Prevention of Suicide Mortality in Noord-Brabant: The Effect of Implementation of a Regional Suicide Prevention system. A staggered implementation stepped wedge trial design.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Suicidal and self-injurious behaviours NEC
Study type	Observational non invasive

Summary

ID

NL-OMON48694

Source
ToetsingOnline

Brief title
SUPREMOCOL - SUicidePREvention by MOnitoring and COLlaborative care

Condition

- Suicidal and self-injurious behaviours NEC

Synonym
suicidal behavior

Research involving
Human

Sponsors and support

Primary sponsor: GGZ Breburg Groep (Rijen)
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: chain of care, decision aid, monitoring, Suicideprevention

Outcome measures

Primary outcome

The primary outcome measure is the number of completed suicides, measured in the 12 months preceding implementation of the regional prevention system, and in the twelve months after implementation of this regional suicide prevention system in the whole province of Noord-Brabant as for the individual districts.

Secondary outcome

Non-fatal suicide attempts: estimated by means of the number of ambulance, presentation at emergency rooms (not by ambulance), admissions to SMHIs and police reports, all in the context of suicidal behaviour. moreover, individual suicidal ideation will be assessed by the Suicidal Ideation Attributes Scale (SIDAS) and the Patient Health Questionnaire (PHQ-9) at baseline, and 3, 6, 9 and 12 months after entering the prevention program. Questions will also be asked on demographics and first experiences with the monitoring system (online and by phone). Finally, implementation outcomes * reach, effectiveness, adoption, implementation and maintenance - and stakeholders* experiences will be assessed.

Study description

Background summary

Suicidal behaviour, defined as suicidal ideation, suicide attempts and completed suicides, is a major public health problem. In the Netherlands, suicide rates have risen since 2007 with 38% to 1871 suicides in 2015. The province Noord-Brabant ranks second in the national rating. Of the completed suicides in Noord-Brabant, 60% occurs in persons not receiving mental health care, although completed suicides occur in the context of mental disorders in 80-90% of the cases. This urgently calls for a regional suicide prevention effort.

Study objective

The aim of this study is to lower suicide rates in Noord-Brabant with 20% by establishing a chain of care and a suicide prevention system in this regional network of chain partners. To this end, two sub-objectives are: (1) to evaluate the effect of the suicide prevention system in terms of completed suicides, non-fatal suicide attempts and patients* suicidal ideation and (2) to explore which factors facilitate or hinder the implementation of the suicide prevention system, or are associated with early withdrawal.

Study design

The study is built on four research questions that relate to the objectives, each with a separate study design:
1. Does the suicide prevention system lead to a reduction of completed suicides by 20%? This research question will be examined with a pre-post design evaluating the number of completed suicides before and after the rollout of the suicide prevention system.
2. Does the suicide prevention system lead to a reduction of non-fatal suicide attempts and completed suicides? This question will be examined with a stepped wedge trial design.
3. Does the suicide prevention system lead to a reduction of suicidal ideation in persons who are registered in the monitoringsystem? This research question will be examined with a longitudinal observational design. This design will be nested in the stepped wedge trial design. Patients* informed consent will be asked.
4. Which factors facilitate or hinder the implementation of the suicide prevention system and what are stakeholders* experiences with the system? This research question will be evaluated with a mixed methods design including a RE-AIM evaluation and a qualitative process evaluation.

The study setting of the first two research questions consists of the

participating chain partners such as general hospital emergency rooms, general practitioners,police, NS and ProRail and safety houses signalling persons with suicidal behaviour in Noord-Brabant, and specialty mental health institutions (SMHIs) providing the specialised MH care. During the project other chain partners, who may play a role in signaling persons with an increased suicide risk, may be included. Research question 3 and 4 are conducted in the clinical setting.

