厚生労働科学研究費補助金（障害者対策総合研究事業）

分担研究報告書

自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較試験

A randomized, controlled, multicenter trial of post-suicide attempt case management for the prevention of further attempts in Japan, ACTION-J

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研究要旨：平成17年度から21年度にかけて，わが国における自殺対策・自殺予防方略の開発を目指した「自殺対策のための戦略研究」が実施された。戦略研究期間中に開始された「自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較試験」は，自殺未遂者の自殺再企図防止方略を高度な科学的根拠性をもって確立するために実施され，戦略研究期間中に，精神医学領域で全例のない大規模研究を運営するためのシステム構築が進められ，912名の研究対象者の登録を得て研究が進められた。本研究は，「自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較試験」で収集されたデータをもとにケース・マネージメントの効果を検証するとともに，データを駆使して本邦初の大規模な未遂者の調査，自殺企図行動の解析を行い，もってわが国における実効性のある効果的な自殺予防方略の開発を行うことを目的とする。このために，本年度は，研究班内に研究部会を立ち上げ，文献のレヴューとワークショップを開催し，多様な研究計画を立案した。また，本研究班内の専門職を対象とした自殺予防，および自殺未遂者ケアの技法向上のための研修会を実施し，地域自殺対策や厚生労働省主催研修会（自殺未遂者ケア研修会）への参加・協力を推進した。

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A．研究の背景と目的

わが国では，昭和 62 年より減少に転じていた自殺者数が平成 7 年以降，明らかな上昇に転じ，1998 年には，前年の 30%以上も増加するという激増をみた。

最近のわが国の高い自殺率は，完全失業率の推移と並行しており，このことにより，経済不況と自殺増加の関連性がマス・メディアなどによりしばしば強調されるところとなっている。しかし広く世界を見渡せば，スウェーデンのように，失業率の増減と関連無く自殺率が漸減を続けている国もあり，自殺問題を経済問題に直結させる考え方はあまりに単純に過ぎ，自殺対策がすなわち経済対策であるかの大きな誤解を生じさせる危険がある。

スウェーデンやフィンランドを含む北欧はもとより，イギリスなどの西欧，オセアニア諸国では国家的な総合的自殺防止対策が実施されており，大きな成果を上げている。これらの国々では，経済対策ではなく，精神保健福祉対策が自殺対策の要諦であることが自明のこととされており，対策の基軸となっている。

本研究は，わが国の実効的な自殺予防法を開発することを目的に行われた「自殺対策のための戦略研究，自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較試験」で実施された研究期間が終了したのち，続けて研究対象者である自殺未遂者に対するケース・マネージメントと評価を行い，介入効果を最終的に検証するとともに，当該の研究で得られた

膨大なデータをもとに，自殺未遂者，および自殺企図行動に関する多面的かつ包括的な研究を行う。そして，これらの結果を踏まえて自殺予防のための効果的な自殺未遂者ケア方略を開発することを目的としている。

「自殺対策のための戦略研究，自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較試験」では，救急医療施設を拠点に，自殺未遂者を対象とした介入試験が行なれた。研究実施施設として救急医療施設が選ばれた最も重要な理由は，そこに自殺企図者が集中するということである．自殺企図の中には既遂に至る事例も少なくないが，未遂で救命し得たとしても，自殺未遂の既往は，その後の自殺既遂の最大の危険予測因子である（Robins ら，1959；Rosenberg ら，1988；Mościcki，1997；Owens ら，2002)。一人の自殺者の背景にはその 10 ないし 18 倍の自殺未遂者が存在すると考えられており（Petronis ら，1990; Mościcki, 1997; Spicer ら，2000)，自殺未遂者への介入は，自殺予防の主要な課題であることが自殺予防学において知られている。救急医療施設における未遂者への介入は，多くの対象者に直接の介入を行うために効果的な場所であると考えられ，また逆に，救急医療施設で実施可能な介入法を開発することが重要であると考えられた。

