医科大学が包括的自殺対策を各医療圏で推進する体制を継続してきた。 実際の調査でも、その理念や実施状況が確認された。

2. 精神科救急システムにおける自殺関連行動への対応

精神科救急システムにおいては自殺関連行動の対応や、合併症対応としての位置づけが主体となっていることが確認された。

3. NOCOMIT-J 結果の要因解明

NOCOMIT-Jにおいて、地方郡部地域で実施した複合的介入は、男性や高齢者に対して有益な効果を示した。我が国では、精神科医と保健師が、訪問や地域の社会的な集会を介して地域社会の人と人との関係(relationship)と連結性(つながり connectedness)を増強する試みを行う介入に関して、高齢者の自殺率減少に効果がある可能性が示されてきた。本介入プログラムは、これらの知見を拡張して開発されたが、我々が予期したように、高齢者に対する介入効果は先行研究と一致していた。そのため、我々の研究は高齢者に対する自殺対策の知見を確認し、この集団に対して顕著な介入効果認められることが結論づけられた。

一方、人口密集地域の自殺企図の発生率は対照地域と比較して同等だったが、これはプログラム実施率が対照地区と有意差がなかったことが影響している可能性がある。複合的介入プログラムを都市部で実施する困難さには、都市部における人的資源や地域ネットワークの不足などの地域の特性が影響している可能性が考えられるが、こうした点についてはさらに研究を進めて課題を解明していく必要がある。

NOCOMIT-J研究には幾つかの制約がある。第一に本研究は無作為割付試験ではない。そのため、マッチドペアデザインを用い、解析において可能性のある交絡要因を調整したモデルを用いた。しかし、測定していない、残りの交絡要因が残っている可能性もあり、我々の識見を確認するために無作為化割付試験を実施する必要がある。第二に本研究の参加者、研究者およびイベントの報告者は介入を盲検化されていない。結果は公的な記録から系統的に収集したが、幾つかの誤分類バイアスがあるかもしれない。第三として介入へのアドヒアランスが限られていた。十分な予算と資源を投資することにより、アドヒアランスは改善されるかもしれない。

4. NOCOMIT－J の研究成果を踏まえた対策の推進

複合的な自殺対策を実施する上では、介入実施率を上げることが重要となる。地域での自殺対策では、新規の事業として自殺対策を実践する過程と、既存の事業を自殺対策として意識化する過程の領域で構成されている。地域の既存のさまざまな事業を自殺対策として位置付け

ていくためにも、ネットワーク活動やゲートキーパー養成プログラムの実施など人材養成事業が重要であると考えられる。人口密集地域においては、人口過疎地域より社会資源は確保されている場合が少なくない。しかし、自殺ハイリスク者に対する複合的なケアを実現するケアの連携を構築するためには、連携を強化するような実務者ネットワークが役立つと考えられる。また、関わる従事者に対する教育的アプローチを行うことで、実務者の自殺ハイリスク者へのかかわりが強化される。一方、自殺対策の領域を効果的に拡大させていくためには、例えば自治体における庁内ネットワークによりさまざまな領域が自殺対策に関わる体制づくりが求められる。岩手県盛岡市で実施されている庁内連携や実務者連携のためのネットワークづくりの考えは以上のようなことから構築されてきたものであった。

また、岩手県久慈地域では東日本大震災における災害の影響を受けた。この地域ではすでに実施されていた自殺対策を災害対策に組み込みながら、自殺対策のネットワークが地域の復興の過程で貢献している。また、被災地の自殺対策を推進する上でも、NOCOMIT-J が提示してきたネットワーク、一次予防、二次予防、三次予防、職域の対策、精神障害への対策という六つの骨子からなる複合的な自殺対策をモデルとして推進している。災害のように地域に多大な困難を与えるリスクを軽減するためには、包括的な自殺対策の実践が求められる。

都市部においても、農村部においても自殺対策の効果を検討していく上では、介入期間と介入の実施率、そして地域診断による介入ポイントを踏まえた対策が重要であることはいうまでもない。地域のリスクの評価や、地域診断と連動した自殺対策の立案を反映した自殺対策のコーディネートが重要と考えられる。自殺対策の教育的アプローチとしてもこのような観点を取り入れることにより、たとえば自治体職員や関係機関の従事者が自殺対策を立案する過程で役立つと考えられる。

E. 結論

岩手県では包括的自殺対策をモデルとして、全県の自殺対策を推進しており、実際に対策が実施されていることが確認できた。今後、自殺対策の事業継続や地域特性にあわせた自殺対策の推進が課題となっていくと考えられる。特に、被災地においても、地域の自殺対策の推進の重要性が高まっていくと考えられた。

一方、精神科救急システムにおいて自殺関連行動は身体合併症の枠組みで対応されることがあり、入院率も高いことから、入院施設を持つ精神科医療施設での対応や連携が重要であると考えられた。この点ではソーシャルワーカーなどを中心としたケースマネジメントのアプローチが臨床現場で求められていると考えられた。

F. 研究発表

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- 大塚耕太郎、岩佐博人、本橋豊、石田康、栗田主一、中村純、亀井雄一、米本直裕、山田光彦、稲垣正俊、高橋清久、酒井明夫、大野裕：シンポジウム 2「NOCOMIT-J の取り組みと成果、今後の対策や被災地での取り組み」，第 38 回日本自殺予防学会総会，北九州国際会議場，北九州市，2014 年 9 月 12 日

G．知的財産権の出願・登録状況

（※予定を含む）

1．特許取得　特記なし

2．実用新案登録　特記なし

3．その他　特記なし

III. 研究成果の刊行に関する一覧表

1. 原著論文

発表者氏名	タイトル	発表誌名	巻号	ページ	出版年
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Kawashima Y, Yonemoto N, Inagaki M, Yamada M	Prevalence of suicide attempters in emergency departments in Japan: A systematic review and meta-analysis.	J Affect Disord	163	33-9	2014
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Kaoru Kudo, Kotaro Otsuka, Junko Yagi, Katsumi Sanjo, Noritaka Koizumi, Atsuhiko Koeda, Miki Yokota Umetsu,	Predictors for delayed encephalopathy following acute carbon monoxide poisoning.	BMC Emerg Med	14		2014

Yasuhito Yoshioka, Ayumi Mizugai, Toshinari Mita, Yu Shiga, Fumito Koizumi, Hikaru Nakamura and Akio Sakai					
大山寧寧, 河西千秋, 平安良雄	医学教育における精神医学の知識習得と精神障害者に対する態度との関連.	精神医学	56	293-8	

2. 総説

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大塚 耕太郎, 酒井 明夫, 岩戸清香, 中村 光, 赤平美津子	自殺念慮の早期発見と求められる対応	精神科治療学	28(11)	1437-41	2013
大塚耕太郎、酒井明夫、中村光、赤平美津子	震災後の自殺対策とゲートキーパーの養成について(After the Great East Japan Earthquake: Suicide prevention and a gatekeeper program)	精神神経学雑誌	116(3)	196-202	2014
大塚耕太郎	日本の自殺対策:NOCOMIT-Jの成果と今後の展望	日本医事新報	No.4729	41	2014
太刀川弘和, 河西千秋, 山田光彦	「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)」の展開	精神科	25	34-8	2014
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IV. 研究成果の刊行物・別刷

