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Service brokerage for improving health outcomes in ex-prisoners (Protocol)

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[Intervention Protocol]

Service brokerage for improving health outcomes in ex-prisoners

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

This review aims to assess the effectiveness of interventions including a service brokerage component for people transitioning out of prison, on health outcomes post-release.

BACKGROUND

Description of the condition

More than 10 million adults are currently incarcerated around the world with more than one in five of these held in jails or prisons (hereafter collectively described as 'prisons') in the US. Although the US has the highest per capita incarceration rate in the world, prison populations in most countries are increasing (Walmsley 2011) and due to the preponderance of short sentences, the number of people moving in and out of prison is considerably larger, with more than 30 million people estimated to move through prison systems worldwide each year (UNODC 2008). High rates of recidivism (Gendreau 1996) and mortality (Binswanger 2007; Kariminia 2007; Merrall 2010) post-release indicate that integration of ex-prisoners into the community is often unsuccessful.

Ex-prisoners are characterised by chronic social disadvantage, poor physical and mental health, and high rates of substance misuse - a continuation of problems experienced prior to imprisonment (Kinner 2006). In many countries the prevalence of infectious diseases including human immunodeficiency virus (HIV), tuberculosis, hepatitis C and sexually transmitted infection (STI) are greatly elevated among prisoners (Butler 2011; David 2003; Hammett 2002; Jürgens 2009; Macalino 2004; Seal 2003); as is the prevalence of mental illness and alcohol and other drug problems, particularly injecting drug use (Fazel 2006; Fazel 2002). Consistent with this, ex-prisoners die at rates that are orders of magnitude higher than their community peers, especially in the first few weeks after release, and often due to drug overdose or suicide (Kariminia 2007; Kinner 2011; Merrall 2010). Time in prison may compound existing problems through the accumulation of debt, loss of housing, isolation from family and friends, and time without ac-

cumulation of work experience and referees (Baldry 2003; Visher 2003). Many prisoners return to the community ill-equipped to deal with their often complex health and psychosocial needs. Although the majority of the world's prisoners are in developing countries, most studies of ex-prisoners take place in developed countries; it remains unclear to what extent the existing evidence can be extrapolated to resource-poor settings (Kinner 2012).

There is growing evidence to suggest that while poor health and psychosocial outcomes for ex-prisoners represent a significant public health issue in their own right, they are also associated with re-offending (Dowden 2002; Hobbs 2006). This relationship is poorly understood, and it is unknown whether a causal relationship between health and justice outcomes exists (i.e. poor health leads to re-offending), or the circumstances associated with poor health overlap with those associated with re-offending (i.e. intermediate mechanisms lead to both poor health and re-offending). In either case, the mechanisms underpinning recidivism and poor health (such as homelessness, unemployment, illicit drug use, poor social support, under-utilisation of healthcare) are important to understanding post-release outcomes. Given the well-documented links between poor health, health risk behaviours and offending, improving health outcomes for ex-prisoners is important from both public health and criminal justice perspectives.

Description of the intervention

Transitional interventions for prisoners usually fall into one of three categories: (1) interventions delivered pre-release, (2) interventions delivered post-release or (3) interventions that involve both pre-release and post-release components. While some interventions have an explicit focus on health or health-related behaviours, others are designed primarily to reduce re-offending. For example, Project Greenlight (Wilson 2006) was a quasi-randomised trial of an intervention delivered to a sample of prisoners in New York State, US, in the eight weeks before their release from custody. The intervention included a cognitive skills component to address antisocial behaviours and thinking; relapse prevention and practical living skills; preparation for accessing community services; identification of relevant community organisations and preparation of a detailed release plan. Although the primary aim of the intervention was to reduce recidivism, it included a focus on substance use, living skills and community engagement, and measured a range of health and psychosocial outcomes including substance use, family relationships and service access. Similarly, the multi-site Serious and Violent Offender Reentry Initiative (SVORI) was designed to reduce recidivism but also sought to improve employment, housing and health outcomes through improved access to services (Lattimore 2009). In this intervention, community agencies were funded to provide needs-based and coordinated support, starting prior to release and continuing for a period of time post-release. By contrast, Project START, another multi-site transitional intervention in the US, was designed primarily to reduce sexual risk behaviour in young men being released from prison, although recidivism was measured as a secondary outcome (Wolitski 2006). This intervention incorporated prevention case management, motivational interviewing and harm reduction, and comprised two pre-release and four post-release sessions. One common feature of these interventions is that they sought to improve outcomes for ex-prisoners through, among other things, facilitating access to services in the community post-release. It is this sort of transitional intervention, hereafter described as 'service brokerage', which is the focus of this review.

