

Pre-Analysis Plan

General information

Title of project:

Oral Health for Prisoners

Authorship:

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Center for Alcohol and Drug Research, Stavanger University Hospital

Regional Alcohol and Drug Competence Center, Rogaland

Conflicts of Interest:

None.

Introduction

Project summary:

This study investigates the effects of an intervention based on Motivational Interviewing (MI, Miller (1983)) on oral hygiene, oral cleaning routines, and attitudes towards own oral health of prisoners in Norway. Motivational Interviewing is a collaborative, person-centered form of guiding to elicit and strengthen motivation for change. It was originally developed for patients with an alcohol use disorder but has since proved effective for other patient groups, and in particular patients with high ambivalence, low confidence, and low desire to change. In recent years, Motivational Interviewing has also shown to be an effective intervention to improve oral hygiene for various patients visiting dental clinics, see e.g., Almomani et al. (2009) and Jönsson et al. (2009).

All prisoners in the study undergo an oral examination to establish a baseline (hereafter T0) of oral health and a comprehensive questionnaire to identify risk factors and their attitude towards their oral health and oral treatment. Norwegian speaking prisoners are then randomized into either a treatment or control group. In the treatment group, dental staff initiate a conversation with the prisoner based on techniques from MI. Both groups finally receive a toilet bag with basic equipment to regularly clean their teeth. After 4 weeks and 12 weeks (hereafter T1 and T2), prisoners are invited back for another oral examination and a follow-up questionnaire, to measure changes in oral hygiene, oral cleaning routines, and attitude towards their oral health. At T1 we also conduct a screening of general learning difficulties using the validated screening tool HASI (Hayes, 2002). If the intervention proves to be an effective tool in improving oral hygiene, oral cleaning routines, and/or attitude towards own oral health, it can serve as an alternative proactive approach to improve oral health of a vulnerable group in society. If the improvements in oral hygiene and oral cleaning routines are long lasting, this may in turn lead to a reduced need of oral treatment. An improved attitude towards own oral health may, together with other rehabilitation programs in prison, improve the prisoner's self-esteem and chances to successfully returning to society after having served their prison sentence.

Study Design

Hypothesis:

H1: The conversation based on Motivating Interviewing (hereby the intervention) leads to a reduction in observed plaque and gingival inflammation for prisoners.

H2: The intervention leads to improved reported cleaning routines of prisoners in general, and particularly brushing of teeth.

H3: The intervention leads to a reduction in prisoners' intake of food and drinks in total, and particularly in-between meals.

H4: The intervention leads to improved perceptions about the prisoner's oral health. It improves how they view their oral health, they consider their oral health as more important, they report an increased wish to improve it, and they have increased efforts to improve it.

H5: The intervention leads to an increase in number of questions the prisoner asks during their visit with the dental staff, suggesting an increase in curiosity concerning their oral health.

Treatment effects and measurements:

The main variable of interest and primary outcome measure of the treatment effect is the mucosal-plaque index (MPS). It consists of the sum of a four-point plaque score (PS) and a four-point mucosal score (MS). For the PS, score of 1 suggests no visible plaque, score of 2 suggests plaque is barely visible, score of 3 suggests a moderate amount of plaque, and score of 4 suggests large amount of plaque almost covering the whole surface of teeth. For the MS, score of 1 suggests normal mucosal, score of 2 suggests mild inflammation, score of 3 suggests medium inflammation, and score of 4 suggests strong inflammation. For both scores, if in doubt between 1 and 2, they are instructed to score 1. If in doubt between 3 and 4, they are instructed to score 4.

The index is designed to evaluate oral health and oral hygiene in groups of individuals, developed for use in institutions. This makes it a suitable index to be used when conditions are not optimal to assess the patient. In prison, dental staff have limited equipment and poor light compared to conditions at a dental clinic. It was therefore important to use an index designed to be used outside of dental clinics with less optimal conditions for oral examination.