９月１０日は、世界自殺予防デーです。

平成 26 年 9 月 8 日

公益財団法人
精神・神経科学振興財団

独立行政法人
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ACTION-J 研究グループ
事務局：横浜市立大学医学部精神医学教室内

自殺企図の再発予防にケース・マネージメントが有効
― 6 か月にわたって自殺企図を抑止 ―

ポイント

- 自殺未遂者は、再び自殺を企図し、死に至るリスクが高い。
- 救急医療施設に搬送される自殺未遂者にケース・マネージメントを実施することで、自殺を再び企図することを 6 か月にわたって抑止できることが明らかとなった。
- 救急医療施設における本研究の成果の速やかな普及により、自殺未遂者のその後の自殺既遂の防止につながるものと期待される。

国立精神・神経医療研究センター総長 樋口輝彦を班長とする研究班により計画された「自殺対策のための戦略研究」（厚生労働科学研究費補助金）の一環として、「自殺企図の再発防止に対する複合的ケース・マネージメントの効果：多施設共同による無作為化比較研究」（通称 ACTION-J）が実施されました。本研究では、横浜市立大学の平安良雄教授が研究リーダーを務め、自殺未遂者に対する支援プログラム（ケース・マネージメント）が新たに開発されました。そして、救急医療部門と精神科がすでに連携関係にある 17 施設からなる全国規模の研究班（ACTION-J グループ）が組織され、その効果が多施設共同無作為化比較試験により検証されました。その結果、ケース・マネージメントは、自殺未遂者の自殺再企図を長期間抑止することはできなかったものの、6 か月にわたって強力に抑止することが明らかとなりました。この効果は、特に、女性、40 歳未満、過去の自殺企図歴があった自殺未遂者により強く認められました。本研究の成果を日本の救急医療の現場に普及させることにより、自殺未遂者の自殺再企図を、そして自殺既遂を減らすことにつながるものと期待されます。

＜研究の背景と経緯＞

わが国の自殺死亡者数は平成 10 年に急騰し年間 3 万人以上という数で推移し、平成 24 年には 3 万人以下に低下したものの、自殺率（人口当たりの自殺者数）は依然として国際的に極めて高い水準を示しています。こうした状況の克服を目指し、当センターの樋口輝彦総長を班長とする研究班により計画された「自殺対策のための戦略研究（以下、戦略研究）」（厚生労働科学研究費補助金）が実施されました。戦略研究においては、当センター精神保健研究所（福田祐典所長）が、精神・神経科学振興財団（髙橋清久理事長）とともに統括推進本部を組織し、科学性の高い適正な臨床研究実施のための研究基盤を確立しました。そして、この研究プラットフォームの中で、「自殺企図の再発防止に対する複

合的ケース・マネージメントの効果：多施設共同による無作為化比較研究」（通称ACTION-J）が実施されました。ACTION-J では、研究リーダーを横浜市立大学の平安良雄教授（精神医学）が、研究班事務局長を同大学の河西千秋教授（健康増進科学）が、研究顧問を昭和大学の有賀徹教授（救急医学）が務めました。

ACTION-J は医薬品や医療機器の開発に加えて厚生労働省が実施するべき重要な健康科学研究の好例であり、当センターは、政策立案に直結する臨床研究実施体制の整備に大きな役割を果たすことができたと考えています。

＜研究の内容＞

自殺の背景には、経済･生活問題、家庭問題、職場問題などの様々な社会的・環境的要因があり、また、健康問題を含む多様なリスク因子が存在し、これらが相互に複雑に作用しますが、この中で、最も明確なものが「自殺未遂の既往」であることが知られています。そのため、自殺未遂者が自殺を再び企図し、自殺に至ることがないようにするために、これまでに多くの介入研究が世界中で試みられてきました。しかし、その有効性が質の高い研究によって科学的に検証された支援法はこれまでに報告されていませんでした。

そこで、本研究では自殺未遂者に対する支援プログラム（ケース･マネージメント）が新たに開発されました（表１）。そして、救急医療部門と精神科がすでに連携関係にある17 施設からなる全国規模の研究班（ACTION-J グループ）が組織され、その効果が多施設共同無作為化比較試験により検証されました。なお、国際的に見ても、本研究のような大規模な多施設共同無作為化比較試験で効果を検討した研究は限られており、本研究は研究開始当初から大きな注目を集めてきました。

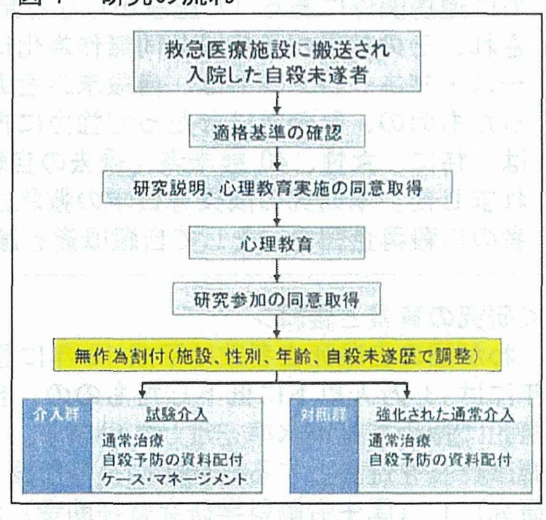
表１　ケース・マネジメントの概要

1）定期的な対象者との面接（あるいは通話）
2）対象者の生活背景・受療状況に関する情報収集
3）精神科受療の促進
4）精神科・身体科かかりつけ医に関する受療調整
5）受療中断者への受療促進
6）公的社会資源・民間援助組織の紹介と利用する際の調整
7）心理教育と情報提供
8）専用ウェブサイトを利用した情報提供

具体的には、救急医療施設に搬送され救命された自殺未遂者の方々全員に対して、危機介入、精神医学的アセスメント、そして心理教育を実施するなどの高い水準の支援をまず実施し、十分な説明と同意をいただいた後に介入群と対照群とに割付けを行い、ケース・マネージメントの効果を比較検証しました（図１）。

介入群には、最初の 6 ヶ月間に、1 週後、1 ヶ月後、2 ヶ月後、3 ヶ月後、6 ヶ月後、と頻回なケース・マネージメントが実施されました。その後は、6 ヶ月おきに支援がなされました。対照群には、通常治療に心理教育や自殺予防の資料配付等を加えた、強化された通常介入が実施されました（図１）。

図１　研究の流れ



検証のための主要な評価項目は、自殺企図（自殺既遂及び未遂）の初回再発でした。対象者の登録期間は 2006 年 7 月～2009 年 12 月で、計 914 名の自殺未遂者（男性 400 名、女性 514 名）にご協力いただきました。そして、1.5 年間以上（研究参加の時期により最長で 5 年間）の追跡調査が実施されました。介入群と対照群の属性は同等であり、両群間で比較可能性が保たれていることが確認されております（表２）。

