Title

Randomised controlled trial of a service brokerage intervention for ex-prisoners in Australia

Authors

Stuart A. Kinner\textsuperscript{1,2,3,4}, Nicholas Lennox\textsuperscript{5}, Gail M. Williams\textsuperscript{6}, Megan Carroll\textsuperscript{1}, Brendan Quinn\textsuperscript{7}, Frances M. Boyle\textsuperscript{6}, Rosa Alati\textsuperscript{6}

\textsuperscript{1} Melbourne School of Population and Global Health, The University of Melbourne. 207 Bouverie Street, Carlton VIC 3010, Australia.
\textsuperscript{2} School of Medicine, The University of Queensland. Herston Road, Herston QLD 4006, Australia.
\textsuperscript{3} School of Public Health and Preventive Medicine, Monash University. The Alfred Centre, 99 Commercial Road, Melbourne VIC 3004, Australia.
\textsuperscript{4} Murdoch Children’s Research Institute. 50 Flemington Road, Parkville VIC 3052, Australia.
\textsuperscript{5} Queensland Centre for Intellectual and Developmental Disability, School of Medicine, The University of Queensland, Mater Misericordiae Hospital, Raymond Terrace, South Brisbane QLD 4101, Australia.
\textsuperscript{6} School of Population Health, The University of Queensland. Herston Road, Herston QLD 4006, Australia.
\textsuperscript{7} Centre for Population Health, Burnet Institute. 85 Commercial Road, Melbourne VIC 3004, Australia.

Corresponding author

Stuart A. Kinner. Phone +61 3 9035 7598. Email s.kinner@unimelb.edu.au

Melbourne School of Population and Global Health, The University of Melbourne

207 Bouverie Street, Carlton VIC 3010 Australia

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Abstract

Background: Health outcomes after release from prison are typically poor with elevated rates of morbidity and mortality widely documented. Under-utilisation of health services contributes to these outcomes, but interventions to increase health service utilisation in ex-prisoners are in their infancy and few have been rigorously evaluated.

Methods: Single-blinded randomised controlled trial of a service brokerage intervention (the ‘Passports study’) for N=1,325 adult ex-prisoners in Queensland, Australia. Participants in the intervention group received a personalised booklet summarising their health status and identifying appropriate community health services; trained workers made weekly telephone contact in the first 4 weeks post-release to identify health needs and facilitate health service utilisation. Participants in the control arm received usual care. Baseline data were collected within 6 weeks of expected release from custody with follow-up telephone interviews 1, 3 and 6 months post-release. Participant identities were linked with federal health service utilisation records, a national death register and corrective services records, two years post-release. The primary outcome was self-reported health service utilisation in the first 6 months post-release.

Results: Between 2008 and 2010 1,976 prisoners were screened for eligibility, 1,665 met eligibility criteria and 1,325 were recruited; 665 were randomised to the intervention and 660 to the control condition. Participants were broadly representative of adults being released from prison in Queensland except that women were intentionally oversampled (21% vs. 11%).

Conclusions: Outcomes from this large RCT will provide the first robust evidence of the effect of service brokerage on health service utilisation and health outcomes for ex-prisoners.

Word count: 250 words

Keywords: prisoners; re-entry; health service utilization; primary care; randomized controlled trial
1. Introduction

The world prison population is growing at a rate well in excess of general population growth with over 10 million adults currently in custody [1] and around 30 million moving through prison systems each year [2]. Despite their relative youth, prisoners often experience a range of complex and chronic health problems [3, 4]. The prevalence of blood-borne viruses, particularly HIV and hepatitis C, is typically much higher than in the community [5, 6]. The prevalence of mental illness is similarly elevated, particularly for post-traumatic stress disorder, psychotic disorders and substance use disorders [7-9]. A history of substance misuse is normative among prisoners in many countries [10] and a considerable number continue to use and inject drugs while in custody [11-13]. These complex and interconnected health problems are typically set against a backdrop of entrenched poverty and relative social disadvantage [14-16].

