Introduction

Suicide is a devastating event for individuals, families, and communities. The World Health Organization estimates that nearly 1,000,000 people worldwide die from suicide every year. [1] Several reviews have indicated that multilevel and multimodal interventions would be the strategy of choice for suicide prevention in the community. [2–4] A synergistic effect between interventions would be theoretically possible. [4] However, the low rate of suicide in the general population has made it difficult for trials to detect differences between groups with statistical power. Indeed, there are few studies that have reported the effect of interventions on suicide rates. [2–4].

We examined the effectiveness of a community-based multi-modal intervention for suicide prevention in rural areas where the suicide rate was high, with a non-randomised comparative intervention trial using parallel prevention-as-usual control. The effectiveness was also examined in highly populated areas near metropolitan cities. In the study, a large population size and an appropriate observational period to observe enough suicidal behaviour, and thus to obtain enough statistical power, were used. In addition, preplanned subgroup analyses were performed to detect effects of the intervention in specific subpopulations.

Methods

Study Designs

We set two areas, rural areas and highly populated areas, as the study targets (Figure 1). Rural areas with a high suicide rate were the primary targets, because these were the areas of focus in the previous community interventions in Japan, which are the basis of the interventions in the present study. [5–7] The entire population was the target of the intervention. The study matched pairs of intervention groups and control groups with past suicide rates and population size. The participants in the rural areas were the inhabitants living in four matched pairs of intervention groups and control groups (consisting of 17 communities, Figure 2). Highly populated areas near metropolitan cities were another target in this study because the suicide rate in these areas had increased prior to the present study. [8] In highly populated areas, two neighbouring communities were designated as the intervention and control groups, respectively. The participants in the highly populated areas were the inhabitants living in three matched pairs of intervention group and control group (consisting of six communities, Figure 2).
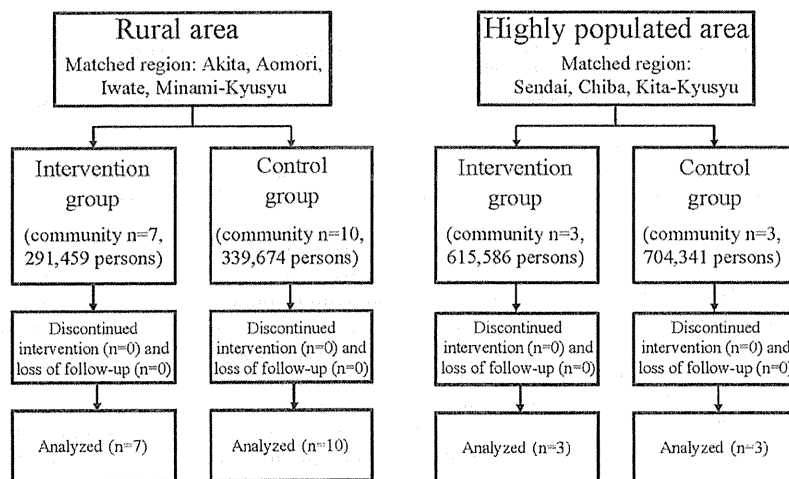
A community-based multimodal intervention for suicide prevention was developed [9] by extending the findings from previous studies focused on depressive elderly living in rural areas of Japan. [5–7] The intervention intended to reinforce human relationships and connectedness in the community by focusing on building social support networks within the general public and the health-related resources. The essential components are listed in Table 1. As shown here, the intervention was multilevel and multimodal, targeting the entire population in the participating communities. Leadership involvement was an important factor for the effective implementation of long-term programs by creating society commitment at multiple levels and establishing community support networks. Education and awareness programs aimed to reduce the stigmatisation of mental illness and suicide. The programs also aimed at improving the recognition of suicide risk and facilitating help-seeking and access to mental health services through improved understanding of the causes and risk factors for suicidal behaviour. Training programs targeting gatekeepers and care providers aimed to facilitate their roles in early detection within potentially vulnerable populations and to increase preventive functions. The screening programs aimed to identify at-risk individuals in the community and direct them to treatment. In addition, the program recommended that the local health authorities provide appropriate care for suicide survivors to support their grief work, if necessary.

Local governments and the local health authorities collaborated and implemented the intervention programs in accordance with the manual (in Japanese; www.mhlw.go.jp/seisakunitsuite/bunya/hukushi_kaigo/shougaishahukushi/jisatsu/index.html,) developed by the program committee of the NOCOMIT-J group. They implemented the intervention with their own budgets. The participants were not blind to the intervention, which started in July 2006. As short duration interventions did not seem to have any detectable effect [2], the intervention continued for 3.5 years. The intervention in the control group was suicide prevention activities as usual. The list of the programs was opened to the control group when the heads of the local governments agreed to participate in this trial. However, we did not show them the detailed intervention manual. The study monitoring and the data collection were conducted in both the intervention group and control group.
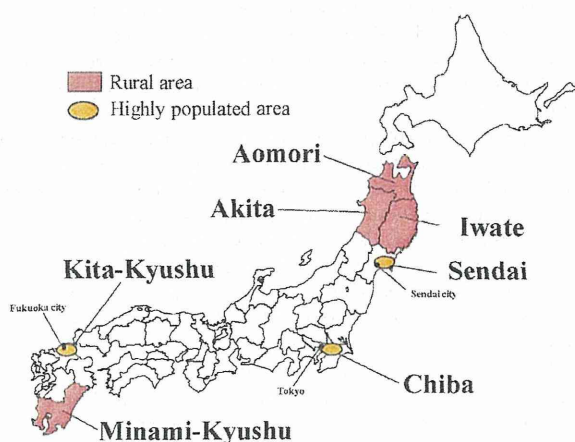
Figure 1. Location map of the study areas. Pink-coloured areas indicate rural study areas. Orange-coloured areas indicate highly populated study areas.
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Rural area		Highly populated area	
Matched region: Akita, Aomori, Iwate, Minami-Kyusyu		Matched region: Sendai, Chiba, Kita-Kyusyu	
Intervention group (community n=7, 291,459 persons)	Control group (community n=10, 339,674 persons)	Intervention group (community n=3, 615,586 persons)	Control group (community n=3, 704,341 persons)
Discontinued intervention (n=0) and loss of follow-up (n=0)	Discontinued intervention (n=0) and loss of follow-up (n=0)	Discontinued intervention (n=0) and loss of follow-up (n=0)	Discontinued intervention (n=0) and loss of follow-up (n=0)
Analyzed (n=7)	Analyzed (n=10)	Analyzed (n=3)	Analyzed (n=3)

Figure 2. Flow chart of the study.
doi:10.1371/journal.pone.0074902.g002

The primary outcome was the incidence of composite outcome, consisting of completed suicides and suicide attempts that required admission to an emergency ward for critical care. Secondary outcomes were as follows: 1) incidence of completed suicides, 2) incidence of suicide attempts that required admission to an emergency ward for critical care, and 3) proportion of adherence with the required components of the intervention described in the manual. For the adherence assessments, information regarding the implementation of the programs described in the manual was collected every 6 months from the month when the study started in all participating regions. The binary questions for the adherence items were prepared based on the essential components listed in Table 1 and were collected from the local health authorities. The reporters of events were not blind to the intervention. Death certificates from the Vital Statistics Records (Ministry of Health, Labour, and Welfare, Japan) for the participating regions from 2003 to 2009 were used every year to collect the following data items: International Classification of Diseases 10th Revision code for intentional self-harm (ICD-10 codes X60–X84), sex, age, and region code. In this study, a suicide attempt patient was defined as a self-harmed individual transported by regional ambulance service and admitted to an emergency ward for critical care. In Japan, fees for ambulance services are covered by the National Health Insurance System, which allows virtually all suicide attempters access to emergency medicine when requested. The following information was collected from the Regional Ambulance Services every 6 months from 2003 to 2009: type of transportation, date of notification, region code, severity, sex and age. Therefore, the data on suicide attempts systematically collected in this study were reliable. The total population numbers by the community, sex and age groups were collected every year from the National Basic Resident Registration System.

Statistical Analysis

In the primary analysis, we compared the rate ratios (RRs) of incidence of the composite outcome as adjusted by covariates for the effect of the intervention. Marginal models (link function; log, distribution; Poisson) with generalised estimating equations [10] were used to examine the effect of the intervention adjusted by sex,

age group (under 25, 25–65, over 65 years), region, period (6-month) and interaction terms (interventions × periods). These variables are well known risk factors from past epidemiological studies and they serve as effect modifications in interventional studies. [11] On the other hand, it takes some time to set up and implement the intervention programs in the community. Therefore, the effects of the intervention would be time-dependent. The 6-month periods were chosen to minimise varying populations. The analysis calculated RRs and their 95% confidence intervals (CI). We conducted an interim analysis 2 years after starting to evaluate the achievement of the primary objective. Therefore, the significance level in the final analysis was set at 0.0492 for the two-sided test based on the method of O'Brien and Fleming. [12].

