams

Figure 2. Overall study design

1. Follow-up assessment will be conducted in April for participants enrolled from January to June,

and in October for participants enrolled from July to December

AUTHOR STATEMENT

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Author Contributions

SY, KU, MI, TK, AH, KY, MN, and SS conceived this work. SY secured the funding. All the authors contributed to the development and refinement of the study protocol. KY, HY, and MW recruited the participating teams. KT played a central role in involving the individuals with lived experience of psychiatric disorders who collaborated in developing the research plan. CF managed research team members. SY, KU, MI, TK, AH, and SS drafted the manuscript. In addition, all the authors have approved the final version of the manuscript.

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Conflicts of interests

The authors declare that there are no conflicts of interest in relation to this study.

Ethics approval

This study was approved by the ethical committee of the National Center of Neurology and Psychiatry (No. A2023-065).

Table 1. Characteristics of 23 multidisciplinary case management and outreach teams

Number of clinical staff members	mean (SD)	9.0	4.6
Adjusted number of clinical staff members[1)]	mean (SD)	6.4	2.8
Percentages of teams containing each type of professional			
Psychiatrist	n (%)	17	73.9%
Nurse	n (%)	23	100.0%
Social worker	n (%)	19	82.6%
Occupational therapy	n (%)	22	95.7%
Clinical psychologist	n (%)	4	17.4%
Pharmacist	n (%)	3	13.0%
Peer support worker	n (%)	3	13.0%
Number of patients contacted at least twice in the past 6 months	mean (SD)	72.8	46.3
Of the above, the number whose last three contacts were at or near their homes	mean (SD)	70.3	45.9
Number of current caseloads per staff member on each team	mean (SD)	11.9	5.7

1) Staff members working more than 32 hours per week are counted as 1; those working between 16 hours and 32 hours per week are counted as 0.5, and those working less than 16 hours per week are counted as 0.

Table 2. Outcomes and instruments for patient participants

Domain	Outcome	Scale	Abbreviation	No of items
Subjective outcome / PROM	Quality of life	Recovering Quality of Life 10-item version	ReQoL-10	10
	Personal agency	Five-item Subjective and Personal Agency scale	SPA-5	5
	Loneliness	University of California, Los Angeles loneliness scale – short form 10-item version	UCLA-LS-SF-10	10
	Well-being	Single-item well-being measure	Well-being	1
	Depression	Patient Health Questionnaire 2-item version	PHQ-2	2
	Symptom	Clinical Global Impression scale – Severity	CGI-S	7
	Symptom	Clinical Global Impression scale – Improvement	CGI-I	7
	Function	World Health Organization Disability Assessment Schedule 2.0, 12-item version	WHODAS 2.0	12
Clinical condition / outcome	Hospitalisation history and duration	Original questions		
	Medication adherence status	Original questions		
	Physical health	Charlson Comorbidity Index	CCI	
Social condition / outcome	Living status	Original questions		
	Family structure	Original questions		
	Employment or educational status	Original questions		
Service	Frequency of visiting services (per month)	Original questions		
	Peer support	Original questions		
	Family psychoeducation	Original questions		
	Cognitive behavioural therapy	Original questions		
	The use of particular medications	Original questions		
	The use of social or medical services other than those provided by participating teams	Original questions		

PROM = Patient-reported outcome measures

Table 3. Outcomes and instruments for family participants

Domain	Outcome	Scale	Abbreviation	No of items
Subjective outcome	Quality of life	Recovering Quality of Life 10-item version	ReQoL-10	10
	Well-being	Single-item well-being measure	Well-being	1
	Burden of family care	8-item Zarit Burden Index	ZBI-8	8
	Family relationships	Family Questionnaire	FQ	20
Social condition	Living status	Original questions		
	Economic condition	Original questions		

PROM = Patient-reported outcome measures

Table 4. Timing of assessments of each measure

Subject	Scale (Abbreviation)*	T0	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10
Patient	ReQoL-10	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	SPA-5	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	UCLA-LS-SF-10	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Well-being	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	PHQ-2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	CGI-S	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	CGI-I		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	WHODAS 2.0	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hospitalisation history and duration	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Medication adherence status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Physical health	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Living status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Family structure	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Employment or educational status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Frequency of visiting services (per month)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Peer support		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Family psychoeducation		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Cognitive behavioural therapy		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	The use of particular medications	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	The use of social or medical services other than those provided by participating teams	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Family	ReQoL-10	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Well-being	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	ZBI-8	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	FQ	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Living status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Economic condition	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

* The full spelling of each measure is shown in Tables 2 and 3.

Figure 1. Locations of the 23 participating teams

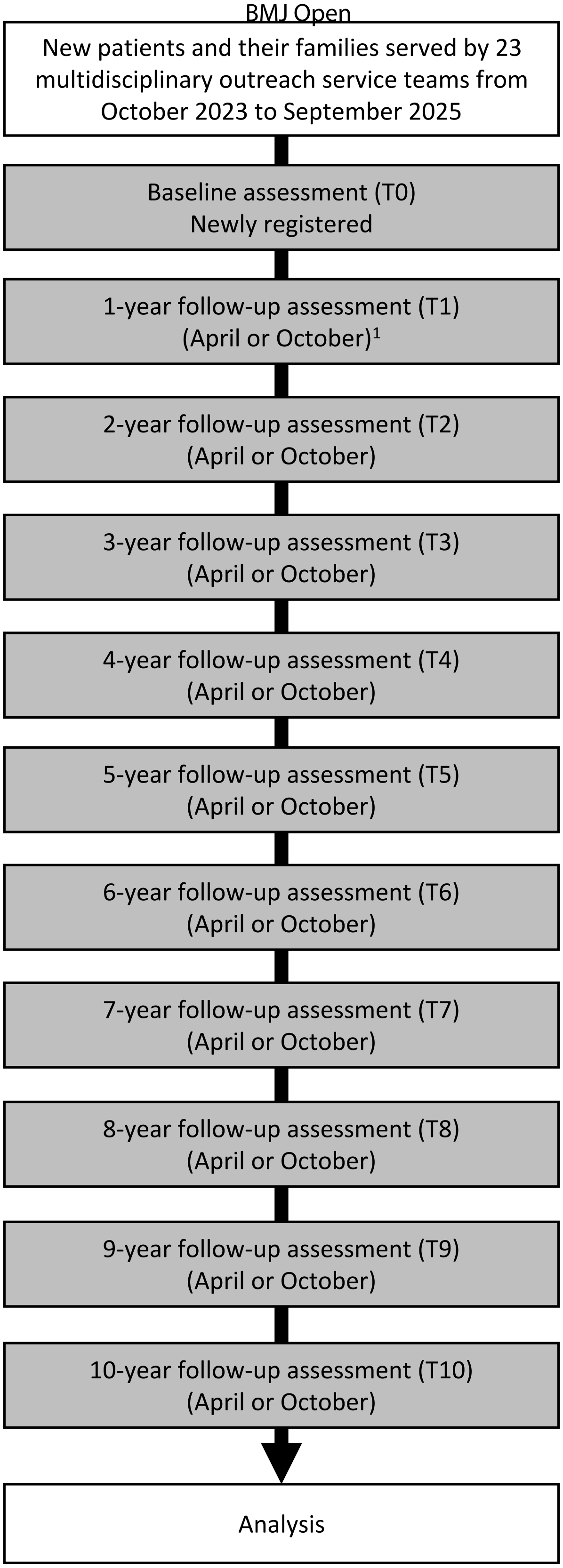

Figure 2. Overall study design

[1] Follow-up assessment will be conducted in April for participants enrolled from January to June, and in October for participants enrolled from July to December.

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Ten-year outcome trajectories of people with mental illness and their families who receive services from multidisciplinary case management and outreach teams: Protocol of a multi-site longitudinal study

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Title

Ten-year outcome trajectories of people with mental illness and their families who receive services from multidisciplinary case management and outreach teams: Protocol of a multi-site longitudinal study

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ABSTRACT

Introduction

Individuals with mental illness and their families often undergo their recovery process in their communities. This study explored the long-term outcome trajectories of individuals and families who received case management services provided by multidisciplinary outreach teams in a community setting. The primary objective of this study was to determine whether trajectories of subjective quality of life (QoL) related to personal recovery were linked to those of clinical and societal outcomes and to changes in outreach service frequency.

Methods and analysis

The protocol of this 10-year multi-site cohort study was collaboratively developed with individuals with lived experience of psychiatric disorders who had received services from participating outreach teams, and with family members in Japanese family associations. The participants in the study include patients and their key family members who receive services from 23 participating multidisciplinary outreach teams. The participant recruitment period is set from October 1, 2023, to September 30, 2025. If necessary, the recruitment period may be extended, and the number of the participating teams may be increased. The study will annually evaluate the following outcomes after participants' initial utilisation of services from each team: QoL related to personal recovery, personal agency, feelings of loneliness, well-being, and symptom and functional assessments. The family outcomes encompass QoL, well-being, care burden, and family relationships. Several meetings will be held to monitor progress and manage issues during the study. Multivariate analyses with repeated measures will be performed to investigate factors influencing changes in the patients' QoL scores as the dependent variable.

Ethics and dissemination

The study protocol was approved by the ethical committee of the National Center of Neurology and Psychiatry (no. A2023-065). The study findings will be reported in peer-reviewed publications and presented at relevant scientific conferences.

Trial registration number

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(300 words)

Keywords

Case management, Cohort study, Multidisciplinary outreach teams: multi-site study, Trajectory

Article summary

Strengths and limitations of this study

The study will examine the long-term trajectories of individuals with mental illness who receive services from 23 multidisciplinary case management and outreach teams.

The study will examine the associations between several aspects of recovery in both individuals with mental illness and their families.

The study will comprehensively assess factors influencing recovery-related quality of life and other patient-reported outcomes over the 10-year study period.