For many, health improves while in custody, where food and accommodation are provided in a highly structured setting, where drugs are less readily available, and where health services are provided at a level well in excess of that found in most communities [17, 18]. However, when prisoners return to the community, they often return to pre-incarceration patterns of behaviour and associated health outcomes within a relatively short period of time [14, 19-21]. This decline in general and mental health status can be life threatening. Ex-prisoners die at rates far higher than their community peers, particularly in the period immediately following release from custody, and overwhelmingly due to drug overdose or suicide [22, 23]. Rates of hospitalisation for physical and mental health problems are similarly elevated [24, 25].

There is increasing recognition of the need to support prisoners in the transition from custody back to the community, and of the centrality of health and social support services to this transition [26]. Although programs supporting the transition from prison to community are becoming widespread in many developed countries, evaluations of these programs have been
few, and rigorous evaluations – particularly randomised controlled trials (RCTs) – fewer still [27, 28]. One quasi-randomised trial of a pre-release program in New York State found no impact on health outcomes and a higher rate of recidivism in the intervention group [29], underscoring the importance of rigorous evaluation and highlighting the potential for interventions to produce both positive and negative effects [30]. Evidence from more recent trials in the US, with various subgroups of prisoners judged to be high risk or high need, suggests that effective transitional programs are distinguished by (a) the provision of tailored support after release as well as in custody, and (b) efforts to facilitate utilisation of existing community services (‘service brokerage’) [31-33]. However, the evidence base remains weak and few studies have been conducted outside the US. To this end, we aimed to determine whether post-release service brokerage was effective in improving health service utilisation and health outcomes in ex-prisoners in Australia. We undertook a RCT comparing the effect of a low-intensity service brokerage intervention and usual care on health service utilisation, health and offending outcomes following release from prison.

2. Methods

2.1 Study design

The Passports study was a multi-site, single-blinded RCT of a transitional intervention for sentenced adult prisoners returning to the community in Queensland, Australia. Participants were recruited within six weeks of expected release from custody and randomised to receive either usual care or a transitional intervention including personalised service brokerage in the first four weeks post-release. The primary outcome was self-reported health service utilisation at 1, 3 and 6 months post-release. Additional outcomes of interest included self-reported general health, mental health and health-related quality of life during the first six months post-
release; and health service utilisation and reincarceration within two years of release, based on linkage with routinely collected data. The design of the trial is depicted in Figure 1.

Figure 1. Design of the Passports trial

2.2 Study setting

Queensland is Australia’s second largest state, covering an area of more than 1.7 million square kilometres (664,000 square miles). The state capital is in the south-east corner where two-thirds of the population of approximately 4.5 million reside. Indigenous people comprise 3.2% of the Queensland population [34] but 29.7% of adult prisoners [35], and the majority of prisoners in the north of the State. The Passports study recruited participants from August 2008 to July 2010 in the seven Queensland prisons identified by Queensland Corrective Services (QCS) as those from which the majority of sentenced prisoners were released. This included four prisons in
south-east Queensland (three male, one female) and three prisons in north Queensland (two male, one female).

At the time of the study a number of transitional supports were available for prisoners in Queensland, although none had been evaluated. For a small subset of prisoners identified as having serious mental illness and high needs, intensive transitional support was provided both pre- and post-release by the Prison Mental Health Service (PMHS). Those who (a) had served at least 12 months in custody and (b) were sexual/violent offenders or assessed as being at high risk of reoffending, were eligible for the Transitions Program, which was a modular release preparation program involving in-reach by community agencies. The remainder (and the majority) of sentenced prisoners were eligible for the Transitional Support Service (TSS), which consisted of a single consultation with a QCS ‘Transitions Manager’ to prepare a release plan. A small minority, with particularly high needs, were also eligible for the Offender Reintegration Support Service (ORSS), which involved post-release support provided by trained case workers. The Passports intervention was designed to complement rather than duplicate these programs.