Sample sizes to be used in the study were calculated based on the assumptions of the suicide rates from 2002 to 2004 in the participating regions. Although the estimated sample sizes were not adjusted for sex, age groups and regions, if all assumptions were met, the statistical power would be over 80%. [9].

Secondary outcomes were analysed to examine whether the rates of completed suicides and suicide attempts were significantly reduced in the intervention group when compared with those of the control group, respectively. Adherence to the interventions was also examined.

Preplanned subgroup analyses of the primary and secondary outcomes by sex and age groups (under 25, 25–65, over 65) were performed. Because these variables were the known risk factors and effect modifications, we also used them for the modelling in the primary analysis. No multiplicity adjustments were made, given the exploratory nature of the analyses.

All analyses were done on an intention-to-treat basis. Statistical analyses were performed using SAS version 9.2 software (SAS Institute Inc., Cary, North Carolina).

The study protocol was approved by the Central Research Ethics Committee of Japan Foundation for Neuroscience and Mental Health. The protocol was also approved by the local Ethics Committees of affiliated universities or institutes in the participating regions. (Aomori region: Kuroishi General Hospital Ethics Committee (http://hospital-kuroishi.jp/) and Hirosaki University Ethics Committee (http://www.hirosaki-u.ac.jp/), Akita region: Akita University Ethics Committee (http://www.akita-u.ac.jp/

Table 1.

	Intervention Level	Target	Objectives and Actions
1	Leadership involvement	Local government	Leadership involvement is a key to effectively implementing long-term programs that utilize a commitment of society at multiple levels and succeed in establishing community support networks. Messages from the mayor have a strong impact on the efficiency of community development and community networking.
			a) Publicizing messages from the mayor to all officials and citizens reminding them of the importance of suicide prevention.
			b) Establishing a regional committee dedicated to suicide prevention chaired by the mayor to promote organization-wide awareness of mental health and suicide prevention and facilitate the collaboration of different sections of the local government.
			c) Formalizing the roles of each service section and promoting pathways to build social support networks within the public and health-related resources, intending to reinforce human relationships and connectedness in the community.
2	Education and awareness programs	Public	The education and awareness programs aim to reduce stigmatization of mental illness and suicide and to improve recognition of suicide risk and facilitation of help seeking.
			a) Waging a campaign for general public education (public events, posters, websites, placards, leaflets and brochures with information about help available locally, self-tests, warning signals and treatment options and announcements of regional educational activities like lectures and seminars).
			b) Providing regional educational opportunities like lectures and seminars to improve understanding of the causes and risk factors for suicidal behavior, particularly mental illness. The programs also cover awareness of availability of social resources and referral procedures for people potentially at risk.
3	Gatekeeper training	Community or organizational gatekeepers	Training programs targeting gatekeepers (community leaders, priests, telephone hotlines, social services, youth workers, geriatric care providers, police, physicians, nurses, pharmacists, mental health providers, and those employed in institutional settings, such as schools) aimed to facilitate their playing important roles in early detection within potentially vulnerable populations and increasing preventive functions. These programs also promote organization-wide awareness of mental health and suicide and facilitate access to mental health services.
			a) Training community or organizational gatekeepers to provide them with an opportunity to identify at-risk individuals within different target populations and direct them to appropriate social and/or mental health services.
4	Supporting individuals at high risk	Individuals at high risk	Home visiting and regional social gatherings aim to reinforce human relationships and connectedness in the community. Screening aims to identify at-risk individuals and direct them to treatment.
			a) Home visiting by regional public health nurses and psychiatrists.
			b) Setting up regional social gatherings.
			c) Screening to identify at-risk individuals and direct them to treatment or follow-up care providers. The focus may be on suicidal behavior directly or on risk factors, such as depression or substance abuse.
			d) Support for self-help activities for high-risk groups, i.e., suicide attempters, to facilitate access to professional help.

*The intervention programs focused on building social support networks within the general public and in health-related resources, intending to reinforce human relationships and connectedness in the community.
**A suicide leaves behind more victims than just the individual, as family, friends, co-workers, and the community can be impacted in many different and unique ways following a suicide. In this study, the program recommended that the local government provide appropriate care for suicide survivors (a person who survives a suicide completer; a suicide griever) to support their grief work, if necessary. Support the activities of self-help groups for suicide survivors and other related organizations.
doi:10.1371/journal.pone.0074902.t001

honbu/), Iwate region: Iwate University Ethics Committee (http://www.iwate-med.ac.jp/), Minami-Kyusyu region: Keio University Ethics Committee (http://www.med.keio.ac.jp/), Sendai region: Tohoku Bunka Gakuen University Ethics Committee (http://www.tbgu.jp/univ/) and Sendai City Hospital Ethics Committee (http://hospital.city.sendai.jp/), Chiba region: National Center Of Neurology And Psychiatry Ethics Committee (http://www.ncnp.go.jp/), Kita-Kyusyu region: University of Occupational And Environmental Health Ethics Committee (http://www.uoeh-u.ac.jp/JP/index.html). We did not directly contact all participants and collect data from all individuals (all data were anonymous) in this study. Therefore, we did not obtain written informed consent from individuals living in the participating regions. Instead, the regional investigators obtained the written authorisation to conduct the study from the head of the local governments on behalf of all inhabitants and announced it as verbal consent in all by public publications in the participated

regions. The processes approved the Central Research Ethics Committee and the local Ethics Committees and complied with the Ethical Guidelines for Epidemiology Research (published by the Ministry of Health, Labour, and Welfare, Japan, http://www.niph.go.jp/wadai/ekigakurinri/guidelines.pdf).

The present study is in accordance with the Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) statement [13,14] and the trial protocol was registered at ClinicalTrials.gov (NCT00737165) and UMIN-CTR (UMIN000000460).

Role of the Funding Source

data interpretation, or writing of the report. YO made the final decision to submit for publication.

Results

Demographic Information of the Participating Regions

The trial flow chart is shown in Figure 2. Population characteristics of the participating areas at baseline are shown in Table 2. In the rural study areas, the total population was 631,133 in 2006. In the highly populated study areas, the total population was 1,319,972 in 2006. Numbers of completed suicides, suicide attempts requiring admission to an emergency ward for critical care, and populations from 2003 to 2009 in the rural areas and the highly populated areas are listed in Table 3 and Table 4, respectively.

The adherence to the suicide prevention programs implemented in the participating areas is shown in Figure 3 and 4. In rural areas, the overall median adherence of the intervention group was 0.65 and significantly higher than that obtained from the control group (beta = 0.42, 95% CI 0.12–0.72, p = 0.0056). On the other hand, in highly populated areas, the overall median adherence of the intervention group was 0.55, not different from that of the control group (beta = 0.35, 95% CI −0.01–0.71, p = 0.0552).

The interim analysis conducted 2 years after the start of the intervention demonstrated that the incidence rates of the composite outcome were similar between the intervention group and control group in the rural areas (RR = 0.99, 95% CI 0.79–1.06, p = 0.257). As the result, the study was continued until the end of the planned period.

As shown in Figure 5, in the rural areas the incidence rates of the composite outcome in the intervention group were slightly lower than those obtained from the control group (RR = 0.93, 95% CI 0.71–1.22, p = 0.598). A subgroup analysis

demonstrated that the incidence rates in the intervention group were significantly lower in males (RR = 0.77, 95% CI 0.59–0.998, p = 0.0485). Also, the analysis demonstrated that the incidence rates in the intervention group were lower in the elderly over 65 years old (RR = 0.76, 95% CI 0.57–1.01, p = 0.062), while the incidence rates were higher in females (RR = 1.34, 95% CI 0.87–2.15, p = 0.174) and in participants younger than 25 years old (RR = 1.44, 95% CI 0.63–3.31, p = 0.386).

In the highly populated areas, the incidence rates of the composite outcome were similar between the intervention group and control group (RR = 1.00, 95% CI 0.85–1.19, p = 0.961).

As shown in Figure 6, in the rural areas the incidence rates of completed suicides were similar between the intervention group and control group (RR = 1.09, 95% CI 0.82–1.45, p = 0.550). A subgroup analysis demonstrated that the incidence rates in the intervention group were higher in females (RR = 1.44, 95% CI 0.85–2.43, p = 0.177).

As shown in Figure 7, in the rural areas, the incidence rates of suicide attempts requiring admission to an emergency ward for critical care in the intervention group were slightly lower than those obtained from the control group (RR = 0.86, 95% CI 0.55–1.36, p = 0.524). A subgroup analysis demonstrated that the incidence rates in the intervention group were significantly lower in males (RR = 0.39, 95% CI 0.22–0.68, p = 0.001) and the elderly over 65 years old (RR = 0.35, 95% CI 0.17–0.71, p = 0.004). The subgroup analysis demonstrated that the incidence rates in the intervention group were lower in participants younger than 25 years old (RR = 0.74, 95% CI 0.24–2.31, p = 0.605), while the incidence rates were higher in females (RR = 1.56, 95% CI 0.80–3.04, p = 0.193).

