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Updated Statistical Analysis Plan for Improving Oral Health in Prisons (PriOH): Protocol for a Randomised Controlled Trial

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Research Article

Keywords: Oral Health, Oral Hygiene, Motivational Interviewing, Prisons, Health Services for Prisoners, Randomized Controlled Trial

Posted Date: September 9th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10957314/v1

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Additional Declarations: The authors declare no competing interests.

Abstract

This update provides a statistical analysis plan for an earlier protocol of the PriOH randomised controlled trial (NCT05695443). The trial assesses whether a single brief motivational interviewing session improves the oral health for incarcerated individuals in Norway. The intervention period lasted 12 weeks, with follow-up assessments after 4 and 12 weeks. Participants in both groups received a clinical oral examination scoring mucosal-plaque and inflammation, completed a questionnaire, and received an oral hygiene care kit at baseline and follow-up visits. Additionally, participants in the intervention arm received a single brief motivational interviewing session at baseline. Data collection was completed in June 2023. To assess the effects of the intervention, the primary outcome is a binary measure of sustained improvement in oral hygiene and inflammation status assessed through the mucosal-plaque index and analysed with a generalised linear mixed model. The analyses will follow the intention-to-treat principle.

Trial registration: ClinicalTrials.gov NCT05695443. First submitted 22 November 2022; first posted 25 January 2023; last updated 23 January 2024. **https://clinicaltrials.gov/ct2/show/NCT05695443**

Introduction

Background and rationale

A recent review concluded that although the prison population experiences high burden of oral disease, interventional studies aimed at improving oral health in prison settings remain scarce (1). The present randomised controlled trial extends a previously conducted pilot study (2) suggesting that motivational interviewing (MI) may improve oral health and oral health-related behaviours among incarcerated individuals.

There is substantial evidence supporting MI as an effective tool for behaviour change (3), including populations residing in prisons (4). Nevertheless, its effectiveness in promoting oral hygiene practices and attitudes for incarcerated individuals remains uncertain. To address this knowledge gap, this statistical analysis plan (SAP) describes planned analyses — as an extension to the trial's protocol (5) — assessing the effect of a brief MI session in improving incarcerated individual's oral health. This SAP follows Gamble et al. (6) proposed guidelines.

Objectives

The PriOH (Prison Oral Health) trial assesses the effect of a brief MI session on oral health among incarcerated individuals. The primary outcome is sustained improvement in oral hygiene and inflammation status, measured by the Mucosal-Plaque Score (MPS) (7).

Oral hygiene routines, intake of sugary food and drinks, self-reported oral health, perceived importance of oral health, desire to improve oral health, self-reported efforts to improve oral health, and oral health-

related questions asked by the participant during the oral health exam and the questionnaire were included as secondary outcomes. Further details related to the secondary outcomes are outlined in the PriOH trial protocol (5).

Study methods

Trial design

PriOH is a multicentre, individually randomised, parallel-group controlled trial with two arms: intervention and augmented control. Participants were allocated after they had given verbal consent and met the eligibility criteria (English/Norwegian comprehension and no risk of harming themselves or others). In both arms, participants received an oral hygiene care kit. The intervention arm also received a brief MI session at baseline.

Randomisation

Participants were randomised in a 1:1 ratio to the intervention or augmented control arm. Randomisation codes were generated off-site through the web-based service Randomization.org and stored in a central randomisation list. No stratification or minimisation procedures were applied. In practice, prison staff forwarded anonymous participant ID-numbers to the research team, which then entered each ID into the central randomisation list. The list allocated participants to either the intervention or augmented control arm according to the prespecified randomisation schedule. Ten dental practitioners performed as research assistants by collecting all data (clinical assessments and questionnaires) in addition to conducting the MI session. These outcome assessors received information about group allocation only after completing the baseline clinical examination and questionnaire, ensuring allocation concealment until the end of survey 1 (T0).