2.3 Inclusion and exclusion criteria

To maximise generalisability, eligibility criteria were as inclusive as possible. Inclusion criteria included (1) sentenced adult prisoner expecting to be released (full-time or on parole) from one of the seven recruitment prisons within the next six weeks, (2) judged safe to be approached, and (3) able to provide informed, written consent. Exclusion criteria included (1) on remand (due to uncertainty around release), and (2) having previously participated in the trial (necessitated by the high rate of recidivism in the population). We intentionally over-sampled women to increase the sample size for sex-stratified analyses. To permit identification of and adjustment for sampling bias, we obtained demographic and offending information from QCS
for all sentenced prisoners released from custody in Queensland during the two years of recruitment (N=10,931).

2.4 Recruitment, enrolment and reimbursement

Trained researchers, independent of QCS, obtained a list of all potentially eligible participants for each prison, from the QCS Integrated Offender Management System (IOMS). These lists were updated weekly during recruitment. Individuals identified as potentially eligible were approached by researchers and invited to participate in the study; this included screening for eligibility, explaining the project in plain language and obtaining informed, written consent. Researchers recorded the outcome of each approach (not eligible, eligible [participated or declined], unknown [missed or unavailable]) in a log book.

Participants were reimbursed AU$10 for participating in the baseline interview; consistent with QCS regulations these funds were placed in the prisoner’s trust account. After completion of each follow-up interview participants were mailed an AU$30 money order exchangeable for cash at any post office. Two advantages of this approach to reimbursement were that (a) it created an incentive for participants to update their contact details with the research team, and (b) receipt of the funds could be independently verified with Australia Post.

2.5 Ethical considerations

The Passports study received approval from the University of Queensland’s Behavioural and Social Sciences Ethical Review Committee, the QCS Research Committee and the Queensland Health Human Research Ethics Committee and was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12608000232336). As the study involved a large proportion of Indigenous Australians, advisory groups with significant representation from Indigenous stakeholders were established to ensure that the project proceeded in a culturally appropriate and sensitive manner.
2.6 Randomisation

Baseline data were entered into a secure Access database and at this point participants were randomised 1:1 to intervention or control using random permuted blocks of size four, stratified by Indigenous status (yes/no) and incarceration history (previous incarceration vs. none).

Randomisation occurred within each of the seven recruitment centres, and was therefore also stratified by sex. Baseline interviewers were blind to intervention status.

2.7 Baseline assessment and follow-up interviews

Baseline information included demographic characteristics, living circumstances before prison, social support, general health, mental health, cognitive functioning, substance use before and in prison, transitional program participation and plans and expectations regarding release.

Participants also underwent a brief, non-invasive physical health assessment including measurement of height and weight, girth at waist and hips, and blood pressure, the latter measured on two occasions approximately five minutes apart using a Livingstone automatic blood pressure monitor. In addition, with participant consent, information on blood-borne viral infections and medication usage was extracted from prison medical records. In addition to questions developed for the study, well-validated and culturally appropriate measures were used where available, including the Alcohol Use Disorders Identification Test (AUDIT) [36]; Alcohol, Smoking and Substance Involvement Screening Test (ASSIST) [37]; Fagerström test for nicotine dependence [38]; Indigenous Risk Impact Screen (IRIS) [39]; Kessler Psychological Distress Scale (K10) [40]; Short-Form 36 Health Survey version 2 (SF-36v2) [41]; Patient Activation Measure (PAM) [42]; Hayes Ability Screening Index (HASI) [43]; and Enriched Social Support Inventory (ESSI) [44].

Follow-up interviews occurred by telephone approximately one, three and six months post-release and, although considerably briefer, covered the same domains assessed in the baseline
interview, as well as self-reported criminal activity and contact with health, social and criminal justice services since release. Self-reported utilisation of primary care, mental health services and alcohol and other drug services since release or last interview were each assessed by three questions asking how many times the participant had (a) contacted, (b) used and (c) felt that they had been helped by [service type]. The primary endpoint for analysis purposes was self-reported service utilisation, dichotomised into none versus any.

