23. アルコール使用障害

表面化している症状:

患者が訴える可能性のある症状:

- 飲酒に関連した問題: 抑うつ気分、神経質さ、不眠、および
- アルコール摂取による身体面での合併症(例:潰瘍、胃炎、肝疾患)
- アルコール摂取による事故または怪我、あるいは
- 記憶力または集中力の低下

他に考えられる可能性:

- アルコール摂取が原因の法的または社会的問題(パートナーや家族との問題、家庭内暴力、欠勤)
- アルコールの離脱症状(発刊、震え、朝の吐き気、幻覚)
- 患者がアルコールの問題を否認、または問題であることに気付いていない可能性もある。

本人に先立って、家族が援助を求めるかもしれない(例:患者が家ではいらいらしている、もしくは欠勤する)。症状表出は、男女間で異なることがある。

臨床記述:

この障害の特徴は、過剰な量のアルコール摂取と、派生する心理的、社会的および身体的な実害と依存である。アルコール摂取の方法は、継続して一定量を摂取する場合もあるし、飲むときには一気に飲む「大量飲酒」する場合もある。

診断に必要な症状:

アルコールの危険な摂取－飲酒が本人および他者の健康に多大なリスクをもたらす。酒量は各地の基準により定義されるものとする。例:男性であれば週に 21 基準飲酒量以上、女性であれば週に 14 基準飲酒量以上(基準酒量の NB アルコール含量は様々である)。

アルコールの有害な摂取－飲酒者にとって、アルコール摂取が身体的、社会的または心理的な実害の原因である(または実質的に貢献している)ことが明らかである。これらの害には、判断の障害や適応的でない行動が含まれる。アルコールの他に楽しめる活動があったとしても、それらが段々と目に入らなくなる。

依存症候群

- 実害があるにも関わらずアルコール摂取を続ける
- アルコール摂取のコントロールが困難である
- アルコール摂取への強い欲求
- 耐性(大量に飲酒しても酩酊しているように見えない)
- 離脱症状(不安、震え、発汗、せん妄、発作)

妊娠時の飲酒は、脳発達の異常、発育不全、典型的な顔の特徴、神経系の異常を伴う胎児性アルコール症候群となる可能性がある。

小児期:

児童であってアルコールを過剰摂取し、アルコール関連障害を発症する可能性がある。

鑑別診断:

不安または抑うつなどの精神医学的な病態もアルコール問題の原因となりうるので、これらを考慮すること。また、これらの精神症状は、一定期間の禁酒の後に現れることもある。

双極性障害は、アルコールおよび薬物の使用の両方と関連する。

24. 薬物使用障害

表面化している問題:

患者が訴える可能性のある症状:

- 抑うつ気分、神経質さ、不眠
- 薬物使用による身体面での合併症
- 薬物使用による事故または怪我
- 急性薬物中毒または離脱による他の様々な症状および兆候

他に考えられる可能性:

- 行動、外見または機能における、薬物のほかに説明がつかない変化
- 薬物使用の否認
- 麻薬または他の薬物を目的に痛みを訴えたり、また直接的にそれらを要求したりする
- 薬物使用が原因の法的または社会的問題(パートナーや家族との問題、家庭内暴力、欠勤)

本人に先立って、家族が援助を求めるかもしれない(例:患者が家ではいらいらしている、もしくは欠勤する)。症状表出は、男女間で異なることがある。

臨床記述:

この障害の特徴は、薬物(違法薬物(例:オピオイド、覚せい剤、大麻)、処方薬(例:ベンゾジアゼピン系薬剤、合成オピオイド)、およびその他の一般的に入手可能な中毒性化学物質(例:ソルベント、軽油)の過剰摂取と、派生する心理的、 社会的および身体的な実害と依存である。

診断に必要な症状:

- 多量の、または頻繁な使用
- 薬物使用が身体的な害(例:中毒状態での怪我)、心理的な害(例:薬物使用による精神症状、薬物使用による精神障害の悪化)

  または
- 薬物使用が有害な社会的帰結(例:失業、深刻な家族およびパートナーとの問題、経済および法的な問題)