表２　研究に参加された自殺未遂者の方々の背景と主たる精神科診断

	介入群（n=460）	対照群（n=454）
性別（女性）	57%	55%
年齢（65 才以上）	9%	10%
自殺未遂歴（無）	50%	52%
主たる精神科診断		
物質関連障害	4%	6%
統合失調症関連障害	20%	19%
気分障害	47%	46%
適応障害	22%	20%
その他	7%	9%

Kawanishi et al. The Lancet Psychiatry, Volume 1, Issue 3, Pages 193 - 201, 2014.を改編

＜研究の成果＞

本研究により、ケース・マネージメントは自殺未遂者の自殺再企図を長期間抑止することはできなかったものの、6 か月にわたって強力に抑止することが、高い科学性をもって明らかになりました。具体的には、ケース・マネージメントを実施した場合に、対照群に比べて１ヶ月の時点で約 5 分の 1（リスク比 0.19）の大変強力な自殺再企図割合の減少効果が認められ、3 ヶ月の時点でもほぼ同様の効果があり（リスク比 0.22）、6 ヶ月の時点では 2 分の 1（リスク比 0.50）の有意な自殺再企図割合の減少効果が認められました（表３）。統計学的な有意差はみとめられませんでしたが、12 ヶ月以降の時点でも、減少は継続していました(12 か月のリスク比 0.72、18 か月のリスク比 0.79)。そのため、適切な時期に、救急医療機関でのケース・マネージメントから、地域での直接支援へとつないでいく必要があると考えられました。また、この効果は、女性、40 歳未満、自殺未遂歴があった者により強く認められました。

表３　自殺再企図割合の減少効果

	1 ヶ月後	3 ヶ月後	6 ヶ月後	12 ヶ月後	18 ヶ月後
リスク比 (95% 信頼区間)	0.19 (0.06–0.64)	0.22 (0.10–0.50)	0.50 (0.32–0.80)	0.72 (0.50–1.04)	0.79 (0.57–1.08)

Kawanishi et al. The Lancet Psychiatry, Volume 1, Issue 3, Pages 193 - 201, 2014.を改編

本研究においてケース・マネージメントを実施したケース・マネージャーは、医療資源に加えて地域の様々な社会資源の利用を積極的に勧奨し、そのコーディネートを行いました。本研究では、介入群の 70% の方々が当初の計画通りにケース・マネージメントを受けていました。このことは、ケース・マネージメントが、実際の医療の現場において十分に実施可能であることを示しています。ケース・マネージャーは、精神保健福祉士、あるいは臨床心理士等の専門性をもった人材でした。現在、医療現場ではチーム医療が重要視されていますが、本研究は、救急部門と精神科を軸としたチーム医療のモデルを提案するものです。

本研究は、これまでに数多く行われてきた介入研究の問題点や課題の多くを克服した研究であることから、その成果は、わが国だけでなく、国際的に重要な知見を提供するところとなります。また、わが国においては、本研究の介入法を着実に日本の救急医療の現場に導入、普及させることで、自殺未遂者の自殺再企図を確実に減らすことができるものと期待され、そして自殺既遂を減らすことにつながるものと期待されます。

＜今後の展開＞

ACTION-J の成果を具体的な施策として普及するためには、その介入法を現場で着実に実施していくためのケース・マネージャーの育成が不可欠ですが、現在、ACTION-J の実務に関わった多くの医療従事者の協力を得て、人材育成プログラムの準備が進められています。今後、このプログラムを事業化することで、十分な人数のケース・マネージャーが確保されることが期待されます。また、医療現場においてケース・マネージメントを実施できる環境が整備されていくことで、実効性のある自殺未遂者支援が全国で本格的に始動していくものと期待されます。

＜日本自殺予防学会での成果報告＞

本研究の内容と成果の詳細は、2014 年 9 月 13 日午前 9 時より、第 38 回日本自殺予防学会総会シンポジウム 6（http://jasp38.umin.jp/index.html、会長：中村純、於：北九州国際会議場）にて詳細に報告いたします。

シンポジウム「自殺対策のための戦略研究 ACTION-J：post-ACTION-J の現状と課題」
座長：山田光彦（国立精神・神経医療研究センター精神保健研究所）
河西千秋（横浜市立大学医学群健康増進科学）

＜研究成果論文の引用先＞

本研究の成果は、国際的精神医学雑誌「The Lancet Psychiatry」に掲載されました。

Kawanishi et al., Assertive case management versus enhanced usual care for people with mental health problems who had attempted suicide and were admitted to hospital emergency departments in Japan (ACTION-J): a multicentre, randomised controlled trial. The Lancet Psychiatry, Volume 1, Issue 3, Pages 193 - 201, 2014. doi:10.1016/S2215-0366(14)70259-7

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Assertive case management versus enhanced usual care for people with mental health problems who had attempted suicide and were admitted to hospital emergency departments in Japan (ACTION-J): a multicentre, randomised controlled trial

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Summary

Background Non-fatal suicide attempt is the most important risk factor for later suicide. Emergency department visits for attempted suicide are increasingly recognised as opportunities for intervention. However, no strong evidence exists that any intervention is effective at preventing repeated suicide attempts. We aimed to investigate whether assertive case management can reduce repetition of suicide attempts in people with mental health problems who had attempted suicide and were admitted to emergency departments.

Methods In this multicentre, randomised controlled trial in 17 hospital emergency departments in Japan, we randomly assigned people aged 20 years and older with mental health problems who had attempted suicide to receive either assertive case management (based on psychiatric diagnoses, social risks, and needs of the patients) or enhanced usual care (control), using an internet-based randomisation system. Interventions were provided until the end of the follow-up period (ie, at least 18 months and up to 5 years). Outcome assessors were masked to group allocation, but patients and case managers who provided the interventions were not. The primary outcome was the incidence of first recurrent suicidal behaviour (attempted suicide or completed suicide); secondary outcomes included completed suicide and all-cause mortality. This study is registered at ClinicalTrials.gov (NCT00736918) and UMIN-CTR (C000000444).

Findings Between July 1, 2006, and Dec 31, 2009, 914 eligible participants were randomly assigned, 460 to the assertive case management group and 456 to the enhanced usual care group. We noted no significant difference in incidence of first recurrent suicidal behaviour between the assertive case management group and the enhanced usual care group over the full study period (log-rank p=0·258). Because the proportional hazards assumption did not hold, we did ad-hoc analyses for cumulative incidence of the primary outcome at months 1, 3, 6, 12, and 18 after randomisation, adjusting for multiplicity with the Bonferroni method. Assertive case management significantly reduced the incidence of first recurrent suicidal behaviour up to the 6-month timepoint (6-month risk ratio 0·50, 95% CI 0·32–0·80; p=0·003), but not at the later timepoints. Prespecified subgroup analyses showed that the intervention had a greater effect in women (up to 18 months), and in participants younger than 40 years and those with a history of previous suicide attempts (up to 6 months). We did not identify any differences between the intervention and control groups for completed suicide (27 [6%] of 460 *vs* 30 [7%] of 454, log-rank p=0·660) or all-cause mortality (46 [10%] of 460 *vs* 42 [9%] of 454, log-rank p=0·698).

