Trial protocol: Effect of physical distancing during vocal ensemble (choir) rehearsals: protocol for a pilot cluster-randomized controlled trial to investigate feasibility, acceptability, adherence, and outcome distribution

Trial registration

ISRCTN80062362

Protocol version

Version 2.0, October 2025

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Roles

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Author's contributions: PE and TB conceived of the trial. PE, TB, ER and AS initiated the trial design, and CJR provided statistical expertise. PE will conduct the primary statistical analysis. All authors contributed to refinement of the trial protocol and approved the final manuscript.

There is no data monitoring committee overseeing the trial.

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Abstract

Background and rationale Maintaining physical distance between individuals was a key measure used to curb the COVID-19 pandemic. Social distancing was widely implemented at considerable cost to individuals and society, yet evidence for its effectiveness in reducing transmission was and remains limited. Vocal ensembles were among the activities curtailed by these measures and provide a pragmatic setting for evaluating social distancing interventions; they involve sustained close interaction and high respiratory tract infection (RTI) risk.

Objectives The primary aim is to evaluate feasibility and acceptability of a planned randomized trial on the effects of physical distancing recommendations during vocal ensembles (choir) rehearsals. We will also investigate adherence to the intervention and characterize a candidate outcome variable to facilitate power analysis for the planned trial.

Methods We will run a pilot pragmatic, parallel, two-arm, cluster-randomized superiority trial. Choirs in the greater Oslo region (Norway) will be randomized 1:1 to either practice as usual or will be instructed to maintain at least 1.5-meter distance during rehearsals for eight weeks. A comparable group not participating in choir rehearsals will be recruited to estimate background frequency of RTI. All trial participants will answer questionnaires on RTI symptoms and perform self-tests using SARS-CoV-2, influenza A/B, and RS-virus rapid antigen test kits weekly during the trial period. The primary outcome is a composite of self-reported RTI and positive antigen test and will be analyzed as time-to-event data following the intention-to-treat principle. We will conduct a study within a trial (SWAT) in which we will film or observe choirs randomized to the intervention during rehearsals to estimate adherence to the intervention.

Discussion This pilot trial will help us determine if a subsequent randomized trial is feasible and acceptable and will provide valuable information to facilitate power analysis. Estimates of adherence based on video recordings and observations of choir rehearsals should help inform the interpretation of the results of the subsequent trial.

Trial registration ISRCTN80062362

Protocol amendments and updates

Version number, date	Updates	Comment
2.0, November 12, 2025	Removed instructions to stop testing at first positive test. Added inclusion criteria regarding venue space. Added more information on user testing and points on interference, limitations on antigen testing and air quality in the discussion. Added plain language summary.	Published at ISRCTN.
1.0, August 15, 2025	Language, removed washout period, added details on analysis.	Submitted to Regional committees for medical and health research ethics (REC).
0.9, March-August 2025	NA	Running version, awaiting feedback from stakeholders.

Project milestones (subject to change)

Milestone	Completed by	Person responsible
Protocol completed	September 1	Erle Refsum
Vocal ensembles recruited	December 1	Erle Refsum
Trial period	January 15-February 15	Erle Refsum
Data collection complete	March 1	Erle Refsum
Primary analysis	April 1	Petter Elstrøm
Code peer-review	May 1	Christopher J. Rose
Manuscript first draft	June 1	Erle Refsum
Manuscript submitted	July 1	Erle Refsum

Introduction

Background and rationale

Physical distancing to limiting contact between people was one of the key measures used to control the COVID-19 pandemic. In many countries, several measures were introduced during the pandemic to prevent the spread of infection in various settings. This included general advice to the public, and recommendations and legal requirements targeting private and public events, schools and workplaces, restaurants, and recreational activities with a high risk of transmission. Strategies for implementing and lifting such measures varied between countries.[1]

In Norway, as in many other countries, the primary recommendation was 1–2 meters distancing, with specific requirements varying by time and setting. Additional measures included limiting the number of individuals present at specific types of events, creating cohorts ("social bubbles"), implementing home schooling and work from home, and restricting the serving of alcohol.[2] General distancing rules and specific measures to limit contact during private and public events were further recommended in the Norwegian government's strategy and preparedness plan for management of the COVID-19 pandemic.[3]

Although the effect of physical distancing seems self-evident, limited evidence exists to evaluate the effectiveness of distancing recommendations or mandates on infection risk. Currently, most of the best available evidence is based on modelling or observational studies, however the certainty of this evidence is generally considered low or very low.[4-6] Two recent Cochrane reviews have summarized the effect of physical interventions to reduce the spread of respiratory viruses: no randomized trials investigating the effects of recommendations or mandates on physical distancing were identified, and the overall evidence certainty was considered to be low to very low.[7,8]

In 2024, the WHO published a report on pathogens that transmit through the air. Several factors influence how pathogens are transmitted as Infectious Respiratory Particles (IRP), such as particle size and mode of expulsion. The experts behind the report agreed that large IRPs fall to the ground within 1-2 meters from the infected person's respiratory tract. During more forceful expiration like coughing, sneezing, and loud singing these particles can move further than 1-2 meters, however the distance travelled depends on multiple factors such as particle size, mode of expulsion and environmental conditions (such as ventilation, humidity, temperature, and airflow).[9]

There is a need for randomized trials on the effect of maintaining distance on the risk of respiratory tract infections (RTIs). Although several studies have investigated the effects of measures that prevent or limit contact between people, existing studies on physical distancing have evaluated the effect of distancing during periods when multiple pandemic measures, such as contact tracing or mask mandates, and when other distancing measures such as quarantining and lockdowns, were implemented simultaneously, making it difficult to isolate the effect of a single distancing measure. Furthermore, the effect of advising the public on physical distancing may vary depending on setting, feasibility, duration of contact, and prevalence of disease.

Singing is a fundamentally human activity that transcends cultural and national boundaries, bringing people together across diverse communities and traditions. Vocal ensembles gather in numerous settings: rehearsals and performances in community centres and concert halls, congregations for religious ceremonies in houses of worship, and groups sing at cultural celebrations and festivals. These activities bring singers, audiences, and communities together in enclosed venues, often for extended periods. During an epidemic or pandemic, rehearsals in shared spaces may pose risks for singers and those who use such spaces afterwards. Singing in a vocal ensemble is an important social activity that was severely curtailed for many people by distancing measures introduced during the COVID-19 pandemic.

We are planning a randomized trial on the effect of instructions to maintain distance on the risk of respiratory infections. We chose the organized vocal ensemble (choir) setting to try to isolate the effect of physical distancing: since regular practices for vocal ensembles usually occur in a set venue, differences in venue properties, such as size, type, and ventilation can be controlled. The risk of infection may be increased in settings with a high number of participants due to a higher density of infectious respiratory particles; a randomized trial should ensure balance between treatment arms with regards to the number of participants. Lastly, loud singing is a high-risk activity with regards to the spread of infectious respiratory particles[9] and therefore represents a setting where knowledge on the effect of maintaining distance is most needed.

In preparation for the planned trial, we designed a pilot trial to examine feasibility and acceptability of the planned trial. Furthermore, the pilot trial will provide key estimates needed for power calculations for the main trial. The pilot trial will also be used to investigate adherence to the intervention measures and allow for more precise estimates on the effect of physical distancing in itself, in addition to the effect of instruction on maintaining a set distance.