Intervention

The suicide prevention system consists of at organisational level, implementing a regional chain of care based on four pillars: (1) implementing a monitoring system with decision aid to support health care professionals in assessing, reporting and monitoring patients at risk for suicide, (2) providing swift access into SMHIs for persons established to be at risk for suicide by the decision aid and provision of treatment (3) positioning nurse care managers collaborating with psychiatrists in assessment, care management and treatment of the persons at risk according to a collaborative care model and (4) providing telephone monitoring of adherence to treatment and treatment experiences, during one year by the nurse care manager.

Study burden and risks

For patients, benefits will be considerable as they will receive regular treatment in organizations collaborating closely to provide a well functioning chain of care for suicidal patients, swift access to care for patients at risk, treatment by trained personnel receiving support of a evidence based decision aid, and 12 months follow up aimed at providing care taking the patient preference for treatment into account, and this will be treatment as usual for these organizations as it will be implemented over all speciality mental health institutions in Noord-Brabant. These benefits account for patients who provide informed consent to participate in the research * which entails filling out the five-item SIDAS and nine-item PHQ-9 questionnaires, and once: the ACE questionnaire, questions on demographics, chronic diseases, pain and first experiences with the monitoring system* and patients who do not give their consent will be the same, since they will receive the same treatment. The burden for the patients providing informed consent for filling out the additional two questionnaires mentioned above will be limited; as this will be done in the context of treatment aimed at their suicidal ideation and thus will not provide an extra mental burden. The time needed to fill out these questionnaires is limited: approximately 10 minutes in total. There are no indications that risks are involved for the patients who will provide informed consent, because all patients will receive treatment as usual as indicated above. The burden of participation in this study is expected to be minimal, and the risks of participation in this study are considered low for the participating organizations, as they will receive support for their regular

health care tasks by this suicide prevention system, and the monitoring system will be built on a secured website. There are potential substantial benefits for the participating professionals as the monitoring system supports the professionals by providing an evidence based decision aid, providing a communication channel that enhances swift referral to specialised mental health care, thus eliminating previous delays in referrals and transitions of care. The additional burden for professionals will be low as they only need to spent time and effort in the use of the monitoring system when they provide treatment to the patients at risk, and this extra time will not exceed 5 minutes per patient, which is the time to take for logging into the system. Finally, all participants will receive an e-booklet and a test account for the monitoring system before they participate, and implementation meetings are organized on a regular basis with the participating professionals, in which all participating professionals can share their experiences and ask questions

Contacts

Public
GGZ Breburg Groep (Rijen)

Lage Witsiebaan 4
Tilburg 5042 DA
NL
Scientific
GGZ Breburg Groep (Rijen)

Lage Witsiebaan 4
Tilburg 5042 DA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Moderate to High suicide risk. Assessing the suicide risk occurs in two steps. First, we look into question 9 'How often have you been bothered by thoughts that you would be better off dead or of hurting yourself in some way in the last two weeks* of the Patient Health Questionnaire (PHQ-9)? When one scores 2 or higher - which means that the person in question has these thoughts in more than half of the days in a week - a number of additional questions will be asked. It concerns the following six questions. Over the past month: 1. Did you think you'd be better off when you were dead or did you wish you were dead? 2. Did you want to hurt yourself? 3. Did you think of suicide? 4. Did you made suicide plans? 5. Did you undertake a suicide attempt? Throughout life: 6. Did you think you'd be better off when you were dead or did you wish you were dead? Based on these questions the suicide risk is assessed. The suicide risk is "high" when a person answers (1) "yes" to question 4 OR; (2) 'yes' to question 5 OR; (3) *yes* to both question 3 and question 6 OR; if (4) the responsible professional has the impression that the suicide risk is high. The suicide risk is "moderate" when a person answers: (1) 'yes' to question 3 and 'no' to question 6 OR; (2) 'yes' to both question 2 and question 6. If the suicide risk is 'moderate' or 'high', the person is assigned into the monitoring system.
- 18 years and older
- Ability to read and write Dutch

Exclusion criteria

- Low suicide risk
- younger than 18 years
- Not able to read and write Dutch

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2018
Enrollment:	296
Type:	Anticipated

Ethics review

Approved WMO Date:	08-11-2017
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	24-10-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	25-03-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL61935.028.17