The study's outcome measures were defined in collaboration with people with lived experience of psychiatric disorders who had received case management services from multidisciplinary outreach teams, and with family members in Japanese family associations.

Due to the study design, the effects of particular interventions cannot be identified, but the findings may suggest potentially important factors affecting the recovery process of both patients and their family members.

INTRODUCTION

People with mental illness and their families tend to experience a gradual recovery process that occurs over a long period of time in a community setting. Since pharmacotherapies and psychotherapies often show modest effect sizes in terms of symptom improvement,[1] some individuals require ongoing community-based treatments such as comprehensive case management services.[2] Consequently, a long-term perspective is essential when considering their lives and community care.[3] In this study, case management is defined as a service that includes assessment and care planning, daily support, and family support, all provided by multidisciplinary outreach teams in a community setting.[4]

Mental health research has extensively evaluated various aspects of recovery in individuals with mental illness. These aspects encompass at least three domains, as follows: clinical outcomes (e.g., symptoms and readmission), societal outcomes (e.g., social skills, employment, and housing), and personal recovery. Particularly under the international recovery movement led by patient groups over the past two decades, stakeholders have focused on patients' subjective outcomes. While personal recovery refers to a self-directed life journey[5] and cannot be directly measured, Leamy et al revealed its relevant constructs, including Connectedness, Hope and Optimism, Identity, Meaning in life, and Empowerment (CHIME framework).[6] In this context, subjective and proximate outcomes related to personal recovery, assessed through patient-reported outcome measures (PROMs), have increasingly become important in mental health services research.[7 8]

Several studies have examined PROMs and clinical outcomes. For instance, meta-analyses have demonstrated that PROM-based personal recovery is associated with clinical,

functional, and societal recovery.[9 10] Furthermore, a recent 4-year longitudinal study indicated a potential correlation between stable symptomatic remission and self-reported quality of life (QoL) in people who had experienced an initial psychotic episode.[11] Given that personal recovery encompasses various facets and represents a long-term individual journey,[6 12] research with even longer follow-up durations and repeat assessments that include not only a QoL measure but also other PROMs could offer deeper insights into recovery trajectories and the interrelations among different recovery aspects. A notable example is a Danish 10-year cohort study currently conducting repeat assessments of multiple outcomes in people with psychotic disorders.[13] On the other hand, recovery is not a concept focused only on schizophrenia or psychotic disorders.[14 15] Additionally, despite the theoretical notion that recovery does not necessarily imply a reduction in services, few long-term studies have scrutinised the relationship between service frequency and recovery outcomes.[16] Moreover, the recovery process is influenced by cultural factors. For instance, in Japan, interactions with familiar persons are deemed particularly significant among people with mental illness, and loneliness and a lack of connectedness may be more serious issues in the recovery process in a Japanese context.[17] Consequently, there is a keen anticipation for evidence on long-term recovery trajectories related to diverse diagnoses and community service settings.

With regard to community care, case management has emerged as a leading evidence-based practice for supporting individuals with mental illness after deinstitutionalisation. In particular, assertive community treatment (ACT) and intensive case management (ICM) are well-known case management models in which a multidisciplinary outreach team provides frequent, comprehensive services to people with very severe mental illness.[18 19] Two reviews, one by Cochrane, have demonstrated that ACT and ICM effectively reduced the duration of hospital stays for 2 years of follow-up, especially among individuals with severe mental illness who have experienced prolonged hospitalisations.[20 21] Another meta-analysis highlighted the potential effects of ACT and ICM in reducing psychiatric symptoms and family burden, and enhancing social functioning and family satisfaction.[22] Japanese studies have also shown similar benefits of ACT. [23-26] Furthermore, a recent meta-analysis, with an average intervention duration of 16 months, concluded that non-intensive case management yielded small but significant improvements in psychiatric symptoms and QoL.[27] This suggests that case management services across multiple countries have a tangible short-term impact on various aspects of recovery in people with severe mental illness.

Despite a substantial body of literature, the long-term trajectories of individuals receiving case management by multidisciplinary outreach teams remain underexplored. First, while at least six studies with over 5 years of follow-up, including a Japanese trial, have investigated primarily clinical outcomes such as readmission rates among ACT participants, the results have been mixed.[28-34] Two of these studies also measured societal outcomes and QoL,[31 34] yet the range of outcomes assessed may be considered limited. Second, previous long-term studies have often focused on ACT, which typically targets people with schizophrenia and bipolar disorder.[28-32] In real-world community care settings, case management services are frequently provided to individuals diagnosed with a diverse range of mental illnesses,[4 35-37] yet data on long-term trajectories encompassing a variety of diagnoses are scarce. Third, assessment of family outcomes appears to be lacking. Whereas case management has been shown to potentially have short-term effects on reducing family burden,[22 25] studies have seldom addressed long-term outcomes related not only to family members' burdens but also to their QoL and well-being.[28-32] Fourth, although personal recovery does not necessarily equate to graduation from community mental health services,[16] the frequency of case management and outreach services is likely to decrease over time.[38,39] Despite the aforementioned findings, few studies have examined the long-term relationship between the service provision process and subjective outcomes.[13,34] In summary, although existing long-term studies offer promising evidence, further research is required on the long-term trajectories of people with mental illness and their families within the context of case management services.

In a national context, Japan has undergone a significant transition from inpatient to community mental health care since the early 2000s.[40,41] Indeed, the current community mental health system in Japan encompasses a range of services that include visiting nurses, brokering case management services, sheltered workshops, employment services, housing services, and services such as support provided by non-multidisciplinary teams comprising social workers or occupational therapists. Additionally, the average length of psychiatric hospital stays has decreased from about 500 days in 1990 to approximately 270 days in 2018.[42] These policy changes have led to an increased utilisation of community services among people with mental illness.[43,44] In this context, multidisciplinary outreach teams provide case management services not only for people with schizophrenia and bipolar disorder, but also for those with diverse mental illness diagnoses and a wide variety of medical and social needs. In some areas, multidisciplinary outreach teams adjusted the ACT model to provide case management services corresponding to their own national and local care systems.[45] In other words, such teams may contribute to community development by treating people with unmet needs. However, since Japan recently launched mental health reforms, information on the long-term outcomes of individuals who require ongoing community care is still limited. This underscores the critical need for empirical evidence regarding the trajectories of individuals with mental illness who receive case management from multidisciplinary outreach teams.

To address the evidence gap, we launched a new project, called the "10-year October/April Follow-up Evaluation of Multidisciplinary Community Outreach Services study (OCTAP-10)". The overarching aim of this project is to describe the changes in outcome measures related to subjective, clinical, and societal outcomes among individuals with mental illness and their families who have received case management services from multidisciplinary outreach teams over a decade-long follow-up period. The study is designed to explore various aspects of the recovery process, and aims to uncover PROM-related mechanisms and factors associated with personal recovery in a community care setting. Specifically, the primary objective of this study is to determine whether trajectories of patients' subjective QoL scores are linked to those of clinical and societal outcomes and to changes in outreach service frequency. Secondary objectives involve examining the relationships between other subjective outcome measures (such as subjective personal agency, loneliness, and well-being) and clinical, societal, or service frequency outcomes over time. The third objective is to examine the correlation between patients' QoL scores and family members' QoL or burdens over time.

[Fig 1 about here]

METHODS AND ANALYSIS

Overall design, settings, and public involvement

A 10-year multi-site cohort study is planned. The study protocol has been collaboratively designed by an array of stakeholders, including researchers, service providers, individuals with lived experience of psychiatric disorders who had received case management services from multidisciplinary outreach teams (with two such individuals serving as co-authors), and family members in Japanese family associations. In particular, to improve the feasibility of this study, the project teams jointly established recruitment methods and selected appropriate outcome measures and timings of assessments over the course of several meetings. The participants in the study include patients who newly received services from participating multidisciplinary outreach teams and their key family members. The participant recruitment period is set from October 1, 2023, to September 30, 2025. The study will annually evaluate participants' outcomes following their initial utilisation of services from each team.

In collaboration with the Japanese Association of Community Mental Health Outreach Services (https://www.outreach-net.or.jp/), the study recruited multidisciplinary outreach teams comprising professionals from at least three different occupations, such as psychiatrists, social workers, nurses, psychologists, occupational therapists, and peer supporters. This collaboration led to the participation of 23 teams across Japan. This was a convenience sampling strategy, although we did solicit study participation from a broad range of Japanese multidisciplinary outreach teams. The geographic distribution of these teams is illustrated in Figure 1, and their characteristics are presented in Table 1. As of October, 2023, the mean number of staff members on each participating team was 9.0 (SD = 4.6), and the mean caseload per staff member was 11.9 (SD = 5.7). Among the 23 teams, the average number of patients who were contacted at least twice in the past 6 months was 72.8 (SD = 46.3). Of these, an average of 70.3 (SD = 45.9) had their last three contacts not at the outreach team's office, but rather in the patient's home or nearby, such as in a coffee shop space, supermarket, or community centre. While this study focuses on patients and their family members who receive multidisciplinary outreach team services that extend beyond assertive community treatment (ACT), the 12participating teams underwent fidelity reviews using the Japanese version of the Dartmouth Assertive Community

Treatment Scale (DACTS) within the past 3 years.[46 47] The average overall fidelity score among these teams was 3.7 (SD = 0.2) (Online supplementary table 1). We provided multiple briefings and training sessions to participating teams prior to the start of the study. This study was registered in the University Hospital Medical Information Network – Clinical Trials Registry (UMIN-CTR, No. UMIN000052275), and was approved by the ethical committee of the National Center of Neurology and Psychiatry (No. A2023-065).