How the intervention might work

Although many transitional interventions aim to reduce recidivism, they may include a focus on health or health risk behaviours, or both, as hypothesised mechanisms of change, based on the assumption that reduced re-offending can be achieved through improved health, reduced health risk behaviour and better psychosocial adjustment. Thus, many transitional interventions aim to maintain or improve health (e.g. reduced incidence of HIV infection, improved mental health), reduce risk behaviour (e.g. injecting drug use, unsafe sex), promote social integration (e.g. employment, sustained relationships) or a combination of these. Rather than targeting these outcomes directly, service brokerage interventions aim to achieve these outcomes through improved access to (and utilisation of) relevant health and community services, after release from custody. An advantage of such interventions is that they do not duplicate existing community resources or, compared with dedicated services for 'ex-prisoners', risk perpetuating stigma by framing service recipients as 'offenders' rather than members of the community.

Why it is important to do this review

Internationally, although a number of interventions designed to improve health outcomes for ex-prisoners have been the subject of evaluation (e.g. Callan 2001; Inciardi 2004; Knight 1999; Prendergast 2004), the evidence base remains weak and these evaluations have never been considered together as a body of evidence. This limited evidence base contrasts with a large literature examining interventions designed to reduce recidivism in ex-prisoners (the 'what works' literature), which has been the subject of several meta-analyses (e.g. Bonta 1998; Dowden 2002; Gendreau 1996). Currently, given the limited evidence base, it is difficult to state with confidence whether, and importantly how, health outcomes for ex-prisoners can be improved. Randomised controlled trials (RCTs) are rare, and many studies are compromised by the use of small convenience samples, exclusive reliance on self-report or administrative data and poor generalisability. Other evaluation studies, particularly of therapeutic communities, often suffer from selection bias and a consequent lack of representativeness. In ad-

dition to these methodological considerations, generalisation of study findings to an international context is problematic, due to important differences in correctional environments, policies and practices, the quality and accessibility of community health services, patterns of substance use and the distribution of disease. Given growing evidence that some widely adopted interventions can actually produce harmful outcomes for ex-prisoners (Petrosino 2002; Wilson 2006), it is insufficient to assume that well-meaning interventions will have either no effect, or a positive effect. Researchers and practitioners alike must "first do no harm" (Wilson 2007).

Given that the literature on improving health outcomes for ex-prisoners has never before been subjected to systematic review, it is also unclear what knowledge gaps exist, and thus how researchers can maximise their impact by prioritising and targeting future research. Critical review of the literature from a methodological perspective will also arm research consumers with appropriate caveats, as they consider the evidence for 'what works' to improve the health of ex-prisoners.

Finally, although a number of studies have included comparisons or stratified analyses by gender, age, minority group status, or a combination of these, these differences have rarely been highlighted by the authors, and subgroup differences have never been considered across studies or contexts. This is a significant omission, given evidence that these groups may have unique strengths, needs and post-release experiences.

This review will address the issues highlighted above by systematically reviewing the evidence for interventions that target people transitioning out of prison and include a service brokerage component. Although the extant literature includes many studies and a number of meta-analyses of interventions to reduce recidivism, this review will address a major research gap by identifying health as the primary outcome measure. To ensure that the review considers the impact of service brokerage interventions on justice outcomes, recidivism will be included as a secondary outcome.

OBJECTIVES

This review aims to assess the effectiveness of interventions including a service brokerage component for people transitioning out of prison, on health outcomes post-release.