Table 2. Population characteristics at baseline (2006.1–6) in rural and highly populated areas N (%).

| | Group 1 (Rural areas) | | Group2 (Highly populated areas) | |
| | Intervention | Control | Intervention | Control |
	n = 7	n = 10	n = 3	n = 3
All	291,459	339,674	615,586	704,341
Sex				
Male	136,399 (47)	159,380 (47)	310,301 (50)	348,153 (49)
Female	155,060 (53)	180,294 (53)	305,285 (50)	356,188 (51)
Age				
under 25	47,892 (16)	52,867 (16)	103,218 (17)	119,512 (17)
25–64	157,887 (55)	181,153 (53)	407,801 (66)	448,270 (64)
65 and over	85,680 (29)	105,654 (31)	104,567 (17)	136,559 (19)
Region				
Aomori	35,668 (12)	60,695 (18)	–	–
Akita	59,237 (20)	66,678 (20)	–	–
Iwate	55,416 (19)	61,589 (18)	–	–
Minami-Kyushu	141,138 (48)	150,712 (44)	–	–
Sendai	–	–	160,368 (26)	197,915 (28)
Chiba	–	–	411,025 (67)	425,177 (60)
Kita-Kyushu	–	–	44,193 (7)	81,259 (12)

Table 3.

		Intervention						Control						
		Combined		Completed suicide		Suicide attempt		Population	Combined		Completed suicide		Suicide attempt		Population
		N	Rate	N	Rate	N	Rate	N	N	Rate	N	Rate	N	Rate	N
Before	2003.1-6	128	86.1	68	45.7	60	40.4	297,397	131	75.3	77	44.2	54	31.0	348,092
	2003. 7-12	91	61.4	68	45.9	23	15.5	296,447	95	54.8	74	42.7	21	12.1	346,639
	2004.1-6	126	85.2	105	71.0	21	14.2	295,655	94	54.4	69	40.0	25	14.5	345,415
	2004. 7-12	70	47.5	49	33.3	21	14.3	294,665	122	71.0	73	42.5	49	28.5	343,825
	2005.1-6	77	52.5	57	38.8	20	13.6	293,589	80	46.7	56	32.7	24	14.0	342,382
	2005. 7-12	102	69.8	51	34.9	51	34.9	292,467	138	81.0	69	40.5	69	40.5	340,927
Reference	2006. 1-6	91	62.4	62	42.5	29	19.9	291,459	139	81.8	76	44.7	63	37.1	339,674
Study	**2006. 7-12**	98	67.6	72	49.6	26	17.9	290,122	89	52.7	57	33.8	32	19.0	337,668
period	**2007. 1-6**	89	61.6	56	38.8	33	22.8	288,882	103	61.3	62	36.9	41	24.4	335,894
	2007. 6-12	66	45.9	41	28.5	25	17.4	287,276	103	61.8	57	34.2	46	27.6	333,409
	2008. 1-6	73	51.1	49	34.3	24	16.8	285,773	92	55.6	60	36.2	32	19.3	331,133
	2008. 7-12	71	49.9	44	30.9	27	19.0	284,379	128	77.8	80	48.6	48	29.2	328,951
	2009. 1-6	93	65.7	61	43.1	32	22.6	283,090	90	55.0	61	37.3	29	17.7	326,977
	2009. 6-12	72	51.1	54	38.3	18	12.8	281,763	114	70.1	70	43.1	44	27.1	325,146

Combined: Completed suicide and suicide attempt.
Rate: per 10,000 persons, per year.
doi:10.1371/journal.pone.0074902.t003

Table 4.

Highly populated areas

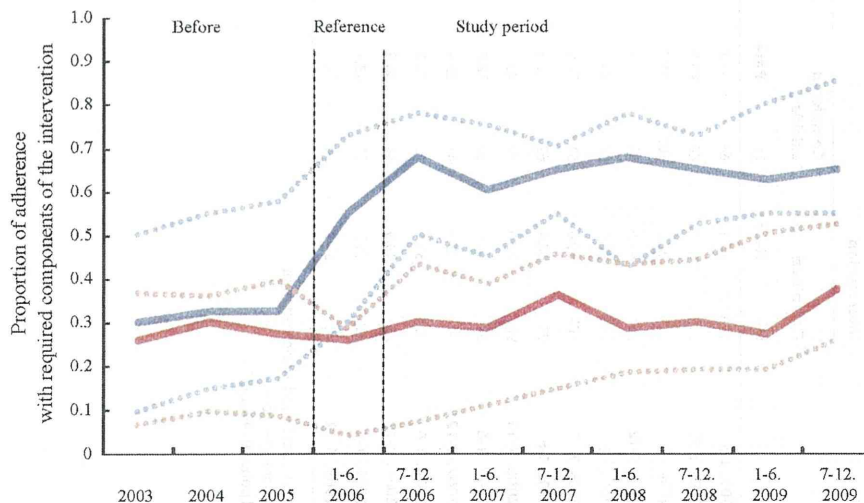|		Intervention							Control						
		Combined		Completed suicide		Suicide attempt		Population	Combined		Completed suicide		Suicide attempt		Population
		N	Rate	N	Rate	N	Rate	N	N	Rate	N	Rate	N	Rate	N
Before	2003.1-6	147	48.3	71	23.3	76	25.0	608,545	176	50.2	99	28.3	77	22.0	700,674
	2003. 7-12	154	50.5	74	24.3	80	26.2	609,571	212	60.5	101	28.8	111	31.7	701,360
	2004.1-6	134	43.9	66	21.6	68	22.3	610,644	168	47.9	79	22.5	89	25.4	702,094
	2004. 7-12	136	44.5	70	22.9	66	21.6	611,912	171	48.7	84	23.9	87	24.8	702,467
	2005.1-6	160	52.2	75	24.5	85	27.7	613,223	199	56.6	94	26.7	105	29.9	702,882
	2005. 7-12	122	39.7	61	19.9	61	19.9	614,385	174	49.5	87	24.7	87	24.7	703,589
Reference	2006. 1-6	166	53.9	70	22.7	96	31.2	615,586	197	55.9	97	27.5	100	28.4	704,341
Study	2006. 7-12	202	65.5	80	25.9	122	39.5	617,137	208	59.0	83	23.5	125	35.5	705,159
period	2007. 1-6	164	53.0	68	22.0	96	31.0	618,734	208	58.9	89	25.2	119	33.7	706,016
	2007. 6-12	154	49.6	74	23.8	80	25.8	620,562	190	53.7	91	25.7	99	28.0	707,088
	2008. 1-6	148	47.6	81	26.0	67	21.5	622,435	202	57.0	89	25.1	113	31.9	708,205
	2008. 7-12	165	52.9	67	21.5	95	30.4	624,319	222	62.6	87	24.5	135	38.0	709,661
	2009. 1-6	156	49.8	80	25.5	76	24.3	626,250	190	53.4	86	24.2	104	29.2	711,167
	2009. 6-12	137	43.7	51	16.3	86	27.4	626,963	208	58.4	92	25.8	116	32.6	711,837

Combined: Completed suicide and suicide attempt.
Rate: per 10000 persons, per year.
doi:10.1371/journal.pone.0074902.t004

As shown in Figure 6 and 7, in the highly populated areas, the RRs of suicide attempts and completed suicide demonstrated heterogeneous effects.

Discussion

In the present study, the intervention had unclear effects on the overall rate ratio of the composite outcome in rural areas where the suicide rate was high. The overall rate ratio of the composite outcome in the intervention group was 7% lower than that obtained from the control group. This was possibly because the intervention had some heterogeneous effects on different subpopulations. Indeed, the RR in males was significantly lower. It was also demonstrated that the RR in the elderly was lower, while it was higher in females and in younger participants. Interestingly, our secondary analysis suggested that the effects were more


