

TREC-SAVE: A randomized trial comparing mechanical restraints with use of seclusion for aggressive patients in psychiatric hospitals

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Background: TREC-SAVE is the third of the TREC studies in Brazil. The first studies evaluated commonly used drug treatments for management of people with psychosis who have become acutely aggressive. TREC-SAVE address issues of seclusion or restraint of this same group. It is the first randomized trial addressing this question.

Methods: This pragmatic trial was designed after close consultation with all involved. Participants were anyone aggressive or violent in the emergency wards of a large psychiatric hospital in Rio de Janeiro (Psychiatric Institute Philippe Pinel) for whom restriction was felt to be indicated by nursing and medical staff, but also for whom they were unsure whether seclusion or restraint would be indicated. People were randomized to use of four-point restraint (strong cotton banding to edge of bed) or use of a minimally furnished seclusion room with open but barred windows onto the nursing station. All participants used medication as prescribed. Protocol and analysis plan was published. Main outcomes were chosen by clinicians and managers, the Ethics Committee of Psychiatric Institute Philippe Pinel approved the study. Data were analyzed by intention-to-treat. Trial registration: ISRCTN4945427

Results: Recruitment started in July 2010 and ended Jan 2011. 105 participants were included (restraints=51; seclusion=54) with similar demographic and clinical data across groups. People allocated to the least restrictive option (seclusion room) were at greater risk of needing an early change of their treatment to restraints compared with those allocated to restraints (RR 1.96 95% CI 1.02-3.80). However, even taking into account the move out of seclusion into restraints, this study provides evidence that this care pathway does not increase overall time in restriction of some sort (RR Not restricted - by 4 hours 1.10 CI 0.74-1.63). Participants tended to be less satisfied with their care in the restraints group (42.2% vs 27.7%) but this did not reach conventional levels of statistical significance ($p=0.47$).

Discussion: This study suggests that opting for the least restrictive option in circumstances where there is clinical doubt does not harm or prolong coercion. This is one small trial of short duration but its outcomes and circumstances of conduct apply to very great numbers of people who are at risk of maltreatment. These most coercive parts of health care have been neglected and have avoided any high-grade evaluation. For the first time, a randomized pragmatic clinical trial was undertaken to illustrate how objective evaluation of these techniques can, humanely and ethically be applicable worldwide.

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