METHODS

Criteria for considering studies for this review

Types of studies

We will include RCTs, cluster RCTs, quasi-RCTs, controlled before-and-after studies (where intervention and outcome measurements are contemporaneous) and interrupted time series studies. Interrupted time series must have a clearly identifiable time point at which the intervention occurred and must include measurements for at least three time points before and after the intervention. Studies where groups are allocated must have at least two groups in each arm of the study. Our reasons for including non-RCT designs are that (a) ethical considerations sometimes necessitate other study designs and (b) interventions in this area are usually delivered by mandated service providers rather than researchers, such that the evaluation design must align with service provision requirements. Process evaluations associated with the included studies (including qualitative data) will be included to provide context for the findings (Popay 2006).

Types of participants

Participants will be adult and juvenile ex-prisoners. For the purposes of this review, ex-prisoners are defined as people who have spent a period of time held against their will in a juvenile or adult prison (or jail) (including pre-trial detention) and who have been released from a juvenile or adult prison (or jail) into the community, without any limits being ascribed to length of time served in custody. Individuals held against their will in psychiatric facilities or other primarily therapeutic contexts will be excluded from this definition. People released into hospitals, including psychiatric hospitals, will also be excluded from this definition. Individuals held against their will in other punitive environments, such as the 06 'compulsory drug rehabilitation' centres in Vietnam (Jürgens 2010) will be included if suitable studies are found.

There will be no limits on geographic location; this review will consider international studies, including studies from developing countries, if available.

Types of interventions

Included interventions will be those that include a component designed to facilitate access to or utilisation of health or psychosocial services (or both) in the community, including, for example, housing or employment services. Examples of eligible interventions include (a) providing prisoners or ex-prisoners with written information about community-based services, (b) 'in-reach' whereby community services visit prisons and engage with prisoners prior to release, and (c) 'case management' whereby a worker in a prison or community setting assists a prisoner/ex-prisoner to access community services by making appointments on their behalf or accompanying them to such services. Interventions may have multiple components, including direct service provision, but must include a service brokerage component. Interventions may include direct or indirect financial incentives or subsidies to increase the affordability of services, but interventions with no such

incentive or subsidy will also be included. Interventions delivered in prison, those delivered post-release, and those with both pre-release and post-release components will be included.

The control/comparator intervention is 'usual care', which may vary between studies. Heterogeneity of the comparator groups will be considered during the review. There will be no restrictions on dose, frequency, intensity or duration of the intervention, although these variables will be considered in specific comparisons.

Types of outcome measures

The focus of this review will be health outcomes so, to be included, studies must report on one or more health-related outcomes, even if these are not the primary focus of the study. Specifically, our primary outcome measures are substance use (a key predictor of both poor health outcomes and recidivism in this population) and health-related quality of life. Secondary outcomes will include health, health service utilisation and recidivism. Qualitative data obtained from process evaluations associated with the included studies and information on cost/resource requirements of the intervention will be collected to provide context for the findings.

For the purposes of this review, we adopt the World Health Organization (WHO) definition of health: "*...a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*" (WHO 1948). With this definition in mind, our secondary health outcomes fall into three broad categories: physical health, mental health and health risk behaviours. To explore the links between health and offending behaviour, we include recidivism as a secondary outcome.

Although we anticipate considerable heterogeneity in outcome measures, under each of the sub-categories below we will select the most frequently reported outcome measure to represent that outcome sub-category in data synthesis. Where the same underlying construct is measured using multiple measures (e.g. health-related quality of life measured by the short form-36 (SF-36) and Symptom Checklist-90 (SCL-90)), we will treat these measures as comparable for the purposes of taking a median effect size.

Where one study provides data on multiple outcomes, each outcome will be considered in the appropriate analysis. Where outcomes are measured at multiple time points, the time point that is measured immediately post-intervention will be the primary measure since this will be most commonly measured in other studies and therefore expected to be the most comparable. Subsequent time points will be considered in assessing the sustainability of interventions. We will consider time points during or within three months of cessation of the intervention to be short-term; time points four to 12 months post-intervention will be considered medium-term, and time points > 12 months' post-intervention will be considered long-term.