Figure 3. Figure 3 shows the proportion of adherence with required components of the intervention in the rural areas. The blue line indicates the proportion of the intervention group, and the red line indicates that of the control group. The dotted lines indicate interquartile ranges. The proportion is shown from the 3.5 years before the start of the study period. The six-month period before the start of the study period was the reference period.
doi:10.1371/journal.pone.0074902.g003
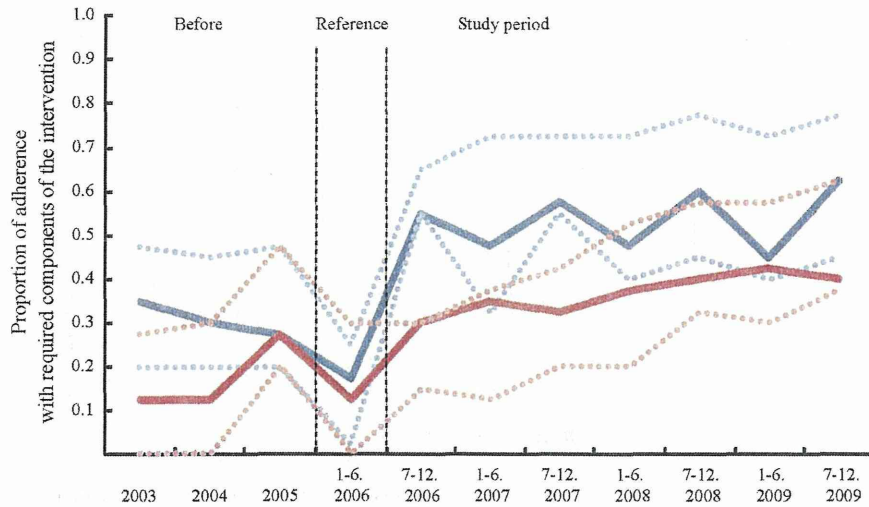
Figure 4. Figure 4 shows the proportion of adherence with required components of the intervention in the highly populated areas.
The blue line indicates the proportion of the intervention group, and the red line indicates that of the control group. The dotted lines indicate interquartile ranges. The proportion is shown from the 3.5 years before the start of the study period. The six-month period before the start of the study period was the reference period.
doi:10.1371/journal.pone.0074902.g004

Primary outcome at all and subgroups (sex and age) in Group1

■ Rate Ratio, — 95%CI
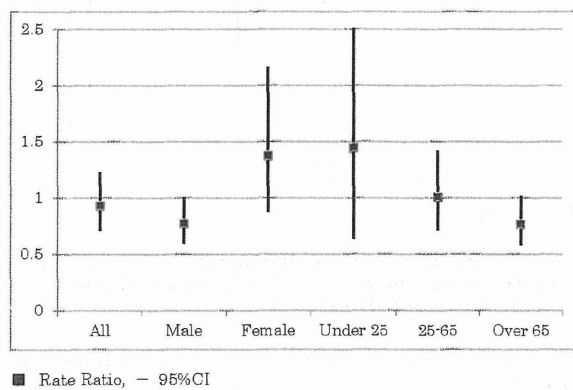
Primary outcome at all and subgroups (sex and age) in Group 2

■ Rate Ratio, — 95%CI
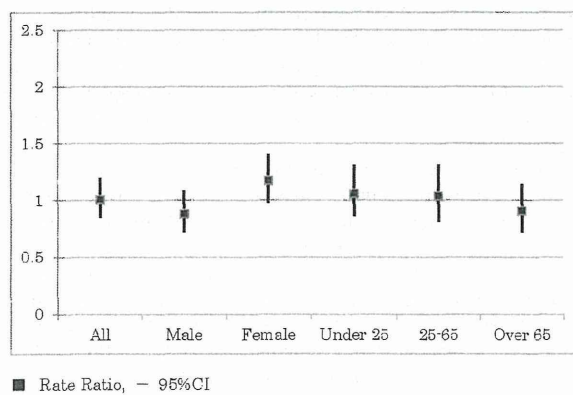
Figure 5. Primary outcome (composite outcome, consisting of completed suicides and suicide attempts requiring admission to an emergency ward for critical care) for all and for subgroups (sex and age) in rural areas and in highly populated areas.
doi:10.1371/journal.pone.0074902.g005

apparent in the incidence of suicide attempts than that of completed suicides. It was demonstrated that the RR of suicide attempts in the intervention group was significantly lower in males and in the elderly. Thus, this study apparently demonstrated the heterogeneous effects of the intervention on the different subpopulations.

The beneficial effect of the intervention in males is consistent with a previous report showing a significant reduction of suicide rate through a community-based intervention in the US Air Force, in which about 84% of participants were males.[15] Interventions used in the study aimed to establish a seamless system of services across multidisciplinary human services with very strong and vertical leadership involvement. From another point of view, it is well known that about 90% of suicides are associated with mental illness, i.e., depression and other affective disorders, schizophrenia, substance/alcohol-related disorders and personality disorders. [16,17] The interventions in the US Air Force study covered not only depression but also a range of psychosocial risk factors for suicide, and thus were multilevel and multimodal. Although the sample size was quite large, the US Air Force study was a quasi-experimental pre-post design conducted in a single organisation (Table 5). In the present study, we conducted a parallel comparative trial in multiple regions to examine the effectiveness of a similar approach. Therefore, our study has reproduced and extended the findings of the US Air Force study. Here, it is concluded that a community-based multimodal intervention would be recommended for males. It is still unclear which component of the complex intervention programs is especially important for males.

In this study, we developed our intervention by extending the findings from previous studies, focusing especially on elderly. [5–7] As we expected, beneficial effects of the intervention in the elderly were consistent with these previous observations. [5–7] In their interventions, psychiatrists and public health nurses tried to reinforce human relationships and connectedness in their community by home visiting and regional social gatherings. However, these previous studies were retrospective pre-post designs with one or a few communities. Therefore, our study confirmed the findings

Secondary outcome (Suicide completed) at all and subgroups in Group1
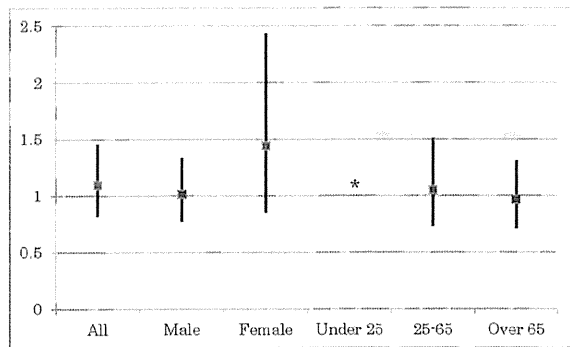
■ Rate Ratio, — 95%CI

* Not calculated

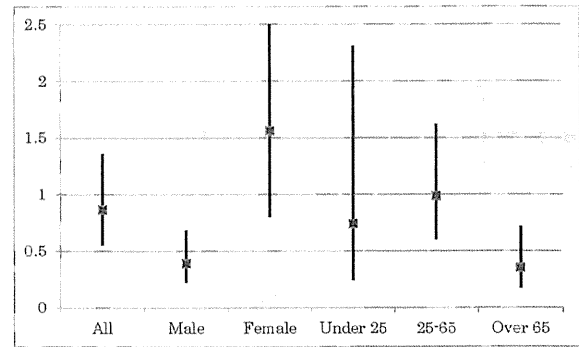Secondary outcome (Suicide completed) at all and subgroups in Group2
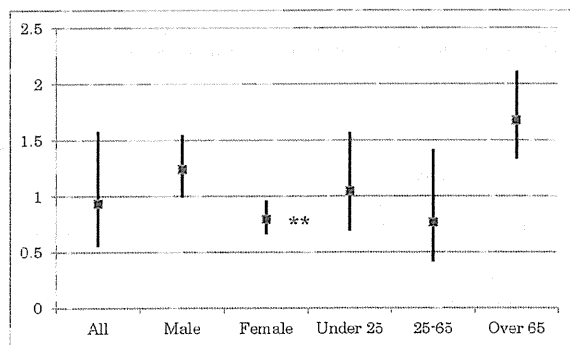
■ Rate Ratio, — 95%CI

** Interaction (intervention × year) was significant, p= 0.0270

Figure 6. Secondary outcome (completed suicides) for all and for subgroups in rural areas and in highly populated areas.
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Secondary outcome (Suicide attempted) at all and subgroups in Group1

■ Rate Ratio, — 95%CI

Secondary outcome (Suicide attempted) at all and subgroups in Group2
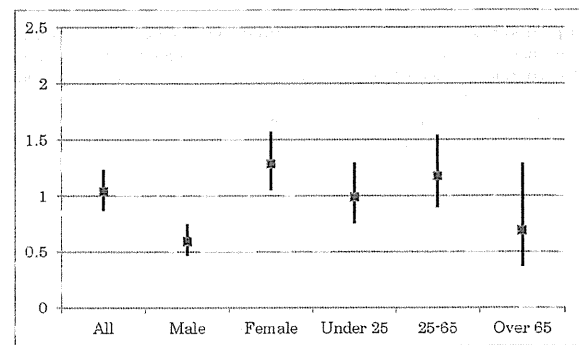
■ Rate Ratio, — 95%CI

Figure 7. Secondary outcome (suicide attempts) for all and for subgroups in rural areas and in highly populated areas.
doi:10.1371/journal.pone.0074902.g007

for elderly and concluded that the effect would be significant in this group.

As shown in Table 5, there are some reports of multilevel interventions focusing on depression care. [18,19] These interventions aimed to introduce untreated depressed patients to appropriate care by public awareness campaigns, educating general practitioners and supporting them with mental health professionals, and encouraging collaborative care. A German study, the Nuremberg Alliance Against Depression, reported a reduction in nonfatal suicide attempts in an intervention region compared with a control region but no difference in effect on the rate of completed suicides. [18] In the report from Hungary, the rate of completed suicides in the intervention region was not different from that in the control region. [19] Although the type of our intervention was different from these two studies, the absence of the effect on the rate of completed suicides in the intervention region was also observed in our NOCOMIT-J. On the contrary, as described above, the US Air Force study, which covered various risk factors, showed a significant reduction of the rate of completed suicides. [15] A high rate of adherence to the intervention (over 80%) might help to achieve the objective of lowering completed suicide rates (Table 5).

