'Integrated violence prevention' – an intervention aimed at preventing violence and threats against employees in psychiatric units and the Prison and Probation Service in Denmark

Submission date	Recruitment status No longer recruiting	Prospectively registered		
29/11/2017		[X] Protocol		
Registration date 20/12/2017	Overall study status Completed Condition category	Statistical analysis plan		
		[X] Results		
Last Edited		Individual participant data		
16/04/2024	Mental and Behavioural Disorders			

Plain English summary of protocol

Background and study aims

Threats and violence at work are caused by a complex interplay between individual, work related and organizational factors. Therefore all of these factors need to be tackled when aiming to improve violence prevention in the workplace. This study aims to test a novel approach to violence prevention. This approach integrates activities on the management and on the employee level and makes both levels an active part in creating an improved safety climate at work. The study is conducted in Danish psychiatric hospitals and in the Danish Prison and Probation Service. Employees in these workplaces are especially likely to experience violent behavior from users. A Danish national survey from 2016 shows that 83% of employees in psychiatric hospitals have experienced threats from patients and 62% have experienced violence within the last year; in the prison and probation service 69% have experienced threats from inmates and 25% have experienced violence. This study aims to develop and test the method 'Integrated Violence Prevention' at workplaces in psychiatric hospitals and the prison and probation service, develop tools for mapping the violence prevention practice, i.e. guidelines and procedures for preventing and dealing with threats and violence as well as the actual practices employed during work, assess the effect of 'Integrated Violence Prevention' on the degree to which managers and employees continuously work on violence prevention practices based on their registration and experiences and to assess the importance of implementation on success of the intervention.

Who can participate?

Workplaces within Danish psychiatric hospitals and 8 workplaces within the Danish prison and probation service.

What does the study involve?

During the study each workplace will be involved in a number of activities. This includes mapping

of violence prevention practice in the workplace by questionnaire and interviews, a seminar for managers underlining their role in violence prevention, a seminar for employees and managers that on the basis of the violence prevention practices mapping point to areas that need improvement, and six meetings in a steering group consisting of employees and the manager. During the period where steering group meetings are held a member of the research team offers three coaching sessions to the manager (and in some cases also to the nearest supervisor) in order to develop ways in which the violence prevention activities can be supported. To evaluate the programme's success, the study conducts a thorough effect and process evaluation. Data is collected using a short questionnaire every three months from September 2017-December 2019. In addition, interviews with managers before the intervention commences are conducted as well as focus groups with employees before, during and after the intervention at all workplaces are conducted. Finally, all activities that the steering group plans to implement, actually implements, evaluates and adjusts are documented.

What are the possible benefits and risks of participating?

The benefits are a potential improvement of violence prevention in the workplace. This will hopefully mean that threats and violence against employees in the long run will diminish. In addition, managers and staff are expected to become better equipped to handle situations where threats and violence occurs. There are no risks of participating.

Where is the study run from?

The study is a collaboration between the Department of Occupational Medicine, Regional Hospital Herning, the Danish National Research Centre for the Working Environment, and Copenhagen University (Denmark).

When is the study starting and how long is it expected to run for? January 2017 to December 2019

Who is funding the study?
The Danish Working Environment Research Fund (Denmark)

Who is the main contact? Lars Peter Sønderbo Andersen Lars.Peter.Sønderbo.Andersen@vest.rm.dk

Study website

http://www.arbejdsmiljoforskning.dk/da/projekter/integreret-voldsforebyggelse--et-randomiseret-kontrolleret-interventionsstudie

Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Integrated violence prevention – a controlled randomised trial assessing the effects of a novel approach combining efforts from management and employees in the prevention of violence and threats against employees in 8 units in Danish psychiatric hospitals and 8 units in the Danish Prison and Probation Service

Acronym

IVP-project

Study objectives

Main hypotheses:

- 1. In the 8 work units from the Prison and Probation Service the intervention will lead to a significant increase in the degree to which managers and employees continuously work on violence prevention practices based on their registration and experiences.
- 2. In the 8 work units from the Psychiatry the intervention will lead to a significant increase in the degree to which managers and employees continuously work on violence prevention practices based on their registration and experiences.