Primary outcomes

1. Health-related quality of life (as measured by self-report instruments such as the SF-36, SCL-90, General Health Questionnaire (GHQ)).

2. Substance use (as measured by self-report instruments such as the Opiate Treatment Index, AUDIT or WHO ASSIST; or by objective measures such as urinalysis).

Secondary outcomes

1. Health service utilisation: initiation, engagement and retention (e.g. incidence of vaccination; count of people or occasions of service utilisation, by service type):
   i) medication adherence.

2. Physical health. Important sub-categories and examples of specific outcomes include:
   i) chronic physical health conditions (e.g. incidence of HIV, hepatitis C, STIs; diabetes; cardiovascular disease; cancer);
   ii) acute physical health conditions (e.g. incidence of acute respiratory infection, non-fatal drug overdose, injury);
   iii) mortality (all-cause, drug-related, suicide).

3. Mental health. Important sub-categories and examples of specific outcomes include:
   i) anxiety disorders (e.g. post-traumatic stress disorder (PTSD), generalised anxiety disorder) and mood disorders (e.g. depression, bipolar disorder);
   ii) substance disorders (abuse, dependence; by drug type);
   iii) psychotic disorders (e.g. drug-induced psychosis).

4. Sexual risk behaviour (e.g. unprotected sex, multiple sex partners).

5. Recidivism (measured as re-offending, re-arrest, re-incarceration within a specified time period, or a combination of these; by self-report or official records).

6. Any unexpected adverse outcome.

Search methods for identification of studies

In order to minimise publication bias, we will attempt to identify both published and unpublished studies, with no language or date restrictions. If we identify articles written in a language other than English we will attempt to obtain full translations. These will be stored in the awaiting assessment section of the review until a translation is obtained. We will also seek to minimise discipline bias by searching databases in the fields of health, social science and criminology.

Electronic searches

We will search the following electronic databases:

- Cochrane Central Register of Controlled Trials (CENTRAL);
- International Initiative for Impact Evaluation (3ie) database;

- British Nursing Index;
- CINAHL;
- CINCH (Australian Institute of Criminology database);
- Criminal Justice Abstracts;
- Dissertation Abstracts;
- EMBASE;
- EPPI-Centre BiblioMap and TRoPHI;
- Health Management Information Consortium (HMIC) Database;
- MEDLINE and MEDLINE In-Process;
- National Criminal Justice Reference Service (NCJRS) abstracts [US Department of Justice];
- Open System for Information on Grey Literature in Europe (OpenGrey);
- ProQuest Social Science Abstracts;
- PsycINFO;
- Sage Full Text collections (Criminology, Sociology);
- Social Services Abstracts;
- Sociological Abstracts;
- SCOPUS;
- Web of Science Social Sciences Citation Index (SSCI) and Science Citation Index (SCI);
- World Health Organization WHOLIS database;
- Many publishers (e.g. Wiley) now have search functions on their websites.

We will also search the Cochrane Public Health Group (CPHG) Specialised Register and the Effective Practice and Organisation of Care (EPOC) Group Specialised Register, and the Campbell Collaboration Social, Psychological, Educational & Criminological Trials Register (C2-SPECTR) bibliography for studies published in 2003 or earlier.

For all electronic searches, the following outline of a search strategy for PubMed will be tailored for each database. Given that relatively few studies have examined health outcomes in ex-prisoners, that interventions may be intended primarily to reduce recidivism (rather than improve health), and that there is no consensus in the literature regarding appropriate terminology to describe service brokerage interventions for this population, the search will not be filtered by intervention terms. Similarly, given that some studies may report health outcomes only incidentally, the search will initially identify studies based on health *or* recidivism outcomes, although studies that do not report at least one health-related outcome will subsequently be excluded.