The secondary measures of outcome are based on questionnaire responses. These are questions asked both prior to treatment and during the follow-up period, and measures changes in how the prisoner perceives his oral health, how his routines are for maintaining his teeth, and his intake of food and drinks. How these questions are formulated can be seen from the questionnaire directly. These questions are designed to measure behavioral changes because of the intervention. As the questions are identical at each meeting point, any difference in changes across the treatment and control group is likely to be a result of the intervention. Importantly, even though the MPS-index may not measure a significant change in oral hygiene, such behavioral changes may still be of great importance. For example, even though a prisoner does not change his cleaning routines and is unable to improve his plaque score, a reduction in intake of unhealthy food and drinks may still reduce the damage on his teeth. Likewise, an improved perception about their oral health, may still improve self-esteem, even though there is no reduction in plaque score.

In addition, as a secondary outcome measure, dental staff take notes of how many times the prisoner asks questions about his teeth. If the intervention successfully increases the prisoner's interest in his own oral health, we could expect more questions about his oral health.

Basic methodology:

The study is a randomized control trial (RCT), testing an MI-based intervention on oral health (oral hygiene) for prisoners in Rogaland County, Norway. More details about the population and the intervention follows in subsequent sections.

We randomize prisoners into treatment or control groups, blocking at prison level, using the randomization tool at www.randomizer.org. See the randomization section for more details on the randomization process. Moreover, we blind prisoners from treatment status, and dental staff is either blind to treatment when doing the oral examinations, or the oral examination is conducted by two dental staff independently of each other. See the blinding section for more details on blinding.

Study design and procedures:

Geographic region

The geographic region of this study is Rogaland County in southwestern part of Norway. Rogaland County is the wealthiest county in Norway measured in terms of household income (2019, SSB). Despite being one of the wealthiest counties in Norway, growing up in Rogaland is similar to growing up in other counties in Norway. An important reason for this is the unitary and federally funded school system, with only a few ideological or pedagogical based private schools. This gives all children growing up in Norway similar opportunities to obtain an education and subsequently enter the labor market.

Research population

There are four prisons in Rogaland County, all of which are included in the study. Three prisons are categorized as high security prisons, and one is categorized as a low security prison. The main difference between high and low security prisons are the level of security measures, as prisoners in the low security prisons are allowed to move more freely within the prison. The low security prison is mainly used for less serious criminal offences, with a sentence time of between six months and two years. Those convicted to less than six months can apply to serve the time with an ankle bracelet, whereas those convicted for more than two years start serving in a high security prison. However, many high security prisoners are transferred to low security prison to serve the final part of their sentence. Hence, the population across prisons are likely to vary due to the severity of the criminal offence they have committed, especially across high and low security prisons. However, as those with the least serious criminal offences serve time with an ankle bracelet, and those with more severe convictions often serve the final part of their sentence in a low security prison, the populations may not be that different from each other.

The prison population may also contain prisoners who normally live outside of Rogaland County. If there is available capacity in the prisons in Rogaland County, and other parts of Norway have queues of people waiting to serve their sentence, they could end up serving their time in a prison in Rogaland County. Hence, the prisoners do not necessarily originate from or live in Rogaland County to serve their prison sentence in Rogaland County.

Recruitment is done somewhat differently across prisons, and different for those already imprisoned at the time of the start of data collection and those arriving in the prison during the data collection period. For those already imprisoned at the start of data collection, they are either informed about the study by prison officers or dental staff. We wanted this process to be done exclusively by prison officers, but capacity constraints forced us to use our own staff in two of the prisons. The information given is the same across all prisons, based on an information letter, which is also distributed to the prisoners. They then give their preliminary consent to participate within a couple of days after being informed.

For those who arrive at the prison during the period of data collection, they are either informed about the study by prison officers or prison health workers during the first days in prison. Again, recruitment is done depending on the capacity of prison officers. The information provided is the same as for those already imprisoned, and they receive the same information letter. Prisoners give their preliminary consent to participate within a couple of days.

The formal consent is given to dental staff in the very beginning of their first meeting.

There are several benefits of participation. Prisoners receive an oral examination. From this they will be informed if they have any treatment needs and can be referred to a dentist for treatment. Moreover, all participants receive a toilet bag with basic equipment to take care of their teeth. Those in the treatment group, may also benefit from guidance and higher awareness in how to better care for their teeth.

There are also some disadvantages of participation. Prisoners have to spend their time on participation, which gives less leisure time, less time to work (although their pay is not reduced) or less time to study. Moreover, they may experience the oral examination and the questionnaire as intrusive. Some of the questions are personal and concerning their life, health, and wellbeing. They are free to skip questions if they prefer not to answer them.

