

Improving Oral Health in Prisons: Protocol for a randomized Controlled Trial (PriOH)

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Submitted to: JMIR Research Protocols
on: May 23, 2024

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Table of Contents

Original Manuscript..... 5
Supplementary Files..... 20
 Figures 21
 Figure 1..... 22

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Abstract

Background: People living in prisons often experience poor oral health, which could be attributed to their limited access to (dental) care, financial constraints, and a general lack of awareness and prioritization towards their oral hygiene. A pilot study involving motivational interviewing has shown promising results for improving the oral health outcomes of people living in prisons.

Objective: The protocol for the current study aims to assess the efficacy of integrated motivational interviewing and oral health care packages in improving oral health among people living in prisons, compared to controls without added motivational interviewing.

Methods: PriOH is a multicenter, randomized, double-blinded controlled trial that recruited inmates from four prisons in Rogaland County. The trial aimed to recruit 320 participants before randomly allocating them to either a control or intervention group. The intervention group received motivational interviewing, consisting of a 30-minute session encouraging inmates to discuss their current and desired oral health behaviours and attitudes, highlighting discrepancies to motivate change. Assessments were conducted at 4 and 12 weeks after initiation. The primary outcome measurement is the mucosal plaque scores to assess oral health behaviours, attitudes, and oral hygiene. Secondary outcome measurements are oral hygiene routines, sugary food and drinks intake, oral health perception and oral health-related quality of life.

Results: Data collection started in November 2021 and ended in June 2023. A total of 327 participants were recruited, of which 126 received the intervention.

Conclusions: Integrating motivational interviewing in oral health programs at prisons can significantly improve the oral health of incarcerated individuals. Should the results from this study demonstrate efficacy, it could be valuable insight for policymakers, oral health practitioners, and correctional services in addressing the needs of a traditionally underserved group before being scaled up to enhance dental care practices in prisons. Clinical Trial: ClinicalTrials.gov Identifier: NCT05695443).

(JMIR Preprints 23/05/2024:60817)

DOI: <https://doi.org/10.2196/preprints.60817>

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Original Manuscript

Improving Oral Health in Prisons: A Randomized Controlled Trial Protocol (PriOH)

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Keywords: Intervention; Motivational Interviewing; Oral Care; Marginalized Groups; Correctional Services; Implementation; Oral Hygiene

Introduction

Background

Poor oral health tends to affect people living in prisons disproportionately [1, 2], which may be attributed to the lack of accessible oral health services within correctional facilities, financial barriers, a lack of awareness and priority, and limited use of oral health hygiene products and tools

[3]. Scholars argue that ensuring good oral health for people who have been incarcerated and are in the process of reintegrating into society is particularly important because it can lead to a more successful outcome [4]. Assuring good oral health for people living in prisons is described as an international challenge. It is often related to the lack of staffing and logistical issues during transfer to and from dental clinics [3, 5, 6]. These barriers may also explain why, in Norwegian prisons, emergency dental treatment tends to be the most sought reason for dental care[6].

Another critical factor as to why people living in prisons tend to have poorer oral health is that they are more likely to have disadvantaged backgrounds, experienced social exclusion and often have lifestyles increasing the risk of developing oral diseases [7-10]. With the prison parameters directly limiting one's ability to engage in risk behaviors leading to poor health, one could argue for exploiting these contextual parameters and providing people living in prisons with oral health improvement measures.

Promoting and assuring good oral health for people in prisons has been advocated at structural levels by The World Health Organization's Prison Programmes, calling for health promotion to be equal outside as within prisons [11], and at the dental practitioners level [6]. Assuring and promoting good oral health is different globally. In Norway, along with France and the UK, the health care for people living in prisons falls under the responsibility of the national public health department [8]. Moreover, Norwegian legislation states that public dental services should work preventatively towards those incarcerated. Currently, people living in prisons receive free dental care for acute matters from their first day of incarceration [12, 13]. After that, regular dental examinations, with means to prevent and treat oral decay, are made accessible and free of cost when incarceration exceeds three months [13]

Nonetheless, a recent Norwegian regional report highlighted the need to strengthen the preventative and health-promotive measures [12]. In light of this recent report and the international literature revealing a lack of interventions despite this population scoring disproportionately poorer on oral health measures [14], the Oral Health Centre of Expertise Rogaland (OHCER) developed an intervention that included motivational interviewing, with means to promote good oral health behaviors and thereby prevent oral diseases for people living in prisons.

