Ministry of Justice

A Randomised Controlled Trial in Four Prisons: Impact of Incentivised Substance Free Living Wings on Prison Stability

Part of the Tackling Drug Misuse in Prisons Evaluation Programme

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List of Abbreviations and Terms

Abbreviation/ Term	Definition
10 Prisons Project	A 2018 initiative to reduce violence and drug use in 10 prisons.
Bayesian analysis	Statistical method combining prior beliefs (priors) with new data (likelihood) to generate updated estimates (posterior distributions).
Compact	An agreement prisoners sign setting behavioural expectations and consequences for removal from ISFLs.
Credible interval (CI)	Range within which the parameter estimate falls with a certain probability (e.g. 80%); Bayesian analogue to a confidence interval.
Disorder incidents	Disruptive prisoner behaviours (e.g. barricading, hostage-taking, incidents at height, concerted indiscipline).
Exponential survival model	A time-to-event (survival) analysis model assuming constant hazard (risk of experiencing the event) over time.
Hazard ratio (HR)	A measure of the relative risk of an event (e.g. assault, self-harm) in one group compared to another over time.
HMC	Hamiltonian Monte Carlo – an algorithm used in Bayesian modelling.
HMPPS	His Majesty's Prison and Probation Service.
Intention-to-treat (ITT) analysis	Analytical approach including all participants as originally allocated, regardless of adherence to the treatment.
ISFL / ISFLs	Incentivised Substance Free Living wings – designated prison wings where prisoners commit to drug-free living.
Likelihood	The probability of observing the data given a model/parameter value.
MCMC	Markov Chain Monte Carlo – methods used in Bayesian statistical computation.
MoJ	Ministry of Justice.
NHS	National Health Service.

Abbreviation/ Term	Definition
NOMIS	National Offender Management Information System – administrative system used by prison staff to record prisoner data and incidents.
Posterior distribution	Updated probability distribution after combining prior information with observed data.
Prior distribution	A probability distribution representing beliefs about a parameter before observing the current data.
Prison stability	Measure of safety and order in a prison environment, often proxied by reduced assaults, self-harm, or disorder.
Prison Strategy White Paper (2021)	Government policy setting out prison reform priorities.
Psychoactive substances	Drugs that alter perception, mood, or consciousness; associated with prison violence.
RCT	Randomised Controlled Trial – an experimental study design where participants are randomly assigned to intervention or control groups.
Rhat	A convergence diagnostic in Bayesian analysis (values close to 1 indicate good convergence).
Right-censoring	When an individual leaves a study before experiencing the event, or the study ends without the event occurring.
SDS40	A scheme introduced in 2024 where prisoners who had served 40 per cent of their sentence were released early.
Sensitivity analysis	Testing how robust results are to different assumptions, such as alternative priors.
Survival analysis	Statistical methods for analysing time-to-event data (e.g. time to assault, self-harm).
Voluntary Testing Units (VTUs)	Precursors to ISFLs introduced after the 1998 National Drug Strategy.
Waitlist randomised controlled trial	A design where participants on a waiting list are randomised into intervention and control groups based on their order of access to a programme.

1. Executive Summary

Substance Misuse in Prisons and Incentivised Substance Free Living Wings

Substance misuse in prisons has been a long-standing issue. Traditional approaches to combat substance misuse in prisons have focussed on deterring prisoners and emphasised the use of punitive sanctions.

Incentivised Substance Free Living wings (ISFLs) are prison wings where prisoners agree to abide by a set of requirements, including regular drug tests. Incentives (e.g. additional time out of cell, gym equipment, entertainment equipment) are offered for those residing on the wing. ISFLs aim to create a stable prison environment, which allows for the development of a supportive community in which prisoners live drug-free, and can better engage with treatment programmes and recovery.

This study does not represent all ISFLs, but only those considered operationally effective. It focuses on safety and stability outcomes, not substance misuse, as these were viewed as essential foundations for ISFL success.

Study Methods

This innovative study utilised a waitlist randomised controlled trial which randomly assigned the order in which prisoners would move from a non-ISFL prison wing to an ISFL prison wing, in four prisons. Those randomised to the top half of the list formed the intervention group, and outcomes were compared to those in the control group (bottom half of the list). The primary outcome measure was time to involvement in an assault incident. This is used as a measure of prison wing stability and was measured over a 3-month period. For the intervention group this follow-up period began from the point of moving onto the ISFL (which was dependent upon spaces becoming available), for the control group follow-up began from the point of randomisation. Results were analysed using Bayesian survival regression.

Results

A total of 60 prisoners were involved in the final intention to treat analysis for our primary outcome measure (28 ISFL and 32 non-ISFL). Bayesian survival analysis estimated there

to be a 93.1% probability that ISFLs have a beneficial effect of any magnitude, in terms of reducing assault incidents. Our analysis estimates, with 80% uncertainty, the size of reduction in assault incidents to be between 5% and 50%, with a median estimate of 31% – ISFL's compared to non-ISFL's.

This means those on ISFL wings were **31% less likely to be involved in an assault incident** compared to those on a non-ISFL wing. **Similar effects were seen for self-harm** (80% probability between 4% and 50% less likely to self-harm, with median at 31%) **and disorder** (80% probability between 6% and 51% less likely to be involved in a disorder incident, with median at 32%).

Conclusions

This study concludes that ISFLs have a high probability of providing a more stable environment for prisoners, compared to non-ISFL wings. It also demonstrates that randomised controlled trials are feasible within a frontline prison setting. This design should be considered by social researchers when developing evaluation plans in the future.

1.1 What you can say about this evaluation

- There is a high probability that Incentivised Substance Free Living wings provide a more stable environment for prisoners when run effectively.
- It is highly likely that Incentivised Substance Free Living wings cause prisoners to engage in fewer incidents of assault, self-harm, and disorder when run effectively.
- Incentivised Substance Free Living wings provide an environment where prisoners are less likely to get involved in assaults, to self-harm, and engage in incidents of disorder.

2. Introduction

Drug misuse causes enormous direct and indirect harm, imparting a heavy cost on society. The scale of this challenge was recognised in the Independent Review of Drugs by Dame Carol Black (Black, 2020), and the subsequent publication in 2021 of a 10-year cross-Government Drugs Strategy (HM Government, 2021).

In the criminal justice system, particularly within prisons, the challenge is even more acute (Ministry of Justice, 2019). Almost 50% of prisoners have an identified drug misuse need (Ministry of Justice, 2022), and inspections by HM Inspectorate of Prisons find widespread drug misuse, particularly in male local and category C prisons[1] (Ministry of Justice, 2019). To respond to this, the Ministry of Justice (MoJ) and His Majesty's Prison and Probation Service (HMPPS) are investing in a range of interventions to tackle drugs and support offenders with addictions – such as expanding the availability of prison environments that reduce demand and support recovery.

Drug misuse in prisons undermines safety for both prisoners and prison staff, as well as the ability of prison staff to deliver effective regimes. It perpetuates a cycle of violence, leading to a reduced or unstable regime, through which unpredictability and a lack of purpose can further encourage prisoners to turn to drugs (Ministry of Justice, 2019). The debt associated with the supply and distribution of drugs also contributes to violence, intimidation, and self-harm across the estate (Hammill & Newby, 2015). Furthermore, the use of psychoactive substances in prisons has been associated with violence (HM Chief Inspectorate of Prisons, 2017; Wheatley, et al., 2015). To effectively tackle drug misuse, it is important to address all parts of this cycle and maintain a stable prison environment that encourages prisoners to engage with rehabilitation (Mann, et al., 2018), in addition to drug treatment and recovery.

Incentivised Substance Free Living wings (ISFLs) are dedicated spaces within prisons for prisoners who want to live drug-free. On ISFLs, prisoners are given incentives (for

[1] Category C prisons house prisoners who are deemed low risk of escape and threat. Category C prisons provide prisoners with the opportunity to develop their own skills to support their resettlement upon release. For more information see: https://prisonjobs.blog.gov.uk/your-a-d-guide-on-prison-categories/

example additional access to gym equipment, entertainment equipment, additional time out of cell) to remain drug free, alongside undergoing regular drug testing. In an ISFL, new residents sign a compact[2] which outlines expectations for acceptable behaviour and what leads to removal from the ISFL. The creation of a positive and supportive environment by both prisoners and staff is a key factor in the perceived? functioning of an ISFL. Therefore, the guidance for ISFLs emphasises the importance of having residents and staff who are both self-motivated and committed to the ethos of ISFLs.

ISFLs follow on from Voluntary Testing Units which were similar spaces introduced in response to the 1998 National Drug Strategy (Home Office, 1998). These were later reintroduced as ISFLs as part of the 10 Prisons Project, which was launched in 2018 to reduce violence and drug use. A commitment to the expansion in provision of ISFLs was made by the MoJ in the Prison Strategy White Paper (Ministry of Justice, 2021) and the cross-Government Drug Strategy (HM Government, 2021). Consequently, as of April 2025, there are currently 85 prisons with ISFLs in operation, out of 123 prisons in England and Wales.

Despite the commitment to roll out ISFLs and the length of time for which they have been in operation, there is a lack of robust evidence around the impact of ISFLs. This study sought to address part of this evidence gap through this pragmatic, waitlist randomised controlled trial (RCT). Ahead of designing this evaluation, an initial theory of change was developed (see Appendix A), which provided a logic model from inputs to outcomes and policy impacts. From this theory of change, mechanisms that describe the processes through which ISFLs exert their impact were hypothesised. Our impact evaluation has been designed to evaluate the first mechanism described in the theory of change:

> If ISFLs provide a safe, stable, and enabling environment then prisoners will have time and space to focus on their recovery and development.

Safety and stability of the prison environment has been highlighted as a key requirement to ISFL success through previous qualitative work (Ministry of Justice, 2024). This

[2] Compacts are contracts between the prison and prisoner stating the terms and conditions of a process or intervention. Please see glossary for additional information.

evaluation seeks to answer the research question: “Do ISFLs provide a more safe and stable prison environment compared to non-ISFLs for prisoners considered eligible to move onto an ISFL and who are currently on the waiting list for an ISFL space?”

Randomised controlled trials (RCTs) are often considered the “gold standard” of evaluation design. The use of them in justice settings has been difficult due to operational barriers. This issue was identified in the Ministry of Justice’s (MoJ) Evaluation and Prototyping Strategy (Ministry of Justice, 2023), which called for the use of more robust evaluation techniques. This evaluation demonstrates the successful delivery of an RCT in a frontline prison setting, something only reported to be achieved 6 times in the last 15 years.

The report is part of a wider evaluation programme, funded by the Cabinet Office’s Evaluation Accelerator Fund,[3] looking at measures to tackle drug misuse in prisons.[4]

[3] Evaluation Accelerator Fund - GOV.UK

[4] Links to the Cabinet Office’s evaluation registry for this evaluation; a related qualitative study; and another qualitative study exploring lived experience of drug testing in prisons

3. Methods

A detailed description of the methods used in this evaluation are outlined in the protocol paper shown in Appendix C. Key aspects are outlined below.