Table 1. Characteristics of 23 multidisciplinary case management and outreach teams

Number of clinical staff members	Mean (SD)	9.0	4.6
Adjusted number of clinical staff members[1)]	Mean (SD)	6.4	2.8
Percentages of teams containing each type of professional			
Psychiatrist	n (%)	17	73.9%
Nurse	n (%)	23	100.0%
Social worker	n (%)	19	82.6%
Occupational therapy	n (%)	22	95.7%
Clinical psychologist	n (%)	4	17.4%
Pharmacist	n (%)	3	13.0%
Peer support worker	n (%)	3	13.0%
Number of patients contacted at least twice in the past 6 months	Mean (SD)	72.8	46.3
Of the above, the number whose last three contacts were at or near their homes	Mean (SD)	70.3	45.9
Number of current caseloads per staff member on each team	Mean (SD)	11.9	5.7

1) Staff members working more than 32 hours per week are counted as 1; those working between 16 hours and 32 hours per week are counted as 0.5, and those working less than 16 hours per week are counted as 0.

Eligibility criteria of service users

Eligible participants are 1) patients aged 55 or younger, 2) those diagnosed with mental and behavioural disorders (F00–F90) according to the International Classification of Diseases

10th Revision (ICD-10), and 3) those who are newly receiving services from the participating teams during the recruitment period. With regard to the age criterion, people aged 65 and older in Japan typically utilise elder care services instead of mental health services. Therefore, we have specified this criterion to recruit individuals who will not reach the age of 65 during the 10-year follow-up period. The exclusion criteria are as follows: 1) inability of staff members on each team to explain the study due to the severity of the patient's illness; 2) only temporary registration with each team for use of services; and 3) anticipation that the patient will be difficult to track for personal reasons, such as relocation to a distant location. Upon registration of a potential participant with each participating team, trained case managers or team psychiatrists assess the patient's eligibility.

Eligibility criteria of family members

For family members, we set two eligibility criteria: 1) resides with the patient participating in the study, lives in close proximity to the patient's home, or frequently visits the patient's home; and 2) is a key person within the family. Family members with suspected or confirmed dementia or other relevant conditions that impede their ability to provide informed consent are excluded from the study. If a participating family member passes away during the 10-year study period, we will not recruit an alternate family member to take their place.

Recruitment procedures

This study utilises a two-stage recruitment process. The initial stage involves an opt-out method to ensure participants have the opportunity to decline participation. All participating teams display an official poster that informs participants about the use of observational data from their service and medical records. The National Center of Neurology and Psychiatry also makes this information available on its website. When a new patient is enrolled in each participating team, a trained case manager or team psychiatrist evaluates the patient's eligibility. In the absence of refusal by eligible patients, trained case managers gather data on observer-rated outcome measures, including symptom and function scales, as well as other characteristics including health and societal information such as living situation and employment statues. Following the enrolment of patient participants in the initial stage, trained case managers provide them with a detailed explanation of the study in the second stage, encompassing its aims and ethical considerations. This explanation fully informs patient participants that they can refuse all participation in the study, including the collection of observer-rated outcome measures. It also makes clear that they can withdraw their consent and stop completing surveys at any point during the 10-year follow-up period and can receive outreach services even if they decline the participation. After each individual provides consent, they are asked to complete all the PROMs. In a parallel process, case managers also present a detailed overview of the study to a key family member of the patient participant. If this family member voluntarily agrees to participate, they are subsequently asked to fill out the PROMs specifically designed for family participants.

[Fig 2 about here]

Timing of data collection

A case manager evaluation and an initial survey that includes PROMs for both patients and their families will be carried out at the commencement of services for eligible participants (i.e., upon their enrolment in the study). This initial data collection will serve as the baseline assessment for the study (T0). Subsequent follow-up assessments (T1 to T10) will be carried out annually, in October for individuals who registered between July and December, and in April for those who registered between January and June. For the 1-year follow-up assessment (T1), a gap of up to 3 months may occur in the timing of follow-up. Considering the 10-year duration of this follow-up study, minimising the case managers' burden is essential. Consequently, after consultation with the participating teams, it was determined to be viable and practical to schedule follow-up assessments twice each year (in October and April). Figure 2 details the schedule for these assessments. Even if patient participants graduate from their involvement with each participating team, case managers maintain contact with them and continue ongoing data collection.

Research measures and variables

At baseline assessment (T0), we collect demographic information such as age, sex, diagnosis based on ICD-10, academic grade, and use of social benefits. The other exposure and outcome measures used at each time point in this study are detailed in Tables 2 and 3. They were selected on the basis of an internationally recommended set of outcome measures for psychotic disorders and through discussion with multiple stakeholders.

PROMs for patients

For patients, the study utilises five PROMs at all time points. These include the following: the Recovering Quality of Life 10-item version (ReQoL-10) as the primary outcome measure;[48] the five-item Subjective and Personal Agency scale (SPA-5);[49] the University of California, Los Angeles loneliness scale – short form, 10-item version (UCAL-LS-SF-10);[50 51] the single-item well-being measure;[52] and the Patient Health Questionnaire 2-item version (PHQ-2).[53-55] All the scales are described in Japanese and utilise paper-based questionnaires rather than online forms.

The ReQoL-10, serving as a shorter version of the 20-item ReQoL, comprises 10 items with scores ranging from 0 to 40.[48] The Japanese translation and back-translation of the ReQoL-10 were conducted by Oxford University Innovation (https://innovation.ox.ac.uk/). The authors confirmed the accuracy of translations.[56] A higher score indicates a better QoL related to personal recovery. The SPA-5 is designed to measure personal agency in people with severe mental illness, and encompasses five items. The scale originated in Japan and was developed through collaboration between researchers and people with schizophrenia.[49] Its overall score ranges from 5 to 25, with higher scores reflecting a stronger sense of personal agency in community life. The UCLA-LS-SF-10 assesses subjective feelings of loneliness and social isolation. While the original UCLA-LS consists of 20 items,[50] a Japanese study validated a 10-item short form (scoring range 10–40), with higher scores indicating greater feelings of loneliness.[51] The single-item well-being measure asks, "Overall, how satisfied are you with life as a whole these days?" using a 0–10 scale, where 0 means "Not at all" and 10 means "Completely". This measure, suggested by VanderWeele et al.[52] is also employed in a Japanese government survey to quickly evaluate an individual's well-being.[57] The PHQ-2 is a self-rated tool for depression screening, and is based on the Diagnostic and Statistical Manual of Mental Disorders.[53-55] The PHQ has several versions; however, this study employs the two-item version to minimise participant burden.[55] The scoring range for the PHQ-2 is 0 to 6, with higher scores indicating more severe depressive symptoms.

Observer-rated outcome measures for patients

The study uses two clinical and social outcome measures rated by trained case managers. Symptom assessment is performed using the Clinical Global Impression scales, encompassing the CGI-S (Severity) and CGI-I (Improvement) measures.[58 59] Both scales are rated on a 7-point scale, with responses ranging from 1 (Normal or Very much improved) to 7 (Among the most severely ill or Very much worse). The CGI-S will be utilised at all time points, but the CGI-I will be excluded at the baseline assessment (T0) due to the nature of the scale. Another staff-rated evaluation is the 12-item version (short-form) of the World Health Organization Disability Assessment Schedule 2.0 (WHODAS), which is designed to assess social functioning and community activities among participants.[60] Although WHODAS is available in a 36-item version, research within a Japanese community mental health care setting has demonstrated a high correlation between the total scores of the 12- and 36-item versions.[61] The scoring for the 12-item WHODAS ranges from 0 to 100, with higher scores indicating increased difficulty in community living.

Other health, social, and service exposure variables for patients

Case managers will gather the following participant information from medical records at each assessment point: living status (such as living with family or alone), family structure, employment or educational status, hospitalisation history and duration, and medication adherence status (categorised as No prescription, Unknown medication status, Taking medication but irregularly, or Taking medication as prescribed). Additionally, the Charlson Comorbidity Index (CCI) will be used to rate participants' physical health. The CCI evaluates the severity and number of comorbidities on the basis of the ICD.[62 63] With regard to service and treatment variables, the use of particular medications (e.g., antipsychotic drugs, clozapine, and long-acting injections) and of social or medical services other than the participating teams are investigated at every assessment point. Beginning with the 1-year follow-up assessment (T1), the study will also evaluate the frequency of visiting services provided monthly to each participant. Additionally, it will examine the provision of specific services such as peer support, family psychoeducation, and cognitive behavioural therapy offered by the participating teams.

Outcome measures and service frequency evaluations for family members

Similar to the patient participants, family members participating in the study will complete the ReQoL-10 [48] and single-item well-being measure.[52] Additionally, two validated family-reported outcome measures are employed: the eight-item Zarit Burden Index (ZBI-8)[64] and the Family Questionnaire (FQ).[65 66] The ZBI-8, a shortened version of the original 22-item ZBI, assesses the burden of family care.[67 68] Its validation, including factor validity and high internal consistency, was confirmed in a Japanese study.[64] The overall ZBI-8 score ranges from 0 to 40, with higher scores indicating a greater burden of family care. The FQ, comprising 20 items, evaluates family relationships and emotional attitudes towards other family members with mental illness.[65] Its overall score ranges from 20 to 80, with higher scores reflecting more negative emotional responses by the family towards the patient. The Japanese FQ's convergent validity, concurrent validity, and test–retest reliability have been confirmed in a previous study.[66] We also created the following two original questions on living and economic conditions: "How have you felt about your finances during the past year?" with response options ranging from 0 (very distressed) to 4 (very comfortable), and "What is your primary income?" with options including labour income, asset management, pension, or other. Regarding service frequency, case managers will document the number of outreach services per month provided to the family throughout the follow-up period (Online supplementary table 2).