Blinding and assessment bias

Participants and outcome assessors were blinded to treatment status during the baseline assessment. At follow-up (T1 and T2), blinding of outcome assessors was compromised, as they could potentially recall which participants engaged in the brief MI. To reduce assessment bias, MPS was obtained independently by two outcome assessors at T1 and T2.

Sample size

The sample size was determined a priori (5). A total of 320 Norwegian-speaking incarcerated participants were planned for inclusion. The sample size calculation was based on the primary outcome analysis.

Framework

The trial is conducted under a superiority framework. The aim is to test whether the intervention arm achieves better outcomes than the augmented control arm dose. The primary null hypothesis (H0) states that the probability of sustained improvement in MPS is the same in both arms. The alternative hypothesis (H1) states that this probability differs between arms, with better sustained improvement in MPS in the intervention arm.

Statistical interim analyses and stopping guidance

No interim analyses of efficacy were conducted during the trial. No formal statistical stopping boundaries or interim efficacy analyses were specified. Safety and security were managed according to the prison's standard security procedures throughout the trial.

Timing of final analysis and trial status

Recruitment started on 1st November 2021 and ended on 19th June 2023. Data collection commenced on 8th November 2021 and was completed on 26th June 2023. Following completion of data collection, all study data were compiled and entered into the study database. No analyses of trial outcome were conducted before finalisation of this SAP.

Timing of outcome assessment

The outcome data were collected at baseline and at two follow-up visits according to predefined time points. The planned time points for the assessment of primary and secondary outcomes are shown in Table 1.

Table 1
Timing and schedule of outcome assessments

Time point	Timing of outcome assessment	Assessment window
T0	Baseline (pre-intervention)	Not applicable
T1	4 weeks after baseline	4–6 weeks after baseline
T2	12 weeks after baseline	12–15 weeks after baseline

Statistical principles

Confidence intervals and P values

The nominal two-sided significance level will be set at 0.05 for the primary and secondary analyses. Effect estimates (odds ratios (OR) from generalised linear mixed models (GLMM)) will be reported with

corresponding p-values and two-sided 95% confidence intervals (CIs). Unless otherwise stated, CIs will be Wald-based. For secondary or exploratory analyses —where standard assumptions may not be met — alternative methods for CIs may be used.

Multiplicity

The primary outcome will be tested at a two-sided significance level of 0.05 without adjusting for multiplicity. All secondary, subgroup, per-protocol (PP) and sensitivity analyses will be considered exploratory. Corresponding effect estimates and 95% CIs will be reported and the findings from these will be interpreted cautiously.

Adherence and protocol deviations

Adherence to the intervention will be assessed in three ways: dental practitioners registering the MI session to the participant, the MI's duration (in minutes), and a register of whether the individualised change plan was completed and provided to the participant. The MI session was planned to last a maximum of 30 minutes and sessions duration will be summarised using mean and standard deviation (SD). Protocol deviations will be defined as deviations from the planned trial protocol occurring after randomisation and will include participants receiving the incorrect allocation; participants randomised to the intervention arm not receiving MI; participants randomised to the augmented control arm receiving MI; non-completion of the change plan, and follow-up assessments outside the assessment timeline. All protocol deviations will be documented and reported descriptively by trial arm.

Analysis populations

The primary analysis will follow the intention-to-treat (ITT) principle. Participants will be analysed according to their randomised arm, irrespective of adherence, protocol deviations, early release, transfer, or receipt of additional oral health care. This includes participants with the best possible MPS at baseline.

A PP analysis will be conducted as a supportive analysis to explore efficacy. The PP population will consist of participants in the intervention arm who completed at least 20 minutes of the MI session, corresponding to approximately 70% of the planned intervention time (8). This chosen threshold reflects a meaningful exposure to the intervention. Additional sub-group PP analyses will be conducted using an adherence-based approach based on the median intervention duration.

