Protocol for a prospective multicentre registry cohort study on suicide attempters given the assertive case management intervention after admission to an emergency department in Japan: post-ACTION-J Study (PACS)

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ABSTRACT
Introduction Suicide attempt is the most important risk factor for later suicide. A randomised-controlled, multicentre trial of postsuicide attempt case management for the prevention of further suicide attempts in Japan, named ACTION-J, has established effective interventions for prevention of suicide reattempts. The ACTION-J assertive case management intervention programme was adopted by the Japanese Ministry of Health, Labour and Welfare in 2016, when medical fees were revised. This nationwide programme is provided to patients who attempt suicide and who are admitted to emergency departments in Japan. The aim of the present study is to examine the current implementation status of the ACTION-J programme. The present study also aims to clarify which patients’ and hospitals’ factors affect the implementation of the programme.

Methods and analysis This is a prospective, multicentre, patient registry cohort study. Participants will be suicide attempters admitted to the emergency departments of medical facilities with both psychiatry and emergency departments. The assertive case management programme will be delivered to participants by a case manager for up to 24 weeks, based on psychiatric diagnoses, social risks and patient needs. The core feature of the programme is to encourage patients to participate in psychiatric treatment. The primary outcome will be the proportion of patients still participating in the case management intervention at 24 weeks after registration. The secondary outcomes will include measures of the fidelity of the case management intervention. The fidelity will be evaluated using a fidelity assessment manual developed by the study group.

Ethics and dissemination This observational study has been approved by the ethics board of Sapporo Medical University. Enrolment began in October 2016 and will continue until December 2018. Dissemination plans include presentations at scientific conferences and scientific publications.

Strengths and limitations of this study
► This study is conducted in real clinical world settings involving both emergency and psychiatric departments.
► The assertive case management intervention programme given to suicide attempters has been already proved feasible and effective by a randomised-controlled trial.
► The number of medical facilities participating in this study is limited.

Trial registration UMIN000024474.

INTRODUCTION
Background and rationale Suicide attempt is the most important risk factor for later suicide.1–3 There have been many efforts to establish effective interventions to prevent suicide reattempts, such as a randomised-controlled trial conducted by Morthorst et al (2013), which tested the effectiveness of the assertive case management intervention.4–7 Case management seems to be effective for individuals, such as suicide attempters, with multiple suicide risk factors. However, Morthorst et al’s intervention did not result in a significant reduction in suicide attempts, possibly because of the small sample size.

Patients who are severely and physically impaired following a suicide attempt are admitted to tertiary emergency departments to receive physical care. In the early 2000s, the Advanced Critical Care and Emergency...
Table 1  Features of the assertive case management intervention derived from the ACTION-J trial

|   | Features                                                                 |
|---|-------------------------------------------------------------------------|
| 1 | Periodic contact (either face-to-face or via telephone) with participants at the participating hospitals during their stay at the emergency department and after discharge |
| 2 | Collection of information about each participant's treatment status and social problems that could disturb their treatment adherence |
| 3 | Encouragement of participants to adhere to psychiatric treatment         |
| 4 | Coordination of appointments with psychiatrists and primary care physicians |
| 5 | Encouragement of participants who discontinued receiving psychiatric treatment to return to treatment |
| 6 | Referrals to social services and private support organisations and coordination for use of these resources to accommodate their individual needs |
| 7 | Provision of the content of psychoeducation and the information about social resources through a dedicated website |

