Statistical Analysis Plan (SAP)

Benefits of in-prison OROS-methylphenidate vs. placebo treatment in detained people with attention-deficit/hyperactivity disorder: A randomised controlled trial

BATIR

Part 2

Administrative Information

Trial registration number:	ClinicalTrials.gov NCT05842330; Kofam.ch SNCTP000005388
SAP version:	SAP version number with dates. 1 of 03.03.2026
Protocol version:	V1 of 03.03.2026

- Variable (endpoint): Number of acute events (refusal to see doctors, nurses or lawyers, hunger strikes, self-harm events, escapes, fights requiring a visit to the medical unit, and disciplinary sanctions) at approximately 3 months post-randomisation.
- Population-level summary: Adjusted* mean difference of number of acute events at 3 months between the OROS-MPH and placebo groups.

* Adjusted for baseline characteristics selected based on a literature review: age, level of education, nationality, having a health insurance before incarceration, type of incarceration, reason for incarceration, presence of psychiatric disorders (other than ADHD), ADHD subtype, baseline CAARS, impulsivity assessed with the UPPS-P, and presence of somatic comorbidities (52-55).

For the secondary estimand targeting the effect assignment to OROS-MPH or placebo during the incarceration period on risk of recidivism, assessed with the Structured Assessment of Protective Factors for Violence Risk (SAPROF) at 3 months (O3):

- Variable (endpoint): SAPROF score at approximately 3 months post-randomisation.
- Population-level summary: Adjusted* mean difference of SAPROF score at 3 months between the OROS-MPH and placebo groups.

* Adjusted for baseline characteristics selected based on a literature review: age, level of education, nationality, marital status, having a health insurance before incarceration, type of incarceration, reason for incarceration, presence of psychiatric disorders (other than ADHD), ADHD subtype, baseline CAARS, and impulsivity assessed with the UPPS-P (53, 55-59).

If the assumptions of the regression model are not met, we will use a log transformation.

4.3.3 Estimands for post-release outcomes

For outcomes assessed after release from incarceration (12 months post-randomisation), the estimands target the effect of assignment to OROS-MPH versus placebo during incarceration on post-release outcomes, irrespective of subsequent initiation of OROS-MPH after release.

ICEs occurring after release, including initiation of OROS-MPH in participants originally assigned to placebo, will be handled using a treatment policy strategy, reflecting the treatment policy defined by the study design. Accordingly, these estimands quantify the effect of early initiation of OROS-MPH during incarceration, followed by usual care after release as specified in the protocol.

Common attributes include:

- Treatment conditions: assignment to OROS-MPH versus assignment to placebo during the overall study period (15 months).
- Target population: All randomised participants meeting the study inclusion and exclusion criteria (ITT).
- ICEs and handling strategy: ICEs occurring between randomisation and the end of the study (15 months) will be handled using a treatment policy strategy. The outcome is defined irrespective of the occurrence of these ICEs.

For the secondary estimand targeting the effect assignment to OROS-MPH or placebo during the entire study period on adherence to medication (O4), we define three estimands:

- Variable (endpoint): Adherence to medication during the 15 months post-randomisation.
- Population-level summary: Adjusted* time-to-event (lack of adherence = failure) with a 15-month follow-up between the OROS-MPH and placebo groups.

* Adjusted for baseline characteristics selected based on a literature review: age, level of education, nationality, having a health insurance before incarceration, type of incarceration, presence of psychiatric disorders (other than ADHD), ADHD subtype, baseline CAARS, and impulsivity assessed with the UPPS-P (51, 60, 61).

- Variable (endpoint): Decision to have the treatment in the outpatient follow-up after 3 months.
- Population-level summary: Adjusted* risk difference at 3 months between the OROS-MPH and placebo groups.

* Same as estimand O4.

- Variable (endpoint): Adherence to medication during 15 months post-randomisation.
- Population-level summary: Adjusted* repeated, correlated measurements (proportions) with a 15-month follow-up between the OROS-MPH and placebo groups.

* Same as estimand O4.

For the secondary estimand targeting the effect assignment to OROS-MPH or placebo during the entire study period on study retention (O5):

- Variable (endpoint): Study retention during 15 months post-randomisation.
- Population-level summary: Adjusted* time-to-event (drop-out or consent withdrawal = failure) with a 15-month follow-up between the OROS-MPH and placebo groups.