Trial population

The trial population consists of incarcerated individuals from four prisons in Rogaland County, Norway. Further details are provided in the published protocol (5). Baseline characteristics of the trial population and each trial arm are described in Table 2. A Consolidated Standards of Reporting Trials (CONSORT) flow diagram will be presented as Fig. 1 (9), showing counts of participants assessed for eligibility, excluded, randomised, allocated to the intervention or augmented control arm, followed up at T1 and T2, and included in the primary analysis. Numbers lost to follow-up will be reported in the flow diagram, and

the reasons (such as withdrawal, prison transfers, or release) will either be described in this diagram or in a supplementary table.

Table 2
Baseline characteristics

Characteristics	**Intervention**	**Control**	**Total**
	n = xxx	**n = xxx**	**N = xxx**
Sociodemographic variables			
Sex, male, n (%)			
Age, mean [SD] [a]			
Imprisonment, n (%) Remand Sentence			
Prison security, n (%) Low High			
Sentence already served (months), mean, [SD] [b]			
Number of times served, n (%) = 1 > 1			
Socioeconomic variables			
Education, n (%) Not finished basic education [c] Finished basic education High school or higher			
Employment, n (%) [d] No Yes			
Income adequacy, n (%) [d] No Yes			
Health variables			

Characteristics	Intervention n = xxx	Control n = xxx	Total N = xxx
Extent of physical pain impact, n (%) Little Some Great			
Mental Health Distress (MHI-5), n (%) [e]			
Oral health variables			
DMFT, mean [SD]			
Self-reported oral health, n (%) Poor Fair Good			
Oral health behaviour variables			
Desire to improve oral health, n (%) None To some degree To a large degree			
Toothbrush frequency, n (%) [f] < 1/day = 1/day ≥ 2/day			
Sugary intake between meals, n (%) [f] < 1/day = 1/day ≥ 2/day			
Daily Tobacco use, n (%)			
Alcohol use (AUDIT-C), n (%) [g] Low risk			

Characteristics	Intervention n = xxx	Control n = xxx	Total N = xxx
High risk			
Use of illicit drugs, n (%) [d] Never Yes			
Note: [a]: data-driven IQR based groups, [b]: time already spent incarcerated among those serving a sentence [c]: in Norway, the first 10 school years are mandatory for pupils, [d]: before prison, [e]: cut off score 68, [f]: last four weeks, [g]: cut off score 4. Abbreviations: DMFT = Number of Decayed; Missing and Filled Teeth due to tooth decay; MHI-5 = Mental Health Inventory-5; AUDIT-C = Alcohol Use Disorders Identification Test – Consumption; IQR = Interquartile Range			

Analysis

Primary outcome

MPS is the main variable of interest and the primary outcome measure of treatment effect (7). MPS is the sum of a four-point mucosal score (MS) and a four-point plaque score (PS). For the MS, 1 indicates normal mucosa, 2 indicates mild inflammation, 3 indicates medium inflammation, and 4 indicates severe inflammation. For the PS, 1 indicates no visible plaque, 2 indicates plaque is barely visible, 3 indicates moderate amounts of plaque, and 4 indicates large amounts of plaque — almost covering the entire surface of teeth or dentures. The total MPS, thus, ranges from 2 to 8, with higher scores indicating poorer oral health. Although MPS is obtained from ordinal component scales, it will be summarised using mean and SD to facilitate comparisons between arms and with other studies. MPS will also be described using median, interquartile range (IQR), and range as supplementary statistics. Table 3 presents the mean and SD of MS, PS and MPS for the randomisation arms at T0, T1 and T2.

Table 3
Summary of MS, PS and MPS across groups and timepoints

	Intervention group			Control group		
	T0	**T1**	**T2**	**T0**	**T1**	**T2**
MS, mean (SD)						
PS, mean (SD)						
MPS, mean (SD)						

Note:

MS: 1 = Normal appearance of the gingiva and oral mucosa; 2 = Mild inflammation; 3 = Moderate inflammation; 4 = Severe inflammation. PS on teeth and dentures: 1 = No visible plaque; 2 = Barely visible plaque; 3 = Moderate amounts of plaque; 4 = Large amounts of plaque.

