Statistical Analysis Plan (SAP)

Testing a new method to improve informed consent in prison research

Spark BATIR

Administrative Information

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Revision	Justification	Timing

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Abbreviations

AE	Adverse event
CI	Confidence Interval
FAIR	Findable, Accessible, Interoperable and Re-usable
FAS	Full Analysis Set
HRA	Federal Act on Research involving Human Beings
ICE	Intercurrent Event
ITT	Intention To Treat
MAR	Missing At Random
MICE	Multiple Imputation with Chained Equations
PI	Principal Investigator
PP	Per Protocol
RCT	Randomised controlled trial
SAE	Severe Adverse Event
SAF	Safety Population
SAP	Statistical Analysis Plan
SMD	Standardised Mean/Proportion Difference

Contents

1. Introduction 6
1.1 Background and rationale 6
1.1.1 The challenges of informed consent 6
1.1.2 Investigational intervention 6
1.1.3 Rationale for the dosage, route, regimen 6
1.1.4 Explanation for choice of comparator 6
1.2 Objectives 7
1.2.1 Overall Objective 7
1.2.2 Primary Objective 7
1.2.3 Secondary Objectives 7
1.2.4 Safety Objectives 7
1.3 Timing of SAP writing 7
2. Study Methods 7
2.1 Trial design 7
2.2 Randomisation 7
2.3 Sample size 7
2.4 Framework 7
2.5 Statistical interim analyses and stopping guidance 8
2.6 Timing of final analysis 8
2.7 Timing of outcome assessments 8
2.8 Blinding 8
3. Data Management 8
3.1 Data export 8
3.2 Data validation 8
3.3 Data preparation 8
3.4 Data sharing 8
4. Statistical Principles 8
4.1 Confidence intervals and *P* values 8
4.2 Analysis populations 8
4.2.1 Randomized Population 8
4.2.2 Full analysis set (FAS) 9
4.2.3 Per-protocol Set (PP) 9
4.2.4 Safety population (SAF) 9
4.3 Estimands 9
4.3.1 Primary estimand 9
4.3.2 Secondary estimands 10
4.3.3 Relationship between estimands and analysis sets 11
4.3.4 Sensitivity and supplementary estimands 11
4.4 Handling of missing data 11
4.4.1 Missing outcome data for primary and secondary estimands 11
4.4.2 Missing baseline covariates 11
4.4.3 Relationship between missing data handling and intercurrent events 11
4.4.4 Sensitivity Analyses for Missing Data 11
5. Trial population 11
5.1 Screening data 12
5.2 Eligibility 12
5.3 Baseline patient characteristics 12
5.4 Adherence and protocol deviations 12
5.5 Withdrawal 12
6. Analysis 12
6.1 Outcome definitions 12

6.1.1 Primary Outcome 12
6.1.2 Secondary Outcomes 13
6.1.3 Other Outcomes of Interest 13
6.1.4 Safety Outcomes 13
6.2 Analysis methods 13
6.2.1 Primary analysis 13
6.2.2 Secondary analyses 13
6.2.3 Sensitivity analyses 13
6.2.4 Subgroup analyses 13
6.2.5 Additional analyses 13
6.2.6 Assessment of statistical assumptions 14
6.3 Interim analyses 14
6.4 Missing data 14
6.5 Safety evaluation 14
6.6 Subproject (if applicable) 14
6.7 Statistical software 14
6.8 Quality control 14
7. Changes from the protocol 14
8. References 14