Norway has more than one thousand vocal ensembles. The majority are non-professional ensembles, organized by voluntary organizations, workplaces, student associations, and religious congregations, where members participate in their spare time. For brevity, in the remainder of this protocol the term “choir” refers to any organized vocal ensemble that practices together regularly (the trial population).

Objectives

The aims of this pilot trial are to:

1. Provide information to facilitate power analysis for a subsequent randomized trial, and to characterize the distribution of RTIs in a comparable background population.
2. Objectively measure adherence to distancing measures (by filming or observing the choirs during their rehearsals).
3. Explore any relationship between reported RTIs and the physical distance and relative direction between infected and infectious individuals (by mapping participants’ physical relation to each other during choir rehearsals).
4. Assess feasibility of a subsequent randomized trial.
5. Assess the acceptability of a subsequent randomized trial by evaluating choir members’ motivations for and experiences of participating in this trial, and their acceptance of the intervention and data collection, particularly weekly questionnaires and testing.

Trial design

The trial is a pilot pragmatic, parallel, two-arm, cluster-randomized superiority trial including adult participants singing in choirs in Norway, comparing choirs with and without instructions on physical distancing. Each choir is treated as a cluster of participants. The choirs will be randomly allocated 1:1 to the intervention and control arms for a trial period of 2 months (Figure 1). In addition, we include an external control group consisting of people not participating in choir singing to represent background distribution of RTI, i.e., the rate of RTI among individuals not participating in choir singing. The external control group will be individuals residing in the same geographical area as the members of the included choirs in the trial.

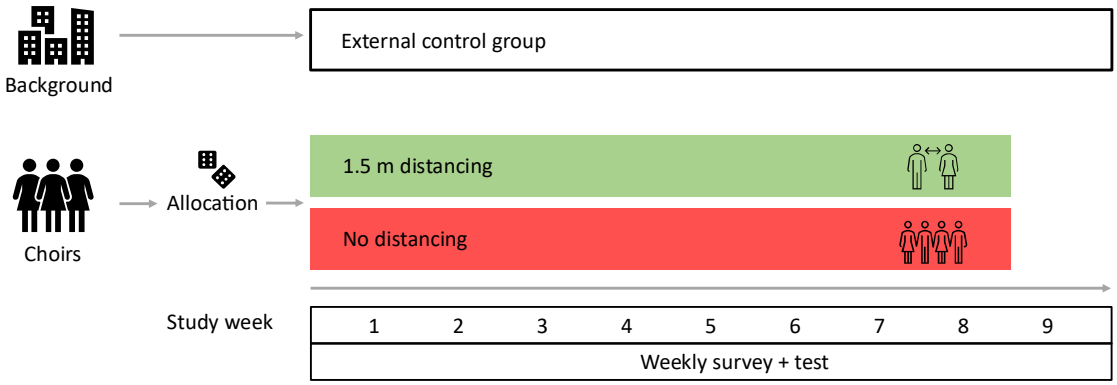

Figure 1. Timeline for the pilot pragmatic, parallel, two-arm, cluster-randomized superiority trial with an external control arm for background distribution of respiratory tract infection. The intervention is conducted over a two-month period including follow-up 3-7 days after the last choir rehearsal. The first outcome ascertainment will be conducted through questionnaires and testing at the first rehearsal in trial week 1.

The primary estimand for Aim 1 is the restricted mean survival time ratio comparing time to RTI in each trial arm. A secondary estimand is the absolute and relative risk of RTI. To estimate the effect of choir singing on time to RTI, restricted mean survival time ratio comparing the control arm and an external control group consisting of people not attending choir practices will also be estimated. See section on Statistical methods for complete list of estimands.

Methods: Participants, intervention, and outcomes

Trial setting

Choirs will be recruited from the greater Oslo region, Norway. The trial will be conducted in the venues in which the choirs regularly hold their practice sessions.

Eligibility criteria

Inclusion criteria for choirs are:

- The choir comprises at least ≥ 15 members

- The choir rehearses at least ≥ once a week
- The majority of the choir members consent to participate in the trial and follow the assigned intervention
- The choir may hold rehearsals in a venue that allow for at least 1.5 meters distance between singers during the trial period

Inclusion criteria for choir members are:

- Aged 18 years or older at the day of signing consent
- Provide informed consent to participate in the trial and contribute weekly data, including
    - willingness to follow the measures applicable during the trial period (maintaining distance, or not) while they remain in the building, during each choir rehearsal, and
    - willingness to take weekly rapid home rapid antigen tests for identification of SARS-CoV-2/influenza virus/RSV, and to report the test results through weekly questionnaires
    - willingness to answer weekly questionnaires, including questions on symptoms of RTI and adherence to instructions on distancing

Inclusion criteria for choir members for a study within a trial (SWAT)[10] on adherence to the intervention are (only including a few choirs in the intervention arm):

- All choir members are willing to have an assigned place for the duration of each practice, and share information on their location, and
- All choir members provide consent to be filmed or monitored during rehearsals

Inclusion criteria for the reference group participants are:

- Member of the Norwegian Institute of Public Health survey panel ("FHI-panel") comprising about 22,000 people who were randomly sampled from the Norwegian National Population Register ("Folkeregisteret") and consented to participate
- Resident of the greater Oslo region, Norway
- Provides informed consent to participate in the trial and contribute weekly data, including
    - willingness to take weekly rapid home rapid antigen tests for identification of SARS-CoV-2/influenza virus/RSV, and to report the test results through weekly questionnaires
    - willingness to answer weekly questionnaires, including questions on symptoms of RTI

Exclusion criterion for the reference group participants is

- Regularly attends choir rehearsals

We will not include risk factors for severe disease due to an RTI as exclusion criteria for the choir members as the intervention entails a decreased rather than increased risk of infection, whereas the control arm will follow standard practice, and participants included in the external

reference group will not be asked to attend choir rehearsals. Choir members who don't consent to the trial may still participate in choir rehearsals per usual and will not be asked to submit surveys or undergo testing.

See section on Monitoring regarding criteria for discontinuing the trial.

Intervention

This trial aims to assess the effectiveness of maintaining physical distance from others in real-life situations. During the intervention, participants will be instructed to avoid close contact (closer than 1.5 meter) with other participants who are not family members during choir rehearsals the entire time while inside the venue. The intervention period will last for eight weeks.

Concerts are exempt from the intervention and may be held as usual, to limit the burden for the participating choirs.

The distance of 1.5 meters was chosen for pragmatic reasons, since many vocal ensembles might not have access to large enough venues to host rehearsals where the members could maintain a minimum distance of 2 meters. Furthermore, the advice of keeping at least 1.5 meters distance is relevant as it was the recommended distance for an extended period in Norway during the Covid-19 pandemic.

However, moving away from the dichotomy of transmission through droplets or aerosols[9] challenges this recommendation. Based on the available literature on the spread of infectious respiratory particles, such particles may be spread further than 2 meters from a person's respiratory tract during loud singing and, depending on a wide range of factors, may stay suspended in the air for longer periods of time.[9]

Comparator

In the control arm, participants will conduct choir rehearsals under standard conditions without any distancing restrictions while they are in the venue. The comparator is chosen to represent the risk of infection during choir singing without any physical distancing measures.