Those who returned to custody during follow-up were re-interviewed in custody either face-to-face or by telephone, using modified versions of the follow-up survey instruments. Methods of recruitment, measures of key constructs and strategies for maintaining contact with participants post-release were first tested in a pilot study involving 160 prisoners/ex-prisoners in south-east Queensland [19, 45].

2.8 Record linkage

Two years after the last participant was released from custody, the identities of participants were linked with QCS data to identify instances of reincarceration, and the National Death Index (NDI) to determine the nature and timing of any deaths in the cohort. With participant consent, we also obtained data from the Commonwealth Department of Human Services (Medicare and Pharmaceutical Benefits Scheme (PBS)) to measure utilisation of federally subsidised health care and pharmaceuticals since release. Linkage with QCS data was deterministic, based on a unique prisoner number, however there was no shared unique identifier in the NDI and Medicare/PBS data, and thus linkage with these data sets was probabilistic. The probabilistic linkage process included all known aliases for participants, consistent with evidence that this increases the sensitivity of linkage without adversely affecting specificity [46].
2.9 Description of intervention and control conditions

The intervention consisted of the provision of materials at the point of release, plus limited telephone support post-release. Intervention materials and protocols were developed during a year-long consultation process involving government, community and consumer stakeholders. This process and the intervention itself are described in more detail elsewhere [47]. The core of the intervention materials was a passport-sized, vinyl-bound document tailored to each participant, and placed inside an unmarked, midsized backpack. This ‘Health Passport’ included (a) plain-language guidance for meeting practical needs (e.g., income, housing) post-release, (b) a user-friendly summary of the participant’s health status and medication requirements, based on findings from the baseline interview, and (c) a list of free or low-cost health and social services in the community tailored to the participant’s health needs, demographic characteristics and expected location post-release. These materials were placed in the participant’s property to be collected at the point of release. Although it may have been beneficial to provide participants with these materials prior to release, the short timeframe between baseline interview and release made this impractical and to do so may have introduced contamination.

The research team aimed to make telephone contact with participants in the intervention group 7, 14, 21 and 28 days post-release. These semi-structured contacts were designed to assess the participant’s functioning in six domains (physical health, mental health, substance use, social support, housing, employment/income) and incorporated elements of motivational interviewing [48]. During the first intervention call we also explained the nature and purpose of the Health Passport, and encouraged participants to use it to (a) identify relevant services, and (b) assist in communicating their health needs to health practitioners. During each intervention call, if the participant reported experiencing difficulty in any domain, they were encouraged to use the
Health Passport to identify appropriate services. The research team did not contact services on behalf of the participant and, regardless of the number of successful contacts, all intervention calls ceased 28 days after the participant’s expected date of release from custody. Participants were also able to contact the research team to obtain specific service referrals for the first six months post-release, using a dedicated 1800 freecall number, although this was rarely utilised. Participants in the control arm received usual care, which may or may not have included transitional support from QCS. In addition, for ethical reasons, control participants received a letter with their personal property providing a brief summary of their health status, identifying whether their assessment results were below average, average or above average in each domain, and specifying dates for follow-up interviews.

2.10 Retention

Given the highly mobile nature of the population, biased attrition during follow-up was expected and was observed [49]. The state of Queensland is large and includes some very remote areas which are difficult to access by road or telephone, and Indigenous participants in remote areas can be particularly difficult to retain in longitudinal studies [50]. Although selectively recruiting individuals with a greater likelihood of follow-up may have improved retention, it would have compromised representativeness, including selectively excluding Indigenous people. Instead, building on previous longitudinal studies of marginalised populations [19, 50-52], we implemented a range of strategies to minimise attrition including: collecting comprehensive contact information for the participant and any collaterals at baseline; provision of forms and reply-paid envelopes for updating contact details after completion of each interview; routine updating of contact details during any contact with the participant; and provision of a small financial incentive (AU$30) for completing each follow-up interview. In addition, with written consent, we attempted to locate participants through the Queensland
Probation and Parole Service and Centrelink, Australia’s national provider of unemployment benefits. Given the high rate of recidivism among ex-prisoners in Queensland [35] we also routinely checked with QCS to identify participants who had returned to custody. Equally important to minimising attrition were the experienced, highly-trained interviewers who adopted a non-judgemental attitude and actively sought to build rapport with participants over the course of the study. Pilot data [19, 45] indicated that setting any cap on the number of follow-up attempts would reduce our follow-up fraction; therefore no cap was set and in some instances more than 30 contact attempts were made to locate a participant. All contact attempts were logged in a secure Access database to permit examination of the association between contact intensity and retention [49].