The incidences of suicidal behaviour were similar between the intervention group and control group in the highly populated areas near metropolitan cities, not unexpected as adherence of the intervention group to the suicide prevention programs was not different from that of the control group. In addition, adherence of the intervention group in highly populated area was relatively low, suggesting the difficulties of implementing the intervention in these areas. Further improvement of the intervention programs would be necessary to make the intervention feasible in the highly populated areas.

There are several limitations of the present study. 1) The study was not a randomised trial. Therefore, we used a matched pair design and a model adjusted for possible confounding factors in the analysis. However, some unmeasured and residual confounders may still persist. We need to perform randomised trials confirming our insights. 2) The study participants, investigators and the reporters of events were not blind to the intervention. Although the outcomes were systematically collected from official records, the study might have some misclassification bias. 3) Adherence to the intervention was limited. The adherence would be improved by investing sufficient budgets and resources.

In conclusion, our findings suggest that the community-based multimodal intervention for suicide could be implemented in the all areas. However, the effectiveness of the intervention are shown

Table 5. Related studies.

Study	Population	Study Size, Sites	Sex, Age	Study Design	Intervention	Pre suicide rate	Duration	Compliance	Outcome	Analysis	Results
Knox et al., BMJ. 2003 Dec 13; 327(7428):1376.	US Air Force personnel	5,260,292	About 84% men	(Quasi-experimental) pre-post design	Multimodal (10 initiatives)	1990–6 (median 13.1)	5 years	Over 80%	Completed suicides, homicide, accidental death,?family?violence	χ2 test for linear trend with the Mantel-Haenszel, and relative-risk (RR),(No adjustment for sex and age)	Significant 33% reduction of suicide (RR 0.67, 0.57–0.80) compared to control
Hegerl et al., Psychol Med. 2006; 36(9): 1225–33.	Inhabitants living in the city	720,000 Intervention: Nuremberg, 480,000 Control: Wurzburg 270,000	No data (no differences between pre-post)	(Non-randomised) concurrent comparative (a city vs. a city) design	4 levels; Training of primary care physicians, public campaign for depression, corporation with facilitators and self-help activities support	Intervention (about 18) vs. control (about 15)	2 years	Unknown percentage (details of activities only)	Completed suicide, suicide attempted, And combined (suicide acts)	Change rate and χ2 test (stratified sex and years, but not adjusted)	19.4% to 24% reduction suicide acts rate (p = 0.082, 0.004) compared to control
Szanto et al., Arch Gen Psychiatry. 2007; 64(8): 914–20.	A region with a high suicide rate in Hungary	127,000 Intervention: Kiskunhalas,73,000 (44,000 in villages and 29,000 in a town) with 28 GPs Control: Bacs-Kuskun,54,000 (22,000 in villages and 32,000 in a town)	48% were men, 22% were over age 60	(Non-randomised) concurrent comparative (a region vs. a region) design	Training of primary care physicians and nurse, plus telephone psychiatrist consultation	Intervention (median 57.5) vs. control (median 56)	5 years	About 60% (39–90%)	Completed suicides (from police), prescription of anti-depressants, alcohol related death and unemployment	Poisson log-link function, Mixed linear models with repeated measures (adjusted years, stratified sex, but not adjusted age)	No significant difference between intervention and control overall, but female suicide decreased by 34% in intervention and increased by 90% in control; significant decrease compared to county and country (Hungary) levels.
NOCOMIT-J	Inhabitants living in high suicide-rate areas in Japan	631,133 (rural area)	47% were men, 30% were 65 over aged	(Non-randomised) controlled (matched) concurrent comparative (2 areas and 4 regions) design	Multimodal (4 levels)	Intervention (median 42.5) vs. control (median 42.5) in rural areas	3.5 years	About 70% in rural areas, About 55% in highly populated areas	Completed suicides from government), suicide attempts, and combined	Poisson log-link function, Marginal models in repeated measures with GEE (adjusted sex, age and years)	9% reduction, not significant, but men 23% (p = 0.0485), over 65 24%(p = 0.062) reduction compared to concurrent control

Table 5. Cont.

Study	Population	Study Size, Sites	Sex, Age	Study Design	Intervention	Pre suicide rate	Duration	Compliance	Outcome	Analysis	Results
		7 intervention vs. 10 control									
		1,319,927 (highly populated area)				Intervention (median 22.9) vs. control (median 26.7) in highly populated areas					
		4 interventions vs. 4 controls									

for males and for the elderly in rural area. Therefore, it would be recommended for males and for the elderly in rural areas.

Author Contributions

Conceived and designed the experiments: YO AS NI HS NY. Performed the experiments: KO HU SA YI HI YK YM JN NN NW TY AN YS MT ET. Analyzed the data: NI HS NY. Contributed reagents/materials/analysis tools: KO HU HO. Wrote the paper: YO AS NY.

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〔特別寄稿〕

「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研究 NOCOMIT-J」を終了して：研究成果と今後の課題

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岩　佐　博　人 [4]　　石　田　　　康 [5]　　宇　田　英　典 [6]　　亀　井　雄　一 [7]
中　村　　　純 [8]　　本　橋　　　豊 [9]　　田　島　美　幸 [1]　　米　本　直　裕 [10]
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Ⅰ．はじめに

　世界保健機関（WHO）は，年間に世界で100万人近くの人々が自殺で死亡していると推定している[1]。WHOが2004年に取りまとめた国際調査では，日本の自殺率は7か国中で第1位であった。厚生労働省「人口動態統計」によれば，2011年における死亡順位では，20〜39歳の日本人の死因の第1位が自殺であり，40〜49歳で第2位，50〜54歳で第3位となっている。

　また，我が国の自殺死亡者数は1997年まで2万5千人前後で推移していたが1998年に急増し，2012年には3万人を下回ったものの，現在も高い水準で推移している。そのため，自殺対策に向けた取り組みは，我が国において安心・安全な社会を構築するために重要かつ緊急の課題である。

　そうしたなか，我が国では，2006年6月に「自殺対策基本法」が成立し，同年10月には異例な早さで施行された。この法律の目的は，自殺対策を総合的に推進して，自殺の防止を図り，あわせて自殺者の親族等に対する支援の充実を図り，もって国民が健康で生きがいをもって暮らすことのできる社会の実現に寄与することとされている。更に，2007年6月には，「自殺総合対策大綱」が閣議決定された。更に，2009年度より実施された自殺対策緊急強化基金（内閣府）を背景に，全国各地でさまざまな関連事業が実施されている。しかし，自殺を減らすための科学的根拠（エビデンス）に裏付けられた介入が明らかでないまま事業だけが進められている状況が続いていた。

　自殺対策に限らず，公共政策の立案と実施に当たっては，科学的根拠に基づく実践（evidence-based practice; EBP）が必要であることはいうまでもない。人的資源や財源が限

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られたなかで確実に成果を得るために施策の最適化を目指すのは当然のことであり，政策立案者は国民に対して十分な説明責任を果たさなければならない。しかし，自殺対策におけるエビデンス（特に介入効果のエビデンス）は，我が国ではもちろんのこと，諸外国においても大きく不足しており，公共政策立案者あるいは研究者が必要なエビデンスを社会に提供できていない状況にある。

それは，自殺対策の効果を厳密な科学的方法で検証することが難しいためでもある[2)3)]。人口全体からみれば，自殺というのは比較的稀な事象であり，疫学統計的に十分な効果を実証するために必要なサンプルサイズが極端に大きくなる。加えて，EBPに精通した公共政策立案者あるいは研究者の不足や，介入効果の実証研究/政策モニタリング研究のための資源が不十分である。更に，自殺に特有なリスク因子も明確に理解されていないため，介入ターゲットや試験介入法，評価項目（あるいは有効な代理指標）の選択にも，かなりの困難が伴う[4)5)]。

そこで，我が国で初めての大型多施設共同による自殺対策のための地域介入研究を実施し，複合的地域自殺対策プログラムの自殺企図予防効果が検討され，その研究成果がPLOS ONE誌に掲載された[6)]。本研究の結果は，我が国における地域の特性に根ざした自殺対策の立案と実践に役立つものと強く期待されている。そこで，本稿では，先にPLOS ONE誌に掲載された研究成果を紹介するとともに，我が国における今後の自殺対策の課題について検討した。

Ⅱ．自殺対策のための戦略研究とは

戦略研究とは，我が国を支える多くの国民の健康を維持・増進させるために，優先順位の高い慢性疾患・健康障害を標的として，その予防・治療介入および診療の質改善介入など，国民の健康を守る政策に関連する「実証的根拠（エビデンス）」を生み出すために実施される厚生労働科学研究費補助金による大型の臨床研究プログラムである。

