**Mental Health Services**
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# The effect of implementing Trauma Informed Care in Danish Psychiatry – A Stepped Wedge Cluster Randomized Controlled Trial

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## INTRODUCTION

Trauma is a public health challenge, which is both harmful to the individual and costly for society (1, 2). In mental health services, there is a high prevalence of individuals with a history of trauma or abuse (3). A prevalence which is much higher than in the general population (2) - some studies report a prevalence as high as 90% among mental health users (4).

There is an urgent need to address trauma in mental health, so as not to distress, retraumatize or inflict patients with additional trauma. Therefore appropriate support and knowledge, provided by mental health staff, through a trauma informed approach could counter this(1). This in turn would reduce the use of a wide range of coercion as well as improve patient-staff relations and improve the work environment as well as lower administration rates for sedative-hypnotic drugs (5-7). In regards to coercion the use of a trauma informed approach has shown reduction of seclusion and restraint from 50% in the intervention arm (8) and up to 82.3% between baseline and follow up in the post-interventions fase (9).

This implementation would be in alignment with The Health Authorities focus on reduction in coercion in The Mental Health Services in Denmark has been the focus of The Health Authorities for several years (10).

## WHAT IS TRAUMA INFORMED CARE?

Trauma Informed Care (TIC) is an approach developed in the Mental Health Services in North America (1). The approach assumes that users are likely to have a history of trauma. Focus is on recognition of trauma symptoms and acknowledgement that trauma plays a role in the individuals' life and subsequently their behaviour and reactions.

The TIC approach is part of the Six Core Strategies (11), which has been part of the successful and lasting reductions in coercion in Mental Health services across the world. TIC is guided by 6 principles 1) Safety, 2) Trustworthiness and Transparency, 3) Peer Support, 4) Collaboration & Mutuality, 5) Empowerment Voice & Choice, 6) Cultural, Historical & Gender Issues. TIC makes the change from the paradigm "What is wrong with You?" to "What has happened to You?"

TIC is now a National recommendation and in 2022 (12)The Danish National TIC Center will publish their recommendations for implementation of TIC. This will spark a rise in implementation of TIC in units across Denmark as we saw with Safewards. It is therefore of the utmost importance that we get in on the ground floor and begin research on TIC in a Danish Setting so we can assess the effectiveness and implementation of TIC. And complement the international findings on TIC, which unfortunately lack effect studies.

## AIM

The aim of this study is to evaluate implementation and effectiveness of Trauma Informed Care in Denmark. Primary outcomes will be effectiveness of TIC and reduction in aggression, violence and coercion following implementation as well as fidelity of implementation.
The results of the study will provide evidence of the effectiveness of TIC in a Danish context across all regions of the country. Also, it will likely provide information on what parts of the implementation program are key to successful implementation of TIC.

**The 6 Guiding Principles of Trauma Informed Care**
SAMHSA 2014

## METHOD

The design that will be utilized for the implementation of TIC is a Stepped Wedge Randomized Controlled Trial (SW-CRT) (13, 14). This has been chosen as it is logistically impossible to implement TIC successfully in the number of wards needed for the trial at the same time. It also hinders contamination and disappointment effects in control wards.

The participating wards will be recruited across Denmark and be randomized into clusters. Data will be collected before, during and after implementation of TIC in each cluster. Implementation will adhere to The Danish National TIC Center guidelines for implementation (15).

The Attitudes Related to Trauma Informed Care (ARTIC) (16) questionnaire will be used both to establish a baseline prior to implementation, and to monitor development in knowledge of and attitudes toward TIC as well as organizational initiatives and change during the implementation. It will be key in assessing satisfaction and perception of TIC, the implementation process, and satisfaction with care before, during and post implementation. Data collection will also include workplace assessment, BVC, coercion and other data that is already being collected by the participating wards.

All outcome measures will be organized using the RE-AIM (reach, effectiveness, adoption, implementation, maintenance) framework (17), including implementation outcomes (e.g. stress, feeling of security), service outcomes (e.g., Coercion), and patient outcomes (e.g., aggression, violence). The Consolidated Framework for Implementation Research framework will be used to identify factors that influence implementation of the interventions (18).

## POWER CALCULATION

For the power calculation for the SW-CRT Hooper et al 2016 (19) and Hemming et al 2020 (20) recommendation was used. The intra-cluster correlation coefficient (ICC) is in the calculation set to be 0.02, to ensure that the clustering effect is eliminated. The cluster size calculation is based on a Power of 0.38 derived from the two effect studies on TIC with the highest evidence (8, 9). The level of significance was set at 0.05. The implementation will be executed in three steps or sequences (19, 20). The Cluster size is determined to be 40 per step totalling 120 participants. This computes to 7 participants per unit. This requires 6 clusters per step totalling 18 units in all.

**References**

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REGION H