3.1 Design, Participants, and Interventions

This evaluation, which took place in four Male Category C prisons in England, utilised a two-arm, waitlist randomised controlled trial. Prisons were selected based on the effectiveness of their Incentivised Substance Free Living wing (ISFL), as determined by operational HMPPS staff. Prisoners deemed eligible by prison staff for relocation to the ISFL were allocated a space on a waitlist at random. When a space became available on the ISFL, the prisoner at the top of the waitlist would be offered the opportunity to relocate to the ISFL.

Table 1. Inclusion and exclusion criteria to take part in the evaluation

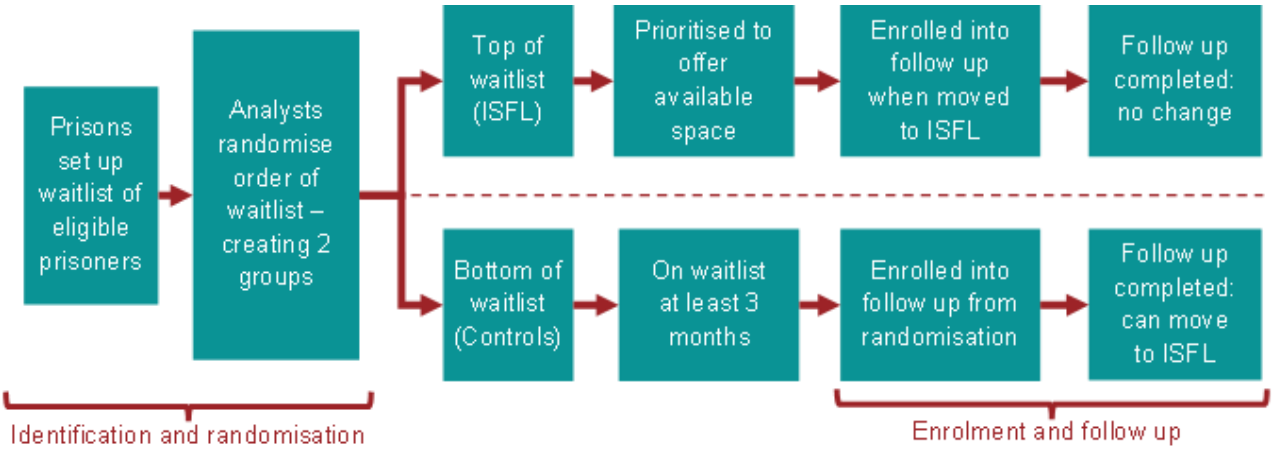
Inclusion Criteria	Exclusion Criteria
Expected to remain within prison custody during evaluation follow-up period	Expected to be released from prison custody during evaluation follow-up period
Capacity to provide informed consent	Lacks capacity to provide informed consent
Willing to sign the behavioural compact for residing on an ISFL (intervention group only)	Identified as having an exceptional requirement for residing on the ISFL without being a part of the evaluation (e.g. specific health or safety need)
Currently on a waiting list for a place on an ISFL	

Randomisation of the waitlist generated two groups. One group, the intervention group, were moved up the waitlist and would be prioritised for a space when it became available. The second group were moved down the wait list and would remain in their current location for at least three months (the duration of follow-up for the study).

Follow-up lasted 3-months and began from the point of enrolment. For the control group enrolment was defined as the point of randomisation, for the ISFL group enrolment was

the point at which the prisoner moved to the ISFL. Figure 1 below depicts the flow of prisoners through the study.

Figure 1. Flow of prisoners through the trial.



The follow-up period of 3 months was chosen based on observational analysis in the design phase of this evaluation. This observational analysis showed that over 80% of incidents occur within the first 90 days of moving to an ISFL, therefore 3-months follow up was deemed sufficient to capture events.

Ethical considerations

Specific ethical considerations and study design choices are detailed in the trial protocol (Appendix C). In brief, our approach was reviewed and approved through the internal, social research Analytical Quality Assurance process. This included advice from the MoJ Ethics Advisory Group and consultation with stakeholders from NHS England. These consultations led to the defining of an exception's procedure in relation to the random allocation. This meant prisoners could be relocated to or from the ISFL if staff had a strong belief that relocation was in the prisoner's best interest. This may have been for reasons related to treatment or safety and aimed to ensure clinical services were not disrupted.

3.2 Outcomes

This evaluation was designed to investigate the short-term impact of ISFLs on prison safety and stability. This has been proxied using safety metrics with our primary outcome being time-to-assault incident. Time to an incident is an important aspect of regime stability as it is expected that more stable, supportive environments would delay violent incidents.

This is an anticipated benefit of greater community support which would add social pressures to avoid engaging in violent behaviours. In addition to this, given the higher probability of violence occurring within prison, a delay in violence is a positive, desirable outcome.

Secondary outcome measures focussed on similar time-to-event analysis for self-harm incidents and disorder incidents. Data were extracted from an analytical extract of the prison-NOMIS system, which is an administrative system used by the prison service to record prisoner related information and incidents.

Incidents of disorder include any incident defined as protesting behaviour in HMPPS Annual Digest. This could include barricading, hostage taking, concerted indiscipline, or an incident at height (normally prisoners jumping onto netting located between the floors of the prison).

3.3 Randomisation and Blinding

Randomisation was undertaken by an independent, blinded researcher. No identifiable information was provided to the independent researcher for randomisation. Randomisation was completed using the crPar function from the R package RandomizeR, which implements a complete randomisation algorithm (Uschner, et al., 2018). The outcome of this algorithm is like flipping a fair coin and then assigning someone to the ISFL group if the coin lands on heads or otherwise assigning to the control group. If the coin is flipped many times, it would be expected for the allocations to balance out (e.g. 50% of prisoners assigned to ISFL and 50% assigned to the control group). Randomisation was run independently for each prison's waiting list.

3.4 Statistical methods

A Bayesian, exponential survival analysis was used to measure the effects of ISFLs on incidents of assault, self-harm, and disorder. Survival analysis lets us analyse time-to-event outcomes (such as time-to-assault incident), incorporating data from everyone up to the point they either experience an event (e.g. are involved in an assault), are removed from the analysis (e.g. leave prison before follow-up is complete; right-censoring), or otherwise reach the end of the follow-up period.

The Bayesian approach allows the data collected in the evaluation to be combined with pre-existing information about what the believed impact is. This pre-existing information is called a “prior” and forms a probability distribution, representing the beliefs or existing data about the impact of ISFLs. Priors can be either informative (the distribution makes an assumption about the shape and spread of values), or non-informative (a flat distribution which makes a minimal assumption about prior information).

The data collected during the evaluation is called the “likelihood” and represents new information about what is being measured. The likelihood data is used to update the prior distribution, and arrive at a new estimate of the effect of the intervention – this new, updated probability distribution is called the “posterior” distribution.

Bayesian analysis is particularly useful when smaller sample sizes are expected. Traditional (non-Bayesian) null-hypothesis significance testing relies on specific sample sizes to determine valid results. These sample sizes are often large, depending on the expected size of the effect to detect. With Bayesian analysis, specific sample sizes for valid inferences are not required. The use of informative prior distributions is important, particularly when sample sizes are smaller because the prior distribution will contribute more to the generation of the posterior distribution. Furthermore, uncertainty of the estimated effect sizes can be directly estimated, giving a more intuitive and transparent summary of findings.

The robustness of conclusions and the impact of certain assumptions (e.g. the shape of the prior distribution) can be explored using sensitivity analysis. For this analysis, sensitivity analyses were used to check how findings would change with different priors. Priors for this analysis were informed by observational analysis of administrative data, undertaken prior to the study beginning. Specific details on the shape of prior distributions are included in the technical annex (Appendix B).

The outcome measure interpreted from the analysis is a hazard ratio – this estimate provides a comparison of the risk of an event occurring, between the two evaluation groups (control and ISFL). In this analysis, a value of less than 1 indicates a favourable outcome for ISFLs - there is a lower risk of violence in ISFLs.

Posterior distributions were summarised in two ways:

1) In terms of the proportion of the posterior distribution favouring ISFL outcomes (hazard ratio <1) – interpreted as the probability of a favourable impact.

2) In terms of the median value of the posterior distribution and an 80% uncertainty distribution – interpreted as the most likely hazard ratio and uncertainty in quantifying this.

Sensitivity analyses were undertaken using alternative priors. Specifically, a pessimistic prior which assumed only a negligible benefit of ISFLs, and a moderate prior which assumed an effect in between that of the pessimistic prior and the prior from the observational data.

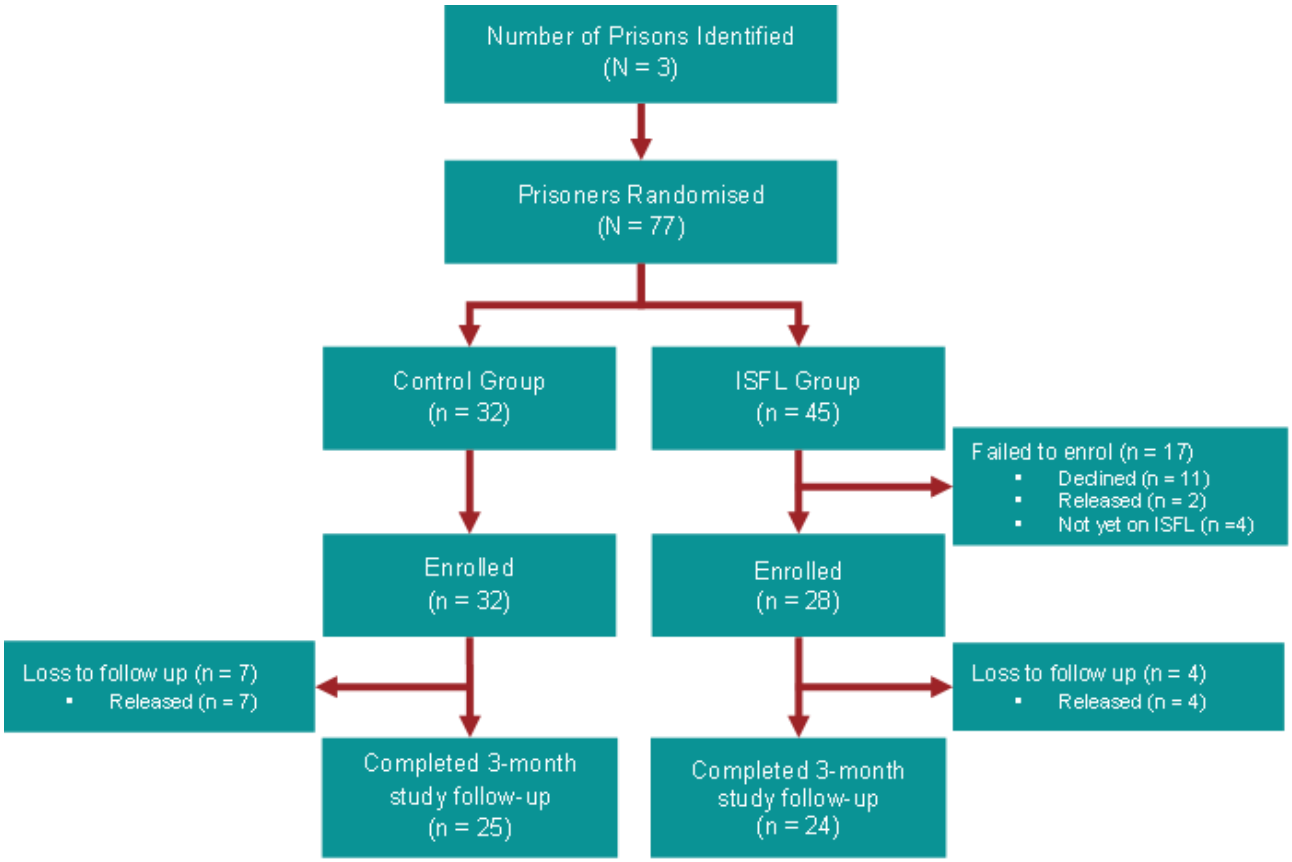
All data was analysed using R software version 4.5.0 (R Core Team, 2025). Bayesian survival analysis was completed using the brms package (Bürkner, 2018; Bürkner, 2017). Data was manipulated using various functions from tidyverse packages (Wickham H, 2019). Results plots were produced using ggplot2 and ggridges (Wickham, 2016; Wilke, 2024). Summary statistics were generated using the bayestestR package (Makowski , et al., 2019). Diagnostic plots in Appendix A were produced using the bayesplot package (Gabry & Mahr, 2024).