Table 2. Outcomes and instruments for patient participants

Domain	Outcome	Scale	No of items
Subjective outcome (PROM)	Quality of life	Recovering Quality of Life 10-item version (ReQoL-10)	10
	Personal agency	Five-item Subjective and Personal Agency scale (SPA-5)	5
	Loneliness	University of California, Los Angeles loneliness scale – short form, 10-item version (UCLA-LS-SF-10)	10
	Well-being	Single-item well-being measure	1
	Depression	Patient Health Questionnaire 2-item version (PHQ-2)	2
Clinical condition / outcome	Symptom	Clinical Global Impression scale – Severity (CGI-S)	7
	Symptom	Clinical Global Impression scale – Improvement (CGI-I)	7
	Function	World Health Organization Disability Assessment Schedule 2.0, 12-item version (WHODAS 2.0)	12
	Hospitalisation history and duration	Original questions	
	Medication adherence status	Original questions	
	Physical health	Charlson Comorbidity Index (CCI)	
Social condition / outcome	Living status	Original questions	
	Family structure	Original questions	
	Employment or educational status	Original questions	
Service	Frequency of visiting services (per month)	Original questions	
	Peer support	Original questions	
	Family psychoeducation	Original questions	
	Cognitive behavioural therapy	Original questions	
	The use of particular medications	Original questions	
	The use of social or medical services other than those provided by participating teams	Original questions	

PROM, Patient-reported outcome measures

Table 3. Outcomes and instruments for family participants

Domain	Outcome	Scale	No of items
Subjective outcome (PROM)	Quality of life	Recovering Quality of Life 10-item version (ReQoL-10)	10
	Well-being	Single-item well-being measure	1
	Burden of family care	8-item Zarit Burden Index (ZBI-8)	8
	Family relationships	Family Questionnaire (FQ)	20
Social condition	Living status	Original questions	
	Economic condition	Original questions	

PROM, Patient-reported outcome measures

Sample size consideration

We have established a maximum enrolment limit of 20 patient participants for each team, given the research burden on each team and the feasibility of this study. With 23 teams participating, the theoretical maximum number of participants is set at 460 each for patient participants and family participants. However, given that some teams may enrol fewer than 10 new patients annually and that some patient participants may live alone, we anticipated that the actual number of participants will be around 200 to 300. Given that not all patient participants live with their family members, the number of family participants is expected to be below 200.

Efforts of participant recruitment, retention, and data management

To enhance participant engagement, a gift card worth 300 Japanese yen will be furnished to both patient and family participants upon completion of the PROMs. Likewise, a gift card of equivalent value will be given to the case managers upon completion of observer-rated outcome measures. Furthermore, we plan to conduct meetings at least annually throughout the research period with staff members from all the participating teams and with patients and family members who collaboratively developed this research protocol. These meetings will serve as a platform to discuss and share recruitment and engagement strategies across the teams. We will extend the recruitment period by one year if the sample size is extremely insufficient. Furthermore, we might enlist additional participating teams to increase the numbers of patients and family participants. Consequently, the final number of participating teams may vary from that specified in this protocol.

Since this study employs paper-based questionnaires, the risk of missing data is higher than with online forms. To mitigate this issue, each case manager will conduct a brief preliminary check to identify any omissions in participants' responses. Additionally, the research team members at the National Centre of Neurology and Psychiatry will further screen for missing information upon receipt of data from each team. They also convene regular meetings at least once a month to monitor the research progress according to the protocol and to address any unforeseen challenges that may arise. These approaches will enhance the overall quality of the research data.

Data analysis

Timing of data analysis

The data will be analysed after their collection at the ends of the 5- and 10-year follow-up periods. To monitor the data and provide feedback to the participating teams, we will conduct annual data checks and calculate descriptive statistics but will not publish the annual analysis results as a standalone report each year.

Descriptive statistics

Descriptive summary statistics will be calculated for each variable. These values will be presented as means, standard deviations, medians, interquartile ranges, frequencies, and proportions as appropriate.

Research objectives

For the primary objective, generalised mixed models with repeated measures (MMRM) will be performed to investigate factors influencing changes in the ReQoL-10 score over time, with this score serving as the dependent variable. Key independent variables will include the CGI-S, the WHODAS, and outreach service frequency. We may also include various demographic and social variables such as age, sex, diagnosis, employment, and living status. Additionally, the variable representing the team will be incorporated as a random effect. For the secondary objective, we will conduct the MMRM again, but instead of using the ReQol-10 score as the dependent variable, we will use the SPA-5, UCAL-LS-SF-10, or single-item well-being score. For the third objective, MMRM will also be performed to compare the ReQoL-10 between patients and family members. However, a decade hence, should new and advanced statistical modelling techniques such as latent growth curve modelling or growth mixture modelling be recommended for the analysis of longitudinal data, we may consider employing these methods as an alternative to MMRM. Missing values in the dataset will be addressed using the multiple imputation method, specifically employing multivariate imputation by chained equations if feasible.

ETHICS and DISSEMINATION

The ethical considerations of the current study, including the informed consent process and patient privacy measures, are based on ethics guidelines for medical research in Japan. The study protocol has been approved by the ethical committee of the National Center of Neurology and Psychiatry (No. A2023-065). The study findings will be reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement[69] in peer-reviewed publications, and presented at relevant scientific conferences. We will also ask an organisation involving patients and families to help disseminate the study findings.

Strengths and limitations

The strengths of this study are twofold. First, the participants in this study include family members in addition to patients. Given that multidisciplinary outreach teams typically extend case management services to family members, evaluating their long-term subjective outcome trajectories promises to yield valuable insights. Second, the study protocol was developed collaboratively with service providers, individuals with lived experience of psychiatric disorders, and family members. This collaboration was particularly crucial in selecting outcome measures, taking into account the collaborators' interests and the participants' burden.

However, we recognise at least five study limitations. First, this study does not employ a randomised controlled trial design, and thus cannot definitively ascertain the effects of interventions, it potentially allows for the identification of factors influencing the trajectories of subjective outcomes in patients and their families who receive services from multidisciplinary outreach teams. The second pertains to sample size. Despite the participation of 23 multidisciplinary outreach teams, the annual number of new patients in each team may be limited. Even with the planned 2-year recruitment period, the participant count might be smaller than anticipated. The third limitation concerns the consent process and the collection of PROM data. Although the study employs a two-stage recruitment strategy, acquiring PROM data necessitates obtaining consent directly from the participants. Given that patients often face challenges when commencing services provided by multidisciplinary outreach teams, such as relationship-building difficulties or severe symptoms, it may not be feasible to seek their consent for participation in the research, and consequently, for completing PROMs, particularly at baseline. Fourth, this study does not evaluate or control the detailed service quality of the participating teams. While organisational structures are examined, such as caseload numbers per case manager and others shown in Table 1, and the MMRM analysis accounts for the team variable as a random effect, the study does not provide evidence on the relationship between each team's service quality and the outcomes. Fifth, while the study design, including informed consent, was developed collaboratively by various stakeholders and the employed measures were validated within Japanese settings, the generalisability of the study findings is primarily limited to countries that are in the process of developing community care systems, rather than those with more advanced community mental health services. Furthermore, given that Japanese individuals with mental illness often suffer from strong social norms during their recovery process in community life,[17] the results of subjective outcome measures might be influenced by this aspect of Japanese culture.

Despite the potential methodological limitations, this study covers multiple variables related to the community lives of people with mental illness. Collecting information for certain variables, particularly PROMs, can pose challenges, especially in retrospective or national database studies. As such, the insights derived from this study will be invaluable in comprehending the recovery processes of patients within their community settings.

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Figure title and legend

Figure 1. Locations of the 23 participating teams

Figure 2. Overall study design

1. Follow-up assessment will be conducted in April for participants enrolled from January to June, and in October for participants enrolled from July to December

AUTHOR STATEMENT

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Author Contributions

SY, KU, MI, TK, AH, KY, MN, and SS conceived this work. SY secured the funding. All the authors contributed to the development and refinement of the study protocol. KY, HY, and MW recruited the participating teams. KT played a central role in involving the individuals with lived experience of psychiatric disorders who collaborated in developing the research plan. CF managed research team members. SY, KU, MI, TK, AH, and SS drafted the manuscript. In addition, all the authors have approved the final version of the manuscript.

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Conflicts of interests

The authors declare that there are no conflicts of interest in relation to this study.

Ethics approval

This study was approved by the ethical committee of the National Center of Neurology and Psychiatry (No. A2023-065).

Figure 1. Locations of the 23 participating teams

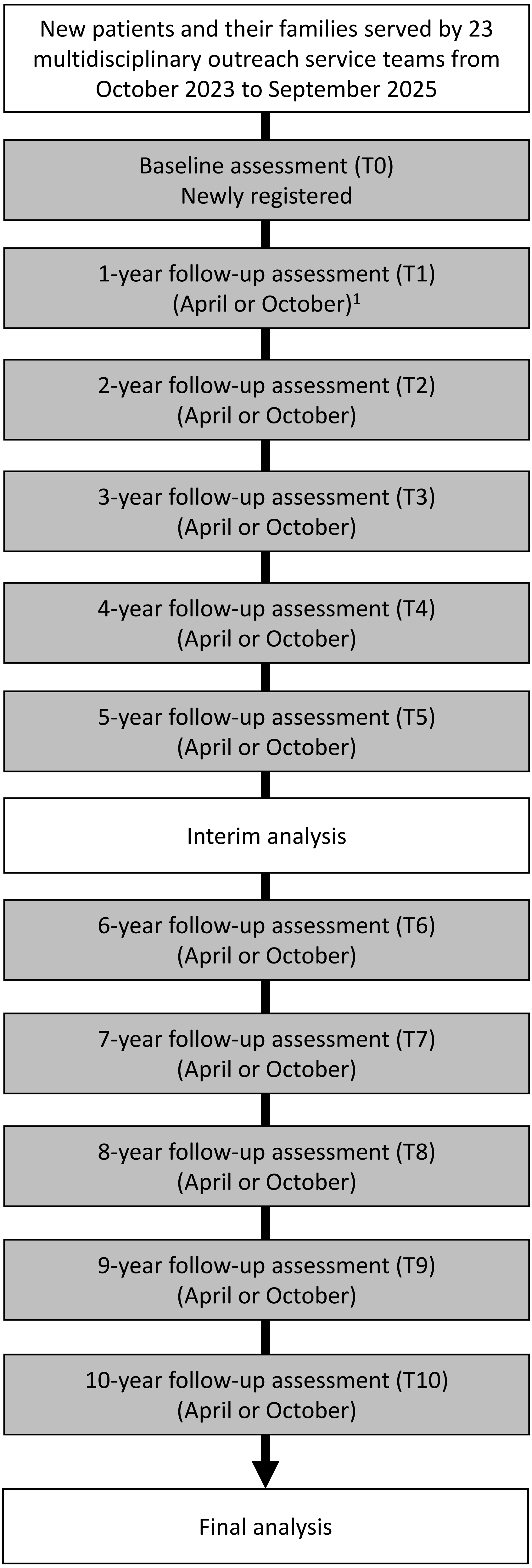

Figure 2. Overall study design

1. Follow-up assessment will be conducted in April for participants enrolled from January to June, and in October for participants enrolled from July to December.