External reference group

To compare the time to developing an RTI among persons participating in vocal ensembles to persons not participating in organized singing, an external reference group, with a similar geographical location as the choirs in the control group will be recruited, as geographical location is a major determinant of risk of RTI. The external reference group will receive questionnaires and perform self-tests weekly, similar to the choir participants. The external reference group will not receive any restrictions on physical distancing. We will not recommend or discourage other infection prevention and control measures for trial participants.

The external reference group will be recruited through the FHI-panel, by contacting members residing in the greater Oslo area. As members of the panel will be contacted in parallel with recruitment of choirs, matching members of the FHI-panel to the recruited choir participants on other prognostic factors such as age, sex, and vaccine status is not feasible. Any differences in

age, sex, vaccine status and known risk factors of severe disease following an RTI will be controlled for in analyses when comparing the external control group to the trial arms.

Outcomes

All participants will be encouraged to take rapid tests weekly regardless of symptoms, and in case of developing symptoms of an RTI, totaling up to nine tests. Test results, test dates, and date of onset of symptoms are reported in weekly questionnaires.

The primary outcome is the time to either the date of a RTI based on self-reported symptoms (listed below), or a positive rapid antigen test of SARS-CoV-2, influenza A/B virus or RSV. The outcome will be measured on the individual level with days as time-unit. Follow-up will start at the first rehearsal. Participants will be followed until their date of first reporting symptoms, first positive test, last filled questionnaire, or end of trial period, whichever comes first.

If preceding tests are negative, the last test should be between 3 and 7 days after the date of the last choir rehearsal in the intervention period, in trial week 9. Participants will be instructed to take the last test during the following rehearsal after the last rehearsal in the trial period. For the external reference group, follow-up will end on day 7 in trial week 9.

Self-reported symptoms: Participants will be asked whether they have experienced a common cold or experienced any of the following symptoms during the last 7 days:

- Sneezing
- Nasal obstruction
- Nasal discharge
- Sore throat
- Cough
- Headache
- Chilliness
- Malaise

Participants are asked to rate each symptom from 0 to 3, where 0 = absent, 1 = mild, 2 = moderate, 3 = severe, in accordance with the Jackson index.[11,12]

We define the primary outcome RTI as reporting a:

- common cold, AND at least 2 points on the Jackson scale, AND at least one of the following symptoms: Sneezing, nasal discharge, nasal obstruction, sore throat

OR

- positive rapid antigen test of SARS-CoV-2, or influenzae virus, or RSV

Primary outcome is defined as participants who were symptom-free and test-negative at trial start (the first rehearsal in the trial period) but developed new symptoms of an RTI or tested positive during the following weeks of the trial period. Requiring either a symptomatic infection OR a positive test will capture both asymptomatic and symptomatic individuals and allow for infections caused by pathogens not detectable in the rapid antigen test to be included.

Secondary outcomes

We will individually evaluate and report outcomes for each element of the composite primary outcome. Secondary outcomes include:

- time to a (first) positive test for SARS-CoV-2, influenza A/B virus, or RSV (time-to-event)
- time to a (first) self-reported respiratory infection (time-to-event)
- number of days with self-reported symptoms of respiratory tract infection (count variable)
- self-reported RTIs or positive rapid antigen test (binary variable)
- distribution of positive tests for SARS-CoV-2, influenza A/B virus, and RSV (categorical variable)

Self-reported respiratory infection will be defined similarly as for the primary outcome. As for the primary outcome, only infections arising after a symptom-free and test-negative trial start will be included. Distribution of test results will be reported descriptively, as the number of positive tests for each pathogen divided by the total number of positive tests per week and per trial arm.

Measure of distancing and physical venue properties

The association of RTI will be assessed at various distances in only intervention choirs in which all participants have provided individual consent to remain in an assigned place throughout all rehearsals. Based on a mapping of where the participants stand in relation to each other during the choir rehearsals, we will measure the relative direction and physical distance (in meters) from the presumed infectious person to the presumed infected persons based on dates of onset of reported symptoms (assuming those with an earlier reported infection represent the primary case), time (incubation period) between cases, reported presence at the rehearsals, and reported positive tests at each occurrence of illness within each choir. We will also gather information on venue properties for each choir.

Adherence to instructions on distancing

In the SWAT, we will request individual consent for participants to film or observe the rehearsals. In choirs where all the participants consent to monitoring, we will analyse adherence to the interventions throughout the rehearsals and over time in the trial period. This is to measure the extent to which participants follow the advice given regarding distance, and to measure whether participants in a distance trial maintain extra distance from others even if they are in the control group and are supposed to have regular interactions without any restrictions. Any cameras will be mounted in similar patterns through all rehearsals, in a non-obstructive manner.

Feasibility and acceptability

This pilot trial will be conducted similarly as the planned main trial. Through both surveys and focus-group interviews, participants will be invited to share their experience participating in the trial and provide feedback regarding the feasibility and acceptability of the trial. In addition, meetings with representatives from the Norwegian Choral association will be initiated to gather further input and assessment of the trial's feasibility and acceptability.

Sample size

One of the main aims of the proposed pilot trial is to provide key estimates needed for a main trial, particularly variation in primary outcome within and between clusters. For the pilot trial we therefore prioritize feasibility over statistical power.

In this pilot trial, we expect that a total of 250 participants (about 10 choirs) will be sufficient to obtain an indicative estimate of intra-cluster coefficient (ICC) that can be used in power analyses for the subsequent trial.

The number of invited participants from the FHI-panel will be based on the total number of participants in the recruited choirs. We will assume a 30-40% response rate to yield a group size similar to that of the control arm. Reminders and further invitations may be sent out to ensure adequate recruitment from the FHI-panel.

For the main trial, the minimal clinically important difference needs to be set following a broader discussion which includes relevant stakeholders. Although the pilot study will not be powered to detect any statistically significant difference, the comparison between the control arm and the external reference arm may indicate at what level choir singing itself is associated with an increased risk of RTI. This may also inform the minimal clinically important difference.

Recruitment

Choirs will be recruited through direct contact with choirs in the greater Oslo region, in cooperation with the Norwegian Choral Association. To support the choir's work with the pilot trial, choirs will receive 4000 NOK (approximately 340 EUR) in funding support.

Participant timeline

Table 1: Participant timeline. Schedule of enrolment, intervention, and assessments. Negative numbers reflect the weeks leading up to the trial period.

	Enrolment	**Allocation**	**Trial period**		
Trial week	**-10 to -2**	**-1**	**1**	**2 to 8**	**9**
Enrolment:					
Eligibility screen	X				
Individual informed consent	X				
Allocation		X			
Intervention:					
Intervention A (distancing recommendations)			X	X	
Intervention B (no distancing recommendations)			X	X	
Assessments:					
Collect individual-level baseline variables	X				
Collect attendance at each event			X	X	
Collect adherence to measures in each trial period, including filming			X	X	
Collect outcome variables			X	X	X

Methods: Assignment of interventions

Random sequence generation and implementation

The included choirs will be randomized 1:1 using a computerized random number generator and assigned either to attend the choir rehearsals with the requirement to maintain distance from others (intervention arm), or with no requirements or recommendations to keep distance (control arm).