* Adjusted for baseline characteristics selected based on a literature review: age, level of education, nationality, marital status, having a health insurance before incarceration, type of incarceration, presence of psychiatric disorders (other than ADHD), baseline CAARS, and impulsivity assessed with the UPPS-P (62, 63).

For the secondary estimand targeting the effect assignment to OROS-MPH or placebo during the entire study period on cost/benefits of ADHD treatment (O6). We define three estimands:

- Variable (endpoint): The healthcare system perspective, including costs associated healthcare use services (outpatient care, inpatient care, emergency intervention, and medications) at approximatively 3 months.
- Population-level summary: Adjusted* mean difference with a 3-month follow-up between the OROS-MPH and placebo groups.

* Same as estimand O4.

- Variable (endpoint): The prison system perspective, including costs associated to security in prison (e.g., sanctions) and recidivism at approximatively 3 months.
- Population-level summary: Adjusted* mean difference with a 3-month follow-up between the OROS-MPH and placebo groups.

* Same as estimand O4.

- Variable (endpoint): The prison system perspective, including costs associated to security in prison (e.g., sanctions) and recidivism at 15 months.
- Population-level summary: Adjusted* mean difference with a 15-month follow-up between the OROS-MPH and placebo groups.

* Same as estimand O4.

For the secondary estimand targeting the effect assignment to OROS-MPH or placebo during the entire study period on rule-breaking behaviours (O7):

- Variable (endpoint): Composite outcome of rule-breaking behaviours during the 12-month outpatient follow-up period (after the 3-month treatment period), including disciplinary infractions in prison and/or recidivism after release in the community.
- Population-level summary: Adjusted* time-to-event with a 12-month outpatient follow-up between the OROS-MPH and placebo groups.

* Adjusted for baseline characteristics selected based on a literature review: age, level of education, nationality, marital status, having a health insurance before incarceration, type of incarceration, reason for incarceration, presence of psychiatric disorders (other than ADHD), ADHD subtype, baseline CAARS, impulsivity assessed with the UPPS-P, and presence of somatic comorbidities (52-59).

For the secondary estimand targeting the effect assignment to OROS-MPH or placebo during three months on side effects (O8), we define two estimands:

- Target population: All randomised participants who receive at least one dose of the medication (SAF).
- Variable (endpoint): Presence of side effect related to the medication.
- Population-level summary: Adjusted* risk difference with a 3-month follow-up between the OROS-MPH and placebo groups.

* Adjusted for baseline presence of psychiatric disorders (other than ADHD) (64, 65).

- Target population: All randomised participants who receive at least one dose of the medication (SAF).
- Variable (endpoint): Number of side effect related to the medication.
- Population-level summary: Adjusted* mean difference with a 3-month follow-up between the OROS-MPH and placebo groups.

* Same as estimand O8.

4.3.4 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.

4.3.5 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 initiating OROS-MPH during incarceration under conditions reflective of clinical practice. 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. Supplementary analyses focusing on subsets of participants defined by post-randomisation characteristics (e.g., adherence to treatment or absence of protocol deviations) will correspond to distinct estimands and will be clearly identified as exploratory and interpreted descriptively.

4.3.5.1 Sensitivity analyses

See section 6.2.3.

4.3.5.2 Supplementary estimands

Supplementary estimands will account for post-randomisation characteristics.

O4, O5, O6, O7: adjusted differences will include the post-randomisation factors: decision to start ADHD treatment at three months and whether participants are still imprisoned or not during the outpatient follow-up period.

O7: analyses separated for participants in prison during the outpatient follow-up period or not. Imbalance between groups will be handled using inverse probability of treatment weights (IPTW).

4.4 Handling of missing data

4.4.1 Missing outcome data for primary and secondary estimands

For the primary estimand and secondary estimands targeting outcomes assessed during incarceration and after release, missing outcome data may arise due to loss to follow-up or consent withdrawal.

The primary way to handle missing values in ITT analyses will be MICE, except for time-to-event outcomes, for which the participant will be censored at the last point of contact. Imputation will be performed under the assumption that data are missing at random (MAR), conditional on the variables included in the model. For models in which MICE is not supported (e.g., IPTW), we will consider using inverse probability of attrition weights (IPAW) to re-equilibrate groups.