1. Introduction

1.1 Background and rationale

1.1.1 The challenges of informed consent

Informed consent is an ethical cornerstone of health research. It was first developed in 1947 in the Nuremberg Code (1) and it is now defined in international guidelines (2). In Switzerland, Art. 16 of the Federal Act on Research Involving Human Beings (HRA) requires researchers to provide participants with comprehensive information on the purpose of the study, its risks and benefits, data protection and participants' rights. Participants must also be given sufficient time to reflect on this information (3).
Despite these requirements, comprehension remains poor. A systematic review found that around half of participants understood core concepts such as voluntary participation and the right to withdraw, but had a much poorer understanding of technical concepts such as randomisation, placebos and side effects (4). In Switzerland, consent forms are often considered too long and complicated (5).
These challenges are exacerbated in prison settings, a context that may undermine voluntariness and autonomy (6, 7). Furthermore, prison populations have disproportionately high rates of low literacy, cognitive impairment and psychiatric conditions, all of which hinder comprehension (6, 8, 9). The few studies conducted in this context consistently report low levels of understanding of informed consent (6-8).
Of the various strategies designed to enhance comprehension, extended discussions and the 'teach-to-goal' approach have demonstrated effectiveness in randomised controlled trials (RCT) (10, 11). This iterative method involves taking a quiz, followed by targeted corrections and re-testing until full understanding is achieved (6). To our knowledge, it has not yet been evaluated using a rigorous RCT design.
To address this, this RCT will compare a modified 'teach-to-goal' approach with standard informed consent procedures within an existing RCT aimed at improving psychiatric outcomes in detained individuals ('parent RCT') (12). This design will provide real-world evidence on the quality of consent while ensuring that the ethical requirements of the parent RCT are met.

1.1.2 Investigational intervention

The intervention consists of a modified teach-to-goal informed consent process. The informed consent materials from the parent RCT were used. After following the standard consent procedure (see section 1.1.4), the interviewer asked the participant to summarise the content of the informed consent. Misunderstood or forgotten components were corrected or prompted. In case of misconceptions, the participant was asked to re-summarise the components. This iterative process continued until adequate understanding was achieved. A checklist of key components, developed by study team members including experts in prison research and ethics and based on Art. 16 of the HRA guided the discussion.

1.1.3 Rationale for the dosage, route, regimen

Not applicable.

1.1.4 Explanation for choice of comparator

The standard informed consent process was used as the comparator. This process is legally required under Art. 16 of the HRA and is therefore the current standard of practice against which modified teach-to-goal informed consent was compared. The interviewer explained the nature of the study, its purposes and duration, and the potential risks and benefits involved. They informed participants that study participation was voluntary and that they could withdraw at any time. They also explained that the study was independent from the prison authorities. Participants were then given enough time to read the informed consent form. If they were unable to read, the interviewer read it to them. The interviewer answered all questions.

1.2 Objectives

1.2.1 Overall Objective

This project aimed to estimate and improve understanding of informed consent in prison research.

1.2.2 Primary Objective

O1. The study compared a modified teach-to-goal versus a standard informed consent process on the understanding of informed consent.

1.2.3 Secondary Objectives

O2. The study compared a modified teach-to-goal versus a standard informed consent process on the level of understanding of informed consent.
O3. The study compared a modified teach-to-goal versus a standard informed consent process on the evaluation of informed consent.

1.2.4 Safety Objectives

Not applicable.

1.3 Timing of SAP writing

This SAP version was written and finalized before enrolment of participants was finished.

2. Study Methods

2.1 Trial design

This was a monocentric, cross-sectional, open-label, superiority RCT with parallel assignment. The trial compared a modified teach-to-goal informed consent process against a standard informed consent process on understanding and evaluation of the informed consent, assessed immediately after the consent procedure.

2.2 Randomisation

The trial statistician randomised the sequence using a generated list (R software). The ratio between the two arms was 1:1 with a block size of 4. The study team received a list with sequential numbering. Each eligible participant was assigned a unique randomisation number that corresponds to the lowest number available on the list. Allocation was made by the interviewer.

