

ICAP Journal Club

ICAP's Journal Club is designed to inform ICAP staff and colleagues of the latest scientific literature by providing a succinct summary and critical analysis of important studies, and by discussing the implications of the research on clinical work.

Article

Mabuto T, Woznica DM, Ndini P, et al. **Transitional community adherence support for people leaving incarceration in South Africa: a pragmatic, open-label, randomised controlled trial.**

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Study Summary

This pragmatic randomized controlled trial evaluated the feasibility of a differentiated model of care for people with HIV returning to the community after incarceration, and whether this intervention increased enrollment in HIV treatment services six months after community re-entry, as compared to usual care.

Study Setting

- Five correctional facilities in the Gauteng province of South Africa.
- All correctional facilities had on-site antiretroviral therapy (ART) programs managed by nurses.

Methods

- People who were incarcerated were eligible to participate if they were receiving ART at one of the study sites; were aged ≥ 18 years; were scheduled for release in the study period; were willing to provide contact details for follow-up, including contact information for next of kin; and were planning to reside in or around Gauteng after release.
- Consenting participants were randomly assigned (1:2) with block randomization to either usual care or the Transitional Community Adherence Club (TCAC) intervention.
- Usual care involved passive referral, in which the released individual was provided a referral letter from the correctional health staff to present at a primary health clinic in the community.
- The TCAC intervention was an adaptation of the community adherence club model, a differentiated model of HIV care used widely in South Africa. Key components included:
 - Participants had two individual sessions with TCAC facilitators to build rapport and identify participant needs. The first session was conducted before release and the second within the first 15 days of release, at which time participants were assigned to a TCAC venue based on residence location and proximity to a local public sector clinic.

- TCAC group meetings were conducted in private spaces in a community venue by two facilitators: a social worker experienced in working with people on ART returning from incarceration; and a peer with a history of incarceration and HIV.
- The facilitators used a curriculum developed specifically for people with HIV returning from incarceration, which consisted of 12 sessions over six months, with meetings every two weeks.
- TCAC sessions covered goal setting, prioritization, and planning; HIV and incarceration stigma; livelihood strengthening; and ART adherence. Each session had a facilitated group discussion of individual goals, challenges faced, and successes related to the previous session's curriculum, followed by new curriculum content.
- The facilitators received a comprehensive seven-day didactic and role-play training on the underlying theory, intervention components, and use of the intervention manual. In addition, facilitators met every two weeks with study investigators during intervention delivery to discuss successes and challenges and to review content and technique for additional guidance on salient topic areas.
- Participants were provided with a standard reimbursement of R100 (US\$6) to cover typical travel costs to TCAC group sessions.
- Participants were also referred by facilitators for additional community-based services such as social welfare schemes (e.g., food parcels), harm reduction services, or employment recruitment agencies.
- Prior to release, participants were administered baseline demographic and social-behavioral questionnaires that elicited information on duration of incarceration, HIV history, perceived strength of relationship networks outside the correctional setting (social capital), HIV stigma, disclosure of HIV status, substance use, and depression.
- Participants in both groups were scheduled for telephone or in-person follow-up visits on days 30, 90, and 180 after release from the correctional facility.
- The primary outcomes were feasibility of TCAC delivery and participant follow-up, and TCAC effectiveness.
- The feasibility outcome was based on a target of at least 90% of participants assigned to a specific TCAC, and physically able to go to the TCAC venue, attending at least one TCAC session.
- The primary effectiveness outcome was the proportion of participants enrolled in HIV treatment services at any medical facility in South Africa at the six-month visit, as reported by participants or next-of-kin. Participants without data on enrollment in HIV treatment were classified as having not enrolled in HIV treatment.
- Secondary outcomes were any harms, including inadvertent disclosure of HIV status or incarceration history, and concerns about safety of participants or staff before, during, or after TCAC sessions.
- The primary analysis was an intention-to-treat analysis, including people who died, left South Africa, or were reincarcerated.
- Subgroup analyses were done of prespecified subgroups that represented demographics of interest (age) and social or behavioral aspects touched on by the intervention.

Study Population and Follow-up

- From March 2019 to December 2019, 222 individuals were screened and 175 were enrolled and included in the final analyses, with 116 in the TCAC intervention group and 59 in the care-as-usual group.
- Baseline characteristics were balanced overall by group. Most participants were men (95%), with a median age of 33 years (interquartile range [IQR] 29–37), and median duration of incarceration of 0.81 years (IQR 0.44–2.00).
- All participants were on ART at the time of release; 34% had initiated ART at community clinics before their current incarceration, and 66% initiated ART during their current or a previous incarceration.
- Enrollment in HIV treatment services at six months was ascertained for 92% of participants.

Effectiveness Outcome

- Among 175 participants, 52% met the primary outcome of enrollment in HIV treatment services six months after release from a correctional facility.
- In the TCAC group, 61% of participants had enrolled in HIV treatment services at six months, compared with 36% of participants in the care-as-usual group (risk ratio 1.7, 95% confidence interval 1.2–2.5; $p=0.0010$).
- Among the 83 participants categorized as not having enrolled in HIV treatment services at six months, 23% were reported by family to be living on the streets and not engaging with HIV treatment services, 11% were reincarcerated, 2% had died, 3% had left South Africa, and 8% had no outcomes reported by themselves or their next of kin.
- Subgroup analyses found that individuals who had not disclosed their HIV status to a friend or family member, who had moderate to severe depression, who used alcohol daily, or who had an opioid use disorder tended to benefit less from the intervention.