Online supplementary table 1.

Dartmouth Assertive Community Treatment Scale (DACTS) scores among twelve teams

Average score (n = 12)1)	Mean	SD
Overall	3.7	0.2
Human Resources	3.5	0.2
Organizational Boundaries	4.2	0.3
Nature of Services	3.5	0.4

1) Most recent score of DACTS within the past 3 years

Online supplementary table 2.

Timing of assessments of each measure

Subject	Scale (Abbreviation)*	T0	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10
Patient	ReQoL-10	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	SPA-5	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	UCLA-LS-SF-10	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Well-being	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	PHQ-2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	CGI-S	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	CGI-I		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	WHODAS 2.0	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hospitalisation history and duration	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Medication adherence status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Physical health	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Living status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Family structure	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Employment or educational status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Frequency of visiting services (per month)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Peer support		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Family psychoeducation		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Cognitive behavioural therapy		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	The use of particular medications	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	The use of social or medical services other than those provided by participating teams	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Family	ReQoL-10	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Well-being	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	ZBI-8	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	FQ	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Living status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Economic condition	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

* The full spelling of each measure is shown in the main texts.

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Title

Ten-year outcome trajectories of people with mental illness and their families who receive services from multidisciplinary case management and outreach teams: Protocol of a multi-site longitudinal study

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ABSTRACT

Introduction

Individuals with mental illness and their families often undergo their recovery process in their communities. This study explored the long-term outcome trajectories of individuals and families who received case management services provided by multidisciplinary outreach teams in a community setting. The primary objective of this study was to determine whether trajectories of subjective quality of life (QoL) related to personal recovery were linked to those of clinical and societal outcomes and to changes in outreach service frequency.

Methods and analysis

The protocol of this 10-year multi-site cohort study was collaboratively developed with individuals with lived experience of psychiatric disorders who had received services from participating outreach teams, and with family members in Japanese family associations. The participants in the study include patients and their key family members who receive services from 23 participating multidisciplinary outreach teams. The participant recruitment period is set from October 1, 2023, to September 30, 2025. If necessary, the recruitment period may be extended, and the number of the participating teams may be increased. The study will annually evaluate the following outcomes after participants' initial utilisation of services from each team: QoL related to personal recovery, personal agency, feelings of loneliness, well-being, and symptom and functional assessments. The family outcomes encompass QoL, well-being, care burden, and family relationships. Several meetings will be held to monitor progress and manage issues during the study. Multivariate analyses with repeated measures will be performed to investigate factors influencing changes in the patients' QoL scores as the dependent variable.

Ethics and dissemination

The study protocol was approved by the ethical committee of the National Center of Neurology and Psychiatry (no. A2023-065). The study findings will be reported in peer-reviewed publications and presented at relevant scientific conferences.

Trial registration number

University Hospital Medical Information Network – Clinical Trials Registry (UMIN-CTR), No. UMIN000052275

(300 words)

Keywords

Case management, Cohort study, Multidisciplinary outreach teams: multi-site study, Trajectory

Article summary

Strengths and limitations of this study

The study will examine the long-term trajectories of individuals with mental illness who receive services from 23 multidisciplinary case management and outreach teams.

The study will examine the associations between several aspects of recovery in both individuals with mental illness and their families.

The study will comprehensively assess factors influencing recovery-related quality of life and other patient-reported outcomes over the 10-year study period.

The study's outcome measures were defined in collaboration with people with lived experience of psychiatric disorders who had received case management services from multidisciplinary outreach teams, and with family members in Japanese family associations.

Due to the study design, the effects of particular interventions cannot be identified, but the findings may suggest potentially important factors affecting the recovery process of both patients and their family members.

INTRODUCTION

People with mental illness and their families tend to experience a gradual recovery process that occurs over a long period of time in a community setting. Since pharmacotherapies and psychotherapies often show modest effect sizes in terms of symptom improvement,[1] some individuals require ongoing community-based treatments such as comprehensive case management services.[2] Consequently, a long-term perspective is essential when considering their lives and community care.[3] In this study, case management is defined as a service that includes assessment and care planning, daily support, and family support, all provided by multidisciplinary outreach teams in a community setting.[4]

Mental health research has extensively evaluated various aspects of recovery in individuals with mental illness. These aspects encompass at least three domains, as follows: clinical outcomes (e.g., symptoms and readmission), societal outcomes (e.g., social skills, employment, and housing), and personal recovery. Particularly under the international recovery movement led by patient groups over the past two decades, stakeholders have focused on patients' subjective outcomes. While personal recovery refers to a self-directed life journey[5] and cannot be directly measured, Leamy et al revealed its relevant constructs, including Connectedness, Hope and Optimism, Identity, Meaning in life, and Empowerment (CHIME framework).[6] In this context, subjective and proximate outcomes related to personal recovery, assessed through patient-reported outcome measures (PROMs), have increasingly become important in mental health services research.[7 8]

Several studies have examined PROMs and clinical outcomes. For instance, meta-analyses have demonstrated that PROM-based personal recovery is associated with clinical,

functional, and societal recovery.[9 10] Furthermore, a recent 4-year longitudinal study indicated a potential correlation between stable symptomatic remission and self-reported quality of life (QoL) in people who had experienced an initial psychotic episode.[11] Given that personal recovery encompasses various facets and represents a long-term individual journey,[6 12] research with even longer follow-up durations and repeat assessments that include not only a QoL measure but also other PROMs could offer deeper insights into recovery trajectories and the interrelations among different recovery aspects. A notable example is a Danish 10-year cohort study currently conducting repeat assessments of multiple outcomes in people with psychotic disorders.[13] On the other hand, recovery is not a concept focused only on schizophrenia or psychotic disorders.[14 15] Additionally, despite the theoretical notion that recovery does not necessarily imply a reduction in services, few long-term studies have scrutinised the relationship between service frequency and recovery outcomes.[16] Moreover, the recovery process is influenced by cultural factors. For instance, in Japan, interactions with familiar persons are deemed particularly significant among people with mental illness, and loneliness and a lack of connectedness may be more serious issues in the recovery process in a Japanese context.[17] Consequently, there is a keen anticipation for evidence on long-term recovery trajectories related to diverse diagnoses and community service settings.

With regard to community care, case management has emerged as a leading evidence-based practice for supporting individuals with mental illness after deinstitutionalisation. In particular, assertive community treatment (ACT) and intensive case management (ICM) are well-known case management models in which a multidisciplinary outreach team provides frequent, comprehensive services to people with very severe mental illness.[18 19] Two reviews, one by Cochrane, have demonstrated that ACT and ICM effectively reduced the duration of hospital stays for 2 years of follow-up, especially among individuals with severe mental illness who have experienced prolonged hospitalisations.[20 21] Another meta-analysis highlighted the potential effects of ACT and ICM in reducing psychiatric symptoms and family burden, and enhancing social functioning and family satisfaction.[22] Japanese studies have also shown similar benefits of ACT. [23-26] Furthermore, a recent meta-analysis, with an average intervention duration of 16 months, concluded that non-intensive case management yielded small but significant improvements in psychiatric symptoms and QoL.[27] This suggests that case management services across multiple countries have a tangible short-term impact on various aspects of recovery in people with severe mental illness.

Despite a substantial body of literature, the long-term trajectories of individuals receiving case management by multidisciplinary outreach teams remain underexplored. First, while at least six studies with over 5 years of follow-up, including a Japanese trial, have investigated primarily clinical outcomes such as readmission rates among ACT participants, the results have been mixed.[28-34] Two of these studies also measured societal outcomes and QoL,[31 34] yet the range of outcomes assessed may be considered limited. Second, previous long-term studies have often focused on ACT, which typically targets people with schizophrenia and bipolar disorder.[28-32] In real-world community care settings, case management services are frequently provided to individuals diagnosed with a diverse range of mental illnesses,[4 35-37] yet data on long-term trajectories encompassing a variety of diagnoses are scarce. Third, assessment of family outcomes appears to be lacking. Whereas case management has been shown to potentially have short-term effects on reducing family burden,[22 25] studies have seldom addressed long-term outcomes related not only to family members' burdens but also to their QoL and well-being.[28-32] Fourth, although personal recovery does not necessarily equate to graduation from community mental health services,[16] the frequency of case management and outreach services is likely to decrease over time.[38,39] Despite the aforementioned findings, few studies have examined the long-term relationship between the service provision process and subjective outcomes.[13,34] In summary, although existing long-term studies offer promising evidence, further research is required on the long-term trajectories of people with mental illness and their families within the context of case management services.