4. Results

4.1 Participant flow

A total of 3 prisons were included in this impact evaluation, with 77 prisoners on their waitlists at the time of randomisation. The flow of participants through the evaluation is depicted in Figure 2 below.

Figure 2. Participant flow diagram showing numbers of prisoners randomised and reasons for loss to follow up.



From these 77 prisoners, 32 were randomised to the control group and 45 were randomised to the ISFL group. In the ISFL group 17 participants failed to enrol in the study with the most common reason being that they declined to move onto the ISFL when a space became available. Once enrolled, during the follow-up period of the study, 7 prisoners in the control group were released and 4 prisoners in the ISFL group were released. A total of 49 prisoners completed the follow-up period, with 25 in the control

group and 24 in the ISFL group. All prisoners enrolled into the study (32 in the control group and 28 in the ISFL group) contributed to the final intention-to-treat analysis.

4.2 Events

The table below shows a count for the recorded number of each event per group, in the 3 month follow up period.

Table 2. Number of events per outcome measure.

Outcome Measure	ISFL group	Control group
Assault (count of incidents)	1	3
Self harm (count of incidents)	1	4
Disorder (count of incidents)	0	2

4.3 Primary analysis

Bayesian survival analysis was used to estimate the impact that living on an Incentivised Substance Free Living wing (ISFL) has on time-to-assault incident. More details on this analysis are reported in the methods section above and the technical annex (Appendix B).

The posterior distribution (our updated beliefs of the effect size) is summarised in terms of:

1) The **probability there is a beneficial effect of ISFLs**, i.e. the proportion of the posterior distribution with a hazard ratio below 1 – interpreted as ISFLs providing a more stable environment compared to non-ISFLs.

2) The **median value of the posterior distribution**, as a point estimate of the most likely value for the estimated true effect, based on our current data. Uncertainty of the point estimate is quantified **with an 80% uncertainty interval** (credible interval), meaning there is an 80% probability the population median value lies within the given range. Also reported are sensitivity analysis, comparing 3 different prior beliefs – as outlined in the methods section.

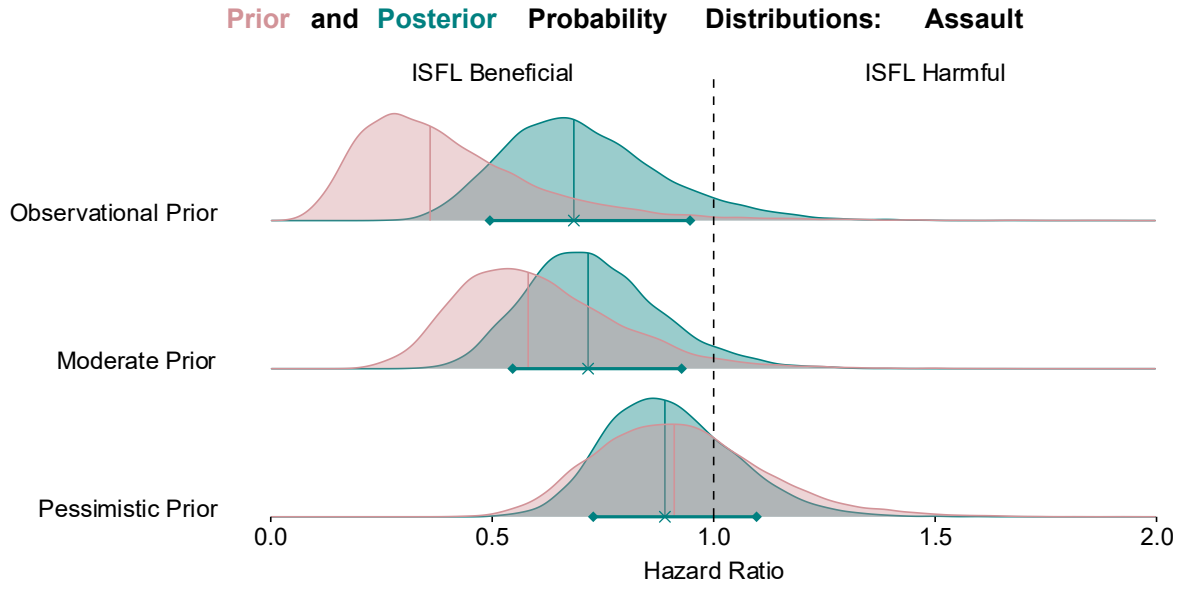
Results relating to assault incidents are reported in Table 3. From this it is shown that the probability that ISFLs provide a more stable prison environment, compared to non-ISFLs ranges across the models from 75.9% to 94.7%.

Table 3. Statistical summaries of the time-to-assault incident outcome measures, under the three different prior belief scenarios.

Prior Belief Scenario	Posterior Distribution Summary: Probability of Benefit (Hazard Ratio < 1)	Posterior Distribution Summary: Median Hazard Ratio (80% Uncertainty Interval)
Observational	93.1%	0.69 (0.50 – 0.95)
Moderate	94.7%	0.71 (0.54 – 0.93)
Pessimistic	75.9%	0.89 (0.72 – 1.10)

In Figure 3 below, the prior and posterior distributions for each prior belief scenario are depicted. In addition to the probability distributions, the median value and 80% uncertainty region around the estimate is shown – this is depicted as the bold line at the bottom of each plot, with an 'x' representing the median and diamond shapes representing the limits of the uncertainty regions. Specific values for these are shown in the right-most column of Table 3.

Figure 3. Prior and posterior distributions for the assault outcome measure.



4.4 Secondary analysis

In addition to the primary outcome measure, the impact of ISFLs on self harm and incidents of disorder was estimated. The impact was estimated in the same way as the primary outcome measure, using a Bayesian survival analysis of the time-to-first event.

Self harm

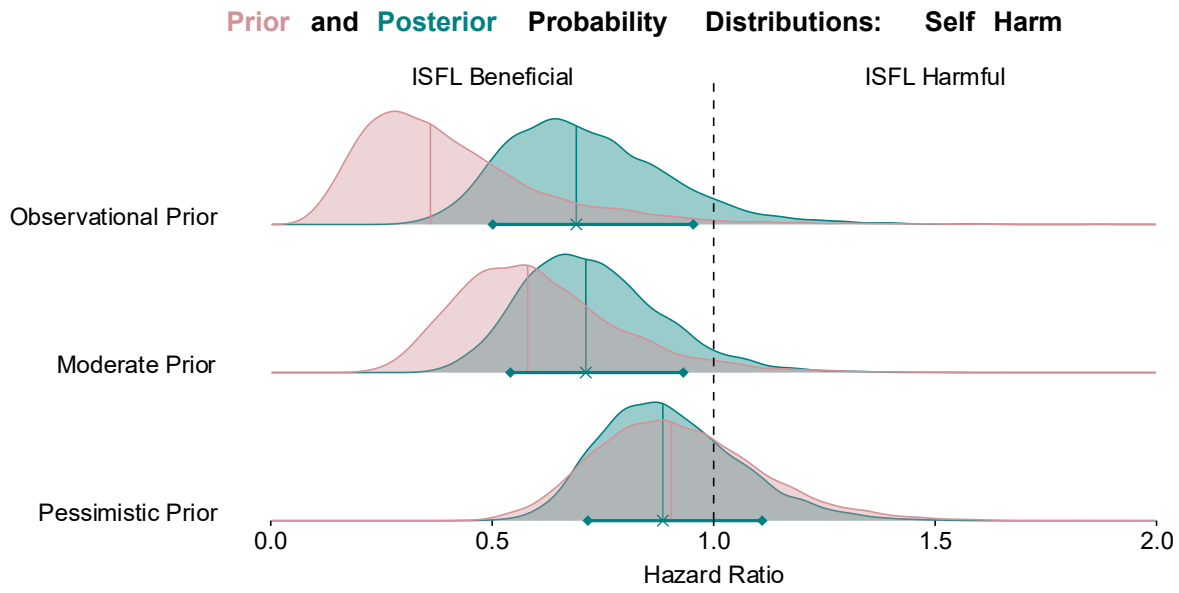
Results relating to self harm incidents are reported in Table 4. From this it is shown that the probability that ISFLs provide a more stable prison environment, compared to non-ISFLs, ranges across the models from 76.1% to 95.2%.

Table 4. Statistical summaries of the time-to-self harm incident outcome measures, under the three different prior belief scenarios.

Prior Scenario	Posterior Distribution Summary: Probability of Benefit (Hazard Ratio < 1)	Posterior Distribution Summary: Median Hazard Ratio (80% Uncertainty Interval)
Observational	92.5%	0.69 (0.50 – 0.96)
Moderate	95.2%	0.71 (0.54 – 0.93)
Pessimistic	76.1%	0.89 (0.72 – 1.10)

Below, in Figure 4, the prior and posterior distributions for each prior belief scenario are depicted. In addition to the probability distributions, the median value and 80% uncertainty region around the estimate are shown – this is depicted as the bold line at the bottom of each plot, with an ‘x’ representing the median and diamond shapes representing the limits of the uncertainty regions. Specific values for these are shown in the right-most column of Table 4.

Figure 4. Prior and posterior distributions for the self-harm outcome measure.



Disorder event

Results relating to disorder incidents are reported in Table 5. It is shown that the probability that ISFLs provide a more stable prison environment, compared to non-ISFLs, ranges across the models from 77.0% to 95.5%.