Ten imputation datasets will be created and results pooled using Rubin's rule. The following auxiliary variables will be used to predict missingness: age, level of education, nationality, marital status, having a health insurance before incarceration, type of incarceration (pre-trial or sentence), presence of psychiatric disorders (other than ADHD), baseline CAARS, and impulsivity assessed with the UPPS-P (62, 63). Variables with missing values will be removed from the auxiliary list of variables if missing values on auxiliary variables cannot be handled in the statistical package. Terminal events such as death will be used as auxiliary variables.

For the PP analyses, we will also use IPAW, which will be combined to inverse probability weights accounting for ICEs by a multiplication. We will use stabilized weights, truncated at the 99th percentile.

The attrition model used to derive inverse probability weights will include the same variables as described in the MICE procedure.

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

Intercurrent events such as treatment discontinuation, non-adherence, or 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.

Sensitivity analyses will be conducted to assess the robustness of the primary and secondary analyses to alternative assumptions regarding missing data. These analyses will target the same estimands as the primary analysis and do not represent alternative estimands.

These analyses may include:

- alternative specifications of the attrition model used for MICE (auxiliary variables) and IPAW (predictors of attrition),
- complete-case analyses as exploratory sensitivity analyses.

The purpose of these analyses is to evaluate the sensitivity of conclusions to departures from the missing at random assumption.

5. Trial population

Data will be collected in four prisons for which the Division of Prison Health provides health care, among sentenced and pre-trial detained men and women located in Geneva: Champ-Dollon, La Brenaz, Villars, and Vallon (n=150, minimum n=126). The study is considered as monocentric, as the same team delivers heath care in the four prisons. Detained persons may move from one prison to another during the study.

5.1 Screening data

Not available.

5.2 Eligibility

Inclusion criteria are: 1) age between 18 and 65, 2) good command of French; 3) stay in prison for at least three months at study inclusion, 4) fulfilling clinical diagnostic criteria for DSM-5 ADHD, and 5) providing written informed consent.
Exclusion criteria are: 1) presence of an acute uncontrolled comorbid psychiatric disorder, 2) medical contraindication to stimulant prescription, 3) potential adverse interaction with another medication, and 4) already receive ADHD treatment.

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.

The baseline table will include standardized mean/proportion differences (Cohen's d) to have an overview of the balance between groups, but no p-values or confidence intervals.

5.4 Adherence and protocol deviations

Protocol deviations, adherence, and ICEs will be summarized by percentages and n in each group.

5.5 Withdrawal/follow-up

The treatment in the OROS-MPH group may be interrupted, and participants may withdraw from the study in case of:

- Withdrawal of consent
- Occurrence of a SUSAR or SAE
- Any other medical concern that may interfere with the completion of the intervention
- Non-compliance that may become obvious to the participant or to the study team.

Participants will be analysed in their initial study group (ITT analyses).

When the study team has no news of the participant, we will make effort to contact them, to establish the reason for discontinuation of treatment, and to suggest the participant to come for an end-of-study visit. If all attempts fail, the participant will be declared as "lost to follow-up".

In case of withdrawal due to an 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 (16%) and MICE will be used to handle missing values.

Withdrawal from the study and lost-to-follow-up will be summarized by percentage and n in each group.

6. Analysis

6.1 Outcome definitions

6.1.1 Primary Outcome

Conners Adult ADHD Rating Scale (CAARS) (66) (O1). We will use the short version of the observer-rated version of this scale to monitor ADHD symptoms over time (CAARS-O:S). It allows a multimodal assessment of adult symptoms and behaviours. The CAARS has demonstrated good psychometric properties (internal consistency, convergent validity, discrimination between clinical and non-clinical groups) (67). The CAARS has been used as the primary outcome in all RCT conducted in prisons (68-70). We will use the total CAARS score before intervention and at the 3-month follow-up, with the 3-month follow-up measure being the primary outcome. A one-week window period will be used (assessment between 12 and 14 weeks).

6.1.2 Secondary Outcomes

Acute events (O2). Conducts like refusal to see doctors, nurses or lawyers, hunger strikes, self-harm events requiring a visit to the medical unit (71), escapes, fights requiring a visit to the medical unit (72), and disciplinary sanctions, including misuse of the prescribed treatment (14) will be recorded. We will use data routinely collected by the medical team and from official prison records. We will use the final number of acute events at the 3-month follow-up.