深刻なケースで起こりうる症状:

依存症候群

- 実害があるにも関わらず薬物使用を続ける
- 薬物使用のコントロールが困難である
- 薬物使用への強い欲求

鑑別診断:

- 不安または抑うつなどの精神医学的な病態も薬物使用問題の原因となりうるので、これらを考慮すること。また、これらの精神症状は、一定期間薬物を使用しなかった期間の後に現れることもある。
- 双極性障害は、アルコールおよび薬物の使用の両方と関連する。

25. タバコ使用障害

表面化している症状:

患者は、禁煙についての相談で来院する可能性がある。

咳、痰または頻繁な呼吸器感染、高血圧または心臓疾患など喫煙による疾患がある患者には、直接喫煙の習慣について尋ねるべきである。

臨床記述:

依存性および身体的実害に繋がるタバコ使用(喫煙または咀嚼)を特徴とする障害である。

診断に必要な症状:

使用形態を問わず、定期的な使用は実害をおよぼす可能性があり、依存につながる。

依存症候群

- 実害があるにも関わらずタバコ使用を続ける
- 使用のコントロールが困難である
- 喫煙への強い欲求
- ニコチンの離脱症状

健康情報

- 親が喫煙者である場合、その子どもは呼吸器系の問題を患う可能性がある。
- 妊娠時の喫煙は、早産や低体重での出生を引き起こす可能性があり、また乳幼児突然死の可能性は二倍になる。
- 喫煙は、肺がん、高血圧、心臓疾患および末梢血管疾患に対し強い因果関係にある。

小児期:

児童は若年時に喫煙を始める可能性があり、また依存の症状を呈することもある。

鑑別診断:

一般に、他の物質使用障害と併発する。

26. パーソナリティ障害

表面化している問題:

他者との関係において、徐々に問題行動の特徴的なパターンを呈する。パターンの表出は、以下の様態を示すことがある:自傷するとの脅しまたは実際の自傷、気分の不安定、他者の行動への猜疑心または反復的な不満、または単純な他者の回避。対人関係における深刻な衝突と攻撃性と暴力のエピソードがみられることもある。

診断に必要な特徴:

他者との関係が困難または荒れるパターンが持続する。

関連する特徴:

他者との関係における困難は、攻撃的または敵対的な態度、社会的接触への猜疑心、ひきこもりまたは回避、またはコントロールと規律への過剰な要求、もしくは怒りや自己嫌悪まで幅のある範囲での情緒の急激な変化のかたちで表出化する。

ケースによっては、激しく不安定な指摘人間関係に巻き込まれる負担が反復的な情緒面での危機的状況を引き起こし、しばしば自傷や自殺の脅しのエピソードがみられることもある。危機に際して、抑うつおよび/あるいは不安症状への急激な移行を伴う過剰な怒りを示すかもしれない。その他に、アルコールや薬物使用、万引き、無謀な運転およびむちゃ食いなど、自己破壊的な行動がある可能性もある。

重度のケースにおける可能性:

- 薬物使用と関連のない短期間の精神病症状
- 自傷または適切な自己管理を怠ることによる自己への深刻なリスク
- 暴力または搾取により、他者の安全に深刻なリスクを及ぼす

鑑別診断

- 双極性障害
- 抑うつ性障害
- 薬物使用障害

27. 認知症

表面化している訴え:

- 患者*自身*は、物忘れや気分の落ち込みを訴えることがある。
- 患者の*家族*は、患者における記憶力の低下、性格または行動上の変化、不衛生を訴えたり、より重篤な病態では、混乱、徘徊、失禁などの症状を訴えたりすることもある。

臨床記述:

認知症は、脳細胞損傷の臨床症状であり、変性過程、脳卒中または代謝要因により引き起こされるものである。

診断に必要な症状:

認知的変化:中核的症状は、記憶における問題である。最近の出来事の回想を含め、新たな情報の学習における困難と、かつて学習した情報回想の困難(**記憶喪失**)の両方が考えられる。

関連症状:

- **失語**(表出性または受容性)、**失行**(感覚および運動器官が損なわれていないにも関わらず、着衣などの行為が遂行できない)および**失認**(身近なひとやものを認識できない)が、他の認知症状に含まれる。
- **行動上の問題**には、騒がしさ、落ち着きのなさ、徘徊や迷子、失禁、脱抑制による反社会的かつ不適切な行動、興奮、ベッドを抜け出すもしくはベッドにこもる、などが挙げられる。料理、買い物、外出や冏年お支払いなど日常生活に影響がおよぶこともある。
- **精神症状**には、気分の落ち込み、猜疑心、妄想思考(他人に害される、または物を盗まれる)、幻覚、眠りが妨げられる、徘徊、無感情もしくは不安が挙げられる。

認知症の一般的な要因は:

- アルツハイマー病(漸進的かつ進行性の過程)
- 血管性認知症(段階的過程をたどり、高血圧と関連する)
- パーキンソン病

下記が認知症の要因となっていれば、治療による回復が見込める:

- 抑うつ－気分の落ち込みが持続的かつ顕著で、記憶と集中の問題を伴う場合
- ビタミン B_{12} および葉酸の欠乏
- コルサコフ症候群(チアミン欠乏による深刻な短期記憶の問題でアルコール依存症にみられる)
- うっ血性心不全
- 尿毒症 －回復の可能性がある
- 肝機能不全－回復の可能性がある
- 硬膜下血腫
- 脳腫瘍
- 常圧水頭症
- HIV 感染
- 神経梅毒
- 処方薬またはアルコール

鑑別診断:

- 軽度の認知機能障害(mild cognitive impairment; MCI):記憶に機能障害があっても、仕事や社会生活を送るうえで支障をきたさない
- 加齢にともない通常みとめられる記憶の機能低下

RESEARCH STUDIES

Association between subjective memory complaints and mental health well-being in urban community-dwelling elderly in Japan

Dear Editor,

The prevalence of subjective memory complaints (SMC) among the elderly has been reported to be between 25% and 50%.[1] Subjective memory complaints are currently the object of growing interest as a possible predictor for future dementia. However, the direct association between SMC and cognitive decline remains controversial.[2] Our previous study based on 95 community-dwelling older adults aged 65 years and older showed that there was no relationship between objective memory impairment and SMC.[3] Besides cognitive decline, variables such as education, sex, age and others might underlie SMC.

As patients with SMC seem distressed by their subjective forgetfulness, we hypothesized that mental health well-being is an important correlate of SMC. Just a few community-based studies have investigated the relationship between SMC and mental health well-being in the elderly.[4–6]

We carried out a community-based, cross-sectional study that included 3195 Japanese persons who were: (i) community residents of Chiyoda ward, Tokyo, Japan; (ii) aged 65 years or older; and (iii) not having long-term care insurance certification. Each participant received a self-administered questionnaire.

The questionnaire included items regarding SMC, sociodemographic factors (age, sex, years of education, living alone or not, at work or not, social support network) and health-related variables (subjective health, current physical illness, pain, instrumental activities of daily living [IADL], mental health well-being, daytime sleepiness), which might affect mental health well-being. Social support network was assessed by the Japanese version of the abbreviated Lubben Social Network Scale,[7] mental health well-being by the World Health Organization Well-Being Index – five items,[8] daytime sleepiness by the Japanese version of the Epworth Sleepiness Scale,[9] and IADL by the Tokyo Metropolitan Institute of Gerontology Index of Competence.[10] SMC were assessed by the question "Do you feel that your memory has worsened in the last 6 months?"

Data were analyzed using PASW Statistics version 18 for Windows (SPSS, Chicago IL, USA). The stepwise linear regression analysis was carried out with SMC as the dependent factor, entering all the health-related variables, and sociodemographic factors including education, sex and age as independent variables. The significance level was set at $\alpha = 0.05$.

A total of 2034 participants (815 males, 1219 females) returned the questionnaire (response rate = 63.7%). The respondents' mean age was 74.6 ± 6.4 years and mean years of education was 13.2 ± 3.0 years. Participants with no missing values for SMC ($n = 1952$) were analyzed.