Interpretation Our results suggest that assertive case management is feasible in real-world clinical settings. Although it was not effective at reducing the incidence of repetition of suicide attempts in the long term, the results of our ad-hoc analyses suggested that it was effective for up to 6 months. This finding should be investigated in future research.

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Lancet Psychiatry 2014; 1: 193–201

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Introduction

Non-fatal suicide attempt is the most potent predictor of later suicide.[1–3] Hospital admissions because of attempted suicide and self-inflicted injury have been increasing worldwide.[3,4] The average number of admissions to emergency departments for attempted suicide and self-inflicted injury per year in the USA more than doubled from about 244000 in 1993–96 to 538000 in 2005–08.[5] In the UK, roughly 220000 patients are admitted to hospital for self-harming annually.[3] Emergency department admission for attempted suicide is therefore increasingly recognised as an opportunity for medical personnel to intervene to prevent future suicide attempts.[6]

Several randomised controlled trials have been done to assess the effectiveness of contact interventions (letters or

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See Online for appendix

postcards, telephone calls, home visits, etc) to prevent repetition of suicide attempts.[7–17] However, no strong evidence has been produced for the effectiveness of this type of intervention.[18] In their systematic review,[19] O'Connor and colleagues showed that psychotherapy reduced suicide attempts in some high-risk adults in populations and settings relevant to primary care. In a randomised controlled trial,[12] cognitive therapy was effective at preventing suicide attempts in adults who had recently attempted suicide. However, the evidence overall is unclear, and the extent to which such findings are applicable to suicidal patients who are admitted to emergency departments is unknown.

Although most suicidal patients who are admitted to emergency departments are suffering from mental health problems, these patients often do not receive adequate mental health-care management in their communities after discharge.[20,21] In a randomised controlled trial, Morthorst and colleagues[22] examined the effects of assertive and intensive case management on repetition of suicide attempts, but the intervention did not lead to a significant reduction in this outcome; however, the study had a small sample size, patients were from a single centre, and individuals with psychosis were excluded from the study.

In this study, we aimed to investigate whether assertive and continuous case management could reduce the incidence of repetition of suicide attempts in adults with mental health problems who had attempted suicide, compared with enhanced usual care.

Methods

Study design and participants

ACTION-J was a multicentre, randomised controlled trial done at 17 Japanese hospitals (appendix) with both an emergency department and a psychiatric department. Potential study participants were adults (aged 20 years and older) who had attempted suicide and were admitted to the emergency department to receive critical care. To be eligible, patients had to have a primary diagnosis of an axis 1 psychiatric disorder, because the case management intervention was developed for patients with these disorders. Psychiatric diagnosis was obtained by structured interview with the Mini-International Neuropsychiatric Interview,[23] and defined as axis 1 in accordance with the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision* (DSM-IV-TR).[24] We excluded patients who had a primary diagnosis that did not meet the definition of a DSM-IV-TR axis 1 disorder.

Action in anticipation of death was confirmed at least twice in each patient by use of the Suicide Intent Scale.[25] Patients had to be able to understand the description of the study, provide informed consent, attend a face-to-face interview and a session for psychoeducation during their stay at the emergency department before enrolment in the study, and visit the participating hospital regularly to attend face-to-face interviews for assessments and case management after discharge from the emergency department.

The study protocol was approved by the Central Research Ethics Committee of the study sponsor (Japan Foundation for Neuroscience and Mental Health, Tokyo, Japan) and by the local ethics committees of all participating hospitals. All participants provided written informed consent.

Randomisation and masking

Participants were randomly assigned (1:1) by an internet-based system operated by a central, independent data centre to either the intervention group (assertive case management) or the control group (enhanced usual care). Assignment was by the minimisation method, with four factors: participating hospital, sex, age (younger than 40 years *vs* 40 years and older), and history of previous suicide attempts before the current episode. We regarded these as factors that could affect the study outcomes.

Outcome assessors were masked to group assignment, but patients and case managers who provided the interventions were not. The outcome assessors, who were trained for the assessments before the trial, collected the information about attempted suicide from participants or their family members by direct interview. The assessors did not know the participants' assigned groups, the status of implementation of the intervention, or information about events obtained by other on-site staff. An event review committee independently assessed all events related to the study outcomes.

Procedures

After patients were physically stabilised and alert consciousness was confirmed, potential study participants received thorough psychosocial assessment, including assessment of the social, psychological, and motivational factors specific to the self-harm event and an assessment of mental health, social risks, and needs, as recommended by UK national clinical practice guidelines.[26] Trained psychiatrists in the study group checked the patients against the inclusion and exclusion criteria, and provided a complete description of the study. Next, psychiatrists or other trained medical personnel from the study group gave the patients semi-structured psychoeducation, as suggested by WHO.[27] After the psychoeducation session, patients were provided with the complete study description again before being asked to provide informed consent. Assigned interventions were provided until the end of the follow-up period (ie, at least 18 months and up to 5 years).

Participants who were randomly assigned to the control group received enhanced usual care at the participating emergency departments.[28] In addition to the psychoeducation session in the emergency department before randomisation, these participants were given an information pamphlet listing available social resources (health care-based and local government services) every time they visited for periodic assessments (6 months and

18 months after randomisation, then annually until the end of the study).

Participants who were randomly assigned to the intervention group were offered assertive and continuous case management (panel 1), delivered by dedicated case managers who were trained experts in mental health (psychiatrists, nurses, social workers, or clinical psychologists). Encouragement to participate in psychiatric treatment was a core feature and appointments with psychiatrists and primary care physicians were organised. To facilitate the case management, the psychoeducation was also provided to participants' family members during the participants' initial stay in the hospital.

The case management was provided in accordance with a manual developed by the intervention programme committee of the study group. Briefly, the case managers periodically contacted participants assigned to the intervention group for 18 months after randomisation (at week 1 and at months 1, 2, 3, 6, 12, and 18) during their stay at the emergency department and after discharge. When applicable, the case managers contacted the participants every 6 months until the end of the trial (June 30, 2011). In principle, case management was accomplished through direct dialogue (face-to-face interviews by the case managers at the hospital), or by telephone conversation as the next best option. When case managers could not reach participants, they approached family members who had given their consent in advance to be contacted; the frequency with which this approach was used was not monitored. To maintain the quality of the standardised intervention, the intervention programme committee (which consisted of the case managers and a group of the study investigators) held case conference meetings every 2 months (fidelity scores were not calculated). The committee also visited the participating hospitals when necessary.