Structured Assessment of Protective Factors for Violence Risk (SAPROF) (O3). This dynamic risk assessment tool will be used to evaluate the risk of recidivism. It is a prevention-focused assessment which identifies protective factors that may moderate risk factors and reduce the likelihood of recidivism (73). It helps achieving a balanced and comprehensive evaluation of the risk of recidivism. It includes three subscales (17 items): Internal items (e.g., self-control, coping), motivational items (e.g., motivation for treatment, attitudes towards authority), and external items (e.g., external control, professional care). Static items (intelligence and secure attachment in childhood will not be assessed). The SAPROF has a good predictive value, interrater reliability, and sensitivity to treatment outcomes (74). We will use the SAPROF score at the 3-month follow-up.

Medication adherence (O4). The local team will provide daily information on medication adherence during imprisonment (direct observed therapy). After release, an electronic pill dispenser will provide a sequence of binary data indicating at each day whether the patient took the OROS-MPH as prescribed or not. It will be used to derive initiation of self-management, medication implementation (quality of daily intake) and persistence on OROS-MPH after release. In addition, we will use three questions to validate the use of the electronic pill dispenser (how soon participants take the medication after opening the pill dispenser, whether they prepare doses of medication in advance without using the pill dispenser, and if there is any period when they did not use the pill dispenser but took the medication, e.g., imprisonment, hospitalisation).

Retention to study (O5). We will register dropout/consent withdrawal from the study (69), registered using the last visit/contact with the medical unit. Reasons for dropout (when given)/consent withdrawal will be registered. We will use the retention to study (yes/no) at 12-month outpatient follow-up with the date of last contact.

For *economic evaluation* (O6), we will evaluate medical and non-medical costs.

Medical costs will be estimated from the healthcare system perspective and will include those of medical services used by patients (outpatient, emergency, and inpatient resources). During detention, they will be obtained from analytical/administrative accountancy systems of the prison and the Geneva University Hospitals which is in charge for health care delivery in prison. We will use medical costs at 3 months.

Non-medical costs are prison system-related costs and will include those related to disciplinary sanctions (use of resources in the prison and in prison staff), and recidivism-related costs (average cost

for one day in prison). Information on costs will be obtained prospectively during the three months in prison, except for recidivism, which will be collected at the end of the study from the Federal Office of Statistics or during the study (e.g., one participant is re-incarcerated in one of the four prisons). We will use prison-related costs at 3 months and 12-month outpatient follow-up.

Rule-breaking behaviours (O7). This outcome will be a composite outcome assessing presence or absence of rule-breaking behaviours, assessed as follows:

- In prison: disciplinary infractions (data routinely collected from official prison records), coded as present or absent during the 12-month outpatient follow-up with the dates of the infractions;
- After release: recidivism (data extracted from official Swiss criminal records), coded as present or absent over the 12-month outpatient follow-up, with the dates of the events.

We will extract data on recidivism from the official Swiss criminal records one year after release. The data will be requested from the Federal Office of Statistics (Criminal Conviction Statistics). In the whole Swiss population, 28% of detained persons have a new conviction one year after they are released from prison (internal information from the Federal Office of Statistics). Recidivism (yes/no) with date will be assessed one year after prison release.

6.1.3 Other Outcomes of Interest

We will collect baseline variables of interest:
Socio-demographic and prison characteristics will include gender, age, level of education, region of origin, marital status, health insurance prior to detention, and reason for incarceration. We will also register whether participants have in/out-patient therapeutic measures (Art. 59 - 63 Swiss Criminal Code).
Medical history, including somatic diseases, medications, and psychiatric disorders. will be assessed through differential diagnostic with the Mini-International Neuropsychiatric Interview (MINI). The MINI is a short structured diagnostic interview which provides an accurate evaluation of the 17 most common mental health disorders (75), also validated for the DSM-5. We will also assess borderline personality disorder (scale of DSM-5 symptoms, 1), a disorder often comorbid with ADHD but not included in the MINI. We will also assess impulsivity using the impulsive behaviour scale (UPPS-P) (76). Previous ADHD treatment and use of psychotropic medications will be registered.