2.11 Sample size and power calculations

Power calculations were based on the outcomes of recidivism (given its high face validity and policy relevance) and health service utilisation (as the proximate outcome of the intervention), and the simplest analysis (logistic regression). Assuming a base (control) rate of 30% for re-incarceration and a target effect size of 10% (absolute reduction in rates) for both end-points, approximately 900 releases overall would be required to achieve 80% power with 1% two-sided significance. We expected to achieve 75% follow-up at six months, resulting in the need to recruit at least 1,200 released prisoners. A nett sample of 900 releases would also enable the detection of a difference of 61.5% (intervention) versus 50.0% (control) in health service utilisation (80% power, 1% significance).

2.12 Data analysis

To assess the representativeness of the sample, we first compared the characteristics of participants with those of all released prisoners who did not participate, using routinely collected data on all separations from Queensland prisons during the period of recruitment.
Next, we compared the baseline characteristics of participants in the intervention and control groups using chi-square tests for categorical variables and t-tests for continuous variables. Our primary analysis will be done on an intention-to-treat (ITT) basis, with a p-value of <0.05 considered statistically significant. Although one eligibility criterion was expected release from custody within six weeks of baseline interview, some participants were not released during this time due to unexpected denial of parole or being remanded (held in custody) on new charges. This information typically emerged after numerous failed contact attempts, or in some cases only through subsequent linkage with QCS data. Those who were not in fact released within six weeks of baseline were deemed ineligible. The sample for ITT analyses will be those who were in fact released within six weeks of baseline interview.

Outcome data from follow-up interviews will be dichotomised and between-group differences examined using logistic regression. Time-to-event outcomes (QCS, NDI, Medicare and PBS data) will be examined using proportional hazards regression with intervention group as a covariate.

Examination of follow-up data revealed that participants in the control group were significantly more likely than those who received all four intervention telephone calls to be lost to follow-up (OR=3.42, 95%CI 2.24-5.24), probably because the intervention itself was protective against attrition [49]. One important consequence of this selective, biased attrition is that it would be expected to attenuate the observed intervention effect in ITT analyses, because more unwell, disadvantaged and marginalised participants would tend to be more prevalent in the intervention group at follow-up, even if the groups were balanced at baseline. Although this design limitation may have been predictable, it was unavoidable. Thus, in addition to ITT analyses we will undertake the following a priori analyses:

1. per-protocol analysis, comparing participants in the control group with those who received at least one intervention telephone call in the first four weeks post-release;
2. Sensitivity analyses (a) excluding ‘higher needs’ participants: those with a history of prior imprisonment, those identifying as Indigenous, and those with a lifetime history of injecting drug use; and (b) adjusting for baseline predictors of selective, biased attrition, using multiple imputation [53].

Our analysis plan is described in more detail as a supplementary document attached to the online version of this manuscript at doi####.

3.1 Results

Baseline interviews were conducted between August 2008 and July 2010 with follow-up completed in March 2011. Overall we assessed 1,976 participants for eligibility, of whom 1,665 were eligible and 1,325 enrolled in the study, giving a recruitment fraction of 80.0%. No potential participant was excluded due to inability to provide informed consent and very few were judged unsafe to approach for interview. The majority of participants (92.2%) were recruited from prisons in the more populous south-east corner of the State. Among those deemed eligible, the main reasons for non-participation were a lack of interest in participating in research, and a desire not to be contacted after release from custody.