The protocol specified two interim analyses to assess the primary outcome, the first at roughly two-thirds into enrolment, and the second at the end of enrolment.[28] An independent data monitoring committee reviewed safety and efficacy issues from the interim analyses and from periodic monitoring reports

Panel 1: Features of the assertive case management intervention

- Periodic contact (either face-to-face or by telephone) with participants during their stay in the emergency department and after discharge
- Collection of information about each participant's treatment status and social problems that could disturb their treatment adherence
- Encouragement of participants to adhere to psychiatric treatment
- Coordination of appointments with psychiatrists and primary care physicians
- Encouragement of participants who discontinued psychiatric treatment to return to treatment
- Referrals to social services and private support organisations, and coordination for use of these resources to accommodate the individual needs of patients
- Provision of the psychoeducation content and information about social resources through a dedicated website

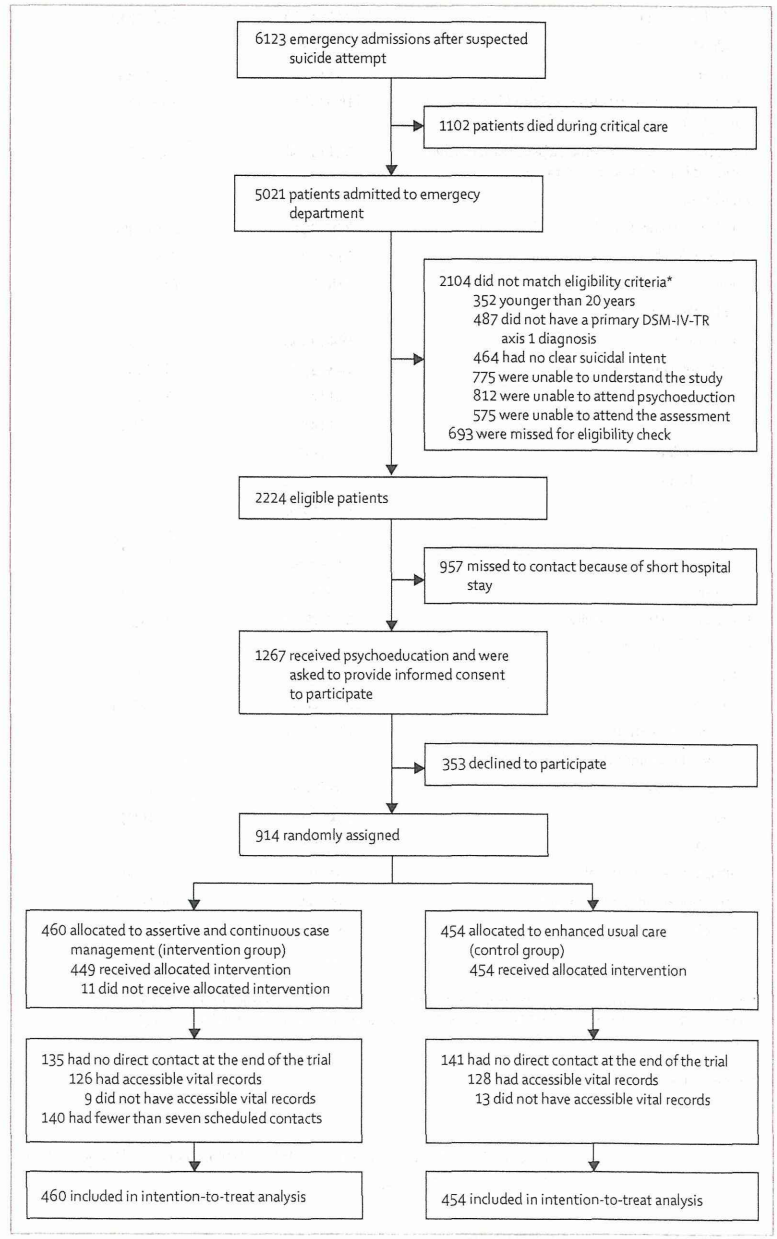

Figure 1: **Trial profile**
DSM-IV-TR=Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision.[24] *Some participants were excluded for more than one reason.

	Assertive case management group (n=460)	Enhanced usual care group (n=454)
Women	263 (57%)	251 (55%)
Mean age (years)	42·9 (14·6)	41·7 (15·2)
Older than 65 years	42 (9%)	44 (10%)
Primary psychiatric diagnosis		
Substance-related disorder	19 (4%)	26 (6%)
Schizophrenia or other psychotic disorder	93 (20%)	86 (19%)
Mood disorder	215 (47%)	211 (46%)
Adjustment disorder	100 (22%)	91 (20%)
Other	33 (7%)	40 (9%)
Visited a psychiatrist within 1 month before the suicide attempt	260 (57%)*	257 (57%)
Visited a physician other than a psychiatrist within 1 month before the suicide attempt	151 (33%)†	135 (30%)
Education		
Less than high school	115 (25%)	108 (24%)
High school	229 (50%)	237 (52%)
Beyond high school	116 (25%)	109 (24%)
Employment status		
Employed	194 (42%)	206 (45%)
Unemployed	243 (53%)	220 (48%)
Retired	11 (2%)	16 (4%)
Student	11 (2%)	12 (3%)
Missing data	1 (<1%)	0
Marital status		
Married	180 (39%)	195 (43%)
Single	169 (37%)	183 (40%)
Divorced	94 (20%)	61 (13%)
Widowed	17 (4%)	15 (3%)
Lives with partner or family	113 (25%)	84 (19%)
Previous suicide attempts		
None	229 (50%)	235 (52%)
One or two times	131 (28%)	125 (28%)
Three or more times	100 (22%)	94 (21%)
Method of the present suicide attempt‡		
Drug overdose	326 (71%)	322 (71%)
Gas	31 (7%)	28 (6%)
Laceration	76 (17%)	71 (16%)
Jumping from a high place	10 (2%)	7 (2%)
Intentional traffic-related injury	55 (12%)	60 (13%)
Hanging	27 (6%)	26 (6%)
Other	21 (5%)	21 (5%)

Data are n (%) or mean (SD). *One individual with missing data excluded from percentage calculation. †Three individuals with missing data excluded from percentage calculation. ‡Totals are greater than 100% because some individuals used more than one method.

Table 1: **Baseline characteristics**

produced every 3 months throughout the study period (under masking).

Outcomes

The primary outcome measure was the incidence of first recurrent suicidal behaviour (attempted suicide or completed suicide). We also measured incidence of completed suicide and all-cause mortality as secondary outcomes to support the primary outcome measure. Because our data for the primary outcome presented time-dependent effects (the proportional hazard assumption did not hold), we also measured the cumulative incidence of the first episode of recurrent suicidal behaviour at 1, 3, 6, 12, and 18 months after randomisation as ad-hoc analyses. Information about participant deaths was obtained by the outcome assessors or from the Government death registry.

Other protocol-specified secondary outcomes were number and incidence of recurrent suicidal behaviours, including repeated suicidal attempts per person-year; number of self-harm behaviours; types and numbers of people or organisations to consult; other medical services (clinical visit or hospital admission); physical function; Beck Hopelessness Scale score;[29] and Health Survey for quality-of-life score (short form-36).[30] We plan to publish results for all these outcomes in a seperate report.