In the main trial, we plan to use covariate-constrained randomization with the following variables: geographical area (municipality), number of choir members (categories: 15-20, 21-25, 26-30, 35-40, >41), sex (categories: mixed, >80% female, >80% male), proportion of participants consenting to the trial (50-80%, >80%), and by the shared immune status for participants in each choir based on baseline survey including information on vaccinations or respiratory infections in the past six months (categories: 0-20%, 21-40%, 41-60%, 61-80%, >80%). Since there will be a limited number of choirs included in the pilot trial, we will perform covariate-constrained randomization based on the number of participants only in the pilot trial.

A week before the trial period begins, participants will receive information about which measure to follow at the start and for the following eight weeks. This will include a detailed explanation of how to implement the measure, specifying that it only applies during choir rehearsal at the venue and not in other settings.

The trial team will stay in contact with the choir's conductors or management to provide necessary information on how each choir should participate in the trial. A reminder of what needs to be done will be sent to the choir's contact person for further distribution to the choir members, with one or several reminders of the trial intervention during the trial period, to be determined after feedback from the recruited choirs and input from the Norwegian Choral association.

Allocation concealment and blinding

Allocation concealment will be ensured with the use of a computerized random number generator. Due to the nature of the intervention, it is not possible to blind the participants to the intervention. A researcher will prepare the collected data and mask the allocation and choir identifiers to blind the statistician who will perform the analysis. The final results will be presented to a group within the research team that does not have access to the data, and these results will be shown without revealing the allocation status. These researchers will assess how the results should be interpreted based on different potential allocation statuses. These alternative assessments of the results will be described and published (e.g., as a preprint on ISRCTN) before the blinding of allocation is lifted.

Methods: Data collection, management, and analysis

Data collection and management

Questionnaires

The first participants will be enrolled during the winter of 2025/2026 (December-January). Each choir's coordinator will submit a registration questionnaire with information on number of choir participants, frequency of rehearsals, minimum age of participants, type of choir and venue properties. If the choir fulfils the inclusion criteria, trial investigators will distribute an electronic informed consent form to choir members via the choir leader. Participants will access and sign the consent form through "Nettskjema", a web-based survey tool.

After providing informed consent, participants will be sent to a baseline questionnaire. Once participants complete and submit the questionnaire responses, their signed consent (obtained from Nettskjema via BankID) and responses will be stored in a secure database (Services for Sensitive Data, TSD, at the University of Oslo).

All trial participants will receive a weekly survey to record symptoms of RTI during the trial period. This means that following the plans for the main trial, each participant will be asked to complete a survey every 7 days, totaling 10 surveys including the starting and exit questionnaire. For the pilot trial, participants will be sent an additional evaluation form 1-2 weeks after the trial period.

To ensure a high response rate and to accommodate the choirs' different schedules (e.g., rehearsals on different days of the week), choir participants will be instructed to answer the following survey at their weekly rehearsals, or at the rehearsal occurring latest in the week, depending on rehearsal frequency.

The baseline questionnaire will collect variables needed for the randomization and include the following variables:

- Age
- Gender
- Municipality of residence
- Whether participants share housing with any other members of the choir
- Choir name and organisation number
- Vaccine status:
    - Vaccinated against COVID more than a week and less than 6 months before the present day (yes/no)
    - Vaccinated against influenza more than a week and less than 6 months before the present day (yes/no)
    - Previous RTIs in the last 6 months, self-reported (yes/no)
- Illness associated with increased risk of severe COVID, influenzae or RSV infection (yes, one risk factor aside from age >64 years/yes, age >64 years only/no risk factors)

During the trial period, participants will be sent **weekly questionnaires** to collect outcome data. The questionnaire will contain information on the following variables, only choir members will receive questions on adherence and placement):

- Presence of RTI symptoms during the last 7 days (yes/no)
- Date of onset of illness (date)
- Type of symptoms (as listed in Outcome section)
- Dates of rehearsals previous week including today (dates)
- Result and date of rapid test (positive/negative/unsure for each virus/not taken)
- Adherence to distancing measures during rehearsals (5-point Likert scale)
- Placement during singing in rehearsals (position according to map)*

*To be able to explore the relative positions of the participants that become infected and/or develop symptoms during the trial period, each choir will create a matrix with numbered positions. Each participant will record their position used during the rehearsal in the questionnaire, and the matrix/map will be submitted to the trial team by each choir's coordinator. Only choir where all participants consent to have and report on set placements will be included.

About 1-2 weeks after the last survey, participants will be sent an **evaluation questionnaire** on how they perceived taking part in the trial, their motivation to participate in future studies, and any factors that may influence their willingness to participate in and complete the trial. They will also be asked whether they could be interested in participating in focus group interviews.

Rapid antigen testing

Each choir will be sent rapid test kits before the trial period starts. The test kits will be kept at the rehearsal venue and distributed by each choir's coordinator to participants at their regular rehearsals, where the participants will be instructed to take a rapid test each week until they have a positive test. Participants will be instructed to take the test after the rehearsal. Additionally, each participant will receive a test kit for use at home. Each participant will be instructed to perform a self-test at home if they develop symptoms of an RTI during the trial period.

Thus, all participants are supposed to take a weekly self-test (antigen rapid test for SARS-CoV-2, influenza virus A/B, and RS-virus) and an additional test if they develop symptoms (maximum nine tests). The test result will be reported in the weekly questionnaire. Additionally, participants will be asked to take a picture of the rapid test results, report the date on which the test was taken and upload the image to TSD.

Fluorecare® SARS-CoV-2 & Influenza A/B & RSV rapid antigen combo test (Microprofit Biotech, Shenzhen, China) will be used in the pilot trial, as this is the only combination test available in Norway which has undergone third-party testing with results published in a peer-reviewed journal.[13] The test has a reported sensitivity for Influenza A at 80.8%, influenza B at 65.9%, SARS-CoV-2 at 77.8%, and RSV at 41.5%, with lower sensitivity with lower viral loads.[13]

Filming/data on close contacts

In a subset of choirs where all participants provide individual consent, the rehearsals will be filmed or observed to assess adherence to the allocated intervention (maintaining distance or not). When analysing the films or observing the choirs, adherence in each rehearsal will be described in three categories:

1. < 1 meter distance between almost all (80% or more) of the members
2. < 1 meter distance between most (50% or more) of the members
3. > 1 meter distance between almost all (80% or more) of the members

Furthermore, observed variations in maintaining distance during singing and breaks will be described. Only the choir's name and rehearsal date will be recorded; no personal details will be collected. Video material will be stored in TSD and deleted after descriptions are completed.

Data management

Questionnaires will be automatically stored in TSD when submitted through "Nettskjema". All storage and further processing of collected data will be done in TSD. Each file with collected data will be stored in its original form, to then be merged into an analysis file where the data are linked at the individual level using personal identification number, as well as at the cluster level and strata. A limited number of researchers will have access to data stored in TSD, and only fully anonymized datasets and aggregated results will be exported and shared outside of TSD. See Figure 2 for planned data flow.