Among participants, 45.9% had SMC (males, 44.4%; females, 46.8%; $\chi^2 = 1.14$, $P = 0.153$). The stepwise linear regression on SMC is shown in Table 1. In the final model, the significant correlates of SMC were lower mental health well-being, older age, daytime sleepiness, pain and lower IADL. The result shows mental health well-being is indeed an important correlate of SMC.

In conclusion, findings of the current study, based on 2034 participants aged 65 years and older, show that SMC are significantly associated with lower mental health well-being along with older age, daytime sleepiness, pain and lower IADL among community-dwelling older adults in Japan.

Table 1 Correlates of subjective memory complaints

	Step 1			Step 2			Step 3			Step 4			Step 5		
	β	t	p	β	t	p	β	t	p	β	t	p	β	t	p
Mental health well-being	−0.23	−7.39	<0.001	−0.22	−7.11	<0.001	−0.19	−6.06	<0.001	−0.18	−5.62	<0.001	−0.16	−4.85	<0.001
Age				0.16	5.39	<0.001	0.17	5.50	<0.001	0.16	5.42	<0.001	0.14	4.57	<0.001
Daytime sleepiness							0.14	4.66	<0.001	0.14	4.60	<0.001	0.13	4.24	<0.001
Pain										−0.07	−2.31	0.021	−0.07	−2.25	0.025
IADL													−0.07	−2.21	0.027

Stepwise multivariate linear regression analysis was carried out entering sociodemographic factors (age, sex, years of education, living alone or not, at work or not, social support network) and health related variables (subjective health, current physical illness, pain, instrumental activities of daily life [IADL], mental health well-being, daytime sleepiness) as independent variables.

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Disclosure statement

The authors have no conflict of interest to declare.

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Surrogate by care managers for individuals with insufficient mental capacity

Dear Editor,

In Japan, the public long-term care insurance (LTCI) program was launched in 2000, when the laws relating to guardianship were also introduced. Although it is estimated that are more than 8 million people with insufficient mental capacity for decision-making, just 226 000 people so far have applied the guardianship since its inception.[1] The prevalence of older Japanese adults living with their children is high (43.2%),[2] so the family members usually act as surrogates for individuals with insufficient mental capacity. However, in the case of individuals without families or proxies, who can support their decision-making becomes a legal and clinical concern. The present survey was carried out in order to shed light on the possibility of surrogate behavior by care managers, who arrange care services under the LTCI program.[3]

The care manager role must be based on defined care professions, years of clinical experience and the candidate must pass a qualification test. The authors distributed self-rated questionnaires to 580 care managers attending a mandatory training program in 2011. They were questioned about their years of experience as care managers, places they were based and the number of clients with legal guardians. Respondents were also asked to provide information about their experiences of surrogating for their clients.

Responses were obtained from 491 (85%) care managers. The mean number of months of experience as a care manager was 30.3 ± 16.3 months (range 0–108 months). Regarding their work, 66.1% were based at home-care support offices, 2.7% worked in community general support centers, 10.2% in group homes and 21.0% in long-term care facilities. The mean number of clients for whom the respondents were responsible was 27.1 ± 19.5. The mean number of clients with guardians was 0.6 ± 1.3.

Figure 1 shows the substitution behaviors reported by care managers. Those working in group homes, where five to nine residents with dementia were housed, felt especially compelled to surrogate often for their clients. A total of 8% of care managers provided consent for medical treatment, and 6% regularly undertook administrative duties associated with their clients' properties.

These results confirmed that many care managers act as surrogate decision-makers for clients with insufficient mental capacity who do not have families or guardians. A previous report showed that 56% of judicial scriveners were requested to provide consent for medical treatment of their clients,[4] and Miyata *et al.* reported that 23% of

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PLOS ONE

Effectiveness of a Multimodal Community Intervention Program to Prevent Suicide and Suicide Attempts: A Quasi-Experimental Study

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Abstract

Background: Multilevel and multimodal interventions have been suggested for suicide prevention. However, few studies have reported the outcomes of such interventions for suicidal behaviours.