Statistical analysis

We estimated that the annual incidence of first recurrent suicidal behaviour would be 15% in the control group[28] and 10·5% in the intervention group. Based on these estimates, we calculated that the minimum number of participants needed per group to confirm the superiority of the assertive case management intervention (with an α of 0·05 and a statistical power of 90%) was 421. In anticipation of withdrawals and missing data, we aimed to recruit 910 participants to the study.

Analyses were done in accordance with the intention-to-treat principle. To check the assumption of proportional hazards for the primary outcome, we generated an overall cumulative incidence curve using the Kaplan-Meier method and log-plot. Because our data presented time-dependent effects (the proportional hazards assumption did not hold), the hazard ratio in the survival analysis was not appropriate as a measure of effects.[31] Therefore, we calculated risk ratios (RRs) with 95% CIs for cumulative incidence at five timepoints as ad-hoc analyses; for comparison with the results obtained from previous reports,[32] we selected months 1, 3, 6, 12, and 18 after randomisation. We set α at 0·008 for adjustment of multiplicity by the Bonferroni method.[31]

We did regression analyses for the calculated RRs.[33] We also made adjustments by using regression models with the randomisation factors: sex (male *vs* female), age (younger than 40 years *vs* 40 years and older), and history of previous suicide attempts before the current episode (yes *vs* no). In sensitivity analyses, we did multiple imputations for missing data (at the ad-hoc timepoints) and used regression models to adjust for the randomisation factors.[34]

We did prespecified subgroup analyses of the primary outcome (using the ad-hoc analyses for the five specified timepoints) by sex (male *vs* female), age (younger than 40 years *vs* 40 years and older), and history of previous suicide attempts before the current episode (yes *vs* no).

Because of the exploratory nature of the subgroup analyses, we did not make any adjustment for multiplicity. We also did a post-hoc regression analysis in each subgroup analysis to investigate the effect of the remaining randomisation factors (sex, age, and previous suicide attempts) on the primary outcome (by timepoints).

This study is registered at ClinicalTrials.gov (NCT00736918) and UMIN-CTR (C000000444).

Role of the funding source

Neither the funder nor the sponsor of the study had any role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Of 6123 emergency admissions after suspected suicide attempt at participating hospitals between July 1, 2006, to Dec 31, 2009, 914 participants were enrolled in the study, of which 460 were randomly assigned to the intervention group (assertive case management) and 545 to the control group (enhanced usual care; figure 1). Baseline characteristics were well balanced between the groups (table 1). As planned in the protocol, two interim analyses were done during the study period (October, 2007, and June, 2008). The results of these analyses were reviewed by the independent data monitoring committee, but conclusive findings were not obtained (data not shown) and the trial was continued until the end of the study period.

The assertive case management group had fairly good adherence to the intervention at the end of the trial (figure 1); 320 (70%) of 460 participants were contacted at least seven times by a case manager. 11 (1%) participants in the assertive case management group did not receive the intervention.

With respect to the primary outcome of incidence of first recurrent suicidal behaviour, there was no difference between the two groups at the end of the study; the survival curve for the assertive case management group was not significantly different from that for the control group (log-rank p=0·258, Wilcoxon p=0·103; figure 2). However, in the ad-hoc analyses at selected timepoints (done because the proportional hazards assumption was not met), the cumulative incidence of first recurrent suicidal behaviour was significantly lower in the intervention group than in the control group at 1, 3, and 6 months after randomisation, but not at 12 or 18 months (table 2).

With respect to the secondary outcomes assessed in support of the primary outcome, we did not identify any differences between the intervention and control groups for completed suicide (27 [6%] of 460 *vs* 30 [7%] of 454, log-rank p=0·660) or all-cause mortality (46 [10%] of 460 *vs* 42 [9%] of 454, log-rank p=0·698).

In the subgroup analyses, the intervention group had a significantly lower cumulative incidence of first recurrent suicidal behaviour in women (up to 18 months), and in participants younger than 40 years (up to 6 months), and those with a history of previous suicide attempts (up to 6 months). We noted no signficant effect of the intervention in the other subgroups, apart from participants with no history of previous suicide attempts at 6 months only (table 3).

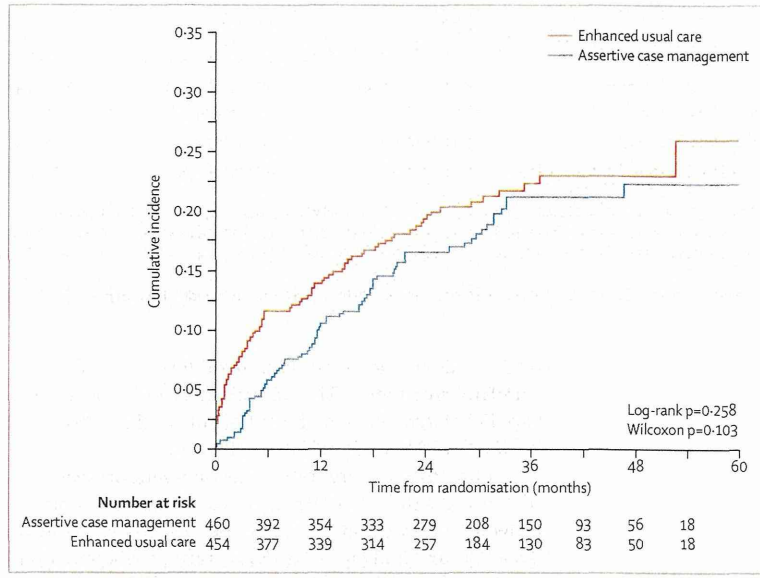

Figure 2: **Kaplan-Meier curve for incidence of first episode of recurrent suicidal behaviour (attempted suicide or completed suicide)**

In the sensitivity analysis for the primary analysis, which we did to investigate possible selection bias caused by missing data, we did not find any differences from the results obtained from the primary analysis when adjusted with randomisation factors (sex, age, and previous suicide attempts; table 2), nor from the results obtained from the subgroup analyses (table 3). The sensitivity analysis in the subgroup analysis, which we did to investigate possible selection bias caused by missing data, likewise showed no differences when adjusted for remaining randomisation factors (sex, age, and previous suicide attempts; table 3).

Discussion

Our results show that assertive and continuous case management based on psychiatric diagnoses, social risks, and needs of adults who had attempted suicide was not effective at reducing the risk of repetition of suicide attempt over the full study period (follow-up time from 18 months to 5 years dependent on time of entry to the study), but it did seem to be effective for up to 6 months in our ad-hoc analyses by time from randomisation (panel 2).