Feasibility and Safety Outcomes

- Of the 116 participants assigned to the intervention group, 65 (59%) were successfully assigned to a specific TCAC post-release.
 - Reasons for non-assignment to a TCAC were a failure of post-release contact ($n=25$); loss to follow-up after initial post-release contact ($n=5$); request not to attend a TCAC ($n=2$); and release from a correctional facility when group gatherings were prohibited due to COVID-19 related restrictions ($n=19$).
- Of the 65 participants assigned to a specific TCAC group post-release, 44 (68%) attended at least one TCAC session.
 - Reasons for not attending were reincarceration ($n=4$), relocating outside of Gauteng province ($n=6$), working during TCAC session times ($n=1$), and lack of interest or ability to get to the session ($n=10$).
- Excluding those reincarcerated and relocated outside Gauteng, 55 (85%) of 65 participants assigned to a specific TCAC group were considered physically able to attend at least one

TCAC session, and of those 44 (80%) succeeded in attending one or more sessions, which is lower than the pre-specified TCAC delivery feasibility goal of 90%.

- Of the individuals assigned to a TCAC, the median number of sessions attended was five (IQR 4–8).
- No adverse events were reported during TCAC sessions, including involuntary disclosure of HIV status or incarceration history, and violence or threat of violence to facilitators or participants during, before, or after TCAC sessions.

Critical Analysis

This pragmatic randomized controlled trial found that a multilevel intervention, comprised of an adapted community adherence club model, with a curriculum and peer support designed specifically for people with HIV returning from incarceration, improved enrollment in HIV treatment services six months after release. Although the intended intervention and evaluation were significantly disrupted by COVID-19 travel and gathering restrictions, the study findings suggest the intervention is a promising approach for this population.

The following points should be considered when interpreting the study findings:

- Because of the nature of the intervention, participants and study staff who recruited and implemented the strategy were unmasked to participants' randomization assignment. However, study assignments were masked to the investigators and staff doing outcome assessments until all outcome data were collected.
- From March 2020 onwards, group sessions could no longer be held because of COVID-19 restrictions, reducing the possible number of sessions to fewer than 12 for most participants, and some participants could not attend any sessions. Furthermore, the intended benefits of peer support were not fully realized during this period. Despite these changes, an intervention effect was seen in the intention-to-treat analysis, which suggests the full intervention may have had an even larger effect.
- The initial intervention intended to provide ART within the TCAC sessions, but this was not fully implemented, initially due to logistical factors, and subsequently due to clinic closures and restrictions on research activities related to COVID-19. Therefore, it remains unknown whether ART delivery could have further improved post-release HIV treatment continuity.
- Additional planned secondary outcomes included verified enrollment in HIV treatment services at the six-month visit; time to linkage to care within the first 90 days of corrections release; virological suppression at six months from release; and changes in employment status, social capital, and stigma index scores. However, the COVID-19 lockdowns limited the research teams' ability to document or capture some of these outcomes. Social capital, stigma, and employment outcomes will be disseminated through future publications.
- Given the high level of vulnerability of this population, COVID-19 lockdowns and the associated disruption in health services could have exacerbated challenges to community reintegration and navigating HIV treatment services. These effects may have impacted

those in the usual care group more than similar populations before the COVID-19 pandemic and may have contributed to the effect size of the intervention.

- Due to COVID-19 restrictions, study staff could not access clinics to verify participants' attendance for HIV treatment services as initially intended. Therefore, the primary analysis relied on self-reported final outcomes, which may have been affected by participants' knowledge of their group assignment. To minimize overreporting of linkage to HIV treatment, researchers made participants aware of their plans to verify all self-reported clinic visits.
- The study was conducted in an urban province in South Africa and excluded those who did not expect to stay in the area, so findings might not be generalizable to all people with HIV returning from incarceration, particularly those who are returning to rural communities or who are highly mobile.
- Findings from subgroup analyses should be interpreted cautiously given the small sample size and limited power; however, they suggest that facilitating HIV status disclosure and identification as well as management of substance use and mental health disorders should be incorporated into any future interventions for this population.
- Only one correctional facility in the study housed women, and they made up a very small proportion of participants; therefore, these findings may not be generalizable to this population.
- Viral suppression and cost effectiveness are important outcomes for programs to consider before adoption of the TCAC model; however, these data were not provided. Further assessments are warranted before adoption and programmatic scale-up of this intervention.

Implications

This pragmatic randomized controlled trial found that a multilevel intervention, which included a differentiated model of care designed specifically for people with HIV returning from incarceration, improved enrollment in HIV treatment services six months after release. It provides evidence that skill development and motivational enhancement strategies, combined with peer support, can improve treatment continuity for this marginalized population. The study also highlights the importance of developing differentiated approaches to care that address the unique, complex needs of highly vulnerable populations.

This article synopsis was written by Dr. Cassia Wells. Share your thoughts on this article or suggest an article for Journal Club by emailing her at caw2208@columbia.edu.