Centre of the Yokohama City University Medical Centre began offering psychological crisis intervention and psychiatric assessments, as well as case management interventions, and demonstrated the effectiveness of this type of intervention model. Thus, in 2005, a randomised-controlled, multicentre trial of postsuicide attempt case management for the prevention of further suicide attempts in Japan, named ACTION-J, was conducted as part of the Ministry of Health, Labour and Welfare’s ‘Strategic research projects’, which aimed to formulate national policies for pressing health issues in Japan, such as suicide. The ACTION-J research group consisted of 17 Japanese hospitals with both an emergency department and a psychiatric department. Potential study participants were suicide attempters who had been admitted to the emergency department and received critical care. After the crisis intervention, an assertive case management intervention, which includes psychoeducation, was provided by trained case managers. The intervention was based on psychiatric diagnoses, social risks and patient needs during the patients’ stay in the emergency departments and continued for at least 1.5 years after discharge. The core feature of the programme was to encourage patients to participate in psychiatric treatment (table 1). The primary outcome of the trial was the first recurrence of suicidal behaviour (attempted suicide or completed suicide). A total of 914 participants was enrolled in the trial. The results showed that the cumulative incidence of first recurrent suicidal behaviour was significantly lower in the assertive case management intervention group than in the control group. Therefore, the assertive intervention programme was adopted to the medical payment scheme by the Japanese Ministry of Health, Labour and Welfare in 2016, when medical fees were revised. The intervention is provided to suicide attempt patients admitted to emergency departments in Japan.

Specific aim
The present study aims to examine the current implementation status of the ACTION-J intervention programme and to determine whether the ACTION-J assertive case management programme works in a real world clinical setting. The present study also aims to clarify which patients’ or hospitals’ factors and psychological measures affect the implementation of the intervention programme.

Significance
Suicide attempt is the most important risk factor for later suicide.

METHODS AND ANALYSIS
Study design
The post-ACTION-J Study (PACS) is a prospective, multicentre, patient registry cohort study. Each participating medical facility has both psychiatry and emergency departments. These facilities also have a case manager who implements the assertive case management intervention derived from the ACTION-J trial with psychiatrists and other medical personnel in each facility. Baseline data of each participating hospital were used to estimate the number of participants as 200.

Recruitment and task schedule
Potential study participants in this cohort are suicide attempters admitted to the emergency departments of nine participating medical facilities (see online supplementary appendix). While the suicide attempters receive critical care, the emergency doctors will consult psychiatrists. After suicide attempters receive physical stabilisation and alert consciousness has been confirmed, potential study participants will receive thorough psychological assessment, including evaluations of the social, psychological and motivational factors specific to the self-harm event and an assessment of mental health, social risks and needs. The trained psychiatrists in the study group will check the inclusion and exclusion criteria. They will provide potential study participants with a complete description of this study, and ask them to give their informed consent. Then, the psychiatrists or other trained medical study group personnel will administer semistructured psychoeducation developed by the ACTION-J Trial. After the psychoeducation session, patients will be provided with an information pamphlet in which social resources (eg, healthcare sector and consultation services provided by local governments) are listed. The assertive and continuous case management
intervention (table 1) will then be offered to participants by officially trained case managers (psychiatric social workers or clinical psychologists). Psychoeducation will also be provided to family members during the participants’ hospital stay. The case management intervention will be provided during their hospital stay and provided periodically after discharge. The case manager will contact participants at the hospital every month for 6 months after registration. The assertive case management intervention will be implemented through direct face-to-face dialogue. Table 1 shows the assertive case management programme.

Study participants
The PACS will target individuals admitted to the emergency departments of nine participating medical facilities because of suicide attempts.

Inclusion/exclusion criteria
The inclusion criteria are: (1) Individuals admitted to an emergency department and assessed by physicians as likely to have inflicted self-injury. (2) Individuals with self-injury who are confirmed as having suicidal ideation according to multiple psychiatric assessments. (3) Individuals who provide informed consent for participation in the ACTION-J intervention programme.

Exclusion criteria are: (1) Individuals with impaired consciousness at the time of informed consent. (2) Individuals who do not understand Japanese. (3) Individuals who are unsuitable for registration in the present study for any other reasons.

Data collection
The data collection process will be as follows (the schedule is shown in table 2):

Basic patient data
This will comprise initials, ID, age, sex, cohabitants, marital status, education, employment status, family history, advisor, history of medical treatment and drinking habits.