Our findings are partly consistent with the results of Morthorst and colleagues' randomised controlled trial in a single Danish hospital.[22] They implemented case management through assertive outreach with eight to 20 outreach consultations over 6 months by specialist nurses to

	1 month	3 months	6 months	12 months	18 months
Intervention vs control	3/444 (1%) vs 16/445 (4%)	7/430 (2%) vs 32/440 (7%)	25/417 (6%) vs 51/428 (12%)	43/397 (11%) vs 60/399 (15%)	55/380 (14%) vs 71/385 (18%)
Unadjusted risk ratio	0·19 (0·06–0·64)	0·22 (0·10–0·50)	0·50 (0·32–0·80)	0·72 (0·50–1·04)	0·79 (0·57–1·08)
Risk ratio (imputed)*	0·19 (0·05–0·63)	0·22 (0·10–0·48)	0·48 (0·31–0·77)	0·71 (0·49–1·02)	0·77 (0·55–1·06)
Risk ratio (adjusted)†	0·19 (0·05–0·60)	0·22 (0·10–0·49)	0·49 (0·31–0·77)	0·72 (0·50–1·04)	0·78 (0·57–1·07)
Risk ratio (imputed plus adjusted)‡	0·18 (0·05–0·60)	0·21 (0·09–0·47)	0·47 (0·30–0·75)	0·70 (0·48–1·00)	0·75 (0·54–1·03)

Data are number of events/population for the intervention (assertive case management) group or control (enhanced usual care) group, or risk ratio (95% CI). *Risk ratios with data imputed for individuals who missed the assessment. †Risk ratios adjusted by use of regression models for the randomisation factors of sex, age, and history of previous suicide attempts before the current episode. ‡Risk ratios with data imputed for individuals who missed the assessment and adjusted by use of regression models for the randomisation factors of sex, age, and history of previous suicide attempts before the current episode.

Table 2: **First recurrent suicidal behaviour (attempted suicide or completed suicide), by timepoint (ad-hoc analysis)**

improve adherence with after-treatment as an add-on to standard treatment. The intervention did not show a significant reduction of repetition of suicide attempt at 12 months (OR 0·69, 95%CI 0·34–1·43).

In our trial, adherence to the intervention was 70% (figure 1). After 6 months, the case management was provided every 6 months until the end of the follow-up period (ie, from 18 months to 5 years after randomisation), whereas before 6 months it was provided more often. The less frequent intervention after 6 months might have weakened the effectiveness of the intervention, although intervention might be effective only for a short period of time. Our results suggest that continuous case management needs to be taken over by community mental health caregivers within 6–12 months, dependent on the availability of medical and social resources in the community.

Because of the high adherence to our intervention programme and the fact that the trial design was embedded in real-world clinical settings, our study shows that the assertive case management intervention is feasible in clinical practice, with social workers or medical personnel playing the part of case managers. Our findings could also be relevant outside of Japan, in other countries with functioning emergency services and comprehensive mental health care services in place.

The subgroup analyses showed that greater effects were seen in women, participants younger than 40 years, and those with a history of previous suicide attempts. Patients attempting suicide constitute a heterogeneous group, differing in age, livelihood conditions, and risk factors. Further research is needed to examine why a greater effect was seen in these specific subgroups.

We noted no difference in the incidence of completed suicide between groups during the overall study period. In their randomised trial, Fleischmann and colleagues[15] reported significantly fewer deaths by suicide among people who had attempted suicide who were given brief intervention and contact than among those given treatment as usual at the 18-month follow-up. However, their trial was deliberately done in five low-resource countries with little infrastructure and scarce financial and human resources. They noted that treatment as usual for the participating sites in their study "would not cover routine or systematic psychiatric or psychological assessment or help", whereas in Japan psychiatric consultation was available at 76% of the registered tertiary emergency medical centres in 2012,[35] although only some of these centres provided routine psychiatric assessment.

Our study had some limitations. First, the enhancement of usual care might have affected the overall results of our study, since the control group received better care than is usual in clinical practice in Japan. We chose to use enhanced usual care as the comparison group for ethical reasons; however, this approach might have reduced the difference in the primary outcome between the assertive case management group and the control group.

Another limitation of our study is that it did not include suicidal patients younger than 20 years. These patients were excluded because individuals younger than 20 years are regarded as minors in Japan and informed consent has to be obtained from legal guardians. Additionally, we excluded suicidal patients without an axis 1 DSM-IV-TR disorder as their primary diagnosis because the intervention was designed specifically for patients with an axis 1 disorder.

Many individuals who had attempted suicide did not participate in the study because their physical conditions were too severe for them to understand the description of the study, and to attend the interview and session for psychoeducation. Additionally, we missed some people who had attempted suicide for eligibility review or contact for the informed consent because of their short hospital stay. Our results might have some selection bias; we could not collect data for people who did not participate in our study because of ethical restrictions. However, the characteristics of our study participants were similar to those described in a national registry study.[5]

Although the outcomes were systematically collected from participants and official records, our results might have some reporting bias. Additionally, we could not compare the self-reported outcome of suicidal behaviour by participants with register data for admissions to emergency wards for critical care or hospital contacts because it was impossible to track all register data or hospital contacts since the catchment areas of some emergency services in urban areas in Japan overlap, and