Intervening with Motivational Interviewing and Training for it

Motivational interviewing (MI) is a collaborative, person-centered technique that strives to achieve change through conversational techniques [15]. The driving conversation aims to last around 30 minutes, exploring the participant's current and desired oral health behaviors and attitudes. An MI-led conversation assumes that asking questions illuminating the discrepancy between the desired and current state and behavior motivates the person to change [15].

The MI approach used in this study closely adheres to the techniques described by Miller and Rollnick [15]. The following section describes how the MI-led conversation played out in the current study and the training dental practitioners received to converse with the MI techniques.

The MI-led conversation starts with asking openly about a topic related to oral health, for example, "What cleaning routines do you have for your teeth?" or "What benefits could you get from brushing your teeth twice daily?". This open question confirms what the participant is doing, for example, "You are truly 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 involves reflection. At the reflection stage, the dental practitioners reflect on what the participants have said by, for example, simply repeating or using synonyms, extracting the underlying opinion or gut feeling, or dually highlighting the participant's pros and cons. The MI-led conversation closes with summarizing the participants' words and filling out a change plan. Following the conversation, the change plan is a printed handout identifying what the dental practitioner and participant agreed should change. The assumption is that

the change plan can be a reminder of the participants' goals, help them with the steps in their change process, and help them overcome obstacles.

The current study used dental practitioners to lead the MI conversation. These dental practitioners were employed by public dental services (Rogaland, Norway) and consisted of six dental hygienists, one dentist and three dental assistants. The dental practitioners recruited themselves to the study after learning about it through an email.

In the prison setting, the dental practitioners performed the MI-led conversation once (figure 1) through individual interviews with imprisoned people. Before conducting the MI-led conversation, the dental practitioners received training from an MI-certified specialist from the Regional Alcohol and Drug Competence Center in Rogaland County (KORUS). The training was a three-day seminar consisting of group work and discussions, followed by a practice session where MI-centre KORUS in Bergen recorded, transcribed, and graded their MI-led conversation. After, dental practitioners received direct feedback on this conversation. The MI specialist at the Center for Alcohol and Drug Research at Stavanger University Hospital, KORFOR, was available for continuous guidance for the dental practitioners if needed.

From here on, this protocol refers to the MI-led conversation as the intervention.

Aims and Objective

Previous research and a pilot study conducted by the OHCER have shown that MI techniques can promote oral health and prevent oral health challenges by altering unhealthy habits and behaviors [15-18]. The current study is a randomized controlled trial that builds on the pilot study [16], to assess whether a conversation following MI techniques (the intervention) can enhance people living in prisons' oral health, cleaning routine behaviors and oral health attitudes. To answer the study aim, five hypotheses have been outlined:

- H1: The intervention will reduce observed plaque and gingival inflammation for prisoners (MPS).
- H2: The intervention will lead to improved reported oral hygiene routines, particularly brushing of teeth.
- H3: The intervention will lead to a reduced intake of food and drinks that contain sugar, specifically in between meals.
- H4: The intervention will lead to improved perceptions about their 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 have increased efforts to improve it.
- H5: The intervention will lead to an increased number of questions asked during the dental practitioners' oral assessment, suggesting increased curiosity concerning their oral health.