6.1.4 Safety Outcomes

Side effect outcomes (O8). The following main side effects will be assessed and recorded at each visit (Swiss compendium): Appetite reduction, weight loss, insomnia, nervousness, mood instability, aggressiveness, agitation, anxiety, depression, irritability, abnormal behaviour, headache, dizziness, dyskinesia, psychomotor hyperactivity, drowsiness, arrhythmia, tachycardia, palpitations, hypertension, cough, pharyngeal and laryngeal pain, abdominal pain, diarrhea, nausea, stomach aches and vomiting, dry mouth, alopecia, pruritus, skin rash, urticaria, arthralgia, and blood pressure change. We will also record unexpected side effects. We will use side effects (yes/no and separate side effects) at the 3-month follow-up, with the date of the side effect.

6.2 Analysis methods

6.2.1 Primary analysis

O1. We will use an adjusted linear regression model to test whether ADHD treatment (OROS-MPH *vs.* placebo) predicts the severity of ADHD core symptoms.

6.2.2 Secondary analyses

O2. We will use an adjusted negative binomial regression model to test whether ADHD treatment (OROS-MPH *vs.* placebo) predicts the number of acute events.

O3. We will use an adjusted linear regression model to test whether ADHD treatment (OROS-MPH *vs.* placebo) predicts the risk of recidivism.

O4. We will use an adjusted Cox regression to test whether ADHD treatment (OROS-MPH *vs.* placebo) predicts adherence to medication during the follow-up period. We will also test whether ADHD treatment (OROS-MPH *vs.* placebo) predicts the decision to take OROS-MPH at three months. Then, the repeated, correlated adherence measurements will be analysed longitudinally using generalized estimating equations models. Systematic computerized term search in the adherence report will be performed to identify the most frequent variables affecting adherence and a regression model will be used to discover their association with adherence.

O5. We will use an adjusted Cox regression to test whether ADHD treatment (OROS-MPH *vs.* placebo) predicts study retention (event: study dropout).

O6. In terms of economic evaluation, cost-benefits analyses will be performed and aggregated outcomes will be computed. We will use an adjusted linear regression model to test whether ADHD treatment (OROS-MPH *vs*. placebo) predicts costs. Uncertainty will be assessed using univariate and probabilistic sensitivity analyses.

O7. We will create a composite outcome of rule-breaking behaviours during the 12-month outpatient follow-up period. An adjusted Cox regression model will be used to test whether ADHD treatment (OROS-MPH *vs*. placebo) predicts rule-breaking behaviours.

6.2.3 Sensitivity analyses

For the secondary outcome O2 (acute events), we will use a sensitivity analysis using an adjusted logistic regression model with the presence or absence of acute events as the outcome and a logistic regression model focusing on misuse of the treatment as an outcome.

For the secondary outcomes O4 (adherence), O5 (study retention), O6 (economic evaluation) and O7 (rule-breaking behaviours), we will run analyses adjusting for the decision to start ADHD treatment or not after three months and whether participants are still imprisoned or released at three months. Additional analyses accounting for time spent outside of prison will be performed, if the sample size is sufficient (≥ 20 participants).

For the secondary outcome O7 (rule-breaking behaviours), we will also conduct two subgroup analyses, separately for those who remain in prison (outcome: disciplinary sanction) and those who are released from prison (outcome: recidivism). We will use adjusted Cox regressions with IPTW to account for the lack of imbalance between study groups.

6.2.4 Subgroup analyses

We will perform analyses stratified by sex. If the number of women is too low, we will report descriptive statistics (if women ≥ 5). We will also perform analyses stratified by type of sentence (pre-trial or sentence).

6.2.5 Additional analyses

We will explore adherence to the psychotherapeutic part of the intervention using generalised estimating equation models. These analyses will explore trajectories to psychotherapy, associations with the treatment group, and impact on study outcomes. These analyses will be described in a separate SAP.

Further analyses on medication adherence will also be described in a separate 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. For IPTW and IPAW, we will check groups' balance using SMD, allowing moderate

imbalance (SMD ≤ .25). If balance is not achieved or at least improved, we will test alternative models and describe them as post-hoc models.

6.3 Interim analyses

No interim analyses are planned.

6.4 Missing data

See section 4.4.

6.5 Safety evaluation

O8. We will compute descriptive statistics for each kind of side effect, presence of any side effect, and sum of side effects. We will compare the two groups (OROS-MPH vs. placebo) using adjusted logistic and negative binomial regression models. Results will be interpreted in light of the effect size, given the potential lack of power for this analysis.

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 18 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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