2.3 Sample size

Participants were incarcerated in four prisons in Geneva, but on average, we expected no difference between participants in these prisons. Based on the previous Swiss study (8), we assumed a mean understanding rate of 58% (standard deviation= 21%) in the control group. Drawing on the meta-analysis of extended-discussion interventions (10), we expected a 14-percentage-point improvement in the intervention group (72%). Using a two-sided independent-samples *t* test with equal variances α=.05, 1-ß=.80, allocation 1:1, G*Power 3.1 indicated that 74 participants were required (37 per group). To account for potential withdrawal, the sample size was rounded to n=100 (50 in each group).

2.4 Framework

This was an open-label superiority randomised controlled trial, comparing participants who received the modified teach-to-goal informed consent process to those who received the standard informed consent process.

2.5 Statistical interim analyses and stopping guidance

No interim analysis was planned nor performed.

2.6 Timing of final analysis

All outcomes will be analysed after study completion, once the database is cleaned, validated, and locked.

2.7 Timing of outcome assessments

All outcomes are assessed immediately after the intervention, using a cross-sectional design.

2.8 Blinding

This was an open-label study.

3. Data Management

3.1 Data export

During data collection, data are hosted in the REDCap® database system of the University of Bern. The database will be exported as a CSV file and imported in Stata 19 or R 4.5.2 (or more recent versions) for analyses. Data will be stored on the server of the University of Lausanne.

3.2 Data validation

Central data monitoring is performed by Yekaterina Prutyanova. Data will be cleaned and validated by the biostatistician Stéphanie Baggio. We will check for outliers, implausible values, and missing data, as well as inconsistencies. We will particularly check outcomes.

3.3 Data preparation

Outcomes will be created as explained in section 6.

3.4 Data sharing

Once the statistical analysis completed, data will be prepared for sharing and storage. Documents will include database and metadata (e.g., statistical analysis plan (SAP), codebook, and statistical code). They will be shared on Findable, Accessible, Interoperable and Re-usable (FAIR) data repository unless the participant refuses reuse of their data for research purposes. Data will be available upon request to the principal investigator (PI), as it includes sensitive data from vulnerable participants.

4. Statistical Principles

4.1 Confidence intervals and *P* values

For all statistical analyses, we will use a two-sided α=.05. When appropriate, 95% confidence intervals (CI) will be reported. We will use a Bonferroni-Holms adjustment in case of multiple testing.

4.2 Analysis populations

4.2.1 Randomized Population

The randomised population consists of all participants who are randomised, irrespective of whether they receive the assigned study treatment. This population defines the target population for all estimands unless otherwise specified.

4.2.2 Full analysis set (FAS)

The Full Analysis Set (FAS) includes all randomised participants. Participants will be analysed according to the group to which they were randomised, regardless of withdrawal or protocol deviations. Analyses will follow the intention-to-treat (ITT) principle, with participants analysed according to their assigned group.
The primary estimand targets the effect of the assignment to the intervention compared with control in the randomised population, regardless of intercurrent events (ICEs) such as protocol deviations (treatment policy estimand). The FAS is used for the estimation of the primary estimand and all secondary estimands unless explicitly stated otherwise.

4.2.3 Per-protocol Set (PP)

No PP analysis set is defined. Analyses based on subsets of participants defined by post-randomisation characteristics (e.g., absence of protocol deviations) may lead to loss of comparability between treatment groups and are therefore not considered appropriate for primary estimation of treatment effects.
ICEs include:
ICE1: Non-respect of the intervention strategy, including for example refusing to participate in the modified teach-to-goal procedure in the intervention group.
ICE2: Protocol deviations.
ICE3: Terminal events, such as death.

4.2.4 Safety population (SAF)

Not applicable.

4.3 Estimands

4.3.1 Primary estimand

The primary estimand targets the effect of the modified teach-to-goal procedure or standard consent process on the understanding of the understanding of informed consent (O1). The attributes of the primary estimand are defined as follows:

- Intervention groups: receive the modified teach-to-goal procedure in addition to the standard informed consent process or receive the standard informed consent process alone.
- Target population: All randomised participants (ITT).
- Variable (endpoint): binary indicator of the understanding of the informed consent: 1 if all questions are answered correctly, and 0 otherwise.
- ICEs and handling strategy: ICEs will be handled using a treatment policy strategy. The outcome is defined irrespective of the occurrence of these ICEs.
- Population-level summary: Adjusted* odds ratio of understanding of the informed consent between groups.