Method

Design

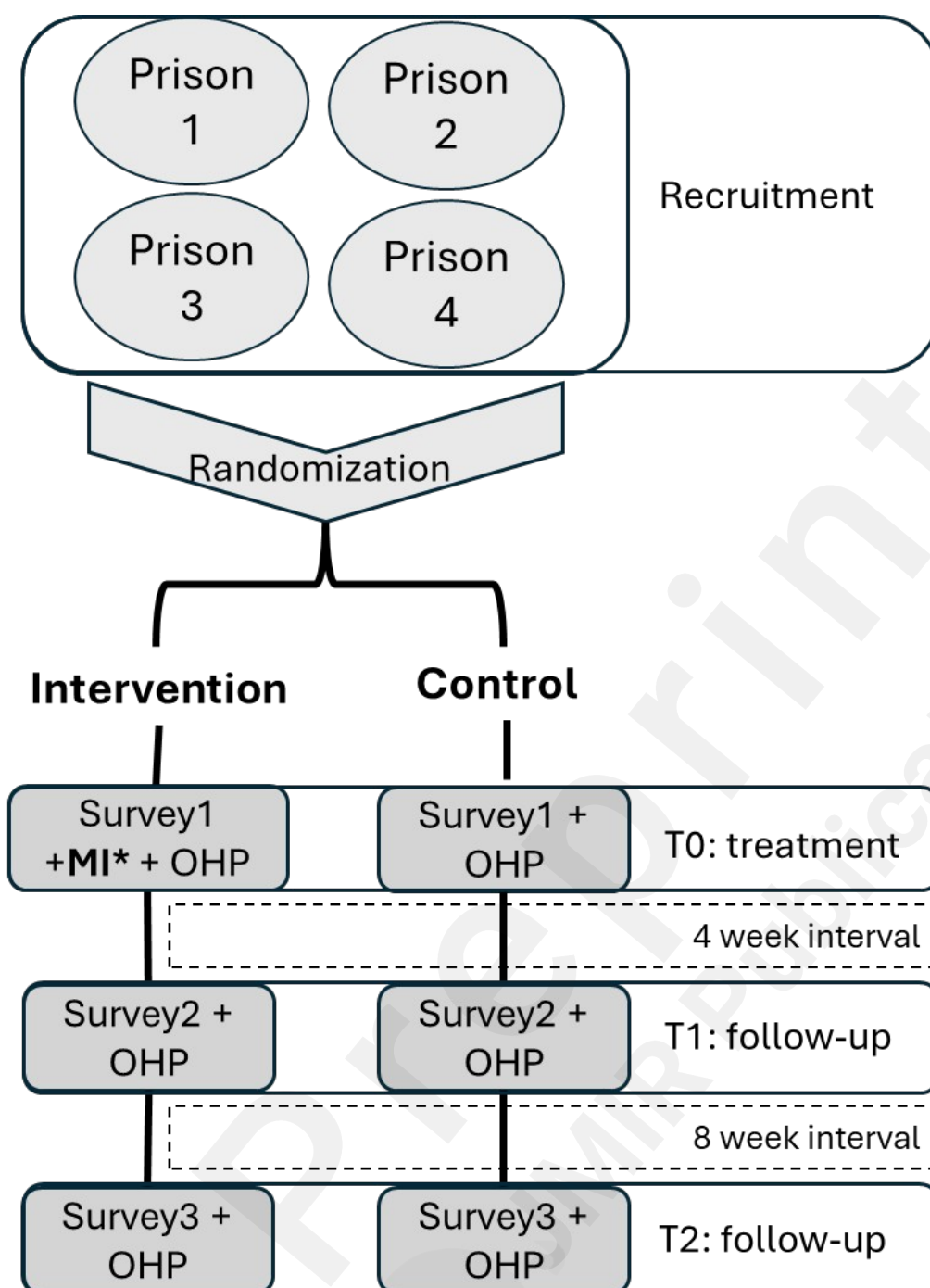
A multicenter randomized controlled trial with a parallel group design and superiority framework will be used to assess the effectiveness of the intervention in improving oral health behaviors, attitudes, and hygiene for people living in prisons. From November 2021 to June 2023, all people convicted of serving time in any of the four correctional facilities (prisons) in Rogaland County and who passed a security and language assessment were recruited.

After giving oral consent, the study participants were randomly assigned to an intervention or augmented control group that was blocked at the prison level. This means although study participants were randomized, there was an equal number of participants in both the intervention and augmented control groups within each of the four participating prisons (striving for 1:1 allocation). The randomization was computer-generated through www.randomizer.org.

To prevent selection bias, this study's concealment methods were computer-generated randomization at the back office by the research team. This, in practice, meant the research team received an unidentifiable participant-numbers that was added to the randomization pool. Prison staff were then notified on which participant-number should receive the intervention or not who then generated a list the dental practitioners performing the intervention conferred with. This study did not employ a data monitoring committee (DMC) as the intervention was assessed as minimally invasive, alluding to a low risk of harming the participants.