PubMed population terms

1. "*prison*"
2. "*offend*"
3. "remand*"
4. "*detain*"
5. "*criminal*"
6. "*convict*"
7. "*felon*"
8. "(pre- OR under-) trial"
9. "jail"
10. "gaol"
11. "detention"
12. "correction*"
13. "sentence*"
14. "probation*"
15. "parole*"
16. "re-entry OR reentry"
17. "post-release"
18. "transition*"
19. "supervis*"
20. or/1-19

PubMed health and recidivism outcome terms

21. "health"
22. "physical health"
23. "general health"
24. "mental health"
25. "illness"
26. "disorder"
27. "well-being"
28. "quality of life"
29. "[drug OR alcohol OR substance] AND [use OR abuse OR misuse OR dependence]"
30. "addict*"
31. "inject*"
32. "overdose"
33. "[unsafe OR risky OR unprotected] AND [sex OR intercourse]"
34. "HIV"
35. "AIDS"
36. "[STI OR STD]"
37. "[sexually transmitted] AND [illness OR infection OR disease]"
38. "service AND [contact OR utilisation OR utilization]"
39. "contact with services"
40. "doctor"
41. "primary care"
42. "general practitioner"
43. "treatment"
44. "recidiv*"
45. "reoffend*"
46. "reincarcerat*"
47. "*arrest*"
48. "*convict*"
49. "violat*"
50. "revoke*"
51. "revocation"
52. "breach"

53. or/21-52

PubMed design terms (filter)

54. "randomised controlled trial"
55. "controlled clinical trial"
56. "controlled trial"
57. "clinical trial"
58. "random*"[Title/Abstract]
59. "controlled"[Title]
60. "control* AND (clinical OR group* OR trial* OR study OR studies OR design* or method*)"[Title/Abstract]
61. "control group*"
62. "single-blind method"
63. "double-blind method"
64. "RCT"
65. "*intervention*"[Title/Abstract]
66. "evaluation"[Title/Abstract]
67. "pre-test OR pretest OR post-test OR posttest"[Title/Abstract]
68. "control* AND (before OR after)"[Title/Abstract]
69. "quasi-experiment* OR quasi-random* OR quasi-control*"[Title\Abstract]
70. "(quasi* OR experimental) AND (method* or study OR studies OR trial OR design*)"[Title/Abstract]
71. "time series"
72. "(multicent* OR multi-cent*)" AND (stud* OR design OR trial)"[Title/Abstract]
73. "(case control OR case-control) AND (design* or stud* or trial*)"[Title/Abstract]
74. "follow up OR follow-up"
75. "(crossover OR cross-over) AND (design* OR stud* OR trial*)"[Title/Abstract]
76. "pilot AND (project* or stud*)"[Title/Abstract]
77. "comparative stud*"[Title/Abstract]
78. "comparison group"
79. "intervention stud*"
80. "program AND (effect* OR evaluat*)"[Title/Abstract]
81. "evaluation"[Title[/Abstract]
82. or/54-81

Searching other resources

We will attempt to identify grey literature using keyword searches in Google and Google Scholar, searches of government and non-government websites (e.g. WHO, United Nations Office on Drugs and Crime (UNODC), and Correctional Service of Canada), and online clearing houses such as the Lloyd Society's Justice Health Library (thelloydsociety.org/work/current_projects/jhl/) and the Offender Health section of the Australian Indigenous Health Clearinghouse (www.healthinfonet.ecu.edu.au/population-groups/offender-health).

We will search the international clinical trials registry platform (ICTRP) and the ANZ Clinical Trials Registry (ANZCTR) to identify ongoing or planned studies. Potential studies will also be identified through consultation with Review Advisory Group (RAG) members.

We will also handsearch the reference lists of included studies and other relevant papers and handsearch key journals for the past 12 months to identify studies that may not yet be indexed in databases.

Data collection and analysis

Selection of studies

All potential studies identified from the searches will be downloaded into reference management software and duplicates removed. The titles and abstracts of identified studies will be screened independently by two review authors to determine eligibility according to the inclusion and exclusion criteria listed above. Full copies of all eligible papers will be retrieved. When a title or abstract cannot be rejected with certainty, the full text of the article will be obtained for further evaluation. If there is disagreement between the two review authors at any stage, this will be resolved by discussion, and if necessary, consultation with a third review author. Multiple reports related to the same study will be linked together. Studies that appear to be relevant but do not meet the inclusion criteria will be listed in the table of excluded studies with reasons given for exclusion.