Abbreviations:

MPS = Mucosal-Plaque Score; MS= Mucosal Score; PS = Plaque Score

Secondary outcome

The secondary outcomes comprise self-reported oral health-related behaviours and attitudes. Oral hygiene routines will be assessed by reported use of toothbrush, toothpaste, mouthwash, floss, and toothpicks during the last four weeks, each measured on a 6-point Likert scale ranging from “Several times a day” to “Never”. Intake of sugary food and drinks will be assessed by three items, each measured on a 6-point Likert scale ranging from “Several times a day” to “Never”. Self-reported oral health will be assessed by a single item with response options on a 5-point Likert scale ranging from “Very poor” to “Very good”. Perceived importance of oral health, desire to improve oral health, and self-reported efforts to improve oral health will each be assessed by a single item, with response options with a 6-point Likert scale ranging from “Not at all” to “To a very large degree”. Oral health-related questions will be assessed by two items on a 5-point Likert scale ranging from “No questions” to “7 or more”.

These secondary outcomes are designed to supplement MPS by capturing broader changes in oral health-related behaviour and attitudes, including participants who choose to focus on oral health-related behaviours other than oral hygiene alone.

The secondary outcomes will be analysed using GLMM with appropriate link functions for ordinal and binary Likert-scale outcomes. Table 4 outlines the planned analyses for the secondary outcomes.

Table 4
Summary of secondary outcomes

Outcome	Hypothesis	Outcome measure	Method of analysis
Oral hygiene routines	H2: The oral hygiene routines improve	A single item self-reported use and frequency of oral health equipment question	GLMM
Intake of sugary food and drinks	H3: The intake of sugary food and drinks decreases	A three-item self-reported intake of sugary food and drinks questions	
Self-reported oral health	H4a: How they view their oral health improves	A single item self-rated Self-reported oral health question	
Perceived importance of oral health	H4b: How important they consider their oral health improves	A single item self-rated perceived importance of oral health question	
Desire to improve oral health	H4c: Their wishes to improve their oral health increases	A single item self-rated desire to improve question	
Self-reported efforts to improve oral health	H4d: The efforts to improve their oral health increases	A single item self-rated self-reported efforts to improve oral health question	
Oral health-related questions	H5: Oral health-related questions asked during the clinical examinations increases	A two-item outcome assessor-rated measure of number of oral health-related questions asked during the oral health examination and questionnaire	

Note:

Secondary outcomes are described in more detail in the protocol (5).

Main outcome analysis model

The primary outcome is a binary indicator of consistent improvement in MPS over 12 weeks, defined as MPS at both T1 and T2 being lower than baseline, thereby measuring a more durable improvement in MPS. Improvement in MPS will therefore be defined as a binary variable, with no improvement coded as 0 and improvement coded as 1. In subgroup analyses, results for participants with baseline MPS ≥ 3 will be presented to evaluate effects among those with a potential for improvement. The binary outcome of MPS will be analysed using a GLMM with a logit link function. The prison in which participants are incarcerated will be included as a random intercept to account for clustering of participants within prisons and to avoid underestimated standard errors and inflated Type I error rates. The primary treatment contrast will be the adjusted OR, with 95% CIs comparing the probability of consistent

improvement between the intervention and augmented control arms, estimated from the GLMM with a logit link. The model will include fixed effects for randomised arm and pre-specified prognostic baseline variables: prison security level, toothbrushing, mental distress, age, and sex. As a secondary, supportive analysis, improvement in MPS at T1 alone (defined as MPS being lower than baseline) will be analysed using the same GLMM. If the amount of missing data at T2 is substantial and results in low precision for the primary comparison, the T1-based comparison will provide additional supportive evidence, although the T2-based consistent improvement outcome will remain the primary outcome. Table 5 outlines the analyses planned for the primary outcome MPS.