A two-fold survey, consisting first of an oral assessment before a questionnaire, was administered at three data collection points that aimed at a 4- and 8-week interval (T0, T1 and T2 in Figure 1). At the end of each survey, all participants were given an oral hygiene package (OHP) consisting of mouthwash, toothpaste, a toothbrush, and interdental cleaners (plackers and soft gum picks). Providing all participants with the same material to enhance their oral health also ensured that all participants had equal equipment and opportunity at baseline to enhance their oral health. Moreover, ethical considerations also played a role in giving the control group an OHP, which is detailed in the Ethics section. Given the prophylactic effect the OHP could have and the presumably increased focus on oral health related to the assessment, the control group is an augmented control group (hereon defined as the control group), as it does not reflect a regular prison context.

Figure 1: Study timeline and process



* Dental practitioners performing the MI were blinded until they had finished the survey (consisting of an oral assessment and questionnaires). Thus, although the research team had already randomized participants into intervention or control groups, dental practitioners did not know the effects of the randomization until measurement scores were taken, to avoid bias.

MI: Motivational interviewing; OHP: Oral hygiene package; Surveys 1,2 and 3 included an oral assessment and questions related to their incarceration and oral hygiene routines, sugary food and drink intake, oral health perception and mental health (MHI-5) but varied in the length of their additional questions.

Study Setting, Participants and Procedures

The study has already collected data. Thus, procedures related to recruitment are written in the past tense. Participants were recruited from four prisons in Rogaland, three being high-security and one being low-security. Low- and high-security prisons differ in their degree of freedom; high-security prisons give prisoners less freedom to move within and outside prisons. Seventy per cent of prisons in Norway are high security, and people penalized are automatically placed there unless the sentencing timeframe is less than two years. Inmates are also often transferred to a low-security

prison at the end of their sentencing. Therefore, the severity of the crime does directly indicate whether you are in a high or low-security prison.

Study recruitment varied due to logistics in the prisons and constant enrollment. Recruiting participants who were already serving time in prison was done by a dental staff or prison officer approaching eligible inmates (table 1) and informing them about the study. For new inmates arriving at the prisons, recruitment became embedded on their first day of entry, as they were informed about study participation by prison staff while learning about the prison's procedures and drills. Participants gave their preliminary consent to participate within a few days after being informed about the study by notifying prison staff. They were then randomized to either the intervention or control group. Formal written consent was given to the dental practitioners after they had been randomized (T0, Figure 1). Information about study participation was similar across all four prisons; they got verbal and written information, which was repeated by the dental staff before the written consent was obtained. At the recruitment stage, individuals were screened for language and study eligibility criteria, including inmates who could speak English or Norwegian and who passed a security assessment (table 1). Only Norwegian-speaking participants were allocated to either the control or intervention group based on the assumption that dental practitioners would struggle with MI in a different language. Table 1 outlines the study's inclusion and exclusion criteria.

Table 1. Inclusion and exclusion criteria for study participation

	Inclusion	Exclusion	Rationale	Procedure
Language	Norwegian speakers and	*English speakers and non-Norwegian speakers	The study lacked trained and calibrated staff to conduct the MI in languages other than Norwegian	Prison staff assessed this either at face value or by asking a standard question from an official Norwegian language test that detects a person's ability to engage in a simple conversation
Security	Who were not at risk of harming themselves or others	Inmates whose incarceration was in isolation	The study did not seek to compromise any of the staff or inmates' security	Prisons staff assessed this throughout the study period
Age	≥ 18 years		The prison facilities in Norway are split for adults and adolescents.	By recruiting at the given prisons, all above 18 years of age were included

			This study recruited from adult prisons	
Gender	All genders: Male, Female and Other	none		By recruiting at the given prisons, a female division at one prison was a natural part of the participation pool

*Considering the potential number of English speakers, the survey and consent form was outlined and administered in English to capture more baseline data. These will not be included in the analyses assessing the effects of MI.