Psychiatric evaluation
Psychiatric evaluation will comprise index suicide attempt, history of psychiatric care and psychiatric diagnosis made by at least two psychiatrists according to the criteria of the Diagnostic and Statistical Manual of Mental Disorders, fifth edition.

Detailed case management information
This will comprise any clinical records.

Survival, suicide reattempts, self-harm
This will comprise number of survivals and any events, including suicide reattempts, deliberate self-harm and suicide ideation.

Treatment adherence
Information about psychiatric treatment and any medical treatment will be recorded.

| Table 2 | Task schedule |
| --- | --- |
| During admission | Inform consent, and registration |
| Four weeks after registration | psychiatric evaluation and diagnosis |
| Eight weeks after registration | Assertive case management |
| Twelve weeks after registration | confirmation of survival and suicide-related events |
| Eighteen months | Treatment adherence |
| Twenty weeks | BAQ |
| Twenty-four weeks | BIS |
| Eighteen months | C-SSRS |
| BAQ, Buss-Perry Aggression Questionnaire; BDI-II, Beck Depression Inventory-II; BIS, Barratt Impulsiveness Scale; C-SSRS, Columbia-Suicide Severity Rating Scale. |
Psychological measures
Buss-Perry Aggression Questionnaire (BAQ): Aggression is a key personality trait and a risk factor associated with suicidal behaviour. The BAQ is one of the most widely used tests for measuring trait aggression.\(^{11-13}\)

Barratt Impulsiveness Scale (BIS): Impulsivity is a key personality trait and a risk factor associated with suicidal behaviour. The BIS is one of the most widely used tests for measuring trait impulsivity.\(^{14,15}\)

Columbia-Suicide Severity Rating Scale (C-SSRS): The C-SSRS is a standardised measure that permits comprehensive assessment of suicidal behaviour and ideation.\(^{16}\)

Beck Depression Inventory-II (BDI-II): The BDI-II is one of the most widely used tests for measuring severity of depression.\(^{17}\)

Fidelity assessment of case management intervention
The outcomes include measurement of the fidelity of the case management intervention. This is crucial in assessing to what extent the intervention prevents suicide reattempts. Fidelity will be evaluated using the fidelity assessment manual developed by the study group. The development process and interval validation of this measure will be reported.

Outcomes
Outcome measures are as follows:

Primary outcome
This is the proportion of the study sample still participating in the continued case management intervention at 24 weeks (6 months) after registration.

Secondary outcomes
1. The following items will be assessed at 24 weeks (6 months) after registration:
   1. Incidence rate (person-years) and proportion of deaths (suicides and any cause), first recurrent suicide attempts/self-injury and frequency of suicide attempts/self-injury
   2. Scores on fidelity assessment of case management intervention
   3. Proportion of treatment adherence
   4. BAQ scores
   5. BIS scores
   6. Difference in C-SSRS scores from baseline to 24 weeks
   7. Difference in BDI-II scores from baseline to 24 weeks
2. The following items will be assessed at 18 months postregistration:
   Incidence rate and proportion of deaths (suicides or any cause), first recurrent suicide attempts/self-injury and frequency of suicide attempts/self-injury
   None of the outcome assessments will be blinded.

Stages of the study
Study period: October 2016 through March 2021
Registration: 31 December 2018

Follow-up: 30 June 2019

Statistical analysis plan
The analysis will be of an exploratory nature. The primary analysis will be based on all the available patient data and will measure the primary outcome. Multivariable logistic regression models will be used to estimate ORs to obtain predictive factors from the binary data. Multivariable Poisson regression models will be used to obtain the incidence rate ratio for frequency of suicide attempts. Then, a zero-inflated Poisson model will be used if the data warrant it. Multivariable linear regression will be performed on the continuous variables (psychological measures). Predictors such as age, sex, cohabitants, marital status, education, employment status, family history, advisor, history of medical treatment, drinking habits, C-SSRS, BDI-II and psychiatric diagnosis will be included into the models. Backward variable selection will be used on the models. Effect estimates, 95% CIs and p values, will be calculated. As a complementary analysis, Cox regression on time-to-event model will be used to analyse secondary outcomes (eg, survival, first recurrent suicide attempts and first recurrent acts of self-injury) if data will be available. Multiple imputations will be performed on the data, if some data will be not available.