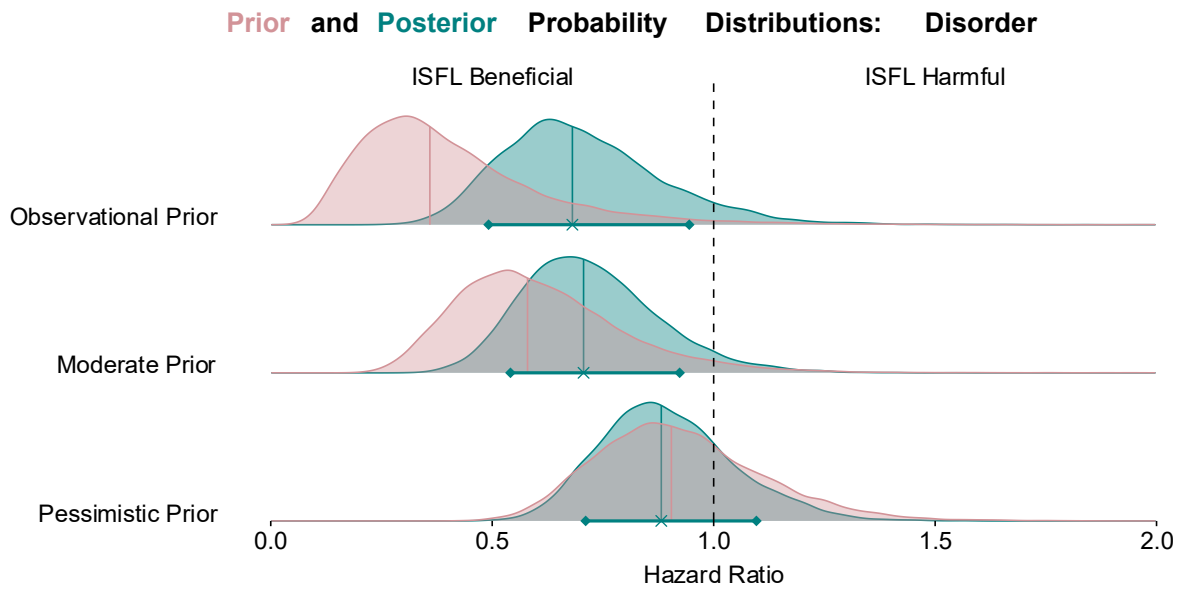
Table 5. Statistical summaries of the time-to-incident of disorder, under the three different prior belief scenarios.

Prior Scenario	Posterior Distribution Summary: Probability of Benefit (Hazard Ratio < 1)	Posterior Distribution Summary: Median Hazard Ratio (80% Uncertainty Interval)
Observational	93.9%	0.68 (0.49 – 0.94)
Moderate	95.5%	0.70 (0.54 – 0.92)
Pessimistic	77.0%	0.89 (0.72 – 1.09)

Below, in Figure 5, the prior and posterior distributions for each prior belief scenario are depicted. In addition to the probability distributions, the median value and 80% uncertainty region around the estimate are shown – this is depicted as the bold line at the bottom of each plot, with an 'x' representing the median and diamond shapes representing the limits

of the uncertainty regions. Specific values for these are shown in the right-most column of Table 5.

Figure 5. Prior and posterior distributions for the disorder outcome measure.



5. Discussion

5.1 Interpretation

These results demonstrate there is a high probability that Incentivised Substance Free Living wings (ISFLs) provide a more stable prison environment compared to non-ISFL wings. The magnitude of reduction in assault incidents is estimated to be between 5% and 50%, compared to non-ISFLs. These results also demonstrate that ISFLs provide an environment where prisoners are less likely to self harm or engage in incidents of disorder. These findings provide validation of the first mechanism in the theory of change (see appendix A), that ISFLs provide a safe and stable environment.

Findings from this evaluation, and the complimentary process evaluation, will be used to develop evidence-based operational guidance for ISFLs currently running across the prison estate.

Further evaluation should be undertaken to explore the additional mechanisms and outcomes depicted in the theory of change and not covered by this evaluation. Specific areas future evaluations could focus on include recovery outcomes and reoffending. Impact in these areas would be of significant policy and public interest. Any future evaluations should also seek to collect data on outcomes that were measured in this study, and use the findings as a basis for informed prior distributions. This would build upon findings and reduce the uncertainty of estimated effects.

5.2 Generalisability

The aim of this analysis was to understand if well-run ISFLs (determined largely by operational opinion) have an impact on prison stability. Although this evaluation was approached with pragmatic criteria, it was required that there be some similarities in operational models between sites, with the aim of enhancing the internal validity of the findings.

Given there are varied delivery models for ISFLs nationwide, the results from this analysis are not necessarily generalisable to all ISFLs.

5.3 Limitations

Given the pragmatic (real-world) approach to the evaluation, and operational challenges beyond the control of the research team, the context of our evaluation may be limited. Below, four limitations relating to this evaluation are discussed.

Firstly, prison capacity issues resulted in the introduction of an early-release programme – Standard Determinate Sentence 40 (SDS40) – which resulted in a larger turnover of prisoners in the prison estate. This programme was introduced in September 2024, so likely had an impact on all the prisoners in the site. A higher turnover of prisoners has been associated with destabilising the prison regime, but the impact of SDS40 with regards to this has not been quantified, nor verified. It is likely that this will have had a similar impact ton both groups.

Secondly, whilst the sample of prisoners exceeded the pre-determined sample size requirement of 30 prisoners, a larger sample would have provided more precise estimates of our posterior distributions – helping to reduce uncertainty in our effect estimates. Increased sample size could have been achieved either through additional rounds of randomisation at each prison, or the inclusion of additional prison sites. However, this action was not possible for this evaluation given time and funding constraints. Furthermore, increasing the number of prison sites may have introduced further variation in the operational characteristics of ISFLs, further limiting the internal validity of findings.

Thirdly, there was a greater amount of prisoner turnover than anticipated when designing the evaluation. Specifically, such a large dropout of participants from the waitlist was not considered. Whilst this did not reduce the number of prisoners enrolled into the evaluation to a level which would limit the usefulness of findings, it does add an extra source of variation which may have increased the uncertainty of our effect estimates.

Fourthly, the length of follow up could have been increased to allow a greater accrual time for incidents. The follow up period of 3-months was chosen based on observational analysis in the design phase of this evaluation. This observational analysis showed that over 80% of incidents would occur within the first 90 days of moving to an ISFL, therefore 3-months follow up was deemed sufficient to capture events.

5.4 Delivering a Random Controlled Trial in Prison

Randomised controlled trials (RCTs) are not commonly used in prison research in England and Wales due to the complexity of delivering them in a sensitive, resource-intensive operational environment. As well as the impact against the main aims of this study, this evaluation demonstrates that an RCT is feasible within a frontline prison setting.

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Appendix A
Theory of Change

Context

Prisoners are more likely to have drug issues than the general population. Prisons traditionally present environments where substance free living is difficult; there is often a lack of meaningful daily activities, a lack of appropriate tailored support and drugs are readily available. Prisoners use drugs for various reasons: they may be addicted on arrival, to cope with trauma, or start / continue using drugs to ease boredom. Prisoners can get into debt through drug use which increases the risk of bullying, violence and self-harm. Prisoners often have low self-esteem and lack the belief, hope or skills to change. To create a sustainable route to recovery, prisoners require a stable, safe, enabling regime which provides the structure and opportunity for personal development through meaningful activities.

Mechanisms of Change

1. If ISFLs provide a safe, stable and enabling environment, prisoners will have time and space to focus on their recovery and development.

2. If staff buy into the ethos of ISFLs, prisoners will be treated fairly, feel trusted, and be supported to take ownership of their recovery and development.

3. If prisoners feel part of a community built on togetherness, connectedness and support, they will develop a sense of hope, self-compassion and a belief that change is possible.

4. If prisoners have visibility of recovery and celebrate success in others it will strengthen the belief that change is possible for them and sustain their motivation to change.

5. If prisoners have access to tailored resources and support, they will be able to develop the self-compassion, resilience and self-management skills to take more

control over life and make better decisions which will support their continued recovery in the community.

6. If voluntary testing demonstrates negative drug results, prisoners can show a change in drug taking behaviour and use this to strengthen family ties and support parole applications.

7. If staff enforce the compact in a timely, compassionate and individualised way with appropriate consequences, prisoners will continue to progress with treatment and recovery.

Assumptions

1. Prison capacity pressures and stability in prison population allow creation of a dedicated wing.

2. There is sufficient senior leadership buy in to prioritise and resource ISFLs.

3. Prisoners who can benefit form ISFL can be identified, the process is fair and equitable and there is sufficient space on the wing.

4. ISFLs are a priority for prisons and there is the capacity and resources to provide required activities and support.

5. Prisoners want to reduce drug use and the regime on ISFLs is motivating.

6. ISFL regime can be consistently delivered.

7. Voluntary testing is administered randomly and is reliable, consistent and can identify appropriate range of drugs.

8. Voluntary testing is a sufficient deterrence.

9. There are sufficient staff in a prison who want to work on an ISFL and buy into the ethos.

10. There is continuity of care in place to support prisoners when released from custody.

11. Extra incentives offered in prison are wanted by prisoners and will translate to sustainable, intrinsic motivation to change.

Risks

1. Pressure from prison capacity, staff shortages, and funding may impact suitability of prisoners on ISFLs or potential for residents to make meaningful progress.
2. ISFLs and drug strategy is not prioritised by leadership within prisons.
3. Differences in operational model of ISFLs or resources available for implementation.
4. Staff knowledge gap in substance misuse impacts delivery.
5. Lack of security does not keep drugs or OCG's off ISFLs and/or security is concentrated on ISFLs with a risk in the wider establishment.
6. No continuity of care results in temporary change.
7. ISFLs do not provide enabling environments, assistance to recovery, or motivating incentives to promote change.
8. Resentment between residents on the ISFLs and those in the wider prison.
9. Resentment between staff working on ISFLs and those in the wider prison.
10. Lack of suitable space for a stand alone ISFL means that prisoners on ISFL mix with other prisoners.

Measures

1. Voluntary drug testing data
2. Prisoner time spent on ISFL
3. Reduction in disorderly conduct
4. Location of drug finds
5. Prisoner on prisoner assaults

6. Prisoner on staff assaults

7. Number of proven adjudications

8. Number and rate of self-harm incidents

9. Fewer drug related deaths in prisons

10. Fewer drug related deaths on release

11. Treatment engagement and completions

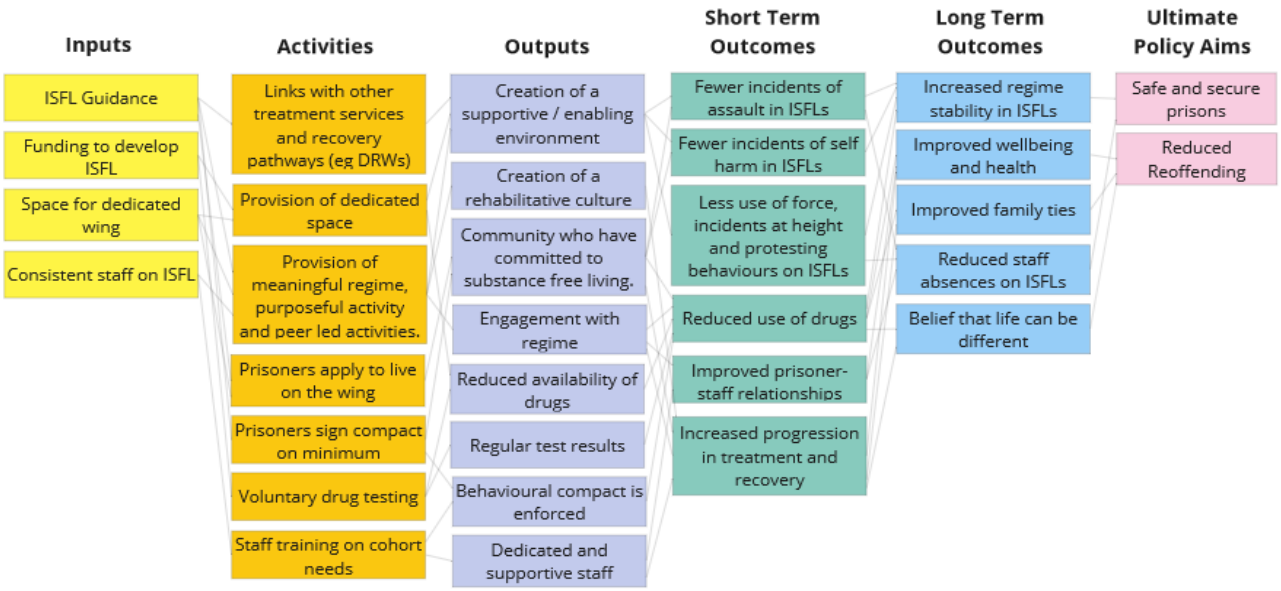
12. Prison leavers remaining in treatment

13. Prisoner leavers in employment

14. Proven reoffending rates

15. Numbers under the influence

Figure 6. Logic model relating to the theory of changed developed prior to the randomised controlled trial being designed.



