





Study Protocol and Statistical Analysis Plan for the 5Ways@School Study

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Unique protocol ID: 110419.

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1 Administrative information

1.1 Title

Promoting mental health and wellbeing through a school-based intervention – a study using a mixed-methods, quasi-experimental Extended Selection Cohorts design – the 5Ways@School study. Norwegian short title: Prosjekt fem gode vaner (Hverdagsglede Skole).

1.2 Funding

Sponsored by Moss Municipality, Norway. Funded by Moss Municipality, Norwegian Institute of Public Health, PROMENTA research centre, University of Oslo, the County Governor of Oslo og Viken, and the Norwegian Research Council (project no. 345560). The County Governor and the Research Council have no role in the research process.

1.3 Roles and responsibilities

Names, affiliations, and roles of protocol contributors:

- Ragnhild Bang Nes, PROMENTA, Norwegian Institute of Public Health (NIPH); principal investigator (PI) and supervisor
- Kristian Krogshus, MD, principal investigator (PI), local project leader in Moss Municipality; PhD student at University of Oslo
- Espen Bjertness, University of Oslo; supervisor
- Nikolai Olavi Czajkowski; PROMENTA, NIPH; supervisor
- Ruben Rodriguez Cano; PROMENTA (guest researcher); supervisor

Organisations who are not funding the project, but who intend to contribute in the development of the intervention and later with the dissemination of results across municipalities:

- The Norwegian Council for Mental Health (Norwegian: Rådet for psykisk helse) is a humanitarian umbrella organisation that consists of 31 membership organisations and institutions with an interest and involvement in the field of mental health.
- Healthy Cities (Norwegian: Sunne kommuner), which is part of the WHO European Healthy Cities Network.

2 Introduction

2.1 Background and rationale

Mental health problems are common among children and adolescents worldwide, with prevalence estimates of 10-20 % (Kieling et al., 2011). In recent years, the prevalence of mental distress and common mental disorders like depression and anxiety has increased in adolescents, especially among girls (Mojtabai et al., 2016; von Soest et al., 2022). Similarly, loneliness has increased recently







among young people (Lee et al., 2020). The COVID-19 pandemic has been challenging for the mental health and wellbeing for many children and adolescents; and in Norway higher levels of depressive symptoms and less optimistic future life expectations have been observed among adolescents during the pandemic (von Soest et al., 2022).

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The global challenge of mental health problems calls for different approaches; both treating mental health disorders, preventing mental health problems, and promoting mental health and wellbeing for all. School-based interventions are a primary tool in universal prevention to promote mental health and alleviate loneliness. Thus, the World Health Organization has advocated for teaching of life skills in schools, i.e., teaching of abilities that are often taken for granted, but nonetheless are positively associated with mental health and wellbeing (World Health Organization. Division of Mental, 1994). Some school-based interventions have had positive short-term effects in teaching life-skills (Kavanagh et al., 2009), building social and emotional competence (Taylor et al., 2017), reducing mental distress and/or preventing common mental disorders (Werner-Seidler et al., 2017), while other interventions have failed in finding such effects (Sælid et al., 2022). To sum up, well-designed interventions with a proven long-term effect on mental health and/or loneliness are rare.

The Norwegian government decided to implement "public health and life skills" as a new interdisciplinary topic at all primary and secondary school levels from the year 2020, in order to promote mental and somatic health. The need for effective teaching material is clear.

The purpose of the current study is to develop an evidence-based, health-promoting intervention and investigate its effects on well-being and mental health among school pupils aged 10 to 16 in Moss municipality, Norway.

In the first phase of the study, we will pilot the intervention at two selected schools in Råde municipality. In the second phase of the study, we will run a full-scale trial at the public schools in Moss (16 schools; approximately 3,300 pupils). For the latter purpose, we will use the quasi-experimental Extended Selection Cohorts design. We will investigate the changes in the pupils' scores on health behaviours, mental health, and well-being from baseline to different timepoints of data collection during a 12 months follow-up period.

2.2 Objectives

Our objectives are:

- 1. To adapt the existing *Five ways to wellbeing* course for adults to a school setting, and to pilot the intervention in two schools.
- 2. To explore how participating pupils, teachers, and other school personnel experience the pilot intervention, and identify aspects that should be adjusted before proceeding to a full scale trial.
- 3. To examine how the teachers deliver the intervention in the full scale trial; their motivation, obstacles they encounter, general satisfaction with the intervention, and their adherence to the intervention manual (i.e., fidelity).
- 4. To investigate whether the intervention is acceptable and experienced as useful for participating school pupils, parents, teachers, and other school personnel.
- 5. To investigate whether the intervention have any adverse effects, such as triggering negative emotions.
- 6. To evaluate the process of implementation.
- 7. To describe the pupils' wellbeing and mental health at baseline (November 2023).
- 8. To examine the immediate and long-term effects of the intervention on the pupils' wellbeing and mental health.







- 9. To assess for whom the intervention is effective (i.e., subgroup analysis and moderation analysis, for example SES, gender, baseline symptom levels, etc.).
- 10. To investigate what mechanisms explain potential improvements in wellbeing after exposure to the interventions.

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2.3 Trial design

In phase 1, we will conduct a pilot study in two chosen schools in Råde Municipality.

