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journal or publication title	BMJ Open
volume	8
number	9
page range	e020517
year	2018-08
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URL	http://hdl.handle.net/2241/00154113

doi: 10.1136/bmjopen-2017-020517

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BMJ Open

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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To cite: Kawanishi C, Ishii T, Yonemoto N, *et al*. 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). *BMJ Open* 2018;**8**:e020517. doi:10.1136/bmjopen-2017-020517

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2017-020517).

Received 21 November 2017
Revised 6 August 2018
Accepted 21 August 2018

Check for updates

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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

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Table 1 Features of the assertive case management intervention derived from the ACTION-J trial

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.[8] 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,[9 10] 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).[9] 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.[10] 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[10] 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 have been physically stabilised and alert consciousness has been confirmed, potential study participants will receive thorough psychosocial 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.[10] 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

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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	At discharge	Four weeks after registration	Eight weeks	Twelve weeks	Sixteen weeks	Twenty weeks	Twenty-four weeks	Eighteen months
Informed consent, and registration	○								
Psychiatric evaluation and diagnosis	○	○						○	
Psychoeducation	○								
Assertive case management	○		○	○	○	○	○	○	
Confirmation of survival and suicide-related events								○	○
Treatment adherence								○	
BAQ								○	
BIS								○	
C-SSRS		○						○	
BDI-II		○						○	

BAQ, Buss-Perry Aggression Questionnaire; BDI-II, Beck Depression Inventory-II; BIS, Barratt Impulsiveness Scale; C-SSRS, Columbia-Suicide Severity Rating Scale.

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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. The subgroup analysis will be performed on the primary outcome and the secondary outcomes.

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

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reducing the short-term risk of repeated suicide attempts after discharge from emergency departments.[10] The ACTION-J study has also shown that the assertive case management programme is feasible.[10] 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, 1422), 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.

Finance and insurance

This work was supported in part by a Research and Development Grant for Comprehensive Research for Persons with Disabilities (Mental Disorder Area) by the Japan Agency for Medical Research and Development.

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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Acknowledgements The authors thank Prof Osamu Shirakawa, Mayuko Matsuo, Yoshitaka Kawashima, Dr Tatsuya Sugimoto, Shigero Shimoda, Atsushi Niwa, Hisako Yamada, Hikaru Nakamura, Dr Daisuke Fujisawa and Dr Nobuaki Eto, for their valuable comments based on their clinical experiences, which helped us write the protocol. The authors also thank Dr Masatoshi Inagaki for his valuable suggestions on the initial draft of the protocol and Diane Williams, PhD, from Edanz Group (www.edanzediting.com/ac) for editing a draft of this manuscript.

Collaborators Y Kawashima, T Sugimoto, A Niwa, T Suenaga and M Inagaki gave their comments based on their clinical and research experiences, which contributed to revise protocol.

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, TKis, NT, SH, MM, RY, TKin and YO 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, TKis, NT, SH, TKin, MM, YO, KO and RY completed the Institutional Review Board approval process.

Funding This study is supported by Research and Development Grants for Comprehensive Research for Persons with Disabilities (18dk0307057h0003), Japan Agency for Medical Research and Development (Tokyo, Japan). The funder did not have any role in the study design. The funder will not have any role in data collection, analysis or interpretation.

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Competing interests None declared.

Patient consent Obtained.

Ethics approval Sapporo Medical University IRB.

Provenance and peer review Not commissioned; externally peer reviewed.

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