Appendix B
Technical Annex

Details contained in this section relate to technical aspects of the analysis that has been conducted, including the model specification and model checks.

All models were fit using the brms package in R. This utilises Hamiltonian Monte Carlo (HMC) algorithms to estimate posterior distributions. For each model 4 chains were utilised, using 1000 warm up iterations and 4000 estimate iterations.

Details of prior distributions

Each of the 3 outcome measures presented in the main report – time-to-assault incident, time-to-self-harm incident, time-to-disorder incident – were analysed using 3 different prior assumptions. This sensitivity analysis allowed us to explore how sensitive our conclusions were to prior specifications.

The prior distributions were described as an “observational”, “moderate”, or “pessimistic” prior. The observational prior was based on observational analysis undertaken in the design phase, and likely represents an optimistic effect given likely unmeasured/adjusted confounding. The pessimistic prior was elicited from views of policy and analysis experts, who estimated a minimally beneficial effect, with a small precision – this represented a worst-case scenario and belief that there would still be some benefits of the intervention, but this may be like the impact seen in the control arm. The moderate prior was based on a mid-point of the two other priors.

Observational priors were modelled using a normal distribution with a mean of -1.02 and standard deviation of 0.5. Moderate priors were modelled using a normal distribution with a mean of -0.54 and standard deviation of 0.3. Pessimistic priors were modelled using a normal distribution with a mean of -0.1 and standard deviation of 0.2. Informative priors were applied to model coefficients and interpreted as Log Hazard Ratios.

Model Diagnostics

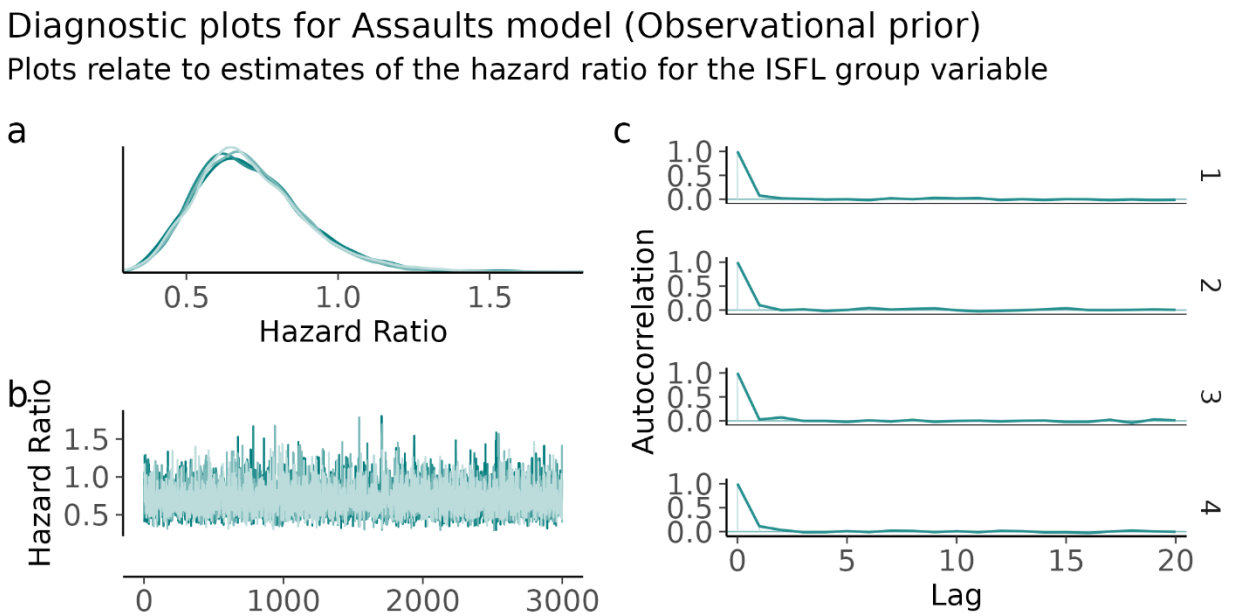
Below are a series of tables and plots used to assess model convergence. All modelled outcomes – accounting for different prior distributions – showed good Rhat values (close to 1), large effective sample sizes, and low monte-carlo standard errors. This suggests that simulations have converged on the posterior distribution.

Table 6. Diagnostic Markov Chain Monte Carlo statistics for each of the 9 models reported in the main body of text.

Outcome	Prior	R hat	Effective Sample Size	Monte-Carlo Standard Error
Assault	Observational	0.99987	9786.0	0.00253
Assault	Moderate	1.00148	4716.4	0.00311
Assault	Pessimistic	1.00103	5457.8	0.00219
Self-harm	Observational	0.99994	7540.8	0.00296
Self-harm	Moderate	1.00023	8330.9	0.00229
Self-harm	Pessimistic	1.00013	8821.8	0.00175
Disorder	Observational	1.00052	7245.6	0.00295
Disorder	Pessimistic	1.00006	5413.0	0.00280
Disorder	Moderate	0.99993	6517.2	0.00203

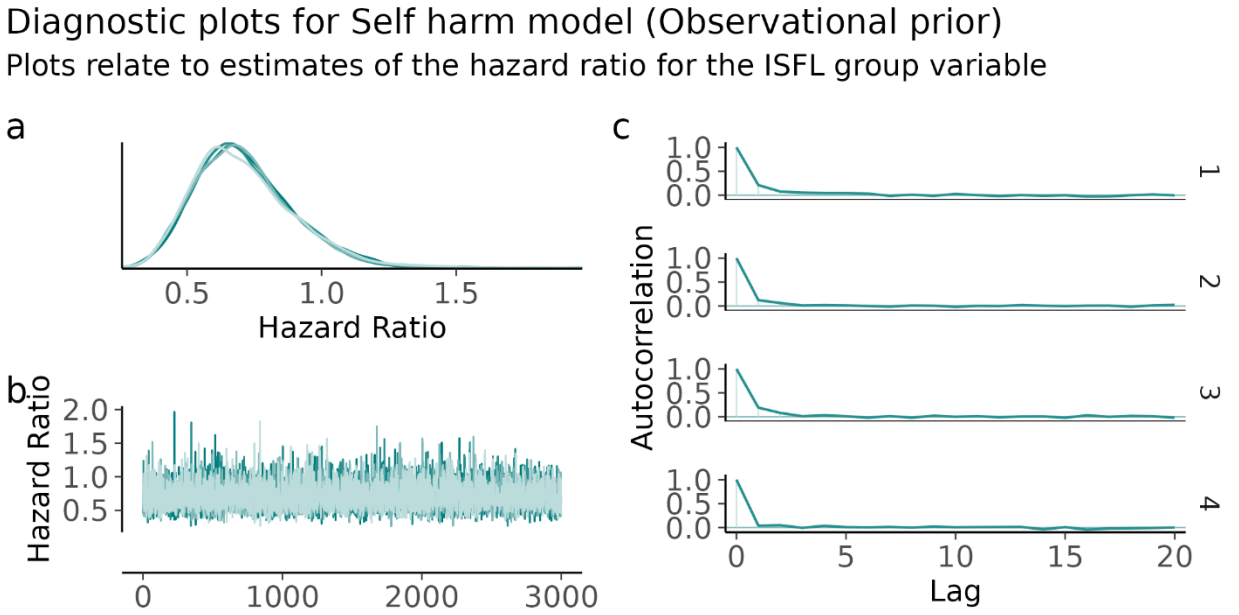
The 3 figures below show graphical assessments of convergence and model performance for posterior estimates resulting from the observational prior, for each outcome measure. Plots suggest good performance with each of the 4 chains roughly aligning, having good coverage in trace plots, and low autocorrelation.

Figure 7. Diagnostic plots of posterior estimates of time-to-assault incident, resulting from observational prior.



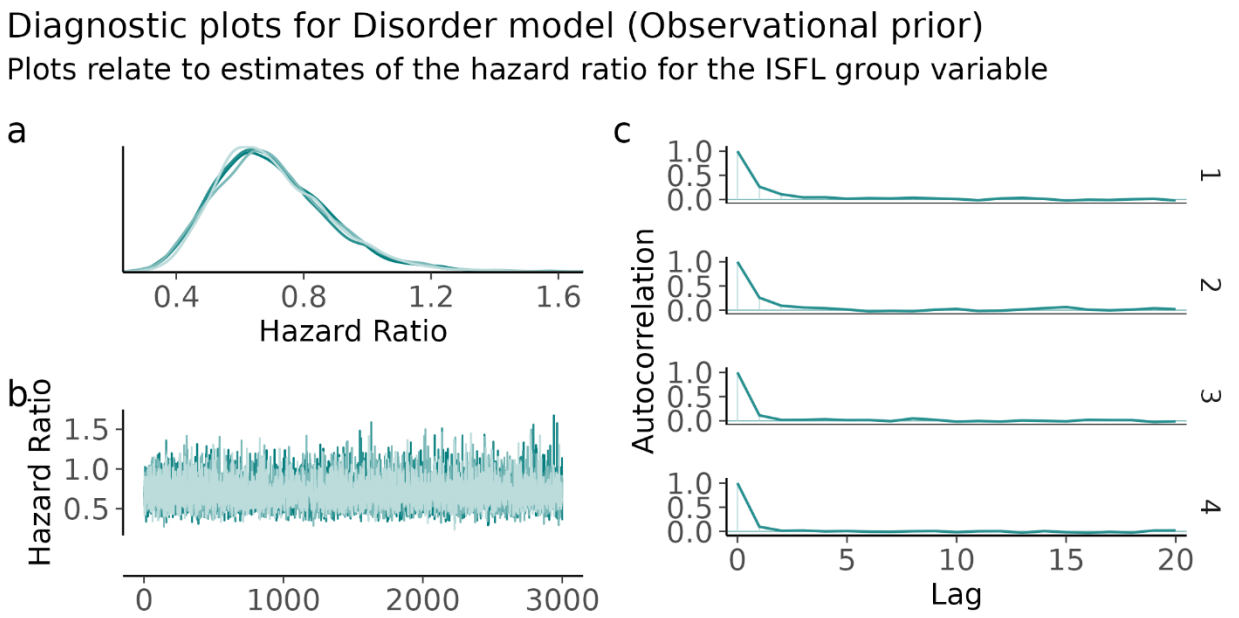
A: Shows density plots for each Markov Chain Monte Carlo estimate;
B: Shows trace plots for each Markov Chain Monte Carlo estimate;
C: Shows autocorrelation diagnostics for each chain

Figure 8. Diagnostic plots of posterior estimates of time-to-self-harm incident, resulting from observational prior.