Inclusion/exclusion criteria

Everyone serving time in one of the four prisons during the period of the study (November 2021 to the beginning of 2023) are invited to participate in the study, independent of what they are convicted for and how long time they have left to serve in prison.

However, as the MI-based conversation is only held in Norwegian, only prisoners with sufficient Norwegian language is included in the sample that is randomized into treatment or control group. The language screening is done by either a prison officer or dental staff. If the prison officer or dental staff is in doubt of the prisoner's ability to complete a conversation in Norwegian, they are to ask a standard screening question. This question is based on a typical question from official Norwegian language test (Bergenstesten) and is taken from the level in which the person should be able to complete a simple conversation in Norwegian (level B1). If the prisoner answers the question sufficiently (according to predefined standards), they are included in the sample drawn to either treatment or control group. If the prisoner does not have sufficient Norwegian language, they are still offered an oral examination, answers the questionnaire, and receive a toilet bag at T0.

We choose not to include those with insufficient Norwegian language skills for two reasons. First, the literature on Motivational Interviewing recommends that the conversation is held without the use of interpreter. In case an interpreter is to be used, this person should also be trained in MI-techniques. A further discussion on the use of interpreter in MI sessions can be found in Miller & Rollnick (2012). Second, we do not have research budgets to hire and train interpreters for this purpose, which would have required interpreters that could speak a variety of languages in order to cover the entire prisoner population.

Withdrawal criteria

Participation in the study is voluntary. We can only speculate on reasons for why some prisoners choose not to participate, as we are not allowed to take records of this. We suspect that some simply do not care about their oral health. Other reasons can be that they are close to finishing their prison sentence, that their health is so bad that they are unable to participate, or that they do not prioritize it ahead of other activities in prison (such as work, school, social activities).

The unit of analysis will be on individual level. We will analyze both individual data from the oral examinations and answers from the questionnaires.

We expect that there will be somewhat high attrition of reasons independent of the intervention. The major reason for attrition is that the prisoner is released from prison sometime between T0 and T1 or between T1 and T2. We do not have capacity or legal rights to follow the prisoner outside of prison, and even if we did it would be hard to get the newly released prisoners to prioritize a follow-up oral examination and questionnaire outside of prison. Another potential reason for attrition is that the prisoner is transferred to a prison outside of Rogaland County. We do not have the capacity to follow a prisoner outside of Rogaland County. However, we do follow-up oral examination and questionnaire on prisoners who are transferred within prisons in Rogaland County.

As participation is voluntarily, prisoners can withdraw their consent, or choose not to show up for T1 and T2. This is a common problem for most RCTs in social science. As subjects in our population is serving time in prison, they have limited alternative activities to engage in, which is likely to somewhat reduce the number of prisoners who choose not to show up at T1 and T2 (except for reasons explained above).

Expected timeline

Data collection started in November 2021 and is likely to continue until the beginning of 2023. We have funding to collect data one day a week for one year in each prison. In the event that we are unable to recruit enough prisoners one of the prisons, resources can be reallocated to one of the other prisons. We have applied for additional funding to extend data collection for an additional two to three months.

We are estimating to recruit around 500 prisoners to the study, based on the capacity we have available in the project. However, the pandemic and access to prisoners makes this estimate very uncertain.

The end date for data collection depends, in addition to uncertainty regarding whether additional funding is approved, on the extent that the ongoing pandemic will affect data collection. If stricter infection control measures are enforced, prisons are likely to quickly deny access for external partners. The new omicron variant of the corona virus has already forced delays in three out of four prisons. During a period in which we are not allowed to enter a prison, we will be forced to do follow-up examinations at times deviating from the times described above and our flow chart presented below. We are also likely to experience higher attrition during such periods, as prisoners are released or moved to a prison outside Rogaland County before we are allowed to do follow-up examinations. Such attrition is independent of treatment status. During periods we are not allowed to enter the prison, dental staff will work in their regular clinic instead. Therefore, we are not spending project resources during lockdowns.