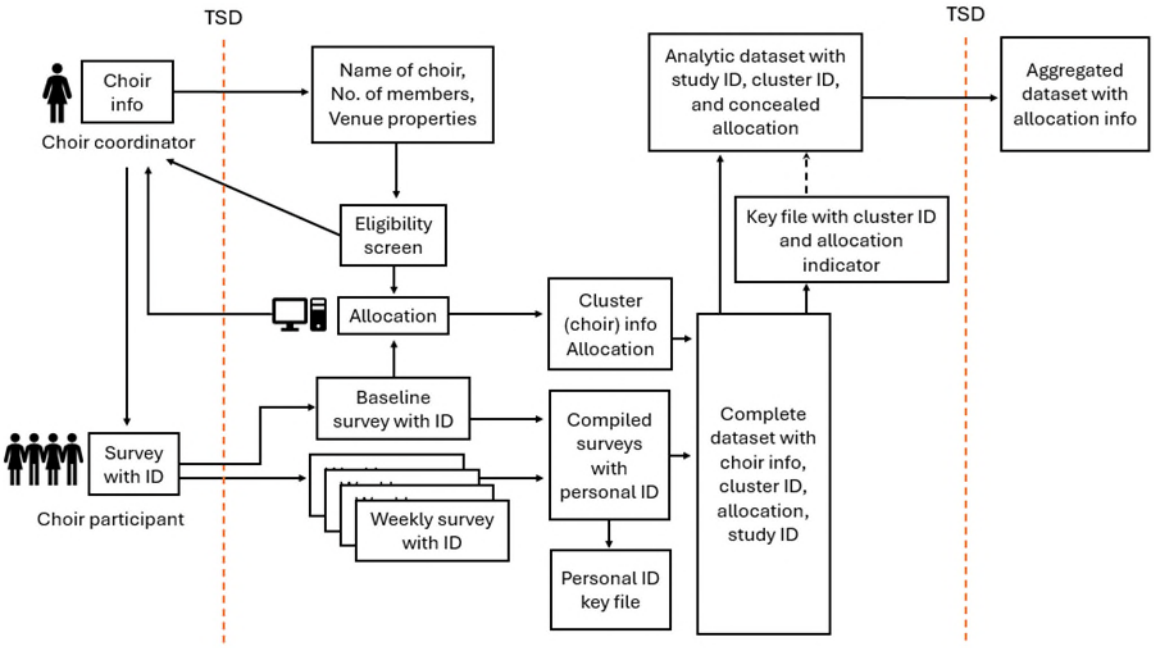

Figure 2 Data flow. Surveys are initially identified by personal ID and name/ID of choir. The choir coordinator distributes the survey link to the choir participants and provides the choir identifier to participants to be able to link surveys from each choir's participants. Analytic dataset: Pseudonymized with trial IDs and cluster IDs.

Statistical methods

Estimands

Estimands are listed in Table 2. We will follow the intention-to-treat principle and analyze all included participants in the arms to which they were randomized; all estimands will include the effects of treatment discontinuation (non-adherence and non-attendance). The target population consists of adults (≥18 years) for all estimands.

Intercurrent events handling strategy

The intercurrent event "intervention discontinuation for any reason" is addressed by the treatment condition of interest attribute (intention-to-treat principle). We do not anticipate any other intercurrent events.

Table 1: Overview of research questions and corresponding estimands

Research Question	Estimand	Effect Measure	Outcome
Primary estimand			
Effect of instructions on physical distancing: Intervention arm compared to control arm			
What is the effect of instructions on physical distancing while singing in a choir on the time to onset of RTI?	Relative and absolute difference in time to RTIs in adult choir participants comparing participants with or without instructions on maintaining at least 1.5 meters distance for eight weeks.	Restricted mean survival time ratio and difference.	Self-reported infection or positive antigen test.
Secondary estimands			
Effect of instructions on physical distancing: Intervention arm compared to control arm			
What is the effect of instructions on physical distancing while singing on the risk of RTI?	Relative and absolute difference in risk of RTIs in adult choir participants comparing participants with or without instructions on maintaining at least 1.5 meters distance.	Absolute risk difference, relative risk.	Self-reported infection or positive antigen test.
What is the effect of instructions on physical distancing while singing in a choir on the time to onset of RTI, measured using rapid antigen tests?	Relative and absolute difference in time to positive tests in adult choir participants comparing participants with and without instructions on maintaining at least 1.5 meters distance.	Restricted mean survival time ratio and difference.	Positive antigen test for Covid-19, influenza A/B or RSV.
What is the effect of instructions on physical distancing while singing in a choir on the time to onset of self-reported RTIs?	Relative and absolute difference in time to self-reported RTI in adult choir participants comparing participants with and without instructions on maintaining at least 1.5 meters distance.	Restricted mean survival time ratio and difference.	Self-reported infection.
What is the effect of distancing while singing in a choir on the burden of disease associated with RTIs?	Difference in the number of days with self-reported symptoms of respiratory infection between the trial arms (intervention and control group).	Incidence rate difference and ratio.	Self-reported sick days due to respiratory tract infection.
Effect of choir singing: Control arm compared to reference population			
Do choir participants have a faster onset of RTI compared to a population that does not attend choir rehearsals?	Relative and absolute difference in time to RTIs in adult choir participants without instructions on distance compared to matched reference group.	Restricted mean survival time ratio and difference.	Self-reported infection or positive antigen test.
Do choir participants have a higher risk of RTI compared to a population that does not attend choir rehearsals?	Relative and absolute difference in risk of RTIs in adult choir participants without instructions on distance compared to matched reference group.	Absolute risk difference, relative risk.	Self-reported infection or positive antigen test.
What is the effect of singing in a choir on the burden of disease associated with RTIs?	Difference in the number of days with self-reported symptoms of respiratory infection between the trial control arm and external reference group.	Incidence rate difference and ratio.	Self-reported sick days due to respiratory tract infection.

Analyses

The unit of randomization is choir, and the unit of analysis is participant (chorist; clustered in choir).

For all estimands, RTI will be coded as a binary variable (ill/not ill) based on symptoms and test results as previously described. The codes for clusters will be handled as a categorical variable based on choir membership.

For time-to-event outcomes, follow-up will begin at the date of participants' first registered rehearsal for choir participants and the Monday of the same week for the matched reference group. Participants will be followed until the date of their first reported positive test, reported first date of infectious symptoms, or date of their last submitted questionnaire (administrative cutoff), whichever comes first. Trial participants who record either presence of symptoms in accordance with the definition of the primary outcome as previously described, will be categorized as experiencing an RTI; remaining trial participants will be censored.

We will estimate the ratio of restricted mean times to RTI, using Bayesian cluster bootstrapping[1] to account for cluster-randomization.[14] We will present Kaplan-Meier curves and assess the proportional hazards assumption by visual inspection. Given the number of clusters in this pilot, formal testing will have limited power to detect violations. If proportionality appears to hold, we will also estimate the population-level (marginal) hazard ratio using Cox proportional hazards regression with cluster-robust standard errors to account for the cluster randomization.

Any variables used for randomization will be included in all models, and we will use marginal standardization to estimate marginal treatment effects from adjusted models. Since age, sex, and immune status are known factors affecting the risk of RTI, we will include and adjust for these covariates in the model for the primary estimand, as recommended by Hernández et al.[15] Attendance at choir rehearsals and adherence to measures will not be included in the model.