Methods: We examined the effectiveness of a community-based multimodal intervention for suicide prevention in rural areas with high suicide rates, compared with a parallel prevention-as-usual control group, covering a total of 631,133 persons. The effectiveness was also examined in highly populated areas near metropolitan cities (1,319,972 persons). The intervention started in July 2006, and continued for 3.5 years. The primary outcome was the incidence of composite outcome, consisting of completed suicides and suicide attempts requiring admission to an emergency ward for critical care. We compared the rate ratios (RRs) of the outcomes adjusted by sex, age group, region, period and interaction terms. Analyses were performed on an intention-to-treat basis and stratified by sex and age groups.

Findings: In the rural areas, the overall median adherence of the intervention was significantly higher. The RR of the composite outcome in the intervention group decreased 7% compared with that of the control group. Subgroup analyses demonstrated heterogeneous effects among subpopulations: the RR of the composite outcome in the intervention group was significantly lower in males (RR = 0.77, 95% CI 0.59–0.998, p = 0.0485) and the RR of suicide attempts was significantly lower in males (RR = 0.39, 95% CI 0.22–0.68, p = 0.001) and the elderly (RR = 0.35, 95% CI 0.17–0.71, p = 0.004). The intervention had no effect on the RR of the composite outcome in the highly populated areas.

Interpretation: Our findings suggest that this community-based multimodal intervention for suicide prevention could be implemented in rural areas, but not in highly populated areas. The effectiveness of the intervention was shown for males and for the elderly in rural areas.

Trial Registration: ClinicalTrials.gov NCT00737165 UMIN Clinical Trials Registry UMIN000000460

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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 multimodal 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).

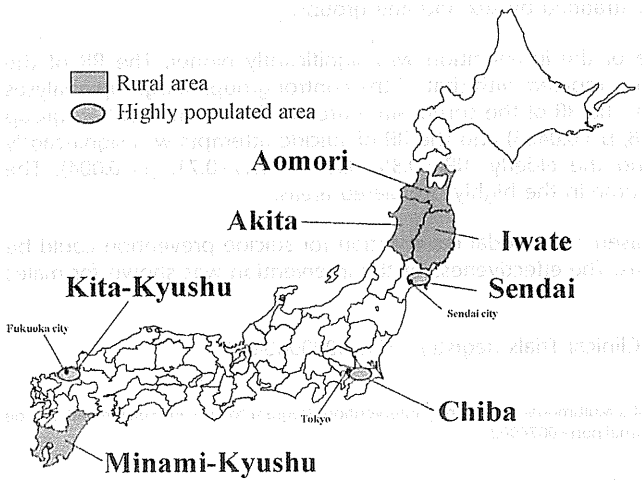

Figure 1. Location map of the study areas. Pink-coloured areas indicate rural study areas. Orange-coloured areas indicate highly populated study areas.
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A community-based multimodal intervention for suicide prevention was developed [9] by extending 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/scisakunitsuite/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.