During the data collection period we are aiming to recruit around 500 subjects. The number of subjects we can recruit depends on several factors. First, we rely on enough people serving their prison sentence during the data collection period. We know that prisons in Rogaland County have not been fully occupied in recent years. Second, the proportion of prisoners who choose to participate is uncertain. Third, time spent on each prisoner depends on how effectively the prison staff can bring prisoners to the examination room and how effective the routines of dental staff are. Forth, we do not know many of the prisoners have sufficient Norwegian language to participate in the study. See the power calculation section for a more detailed discussion about the required sample size.

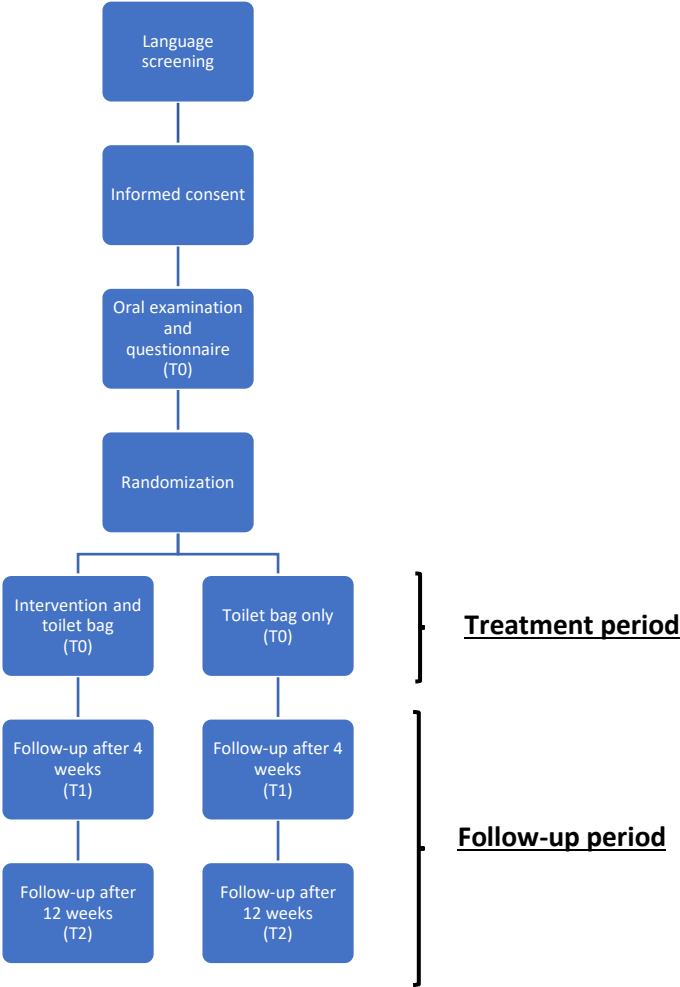
Each prisoner is followed for 12 weeks in total, and we continuously recruit prisoners in the data collection period. The intervention occurs only at time T₀, and only for those randomized to the treatment group. During the first few months we recruit primarily those who are already imprisoned, and once all of them have been given the chance to participate, we start recruiting new prisoners.

Intervention

The intervention is a conversation lasting up to 30 minutes with the prisoner about his or her oral health, based on Motivational Interviewing. The intervention is carried out by dental staff in prison. Prior to the start of data collection, dental staff has been trained by MI certified specialists from the Regional Alcohol and Drug Competence Center in Rogaland County. The training has consisted of three days of seminar with group work and discussions, a practice MI-conversation that has been recorded, transcribed, and graded by the MI-center in Bergen, and direct feedback on this practice conversation. In addition, they receive continuous guidance from a MI specialist at the Center for Alcohol and Drug Research at Stavanger University Hospital.

The MI conversation follows the methodology of MI closely. The first step is for the dental staff to ask open questions to the prisoner, for example “what cleaning routines do you have for your teeth?” or “what benefits could you get from brushing your teeth twice a day?”. The next step is to confirm to the prisoner what he or she is doing, for example “you are really trying hard to take good care of your teeth” or “you have managed to have good cleaning routines multiple times in the past”. The third step is called reflection. At this stage, dental staff tries to provide reflections on what the prisoner have said, for example by repeating what the prisoner have said or say the same using synonyms (simple reflection), by extracting the underlying opinion or feeling (complex reflection), or by illuminate both negative and positive sides of the situation (double sided reflection). The final step is to summarize the conversation. In addition, the intervention included a change plan, in which the prisoner and dental staff agrees on specific behavior that the prisoner should follow based on the MI conversation.