	1 month	3 months	6 months	12 months	18 months
Sex					
Men (n=400)					
Intervention vs control	2/190 (1%) vs 3/202 (1%)	4/184 (2%) vs 9/200 (5%)	10/178 (6%) vs 17/197 (9%)	18/172 (10%) vs 21/183 (11%)	24/168 (14%) vs 25/177 (14%)
Unadjusted risk ratio	0·69 (0·12–4·07)	0·48 (0·15–1·54)	0·65 (0·31–1·38)	0·91 (0·50–1·65)	1·01 (0·60–1·70)
Risk ratio (imputed)*	0·79 (0·13–4·66)	0·46 (0·14–1·46)	0·61 (0·29–1·29)	0·88 (0·48–1·61)	0·99 (0·59–1·67)
Risk ratio (adjusted)†	0·79 (0·13–4·66)	0·48 (0·15–1·52)	0·64 (0·30–1·36)	0·90 (0·50–1·62)	0·99 (0·60–1·66)
Risk ratio (imputed plus adjusted)‡	0·76 (0·13–4·48)	0·45 (0·14–1·44)	0·60 (0·28–1·27)	0·87 (0·48–1·57)	0·96 (0·57–1·62)
Women (n=514)					
Intervention vs control	1/254 (<1%) vs 13/243 (5%)	3/246 (1%) vs 23/240 (10%)	15/239 (6%) vs 34/231 (15)	25/225 (11%) vs 39/216 (18%))	31/212 (15%) vs 46/208 (22%)
Unadjusted risk ratio	0·07 (0·01–0·56)	0·13 (0·04–0·43)	0·43 (0·24–0·76)	0·62 (0·39–0·98)	0·66 (0·44–0·99)
Risk ratio (imputed)*	0·07 (0·01–0·56)	0·13 (0·04–0·41)	0·42 (0·24–0·75)	0·61 (0·38–0·98)	0·64 (0·42–0·98)
Risk ratio (adjusted)†	0·07 (0·01–0·54)	0·13 (0·04–0·41)	0·43 (0·24–0·76)	0·64 (0·40–1·00)	0·66 (0·44–0·99)
Risk ratio (imputed plus adjusted)‡	0·01 (0·04–0·55)	0·12 (0·04–0·40)	0·42 (0·24–0·74)	0·61 (0·38–0·96)	0·63 (0·42–0·95)
Age					
Younger than 40 years (n=453)					
Intervention vs control	0/216 vs 12/222 (5%)	3/210 (1%) vs 23/221 (10%)	14/204 (7%) vs 37/216 (17%)	27/193 (14%) vs 41/207 (20%)	32/186 (17%) vs 49/200 (25%)
Unadjusted risk ratio	..	0·14 (0·04–0·45)	0·40 (0·22–0·72)	0·71 (0·45–1·10)	0·70 (0·47–1·05)
Risk ratio (imputed)*	..	0·13 (0·04–0·43)	0·38 (0·21–0·69)	0·67 (0·43–1·05)	0·66 (0·44–0·99)
Risk ratio (adjusted)†	..	0·13 (0·04–0·43)	0·39 (0·22–0·69)	0·69 (0·44–1·07)	0·68 (0·46–1·01)
Risk ratio (imputed plus adjusted)‡	..	0·13 (0·04–0·42)	0·37 (0·21–0·67)	0·65 (0·41–1·01)	0·64 (0·43–0·96)
Older than 40 years (n=461)					
Intervention vs control	3/228 (1%) vs 4/223 (2%)	4/220 (2%) vs 9/219 (4%)	11/213 (5%) vs 14/212 (7%)	16/204 (8%) vs 19/192 (10%)	23/194 (12%) vs 22/185 (12%)
Unadjusted risk ratio	0·73 (0·17–3·24)	0·44 (0·14–1·41)	0·78 (0·36–1·68)	0·79 (0·42–1·50)	1·00 (0·58–1·73)
Risk ratio (imputed)*	0·72 (0·16–3·19)	0·43 (0·13–1·37)	0·76 (0·35–1·63)	0·81 (0·43–1·54)	1·01 (0·58–1·75)
Risk ratio (adjusted)†	0·81 (0·18–3·59)	0·45 (0·14–1·43)	0·80 (0·37–1·73)	0·81 (0·43–1·52)	0·99 (0·58–1·72)
Risk ratio (imputed plus adjusted)‡	0·78 (0·18–3·48)	0·43 (0·13–1·38)	0·77 (0·36–1·67)	0·82 (0·43–1·54)	1·00 (0·57–1·74)
Previous suicide attempt					
None (n=464)					
Intervention vs control	1/223 (<1%) vs 3/234 (1%)	3/216 (1%) vs 10/230 (4%)	7/207 (3%) vs 19/220 (9%)	14/202 (7%) vs 21/204 (10%)	17/192 (9%) vs 24/198 (12%)
Unadjusted risk ratio	0·35 (0·04–3·34)	0·32 (0·09–1·15)	0·39 (0·17–0·91)	0·67 (0·35–1·29)	0·73 (0·41–1·32)
Risk ratio (imputed)*	0·34 (0·04–3·27)	0·31 (0·09–1·10)	0·38 (0·16–0·88)	0·68 (0·36–1·31)	0·73 (0·40–1·32)
Risk ratio (adjusted)†	0·36 (0·04–3·40)	0·33 (0·09–1·18)	0·41 (0·18–0·95)	0·70 (0·37–1·34)	0·75 (0·42–1·34)
Risk ratio (imputed plus adjusted)‡	0·35 (0·04–3·32)	0·32 (0·09–1·13)	0·39 (0·17–0·91)	0·70 (0·37–1·34)	0·73 (0·41–1·33)
One or more (n=450)					
Intervention vs control	2/221 (1%) vs 13/211 (6%)	4/214 (2%) vs 22/210 (10%)	18/210 (9%) vs 32/208 (15%)	29/195 (15%) vs 39/195 (20%)	38/188 (20%) vs 47/187 (25%)
Unadjusted risk ratio	0·15 (0·03–0·64)	0·18 (0·06–0·51)	0·56 (0·32–0·96)	0·74 (0·48–1·15)	0·80 (0·55–1·17)
Risk ratio (imputed)*	0·15 (0·03–0·64)	0·17 (0·06–0·49)	0·53 (0·31–0·92)	0·71 (0·45–1·10)	0·77 (0·52–1·12)
Risk ratio (adjusted)†	0·14 (0·03–0·61)	0·17 (0·06–0·49)	0·53 (0·31–0·91)	0·73 (0·57–1·12)	0·78 (0·54–1·14)
Risk ratio (imputed plus adjusted)‡	0·14 (0·03–0·62)	0·17 (0·06–0·48)	0·51 (0·30–0·88)	0·69 (0·44–1·06)	0·74 (0·51–1·09)

Data are number of events/population for the intervention (assertive case management) group or control (enhanced usual care) group, or risk ratio (95% CI). *Risk ratios with data imputed for individuals who missed the assessment. †Risk ratios adjusted by use of regression models for the randomisation factors of sex, age, and history of previous suicide attempts before the current episode. ‡Risk ratios with data imputed for individuals who missed the assessment and adjusted by use of regression models for the randomisation factors of sex, age, and history of previous suicide attempts before the current episode.

Table 3: **First recurrent suicidal behaviour (attempted suicide or completed suicide), by subgroup (ad-hoc analysis by timepoint)**

Panel 2: Research in context

Systematic review

We searched PubMed for articles published from Jan 1, 1949, to Feb 28, 2014, using the search terms "suicid*" OR "self-harm" OR "self-injury" AND "random*" OR "interventions". We identified 12 relevant systematic reviews of randomised trials; the most recent systematic review was by O'Connor and colleagues,[19] which showed that psychotherapy reduced suicide attempts in some high-risk adults in populations and settings relevant to primary care. In a recent randomised trial, Morthorst and colleagues[22] examined the effects of assertive and intensive case management on repetition of suicide attempt, but the intervention did not lead to a significant reduction in repetition of suicide attempt.

Interpretation

In our large, multicentre, randomised controlled trial assertive case management was feasible in real-world clinical settings for suicidal patients with psychiatric disorders admitted to the emergency department. Although it was not effective at reducing the incidence of repetition of suicide attempts in the long term, the results of our ad-hoc analyses suggested that it was effective for up to 6 months. Our results also suggest potentially heterogeneous effects of assertive case management; the intervention seemed to be more effective in women, participants younger than 40 years, and those with a history of previous suicide attempts.

some participants might have moved out of the catchment areas. Finally, although outcome data were collected by trained assessors, possible variability of the assessments might have introduced bias into the results.

Contributors

YHir, CK, TA, NI, and NY conceived and designed the study. YHir was the principal investigator. YHir, CK, KO, YO, KI, AS, HM, YHit, AIwak, TK, JA, NH, HH, NE, NI, MK, AIwan, MM, and TA enrolled patients. YHir, CK, KO, YK, YO, KI, AS, HM, YHit, AIwak, TK, JA, NH, HH, NE, NI, MK, AIwan, MM, and TA managed the study at the participating sites. NI and NY analysed the data. CK wrote the first draft of the report. YHir, TA, KO, YK, YO, KI, AS, HM, YHit, AIwak, TK, JA, NH, HH, NE, NI, MK, AIwan, MM, and TA contributed to the writing of the report.

Declaration of interests

We declare no competing interests.

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