As outlined in Figure 1, the study has three data collection points: baseline (T0) and follow-up (T1 and T2). At T0, the participants were administered Survey1, which was two-fold and consisted of an oral assessment and questionnaires. The oral assessment examined the mean number of Decayed, Missing and Filled Permanent teeth (DMFT)[19] and the Mucosal-plaque score (MPS)[20]. The questionnaire in Survey1 consisted of 83 questions on their incarceration, oral hygiene routines, sugary food and drink intake, oral health perception and oral health-related questions on dental anxiety (MDAS) and quality of life (OHIP-14), sociodemographic and socioeconomic factors, use of dental and health services, general health and mental health (MIH-5) and alcohol and drug use (AUDIT-4 and DUDIT). Survey 1 was expected to take around 60 minutes. Data collection with participants receiving MI was expected to last around 90 minutes, and an additional 30 minutes were allocated to the intervention.

The follow-up phases, T1 and T2, each lasted around 30 minutes. At T1, Survey2 was administered, which contained the MPS oral examination and questions related to their incarceration, oral hygiene routines, sugary food and drinks intake, oral health perception, the MIH-5 and a short screening for learning disabilities (HASI). At T2, Survey3 was administered, which contained the MPS oral examination and questions related to their incarceration, oral hygiene routines, sugary food and drink intake, oral health perception and the MIH-5.

Measurements

Primary Outcome

The primary outcome measurement to assess the interventions' effectiveness in improving oral health behaviours, attitude, and oral hygiene for people living in prisons is the Mucosal plaque score (MPS). This score is a composite measure that includes assessments of mucosal inflammation (MS) and plaque (PS), which are indicators of changes in dental hygiene routines and attitudes [20]. The MPS was assessed at three time points: baseline (T0), midpoint (T1), and at the completion of the study (T2). The assessment procedure is simple and minimally invasive, ensuring minimal participant discomfort. Both the MS and PS scores range from one to four.

During scoring, dental practitioners undertaking the clinical MPS assessment are advised to score lower (a score of 1) in cases where there is doubt between the score of 1 and 2, and higher (a score of 4) for cases where there is doubt between the score of 3 or 4—combined the MS and PS give an MPS score that has a total score of 8 and a minimum score of 2. Assessment guidelines define a score of 2-4 as good/ acceptable, 5-6 as not acceptable and 7-8 as in no way acceptable [20].

Secondary Outcome

Secondary outcome measurements this study is interested in are oral hygiene routines, sugary food and drink intake, oral health perception, and oral health-related questions, which were assessed in the survey at T0, T1 and T2.

For oral hygiene routines, participants were asked about their use of dental hygiene products such as toothbrushes, toothpaste, mouthwash, floss, and toothpicks over the last four weeks.

Participants were asked about their consumption within the last four weeks for sugary food and drink intake.

For oral health perception, participants were asked about their view of their health, the importance of good oral health, and their willingness to improve and take better care of their oral health. Dental practitioners noted how often study participants asked about their oral health during the oral assessment.

Participants were also asked about using a change plan (handed out after the MI-led conversation), which also serves as a secondary outcome measure.

Lastly, the survey collected descriptive data from participants that will be used to describe the population based on sociodemographic and socioeconomic factors, the use of dental health services and health services, and indicators of general and mental health (MIH-5). Additionally, the burden of oral decay (DMFT), substance use patterns (assessed by AUDIT-4 for alcohol and DUDIT for drug use), the presence of learning disabilities (HASI), levels of dental anxiety (MDAS), and the impact of oral health-related quality of life (OHIP-14) were also collected and will be used as descriptive data for the population. These data will also serve as covariates in the statistical analysis evaluating variables associated with oral health.

Sample Size and Justifications

Determining the needed sample size and power was assumed before data collection (ClinicalTrials.gov Identifier: NCT05695443). Setting the alpha at 0.05, power of 0.80, for a non-parametric Wilcoxon-Mann-Whitney test. Data from previous studies employing MI to improve oral health deviates from this study's population and in scoring plaque. Studies with a plaque index score as the primary variable to explain the effect reported a plaque range from 0.286 to 1.213 [21, 22]. A conservative calculation through the computation tool GPower, determined a sample size of 320 people living in prisons to meet an observable effect size of 0.80, which was strived for. Given data has already been collected, we have performed a sensitivity power analysis through the computation tool GPower, to compute the required effect size with our sample size of 126 in the Intervention group and 157 in the Control group. Setting the same parameters as prior (alpha at 0.05 and power at 0.8) gives us an effect size of 0.305.