* Adjusted for baseline characteristics selected based on a literature review: age, level of education, nationality, marital status, and legal status (8, 13). Gender will not be included as a covariate because the number of women is expected to be very low. If there are 15 women or more, gender will be added in the adjusted model.
If a covariate has a very low variance (e.g., < 15 cases for binary variables), the variable will be removed from the model. For categorical variables (e.g., level of education, nationality, marital status, and legal status), broader categories may be created. We do not expect lack of variance for continuous variables (age). In case of multicollinearity, one colinear variable will be removed based on theoretical reasons.
If the outcome's variance is too low, a Firth's penalised logistic regression will be used.

4.3.2 Secondary estimands

The first secondary estimand targets the effect of the modified teach-to-goal procedure or standard consent process on the level of understanding of informed consent (O2). The attributes of this secondary estimand are defined as follows:

- Intervention groups: receive the modified teach-to-goal procedure in addition to the standard informed consent process or receive the standard informed consent process alone.
- Target population: All randomised participants (ITT).
- Variable (endpoint): continuous variable of the understanding of the informed consent: sum score of the 20 binary (true/false) questions (score 0-20).
- ICEs and handling strategy: ICEs will be handled using a treatment policy strategy. The outcome is defined irrespective of the occurrence of these ICEs.
- Population-level summary: Adjusted* slope of understanding of the informed consent between groups.

* Adjusted for baseline characteristics selected based on a literature review: age, level of education, nationality, marital status, and legal status (8, 13). Gender will not be included as a covariate because the number of women is expected to be very low. If there are 15 women or more, gender will be added in the adjusted model.
If a covariate has a very low variance (e.g., < 15 cases for binary variables), the variable will be removed from the model. For categorical variables (e.g., level of education, nationality, marital status, and legal status), broader categories may be created. We do not expect lack of variance for continuous variables (age). In case of multicollinearity, one colinear variable will be removed based on theoretical reasons.
If the assumptions of the linear regression are not met due to skewness, we will use the following modelling alternatives. If the outcome is positively skewed, we will use a negative binomial regression. If the outcome is negatively skewed, we will use the quartiles to derive a 4-category outcome and use an ordered logistic regression.

The second secondary estimand targets the effect of the modified teach-to-goal procedure or standard consent process on the evaluation of informed consent (O3). The attributes of this secondary estimand are defined as follows:

- Intervention groups: receive the modified teach-to-goal procedure in addition to the standard informed consent process or receive the standard informed consent process alone.
- Target population: All randomised participants (ITT).
- Variable (endpoint): continuous variable of the evaluation of the informed consent: sum score of the 10 questions assessed on a 6-point Likert scale (score 0-50).
- ICEs and handling strategy: ICEs will be handled using a treatment policy strategy. The outcome is defined irrespective of the occurrence of these ICEs.
- Population-level summary: Adjusted* slope of evaluation of the informed consent between groups.

* Adjusted for baseline characteristics selected based on a literature review: age, level of education, nationality, marital status, and legal status (8, 13). Gender will not be included as a covariate because the number of women is expected to be very low. If there are 15 women or more, gender will be added in the adjusted model.
If a covariate has a very low variance (e.g., < 15 cases for binary variables), the variable will be removed from the model. For categorical variables (e.g., level of education, nationality, marital status, and legal status), broader categories may be created. We do not expect lack of variance for continuous variables (age). In case of multicollinearity, one colinear variable will be removed based on theoretical reasons.
If the assumptions of the linear regression are not met due to skewness, we will use the following modelling alternatives. If the outcome is positively skewed, we will use a negative binomial regression. If the outcome is negatively skewed, we will use the quartiles to derive a 4-category outcome and use an ordered logistic regression.