2005年度より創設された戦略研究は，「厚生労働省が，あらかじめ国民のニーズに基づいて策定された行政の方針に従って具体的な政策目標を定めたうえで，成果（アウトカム）指標と研究計画の骨子を定める」という点で成果指標，研究計画をすべて研究者に一任してきたこれまでの厚生労働科学研究の一般公募研究，あるいは，班研究とは一線を画すものである。研究費も従来の厚生労働科学研究費補助金では原則として年間約2千万円から3千万円の研究費を使って3年の期間で研究を行うことになっていたのに対し，自殺対策のための戦略研究では年間約2億円の研究費を使って5年の期間をかけて研究が行われることになった。一方，同年に採択された糖尿病予防のための戦略研究では年間約8.6億円の研究費が拠出された（週刊医学界新聞，第2644号，2005年8月1日）。2つの課題間で研究費の配分額に違いができた経緯は不明である。

年間約2億円というと大きな金額のように思えるが，実際に研究を始めると必ずしもそうではないことがわかってきた。後述するように，自殺対策のための戦略研究では地域介入研究（NOCOMIT-J）と救急介入研究（ACTION-J）の2つの班が立ち上がり（Fig.1），地域介入班では年間約1億円の研究費を使って7地域で介入を行った。中央運営費用を除くと一地域で使える費用は7百万円から8

研 究 課 題	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研究（NOCOMIT-J）	自殺企図の再発防止に対する複合的ケースマネジメントの効果：多施設共同による無作為化比較研究（ACTION-J）
研 究 目 的	自殺死亡率が長年にわたって高率な地域において，一次から三次までのさまざまな自殺予防対策を組み合わせた新しい複合的自殺予防対策プログラムを介入地区で実施し，通常の自殺予防対策を行う対照地区と比較して，自殺企図（自殺死亡および自殺未遂）の発生に効果があるかどうかを検証する。	救急施設に搬送された自殺未遂者に対するケース・マネージメント（心理教育や受療支援，背景にある問題解決のための社会資源利用支援など）の自殺企図再発防止効果を検証する。
設 定 目 標	地域における自殺企図率の減少	自殺未遂者の自殺企図再発率の減少
研究リーダー	大野　裕 国立精神・神経医療研究センター認知行動療法センター　センター長	平安　良雄 横浜市立大学附属市民総合医療センター病院長/横浜市立大学大学院医学研究科精神医学部門教授
研究実施団体	財団法人 精神・神経科学振興財団	

より効果的な自殺防止対策を確立

Fig.1 自殺対策のための戦略研究の概要

百万円であり，研究班事務局，あるいは，財団に設置された統括推進本部と連絡を取りながら介入活動を管理・運営し，データを収集するための人材を一人確保すると，その人件費だけで年間予算の半分が消費されることになる。したがって，介入活動自体の費用や人材は自治体に依存し，研究のための活動を研究費で行うという，自治体と研究班の共同作業として地域介入研究を行うことになった。

　さて，このようにして行われることになった戦略研究であるが，その成果指標および研究計画の骨子は，その研究成果を「政策」として全国に均てん化することを前提として，厚生労働省の研究班により作成されていた。つまり，戦略研究は，その成果が「現実的な問題解決」のために利用可能かどうかを検討することを目的として実施された研究である。自殺対策に関しては，2004 年度に厚生労働

科学研究費補助金（厚生労働科学特別研究事業）「うつ病関連の自殺予防戦略研究課題の提案と評価に関する研究」（主任研究者：樋口輝彦）が，それまでの内外の自殺研究をレビューし，「自殺関連うつ対策戦略研究」という課題で研究を進めることが適切であると提言し，2005 年度からその提言に沿った研究が行われることになった。

　ただし，戦略研究を開始するに当たって，研究班は研究課題名を「自殺対策のための戦略研究」に変更した。それは，自殺者の大半が自殺直前に精神疾患にかかっていることが多くの研究で報告されているが，そのなかでうつ病は 3〜4 割前後であり，統合失調症を始めとする多くの精神疾患もまた自殺の原因としては重要であることから，自殺対策をうつ病に限定することは好ましくないと判断したからである。また，「予防」という表現は，

自死遺族が自殺の可能性に気づきそれを止めることができなかったと非難されているように感じる可能性が高いことから，「自殺予防」ではなく「自殺対策」とした。

こうして，「自殺対策のための戦略研究」班は，自殺対策では「地域特性に応じた自殺予防プログラムの開発（ポピュレーションアプローチ）」と「自殺企図者の再発防止策の開発（ハイリスクアプローチ）」の両方が必要であり，自殺者の減少に向けた取り組みが重要かつ緊急の課題として必要であると考えて研究に取り組むことになった。そこで，ここからは，「地域特性に応じた自殺予防プログラムの開発（ポピュレーションアプローチ）」を目的としたNOCOMIT-J研究の具体的な内容と成果について論じることにする。

III. NOCOMIT-J 研究の背景と目的

自殺の背景には，健康問題（精神疾患・身体疾患），経済・生活問題，家庭問題の他，人生観・価値観や地域・職場のあり方の変化等さまざまな社会的要因が複雑に関係しており，予防対策の実施に当たっては多角的な検討と包括的な対策が必要になる。しかし，効果的な複合的自殺予防対策のあり方に注目した研究および施策ははなはだ不十分な現状である。また，自殺の要因についてより詳しく調べる目的で心理学的剖検などの研究も行われているが，協力率の低さや協力者の属性の偏りなどから，研究結果は慎重に検討しなくてはならない。また，自殺者の大半が自殺直前に精神疾患にかかっており，体調不良を訴えて精神科以外の診療科を受診していることが多いことから，精神科以外の診療科の医療機関と精神科の医療機関が連携する啓発活動が全国レベルで展開されたこともあったが，

その効果も科学的には実証されていない。

これまでの系統的レビュー論文では，多段階かつ複合的な介入が地域での自殺予防の戦略となり得ることが示されており[2)7)8)]，理論的には複数の介入間の相乗効果が見込まれる[8)]。しかし，一般集団における自殺率が低い値であるために統計的な検出力をもって群間の差を検出する研究が困難であった。実際，自殺率への介入の影響を報告した研究はほとんどなかった[2)7)8)]。

そこでNOCOMIT-Jでは，大規模集団を対象として，十分に自殺行動を観察するための適切な観察期間を用いて，そのため，十分な統計学的検出力を得たうえで研究を行った。更に，事前に計画したサブグループ解析を特定のサブ集団における介入の効果を検出するために実施した。

全国各地の先駆的な取り組みを踏まえ，効果的な支援方法に関するエビデンスを大規模多施設共同研究により構築し，今後の政策立案に役立てることが必要であるとの認識のもと，2005年度より，厚生労働科学研究費補助金による研究事業として「自殺対策のための戦略研究」が実施された。本稿で詳しく紹介するNOCOMIT-Jは，そのうちの1つである（Fig.1）。

本戦略研究の実施主体は財団法人 精神・神経科学振興財団（現在は公益財団法人）であり，研究グループを全国で組織し，関連する自治体等の協力を得て複合的地域自殺対策プログラムの自殺企図予防効果を検証した。NOCOMIT-J研究班の構成はFig.2に示したとおりである（所属は当時のものを掲載してある）。また，図に示したように各種委員会を立ち上げて，研究の計画，倫理的検討，進捗管理等を行った。本研究の意義は，こうし
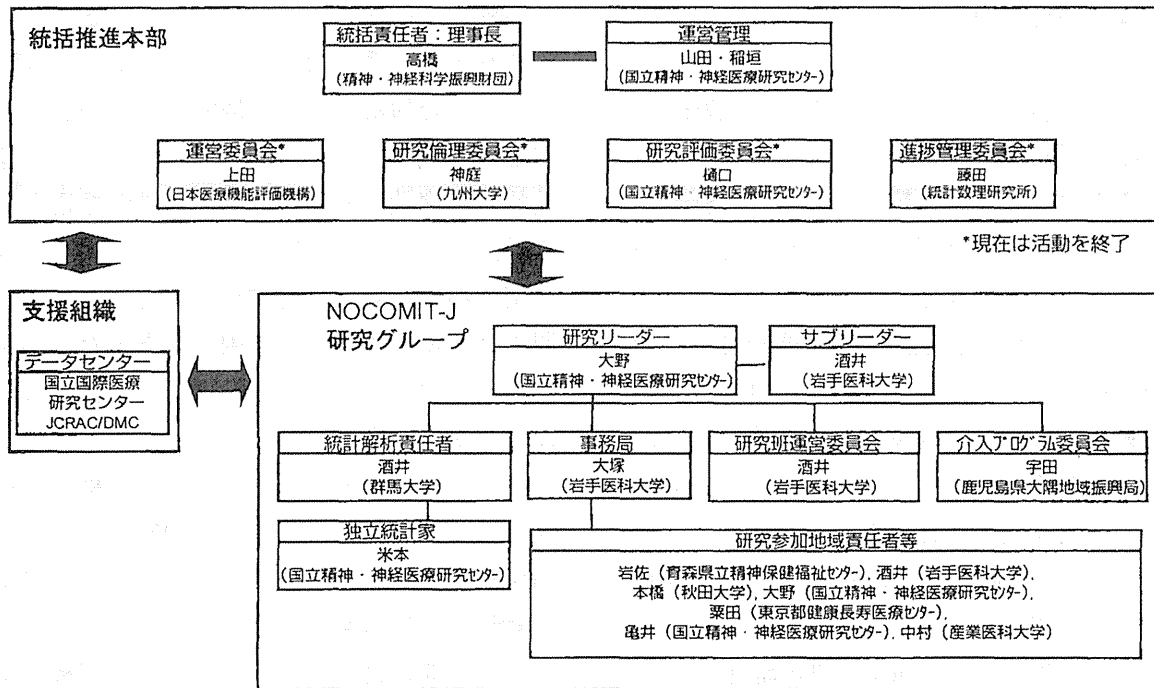
Fig.2 NOCOMIT-J の研究班の構成