Secondary hypotheses:

- 1. Workplaces within psychiatry which have a higher degree of implementation will have a greater increase in the degree to which managers and employees continuously work on violence prevention practices based on their registration and experiences than workplaces within psychiatry which have a lower degree of implementation.
- 2. Workplaces within the prison and probation service which have a higher degree of implementation will have a greater increase in the degree to which managers and employees continuously work on violence prevention practices based on their registration and experiences than workplaces within the prison and probation service which have a lower degree of implementation.
- 3. Workplaces within psychiatry which have a higher degree of implementation will have a larger improvement in a) cooperation between managers and employees; b) attention to violence prevention; c) the number of actions taken to prevent violence and threats; d) the violence prevention climate; e) the employees' self-efficacy in violence prevention; and f) the employees'

sense of safety at work than workplaces within psychiatry which have a lower degree of implementation

- 4. Workplaces within the prison and probation service which have a higher degree of implementation will have a larger improvement in a) cooperation between managers and employees; b) attention to violence prevention; c) the number of actions taken to prevent violence and threats; d) the violence prevention climate; e) the employees' self-efficacy in violence prevention; and f) the employees' sense of safety at work than workplaces within the prison and probation service which have a lower degree of implementation
- 5. Across the two sectors workplaces with a higher baseline score of outcome measures will experience smaller improvements post intervention due to a ceiling effect, even when the implementation degree is high.
- 6. In both sectors the implementation of the intervention will be shaped by contextual factors such as changes in management, activities of the working environment organization and the organization's readiness for change.
- 7. In both sectors we will explore the role of the auxiliary processes (trust between management and employees, affective commitment, balanced attributions of responsibility of prevention work, and reciprocity between managers and employees in violence prevention efforts) on the implementation process.

We expect that the intervention in time will have an effect on the incidence of violence and threats in the participating workplaces in both sectors. We do, however, not expect that this change will happen during the follow-up period in this study. During the follow-up period the reported incidents of violence and threats may instead increase due to the heightened focus on violence and threats during the intervention. Although the main aim of the intervention is to decrease violent and threatening incidents in the participating workplaces, we do not have a hypothesis on the short term effect on these outcomes. We will however in an explorative manner evaluate the effect of the intervention on incidence of violence and threats in the two sectors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

We will collect data by use of questionnaires, focus groups, interviews, action plans, implementation documentation and background documents (for example organizational structure) from the participating workplaces. As no biological data is collected ethics approval is not necessary according to the Danish regulations. The project has been approved by The National Research Center for the Working Environment that has been authorized by the Danish Data Protection Agency to assess their internal projects (Project is registered on the titel "Integreret Voldsforebyggelse").

Study design

Multicentred stepped wedged interventional design with start dates stratified and randomly assigned to workplaces

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital, Prison/detention, Workplace

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

The domain under study is violence-prevention climate, violence-prevention strategies and actions performed by management and employees in psychiatric hospitals and the prison and probation service. The study also concerns contextual factors in these job-sectors, which may or may not influence the effect of the intervention.

Interventions

The intervention consists of:

Month 0: Mapping of the current violence prevention practices using interviews with managers and with employees and by questionnaires sent to all employees at the workplace.

Month 1: A seminar with managers to inform them about the results from the mapping and equip them to support the process of violence prevention efficiently.

Month 1: A seminar with employees and their manager where the results from the mapping is used as a starting point for a discussion among employees and their manager on what aspects of violence prevention need improvement.

Month 1-3: Three coaching sessions with the manager in order to support actions that will show the employees that he/she is committed to violence prevention and to the ongoing project. Month 2-3: Three meetings with a steering group consisting of employees, the manager, and a member of the research team. The goal of the steering group is to use the ideas for improvement developed at the seminar with employees and managers to develop plans for concrete changes and start implementing them. A member of the research team participates in order to facilitate the steering group's ongoing process with implementing, evaluating and adjusting these activities.