The following subgroup analyses will be conducted:
(1) Diagnosis (those with personality disorders). (2) Less than 18 years of age. (3) By emergency care facility.

We plan to include 200 patients. If we assume that a power analysis indicates 100 non-exposure patients whose prior data indicate an event proportion of 0.1 and 100 exposure patients with an event proportion of 0.25, the statistical power will be 0.802 with an α level of 0.05.

Safety management
The study group will design a counselling system to enable case managers to consult each other about case management interventions. The on-site research staff at the participating hospitals will take necessary and appropriate actions to ensure the safety of participants if a serious adverse event occurs or if a participant is at imminent risk of suicide during the study. The on-site research staff will contact the on-site research coordinator at the hospital.

The assertive case management intervention has been adopted by the national medical payment system in Japan; therefore, we do not anticipate any negative health impact from the research itself. If health issues arise among any of the participants, these will be handled through the normal protocols of medical care provision.

Strengths and limitations
Strengths
This study follows on from the ACTION-J trial, a randomised-controlled trial that demonstrated the effectiveness of an assertive case management intervention for
reducing the short-term risk of repeated suicide attempts after discharge from emergency departments. The ACTION-J study has also shown that the assertive case management programme is feasible. With the recent introduction of the assertive case management intervention payment scheme, the implementation and feasibility of the ACTION-J assertive case management programme in real-world clinical settings (and the factors influencing feasibility, fidelity and dissemination of the programme) need investigation. As the national medical fee system covers interventions for suicide attempters, participating facilities can obtain funding for this intervention. Thus, we believe that the study protocol has high feasibility.

Limitations
As the national medical fee payment scheme for the assertive case management intervention has just been launched, the number of participating medical facilities is limited.

The number of case managers varies among facilities. In the case of facilities with only one or a few case managers, it will be hard to discriminate between the effect of facility characteristics and the effect of case manager characteristics on the outcome variables.

Compliance
The case management implementation rate at 24 weeks (6 months) postregistration is the primary outcome. Quality assessment of case management and treatment adherence are the secondary outcomes.

Patient and public involvement
This study is a disseminating research. Participation of patients is not for development of new medical intervention methods. The patients are not directly involved in the study design and conduct of the present study.

ETHICS AND DISSEMINATION
The rights and welfare of study participants will be protected according to the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects. This study complies with the ethical guidelines of the Japanese Ministry of Health, Labour and Welfare. Ethical validity, including the safety, scientific legitimacy and reliability of results, will be ensured and approved by the Research Ethical Committee of Sapporo Medical University (registered, 282–81), and the institutional review boards of each participating facility, Institutional Review Boards of Nara Medical University (registered, 1429), Institutional Review Boards of Kindai University (registered, 28–144), Institutional Review Boards of Kumamoto Medical Centre (registered, 721), Institutional Review Boards of Kansai Medical University (registered, T28-15), Institutional Review Boards of Keio University (registered, 20160310), Institutional Review Boards of Japan Medical University (registered, 28-01-708), Institutional Review Boards of Iwate Medical University (registered, H28-96), and Institutional Review Boards of University of Occupational and Environmental Health (registered, H29-139). Written informed consent and assent will be obtained from participants. If important protocol modifications are made, they will be submitted to the Research Ethical Committee of Sapporo Medical University and the institutional review boards of each participating facility.

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Reporting and dissemination
The principal investigator will have access to the final study data set. The principal investigator will decide the authorship eligibility, and the results of this study will be presented at national and international meetings and published in a scientific journal. Participants will not be individually notified of the study results.