With the exception of intentionally over-sampling women, the Passports sample is broadly representative of adults being released from prison in Queensland. Table 1 compares the characteristics of participants with those of all other releases during the period of baseline recruitment, using routinely collected data provided by QCS. Compared with those not recruited, Passports participants were significantly less likely to be male or Indigenous, more likely to have been in prison previously, and less likely to be subject to a supervision order (usually parole) post-release.
Table 1. Characteristics of participants and other persons released from custody during the
period of recruitment.

<table>
<thead>
<tr>
<th></th>
<th>Passports participants (%)</th>
<th>Other releases (%)</th>
<th>p value a</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N=1,325)</td>
<td>(N=9,681)</td>
<td></td>
</tr>
<tr>
<td>Mean age in years (SD)</td>
<td>32.7 (11.1)</td>
<td>32.4 (10.4)</td>
<td>0.22</td>
</tr>
<tr>
<td>Male</td>
<td>79.0</td>
<td>89.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Indigenous</td>
<td>24.2</td>
<td>30.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Married/de facto</td>
<td>31.8</td>
<td>30.6</td>
<td>0.36</td>
</tr>
<tr>
<td>Median days in prison (IQR)</td>
<td>157 (88-351)</td>
<td>114 (53-288)</td>
<td>0.23</td>
</tr>
<tr>
<td>Prior prison admission</td>
<td>66.7</td>
<td>62.2</td>
<td>0.001</td>
</tr>
<tr>
<td>Post-release supervision</td>
<td>60.1</td>
<td>71.0</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

a independent samples t-test for continuous variables, chi-square test for categorical variables

Among those released within six weeks of baseline (N=1,182) 85% completed at least one
follow-up interview (Figure 2). Including those re-interviewed in custody, follow-up fractions at
each follow-up interview were 69% (FU1), 68% (FU2) and 72% (FU3). The last participant was
expected to be released from custody in August 2010 but due to unexpected delays was in fact
released in November 2011. Two-year recidivism data from QCS and health service utilisation
data from Medicare will be obtained in early 2014.
Figure 2. CONSORT diagram

Table 2 compares the baseline characteristics of participants in the intervention and control arms. The two groups were similar with respect to demographic characteristics, prison history and health status.
Table 2. Baseline characteristics of Passports participants, according to intervention arm