A: Shows density plots for each Markov Chain Monte Carlo estimate;
B: Shows trace plots for each Markov Chain Monte Carlo estimate;
C: Shows autocorrelation diagnostics for each chain

Figure 9. Diagnostic plots of posterior estimates of time-to-assault incident, resulting from observational prior.



A: Shows density plots for each Markov Chain Monte Carlo estimate;
B: Shows trace plots for each Markov Chain Monte Carlo estimate;
C: Shows autocorrelation diagnostics for each chain

Frequentist Analysis

The table below presents the results from a frequentist exponential survival analysis of the data collated during this study. For each of the outcomes, the following general model was evaluated:

$$log(\lambda_i) = \beta_0 + \beta_1 group_i$$

Where λ_i represents the hazard rate parameter for the specific outcome of the i^{th} individual, β_0 is the baseline hazard, and β_1 is the hazard ratio for the group variable.

In table 7 below, statistics from the frequentist, exponential survival analysis are shown. Hazard ratios and standard errors have been exponentiated to avoid presenting values on the log scale.

Table 7. Key statistics from frequentist analysis of data.

Outcome	Hazard ratio	Standard Error	z value	p value
Assault	0.389	0.315	0.817	0.414
Self-harm	0.294	0.327	1.096	0.273
Disorder	<0.001	0	0.001	0.999

Appendix C
Protocol

This protocol has been formatted using the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) checklist.[5]

Administrative Information

Title {1}: Do Incentivised Substance Free Living wings create more stable prison environments? Protocol for a Randomised Controlled Trial

Trial registration {2}: NA

Protocol Version {3}: 1, 2024-02-08

Funding {4}: Evaluation Accelerator Fund (Cabinet Office, Evaluation Task Force)

Names, affiliations, and roles of protocol contributors {5a}: Gurmukh Panesar[1], Maika Terashima[1], Lucy Cuppleditch[1], Jo Voisey[2], Barnaby Elwes[3], Giles Stephenson[3], Lauren Withall[4], Nick Harris[5], Katie Lawley[5], Jason Hancock[5], Mike Wheatly[5], Darren Churchward[1]

1 – Ministry of Justice, Data and Analysis, Analytical Priority Projects, Prison Safety and Security Programme; 2 – Ministry of Justice, Data and Analysis, Evaluation and Prototyping Hub; 3 – Ministry of Justice, Data and Analysis, Offender Health Business Partnering; 4 – Ministry of Justice, Youth Justice and Offender Policy, Substance Misuse Policy; 5 – HM Prison and Probation Service, Security Directorate, Substance Misuse Group

Author contributions are listed under the relevant section (Author Contributions {31b})

Name and contact information for the trial sponsor {5b}: Ministry of Justice, Data and Analysis

[5] Home | consort-spirit.org

Role of study sponsor and funders {5c}: Overall oversight will lie with the sponsor, however responsibility for study design and conduct, data analysis, and report writing will be delegated to trial team. Funder will remain independent from trial conduct and reporting.

Introduction

Background and Rationale {6a}

Drug misuse causes enormous harm and has a heavy cost on society. The scale of the challenge was recognised by Government commissioning Dame Carol Black's independent Review of Drugs,[6] and the subsequent publication in 2020 of a 10-year cross-Government Drugs Strategy.[7]

In the criminal justice system, particularly within prisons, the challenge is even more acute.[8] Almost 50% of prisoners have an identified drug misuse need,[9] and inspections by HM Inspectorate of Prisons find widespread drug misuse, particularly in male local and category C prisons[10]. To respond to this, the Ministry of Justice (MoJ) and His Majesty's Prison and Probation Service (HMPPS) are investing in a range of interventions to tackle drugs and support offenders with addictions - such as expanding the availability of prison environments that support recovery. Drug misuse in prisons undermines safety for both prisoners and prison staff, as well as the ability of prison staff to deliver effective regimes. Reducing drug misuse is crucial to the safety and stability of our prisons as well as the rehabilitation of prisoners. It perpetuates a cycle of violence, leading to a reduced or unstable regime, through which unpredictability and a lack of purpose can further encourage prisoners to turn to drugs. The debt associated with the supply and distribution of drugs also contributes to violence, intimidation, and self-harm across the estate[11]. Furthermore, the use of new psychoactive substances in prisons has

[6] Dame Carol Black. 'Review of Drugs'. Accessed 20 October 2023 at Microsoft Word - SummaryPhaseOne+foreword200219 (publishing.service.gov.uk)

[7] HM Government. 'From harm to hope'. Accessed 20 October 2023 at From harm to hope: a 10-year drugs plan to cut crime and save lives (publishing.service.gov.uk)

[8] HM Prison & Probation Service. (2019). 'Prison Drugs Strategy'. Accessed 20 October 2023 at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/792125/prison-drugs-strategy.pdf

[9] Ministry of Justice. (2022). 'Identified needs of offenders in custody and the community from the Offender Assessment System, 30 June 2021. Accessed 20 October 2023 at Identified needs of offenders in custody and the community from the Offender Assessment System, 30 June 2021 - GOV.UK (www.gov.uk)

[10] HM Prison & Probation Service. (2019). 'Prison Drugs Strategy'. Accessed 20 October 2023 at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/792125/prison-drugs-strategy.pdf

[11] Hammill, A., & Newby, R. (2015). The illicit economy, debt and prison violence: Is prisoner debt inevitable? *The Prison Service Journal, 221*, 30-35.

been associated with violence.[12,13] To effectively tackle drug misuse, we must address all parts of this cycle and maintain a stable prison environment that encourages prisoners to engage with rehabilitation,[14] in addition to drug treatment and recovery.

ISFLs are dedicated spaces within prisons for prisoners who want to live drug-free. As its name suggests, residents are given incentives (e.g. access to gym equipment, cooking equipment) to remain drug free, alongside undergoing regular drug testing. In an ISFL, new residents sign a compact which outlines expectations for acceptable behaviour and what leads to removal from the ISFL. The creation of a positive and supportive environment by both prisoners and staff is a key factor in the functioning of an ISFL. Therefore, the guidance for ISFLs emphasises the importance of having residents and staff who are both self-motivated and committed to the ethos of ISFLs.

ISFLs follow on from Voluntary Testing Units which were similar spaces introduced in response to the 1998 national drug strategy.[15] These were later reintroduced as ISFLs as part of the 10 Prisons Project (10PP), which was launched in 2018 to reduce violence and drug use. A commitment to the expansion in provision of ISFLs has also been made by the MoJ in the Prison Strategy White Paper[16] and the cross-Government Drug Strategy.[17] Consequently, as of April 2024, there are currently 80 prisons with ISFLs in operation.

We will address the evidence gap on the impact of ISFLs by conducting a pragmatic randomised controlled trial (RCT), which will robustly determine the impact of ISFLs on regime stability and provide novel, high quality evidence.[18] This, in turn, can be used by HMPPS to provide guidance on how ISFLs should operate based on best practice. Currently, ISFLs in operation have been given limited guidance on how they

[12] HM Chief Inspector of Prisons for England and Wales. (2017). 'HM Chief Inspector of Prisons for England and Wales: Annual Report 2016-2017.' Accessed 23 October 2023 at https://assets.publishing.service.gov.uk/media/5a82da01ed915d74e6237f3d/hmip-annual-report-2016-17.pdf

[13] Wheatley, M., Stephens, M., & Clarke, M. (2015). Violence, Aggression and Agitation-What Part Do New Psychoactive Substances Play. *Prison Service Journal*, (221), 5-6.

[14] Mann, R., Howard, F. F., & Tew, J. (2018). What is a rehabilitative prison culture. *Prison Service Journal, 235*, 3-9.

[15] Tackling Drugs to Build a Better Britain (publishing.service.gov.uk)

[16] Ministry of Justice. 'Prisons Strategy White Paper'. Accessed 20 October 2023 at Prisons Strategy White Paper (publishing.service.gov.uk)

[17] HM Government. 'From harm to hope'. Accessed 20 October 2023 at From harm to hope: a 10-year drugs plan to cut crime and save lives (publishing.service.gov.uk)

[18] See Objectives {7} for the full study hypothesis.

should function and what their operating model should look like. This is partly due to the speed at which previous ministerial decisions mandated the roll out of ISFLs, and partly due to the lack of evidence surrounding impact of ISFLs. This means that ISFLs have different operating models across the prison estate.

This trial is being funded by the Evaluation Accelerator Fund (EAF), as part of a wider bid investigating wastewater testing and random mandatory drugs testing. One of the funding requirements is that this impact evaluation must use an experimental design.

Objectives {7}

Our primary research question is:

Do ISFL wings create more stable environments[19] compared to non-ISFL wings? Regime stability will be proxied by the safety metrics of assault and self-harm incidents.

Our hypothesis is that ISFL wings will have more stable environments compared to non-ISFL wings. This will be indicated by a lower risk of assault and self-harm incidents in ISFLs compared to non-ISFL wings in the same prison.

Trial Design {8}

We will conduct a two-arm RCT with the randomisation using a Zelen design. We will aim to establish whether ISFL wings create more stable environments compared to non-ISFL wings using a waitlist design which will randomise prisoners eligible and waiting for a place on an ISFL with a follow-up lasting three months.

Methods: Participants, interventions, and outcomes

Study Setting {9}

The trial is planned to take place across three to five male prisons with an existing ISFL. Given the variability in ISFL models, sites will be selected purposefully to maximise the potential for learning best practice. Previous qualitative work highlighted the main purpose of ISFLs was to provide a settled and supportive

[19] Stable prison environments refer to prison settings where lower/no levels of rule breaking are recorded. This preferred scenario allows for the more effective management prisoners and delivery of prison regime (time out of cell, education, work, etc.).

environment;[20] this is further highlighted in the first mechanism of change from our theory of change. Therefore, sites will be selected initially from a shortlist of prisons with better performing ISFLs in terms of safety metrics, used as a proxy for prison regime stability in the units.

This shortlist was created by assessing sites with ISFL wings that had been open for 6 months or longer. These sites were assessed through assault and self-harm rates of ISFL wings compared to standard wings in the same period, average time spent on ISFL wings, and time to first violent incident. This list was then validated by operational colleagues who advised on variability in how the ISFL wing was functioning from an operational perspective.

Participating prisons will not have a Drug Recovery Wing (DRW) to ensure that there is no disruption to treatment pathways given a period on an ISFL is often the precursor to a prisoner moving onto a DRW.