一方，自殺と精神疾患との間に密接な関連性があり，精神疾患の発見と適切な治療的対応が，やはり自殺の予防に重要であることも示されている。これまでの心理学的剖検研究によれば，自殺既遂者の 90%以上が，自殺遂行時に精神疾患に罹患していたことが示されている（Mościcki, 1997；Cavanagh ら，2003；Bertolote ら，2004；)．わが国において，DSM による多軸診断を，しかも高度救命救急センターに搬送された自殺未遂者について行った研究（Yamada ら，2007）でも，やはり自殺未遂者の 80%以上に精神疾患が認められている。Rutz ら（1992)は，スウェーデン・ゴットランド島のすべての General practitioner を対象にうつ病の診断と治療に関する講習を行った結果，同島における自殺率の低下を観察している。自殺未遂者に適切な精神医学的評価を行い治療を提供することが，自殺予防のひとつの重要な鍵となるものと考えられ，WHO が策定した自殺予防行動計画（SUPRE）の中でもそのことが明示されている。このような事柄を踏まえ，「自殺対策のための戦略研究，自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較試験」では，救急医学と精神医学との密接な連携の下に，精神疾患を有する自殺未遂者を対象に介入研究を実施した。

「自殺対策のための戦略研究，自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較試験」の介入方法はケース・マネージメントであり，身体的治療と詳細な精神医学的・心理社会的評価が実施された後に，心理教育，精神科受療支援，そしてソーシャルワーク介入などを含む個別性の高いケース・ワークが為される。さらに，試験介入群には，継続して定期的なケース・マネージメント介入と IT

を用いた情報提供が行われ，通常介入群との比較により自殺再企図防止効果が検証される。

自殺未遂者への介入研究については，これまでに海外からさまざまな報告があり，系統的レヴューも行われている（van der Sande ら，1997; Hawton ら，1998, 2000; Gaynes ら，2004; Man JJ ら，2005）。無作為化比較介入試験による自殺予防可能性の検討も行われており，自殺未遂者に対するケース・マネージメントや認知行動療法，対人関係療法などが行われている。しかしながら，救急医療施設（身体救急）単独で行なわれた介入研究は研究報告自体が極めて少なく，Rotheram-Borus ら（2000）による外来精神療法（構造化面接）による介入研究以外には有効性が示された介入方法はほとんどない。しかも，この Rotheram-Borus らの研究でさえ対象者は 140 名とサンプル数が非常に少なく，エビデンスとして弱い。研究実施拠点を考慮せず介入方法に着目すると，従来の無作為化比較試験では有意な自殺再企図率の減少を認めたものはほとんどない。1995 年に報告された介入研究では，受療促進の効果について検討がなされたが，介入群での自殺企図率は 21/196（10.7%），通常治療が行われた対照群では 34/195（17.4%）であり，オッズ比は 0.57（95%信頼区間 0.32-1.02）であった（van Heeringen ら，1995）。認知行動療法を検討した 5 つの研究での自殺防止効果を示す要約オッズ比は 0.70（95%信頼区間 0.45-1.11），積極的なアウトリーチと，介入目的の短期入院治療と看護ケアをそれぞれ含む 6 研究の要約オッズ比は 0.83（95%信頼区間 0.61-1.14）であった。いずれの要約オッズ比の信頼区間もレンジが広いが，これは系統的レヴューの元となっている一次研究において対象症例数がそれぞれ少ないことに因る。認知行動療法を検討した 5 つの研究の対象者数は，介入群と対照群を合わせても総計 600 例以下であり，またアウトリーチなどを検討した 6 研究では総症例数は 1,200 例以下であった（Gaynes ら，2004）。また，それぞれの登録後観察期間は 6－12 ヶ月と短い。このように，先行研究においては，対象者数の少なさや研究期間の短さから介入効果を検証するのに限界があり，エビデンスを提示するためには多施設共同による大規模研究の必要性があるということが Howton ら（1999）や Gaynes ら（2004）により指摘されている。

「自殺対策のための戦略研究，自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較試験」は，この問題を克服するために多施設共同で実施され，全国 14 の医療施設で介入，追跡が実施された。これらの施設では，後述の研究プロトコールの実施を可能とする一般救急医療部門と精神科部門との連携が確立されており，救急医療部門に入院した自殺未遂者全例を対象に適応基準の判定がされ，基準を満たすほぼ全例に研究説明が為され，最終的に研究に参加を同意した 912 名の対象者が登録された。

「自殺対策のための戦略研究，自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較

試験」は，2011年6月をもって対象者に対するすべての介入と評価を終える予定である。

B．研究方法

1．「自殺対策のための戦略研究，自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較試験」プロトコールの概要

1）目的

救急医療施設に搬送され入院となった自殺未遂者に対して，試験介入としてケース・マネージメントを行い，試験介入が通常介入と比較して自殺企図再発の防止に効果を有するか否かを検証する。