In a national context, Japan has undergone a significant transition from inpatient to community mental health care since the early 2000s.[40,41] Indeed, the current community mental health system in Japan encompasses a range of services that include visiting nurses, brokering case management services, sheltered workshops, employment services, housing services, and services such as support provided by non-multidisciplinary teams comprising social workers or occupational therapists. Although Japanese health policy does not formally integrate case management services by a multidisciplinary outreach team into the community mental health system, several municipalities and service providers have independently implemented such services. Additionally, the average length of psychiatric hospital stays has decreased from about 500 days in 1990 to approximately 270 days in 2018.[42] These policy changes have led to an increased utilisation of community services among people with mental illness.[43,44] In this context, multidisciplinary outreach teams provide case management services not only for people with schizophrenia and bipolar disorder, but also for those with diverse mental illness diagnoses and a wide variety of medical and social needs. In some areas, multidisciplinary outreach teams adjusted the ACT model to provide case management services corresponding to their own local care systems.[45] In other words, such teams may contribute to community development by treating people with unmet needs. However, since Japan recently launched mental health reforms, information on the long-term outcomes of individuals who require ongoing community care is still limited. This underscores the critical need for empirical evidence regarding the trajectories of individuals with mental illness who receive case management from multidisciplinary outreach teams.

To address the evidence gap, we launched a new project, called the "10-year October/April Follow-up Evaluation of Multidisciplinary Community Outreach Services study (OCTAP-10)". The overarching aim of this project is to describe the changes in outcome measures related to subjective, clinical, and societal outcomes among individuals with mental illness and their families who have received case management services from multidisciplinary outreach teams over a decade-long follow-up period. The study is designed to explore various aspects of the recovery process, and aims to uncover PROM-related mechanisms and factors associated with personal recovery in a community care setting. Specifically, the primary objective of this study is to determine whether trajectories of patients' subjective QoL scores are linked to those of clinical outcomes (e.g., symptoms, readmission, physical health) and societal outcomes (e.g., social functioning, living status, employment) and to changes in outreach service frequency. Secondary objectives involve examining the relationships between other subjective outcome measures (such as subjective personal agency, loneliness, and well-being) and clinical, societal, or service frequency outcomes over time. The third objective is to examine how patients' QoL scores correlate with family members' QoL scores, family relationship or burdens over time.

[Fig 1 about here]

METHODS AND ANALYSIS

Overall design, settings, and public involvement

A 10-year multi-site cohort study is planned. The study protocol has been collaboratively designed by an array of stakeholders, including researchers, service providers, individuals with lived experience of psychiatric disorders who had received case management services from multidisciplinary outreach teams (with two such individuals serving as co-authors), and family members in Japanese family associations. In particular, to improve the feasibility of this study, the project teams jointly established recruitment methods and selected appropriate outcome measures and timings of assessments over the course of several meetings. The participants in the study include patients who newly received services from participating multidisciplinary outreach teams and their key family members. The participant recruitment period is set from October 1, 2023, to September 30, 2025. The study will annually evaluate participants' outcomes following their initial utilisation of services from each team.

Concerning team recruitment, random sampling across all multidisciplinary outreach teams in Japan was impossible due to the absence of Japanese laws establishing a formal system of such teams, resulting in a scarcity of publicly available data on the extent of their establishment throughout the country. Therefore, we selected a convenience sampling strategy, although we did solicit study participation from a broad range of Japanese multidisciplinary outreach teams in collaboration with the Japanese Association of Community Mental Health Outreach Services (https://www.outreach-net.or.jp/). Specifically, the study recruited multidisciplinary outreach teams comprising professionals from at least three different occupations, such as psychiatrists, social workers, nurses, psychologists, occupational therapists, and peer supporters. The geographic distribution of these teams is illustrated in Figure 1, and their characteristics are presented in Table 1. As of October, 2023, the mean number of staff members on each participating team was 9.0 (SD = 4.6), and the mean caseload per staff member was 11.9 (SD = 5.7). Among the 23 teams, the average number of patients who were contacted at least twice in the past 6 months was 72.8 (SD = 46.3). Of these, an average of 70.3 (SD = 45.9) had their last three contacts not at the outreach team's office, but rather in the patient's home or nearby, such as in a coffee shop space, supermarket, or community centre. While this study focuses on patients and their family members who receive multidisciplinary outreach team services that extend beyond assertive community treatment (ACT), the 12participating teams underwent fidelity reviews using the Japanese version of the Dartmouth Assertive Community Treatment Scale (DACTS) within the past 3 years.[46 47] The average overall fidelity score among these teams was 3.7 (SD = 0.2) (Online supplementary table 1). We provided multiple briefings and training sessions to participating teams prior to the start of the study. This study was registered in the University Hospital Medical Information Network – Clinical Trials Registry (UMIN-CTR, No. UMIN000052275), and was approved by the ethical committee of the National Center of Neurology and Psychiatry (No. A2023-065).

Table 1. Characteristics of 23 multidisciplinary case management and outreach teams

Number of clinical staff members	Mean (SD)	9.0 (4.6)
Adjusted number of clinical staff members[1)]	Mean (SD)	6.4 (2.8)
Number of teams containing each type of professional		
Psychiatrist	n (%)	17 (73.9)
Nurse	n (%)	23 (100.0)
Social worker	n (%)	19 (82.6)
Occupational therapy	n (%)	22 (95.7)
Clinical psychologist	n (%)	4 (17.4)
Pharmacist	n (%)	3 (13.0)
Peer support worker	n (%)	3 (13.0)
Number of patients contacted at least twice in the past 6 months	Mean (SD)	72.8 (46.3)
Of the above, the number whose last three contacts were at or near their homes	Mean (SD)	70.3 (45.9)
Number of current caseloads per staff member on each team	Mean (SD)	11.9 (5.7)

1) Staff members working more than 32 hours per week are counted as 1; those working between 16 hours and 32 hours per week are counted as 0.5, and those working less than 16 hours per week are counted as 0.

Eligibility criteria of service users

Eligible participants are 1) patients aged 55 or younger, 2) those diagnosed with mental and behavioural disorders (F00–F90) according to the International Classification of Diseases 10th Revision (ICD-10), and 3) those who are newly receiving services from the participating teams during the recruitment period. With regard to the age criterion, people aged 65 and older in Japan typically utilise elder care services instead of mental health services. Therefore, we have specified this criterion to recruit individuals who will not reach the age of 65 during the 10-year follow-up period. The exclusion criteria are as follows: 1) inability of staff members on each team to explain the study due to the severity of the patient's illness; 2) only temporary registration with each team for use of services; and 3) anticipation that the patient will be difficult to track for personal reasons, such as relocation to a distant location. Upon registration of a potential participant with each participating team, trained case managers or team psychiatrists assess the patient's eligibility.

Eligibility criteria of family members

For family members, we set two eligibility criteria: 1) resides with the patient participating in the study, lives in close proximity to the patient's home, or frequently visits the patient's home; and 2) is a key person within the family. Family members with suspected or confirmed dementia or other relevant conditions that impede their ability to provide informed consent are excluded from the study. If a participating family member passes away during the 10-year study period, we will not recruit an alternate family member to take their place.

Recruitment procedures

This study utilises a two-stage recruitment process. The initial stage involves an opt-out method to ensure participants have the opportunity to decline participation. All participating teams display an official poster that informs participants about the use of observational data from their service and medical records. The National Center of Neurology and Psychiatry also makes this information available on its website. When a new patient is enrolled in each participating team, a trained case manager or team psychiatrist evaluates the patient's eligibility. In the absence of refusal by eligible patients, trained case managers gather data on observer-rated outcome measures, including symptom and function scales, as well as other characteristics including health and societal information such as living situation and employment statues. Following the enrolment of patient participants in the initial stage, trained case managers provide them with a detailed explanation of the study in the second stage, encompassing its aims and ethical considerations. This explanation fully informs patient participants that they can refuse all participation in the study, including the collection of observer-rated outcome measures. It also makes clear that they can withdraw their consent and stop completing surveys at any point during the 10-year follow-up period and can receive outreach services even if they decline the participation. After each individual provides consent, they are asked to complete all the PROMs. In a parallel process, case managers also present a detailed overview of the study to a key family member of the patient participant. If this family member voluntarily agrees to participate, they are subsequently asked to fill out the PROMs specifically designed for family participants.

[Fig 2 about here]

Timing of data collection

A case manager evaluation and an initial survey that includes PROMs for both patients and their families will be carried out at the commencement of services for eligible participants (i.e., upon their enrolment in the study). This initial data collection will serve as the baseline assessment for the study (T0). Subsequent follow-up assessments (T1 to T10) will be carried out annually, in October for individuals who registered between July and December, and in April for those who registered between January and June. For the 1-year follow-up assessment (T1), a gap of up to 3 months may occur in the timing of follow-up. Considering the 10-year duration of this follow-up study, minimising the case managers' burden is essential. Consequently, after consultation with the participating teams, it was determined to be viable and practical to schedule follow-up assessments twice each year (in October and April). Figure 2 details the schedule for these assessments. Even if patient participants graduate from their involvement with each participating team, case managers maintain contact with them and continue ongoing data collection.

Research measures and variables

At baseline assessment (T0), we collect demographic information such as age, sex, diagnosis based on ICD-10, academic grade, and use of social benefits. The other exposure and outcome measures used at each time point in this study are detailed in Tables 2 and 3. They were selected on the basis of an internationally recommended set of outcome measures for psychotic disorders and through discussion with multiple stakeholders. When choosing PROMs for use in this study, we considered their validity in both patients and family members within a Japanese cultural context, as well as their availability in a Japanese language version. Consequently, all the scales used in this study are presented in Japanese and employed paper-based questionnaires rather than online forms.