Data extraction and management

Data will be extracted independently by two review authors using a data extraction form based on the template provided by the Cochrane Public Health Group. Any disagreements will be resolved by discussion and, if necessary, consultation with a third review author. Study information to be extracted, where available, will include:

- year of publication;
- country of origin;
- study design;
- sample size;
- recruitment details;
- sample description (i.e. gender, age, ethnicity);
- theoretical basis for intervention;
- intervention type (i.e. pre-release only, throughcare, or post-release only; manualised or tailored);
- delivery of intervention;
- direct resource/cost requirements of the intervention;
- duration of intervention and follow-up;
- intensity of intervention;
- outcomes (including scales/measures used, time points and results);

- whether or not adverse outcomes were measured and reported;
- potential moderators/confounders of study outcomes and any adjustment processes used;
- population characteristics in terms of the factors outlined by PROGRESS-Plus (Place, Race, Occupation, Gender, Religion, Education, SES [socioeconomic status], Social capital PLUS disability, sexual orientation), as well as analyses of outcomes by any of these factors;
- process evaluation measures;
- presence and extent of any bias in attrition.

Data from multiple reports of the same study will be collated into one data extraction form pertaining to the study. Data will be entered into Review Manager (RevMan 2011) software and checked for accuracy.

Assessment of risk of bias in included studies

Risk of bias of included studies, with the exception of interrupted time series, will be assessed using the Cochrane EPOC (Effective Practice and Organisation of Care) 'Risk of bias' tool for studies with a separate control group. This includes the assessment of sequence generation; allocation concealment; confounding; incomplete outcome data; blinding of participants, personnel and outcome assessors; contamination; selective outcome reporting and other sources of bias.

Risk of bias for interrupted time series designs will be assessed using the Cochrane EPOC 'Risk of bias' tool for such designs. This includes the assessment of whether the intervention was independent of other changes, unlikely to affect data collection; and whether the shape of the intervention effect was pre-specified. Also included is the assessment of blinding of participants, personnel and outcome assessors; incomplete outcome data; selective outcome reporting and other sources of bias.

Risk of bias will be assessed independently by two review authors and any discrepancies will be resolved by discussion or consultation with a third review author if necessary.

Overall risk of bias

For all included studies, the overall risk of bias will be summarised at the outcome level within each study. This is the recommended level at which to summarise 'Risk of bias' assessments, since some risks of bias may be different for different outcomes within the same study (Higgins 2011). This summary assessment will take into account domains that are at the study level, such as adequate sequence generation, as well as those at the outcome level, such as blinding. Judgements about overall risk of bias will also take into account the likely magnitude and direction of bias and whether it is likely to impact on the findings of the study. The overall risk of bias will then be summarised at the outcome level across studies reporting similar outcomes taking into account the proportion of information from studies at low, high and unclear risk of bias. The impact of including studies at high risk of bias will be explored using a sensitivity analysis. For the purposes of this analysis, studies at 'high risk' of bias will be those assessed as having a high risk of bias with respect to sequence generation or confounding, or both.

Measures of treatment effect

Dichotomous outcomes will be reported as mean risk ratios (RR) with 95% confidence intervals (CI). Continuous outcomes will be presented as the difference in mean values with 95% CIs. If studies use different measures for the same outcome, we will use standardised mean difference (SMD) as a relative measure for continuous outcomes, where appropriate. No re-calculations of means will be performed; however, if standard deviations are not reported, they will be derived from the reported standard error of the mean, or 95% CIs using the equations provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Ordinal outcome measures may be analysed as either dichotomous or continuous data and reported in the corresponding format described above. Where possible, based on reporting and analysis in primary studies, effect sizes derived from interrupted time series designs will be reported as the change in the level of outcome at the first measurement point after the introduction of the intervention or the change in the slopes of the regression lines (post-intervention minus pre-intervention slope), or both (Ramsay 2003). Either of these effect sizes will be considered as evidence of intervention effect, if deemed significant. Qualitative process data will be used to assess intervention intensity and provide context for the findings.