Data Analysis

Analysis will be performed using the statistical software package SPSS (IBM). The unit of analysis is at the individual level. As the study is interested in uncovering the group differences between the intervention and control groups, a non-parametric Wilcoxon Mann-Whitney U-test will be run, and

group means will be compared at T0, T1 and T2 (figure 1). The outcome of interest (primary outcome variable) is whether the participants' MPS scores have changed since baseline. The main covariate is the pre-intervention (T0) MPS index score.

Double Blinding

Study participants and dental practitioners were blinded to group assignments during the initial oral examinations and questionnaires (Survey1) at baseline (T0). This double blinding was maintained until the dental practitioners completed the initial survey, after which they conferred with a list to check if participants were in the intervention or control group. At the follow-up data collection points (T1 and T2), dental practitioners might have recalled the participants' group assignments, potentially introducing bias. To mitigate this, the study incorporated MPS assessments from two independent dental practitioners at these stages, and scores were confidentially maintained to prevent bias.

As a final measure to ensure objectivity, data analysis will be conducted by a researcher who was not involved in any previous stages of the study, effectively establishing a third level of blinding during the analytical stage.

Missing Values

Missingness is presumed to be unrelated to the observed and unobserved data, thus, as missing completely at random. For analytical purposes, variables missing for the primary outcome will be handled with an intention-to-treat approach, allowing the study to use baseline data.

Ethics

The Norwegian Regional Committee for Medical and Health Research Ethics (282231), Criminal Services and Norwegian Agency for Shared Services in Education and Research (300281) has approved this study.

The study relies on informed written consent. To ensure prison inmates have been fully informed about study participation, recruitment processes have relied on help from both dental practitioners and prison staff. The written consent form was read out loud as well as handed out to ensure those with reading deficiencies understood what study participation entailed. As English speakers were included for baseline data, a consent form in English was also presented.

Ethical deliberations led the study to administer the questionnaire part of the surveys verbally to ensure participants fully comprehended the questions asked. Verbally performing the questionnaires also gave latitude for the participant to ask questions in return and the dental practitioners to remind participants that they could withdraw or refrain from answering at any point without any form of consequence.

All participants (intervention and control group and English speakers) received an oral hygiene package because of the assumption that not all prison inmates had equal and sufficient tools to perform and potentially enhance their oral hygiene routines. Considering participants were randomly allocated into the control or intervention group, it was considered unethical to only give a hygiene package to those enrolled in the intervention group. The oral hygiene package passed prison security clearance.

All study participants (intervention and control group and English speakers) also received an oral assessment, which allowed dental practitioners to refer participants who needed dental treatment. This referral line was established due to ethical concerns, deeming it unethical for dental practitioners to detect oral diseases needing treatment without attending to them.

This study chose not to ask and collect data on what offences were committed due to ethical and safety concerns. It was believed that knowing the crime offended could affect the dental practitioner's

approach and conduct towards the study participants.

Although this study was assessed as minimally invasive for its participants, all studies can impose a risk of impairment resulting from participation. To ensure this study limited its adverse events, dental practitioners who conducted the intervention and survey had direct contact with prison staff and were on alert, reacting to any signs of harm following the survey or intervention.

Results

Data collection started November 2021 and finished June 2023. Out of the total 327 participants, 283 were given the questionnaire in Norwegian, while 44 received it in English. A total of 126 of these received the intervention. The study is still plotting all data and will refrain from analysis until this protocol has been reviewed. All results from the data collection phases are expected to be ready by 2026.

Discussion

Principal Considerations

The global prison population has grown by 27% since 2000, and currently, over 11 million people are living in prisons [23]. Being incarcerated directly limits the ability to access health care services. This might be attributed to the lower outcome measurements of oral health for inmates in prisons. Moreover, routine interventions in prison contexts are scarce [14], and there is a lack of focus on oral health promotion in prison research [24].

This calls for a change in how oral health is promoted for people living in prisons. The opportunities the MI techniques provide could lead to more health promotion, less need for acute treatment, saving resources for the prison, and reducing the number of prison inmates who need transport to the dental clinic. The current study was developed to improve the oral health for people living in prisons. Thus, the findings from this study will allow us to understand if the currently underserved population could benefit from an alternative approach.