Include a flow chart:



Data collection and sources of data:

Data collection will be carried out by trained dental staff inside the prisons during the data collection period. Most data collected will be on individual (prisoner) level. Moreover, we will collect basic information about each of the four prisons in our study.

The source of data will be a combination of clinical information from the oral examination, answers from the questionnaire, and a few observations done by dental staff during the consultation.

Clinical data will include information on decayed, missing and filled teeth (DMFT). This data will only be collected at T0, as it is not possible to observe any change during the follow-up period. Moreover, we will collect clinical data on plaque and mucosal inflammation, using the MPS index. This is our main variable of interest. Plaque is affected by oral hygiene routines and the intake of drinks and food that can damage teeth, and thus any observed difference in changes in plaque between the treatment group and the control group may be interpreted as an effect of the intervention. Dental staff has undergone a calibration exercise of both DMFT and MPS.

The questionnaire is extensive. It starts with some background questions about demographic and socio-economic status, which are not likely to change during the follow-up period, and thus only asked at T0. Next, we ask questions about their views on their own oral health. In particular, we ask them about how they perceive the condition of their own oral health, whether they want to improve it, whether they regularly visit a dentist outside of prison, their cleaning routines and their intake of food and drinks. Some of these questions are secondary variables of interest. In the case of an intervention effect, prisoners may have an adjusted view on their oral health, and they may change their oral cleaning routines and intake of food and drinks. We also ask them standardized questionnaires about their oral-health quality of life (OHIP-14) and their self-reported anxiety and discomfort to dental treatment (Corah). As these are unlikely to change during the follow-up period, they are only asked at T0.

We also collect data on their general physical and mental health. To measure mental health, we use the standardized questionnaire Mental Health Inventory 5 (MHI-5). We conduct the MHI-5 questionnaire at all meeting points, T0, T1 and T2, as we expect reduced effects of the intervention if they are experiencing worsened mental health. This may be important when studying heterogeneous effects of the intervention. Lastly, we collect data on their alcohol and drug use (outside of prison), using the short versions of alcohol use disorders identification test (AUDIT-4) and the drug use disorders identification test (DUDIT), collected only at T0.

Dental staff also take note about how many times the prisoner ask questions about their findings from the oral examination. If the intervention raises their awareness to oral health, it is likely that those in the intervention group ask more questions during the follow-up period. Hence, this is also a secondary variable of interest.

We choose not to include questions about what sort of criminal offence the prisoner had committed and related questions that could challenge dental staffs perceived safety. For example, knowing you are talking to a sexual offender or murderer is likely to affect our dental staff negatively. When the prisoner signs the consent to participate in the study, he also approves that we are allowed to collect such data from the Norwegian Correctional Service. However, we are still not sure whether they will gain us access to such administrative data.

Randomization:

Randomization is done using the randomization tool www.randomizer.org. We randomize prisoners in the order that we receive lists of prisoners who have signed up to participate. Although this order

may not be random, the randomization process ensures that assignment to treatment and control group is. We block on prison level, to ensure a balance between treatment and control group in each prison. To ensure that there is not, by chance, an unequal assignment into treatment or control, we force the randomization to balance assignment into treatment and control for every fourth prisoner. That is, in groups of four, if the first two are assigned to the treatment group, the next two will be control group. To reduce the likelihood that dental staff in prison could guess the assignment of the next prisoner, we used every fourth prisoner rather than every second prisoner. The order that the prisoners meet may not be the same order as we randomize, further ensuring that dental staff may not guess whether the next prisoner is in the treatment group or not.

It would be very interesting to stratify the sample on gender, however we expect at most only to have a few observations on female prisoners. From early 2022, female prisoners will serve time outside of Rogaland County.

The unit of observation is at individual level. To ensure privacy of the prisoners, we do not collect any information that directly identifies them. However, given the detailed questionnaire, we do collect data that contains identifiable information.