PROMs for patients

For patients, the study utilises five PROMs at all time points. These include the following: the Recovering Quality of Life 10-item version (ReQoL-10) as the primary outcome measure;[48] the five-item Subjective and Personal Agency scale (SPA-5);[49] the University of California, Los Angeles loneliness scale – short form, 10-item version (UCAL-LS-SF-10);[50 51] the single-item well-being measure;[52] and the Patient Health Questionnaire 2-item version (PHQ-2).[53-55]

The ReQoL-10, serving as a shorter version of the 20-item ReQoL, comprises 10 items with scores ranging from 0 to 40.[48] The Japanese translation and back-translation of the ReQoL-

10 were conducted by Oxford University Innovation (https://innovation.ox.ac.uk/). The authors confirmed the accuracy of translations.[56] A higher score indicates a better QoL related to personal recovery. The SPA-5 is designed to measure personal agency in people with severe mental illness, and encompasses five items. The scale originated in Japan and was developed through collaboration between researchers and people with schizophrenia.[49] Its overall score ranges from 5 to 25, with higher scores reflecting a stronger sense of personal agency in community life. The UCLA-LS-SF-10 assesses subjective feelings of loneliness and social isolation. While the original UCLA-LS consists of 20 items,[50] a Japanese study validated a 10-item short form (scoring range 10–40), with higher scores indicating greater feelings of loneliness.[51] The single-item well-being measure asks, "Overall, how satisfied are you with life as a whole these days?" using a 0–10 scale, where 0 means "Not at all" and 10 means "Completely". This measure, suggested by VanderWeele et al.[52] is also employed in a Japanese government survey to quickly evaluate an individual's well-being.[57] The PHQ-2 is a self-rated tool for depression screening, and is based on the Diagnostic and Statistical Manual of Mental Disorders.[53-55] The PHQ has several versions; however, this study employs the two-item version to minimise participant burden.[55] The scoring range for the PHQ-2 is 0 to 6, with higher scores indicating more severe depressive symptoms.

Observer-rated outcome measures for patients

The study uses two clinical and social outcome measures rated by trained case managers. Symptom assessment is performed using the Clinical Global Impression scales, encompassing the CGI-S (Severity) and CGI-I (Improvement) measures.[58 59] Both scales are rated on a 7-point scale, with responses ranging from 1 (Normal or Very much improved) to 7 (Among the most severely ill or Very much worse). The CGI-S will be utilised at all time points, but the CGI-I will be excluded at the baseline assessment (T0) due to the nature of the scale. Another staff-rated evaluation is the 12-item version (short-form) of the World Health Organization Disability Assessment Schedule 2.0 (WHODAS), which is designed to assess social functioning and community activities among participants.[60] Although WHODAS is available in a 36-item version, research within a Japanese community mental health care setting has demonstrated a high correlation between the total scores of the 12- and 36-item versions.[61] The scoring for the 12-item WHODAS ranges from 0 to 100, with higher scores indicating increased difficulty in community living.

Other health, social, and service exposure variables for patients

Case managers will gather the following participant information from medical records at each assessment point: living status (such as living with family or alone), family structure, employment or educational status, hospitalisation history and duration, and medication adherence status (categorised as No prescription, Unknown medication status, Taking medication but irregularly, or Taking medication as prescribed). Additionally, the Charlson Comorbidity Index (CCI) will be used to rate participants' physical health. The CCI evaluates the severity and number of comorbidities on the basis of the ICD.[62 63] With regard to service and treatment variables, the use of particular medications (e.g., antipsychotic drugs, clozapine, and long-acting injections) and of social or medical services other than the participating teams are investigated at every assessment point. Beginning with the 1-year follow-up assessment (T1), the study will also evaluate the frequency of visiting services provided monthly to each participant. Additionally, it will examine the provision of specific services such as peer support, family psychoeducation, and cognitive behavioural therapy offered by the participating teams.

Outcome measures and service frequency evaluations for family members

Similar to the patient participants, family members participating in the study will complete the ReQoL-10 [48] and single-item well-being measure.[52] Additionally, two validated family-reported outcome measures are employed: the eight-item Zarit Burden Index (ZBI-8)[64] and the Family Questionnaire (FQ).[65 66] The ZBI-8, a shortened version of the original 22-item ZBI, assesses the burden of family care.[67 68] Its validation, including factor validity and high internal consistency, was confirmed in a Japanese study.[64] The overall ZBI-8 score ranges from 0 to 40, with higher scores indicating a greater burden of family care. The FQ, comprising 20 items, evaluates family relationships and emotional attitudes towards other family members with mental illness.[65] Its overall score ranges from 20 to 80, with higher scores reflecting more negative emotional responses by the family towards the patient. The Japanese FQ's convergent validity, concurrent validity, and test–retest reliability have been confirmed in a previous study.[66] We also created the following two original questions on living and economic conditions: "How have you felt about your finances during the past year?" with response options ranging from 0 (very distressed) to 4 (very comfortable), and "What is your primary income?" with options including labour income, asset management, pension, or other. Regarding service frequency, case managers will document the number of outreach services per month provided to the family throughout the follow-up period (Online supplementary table 2).

Table 2. Outcomes and instruments for patient participants

Domain	Outcome	Scale or information source
Subjective outcome (PROM)	Quality of life	Recovering Quality of Life 10-item version (ReQoL-10)
	Personal agency	Five-item Subjective and Personal Agency scale (SPA-5)
	Loneliness	University of California, Los Angeles loneliness scale – short form, 10-item version (UCLA-LS-SF-10)
	Well-being	Single-item well-being measure
	Depression	Patient Health Questionnaire 2-item version (PHQ-2)
Clinical condition / outcome	Symptom	Clinical Global Impression scale – Severity (CGI-S)
	Symptom	Clinical Global Impression scale – Improvement (CGI-I)
	Function	World Health Organization Disability Assessment Schedule 2.0, 12-item version (WHODAS 2.0)
	Hospitalisation history and duration (days)	Medical or service records
	Medication adherence status	Medical or service records
	Physical health	Charlson Comorbidity Index (CCI)
Social condition / outcome	Living status	Medical or service records
	Family structure	Medical or service records
	Employment or educational status	Medical or service records
Service	Frequency of visiting services (per month)	Medical or service records
	Peer support	Medical or service records
	Family psychoeducation	Medical or service records
	Cognitive behavioural therapy	Medical or service records
	The use of particular medications	Medical or service records
	The use of social or medical services other than those provided by participating teams	Medical or service records

PROM, Patient-reported outcome measures

Table 3. Outcomes and instruments for family participants

Domain	Outcome	Scale
Subjective outcome (PROM)	Quality of life	Recovering Quality of Life 10-item version (ReQoL-10)
	Well-being	Single-item well-being measure
	Burden of family care	8-item Zarit Burden Index (ZBI-8)
	Family relationships	Family Questionnaire (FQ)
Social condition	Living status and Economic condition	Original questions "How have you felt about your finances during the past year?" "What is your primary source of income?"

PROM, Patient-reported outcome measures

Sample size consideration

We have established a maximum enrolment limit of 20 patient participants for each team, given the research burden on each team and the feasibility of this study. With 23 teams participating, the theoretical maximum number of participants is set at 460 each for patient participants and family participants. However, given that some teams may enrol fewer than 10 new patients annually and that some patient participants may live alone, we anticipated that the actual number of participants will be around 200 to 300. Given that not all patient participants live with their family members, the number of family participants is expected to be below 200.

Efforts of participant recruitment, retention, and data management

To enhance participant engagement, a gift card worth 300 Japanese yen will be furnished to both patient and family participants upon completion of the PROMs. Likewise, a gift card of equivalent value will be given to the case managers upon completion of observer-rated outcome measures. Furthermore, we plan to conduct meetings at least annually throughout the research period with staff members from all the participating teams and with patients and family members who collaboratively developed this research protocol. These meetings will serve as a platform to discuss and share recruitment and engagement strategies across the teams. We will extend the recruitment period by one year if the sample size is extremely insufficient. Furthermore, we might enlist additional participating teams to increase the numbers of patients and family participants. Consequently, the final number of participating teams may vary from that specified in this protocol.

Since this study employs paper-based questionnaires, the risk of missing data is higher than with online forms. To mitigate this issue, each case manager will conduct a brief preliminary check to identify any omissions in participants' responses. Additionally, the research team members at the National Centre of Neurology and Psychiatry will further screen for missing information upon receipt of data from each team. They also convene regular meetings at least once a month to monitor the research progress according to the protocol and to address any unforeseen challenges that may arise. These approaches will enhance the overall quality of the research data. If missing values persist despite our monitoring efforts, we will first attempt missing value imputation as per the scoring guidelines of each scale, if available. For instance, the ReQoL scoring guide specifies that if a single question is unanswered, the mean value of the other responses should be used. If a scale lacks a specific scoring guide, we will address the missing data using appropriate statistical analysis methods.

Data analysis

Timing of data analysis

The data will be analysed mainly after their collection at the ends of the 5- and 10-year follow-up periods. These analyses will include the descriptive statistics for all the variables and multivariate analysis corresponding to the research objectives. To monitor the data and provide feedback to the participating teams, we will conduct annual data checks and calculate descriptive statistics. For example, the annual analysis will only calculate the drop-out rate and the means of each scale. We will not publish the annual analysis results as a standalone report each year.

Descriptive statistics

Descriptive summary statistics will be calculated for each variable. These values will be presented as means, standard deviations, medians, interquartile ranges, frequencies, and proportions as appropriate.