Table 5
Intervention effects on MPS, MS and PS

Outcome	**Population**	**Intervention n**	**Control n (%)**	**OR (Adjusted OR) ***	**95% CI (95% CI adjusted) ***	**p-value (p-value adjusted) ***
MPS	ITT					
MPS	PP[1]					
MPS	PP[2]					
MS	ITT					
MS	PP[1]					
MS	PP[2]					
PS	ITT					
PS	PP[1]					

Note:

MS: 1 = Normal appearance of the gingiva and oral mucosa; 2 = Mild inflammation; 3 = Moderate inflammation; 4 = Severe inflammation. PS on teeth and dentures: 1 = No visible plaque; 2 = Barely visible plaque; 3 = Moderate amounts of plaque; 4 = Large amounts of plaque.

[1]: Participants receiving ≥ 70% of planned MI time (20 of 30 minutes).

[2]: Participants with brief MI session duration at the median observed intervention duration.

* The binary MPS endpoints will be analysed using a GLMM with a logit link function. The model will include fixed effects for randomised arm and pre-specified prognostic baseline variables: prison security level, toothbrushing, mental distress, age, and sex. Prison will be included as a fixed effect to account for the blocked randomisation by prison.

Abbreviations:

ITT = Intention-to-Treat Population; PP = Per-Protocol Population; CI = Confidence Interval; OR = Odds Ratio; MPS = Mucosal-Plaque Score; MS = Mucosal Score; PS = Plaque Score

Methods used for assumptions to be checked for statistical methods

Statistical analyses and trial results will be reported in line with the CONSORT guidelines (9). Assumptions regarding independence of observations, model fit, influential observations, and multicollinearity will be evaluated.

Sensitivity analysis

Sensitivity analyses addressing the effect of missing data on the primary outcome will be conducted as outlined in Table 6. Sentence already served at baseline will be included in sensitivity analyses, as it may be associated with both MPS change and loss to follow-up due to release or transfer, pre-post changes in the outcome will be examined in relation to this variable.

Table 6
Sensitivity analyses for handling missing data on the primary outcome

Outcome	Analysis population	Handling of missing data at T1 and T2	Intervention n analysed	Control n analysed	GLMM with a logit link (OR with 95% CI)
MPS	ITT	Equal to baseline [a]			
MPS	ITT	Person excluded [b]			
MPS	PP	Equal to baseline [a]			
MPS	PP	Person excluded [b]			
MS	ITT	Equal to baseline [a]			
MS	ITT	Person excluded [b]			
MS	PP	Equal to baseline [a]			
MS	PP	Person excluded [b]			
PS	ITT	Equal to baseline [a]			
PS	ITT	Person excluded [b]			
PS	PP	Equal to baseline [a]			
PS	PP	Person excluded [b]			

Note:

MS: 1 = Normal appearance of the gingiva and oral mucosa; 2 = Mild inflammation; 3 = Moderate inflammation; 4 = Severe inflammation. PS on teeth and dentures: 1 = No visible plaque; 2 = Barely visible plaque; 3 = Moderate amounts of plaque; 4 = Large amounts of plaque.

[a]: If data on the primary outcome are missing in T1 and T2, the results are set equal to baseline (baseline observation carried forward)

[b]: If data on the primary outcome are missing in T1 and T2, the person is excluded from the analysis (case-complete)

Outcome	Analysis population	Handling of missing data at T1 and T2	Intervention n analysed	Control n analysed	GLMM with a logit link (OR with 95% CI)
The same adjusted GLMM as in the primary analysis will be used in all sensitivity analyses. In addition, sentence already served at baseline will be included as a fixed effect. Abbreviations: MPS = Mucosal-Plaque score; MS = Mucosal Score; PS = Plaque Score; ITT = Intention-to-Treat Population; PP = Per-Protocol population					

Subgroup analysis

Exploratory subgroup analyses of the primary outcome will be conducted and presented as forest plots.