2）対象

救急医療施設に搬送され入院となり，救急部門にて救急医または精神科医により自殺未遂と判断されたもののうち，1）20歳以上，2）DSM-IVのI軸に該当する精神科疾患を有する，3）2回以上の判定により自殺の意志が確認された，4）本研究の内容を理解し，同意取得が可能，5）入院中に，登録実施に必要な面接・心理教育[1]を受けることができる，6）評価面接，ケース・マネージメントのための定期的な来院が可能で，実施施設から定期的に連絡を取ることができるを満たすものであり，除外基準としては，主要精神科診断が，DSM-IVのI軸診断に該当しないものである。

3）介入方法

対象者は，無作為に試験介入群と通常介入群に分かたれ，以下の介入を実施される。

（1）試験介入群：1）通常治療，2）自殺予防に関する資料（パンフレット）の配布，3）ケース・マネージメント（心理教育[2]を含む），4）ITを利用した情報提供（介入専用ウェブサイトの利用）

（2）通常介入群：1）通常治療，2）自殺予防に関する資料（パンフレット）の配布

4）主要評価項目

自殺企図（自殺既遂，及び未遂）の再発発生率

2．本研究で実施する調査と研究

本研究は，「自殺対策のための戦略研究，自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較試験」で得られたデータ・セットをクリーニング，固定し，独立統計家により解析を実施する。そして，ケース・マネージメント介入による自殺企図の再発防止効果の有無を明らかにする予定である。

さらに，本研究班では，当該研究で得られた膨大な自殺未遂者データをもとに，さまざまな観点から自殺未遂者，自殺企図行動に関する調査・研究を実施する予定であり，そのために研究部会を設置した。また，自殺未遂者ケアの技法の向上や，啓発・教育の普及を目指した研修会を実施し，本研究に関わるものが厚生労働省主催研修会の講演者，ファシリテーターとして参加した。

C．結果と考察

本研究班において，研究部会を全8回実施し，システマティック・レヴューを中心とした文献レヴューと生物統計学に関する学習を行い，介入研究終了後の研究計画を立案し

た。研究計画案は，例えば以下のものである。1）全死因死亡率（死因を問わない死亡），2）繰り返しを含む自殺企図再発回数と発生率，3）自傷行為の回数，4）その他のインシデントとライフイベント，5）受療状況，6）健康状態・精神症状の経過，絶望感の経過，7）希救行動，8）精神疾患ごとの比較，9）飲酒行動などである。

さらに，本研究班では研修会を実施し，1）我が国の自殺問題と自殺対策の現況，2）自殺対策基本法施行・自殺総合対策大綱公表後の地域自殺対策の現況，3）「自殺対策のための戦略研究：複合的自殺対策プログラムの自殺企図予防効果に関する地域介入試験」の実施内容とその成果について，学習と参加者からの活動・研究報告と討議を行った。

また，2010 年 11 月，12 月，2011 年 1 月に実施された，厚生労働省主催「自殺未遂者ケア研修会」（自殺総合対策大綱に基づく事業であり，対象者は，一般救急部門で業務にあたる専門職）に本研究班研究者が多数招聘され参加し，それぞれ講演者，コメンテーター，ファシリテーターを務めた。

D．健康危険情報

特記すべきことなし

E．研究発表

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E． 知的財産権の出願・登録状況

1．特許取得：なし

2．実用新案：なし

3．その他：なし

III. 研究成果の刊行に関する一覧表

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Ⅳ．参考資料

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Study protocol

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A community intervention trial of multimodal suicide prevention program in Japan: A Novel multimodal Community Intervention program to prevent suicide and suicide attempt in Japan, NOCOMIT-J

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Abstract

Background: To respond to the rapid surge in the incidence of suicide in Japan, which appears to be an ongoing trend, the Japanese Multimodal Intervention Trials for Suicide Prevention (J-MISP) have launched a multimodal community-based suicide prevention program, NOCOMIT-J. The primary aim of this study is to examine whether NOCOMIT-J is effective in reducing suicidal behavior in the community.

Methods/DesignThis study is a community intervention trial involving seven intervention regions with accompanying control regions, all with populations of statistically sufficient size. The program focuses on building social support networks in the public health system for suicide prevention and mental health promotion, intending to reinforce human relationships in the community. The intervention program components includes a primary prevention measures of awareness campaign for the public and key personnel, secondary prevention measures for screening of, and assisting, high-risk individuals, after-care for individuals bereaved by suicide, and other measures. The intervention started in July 2006, and will continue for 3.5 years. Participants are Japanese and foreign residents living in the intervention and control regions (a total of population of 2,120,000 individuals).