Secondary estimands will be analyzed in the same way as described for the primary estimand with the following exceptions:

- For the comparison of risk of RTI in the external reference group and control arm: The individual participant will be the unit of analysis. We will control for the reduced variation in the control group by cluster-robust standard-errors.
- The number of days with self-reported symptoms of respiratory infection will be analyzed as count data with the individual participants as unit of analysis. The rates between the trial arms (intervention and control group) will be compared using Poisson regression. Here, the entire trial period will be set as exposure and participants censored at their last submitted questionnaire or end of trial period.

[1] The Bayesian cluster bootstrap assigns smooth, continuous weights to clusters rather than including or excluding them outright as in the traditional bootstrap, which helps avoid certain problems in resampled data. Despite its name, it yields frequentist (not Bayesian) confidence intervals.

Baseline characteristics, along with registered immune status (vaccinated or diagnosed RTI) and attendance and adherence, will be reported descriptively.

Information from surveys on feasibility and acceptability of the trials will be tabulated and reported descriptively.

A hypothesis-generating analysis will be conducted in choirs where the participants are assigned fixed positions during rehearsals, to describe whether physical distance from the index case (the first symptomatic individual) is associated with the risk of developing respiratory symptoms among secondary cases within the same choir (new symptomatic choir members within the incubation time). A logistic regression model will be used to assess the association between distance (as a continuous variable) and the probability of RTI (as a binary variable).

A descriptive analysis will be conducted on adherence to the allocated intervention in choirs where all participants have consented to be filmed or monitored.

Handling missing data and loss to follow-up

We will send up to two reminders to non-responding participants to minimize loss to follow-up. In the questionnaires, all questions regarding outcome reporting will be mandatory.

For all estimands, loss to follow-up will be defined as not submitting an answer to the last survey sent, and participants will be censored at the date of their last completed survey, since the occurrence of an RTI cannot be captured without survey data. In the scenario where participants answer only some surveys, we will assume no RTI occurred in the weeks with missing responses and include all available data in the analysis. While this approach results in no formally missing outcome data under our assumptions, we acknowledge that this may lead to non-detection of RTI if missingness is related to the outcome. However, given this is a pilot, our aim is to keep the methods simple and practical.

If data appears to be missing not at random (e.g., depending on trial arm), we will perform a sensitivity analysis on risk of RTI, where a proportion of those with missing data on RTI will be counted as experiencing the outcome and any effect of missing data on the estimates will be evaluated by comparing results of this analysis to the main analysis. Here, the frequency of infections in the external control arm will be used as reference for the imputed infections among participants with missing data.

In the case of unclear or unreadable test results, tests will be analyzed as positive in main analyses and as negative in a sensitivity analysis for the primary estimand.

Monitoring

Interim analyses will not be performed for the pilot trial. The trial will be discontinued if central or local authorities introduce general recommendation or mandate to maintain distance from others, or recommendations that limits the possibilities of public gatherings.

A data monitoring committee is not needed as the intervention entails no increased risk to participants. Any harms and adverse events will be collected and reported descriptively. There will be no independent audit of trial conduct.

Ethics and Dissemination

Research ethics approval

Approval from the regional ethics committee (REC) is required before conducting the trial.

The trial participants are adults who regularly attend choir rehearsals. During the trial they are encouraged to keep at least 1.5 m distance during choir rehearsal or their usual distance. While singing is considered a high-risk activity for the transmission of infectious respiratory particles, the trial intervention itself confers no increased risk or disadvantages compared to the trial participants' normal activity. Participating in the trial involves testing with rapid test kits, which is of minimal risk but may be uncomfortable. Trial participants may at any time choose to withdraw from the trial, both by deviating from distancing measures or by choosing not to submit questionnaires or test results.

The questionnaires will ask for sensitive information, particularly on vaccine status, test results, and risk of severe disease. We have selected the minimal set of questions to be able to adequately address the research question. To mitigate any risks of compromising trial participants, all data on trial participants will be stored on a highly secure server with controlled access (TSD), will be handled de-identified in analyses, and reported on a group level (see Data management).

We plan to film a selection of choirs to explore how trial participants interact with restrictions on physical distancing. Video material will be stored in TSD and will only be available to the trial investigators. Only choirs where all participants provide individual consent to filming at the starting questionnaire will be eligible, and as individual responses are not shared between participants there should be no undue pressure towards each individual participant.

Distancing measures during an epidemic or pandemic can lead to a significant burden both on the individual and society. Increased knowledge of the effect of such measures on the risk of infection is therefore needed, to avoid any unnecessary and unintended harm. Participation in the trial confers no increased health risk to the participants and any findings can inform future measures on infection control. We therefore believe any potential risk to the participants is far outweighed by the potential benefits.

Protocol amendments

Any important protocol amendments will be published at ISRCTN and communicated to the REC if relevant. Protocol deviations and their rationale will also be listed in the methods section of the published manuscript.

Consent

All choirs that register their interest in the trial will be contacted by the trial team and informed whether they meet the inclusion criteria for choirs or not. Choirs who meet the criteria will then be given the URL of a website where each choir member can sign up for the trial. Informed, electronically signed consent (using minID or BankID) will be collected in the webpage where people sign up to participate. Participants will also provide individual consent to the collection and use of information from questionnaires and rapid antigen tests and to potentially be filmed.

Confidentiality

All personal information on trial participants will be collected through electronic forms and stored directly at TSD. Information will only be shared on a group level, also after the trial (see Data flow). Any information retrieved through direct contact to trial investigators will be kept confidential.

Conflict of interest

The trial investigators declare no conflicts of interest.

Access to data

Trial investigators will have access to the final trial dataset (namely Chris Rose, Petter Elstrøm, and Erle Refsum).

Ancillary and post-trial care

There is no reason to think that singing in a choir, with or without physical distancing measure, will entail any harm to the participants. There will therefore be no ancillary or post-trial care.

Dissemination policy

We plan to report the pilot trial findings in high-impact peer-reviewed journals and promote the trial results via outreach to various media outlets, including social media. There will be no use of professional writers. In addition to the protocol developers (listed at page 1), any contributor who fulfils the ICMJE criteria for authors will be listed as co-author.

Code for data preparation and statistical analysis will be made public (e.g., via GitHub, ISRCTN or Zenodo), along with an anonymized version of the final data set used for analysis. The trial protocol, any protocol amendments, and interpretation of the blinded analysis will be published on ISRCTN.

Stakeholder Engagement

We will contact the Norwegian Choral Association and reach out to choirs to gather feedback from choir participants on the plans for conducting the trial. We will also use these stakeholders to test the utility, understanding, acceptance, and feasibility of the informational materials and questionnaires to be used in the trial, as well as the planned use of rapid tests.

Feedback from stakeholders will be collected before finalizing the protocol, questionnaires and information material. User testing will be performed in-person or online.

Discussion

This pilot trial will provide valuable information on how well people adhere to the instruction of maintaining distance and provide important insights for future trials on the effects of PHSMs. One of the challenges of the planned main trial is the uncertainties underlying the estimates used in the power calculations. A pilot trial will give more exact information on the variance within and between choirs and in a control population, which will inform power analyses and feasibility of the planned main trial.