Subgroups will include:

- Age group (IQR-based groups)
- Length of sentence
- Previous incarceration experience
- Education level
- Baseline MPS = 3–8; participants with no room for improvement (baseline MPS = 2) are excluded
- Dental anxiety (MDAS)
- Substance use prior to imprisonment

Missing data

Missing data are anticipated to be largely driven by administrative factors (e.g. release or transfer), and primary analyses will proceed under a missing at random (MAR) assumption, informed by observed patterns of loss to follow-up. However, when interpreting the results, the possibility of missing not at random will be considered. Missing data in the primary outcome variable will be handled in two ways. The primary analysis will use the ITT strategy; for participants missing T1 or T2 values, the missing value is set equal to the baseline value (baseline observation carried forward). In addition, a secondary sensitivity analysis will be performed, including only participants with valid data at both T1 and T2 (case-complete).

Additional analyses

Additional analyses will include a description of the dropout population, focusing on baseline characteristics of participants lost to follow-up and a comparison with those who completed the trial.

Exploratory post hoc analyses will be conducted as appropriate, depending on the observed data patterns in the results.

As a supplementary analysis, MPS will be analysed as an ordinal outcome using a GLMM to assess whether similar results are obtained when MPS is treated as an ordinal outcome.

Harms and adverse events

Because MI is a person-centred driven conversation, focusing on expressing empathy and avoiding argumentation for change (10), this treatment was assessed as minimally invasive. Previous studies have not found MI to be harmful or have any adverse effects (3). However, any research participation may still involve some risk of harm. In the prison setting, both incarcerated participants and outcome assessors were safeguarded by the prison's standard security procedures. For some participants, the oral examination and the questionnaire could have been experienced as intrusive; hence the participants were reminded that they were free to omit any questions. All participants with acute dental treatment needs identified during clinical assessment at any time point (T0, T1 or T2) were directly referred to the public dental service for treatment. No trial-related adverse events (AEs) were expected for this minimally invasive behavioural intervention, and therefore no formal AEs monitoring system was established beyond passive monitoring for AEs by the research team. However, all acute and non-acute dental treatment needs identified during the clinical examinations, all of which are likely to be unrelated to the intervention, were recorded. Additional ethical considerations are outlined in the trial protocol (5).

Statistical software

Statistical analyses will primarily be conducted using IBM SPSS Statistics software (IBM Corp., Armonk, NY, USA). Additional software may be used for supplementary analyses and graphical presentation.

Figures

Other figures or graphical presentations will be produced and selected as appropriate, to illustrate key findings in future publications.

Declarations

Ethics approval

Approval for the trial was granted by the Norwegian Agency for Shared Services in Education and Research (ID:300281), the Regional Committee for Medical and Health Research Ethics, Western Norway (REK no:282231), and the Norwegian Correctional Service. Verbal and written information about the trial was provided to all participants and informed consent was obtained.

Consent for publication

Informed consent was obtained from all the participants.

Data availability

The trial data are sensitive, and participants did not provide consent for open distribution. Thus, access to the data is restricted.

Competing interests

The authors report no conflicts of interest.

Funding

The trial was funded by the Oral Health Centre of Expertise in Rogaland and the Public Dental Health Service in Rogaland.

Author contributions

All authors contributed to the conception and development of the SAP. KHB prepared the first draft. All the authors reviewed, revised and approved the final SAP.

Acknowledgements

We gratefully acknowledge our collaborative partners KORUS for their contributions to the development of the MI intervention and training of the dental personnel; the Centre for Alcohol and Drug Research, Stavanger University Hospital for their work on the questionnaires and supervision of the dental personnel regarding MI; the Public Dental Health Service in Rogaland for providing personnel resources for this trial; and the Directorate of Norwegian Correctional Service, Rogaland, together with the four prisons, for their efforts in recruiting participants and facilitating the project.

We are deeply thankful to all trial participants and the dental personnel participating in data collection. We also extend our gratitude to the wider research team, in particular to former members who laid the groundwork for this trial by conceptualising and developing it. Finally, we thank Else Hageland and Ann-Kristin Berge Haugland for their assistance with data entering, and Knut Helge Midtbø Jensen for statistical consulting.