Unit of analysis issues

Cluster randomised trials

Studies that allocate or randomise clusters and conduct their analysis at a different level to that of allocation need to account for clustering in their analysis to avoid potential unit of analysis errors. For studies that do not report appropriately accounting for clustering, we will contact the study authors to request missing information and attempt to re-analyse the data using the method outlined in the *Cochrane Handbook for Systematic Reviews of Interventions*. If this approach is used, we will mark the data as re-analysed. If re-analysis is not possible, we will note all studies with potential unit of analysis errors and discuss the implications for precision of effect estimates.

Studies with more than two treatment groups

If we identify studies with more than two intervention groups (multi-arm studies), where possible we will combine groups to create a single pair-wise comparison or use the methods set out in the *Cochrane Handbook for Systematic Reviews of Interventions* to

avoid double-counting of study participants (Higgins 2011). For subgroup analyses, where the control group is shared by two or more study arms, we will divide the control group by the number of relevant subgroups to avoid double-counting of participants.

Dealing with missing data

For missing summary data, we will contact study investigators for clarification, or if possible, we will estimate missing summary data using other information provided in the publication. We will carry out analyses, as far as possible, on an intention-to-treat basis, analysing participants in the group to which they were allocated regardless of whether or not they received the allocated intervention. It is also recognised that not all intervention group participants may receive the same 'dosage' of intervention; accordingly, we will conduct an intention-to-treat analysis wherever possible.

Assessment of heterogeneity

Heterogeneity will initially be considered in terms of meaningful variation in the participants, interventions and outcomes measured in included studies, sometimes known as clinical heterogeneity. Methodological heterogeneity will also be considered in terms of the variation in the study designs of included studies. If meta-analyses are appropriate, we will conduct a visual assessment of all forest plots and generate Chi^2 and I^2 statistics to quantify the level of statistical heterogeneity, which may be a consequence of clinical or methodological heterogeneity or both. We will not combine results from different types of study designs together in a meta-analysis. We expect considerable heterogeneity due to the broad scope of this review, and we plan to group studies by population, interventions and outcomes where it might be more meaningful to do so, based on clinical heterogeneity. We also plan to use a random-effects model for meta-analyses to incorporate likely statistical heterogeneity. If we find that $I^2 < 30$ (along with a high P value from the Chi^2 test), we will consider using a fixed-effect model as the primary model. Depending on the number of available studies, we will explore potential causes of heterogeneity, based on the pre-specified subgroup analyses listed below. Caution will be taken in the interpretation of results with a high level of unexplained heterogeneity.

Assessment of reporting biases

If more than 10 studies are identified that report the same outcome of interest, we will explore publication bias using funnel plots to assess the relationship between effect size and study precision. If meta-analyses have been conducted and we are concerned about small study effects, we will compare the fixed- and random-effects estimate of the intervention effect in a sensitivity analysis to identify the level of impact caused by different effect estimates in small studies. A random-effects meta-analysis weights the studies more equally than a fixed-effect analysis, therefore in the case where the intervention effect is more beneficial in smaller studies, the random-effects estimate will be expected to be more beneficial than the fixed-effect estimate (Poole 1999). If we find that there is a large difference between the random-effects estimate and the fixed-effect estimate, we will examine whether there are consistent differences between the smaller and larger studies in risk of bias, population or intervention (according to our pre-specified groupings identified in the Data synthesis and Subgroup analysis and investigation of heterogeneity sections) to determine possible causes and to decide on the most appropriate way to present studies in meta-analyses. For example, if the larger studies were generally assessed to be at a lower risk of bias and were conducted in circumstances that reflect the more typical or appropriate use of the intervention in practice, meta-analyses may be restricted to those larger studies.

Data synthesis

Where studies are sufficiently similar in terms of population, intervention and comparisons, pooled estimates of effectiveness will be generated for similar outcomes, as appropriate. This will be conducted by meta-analysing the data using a random-effects model as the default method where $I^2 > 30$ (see Assessment of heterogeneity).