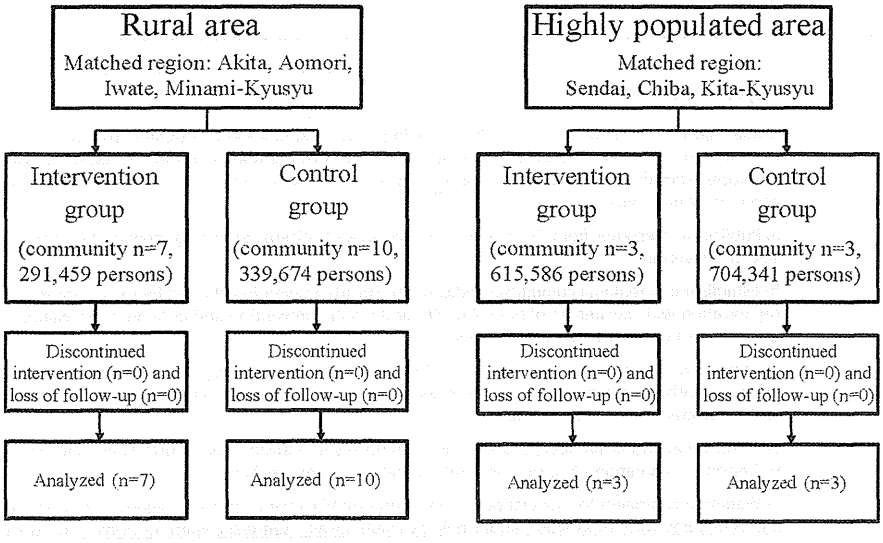

Figure 2. Flow chart of the study.
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The primary outcome was the incidence of composite outcome, consisting of completed suicides and suicide attempts that required admission to an emergency ward for critical care. Secondary outcomes were as follows: 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.

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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

The study was conceived and developed by the NOCOMIT-J group, and was funded by the Ministry of Health, Labour, and Welfare of Japan. The Japan Foundation for Neuroscience and Mental Health was the sponsor. Neither the funder nor the sponsor had any role in study design, data collection, data analysis,

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)

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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.
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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

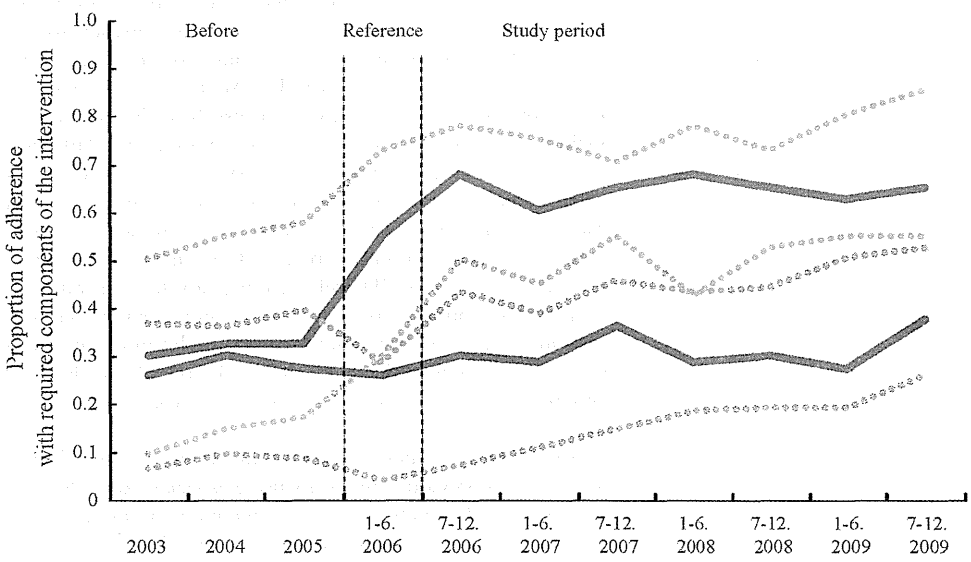


Figure 3. Figure 3 shows the proportion of adherence with required components of the intervention in the rural areas. The blue line indicates the proportion of the intervention group, and the red line indicates that of the control group. The dotted lines indicate interquartile ranges. The proportion 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