Month 4-6: The steering group has three additional meetings, without the participation of a member of the research team. During these meetings the steering group has the full responsibility for the ongoing process with implementing, evaluating and adjusting activities. In the 6th month a physical or telephonic meeting is offered to the manager to evaluate the process and hear about the plans for future violence prevention activities.

It is planned to randomize the 16 participating workplaces to four different starting dates (October 2017, January 2018, October 2018, and January 2019). At each starting point two psychiatric units and two units from the Prison and Probation Service were supposed to enter into the intervention. The workplaces function as control units until their starting date for the intervention, at which point they become intervention units. Due to logistical challenges the 8 workplaces from the Prison and Probation Service do not follow this scheme and are randomized only to the last three starting points.

Intervention Type

Behavioural

Primary outcome measure

The degree to which managers and employees continuously work on violence prevention practices based on their registration and experiences is measured using a questionnaire at every three months.

Secondary outcome measures

- 1. Cooperation between managers and employees is measured using a questionnaire at every three months
- 2. Attention to violence prevention is measured using a questionnaire at every three months
- 3. Actions taken to prevent violence and threats measured using a questionnaire at every three months
- 4. Violence prevention climate is measured by a number of single items and the violence prevention climate scale from Kessler et al., 2008 at every three months5. Self-efficacy in violence prevention is measured using a questionnaire at every three months
- 6. Sense of safety at work is measured using a questionnaire at every three months
- 7. Implementation degree is measured using registration of reach, fidelity and dose received after the introduction of each core element of the intervention (mapping, leader seminar, employee seminar, monthly coachings during 3 months, and monthly steering group meetings during 3 months

Overall study start date

01/01/2017

Completion date

31/12/2019

Eligibility

Key inclusion criteria

Workplace level:

- 1. Psychiatric hospital or prison and probation service
- 2. Main task of the workplace is to work with psychiatric patients/inmates

Individual level:

- 1. Manager or employee at participating workplace
- 2. Employees are in direct contact with inmates/patients
- 3. Aged 18 to 67 years old

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

8 units in Danish Psychiatric Hospitals (approximately 200 individuals) and 8 units in the Danish Prison and Probation Service (approximately 200 individuals)

Total final enrolment

775

Key exclusion criteria

Workplace level:

1. Workplaces with less than 10 employees

Individual level:

- 1. Employees with no contact with inmates/patients
- 2. Individuals with a manager that is not employed at the workplace

Date of first enrolment

01/04/2017

Date of final enrolment

15/11/2017

Locations

Countries of recruitment

Denmark

Study participating centre Danish Ramazzini Centre

Department of Occupational Medicine University Research Clinic, Regional Hospital West Jutland, Herning, Denmark Herning Denmark 7400

Study participating centre National Research Centre for the Working Environment

Lersø Parkallé 105 Copenhagen Denmark 2100

Study participating centre University of Copenhagen Nørregade 10, PO Box 2177

Sponsor information

Organisation

The National Research Centre for the Working Environment

Sponsor details

Lersø Parkalle 105 København Denmark 2100

Sponsor type

Research organisation

ROR

https://ror.org/03f61zm76

Funder(s)

Funder type

Government

Funder Name

The Danish Working Environment Research Fund

Results and Publications

Publication and dissemination plan

Planned publication of study results in a high-impact peer reviewed journal in 2020. We are planning to publish an article describing the study design in 2018.

Intention to publish date

01/12/2022

Individual participant data (IPD) sharing plan

The data will eventually be made available for other researchers on request. Once the study is finished the participant level data will be send to the Danish Data Protection Agency where it will be stored. Requests for using the data can then be directed to the Danish Data Protection Agency who will inform us.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	01/01/2019	08/12/2020	Yes	No
Thesis results			13/01/2022	No	No
Results article		15/04/2024	16/04/2024	Yes	No