For analysis, studies will be grouped by intervention type. While this will depend on what is found in included studies, this will most likely be based on the point of delivery or the timing of the intervention (in custody (i.e. pre-release), post-release, both pre- and post-release components) and whether or not the intervention is 'tailored' or personalised for individual circumstances, characteristics, needs, or a combination of these.

Within each intervention type, studies will be grouped by study design with RCTs and cluster RCTs in one group, quasi-RCTs and controlled before-and-after studies in a second group and interrupted time series in a third group. Outcomes will be reported in the review according to the primary and secondary review outcomes and within those categories, will be grouped as follows: substance use, health-related quality of life, physical health, mental health, health service utilisation, sexual risk behaviour and recidivism.

Qualitative data will be used to provide context for the findings and information about intervention implementation. Where appropriate, this will be used to guide risk of bias assessment as well as assessment of the intensity of interventions. If sufficient information related to the implementation of interventions in included studies is available, this will be tabulated separately in the review alongside information about cost/resource requirements to assist readers in their assessment of applicability and transferability.

For each study, we will capture whether or not outcomes are reported by any of the socio-demographic characteristics known to be important from an equity perspective based on the PROGRESS-Plus framework. Where outcomes are reported by

any of the PROGRESS-Plus factors, we will highlight narratively whether or not the primary authors found differences in the impact of interventions by those factors. Selected factors have been nominated below for subgroup analyses (gender, racial/ethnic minority status).

The main findings of the review will be set out in a 'Summary of findings' table that will incorporate findings for the primary review outcomes as well as the secondary review outcome, health service utilisation (the hypothesised proximate outcome), along with number of participants and studies. The number of studies reporting at least one adverse outcome will also be reported in the 'Summary of findings' table; however, due to expected heterogeneity in potential adverse outcomes, this will not be disaggregated by specific adverse outcome type. The overall quality of the body of evidence for primary outcomes will be summarised at the outcome level according to the GRADE criteria: study limitations, inconsistency, imprecision, indirectness and publication bias.

Subgroup analysis and investigation of heterogeneity

Subject to data availability, we will conduct the following subgroup analyses:

1. demographic characteristics: does the treatment effect differ as a function of (a) age (< 25 years vs. $\geq$ 25 years), (b) gender (male vs. female), or (c) racial/ethnic minority group status (minority vs. not, recognising the limitations of aggregating diverse cultural groups)?
2. sentencing status: does the treatment effect differ for those released from pre-trial detention (remand) and those released after a prison sentence?
3. tailoring of intervention: is the treatment effect different for interventions delivered in a manualised ('one size fits all') style versus tailored to individual circumstances, characteristics, needs, or a combination of these?

These subgroup analyses will be applied to our two primary outcomes and one secondary outcome (health service utilisation) as the hypothesised 'proximate' outcome. Each analysis is comparing only two subgroups (based on derived binary exposure variables), so we will examine differences between subgroups by inspection of the CIs for the summary estimates in the two groups, where non-overlapping CIs will indicate a statistically significant difference between the summary estimate in each group.

Sensitivity analysis

Studies judged to be at high risk of bias will be excluded in a sensitivity analysis. Studies where participation in the intervention was mandatory (vs. voluntary) will be excluded in a second sensitivity analysis. If meta-analyses have been conducted and we are concerned about small study effects, we will compare the fixed- and random-effects estimate of the intervention effect in a third sensitivity analysis. All sensitivity analyses will be conducted on our two primary outcomes and one secondary outcome, health service utilisation, as the hypothesis 'proximate' outcome.

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* *Indicates the major publication for the study*

CONTRIBUTIONS OF AUTHORS

Prof. Kinner proposed and designed the protocol, drafted the protocol and incorporated feedback from the RAG and co-authors.

Dr. Burford provided methodological and statistical advice, and contributed to drafting of the manuscript.

Dr. van Dooren provided expertise in the relevant literature and contributed to drafting of the manuscript.

Dr. Gill provided expertise in the relevant literature and contributed to drafting of the manuscript.

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