# A RANDOMIZED STUDY OF PRISON-BASED METHADONE MAINTENANCE THERAPY

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Globally, prevalence of HIV and associated infections is significantly higher in the prison system than in the general population[1]. In a certain Asian country, illicit opioid use is widespread and crimes directly and indirectly associated with drug use substantially contribute to imprisonment. Drug-related sentences typically include judicial corporal punishment ("caning")[2]. In addition, the HIV epidemic is concentrated among people who inject drugs and who are in the criminal justice system[2]. Upon incarceration, there is mandatory rapid HIV-testing and all those found to have HIV are segregated into a dedicated housing unit within the prison. Addiction treatment in the prison is primarily faith-based counseling, which is delivered weekly in the segregated cell block where prisoners with HIV are housed.

Decades of evidence support the use of Methadone Maintenance Therapy (MMT) in community settings for the treatment of opioid use disorders, reduction of HIV risk behaviors and criminal behaviour[3]. Professor M, who has extensive experience in prison research, designed a randomized study to establish evidence for a MMT program in a prison in this country. Professor M recruited participants from a male prison, who were randomized into intervention and control arms. In the intervention arm, MMT was initiated in prison, followed by linking these individuals to community-based MMT program after release from prison. The control arm provided faith-based counselling in the prison only.

Study eligibility criteria were: (1) ≥18 years of age; (2) HIV-positive; (3) opioid-dependent in the 12 months prior to incarceration, determined initially by an abbreviated screening and (4) citizenship, to assure availability of nationally subsidized methadone. Prison officers provided Professor M and his research team with lists of all prisoners in the dedicated HIV housing block after removing names of those who were not citizens, sentenced to life in prison, or were awaiting execution. Eligible individuals were invited by prison staff to voluntarily attend group information sessions about the study. Prisoners did not receive any financial incentives to participate in the study while in prison, however, financial incentives were provided during the post-release linkage to care program.

In order to help ensure safety of the research team and protect privacy of research participants, prison officers recommended the use of plexiglass windows on all rooms where in-prison research activities were conducted. During the interview process with the inmates, prison security waited outside of the plexiglass windows. All interested individuals underwent a detailed informed consent process. The consent process was repeated after release from prison to accompany initiation of the post-release component of the study.

**Questions:**

1. International ethics guidelines recommend that research in correctional settings receive extra attention to concerns of coercion and consent. Does the case raise any such concerns? If so, what are they and how might the researcher address them?
2. Was Professor M justified in conducting a randomized controlled trial design? Do you think it was justifiable to offer 'no addiction treatment' to the control arm? Would another study design be preferable? Why/Why not?
3. Do you have any ethical concerns regarding the stated inclusion criteria or the recruitment procedures?
4. What are your thoughts about the interview rooms, where plexiglass windows were installed? Can you recommend any other strategy in a prison setting to ensure the research team's safety and at the same time, protect participants' privacy?

**References:**

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