Discussion: The present study is designed to evaluate the effectiveness of the community-based suicide prevention program in the seven participating areas.

Trial registration: UMIN Clinical Trials Registry (UMIN-CTR) UMIN000000460.

Background

Recent rapid increase of suicide in Japan

(1) Changes in suicide incidence

According to vital statistics collected by the Japan Ministry of Health, Labour, and Welfare in 1997, there were 23,494 suicides (15,901 men and 7,593 women), with the number rising to 31,755 (22,349 men and 9,406 women) in 1998, which represented a 35% increase. This was the highest rate of increase recorded since the Ministry began tracking mortality statistics. The number of suicides remained high in subsequent years, reaching 29,949 in 2002 and 32,109 in 2003.

In 2002, the World Health Organization (WHO) reported that the suicide rate in Japan (25.3 per 100,000) was higher than in any other developed nation (for comparison: France: 17.5, Germany: 13.5, Canada: 11.7, United States of America: 10.4, United Kingdom: 7.5, Italy: 7.1).

In terms of the number of suicides, three peaks have emerged since World War II. However, the most recent rise that started in 1998 has shown no signs of abating, and represents the worst in Japan's history. Therefore, it is clear that suicide prevention measures are urgently needed in Japan.

(2) Regional tendencies

It has been pointed out that the suicide rate has traditionally been high in the three prefectures of the northern Tohoku area (Akita, Iwate, and Aomori), Niigata, Shimane, and the Kyushu area (Miyazaki, Kagoshima, and Okinawa) [1].

The increase in the number of suicides that began in 1998, however, was not necessarily attributable to suicides in these rural areas. Fujita (2003) [2] conducted a comparative study of suicide rates by prefecture by comparing a time period with a low number of suicides (1989–1995) to time periods before and after, during which the number of suicides was on the rise (1983–1987 and 1998–2000, respectively). The findings indicated that the recent increase in the number of suicides has been significantly more prominent in urban areas such as Tokyo, Osaka, and their surrounding areas, than in rural areas. During the two periods 1989–1995 and 1998–2000, the mean number of suicides among people 15 years of age or older rose from 894 to 1,658 in Osaka, from 713 to 1,309 in Kanagawa, and from 1,129 to 1,938 in Tokyo.

With regard to recent trends in suicide rate by age, the middle-aged population was found to have higher suicide rates. In 2004, 42.1% of those who committed suicide were 45 to 64 years old. This tendency was particularly evident among men, in whom the suicide rate peaked at 55 to 59 years of age, whereas a similar trend was not found in women, in whom the suicide rate generally increased with age.

(3) Causes and motives for suicide

According to the statistics of the National Police Agency, health and financial/lifestyle problems were the top two reasons for suicide. Although this tendency remained the same during the increase in suicides that began in 1998, the number of suicides due to financial/lifestyle problems has increased more rapidly compared to suicides commit-

ted due to health problems. Among those who committed suicide with or without suicide notes in 1997, 13,659 individuals (56.0%) did so due to health problems and 3,556 individuals (14.6%) due to financial/lifestyle problems. These numbers rose to 16,769 (51.0%, a 22.8% increase over the previous year) and 6,058 (18.4%, a 70.4% increase over the previous year), respectively, in 1998. In terms of those with health problems, the number of suicides subsequently decreased in 2004 to 14,786 (45.7%), whereas the number of suicides due to financial/lifestyle problems increased to 7,947 (24.6%). This indicates that the percentage of suicides due to financial/lifestyle problems has been increasing.

Recent suicide prevention programs in Japan

Many suicide prevention measures have been implemented internationally [3-5]. In Japan, evidence has also emerged recently to support the effectiveness of community-based programs for suicide prevention. Seven community-based intervention trials implemented for five years or more have been conducted between 1985 and 2005 in Japan. All the trials used a quasi-experimental design and included suicide rate as the primary outcome. These suicide prevention programs included the development of social support networks in the community and/or depression screening for residents with follow-up by physicians. All the intervention programs were also administered by local governments. Six of the seven trials targeted individuals aged 65 years and older.

The first trial was conducted in Matsunoyama, Niigata prefecture. During the 10-year implementation period, the suicide rate of over 150 per 100,000 decreased by 75% for both men and women aged 65 years and older [6]. In the trials conducted in Joboji (Iwate pref.), Nagawa (Aomori pref.), Matsudai and Yasuzuka (Niigata pref.), and Yuri (Akita pref.), the suicide prevention program significantly reduced the suicide risk for individuals aged 65 years and older [7-10].