た委員会の指導のもと，研究班が事前に研究計画と解析計画を立て，それを公にしたうえで計画に沿って研究を進めることで，恣意的な解釈や推測が入るのを極力排したところにもある。

IV. NOCOMIT-J 研究の方法・研究デザイン

1 研究参加地域

NOCOMIT-J 研究では，地域介入の対象として，自殺死亡率が長年にわたって高率な地方郡部の地域と，都市部近郊の人口密集地域の2つの地域を設定した。特に，前者は本研究の介入の基盤となった，これまでに日本で行われた地域介入が焦点を当てていた地域である[9)~11)]。地域に居住する全集団が介入の標的である。本研究では，過去の自殺率および人口規模を用いてマッチさせた介入群と対照群を対とした。地方郡部地域の対象は4つの介入地域に居住する住民と4つの対照地域に居住する住民とした。都市部近郊の人口密集地域は，本研究の実施前に自殺率が上昇しており，地方郡部地域とは別に標的として設定した。人口密集地域の参加者は3つの介入地域と3つのマッチさせた対照地域に居住する住民とした。

2 複合的自殺予防対策プログラムに基づく地域介入

NOCOMIT-J で検証した多段階かつ複合的な地域介入は，日本の地方郡部地域に居住するうつ病高齢者に焦点を当てた以前の研究の知見[9)~11)]を拡張して開発した[12)]。その基本コンセプトは「こころの健康を守る地域の環境作り」「地域の絆の再構築」「地域での弱者支援」である。

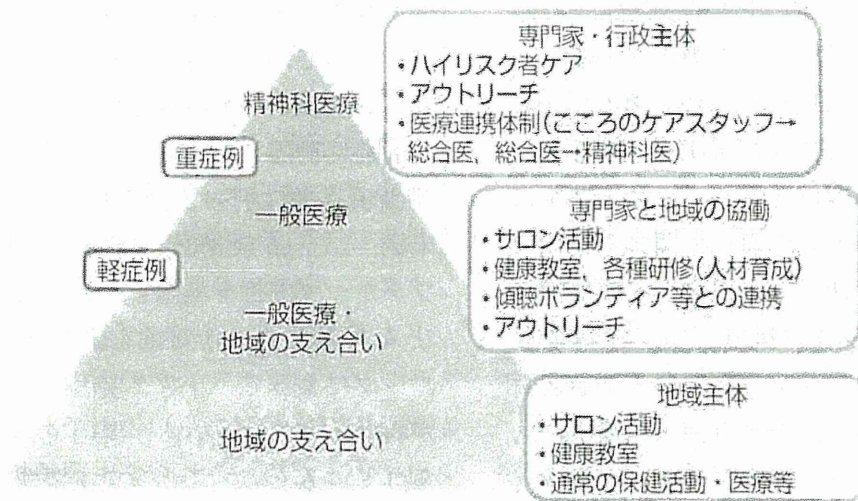本介入は，一般社会と健康に関連する資源の社会支援ネットワークを構築することに焦点を当て，地域社会の人と人の関係（relationship）と連結性（つながり connectedness）を

Fig.3 介入必須項目の構成要素
(岩手医科大学　大塚先生資料，宇田先生改変)

増強することを意図したものである。必須の構成要素を Fig.3 に列記した。ここに示すように，介入は複数の段階からなり，複数の様式の介入を組み合わせたもので，参加地域の全住民を標的としている。

同時に，自殺行動の原因とリスク要因に対する理解を改善することにより，自殺リスクを認識させ，援助希求行動を促進し，精神保健サービスへのアクセスを改善することを目的とした。訓練プログラムは，ゲートキーパーやケア提供者を標的として，脆弱な人々を早期に同定する役割を促進し，自殺予防的な機能を向上させることを目的とした。スクリーニングプログラムは，地域社会のなかのリスクのある個人を同定し，治療へと促すことを目的とした。更に，地域の保健部局が必要に応じて自死遺族に対して喪の作業を支援するための適切なケアの提供を推奨した。

地方自治体および地方の健康部局は協働して，NOCOMIT-J グループのプログラム委員会が開発した介入プログラムをマニュアルに従い実施した[13]。このように，NOCOMIT-J は，さまざまな行政機関・医療機関・教育機関や NPO 等の組織，そして，地域住民の方々の理解と協力なしには進めることができない大規模な地域介入研究であった。

対照群での介入は通常の自殺予防活動とした。対照群に対しても，地方自治体の首長が研究参加に同意した後にプログラムのリストを開示した。しかし，介入マニュアルの詳細は開示していない。研究モニタリングとデータの収集は介入群，対照群の両群で行われた。

地域介入は 2006 年 6 月に開始された。短期間の介入では検出可能な効果が得られない可能性があるため[2]，介入を 3.5 年間継続した。それと併行して，地域間で均一な介入が行われるように，半年ごとに中央での研修会を開催し，各介入地域の関係者が集まって，お互いの介入の現状を報告し，スキルアップを図った。

3 評価項目

主要評価項目は自殺企図（自殺死亡および救急事故等報告に基づく自殺未遂（重症ないし中等症）の発生）とした。副次評価項目は，

1) 自殺死亡の発生，2) 救急事故等報告に基づく自殺未遂（重症ないし中等症）の発生，3) 介入マニュアルに必須と記述された介入構成要素へのアドヒアランス割合，とした。アドヒアランスの評価として，マニュアルに記述されたプログラムの実施に関する情報を研究開始時から 6 か月ごとにすべての参加地域で収集した。Fig.3 に列記した必須構成要素に基づきアドヒアランスに関する 2 値変数の質問項目を準備し，地域自治体の健康部局から収集した。イベントの報告者は介入に対して盲検化していない。参加地域の 2003 年から 2009 年の人口動態統計（厚生労働省）を用いて，国際疾病分類第 10 版の「故意の自傷及び自殺（ICD10 分類 X60-X84）」，性別，年齢，地区コードについての情報を収集した。本研究では，自殺未遂の患者は自傷により救急サービスに搬送された重傷ないし中等症の自損患者と定義した。日本では，救急サービスは国の医療保険制度でカバーされており，すべての自殺未遂患者が必要に応じて救急医療へアクセス可能である。救急事故等報告からは，搬送の種類，日付，地区，重傷度，性別，年齢，についての情報を 6 か月ごとに 2003 年から 2009 年まで収集した。そのため，本研究の自損による救急搬送の日付は系統的に収集されており信頼できる。また，地域，性別，年齢グループごとの全人口を，住民基本台帳を基に収集した。

4　統計解析

主要解析において，主要評価項目である交絡要因（共変量）を調整した自殺死亡と自殺企図を合わせた複合アウトカムの発生率比（rate ratios; RRs）を介入効果の指標として比較した。

副次評価項目は自殺死亡と自殺企図の発生率それぞれが対照群と比較して介入群で有意に低下しているか否かを検討した。介入へのアドヒアランスも検討した。

事前に計画していた，主要評価項目と副次評価項目の性別および年齢グループ（25 歳未満，25〜65 歳未満，65 歳以上）ごとのサブグループ解析を実施した。これらの変数はリスク要因であり効果を修飾する（サブグループによって，リスク要因の影響の大きさが異なる可能性がある）要因であることが知られているため，これらを主要解析のモデリングにも使用した。探索的な解析であることを考慮して，多重比較の調整は行わなかった。