4.3.3 Relationship between estimands and analysis sets

The primary and secondary estimands are estimated using the FAS (ITT), which includes all randomised participants analysed according to their randomised treatment assignment. This analysis set is aligned with the treatment policy strategy adopted for handling ICEs.

4.3.4 Sensitivity and supplementary estimands

The estimands defined in this SAP are aligned with the study objectives and are intended to support inference on the effect of the modified teach-to-goal inform consent process. Sensitivity analyses will be conducted to assess the robustness of conclusions to alternative assumptions regarding missing data and analytical choices, while targeting the same estimands as the primary analysis.

4.3.4.1 Sensitivity analyses

For the secondary outcomes, in case of negative skewness, we will use the median as the cut-point and a logistic regression model to test whether results of the ordered logistic regressions are robust. Additional sensitivity analyses will account for potential heteroscedasticity using robust standard errors.

4.3.4.2 Supplementary estimands

Not applicable.

4.4 Handling of missing data

4.4.1 Missing outcome data for primary and secondary estimands

Missing outcome data may arise due to withdrawal or refusal to answer some questions.
The primary way to handle missing values in ITT analyses will be multiple imputation with chained equation (MICE). Imputation will be performed under the assumption that data are missing at random (MAR), conditional on the variables included in the model.
Fifty imputation datasets will be created and results pooled using Rubin's rule. The number will be increased to one hundred if the fraction of missing information is high (≥ 50%). The following auxiliary variables will be used to predict missingness: age, level of education, nationality, marital status, and legal status. Terminal events such as death will be used as auxiliary variables.

4.4.2 Missing baseline covariates

Missing baseline covariates, if any, will be handled using MICE. It will be performed independently of treatment group and outcome data, using other baseline covariates (see above).

4.4.3 Relationship between missing data handling and intercurrent events

ICEs such as protocol deviations will be addressed through the definition of the estimands using a treatment policy strategy and do not, in themselves, define missing data.
Missing data methods will be applied only to address incomplete observation of outcome data that are relevant to the estimands.

4.4.4 Sensitivity Analyses for Missing Data

We will conduct a tipping-point analysis to assess the influence of missing values on our conclusion for the primary outcome.

5. Trial population

Data were collected in four prisons for which the Division of Prison Health provides health care, among sentenced and pre-trial detained persons located in Geneva: Champ-Dollon, La Brenaz, Villars, and

Vallon (n=100). The study was considered as monocentric, as the same team collected data in these prisons.

5.1 Screening data

Not available.

5.2 Eligibility

Inclusion criteria are: 1) being screened in the parent RCT; 2) age ≥18 years; 3) good command of French; 4) absence of an acute psychiatric disorder; and 5) provision of written informed consent to participate in the parent RCT.
No exclusion criteria were applied.
A CONSORT patient flow diagram will be drawn.

5.3 Baseline patient characteristics

Baseline parameters will be presented as means and standard deviations for continuous variables, or percentages and n for categorical variables. In case of non-normal distributions for continuous or count variables, we will present medians and interquartile ranges. Whenever relevant, 95% CI will be reported. The baseline table will include standardized mean/proportion differences (SMD) (Cohen's d) to have an overview of the balance between groups, but no p-values or confidence intervals. A SMD of 0.1 will be considered as achieved balance between groups.

5.4 Adherence and protocol deviations

Protocol deviations and ICEs will be summarized by percentages and n in each group. As the study was cross-sectional with a one-time intervention, adherence is not relevant.

5.5 Withdrawal

Participants may withdraw from the study in case of:

- Withdrawal of consent
- Occurrence of a or SAE

Participants will be analysed in their initial study group (ITT analyses).
Although no study-specific safety outcomes are anticipated, participants may withdraw from the study if they experience any (S)AEs during the study, in accordance with institutional procedures. In case of withdrawal due to an (S)AE, the study team will make every effort to collect information. Withdrawn participants will not be replaced. The sample size calculation took attrition into account and MICE will be used to handle missing values.
Withdrawal from the study will be summarized by percentage and n in each group.