Recently, a relatively large, multimodal intervention trial targeting all age groups was conducted in four municipalities of Akita. During the four-year implementation period, the suicide rate of 68 per 100,000 for all residents was reduced by 27% [11].

The results of these seven trials suggest that community-based intervention would be effective for preventing suicide and that the increase of suicide deaths in Japan may be related to more pervasive social isolation than in the past, and to an absence of personal psycho-social development compared with financial success.

However, the sample sizes in these trials were relatively small and the monitoring of the implementation process was insufficient. Furthermore, since the trials were conducted in rural areas with high suicide rates, it is still unclear whether similar community-based programs would be effective in urban areas where the suicide rates have increased rapidly. Therefore large, community-based intervention trials with adequate controls should be conducted to develop an effective, evidence-based suicide prevention program to reduce the future suicide rate in Japan.

Objectives of this study

(1) The primary goal is to examine the effectiveness of a community-based multimodal intervention program for suicide prevention in regions where the suicide rate was relatively high compared to control regions. These target areas were designated "Group 1".

(2) The secondary goal was to explore the effectiveness of a community-based multimodal intervention program for suicide prevention in highly populated regions. These target areas were designated "Group 2".

Methods/Design

A community intervention trial will be conducted to evaluate the effectiveness of a novel suicide intervention program. In this study, the incidence of suicidal behavior in an intervention group and a control group will be compared.

Organization

The Japan Ministry of Health, Labour, and Welfare selected the Japan Foundation for Neuroscience and Mental Health (JFNMH) as the primary institution responsible for the strategic research program for suicide prevention. The JFNMH conducts the program "Japanese Multimodal Intervention Trials for Suicide Prevention, J-MISP" in close collaboration with the National Center of Neurology and Psychiatry. NOCOMIT-J is one of two research projects being conducted by J-MISP. The other is a randomized, controlled, multicenter trial of post-suicide attempt case management for prevention of further attempts in Japan (ACTION-J).

The principal investigator of NOCOMIT-J and the subleader will supervise the study group in order to conduct and complete the study effectively.

The study group management office will engage in overall administrative procedures regarding the operation of the study group. It will also set up and operate the study group steering committee and the intervention program committees, hold the research conference, and respond to questions from institutions in the participating regions.

The J-MISP director, the principal investigator of the NOCOMIT-J, and the regional leaders share the informa-

tion and collaborate to resolve problems and safety issues with the help of the steering committee and the Central and Local Research Ethics Committee.

The study group steering committee will be composed of regional leaders and other key members of the study group. Research meetings will be held upon the principal investigator's request. At the meetings, the intervention program committee will present the agenda, after which important issues, such as revision of the protocol or stopping of the study, will be discussed.

Participants and Participating Areas

Participants

The participants will include Japanese and foreign residents living in the intervention and control regions.

Eligibility Criteria

Target areas will be selected and divided into two groups: "Group 1" and "Group 2" as mentioned above. The areas meeting the following criteria will be eligible for the study:

a) Areas with strong support from local government and other organizations to conduct this multimodal suicide prevention program.

b) Areas capable of selecting intervention and control regions.

c) Areas capable of following the data collection procedure.

d) Areas with comparable baseline data on suicide attempts in intervention and control regions.

e) Areas with comparable baseline demographic data in intervention and control regions.

Participating regions and sample size estimation

(1) Group 1: Regions in Aomori, Akita, Iwate, and the Minamikyushu area, with a total population of 670,000 individuals.

(2) Group 2: Regions in Sendai, Chiba, and the Kitakyushu area, with a total population of 1,450,000 individuals.

After a preliminary survey to record the rate of suicidal behavior and other information in the target regions in these areas, intervention and control regions will be selected based on the similarity in community characteristics and the incidence of suicidal behavior (Figure 1).

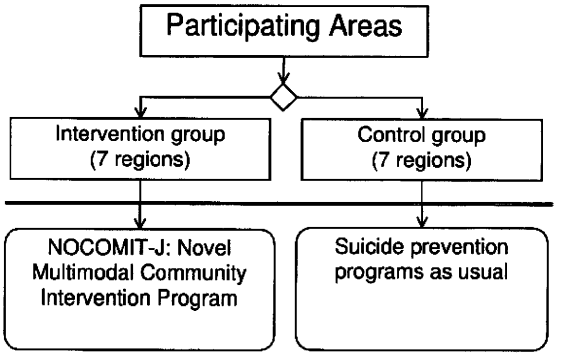

Figure 1
Flow diagram of the study.