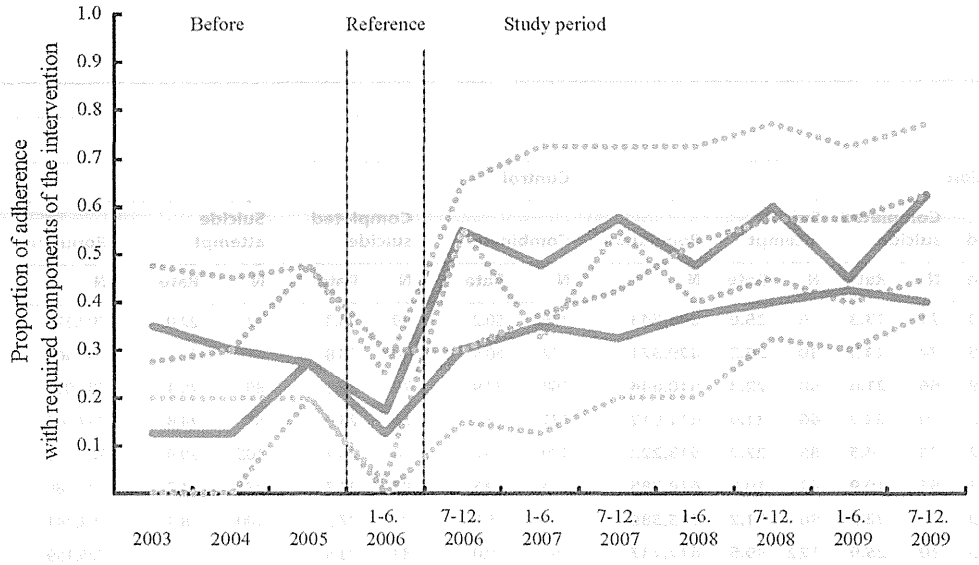


Figure 4. Figure 4 shows the proportion of adherence with required components of the intervention in the highly populated areas. The blue line indicates the proportion of the intervention group, and the red line indicates that of the control group. The dotted lines indicate interquartile ranges. The 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

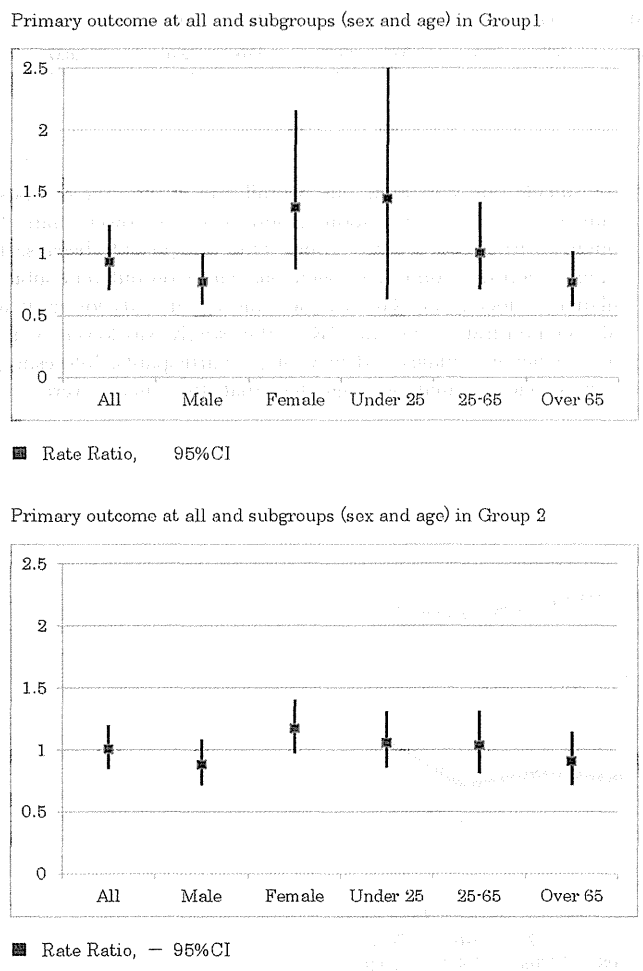


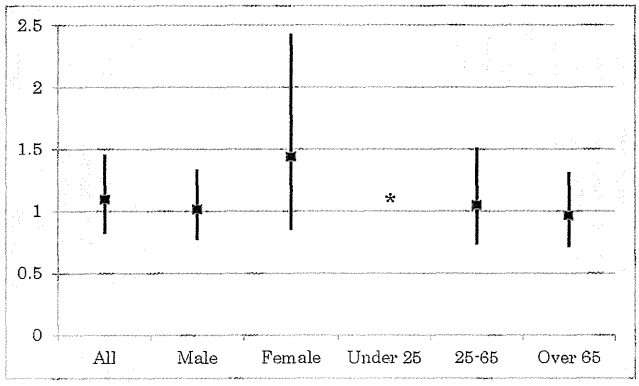
Figure 5. Primary outcome (composite outcome, consisting of completed suicides and suicide attempts requiring admission to an emergency ward for critical care) for all and for subgroups (sex and age) in rural areas and in highly populated areas.
doi:10.1371/journal.pone.0074902.g005