Prisoner Eligibility Criteria {10}
The prisoner eligibility criteria for the trial are reported below:

Inclusion criteria:

1. Eligible and currently on a waiting list for a place on an ISFL
2. Capacity to provide informed consent if in the intervention arm
3. Is expected to remain within prison custody for the duration of their trial follow up period
4. Willing to sign the behavioural compact for residing on an ISFL (only the intervention group of the trial)

Exclusion criteria:

1. Is expected to be released from custody at some point in the trial follow up period
2. Lacks capacity to provide informed consent

[20] https://www.gov.uk/government/publications/tackling-drug-misuse-in-prisons-a-qualitative-study

3. Individuals identified as having an exceptional requirement for residing on the ISFL without being a part of the evaluation. Identification of these individuals will be discussed and agreed by the data safety monitoring boards (see sections 21 and 22, Data Monitoring and Harms).

Interventions {11a}

Prisoners allocated to the intervention group will move onto an ISFL. Prisoners allocated to the control group will remain on a non-ISFL for the duration of the follow-up period.

Criteria for discontinuing or modifying allocated interventions {11b}

The prison and investigators will remove a participant from the trial if deemed necessary, e.g., if there is a potential safety concern. This will be assessed on an individual basis and decisions will be led by operational staff in the prison where the prisoner resides.

Prisoners may be removed from the ISFL by the prison. Prisoners who leave the ISFL during the trial will be followed up and have their data included in the final analysis.

Strategies to improve adherence to interventions {11c}

Each ISFL has a compact that the prisoners are required to sign. This is a type of contract which outlines expectations of the prisoner moving onto the ISFL. The compact provides explicit guidance on expected standards of behaviour and conduct whilst on the ISFL. To deter prisoners from engaging in undesirable behaviour, a consequence of failing to abide by the compact could result in a prisoner being moved from an ISFL to a non-ISFL wing. It is expected that this should be enforced on a case-by-case basis considering prisoners personal circumstances and recovery needs.

Relevant concomitant care permitted or prohibited during the trial {11d}

This trial will not prohibit the provision of any required care to prisoners. The healthcare and treatment ISFL prisoners access will be equivalent to that available on non-ISFL wings. Similarly, prisoners allocated to the control group will continue to have access to existing privileges, that would normally be available to them. The sole restriction to the control group is access to the living on the ISFL wing for the duration of the trial.

Outcomes {12}

Primary outcome measure:

Our primary outcome measure is time to assault incident[21] during the follow-up period. Any assault incident where a prisoner in the trial is classed as a victim will not be counted. Incidents are recorded by prisons on the HMPPS Incident Reporting System (IRS). We have chosen this measure as it will serve as a proxy to assess the stability of prison environments. The trial will evaluate the first mechanism of change outlined in the Theory of Change for ISFLs which was developed by operational, analytical and policy colleagues (see Appendix 1). The mechanism of change proposes that if ISFLs provide a safe, stable and enabling environment, prisoners will have time and space to focus on their recovery and development. The Theory of Change also illustrates a pathway where fewer incidents of assault on ISFLs (a short-term outcome) contributes to increased regime stability (a long-term outcome). This in turn leads to safer and more secure prisons which is an ultimate policy aim. Similarly, previous research on drug recovery wings (DRWs) sought to collect data on incidents of assault as a measure of 'safer and calmer wings'.[22] However, they were not included in the final analysis due to issues with data collection.

Data relating to incidents of assaults is routinely recorded on IRS and audited by the prison and HMPPS so it provides a convenient and reliable measure of assaults. By using assault incidents, a routinely collected data source, we avoid relying on a measure that may introduce a behaviour change in prisoners (i.e., Hawthorne effect). This concern may have arisen if we solely depended on a non-standard data source, such as voluntary drug testing, which is also only available for one group in the trial. Using assault incidents is congruent with the trial design. Other relevant metrics such as recidivism do not fit into the timeframes for this trial.

Secondary outcome measures:

We will include time to self-harm incidents as a secondary outcome measure. These are recorded in the same way as assault incidents on IRS, as described previously.

[22] Powis, B., Walton, C., & Randhawa, K. (2014). Drug recovery wings set up, delivery and lessons learned: Process study of first tranche DRW pilot sites. Ministry of Justice Analytical Series.

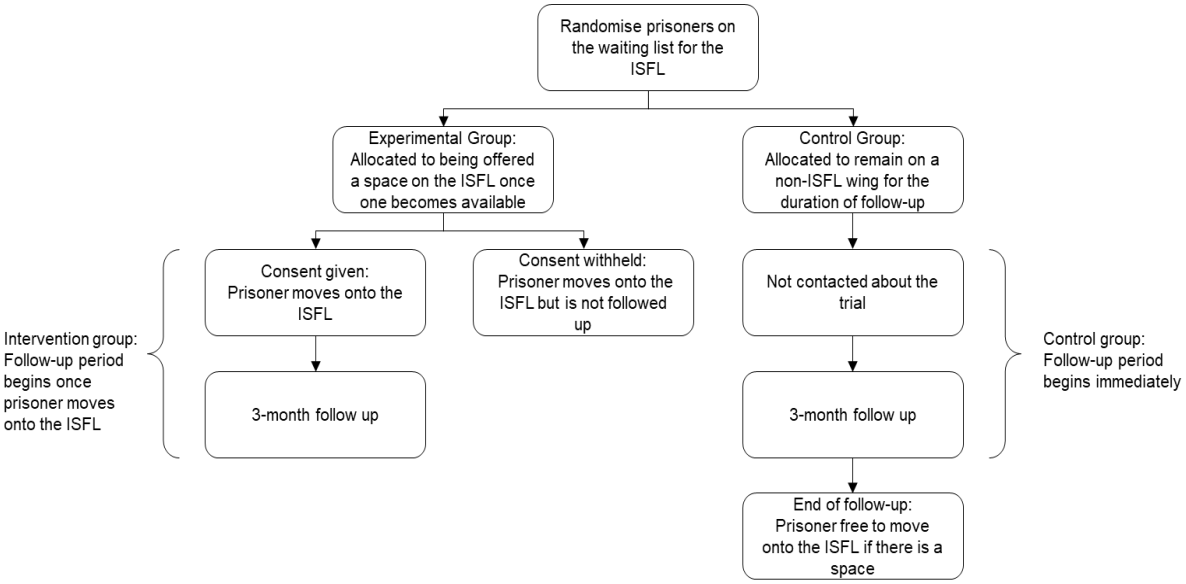
As shown in the Theory of Change, self-harm incidents follow the same pathway as assault incidents.

Where possible we will record the outcomes of voluntary drug testing as a descriptive measure, this outcome is likely to only be available for the ISFL arm. Comparisons will remain descriptive and not be inferentially tested due to the following caveats: (1) prisoners on ISFL waiting lists may change their behaviour if voluntary drug testing is introduced and, (2) the capacity for voluntary drug testing will not be prison wide, which would limit the ability to compare the intervention and control groups.

Participant Timeline {13}

An overview of the participant timeline is provided in Figure 10.[23]

Figure 10. Overview of the trial which uses the Zelen design.



Sample Size {14}

Our primary approach to analysis will use a Bayesian approach. As Bayesian inference does not make the same assumptions as frequentist approaches. Power, in terms of minimising type 2 errors, is not required as a design aspect. Despite this,

23 As per Consent {16 a-b} the control group will not be made aware of the trial, earlier unpublished research has identified resentment between ISFL and non-ISFL residents. To mitigate this, we will not approach the control group for consent as the trial will cause no change to their environment. After 3 months, prisoners in the control group will be released and will be free to join the waiting list for an ISFL place.

we have used simulations to understand how sample size would alter conclusions under a frequentist paradigm.

Previous observational analysis, which collated data from 23 prisons with ISFLs, observed a hazard ratio (effect size) of 0.36 for assault incidents which we used as a reference point for our analysis. Using the simsurv package[24] we created 1,000 random datasets for each combination of a range of effects sizes and sample sizes. The effect sizes included 0.20, 0.25, 0.30, 0.35, 0.40, 0.45, 0.50, 0.60, and 0.70. The sample sizes were 20, 30, 40, and 50 prisoners (split equally between the intervention arm (ISFL) and control arm (non-ISFL). These proposed sample sizes were based on understanding of current ISFL waiting list sizes within the prisons, which tended to vary between 5 and 20. Survival models (cox proportional hazard model and exponential model) were then fitted to the simulated data sets and statistical significance assessed ($p < 0.05$). The power for each sample size and effect size was then calculated as the proportion of samples returning a significant result. This was then repeated 5 times and the average power of the repetitions taken.

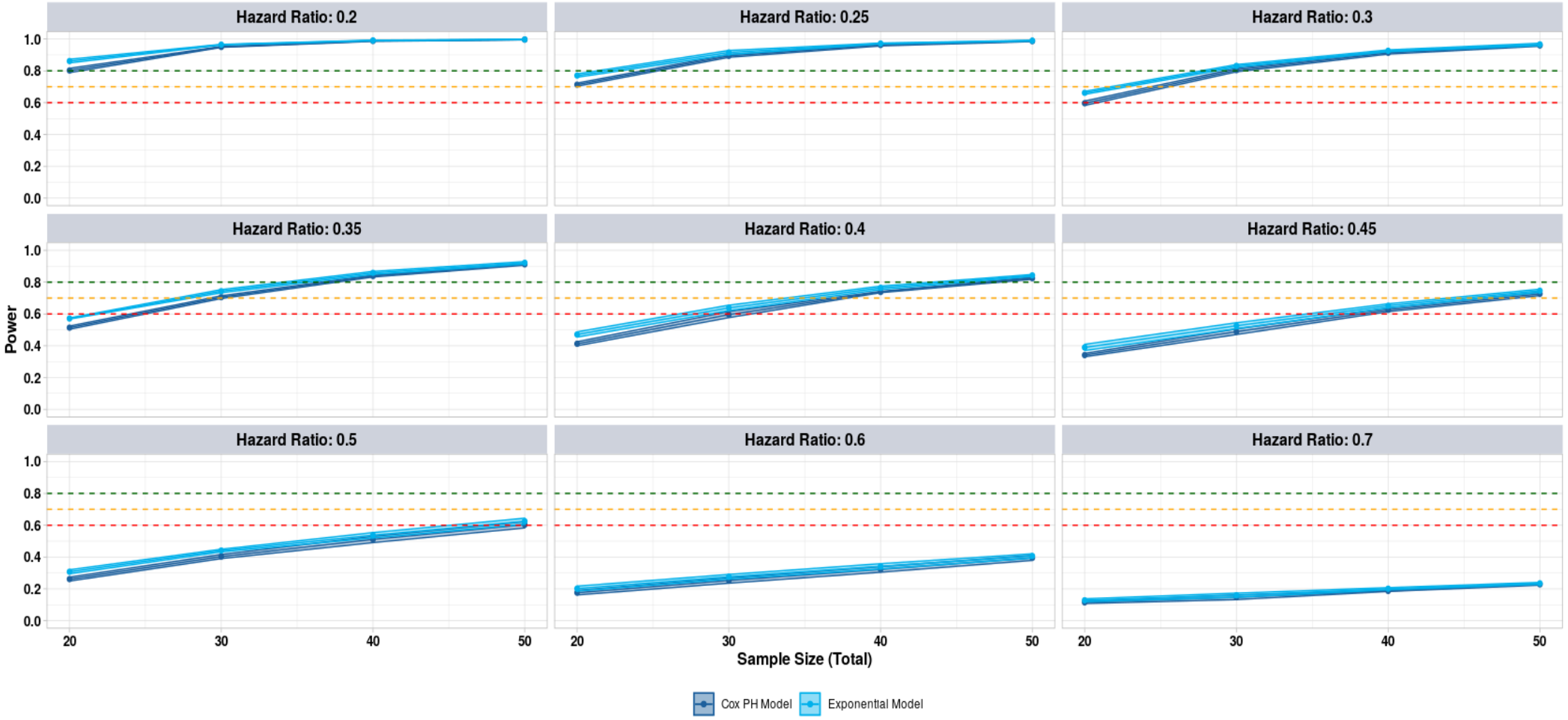
During the trial, the investigators will review recruitment where necessary and consider the impact this may have on interpretation of results.