Analysis corresponding to the objectives

For the primary objective, generalised mixed models with repeated measures (MMRM) will be performed to investigate factors influencing changes in the ReQoL-10 score over time, with this score serving as the dependent variable. Key independent variables will include the CGI-S, the WHODAS, and outreach service frequency. We may also include various demographic and social variables such as age, sex, diagnosis, employment, and living status. Additionally, the variable representing the team will be incorporated as a random effect. For the secondary objective, we will conduct the MMRM again, but instead of using the ReQol-10 score as the dependent variable, we will use the SPA-5, UCAL-LS-SF-10, or single-item well-being score. For the third objective, MMRM will also be performed to compare the ReQoL-10 between patients and family members. However, a decade hence, should new and advanced statistical modelling techniques such as latent growth curve modelling or growth mixture modelling be recommended for the analysis of longitudinal data, we may consider employing these methods as an alternative to MMRM. Missing values in the dataset will be addressed using the multiple imputation method, specifically employing multivariate imputation by chained equations if feasible.

ETHICS and DISSEMINATION

The ethical considerations of the current study, including the informed consent process and patient privacy measures, are based on ethics guidelines for medical research in Japan. The study protocol has been approved by the ethical committee of the National Center of Neurology and Psychiatry (No. A2023-065). The study findings will be reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement[69] in peer-reviewed publications, and presented at relevant scientific conferences. We will also ask an organisation involving patients and families to help disseminate the study findings.

Strengths and limitations

The strengths of this study are twofold. First, the participants in this study include family members in addition to patients. Given that multidisciplinary outreach teams typically extend case management services to family members, evaluating their long-term subjective outcome trajectories promises to yield valuable insights. Second, the study protocol was developed collaboratively with service providers, individuals with lived experience of psychiatric disorders, and family members. This collaboration was particularly crucial in selecting outcome measures, taking into account the collaborators' interests and the participants' burden.

However, we recognise at least five study limitations. First, this study does not employ a randomised controlled trial design, and thus cannot definitively ascertain the effects of interventions, it potentially allows for the identification of factors influencing the trajectories of subjective outcomes in patients and their families who receive services from multidisciplinary outreach teams. The second pertains to sample size. Despite the participation of 23 multidisciplinary outreach teams, the annual number of new patients in each team may be limited. Even with the planned 2-year recruitment period, the participant count might be smaller than anticipated. This situation may result in a lack of statistical power, potentially leading to a Type II error. The third limitation concerns the consent process and the collection of PROM data. Although the study employs a two-stage recruitment strategy, acquiring PROM data necessitates obtaining consent directly from the participants. Given that patients often face challenges when commencing services provided by multidisciplinary outreach teams, such as relationship-building difficulties or severe symptoms, it may not be feasible to seek their consent for participation in the research, and consequently, for completing PROMs, particularly at baseline. In other words, the PROM data will not reflect all the experiences of people who receive the services of the 23 multidisciplinary outreach teams. Fourth, this study does not control the detailed service quality of the participating teams or evaluate their fidelity, since it examined multidisciplinary outreach teams and not just those providing ACT. While organisational structures are examined, such as caseload numbers per case manager and others shown in Table 1, and the MMRM analysis accounts for the team variable as a random effect, the study does not provide evidence on the relationship between each team's service quality and the outcomes. Fifth, while the study design, including informed consent, was developed collaboratively by various stakeholders and the employed measures were validated within Japanese settings, the generalisability of the study findings is primarily limited to countries that are in the process of developing community care systems, rather than those with more advanced community mental health services. Furthermore, given that Japanese individuals with mental illness often suffer from strong social norms during their recovery process in community life.[17] Indeed, a meta-analysis revealed that individuals with schizophrenia in Asian countries, including Japan, generally had lower QoL scores compared with those in European countries.[70] Consequently, the scores of subjective outcome measures in this study might be low due to the influence of cultural factors, and this pattern could persist throughout the follow-up period regardless of improvements in clinical and societal outcomes.

Summary and implications

This study will delineate the trajectories of several recovery types in patients with mental illness and their families, all of whom receive services from Japanese multidisciplinary outreach teams. Despite the potential methodological limitations, this study covers multiple variables related to the community lives of people with mental illness. Collecting information for certain variables, particularly PROMs, can pose challenges, especially in retrospective or national database studies. The analyses in this study will shed light on the relationships between changes in PROMs and other outcome dimensions over time. They will potentially allow for the identification of factors influencing the trajectories of subjective outcomes in patients and their families who receive services from multidisciplinary outreach teams in Japan, where people generally perceive strong social norms. Such insights will be invaluable in comprehending the recovery processes of patients within their community settings, and could significantly contribute to the development of future effective community mental health interventions in a variety of cultural contexts not limited to Western culture.

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Figure title and legend

Figure 1. Locations of the 23 participating teams

Figure 2. Overall study design

1. Follow-up assessment will be conducted in April for participants enrolled from January to June, and in October for participants enrolled from July to December

AUTHOR STATEMENT

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Author Contributions

Sosei Yamaguchi, Kaori Usui, Mai Iwanaga, Takayuki Kawaguchi, Ayako Hada, Koji Yoshida, Masaaki Nishio, and Sayaka Sato conceived this work. Sosei Yamaguchi secured the funding and acted as guarantor. All the authors contributed to the development and refinement of the study protocol. Koji Yoshida, Hidemaro Yanata, and Mariko Watanabe recruited the participating teams. Kenichirou Taniguchi played a central role in involving the individuals with lived experience of mental health condition who collaborated in developing the research plan. Hirofumi Aoki and Yuichiro Hisajima provided valuable insights and contributed to the development of our protocol, drawing on their lived experiences with mental health conditions. Chiyo Fujii managed research team members. Sosei Yamaguchi, Kaori Usui, Mai Iwanaga, Takayuki Kawaguchi, Ayako Hada, and Sayaka Sato drafted the manuscript. In addition, all the authors have approved the final version of the manuscript.

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Conflicts of interests

The authors declare that there are no conflicts of interest in relation to this study.

Ethics approval

This study was approved by the ethical committee of the National Center of Neurology and Psychiatry (No. A2023-065).

Figure 1. Locations of the 23 participating teams

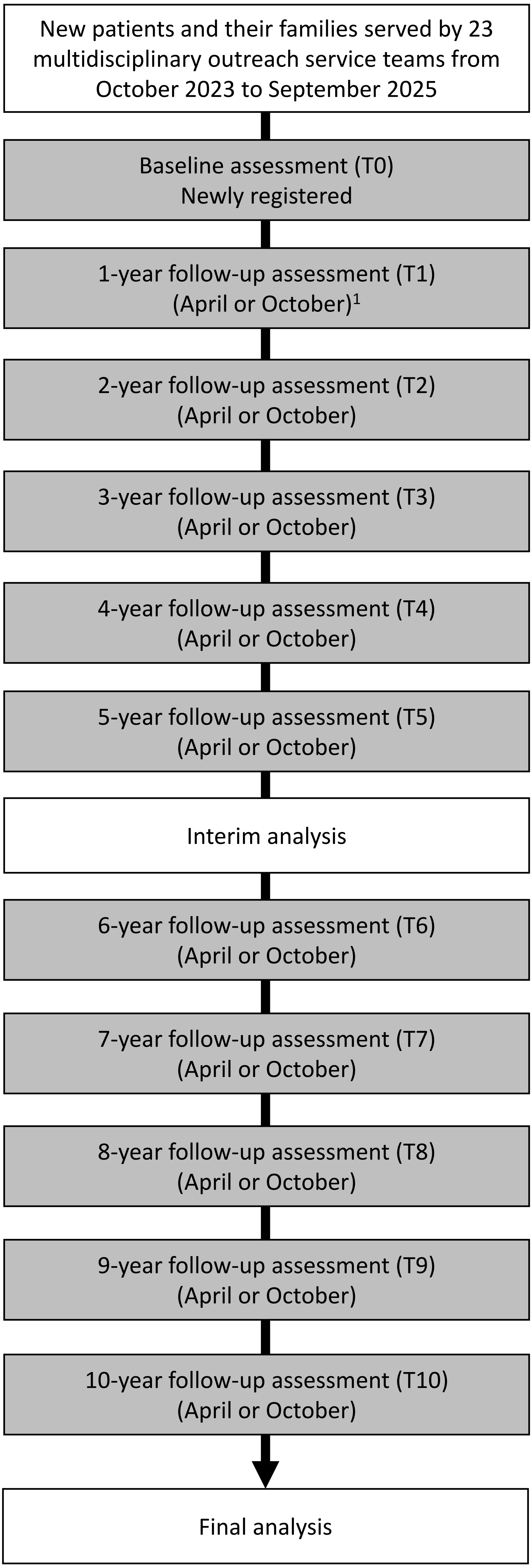

Figure 2. Overall study design

1. Follow-up assessment will be conducted in April for participants enrolled from January to June, and in October for participants enrolled from July to December.

Online supplementary table 1.

Dartmouth Assertive Community Treatment Scale (DACTS) scores among twelve teams

Average score (n = 12)[1]	Mean	SD
Overall	3.7	0.2
Human Resources	3.5	0.2
Organizational Boundaries	4.2	0.3
Nature of Services	3.5	0.4

1) Most recent score of DACTS within the past 3 years

Online supplementary table 2.

Timing of assessments of each measure

Subject	Scale (Abbreviation)*	T0	T1	T2	T3	T4	T5	T6	T7	T8	T9	T10
Patient	ReQoL-10	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	SPA-5	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	UCLA-LS-SF-10	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Well-being	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	PHQ-2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	CGI-S	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	CGI-I		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	WHODAS 2.0	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Hospitalisation history and duration	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Medication adherence status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Physical health	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Living status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Family structure	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Employment or educational status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Frequency of visiting services (per month)		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Peer support		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Family psychoeducation		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Cognitive behavioural therapy		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	The use of particular medications	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	The use of social or medical services other than those provided by participating teams	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Family	ReQoL-10	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Well-being	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	ZBI-8	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	FQ	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Living status	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Economic condition	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

* The full spelling of each measure is shown in the main texts.