Blinding:

Prisoners are not informed whether they are in the treatment or control group and are therefore blind to treatment status. Dental staff are blind to prisoners' treatment status at the time of the first oral examination and questionnaire. The prisoner's treatment status is revealed just after this. Hence, dental staff collects all data prior to knowing the prisoner's treatment status, and only learn this when they start the MI-based conversation. When prisoners are back at T1 and T2 for follow-up oral examinations and questionnaires, dental staff might still remember whether the prisoner was treated or not. To partially account for potential bias in the oral examination (assessment of oral hygiene and inflammation in gingival), there are two independent assessments of this at T1 and T2. See pre-specification of analytical decisions for more on this.

Power calculations:

We have used GPower and Optimal Design to conduct power calculations.

GPower is used to calculate required sample size for simple comparison of means for the main variables of interest between the treatment and control group, without considering that data is collected at multiple sites. We choose the non-parametric Wilcoxon-Mann-Whitney test, set alpha to 0.05 and required power to 0.8. There is uncertainty concerning the effect size. Previous literature offers some guidance, however there are several important differences to our study. MI-interventions to change oral health have previously been tested on periodontist patients and patients with mental illness, populations that differ from ours. For our main variable of interest, level of plaque, these studies have found effect sizes ranging from 0.286 to 1.213¹. However, one should note that these studies have used different indexes to measure plaque, questioning the comparability of the effect sizes. Setting the power estimate to a moderate level in this range, to 0.5,

¹ An effect size of 0.286 was found after 12 weeks in Brand et al. (2012), whereas an effect size of 1.213 was found in Godard et al. (2011).

our required sample size is 106 prisoners. If we use a more conservative estimate and set it to the lowest effect size observed in the studies referred to above (0.286), the required sample size is 320.

Optimal Design is used to calculate the Minimum Detectable Effect Size (MDES) given that we block on prison level. Here we choose the Multi-Site trials under Person Randomized Trials. We set alpha to 0.05 and required power to 0.8. As we block on prison, we set number of sites (J) to 4. There are great uncertainty concerning effect size variation, how much of the variation in the outcome that can be explained by the blocking variable, and how much of the variation in the outcome can be explained by the covariate variable. Thus, we present power calculations based on bounds of these values. We set the range of effect size variation from 0.0 (equivalent to the fixed-effects model) to 0.05. Furthermore, we assume that the blocking variable can explain 20% to 30% of the variation in the outcome. And finally, we use the pre-intervention MPS index score from the oral examination as a covariate, expected to explain 50% to 60% of the variation in the post-intervention MPS index score.

Given these boundaries, and assuming we can recruit 100 prisoners in each prison, the most optimistic scenario allows us to detect an effect size of about 0.15. On the other hand, should we end up in the other end of the boundaries, we are only able to detect an effect size of about 0.55. The calculation is very sensitive to changes in the effect size variation, and less sensitive to changes in how much variation the blocking variable and the covariate variable can explain. The number of prisoners recruited in each prison is also an uncertain number. The prisons differ in size and number of prisoners. We are likely to have more than 100 prisoners recruited in three out of four prisons. The smallest prison in the region has only 18 rooms. The calculations above have not considered the imbalance of prison size.

Pre-specification of analytical decisions

Statistical model specification:

To test the overall effects of the intervention on our primary and secondary outcome variables, we will conduct non-parametric Wilcoxon Mann-Whitney U-tests. Given the ordinal outcome variables, we consider this test as more appropriate alternative relative to traditional two independent sample t-tests. We will compare the means of the treatment group and the control group at T0, T1 and T2. At T0 we expect no differences in means as no intervention has occurred. At T1 and T2 we expect better scores for the treatment group relative to the control group. Notably, our primary interest will be the difference in means at T1, as we expect more missing data at T2 due to prisoners being released from prison. However, for the intervention to have a long-lasting improvement on the prisoner's oral health, it is important that the intervention successfully enables the prisoner to make lasting changes. If we do not find a statistical difference between the treatment and the control group at T2, however, it may be hard to tell whether this is due to the intervention effect fading out or lack of power. See power analysis for more details on this, in which we show effect sizes possible to detect at different number of observations, given that power is set to 0.8 and number of sites is set to 4. As drop-out increases at T2, the higher the effect size must be for us to be able to detect any statistical difference between the groups.