Interpretation of results depends on the frequency of infections in the general population, and on adherence to the trial intervention. This warrants the use of an external control arm to represent the background prevalence of infection and measures to gauge adherence to the intervention.

Table 3: Possible trial findings and interpretations.

Trial Finding	Possible Interpretations (Incomplete)
Time to RTI is ***lower*** and risk of RTI is ***higher*** in the control arm compared to the background.	Choir singing represents an increased risk of RTIs. Choir participants behave in a way that decreases their time to onset of RTI and increases their risk of RTI.
Time to and risk of RTI is ***equal*** in the control arm compared to the background.	Choir singing does not represent an increased risk of RTI. The exposure of singing in a choir is not sufficient to detect a difference in risk or a difference in time to onset of RTI.
Time to RTI is ***higher*** and risk of RTI is ***lower*** in the control arm compared to the background.	Choir participants behave in a way that delays onset of RTI and decrease their overall risk of RTI. The exposure of singing in a choir is not sufficient to detect a difference in time to onset of RTI or risk of RTI compared to the background.
Time to RTI is ***higher*** and risk of RTI is ***lower*** in the intervention arm compared to the control arm.	Instructions of distancing during choir rehearsals delays onset of RTI and decrease the risk of RTI.
Time to RTI is ***lower*** and risk of RTI is ***higher*** in the intervention arm compared to the control arm.	Instructions of distancing during choir rehearsals does not delay onset of RTI or decrease the risk of RTI. Choir participants are unable to adhere to instructions on distancing.
Time to RTI and risk of RTI is ***equal*** in the intervention arm compared to the control arm.	Distancing during choir rehearsals does not decrease the risk of RTI and has no effect on the time to onset of RTI. Choir participants are unable to adhere to instructions on distancing. In the case of high prevalence of disease (high risk of RTI also in the background), attending choir rehearsals does not substantially delay onset of RTI or decrease an already high risk of RTI. In the case of low prevalence of disease (low risk of RTI also in the background), attending choir rehearsals does not accelerate the time to RTI or entail an increased risk of RTI.

Interference

For the pilot trial, choirs will be recruited from the greater Oslo region. In theory, clusters within close geographical distance from each other may lead to interference (spillover) effects between clusters. We expect any interference to be negligible in this trial given that the exposure during choir rehearsal is just one of many exposures to transmission that participants experience throughout the trial period and that the participating choirs represent a small fraction of the population in the Oslo region. Furthermore, we expect the choirs to have little

direct contact with each other. In a main trial where many more choirs may be recruited, interference may be a greater concern and contact between the choirs should then be surveyed.

Rapid antigen testing as an intervention

We plan to include results from antigen testing in the composite primary outcome. Participants will be instructed to perform the test after each week's rehearsal. Asymptomatic participants who test positive could be less inclined to participate in the next week's rehearsal due to fear of spreading disease. This could lead to bias if participants in the control arm are less likely to participate in rehearsals compared to the intervention arm, or vice versa. We expect this effect to be small, since for most participants, a week will pass between positive test result and the next rehearsal. We will mitigate this bias by carefully informing participants that they may partake in choir rehearsals with a positive test and instruct them to take the test *after* each week's rehearsal. Through questionnaires, we also gather information on whether the participants attended rehearsals or not, and reasons for staying at home. Any imbalance between absence related to test results between trial arms in the pilot trial will be used to inform feasibility of the main trial.

We will also mitigate this bias by exploring the feasibility of performing PCR testing, which allows for temporary blinding of test results for the participants. If feasible, details will be described in a separate protocol amendment. Briefly, we will select 1-2 choirs to undergo PCR testing instead of rapid antigen tests. Participants will perform self-sampling (similar to the procedure for the antigen tests) using pre-labelled virus transport media. Detailed logistics on how the samples will be collected will be determined through direct communication with the participating choir. Samples will be analyzed at the Dept. of Microbiology at Oslo University Hospital, Oslo, Norway, by standard multiplex PCR including the following targets: Influenza A, influenza B, respiratory syncytial virus (RSV), human metapneumovirus, rhinovirus and SARS-CoV-2. Test results will be communicated to participants through the hospital's routine-care systems [details to be determined].

Air quality

The dispersion of infectious respiratory particles in the air is affected by physical properties such as air temperature and humidity. One could think that differences in venues could affect the physical environment during rehearsals and subsequently affect risk of RTIs. If air quality is unequally distributed between trial arms, this should be controlled for in analyses of a main study. On the other hand, data on venue properties, such as ceiling height and size, might more easily be collected and work as a proxy. In the pilot study, we will explore the feasibility of measuring air quality. Briefly, measurements will be performed in a standardized way at one rehearsal for each choir and be analyzed in relation to venue properties and recommended threshold values for air quality (e.g., CO_2 concentration). If feasible, details will be described in a separate protocol amendment.

Potential bias

There are several sources of potential bias that may occur and affect trial estimates to a varying degree:

Detection bias (measurement bias): Since participants are not blinded, those included in the control arm may be more inclined to adhere to weekly testing and be more aware of any RTI symptoms compared to the intervention arm, or vice versa (e.g., less likely to submit questionnaires as they don't feel they are participating in a trial). We will seek to mitigate any

differences in reporting between trial arms by instructing all choirs to submit surveys and undergo testing during rehearsals and ask the choir coordinators to follow up with participants not attending rehearsals to remind them of the weekly surveys and testing. Participants will also receive testing kits to keep at home. Differences in the degree to which participants overestimate or underestimate their symptoms, which could affect the outcome assessment for self-reported symptoms, is more challenging to mitigate. Such a bias would likely drive our estimates away from the null, assuming participants in **one** arm answer surveys more consistently and report more symptoms. We partly mitigate this bias by including antigen-testing in our composite primary outcome. A more objective measure of infection could be to measure the development of antibodies towards a panel of respiratory infectious agents by drawing blood samples at the start and end of the trial period. However, we consider this to be too invasive, impractical and resource demanding.

Selection bias: Both participants and trial investigators will be blinded to the allocation, through a computerized randomization process. Selection bias due to inappropriate concealment of the allocation sequence is therefore unlikely. However, we might by chance have an imbalance of prognostic factors (i.e. risk of developing severe disease in the case of a respiratory infection) in the two arms which may affect the decision to adhere to the assigned treatment (e.g., participants in the control arm may be less likely to attend rehearsals during periods with a high prevalence of disease). This imbalance will not lead to bias since effects will be estimated according to a intention-to-treat principle.[16]

Attrition bias (selection bias): If the trial period overlaps with a period of high prevalence of disease, trial participants in the control arm may in theory be more inclined to stop attending rehearsals and withdraw from the trial. Not attending rehearsals will not contribute to bias if the participants continue to answer the weekly survey but may lead to biased risk estimates if they don't undergo weekly testing or stop submitting surveys. We believe the effect of such bias would be small, as the control arm represents the conduction of a normal choir rehearsal which the trial participants already regularly attend on a voluntary basis. Moreover, this should not lead to bias for time-to-event analyses as participants will be censored at the last submitted survey.