すべての解析は intention-to-treat の原則に基づき実施した。統計解析は SAS ソフトウェアを用いて実施した。

5　倫理的配慮等

自殺を対象とした地域介入研究は，研究倫理についての議論もあり，また，極めて頻度の低いアウトカムについての評価が要求されるため，諸外国においてもハードルが高いとされている。NOCOMIT-J の研究プロトコルは，公益財団法人精神・神経科学振興財団の中央研究倫理委員会で承認された。また，プロトコルは参加地域各地の大学または研究機関の倫理委員会で承認された。研究担当者は，参加者と直接接することはなく，すべての個票データ（すべてのデータは匿名化されている）を収集した。そのため，参加地域の住民から書面によるインフォームドコンセントは得ていない。代替として，地域の研究者は，住民の代理として地方自治体の長から研究実施の認可を書面で得て，参加地域の公共出版物に口頭同意としての告知を行った。この過程は中央研究倫理委員会および地域の倫理委員会で承認されており，疫学研究に関する倫

理指針に則っている（http://www.niph.go.jp/ wadai/ekigakurinri/guidelines.pdf）。

また，研究成果論文[6]はTransparent Reporting of Evaluations with Nonrandomized Designs（TREND）宣言[14][15]に則っており，NOCOMIT-JのプロトコルはClinicalTrials. gov（NCT00737165）およびUMIN-CTR（UMIN 000000460）に登録されている。また，NO-COMIT-Jのプロトコルは学術論文として公開した[12]。

Ⅴ．NOCOMIT-J 研究の結果

1　参加地域の人口統計学的情報

Fig.4に本研究のサンプリングフローを示した。2006年の自殺死亡率が長年にわたって高率な地方郡部の地域の研究対象者数は631,133名だった。都市部近郊の人口密集地域の全対象者数は1,319,927名であった。

2　自殺予防プログラムへのアドヒアランス

参加地域で実施された自殺予防プログラムへのアドヒアランスをFig.5, 6に示した。

自殺死亡率が長年にわたって高率な地方郡部の地域では，介入グループ全体のアドヒアランスの中央値は0.65で，対照グループのアドヒアランスよりも有意に高かった（β=0.42，95%信頼区間0.12〜0.72，p=0.0056）。一方で，都市部近郊の人口密集地域では，介入グループ全体のアドヒアランスの中央値は0.55で，対照グループのアドヒアランスと差がなかった（β=0.35，95%信頼区間20.01〜0.71，p=0.0552）。

3　主要評価項目への効果

自殺死亡率が長年にわたって高率な地方郡部の地域では，介入開始から2年後の中間解析から主要評価項目は自殺企図（自殺死亡および救急事故等報告に基づく自殺未遂（重症ないし中等症））の発生率は介入群と対照群で同様であった（RR=0.99，95%信頼区間0.79〜1.06，p=0.257）。この結果から，予定どおりの期間研究が継続された。
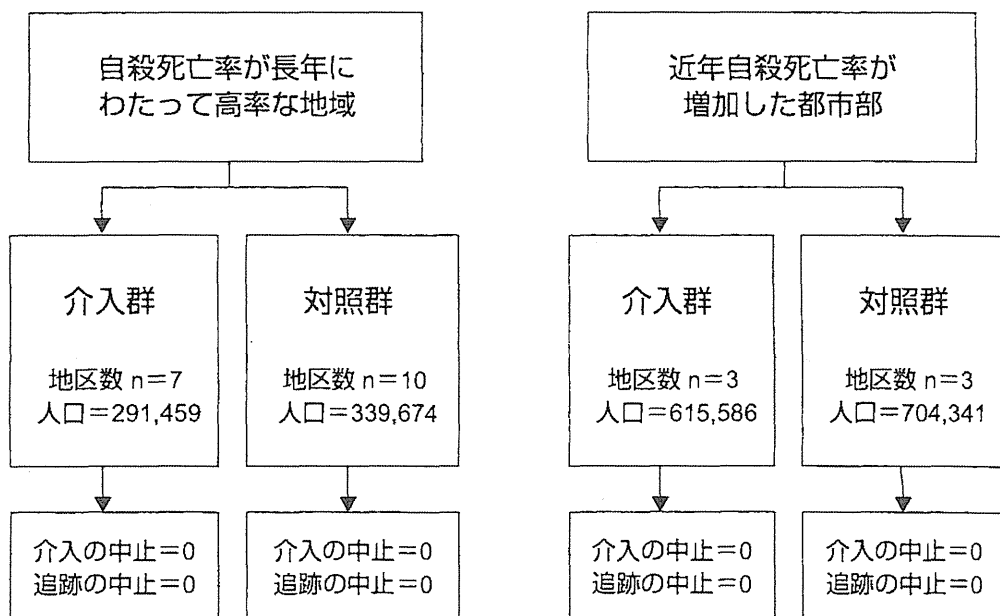
Fig.7に示すように，地方郡部地域では，介入群の主要評価項目は自殺企図（自殺死亡
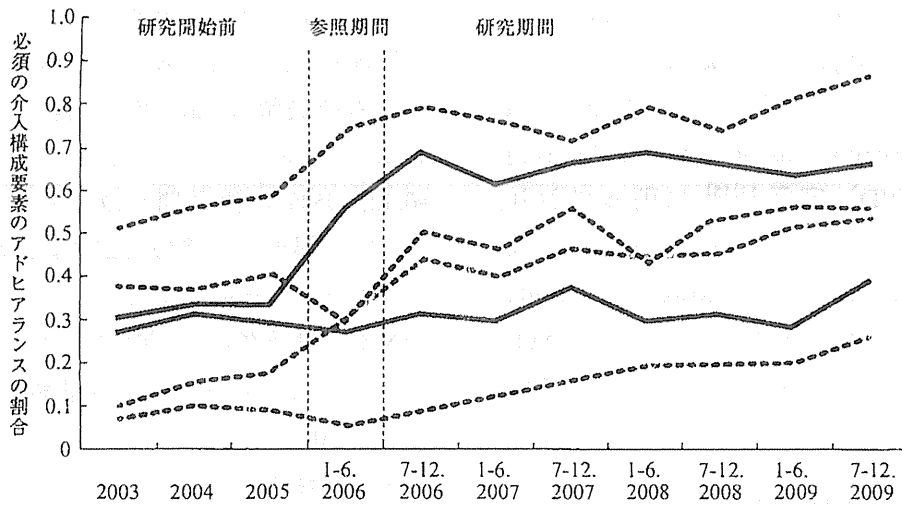

Fig.4　サンプリングフロー

Fig.5 地方郡部地域における自殺予防プログラムのアドヒアランス
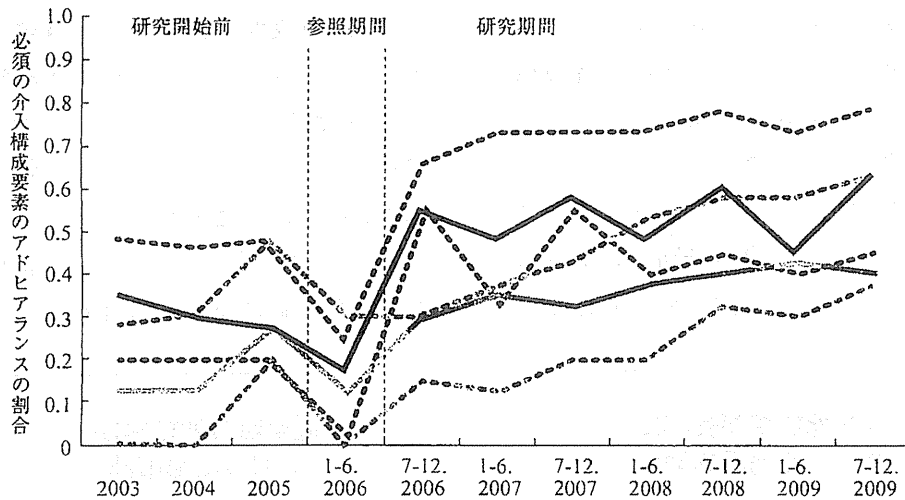黒実線：介入群中央値, 黒点線：四分位範囲, グレー実線：対照群中央値, グレー点線：四分位範囲

Fig.6 人口密集地域における自殺予防プログラムのアドヒアランス
黒実線：介入群中央値, 黒点線：四分位範囲, グレー実線：対照群中央値, グレー点線：四分位範囲

および救急事故等報告に基づく自殺未遂（重症ないし中等症））の発生率は対照群よりもわずかに低い値であった（RR=0.93, 95% 信頼区間 0.71〜1.22, p=0.598）。サブグループ解析から男性では介入群の発生率は有意に低いことが示された（RR=0.77, 95% 信頼区間 0.59〜0.998, p=0.0485）。また, 65 歳以上の高齢者においても有意に低いことが示された（RR=0.76, 95% 信頼区間 0.57〜1.01, p=0.062）が, 女性（RR=1.34, 95% 信頼区間 0.87〜2.15, p=0.174）および特に 25 歳未満において（RR=1.44, ·95% 信頼区間 0.63〜3.31, p=0.386）発生率が高いことが示された。

都市部近郊の人口密集地域では, 主要評価項目である自殺企図（自殺死亡および救急事故等報告に基づく自殺未遂（重症ないし中等