Each region has a designated regional leader. The personnel associated with each region include psychiatrists, researchers supporting community intervention, and personnel in charge of regional health administration.

Rationale for estimation of sample sizes

Sample sizes to be used in the study were calculated based on the assumptions of the outcome and suicide rates from 2002 to 2004 in Groups 1 and 2 presented in Table 1.

Although the estimated sample sizes are not adjusted for 5-year age group, sex, and regional characteristics, if all assumptions are met, the statistical power will be over 80% for each group, regarding person-year incidences in the intervention and control regions.

Using the O'Brien-Fleming method [12] in the interim analysis, the significance level in the final analysis is estimated to be 4.9% for a two-sided test. In addition, the statistical power will be over 80% in each group.

Intervention

The intervention program will be implemented by local authorities.

Suicide prevention program in control regions

The interventions in the control regions include the usual suicide prevention programs.

Suicide prevention programs in intervention regions

The local health authorities will implement the suicide prevention measures in accordance with the intervention manual developed by the program committee of the study group. To better enhance the quality of the essential intervention activities, the local health authority is also requested to share with the other study group members the information on the program tools.

Table 1: Assumptions of the outcome and suicide rates in Group 1 and Group 2

	Group 1	Group 2
Suicide rate in control regions (per 100,000 individuals)	30	20
Proportion of expected numbers of ambulance transports due to "self-harm" (severe and mild cases) relative to completed suicides	50%	50%
Expected suicide rate reduction over observed 3 years by intervention	20%	15%
Significance level (two-sided)	5%	5%

Notes. These assumptions of the outcome and suicide rates (2002–2004) are used to calculate the sample sizes in this study.
Group1: regions with a relatively high suicide rate compared to control regions, examined to gauge the effectiveness of the community-based multimodal intervention program for suicide prevention.
Group 2: highly-populated regions, examined in order to explore the effectiveness of the community-based multimodal intervention program for suicide prevention.

The program components

The program stresses that bonds between human beings, social support, and social capital within communities are key factors for reducing suicide. Its essential components are listed below.

(1) The program focuses on building social support networks in the public health system for suicide prevention and mental health promotion, which will reinforce human relationships in the community.

- Network meetings of related departments and organizations will be held.

- Coordinating committees for the program will be formed in the intervention regions.

(2) Primary prevention measures for suicide and suicide-related behavior

- An public awareness campaign will be set up.

- Community programs will be set up to allow residents to gather and communicate.

(3) Secondary prevention measures for suicide and suicide-related behavior

- High-risk individuals will be screened.

- Counseling and outreach services will be provided.

(4) After-care for individuals bereaved by suicide

(5) Suicide prevention measures targeting individuals with substance/alcohol-related disorders, schizophrenia, and other mental health disorders

(6) Suicide prevention measures targeting individuals with work-related problems.

Study period

Study period: August 2005 to March 2010.

Intervention period: July 2006 to December 2009.

Approval of the study protocol

This study protocol was reviewed and approved by the Central Research Ethics Committee of the J-MISP. Additionally, the regional leaders will ask the local governors for cooperation, and obtain written authorization to conduct the study. Regional leaders will obtain approval from the ethics committees of affiliated universities or hospitals.

Data collection

Baseline Information

Data will be collected for the items below:

(1) Statistics on suicide

The number of suicides in the 3 years prior to the study (2003–2005) in the study regions was recorded by sex and 5-year age group the Japan Ministry of Health, Labour, and Welfare.

(2) Information from the emergency report

Information on "self-harmed" individuals transported by ambulance in the 3 years prior to the study was collected from the emergency reports of ambulance service.

(3) Demographic information

A total population count in the regions in the 3 years prior to the study was recorded by sex and 5-year age group by each local governments.

(4) Regional characteristics

The following information was collected from published statistical data sources: geographic information, proportion of unmarried individuals, widowed spouses, divorcees, nuclear families, the unemployed, individuals in the labor force, and the annual population turnover in the regions.

(5) Suicide prevention programs in existence prior to the study
Baseline information concerning suicide prevention programs implemented in each region 3 years prior to the study will be recorded by each regions.

Intervention program process monitoring
Every 6 months, each regional leader will collect information regarding the implemented projects described in the intervention program manual.