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Intervention (%) (n=665)</th>
<th>Control (%) (n=660)</th>
<th>p value $^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age in years (SD)</td>
<td>1,325</td>
<td>32.7 (11.3)</td>
<td>32.8 (10.9)</td>
<td>0.86</td>
</tr>
<tr>
<td>Male</td>
<td>1,325</td>
<td>78.5</td>
<td>79.2</td>
<td>0.74</td>
</tr>
<tr>
<td>Indigenous</td>
<td>1,325</td>
<td>25.4</td>
<td>25.6</td>
<td>0.94</td>
</tr>
<tr>
<td>Married/de facto</td>
<td>1,325</td>
<td>34.9</td>
<td>34.2</td>
<td>0.76</td>
</tr>
<tr>
<td>Median days in prison (SD)</td>
<td>1,325</td>
<td>309.8 (549.7)</td>
<td>321.1 (567.0)</td>
<td>0.71</td>
</tr>
<tr>
<td>Prior prison admission</td>
<td>1,325</td>
<td>67.4</td>
<td>67.0</td>
<td>0.88</td>
</tr>
<tr>
<td>Most serious offence</td>
<td>1,325</td>
<td>54.4</td>
<td>53.2</td>
<td>0.65</td>
</tr>
<tr>
<td>violent/sexual</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unstable accommodation before prison</td>
<td>1,320</td>
<td>17.5</td>
<td>16.0</td>
<td>0.46</td>
</tr>
<tr>
<td>&lt;10 years of schooling</td>
<td>1,325</td>
<td>41.4</td>
<td>45.3</td>
<td>0.15</td>
</tr>
<tr>
<td>Unemployed before prison</td>
<td>1,325</td>
<td>52.6</td>
<td>53.5</td>
<td>0.76</td>
</tr>
<tr>
<td>1 or more contact visits in the last 4 weeks</td>
<td>1,325</td>
<td>47.5</td>
<td>45.0</td>
<td>0.36</td>
</tr>
<tr>
<td>SF-36 PCS &lt;50</td>
<td>1,305</td>
<td>23.7</td>
<td>21.3</td>
<td>0.29</td>
</tr>
<tr>
<td>SF-36 MCS &lt;50</td>
<td>1,305</td>
<td>56.0</td>
<td>56.9</td>
<td>0.73</td>
</tr>
<tr>
<td>Hepatitis C antibody positive from medical records</td>
<td>1,246</td>
<td>17.8</td>
<td>14.4</td>
<td>0.10</td>
</tr>
<tr>
<td>Taking 1 or more medications according to medical records</td>
<td>1,231</td>
<td>48.3</td>
<td>43.6</td>
<td>0.09</td>
</tr>
<tr>
<td>High/very high K10</td>
<td>1,320</td>
<td>27.8</td>
<td>24.2</td>
<td>0.13</td>
</tr>
<tr>
<td>Lifetime diagnosis of mental illness</td>
<td>1,324</td>
<td>45.3</td>
<td>41.6</td>
<td>0.18</td>
</tr>
<tr>
<td>Lifetime IDU history</td>
<td>1,322</td>
<td>57.2</td>
<td>54.3</td>
<td>0.30</td>
</tr>
<tr>
<td>ASSIST cannabis risk</td>
<td>1,324</td>
<td>47.1</td>
<td>45.6</td>
<td>0.58</td>
</tr>
<tr>
<td>ASSIST heroin risk</td>
<td>1,322</td>
<td>17.2</td>
<td>17.9</td>
<td>0.73</td>
</tr>
<tr>
<td>ASSIST methamphetamine risk</td>
<td>1,323</td>
<td>38.6</td>
<td>37.9</td>
<td>0.82</td>
</tr>
<tr>
<td>AUDIT alcohol risk</td>
<td>1,296</td>
<td>61.6</td>
<td>61.4</td>
<td>0.93</td>
</tr>
<tr>
<td>Current tobacco smoker</td>
<td>1,324</td>
<td>80.1</td>
<td>76.4</td>
<td>0.10</td>
</tr>
<tr>
<td>Accessed TSS</td>
<td>1,324</td>
<td>22.3</td>
<td>25.6</td>
<td>0.16</td>
</tr>
<tr>
<td>Accessed Transitions Program</td>
<td>1,324</td>
<td>16.7</td>
<td>15.9</td>
<td>0.69</td>
</tr>
<tr>
<td>Accessed ORSS</td>
<td>1,324</td>
<td>8.3</td>
<td>7.7</td>
<td>0.71</td>
</tr>
<tr>
<td>Accessed transitional support from PMHS</td>
<td>1,324</td>
<td>6.9</td>
<td>5.2</td>
<td>0.18</td>
</tr>
<tr>
<td>Supervision post-release</td>
<td>1,324</td>
<td>59.2</td>
<td>61.1</td>
<td>0.49</td>
</tr>
</tbody>
</table>

$^a$ independent samples t-test for continuous variables, chi-square test for categorical variables

4. Discussion

Prisoners are a highly marginalised group characterised by complex and often under-treated health problems. Health often improves in custody, however post-release outcomes are
typically poor with elevated rates of morbidity, mortality and recidivism. These poor outcomes have proven to be intractable: efforts to improve health outcomes for ex-prisoners are in their infancy and few programs have been rigorously evaluated [27, 54]. Not all have proven effective. Key features of successful interventions include the provision of support after release from custody [55] and a focus on personalised ‘service brokerage’ [54], however it remains unclear to what extent the largely US-centric evidence, based on studies targeting high-needs prisoners, can be applied in other settings or with the wider prisoner population. To have a measurable impact on health outcomes for the ex-prisoner population as a whole, evidence-based population-wide interventions are required.