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

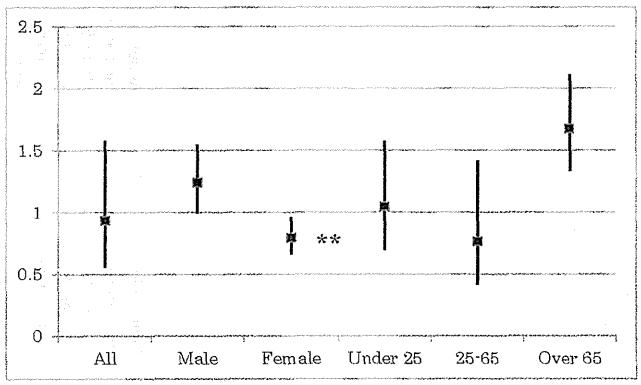
Secondary outcome (Suicide completed) at all and subgroups in Group1



■ Rate Ratio, — 95%CI

* Not calculated

Secondary outcome (Suicide completed) at all and subgroups in Group2



■ Rate Ratio, — 95%CI

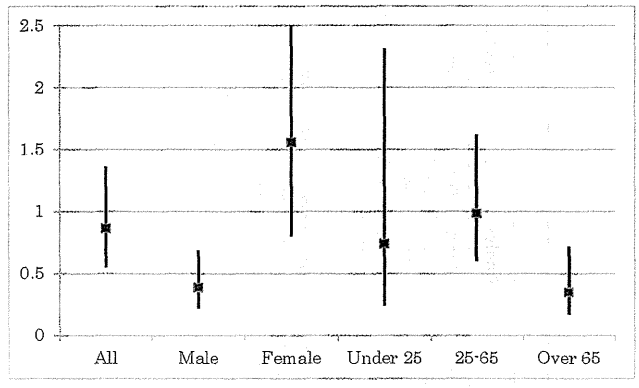
** Interaction (intervention × year) was significant, p= 0.0270

Figure 6. Secondary outcome (completed suicides) for all and for subgroups in rural areas and in highly populated areas.
doi:10.1371/journal.pone.0074902.g006

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

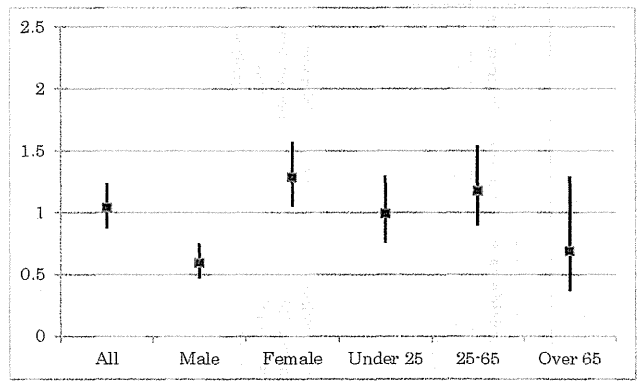
As shown in Table 5, there are some reports of multilevel interventions focusing on depression care. [18,19] These interventions aimed to introduce untreated depressed patients to appropriate care by public awareness campaigns, educating general practitioners and supporting them with mental health professionals, 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).

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

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	$\chi 2$ 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	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 $\chi 2$ test (stratified sex and years, but not adjusted)	19.4% to 24% reduction suicide acts rate ($p = 0.082$, 0.004) compared to control
		Intervention: Nuremberg, 480,000									
		Control: Wurzburg 270,000									
Szanto et al., Arch Gen Psychiatry. 2007; 64(8): 914–20.	A region with a igh suicide rate in Hungary	127,000	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 tele-phone 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.
		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)									
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									

doi:10.1371/journal.pone.0074902.t005