6. Analysis

6.1 Outcome definitions

6.1.1 Primary Outcome

Understanding of the informed consent (binary): The primary outcome is the participant's understanding of the informed-consent information, assessed using a 20-item questionnaire consisting of true/false questions. Answers "I don't know" is considered as an incorrect answer. The questionnaire assessed understanding of the key elements of the informed-consent process, including the study's purpose and procedures, duration, potential risks and benefits, data protection measures, voluntary participation, and the participant's right to withdraw. The questionnaire has been developed by experts in prison research and ethics and has been pretested on the targeted population. A binary variable coded 1 if all questions are answered correctly and 0 otherwise will be computed. A stringent all-or-none definition

was chosen because informed consent relies on a full understanding of all the key components included in the questionnaire. Its psychometric properties will be explored using an exploratory factor analysis.

6.1.2 Secondary Outcomes

Understanding of the informed consent (continuous): A secondary outcome is the participant's understanding of the informed-consent information, assessed using the same questionnaire described in 6.1.1. A continuous variable will be computed as the sum of correctly answered items, yielding a score ranging from 0 to 20.
Evaluation of the informed consent: A secondary outcome is the participant's subjective evaluation of the informed consent information received, assessed using a 10-item questionnaire rated on a 6-point Likert scale. The questionnaire assesses participants' perceptions of the clarity, comprehensibility, and adequacy of the information provided. The questionnaire has also been developed by experts in prison research and ethics and has been pretested on the targeted population. A continuous variable will be computed as the sum of all items. Its psychometric properties will be explored using an exploratory factor analysis.

6.1.3 Other Outcomes of Interest

Socio-demographic characteristics: We will also collect age, nationality, legal status, country of origin, age at the end of schooling, education level, marital status, health insurance prior to detention.

6.1.4 Safety Outcomes

Not applicable.

6.2 Analysis methods

6.2.1 Primary analysis

O1. We will use an adjusted logistic regression model to test whether the intervention (modified teach-to-goal versus standard inform consent process) predicts the probability of understanding the informed consent. We will report the odds ratio with 95% CI and p-value.

6.2.2 Secondary analyses

O2. We will use an adjusted linear regression model to test whether the intervention (modified teach-to-goal versus standard inform consent process) predicts the level of understanding the informed consent. We will report the slope with 95% CI and p-value.
O3. We will use an adjusted linear regression model to test whether the intervention (modified teach-to-goal versus standard inform consent process) predicts the evaluation of the informed consent. We will report the slope with 95% CI and p-value.

6.2.3 Sensitivity analyses

N/A.

6.2.4 Subgroup analyses

Not applicable.

6.2.5 Additional analyses

Additional analyses will be described in their own SAP.

6.2.6 Assessment of statistical assumptions

Statistical assumptions will be assessed using appropriate tools and diagnostic plots. Alternative models have been described above. If alternative models are not sufficient to meet statistical assumptions, we will use alternative modelling strategies, such as bootstrap or generalised linear models. If balance between groups (SMD ≤ 0.1) is not achieved, we will test alternative models and describe them as post-hoc models (e.g., inverse probability of treatment weights).

6.3 Interim analyses

No interim analyses are planned.

6.4 Missing data

See section 4.4.

6.5 Safety evaluation

Not applicable.

6.6 Subproject (if applicable)

Subprojects will be described in their own SAPs, if appropriate.

6.7 Statistical software

Statistical analysis will be performed with Stata (version 19 or more recent) or R (version 4.5.2 or more recent).

6.8 Quality control

An independent statistician will check the code of analyses.

7. Changes from the protocol

Not applicable. The SAP can be modified until the database is locked.
Deviation to the original SAP will be reported in the final report with justification. They will be reported as post-hoc analyses.

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