Figure 11 shows the power curves resulting from the simulations. From these curves we see that a sample size of 30 would provide over 70% power for an effect size ranging between 0.2 and 0.35.

24 Brilleman SL, Wolfe R, Moreno-Betancur M, Crowther MJ (2020). “Simulating Survival Data Using the simsurv R Package.” Journal of Statistical Software, 97(3), 1–27. doi:10.18637/jss.v097.i03.

During the trial, the investigators will review recruitment where necessary and consider the impact this may have on interpretation of results.

Figure 11. Power curves for simulated datasets, showing expected statistical power for a range of effect sizes.



Recruitment {15}

We will start by recruiting prisoners from three of the sites shortlisted. If recruitment is slow or if the spaces on an ISFL become available infrequently, we will look to include other short-listed sites.

Methods: Assignment of Interventions

Allocation: Sequence generation {16a}

Randomisation will occur prior to informed consent, as is consistent with the Zelen design (discussed in the trial design section and depicted in figure 1), and prisoners will be allocated in a 1:1 ratio. The randomisation sequence will be generated using the crPar function from the R package randomizeR.[25] This implements a complete randomisation algorithm.

Allocation: Concealment mechanism {16b}

An analyst independent of the study will hold the randomisation sequence in a secure and private location. They will ensure this remains concealed from operational staff and the evaluation team.

Allocation: Implementation {16c}

The evaluation team will work with operational staff to identify a waitlist for the ISFL at each prison. When this waitlist is identified a pseudonymised identifier will be assigned to participants and the mapping list kept by evaluation team. The identifiers will be passed to the independent analyst who will work through the list in order and assign consecutive prisoners to study arms as defined by the randomisation list.

Blinding {17a-b}

The study will be an open-label trial, with evaluators knowing who is in the control and intervention arms; prisoners will also be aware of which wing they are residing on. An analyst external to the immediate evaluation team will be responsible for conducting the analysis. This analyst will be blinded to which group the data has comes from.

[25] D. Uschner, D. Schindler, R. D. Hilgers and N. Heussen (2018). "randomizeR: An R Package for the Assessment and Implementation of Randomization in Clinical Trials." *Journal of Statistical Software, 85*(8), pp. 1-22. doi: 10.18637/jss.v085.i08

Methods: Data collection, management, and analysis

Data Collection Methods {18a-b}

All prisoners are allocated a unique identifying number upon arrival in HMPPS custody. This is known as a NOMIS number and can be used to identify prisoners' involvement in any reported incident occurring in a prison. After identification of prisoners on the waitlist, prison staff will be asked to provide a list of NOMIS numbers for each participant to the evaluation team.

At regular intervals during the evaluation follow-up period, the incident reporting system will be filtered for any assault and self-harm incidents involving the prisoners in the trial. For assault incidents this will only include incidents where the prisoner was not a victim. All incidents must have occurred during the trial, after randomisation, and after consent is obtained (where appropriate).

Data Management {19}

Incidents in prison are recorded centrally on the NOMIS Incident Reporting System. The evaluation team will make regular checks of the incident reporting system to create a separate study database of any incidents involving prisoners in the study. An anonymised version of this database will be created at the end of the study, which access will be given to a blinded analyst.

Statistical Methods {20a-c}

Data will be analysed using an intention-to-treat approach (i.e. participants will be analysed in the group they were randomised to regardless of adherence). Given a requirement for inclusion is that prisoners must be expected to remain in custody for the duration of evaluation follow up we do not envision any loss to follow up. Data is recorded centrally across all prisons, so relevant outcome measures can be collected if prisoners move prison. If a prisoner is released from custody during the evaluation, then this will indicate a censoring event for the primary outcome measure and other time-to-event data. Other outcome measures will provide descriptive results only, so techniques to handle missing data would not be necessary. The extent of loss to follow up will be reported in the final manuscript.

The impact of missing data will be continuously monitored for the duration of the evaluation and approaches will be adapted if necessary to account for unanticipated loss to follow up.

No planned subgroup analyses have been proposed.

Primary outcome measure

Analysis of the primary outcome measure will utilise parametric survival analysis techniques. Specifically, an exponential survival model will be fitted. Inference will be made using a Bayesian approach, with sensitivity analyses applied using different priors. Specifically, an optimistic prior (based on unpublished observational analysis), a pessimistic prior (assuming only a negligible improvement), and a moderate prior will be used to challenge conclusions made based on data collected during the study.

The main aim of the study is to understand the impact of ISFL's on prison regime stability. In this regard, time to an incident is an important aspect of regime stability as we would expect that more stable, supportive environments would likely delay violent incidents if not reduce them. This is an anticipated benefit of greater community support which would add social pressures to avoid engaging in violent behaviours. In addition to this, given the higher probability of violence occurring within prison, a delay in violence is a positive, desirable outcome.

Secondary *outcome* measures

For secondary outcome measures with time to event outcomes (e.g., time to self-harm incident), data will be analysed in a similar approach to that for the primary outcome measure. Other secondary outcome measures will be summarised and reported descriptively only.

Methods: Monitoring

Data Monitoring {21a-b}

An explicit data monitoring committee will not be present, instead, the evaluation team will present interim analysis reports to internal boards (Evaluation Task Force and Cabinet Office) and a working group. The working group will consist of researchers from the

evaluation team, policy, and operational colleagues from the MoJ, and external health colleagues from the NHS. These reports will be produced during the running of the trial and at an early stage of the analysis. The results from the interim analysis will also feed into the data safety board which will be created to monitor potential adverse effects to prisoners (see Harms {22}).

Harms {22}

A data safety board will be created for the trial for each site within the sample. It is envisioned that this board will consist of representatives from the establishment, policy, and operational colleagues from MoJ, the NHS, the evaluation team. The data safety board will allow a dual pathway for the reporting of any serious adverse events by sites and abnormal data trends by the evaluation team. It is not expected that prisoners will be subjected to a greater level of danger in either the control or experimental group. The control group will be subjected to business as usual, with the only restriction being access to the ISFL. The data safety board will ultimately have the power to stop the trial.

Auditing {23}

Trial auditing will be completed through two main streams: monitoring abnormal data trends and a fidelity checklist. The evaluation team will monitor data trends during the running of the trial. Any points for concern will be raised in the data safety board and/or working group. We will consider raising points that relate to participant safety, the integrity of the trial, and validity of the data. For instance, data may show an increased number of prisoner movements off ISFL wings, which may be indicative of prisoners not following or understanding the behavioural compacts that were signed.

The second stream consists of a fidelity checklist. This checklist will be offered to sites to ensure that the ISFL wing is operating in line with core criteria. Whilst flexibility will exist to help accommodate operational realism, the fidelity checklist will ensure that the sites selected remain operating similarly to one another.

Ethics and Dissemination

Research Ethics Approval {24}

The trial has undergone internal Analytical Quality Assurance (AQA) processes. These are a set of internal guidelines within the MoJ that ensures quality research is delivered in a

timely manner, is of sufficient scientific quality, and delivers the intended outputs. Feedback on ethics has also been sought through the Ethics Advisory Group, a MoJ board of researcher and analysts. Advice from the board has been actioned where necessary. Lastly, the NHS decision tool was used to determine whether the trial required a review by an NHS Research Ethics Committee. Whilst the decision tool stated that it was not necessary, colleagues in NHS England were consulted, resulting in changes to the trial design to ensure clinical services would not be disrupted.

Protocol Amendments {25}

A fortnightly working group meeting with policy and operational colleagues will be used to discuss any abnormal data trends and discussion points to the protocol. A data safety board will also be created, with an external chair, which will include representatives from the sites in the trial. This data safety board will also have the ability to recommend stopping of the trial if adverse effects are found. Lastly, a wider working group will be used to keep NHS, senior operational, and senior policy colleagues informed of any risks and changes to the protocol that relate to the health of prisoners and wider operational issues.

Consent {26 a-b}

As per the trial design {8}, informed consent will only be sought from the experimental arm. After prisoners are randomised from the waiting list for ISFL wings, they will be approached by the evaluation team for informed consent to participate in the trial. If consent is obtained, they will move onto the ISFL wing. If consent is withheld, the prisoner will still progress onto the ISFL wing but their data will not be collected or included in the analysis. Lastly, prisoners randomised to the control group, will remain on the non-ISFL wing and not be approached for consent, and will be unaware they are in the trial.

Confidentiality {27}

Prisoner ID numbers will be collected from NOMIS (National Offender Management Information System) in order to analyse effects on stability of the prison regime (assaults). Statistics will not be presented on an individual basis to protect anonymity. Datasets and results will be archived in line with MoJ retention policy.[26]

26 Information Wise — What to keep (publishing.service.gov.uk)

Declaration of Interests {28}

No interests to declare.

Access to Data {29}

Access to the final trial dataset will only be permissible by the in-house trial team. There are no external contractors involved on the trial.

Ancillary and Post-trial Care {30}

Prisoners in the trial will not be subjected to any additional experimental measures (other than restriction to the ISFL wing for prisoners in the control group), therefore no post-trial care will be implemented. Access to any healthcare services, support services, or legal pathways will remain universal and consistent for all prisoners participating in the trial, in line standard prison procedures.

Dissemination Plans {31a}

Publication of the trial report will abide by government research guidelines and will be made publicly available on the MoJ research page. The trial team will retain responsibility of the report authorship. There is also scope to present preliminary monitoring data and early analysis to internal boards during the respective trial and analysis stages, which will be explored at the request of the sponsor.

Author Contributions {31b}

Authorship of the report will remain with the trial team and will be independent from the sponsor. No professional writer resource will be used. All authors are part of the trial working group, with key roles in developing and facilitating the conduct of the trial. Individual contributions to the trial protocol are as follows:

- Gurmukh Panesar – Methodology development, manuscript drafting and editing.
- Maika Terashima – Methodology development, manuscript drafting and editing.
- Lucy Cuppleditch – Conceptualisation, methodology development, manuscript review and editing.
- Jo Voisey – Conceptualisation, methodology development, manuscript review and editing.

- Barnaby Elwes – manuscript review and editing.
- Giles Stephenson – manuscript review and editing.
- Lauren Withall – manuscript review and editing.
- Nick Harris – manuscript review and editing.
- Katie Lawley– manuscript review and editing.
- Jason Hancock – manuscript review and editing.
- Mike Wheatly – manuscript review and editing.
- Darren Churchward – Conceptualisation, methodology development, manuscript drafting and editing.

Accessing Participant Level Data, Protocol, and Statistical Code {31c}

Both the finalised report and the protocol paper will be published publicly through government research guidelines. Statistical code and participant level data will be archived in line the MoJ retention policy.