Moreover, we are going to run multiple ordinal logistic regressions where we include selected covariates (see below). Running regressions allow us to control for the baseline measures of plaque

by using the baseline score of the outcome variables as a lagged dependent variable, in addition to including other covariates likely to correlate with the treatment and to explain variation in the dependent variable. For robustness purposes we also run regressions with fixed effects, controlling for unobserved individual time-invariant characteristics.

Covariates:

The main covariate included in the analysis is the pre-intervention MPS index score. For our secondary outcome variables, the equivalent pre-treatment observation is used as covariate to control for pre-intervention status. We include these as they are likely to explain a lot of the variation in the outcome variable. Furthermore, we include a dummy variable for each prison, to control for prison-specific variation, and a dummy variable for the person who completed the MI-intervention with the prisoner.

As described below, we will also conduct heterogeneous analysis. Covariates that are relevant for such analysis (HASI and depressive symptoms) will also be included in the overall analysis.

Other covariates may be included, however given that we have successfully randomized prisoners, they should not affect our results. For robustness purposes, we will run analysis that include individual-specific covariates such as age, education, and length of prison sentence.

Heterogeneous analysis:

We will study heterogeneous effects of the intervention depending on their baseline score of the primary outcome variable. Those who score high on level of plaque have the greatest improvement potential. However, they might also be those with the least interest in taking care of their oral health. As motivational interviewing is designed to also motivate those who are not motivated, they may still experience the greatest improvement from the intervention.

Moreover, we will study heterogeneous effects of the intervention depending on the prisoner's score on the learning ability screening test (HASI). The minimum and maximum score on the screening test is 45,7 and 96,4 points, respectively. HASI suggests that the border line of 85 should be used to indicate possible intellectual disabilities. However, when Søndena et al. (2008) validated the Norwegian translated version of the test on a sample of prisoners in the Norwegian Correctional Service, they found that this cut off provided many false positive cases compared to the more comprehensive Wechsler Abbreviated Scale of Intelligence (WASI). They suggested a lower cut off score of 80 to avoid too many false positives. We will study heterogeneous effects using both these cut offs in separate regressions, constructing dummy variables that separate those below or above the cut off, and interact these dummy variables with the treatment variable. There are two main reasons why we might expect (or not expect) a heterogeneous effect of the intervention for these groups. Motivational interviewing is developed to help patient groups that do not respond to traditional therapy, suggesting that prisoners with possible intellectual disabilities may still benefit from the intervention. On the other hand, however, scoring low on the ability screening may make it more difficult to benefit from the from the MI-based conversation and to use it as a basis for change.

Finally, we are going to study heterogeneous effects of the intervention depending on the prisoner's depressive symptoms, measured by MHI-5. We expect those with stronger depressive symptoms to respond less to the intervention, as they are less likely to be in a state where they prioritize their oral health and to benefit from the MI-based conversation. We collect MHI-5 at both T0, T1 and T2. As MHI-5 at T1 and T2 may be correlated with the intervention, we must use MHI-5 measured at T0 as

basis for differential effects in this analysis. The scale of MHI-5 is 0 (poor mental health) to 100 (good mental health). In the literature, the most frequent cut offs used to describe depressive symptoms seems to be 52 points (severe depressive symptoms), 60 points (moderate or severe depressive symptoms), and 68 points (mild, moderate, or severe depressive symptoms). We expect the number prisoners with depressive symptoms to be substantial. In a study of prisoners in the Norwegian Correctional Service, Friestad & Kjelsberg (2009) showed that 27% of the prisoners had mental health problems of significant intensity (classified as “psychiatric case” using the Hopkin Symptom Checklist). We are going to study the interaction effect between MHI-5 and the treatment in two ways. One way is to create dummy variables based on the cut offs suggested above and run separate regressions for each cut off (interacted with the treatment variable). The other approach is to include the MHI-5 variable as a continuous variable and interact it with the treatment variable. For the latter case to have a correct specification, MHI-5 would need to have a linear relationship to the dependent variable, which may not be realistic. One might think that those with more severe depressive symptoms are substantially more affected than those with very mild depressive symptoms. Adding a squared term of the MHI-5 variable will account for a potential quadratic relationship to the dependent variable. Additionally, we will run analysis to control for changes in depressive symptoms when studying the overall effect of the treatment. As the variation in depressive symptoms between T0, T1 and T2 may be correlated with the treatment, this will be an endogenous analysis that might still shed some light under which conditions the treatment works.