Bias towards the null: Although not a bias in the epidemiological term, it is likely that the main trial estimates will be driven towards the null for several reasons: First, the exposure of attending choir rehearsals may be insufficient to cause an increase in RTIs, particularly in periods with low prevalence of disease. This is a power issue that we will mitigate by considering repeating the trial in a group sequential design. There is great uncertainty regarding several estimates included in the power calculations, which emphasizes the need for a pilot trial. Second, varying attendance to choir rehearsals and adherence to the intervention may dilute any effects of the intervention. We estimate the intention-to-treat effect in a pragmatic trial to estimate the effect of the intervention in real-world conditions; our estimates would then represent the effect of advice on distancing in the scenario where restrictions on distancing are implemented for high-risk activities such as singing only. It does not estimate the effect of physical distancing on risk of infection in itself. Participants may encounter several other exposures that increase their risk of infection, and the intervention only applies to choir rehearsals. Furthermore, we estimate the effect of recommendations on physical distancing, not the absolute effect of physical distancing on risk of infection. For these reasons, a null result should not be interpreted as a null effect of recommendations on physical distancing.

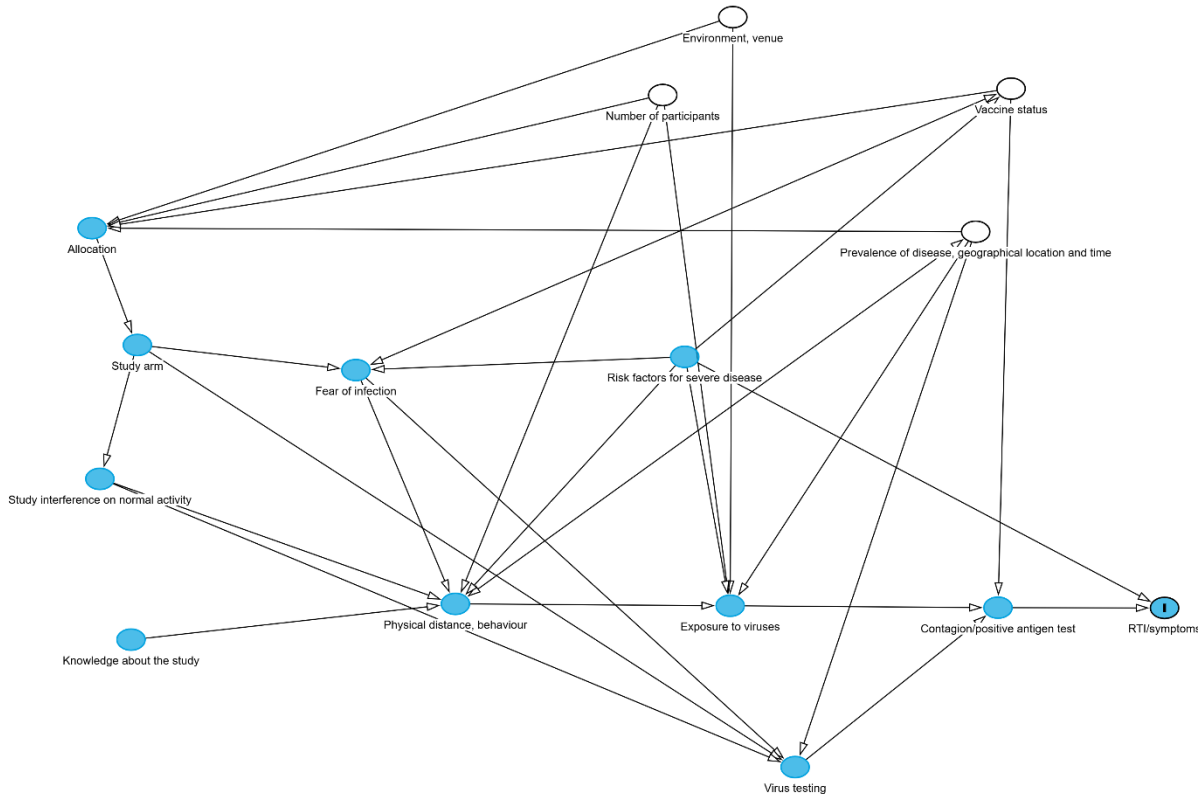

Figure 3 Directed acyclic graph depicting the most central factors affecting the exposure and outcome. Produced using DAGitty.net. Number of participants, venue properties, vaccine status and geographical location is planned to be controlled for in the randomization and analyses of the main trial. The frequency of risk factors in each group will be reported descriptively.

Plain Language Summary

Background and trial aims During the COVID-19 pandemic, the authorities advised that people should keep distance between one another. They broadly advised physical distancing, such as keeping 1-2 meters away from one another in general, and also implemented more specific guidelines and mandates such as increased distance during physical exercise, singing or other activities that could increase the risk of transmission. Collectively, such preventative measures contributed to decreased transmission during the pandemic, but there is still uncertainty around the effects of the individual measures. We need more knowledge on the effect of individual measures to be prepared for future pandemics. Increased knowledge of the effect of physical distancing may contribute to the continuation of social activities such as choir practices in a safe manner during future pandemics. We therefore aim to investigate whether physical distancing during choir practices can reduce the risk for respiratory tract infections. In preparation for the main trial, we are planning a test project (pilot trial), to assess whether a larger trial is feasible.

Who can participate? For this trial, choirs with at least 15 adult members who rehearse at least weekly are eligible to participate. In addition, we will recruit adults who don't participate in organized choir singing as a reference from the greater Oslo area through the FHI-panel. We plan to recruit about 10 choirs, who will be randomly divided into two groups:

1. **Distancing group**: Choirs in this group will be advised to keep 1.5 meters distance from each other during the choir practice, starting from when they enter the venue and up until the choir practice is finished.
2. **Control group**: Choirs in this group will conduct their practice as usual.

What does the trial involve? The trial period lasts for 9 weeks and consists of the following:

- The choir will practice with or without instructions on distancing during the first 8 weeks of the trial period.
- You will be asked to fill out a questionnaire ahead of the trial period, every week of the trial period and after the trial period. Each questionnaire takes less than 10 minutes.
- In the questionnaire we collect data on:
    - Symptoms of common cold or other respiratory infections
    - Vaccinations against COVID-19 and influenza
    - Whether or not you belong in a risk group for developing severe disease during respiratory tract infections
    - Participation in choir practices and if you have followed recommendations for distancing

In addition, we ask that you take rapid tests every week to see if you have been infected with COVID-19, influenza or RSV during the trial.

After the trial period is over, the participants will be asked to evaluate their experience of being involved with the trial. A subset of participants will also be invited to focus group interviews to give feedback on their experiences so that we can improve the future main trial.

We will not be collecting information from registers or other sources, we rely on information the participants submit in the questionnaires themselves.

What are the possible benefits and risks of participating? The trial entails no increased health risks for the participants compared to their normal activity. The choir will receive NOK 4000,- (about EUR 350,-) in support for funding as compensation.

Where is the trial run from? The trial is run from Centre for Epidemic Interventions Research, at the Norwegian Institute of Public Health, Oslo, Norway.

When is the trial starting and how long is it expected to run for? The trial will start in February 2026 and run for a total of nine weeks.

Who is funding the trial? No sponsors are involved in the trial, the trial is funded by intramural funding at the Norwegian Institute of Public Health.

Who is the main contact? Project leader Erle Refsum is the main contact: erle.refsum@fhi.no

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