Data collection during the study
(1) Information on suicides
After consent is obtained for the use of designated statistics for other purposes, information regarding the number of suicides in the participating regions will be collected. Death certificates from the Vital Statistics records from 2006, 2007, 2008, and 2009 for the intervention and control regions will be used to collect the following data items: International Classification of Diseases 10th Revision (ICD-10) code for intentional self-harm (ICD-10 codes X60–X84), residence of individuals who committed suicide (municipality codes), cause of death, external cause of death (ICD-10 code), measure of suicide (ICD-10), sex, age, reported place (municipality codes), and identification number.

(2) Information regarding suicidal behavior
Information regarding "self-harmed" individuals transported by ambulance will be collected from emergency reports.

The following information will be collected regarding "self-harmed" individuals every 6 months: type of transportation, date of notification, residence address, destination address, incidence location, severity (death, severe, moderate, mild, other), sex, age, and means of self-harm infliction.

(3) Demographic information
Total population numbers in the regions will be collected every year between 2006 and 2009.

(4) Information regarding ongoing suicide prevention programs
Information regarding the existence and implementation of suicide prevention programs in each participating region will be collected every 6 months.

Responsibility for data collection
Regional leaders are responsible for collecting data from each municipality and sending the data set to the data management center in a timely manner.

Data management
Collected data will be exclusively managed by the data management center. The data set will comply with the data management procedures and the Personal Information Protection Law. The data set will be periodically duplicated and saved as a backup file.

Outcomes
Primary outcome
The incidence of suicidal behavior (completed suicides and suicide attempts excluding mild cases reported on emergency reports).

Secondary outcomes
(1) Incidence of completed suicides.

(2) Incidence of suicide attempts.

Statistical analysis
Primary analysis
In the primary analysis, the incidence of suicidal behavior will be calculated based on the number of suicidal behavior per person-year for the annual population. Data obtained will include the incidence of suicidal behavior and its 95% confidence intervals adjusted by sex, 5-year age group, and regional characteristics. This data will be compared between the intervention and control regions in "Group 1".

The significance level will be set at 0.05 for the two-sided test, and will be adjusted in the final analysis based on the methods of O'Brien and Fleming [12] for interim analysis.

Additionally, regression analysis will also be performed to examine the interactions among sex, 5-year age group, and regional characteristics. A statistician in the study group will determine the analysis plan, whereas a different independent statistician will perform the interim analysis. The independent statistician will not contribute to the revision of the statistical analysis plan after interim analysis.

Interim analysis and rules for stopping or revising the study protocol
The interim analysis in "Group 1" will be performed 2 years after the study's implementation to evaluate the achievement of the primary objectives. Multiplicity will be adjusted using the methods of O'Brien and Fleming, in order to maintain Type-1 error at 0.05 for the two-sided test. The results will be reported to the Central Research Ethics Committee, which is expected to make recommendations to the J-MISP director to either stop the study or revise the study protocol if the primary objective of the study has already been achieved or is unlikely to be achieved.

Secondary analysis
In addition to the primary analysis, it will also be evaluated whether the primary outcome (the incidence of sui-

cidal behavior) is also significantly reduced in intervention regions of "Group 2" areas, as a consequence of implementation of the program, when compared to control regions. The incidence of suicidal behavior will be investigated in Groups 1 and 2 combined. The analysis will be performed using the primary analysis plan described above.

Secondary outcomes will also be examined in order to determine whether the rate of completed suicides and suicide attempts – including individuals with severe, moderate, and mild self-harm transported to a hospital – is significantly reduced in the intervention regions, when compared to the control regions in "Group 1" and "Group 2". The same will be examined for both groups combined.

Subgroup analysis of the primary and secondary outcomes will be performed by sex, 5-year age group, and regional characteristics in "Group 1", "Group 2", and both groups combined. In addition, the incidence of suicidal behavior adjusted by sex and 5-year age group in the intervention and control regions will be calculated using the model population in 1985 as a reference population. Because of the exploratory nature of the secondary analysis, no adjustment for multiplicity will be made.

Ethical considerations

The rights and welfare of the participating residents will be protected according to the World Medical Association Declaration of Helsinki Ethical Principles for Medical Research Involving Human Subjects. The study will comply with the ethical guidelines of the Ministry of Education, Culture, Sports, Science and Technology, as well as the Ministry of Health, Labour, and Welfare. Ethical validity, including safety, scientific legitimacy, and the reliability of results are to be ensured. This study will also comply with the ethical guidelines for epidemiologic studies and the Personal Information Protection law. The NOCOMIT-J principal investigator and the J-MISP director will be responsible for the protection of personal information during the study.

The data collected in this study will not include personal identification that would enable individuals to be identified. The data management center will collect only anonymous data.