Other issues:

The covid-19 pandemic is still ongoing at the start of data collection. Even though everyone in Norway have been offered two doses of the vaccine when data collection started, new variants of the virus and larger outbreaks of existing variants are likely to cause delays and possibly missing data. The omicron variant of the virus has already forced temporary suspension of data collection, and we expect to have follow-up observations at times different from what is stated in the flow chart, and missing observations as prisoners have been released from prison or transferred to a different prison prior to follow-up observations (especially during a temporary suspension of data collection). These issues occur independent of whether the prisoner is in the treatment group or not.

Delay in data collection due to temporarily suspension of the trial, may force us to redefine the follow-up periods from 4 and 12 weeks to a range of weeks such as 4-6 and 12-15 weeks. Despite making the follow-up periods more flexible, we are likely to have observations delayed even beyond this, leading to missing data. Additionally, as already mentioned, we are likely to have missing data due to prisoners being released or transferred to a prison that is not part of our study. To partially account for this, we will consider multiple imputations and/or maximum likelihood estimation to replace missing data.

Although we are unlikely to experience non-compliance of treatment prior to the time of the intervention, there is a real concern about attrition between the intervention and the follow-up observations. We can only speculate on reasons to why they choose not to participate any further. Prisoners are in a vulnerable position, and many of them have severe health issues stopping them from participating. They might also be busy working or studying, find it unnecessary (less informative) to see dental staff multiple times, choose not to prioritize it at the expense of leisure time or other activities, and so on. Importantly, attrition may be correlated with the intervention itself.

We carefully note any missing data and separate reasons depending on whether it is due to the prisoner being released from prison, moved to a prison outside our trial sites, temporary suspension of data collection due to the pandemic, if they choose not to meet at T1 or T2 despite still being available in the prison, or any other reason.

As mentioned under the section for blinding, there will be two assessments of the MPS index score at T1 and T2, as dental staff are not blind to their second and third meeting with the prisoner. If the original examiner finds no improvement in the MPS-index score, the second examiner's score will be ignored. If the original examiner finds an improvement, the average score of the original examiner and the second examiner will be used, however the second examiner's score will not be used to increase the average score above the assessment of the original examiner. We consider this a conservative approach. If the original examiner is not part of the team that evaluates at T1 and T2 (for example if the prisoner has been transferred to a different prison, or due to sick absence), an average score of the two assessments by the new examiners will be used.

Another concern is potential differences in how oral examinations and the intervention is conducted across multiple sites. To minimize differences, all dental staff have undergone the same MI training and practice. All oral examinations are being conducted by trained professionals, and they have gone through a calibration day prior to the start of the data collection. Moreover, they will continuously be provided guidance from a professional MI-consultant. In addition, we track the time they spend on each MI-based conversation.

Recruitment of prisoners may also be slightly different from one prison to another, as in half of the prisons it is done by prison officers and the other half it is done by dental staff. Prisoners may perceive the question of whether they want to participate or not differently, depending on whether they are asked by a prison officer compared to a dental staff. Moreover, the language assessment may also be different. Although this occurs independent of the randomization, it might lead to a difference in the population recruited to the experiment across prisons. Unfortunately, we could not have the same recruiter across all prisons. However, the information provided to the prisoners is the same across all prisons. This also applies to the instructions concerning language assessment; in the case of uncertainty about Norwegian language skills, the same screening question is asked across prisons, and the same evaluation criteria is being used.

Conclusion

Conducting randomized controlled experiments in prison are challenging, especially during a pandemic. It requires solid external partners willing to adapt to unforeseen challenges that arise prior to and during data collection, and a research plan that likely need adjustment along the way to meet such challenges. This pre-analysis plan was written before any data analysis had been done, but after data collection was initiated. It therefore includes some of the initial unforeseen challenges the study faced, with prisons going into full lockdown due to the Omicron-variant of the Coronavirus flourishing in November and December 2021.

The pre-analysis plan includes detailed descriptions of the population, data collection and analytical decisions made prior to any analysis being conducted. It raises several issues that may arise during the data collection and data analysis, and how to cope with these issues if they arise. However,

conducting research on this population in such an institutional setting is still challenging, and unforeseen events may still arise.

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