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Collaborators
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Contributors
CK, NY and MY conceived the initial idea for the study. TI, CK, NY and MY wrote the first draft of the protocol. CK, NY, MY and HT worked on the primary and secondary outcomes. All authors contributed to writing the protocol. TI, KO, TKi, NT, SH, MM, MY, TY, KTN and Y0 will assist in recruiting participants and data collection. CK, TI, NY, MY and HT contributed equally to study conceptualisation, protocol drafting and protocol editing. NY contributed to the statistical design. CK wrote the first draft of the manuscript. CK, TI, TKi, NT, SH, KTN, MM, YY, KO and KY completed the institutional review board approval process.

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Competing interests None declared.

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REFERENCES

1. Isometsä ET, Lönnqvist JK. Suicide attempts preceding completed suicide. Br J Psychiatry 1998;173:531–5.
2. Da Cruz D, Pearson A, Saini P, et al. Emergency department contact prior to suicide in mental health patients. Emerg Med J 2011;28:467–71.
3. Nordentoft M, Mortensen PB, Pedersen CB. Absolute risk of suicide after first hospital contact in mental disorder. Arch Gen Psychiatry 2011;68:1058–64.
4. Morthorst B, Krogh J, Erlangsen A, et al. Effect of assertive outreach after suicide attempt in the AID (assertive intervention for deliberate self harm) trial: randomised controlled trial. BMJ 2012;345:e4972.
5. Inagaki M, Kawashima Y, Kawanishi C, et al. Interventions to prevent repeat suicidal behavior in patients admitted to an emergency department for a suicide attempt: a meta-analysis. J Affect Disord 2015;175:66–78.
6. O’Connor RC, Ferguson E, Scott F, et al. A brief psychological intervention to reduce repetition of self-harm in patients admitted to hospital following a suicide attempt: a randomised controlled trial. Lancet Psychiatry 2017;4:451–60.
7. Miller IW, Camargo CA, Arias SA, et al. Suicide prevention in an emergency department population: The ED-SAFE Study. JAMA Psychiatry 2017;74:563–70.
8. Nakagawa M, Yamada T, Yamada S, et al. Follow-up study of suicide attempters who were given crisis intervention during hospital stay: pilot study. Psychiatry Clin Neurosci 2009;63:122–3.
9. Hirayasu Y, Kawanishi C, Yonemoto N, et al. A randomized controlled multicenter trial of post-suicide attempt case management for the prevention of further attempts in Japan (ACTION-J). BMC Public Health 2009;9:364.
10. Kawanishi C, Aruga T, Ishizuka N, et al. Assertive case management versus enhanced usual care for people with mental health problems who had attempted suicide and were admitted to hospital emergency departments in Japan (ACTION-J): a multicentre, randomised controlled trial. Lancet Psychiatry 2014;1:193–201.
11. Buss AH, Perry M. The aggression questionnaire. J Pers Soc Psychol 1992;63:452–9.
12. Ando A, Soga S, Yamasaki K, et al. [Development of the Japanese version of the Buss-Perry Aggression Questionnaire (BAQ)]. Shinrigaku Kenkyu 1999;70:384–92.
13. Doihara C, Kawanishi C, Yamada T, et al. Trait aggression in suicide attempters: a pilot study. Psychiatry Clin Neurosci 2008;62:352–4.
14. Kobashi M, Ida M. Making the Revised Version of Barratt Impulsiveness Scale 11th in Japanese: A Study on Reliability and Validity. J Psychol Rissho Univ 2013;4:53–61.
15. Doihara C, Kawanishi C, Ohyama N, et al. Trait impulsivity in suicide attempters: preliminary study. Psychiatry Clin Neurosci 2012;66:529–32.
16. Posner K, Brown GK, Stanley B, et al. The Columbia-Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. Am J Psychiatry 2011;168:1266–77.
17. Beck AT, Steer RA, Ball R, et al. Comparison of Beck Depression Inventories -IA and -II in psychiatric outpatients. J Pers Assess 1996;67:588–97.