Moreover, providing MI to the prison population can serve as a low-cost, effective procedure for increasing prison inmates' motivation to routinely care for their oral health by engaging a dental hygienist to conduct the conversation. Cost-effective studies could investigate whether MI with people living in prisons could be a more cost-effective way to build a dental clinic at the prison site.

Strengths and Limitations

A strength of this study is ensuring that dental practitioners who were undertaking the oral assessment were calibrated and received the same MI training. Dental practitioners were calibrated through a one-day workshop where they met physically to discuss clinical oral examinations, questionnaires, and procedures. Fifteen clinical photos were scored for MPS: First, the photos were individually scored before being jointly discussed and agreed upon. As the dental practitioners varied in background, the three participating dental assistants received an additional hour of calibration, compensating for their lack of clinical experience. This supplementary calibration hour for the dental assistants involved reviewing and MPS scoring 50 clinical photos. Lastly, two independent MPS scores on the participants were retained to avoid biases during data collection by having two dental practitioners scoring the same person individually.

Although dental practitioners who led the intervention were trained, they could also lack confidence in the therapeutic role due to the novelty of using MI in prisons, which could affect the intervention delivery and outcome.

A notable limitation of this study is that both groups received an oral hygiene package comprising

oral hygiene products that could act as a preventative for oral decay. Moreover, Survey 1 included 83 questions, which were asked prior to the MI-led conversation. These questions might have caused fatigue in participants, deterring the effects of the motivational interview.

Lastly, the current study deviates from the pilot study by including the MI communication element of *reflection* [15, 16].

Conclusion and Directions for Dissemination

The study aims to test and measure the effects of an MI-led conversation on improving people living in prisons' oral hygiene, cleaning routines, and attitudes. Granted that the intervention has an effect, the results can aid in how public dental health services can promote oral health for an underserved population, thereby increasing their objective of acting health promotive.

Results from the study will be published in national and international academic journals. The study's findings will also be shared through conferences for academics and practitioners and various forms of public media. A report of the project will also be written and shared with the collaborating partners and will also be open to the public.

This protocol has followed SPIRIT guidelines.

Acknowledgements:

We want to thank our collaborative partners, the Regional Alcohol and Drug Competency Center, Rogaland (KORUS), who contributed to the design of the MI-intervention and training of dental practitioners; Center for Alcohol and Drug Research, Stavanger University Hospital (KORFOR), who contributed to developing the questionnaires, and in supervising dental practitioners in MI; the Directorate of Norwegian Correctional Service, Rogaland, and the four prisons for recruiting study participants and facilitating this study.

We extend our utmost gratitude to the study participants and dental practitioners for their time, encouragement, and motivation. We also want to thank the Regional and Public Oral Health clinic leaders for managing logistics. A major thanks to Kjersti Berge Evensen for aiding the study's conceptualization and development and setting the necessary grounds for continuing this study. Lastly, Else Bjørheim, thank you for helping with the ongoing data plotting.

Funding

PriOH is funded by OCHER and public dental services in Rogaland, providing the study with material support for oral health packages and financial support for utilizing dental practitioners.

Data Availability

Data collected from this study is sensitive, and participants have not consented to freely distributing it, limiting its availability.

Authors' Contributions

WG has led the study's conceptualization and development of the study's methodology. KHB and WG contributed to the study's data collection procedures and project administration.

EB and KHB drafted the manuscript. All authors have read and approved the final manuscript for publication.

Conflicts of Interest

The authors declare no conflict of interest.

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Supplementary Files

Figures

* Dental practitioners performing the MI were blinded until they had finished the survey (consisting of an oral assessment and questionnaires). Thus, although the research team had already randomized participants into intervention or control groups, dental practitioners did not know the effects of the randomization until measurement scores were taken, to avoid bias. MI: Motivational interviewing; OHP: Oral hygiene package; Surveys 1,2 and 3 included an oral assessment and questions related to their incarceration and oral hygiene routines, sugary food and drink intake, oral health perception and mental health (MHI-5) but varied in the length of their additional questions.