In this paper we have described the development and design of an RCT to evaluate such an intervention, with a large and largely representative sample of adult ex-prisoners in Queensland, Australia. To the best of our knowledge, this is the first study of its kind internationally. In designing and implementing the Passports study we encountered a number of challenges, and our responses to these may prove instructive to future researchers.

RCTs in this area are often difficult to implement. They require working with correctional authorities that often have competing priorities and, as a policy audience, may not fully appreciate the importance of subtleties in methodology. Although negotiating protocols with QCS was challenging, we managed to maintain a high degree of methodological rigour while operating within a ‘real-world’ context. Few studies of the re-entry process have achieved this level of rigour [27, 54]. Some of the challenges surrounding the implementation of the Passports study were alleviated by the pre-existing links between our research team and QCS, as well as experience working in related research areas including intellectual disability, alcohol and other drugs and Indigenous health.
A major concern in studies of this nature, especially in marginalised populations, is loss to follow-up. We considered restricting recruitment to those easier to retain but rejected this option for both methodological and ethical reasons. As well as reducing the generalisability of findings, excluding those most marginalised would perpetuate their disadvantage and mirror the tendency for community services to place some highly vulnerable individuals in the ‘too hard basket’. Instead, based on a thorough review of the literature, consultation with QCS and other stakeholders and our own extensive research experience, we implemented a range of strategies to maximise retention. We also considered providing mobile phones to particularly vulnerable participants who were unable to provide any contact details at baseline, however this was both financially prohibitive and considered unlikely to substantially increase follow-up because (a) there was a significant risk that these phones would be lost, stolen or traded, (b) we found that many participants who had mobile phones were uncontactable on these numbers, as they had run out of credit, and (c) many of our more vulnerable participants expected to return to rural or remote areas, without mobile phone coverage. Although participant attrition is a limitation intrinsic to prospective studies, the focus on maximising retention while maintaining a high level of ethical rigour is a key strength of this study. We would encourage others to share their experiences and strategies for following up marginalised populations, so that ethically sound strategies for retaining marginalised populations in longitudinal studies can be developed. In parallel with this, we encourage other researchers to closely examine the nature of attrition in their cohorts, including testing for the possibility of selective biased attrition in trials, and to consider novel approaches to analysing longitudinal data to properly account for biased attrition. Although incomplete follow-up of the cohort was inevitable, access through record linkage to routinely collected data for all participants at baseline and two years post-release will assist us in identifying and adjusting for biased attrition.
The Passports study has demonstrated the usefulness of combining record linkage with longitudinal research to provide a comprehensive understanding of an often difficult to study population. Further multi-sectoral record linkage, perhaps in parallel with longitudinal work, is important to build on the findings of this and similar studies [56], in both adult ex-prisoners and similar at-risk groups, such as young people in the juvenile justice system [57]. We have recently been funded to expand our study of this cohort through detailed examination of prison health records, expanded linkage to other health records, and qualitative interviews.

The development and design of this study has identified several areas that require further development and research. The high proportion of Indigenous persons participating in our study suggests that the challenges of working with a culturally diverse population can be overcome, however attrition among Indigenous research participants remains a perennial challenge [50].

**Conclusion**

In an area characterised by a dearth of high-quality research, we have demonstrated that it is possible to conduct an RCT evaluating a transitional intervention for prisoners and ex-prisoners. To the best of our knowledge, the Passports study is the first RCT of a service brokerage intervention for ex-prisoners anywhere in the world. The unprecedented size of the sample will permit more sophisticated, multivariate analysis of pathways to post-release outcomes than has heretofore been possible. Our success has been based on a commitment to collaboration with key stakeholders, engagement with consumers and a focus on sustainability, in terms of complementing existing (pre-release) interventions, and supporting existing (post-release) services, through tailored service brokerage, and establishing sustainable service relationships and service access for our participants.
COMPETING INTERESTS

None.

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Author/s:
Kinner, SA; Lennox, N; Williams, GM; Carroll, M; Quinn, B; Boyle, FM; Alati, R

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