Stopping of the study

The J-MISP director is to inform the principal investigator of the NOCOMIT-J of the decisions of the Central Research Ethics Committee in the cases described below to discuss whether the study in each region or all of them should be discontinued.

a) The results of the interim analysis do not satisfy the standards set by the committee.

b) Safety issues that might affect the conduct of future studies arise from the results of interim analysis or the results of periodic monitoring.

c) The Local Research Ethics Committee of a region retracts consent to participate.

Revision of the study protocol and due process

The J-MISP director is to inform the NOCOMIT-J principal investigator of the decisions of the Central Research Ethics Committee as soon as possible, when the Central Research Ethics Committee recommends that the study be redesigned due to the emergence of safety issues based on the interim analysis, periodic monitoring, and/or emergence of serious issues that might affect the conduct of future studies. The J-MISP director is to call a meeting of the study group and discuss the revision of the study protocol. If a recommendation to revise the study protocol is made, the principal investigator of the NOCOMIT-J will propose the revised study protocol as soon as possible and submit the proposal to the J-MISP director.

The J-MISP director will deliberate and approve the proposal at the Central Research Ethics Committee meeting and adopt the revision of the study protocol after deliberation in the steering committee. The study group management office will inform all of the participating researchers, and regional leaders will submit the proposed revision to the Local Research Ethics Committee and local government in each of the participating regions. The revision of the study protocol is to be implemented when approved.

Study monitoring

Periodic monitoring

The regional leaders will periodically (once every 6 months) submit reports evaluating the progress of the study to the intervention program committee. The intervention program committee will submit a process evaluation monitoring report to the study group management office and J-MISP administration office once every 6 months. The J-MISP administration office will consider the progress of the research and submit the process evaluation monitoring report to the progress control committee and the Central Research Ethics Committee of the J-MISP.

The data management center will submit an event monitoring report to the J-MISP administration office. The office will submit event monitoring reports to the progress control committee, Central Research Ethics Committee, and the study group management office. The event monitoring report, which will contain the results of the analysis

separated by intervention and control groups, will be submitted to the progress control committee and Central Research Ethics Committee. The results of the data analyzed from both groups combined will be submitted to the study group management office.

The progress control committee will examine the monitoring reports and submit the evaluation to the J-MISP director. The Central Research Ethics Committee will examine the monitoring reports as a third party, and make recommendations to revise the study protocol or discontinue the study to the J-MISP director when and if ethical problems, such as safety and efficacy issues, arise.

Monitoring reports

The process evaluation monitoring report will contain the following:

(1) An evaluation of the implementation progress of the study.

(2) A program process evaluation.

(3) Reports of individual cases and events requiring intervention and other information.

The event monitoring report will contain the following:

(1) Data on the incidence of suicidal behavior (total number of both suicide completions and attempts) in the intervention and control groups, etc.

(2) Other relevant information.

Discussion

The study presented here is designed to evaluate the effectiveness of the community-based suicide prevention program in seven participating areas. Because treatment and prevention of suicide are complex and encompass many factors, success

will need multi-sector collaboration. We hope that the results of NOCOMIT-J will help to develop effective strategies to reduce future suicide rate in Japan.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

All authors participated in the design of the study. All authors contributed to the writing of the manuscript and have approved the final manuscript.

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Study protocol

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A randomized controlled multicenter trial of post-suicide attempt case management for the prevention of further attempts in Japan (ACTION-J)

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Abstract

Background: A previous suicide attempt is a potent risk factor for suicide later on. Crisis intervention, psychiatric and psychosocial evaluation at emergency medical facilities, and follow-up care for suicide attempters are considered important components for suicide prevention. The Japanese Multimodal Intervention Trials for Suicide Prevention (J-MISP) includes a randomized, controlled, multicenter trial of post-suicide attempt case management for the prevention of further attempts (ACTION-J) to address the continuing increase in suicides in Japan. The primary aim of ACTION-J is to examine the effectiveness of an extensive intervention for suicide attempters in prevention of recurrent suicidal behavior, as compared with standard intervention. This paper describes the rationale and protocol of the ACTION-J trial.

Methods/Design: In this clinical trial, case management intervention will be provided at 19 emergency medical facilities in Japan. After crisis intervention including psychiatric evaluation, psychosocial assessment, and psychological education, subjects will be randomly assigned to either a group receiving continuous case management or a control group receiving standard care. Suicidal ideation, depressive symptoms, and general health condition will be evaluated as secondary