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Figures

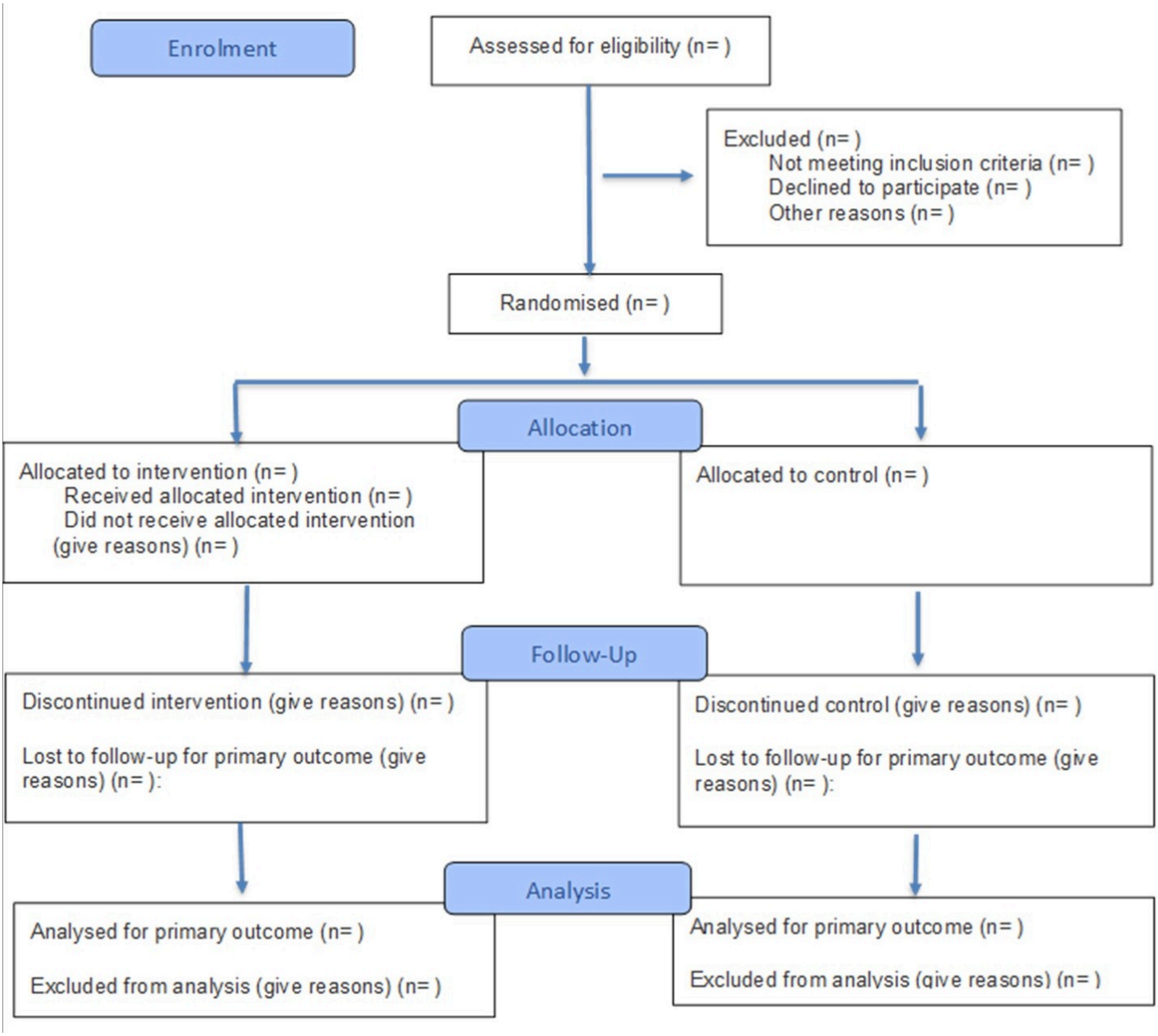


Figure 1

CONSORT Flow Diagram. This flow diagram depicts the trial phases and randomisation of the two arms.