In phase 2, we will use the quasi-experimental Extended Selection Cohorts (ESC) design. The ESC design is an option for real-life settings when an RCT is not feasible, because the ESC design makes it possible to compare same-age treatment groups. For the current study, a cluster-RCT of sufficient power would have needed a large number of schools and is therefore not feasible. The ESC design is a cohort-longitudinal design with adjacent cohorts, that are measured at two or more time points; a design that has been used to evaluate effects of school-based interventions, for example antibullying programmes (Kärnä et al., 2011; Olweus, 2005) and a programme that promotes physical activity and a healthy diet (Takens et al., 2020). Each cohort comprises subjects of approximately the same age. In a standard RCT design, the pupils, classes, or schools are randomly allocated to different intervention and control groups; but in the ESC design intervention and control groups belong to the same schools, and fewer schools or pupils are therefore needed. The cohorts that are exposed to the intervention are compared with unexposed cohorts from the same school, ensuring that the research subjects are recruited from a relatively stable population with the same sociodemographic characteristics (Olweus, 2005; Takens et al., 2020). This is important when studying health and health behaviour, which differs according to different SES and ethnicity groups. The ESC design does not, however, allow us to control for general societal time trends that coincide with the intervention.

In our study, we will collect data from each cohort (i.e., school grade) five times: at baseline, immediately after the last teaching session in week 6 of the intervention, and 3, 6, and 12 months after baseline measurements, respectively.

At 12 months follow-up, each cohort will be compared to the same-age adjacent baseline cohort group (see Figure 1). For instance, the measures of the grade 5 cohorts that will have been *exposed* to the intervention (grade 5 in 2024–2025) will be compared to the baseline measures of the *unexposed* grade 5 cohorts (grade 5 in 2023–2024).

	Cohort A	Cohort B	Cohort C	Cohort D	Cohort E	Cohort F
Baseline	Grade 5	Grade 6	Grade 7	Grade 8	Grade 9	Grade 10
(Nov. 2023)				▼ /		×
Intervention						
Follow-up	Grade 6	Grade 7	Grade 8	Grade 9	Grade 10	

Figure 1. How exposed cohorts can be compared to unexposed cohorts at 12 months follow-up

In order to separate any effects of the intervention from changes in variables due to other causes, we will apply a «wait list control group» element, i.e., delayed intervention: approximately ½ of the schools will start the intervention in November 2023, while the remaining schools will start the intervention approx. 7 weeks later. We will collect data from all pupils in November 2023, and in January 2024 we will compare the scores of the intervention group with the «wait list» group.









3 Methods

3.1 Study setting

The study will take place at public schools in Moss municipality, Norway, and pupils in grades 5 to 10 (aged 10-16 years) will be invited to participate.

3.2 Eligibility criteria

In Moss municipality, all public schools will be included in the study, except one school for pupils with special needs, a setting which makes it impossible to study the effects of the intervention in a comparable way.

3.3 Intervention

Our intervention, *5Ways@School*, will be based on the *Five Ways to Wellbeing* programme , which is a set of evidence-based public mental health messages aimed at improving the mental health and wellbeing of the whole population. The *Five Ways* promote five dimensions of activities, each of them being associated with mental health and quality of life; making up a «mental health literacy tool box» (Aked et al., 2008). They were developed by the New Economics Foundation in the UK, and the *Five Ways to Wellbeing* programme is currently being used for adults in Norwegian Healthy Lifestyle Centres. Several studies have been conducted, examining potential benefits of the *Five Ways* and similar interventions (Mackay et al., 2019), and two studies are currently being conducted in Norway among adult populations (Eilertsen, 2020; Prydz, 2021). To our knowledge, there is no previous research on the *Five Ways* in Norwegian children or adolescents.

The *5Ways@School* intervention will be a teaching material consisting of five elements; Take notice, Be active, Keep Learning, Connect, and Give. The intervention will be given in an ordinary classroom setting by the class's main teacher in two school hours of 45 minutes each week for six consecutive weeks, i.e., a total of 12 school hours. The teaching sessions will consist of presentations of the five elements, videos, reflection exercises, focused group discussions, creative group work, and giving the pupils small "challenges" to practice what they have learned between the weekly sessions. There will also be a 45 minutes booster session after 3 months.

Prior to the intervention, the teachers will attend a whole day seminar where they will learn the scientific background of the intervention, the intervention manual will be presented, and any questions responded to. They will receive a copy of the intervention manual one week before this seminar. School nurses, social teachers, and other school personnel will also be given this seminar, so that they may use the same five elements in their follow-up of individual pupils who need extra support.

To avoid potentially confounding effects from other health promoting initiatives, the municipality will not promote the implementation of other, similar interventions or teaching materials during the study period and follow-up period, so that any effect we detect should be attributable to the *SWays@School* intervention. However, some teachers might choose to use other teaching material on their own initiative, like UNICEF's recently available "Sammen og aktiv med mening (SAM)" (Eng.: "Together and active with meaning"). We have investigated whether the participating schools are currently using other health promoting programmes, and found that one school is currently using one such programme, called "Robust Youth 12–16", which is aimed at "Strengthening the individual's robustness and class environments and school cultures where all are included" (*Robust Youth 12–16*, 2022). The school in question will continue using the "Robust Youth 12–16" programme during the study period, and we will take this into account when analysing the data: We







will ask the participating pupils whether they have had the teaching material "SAM" or "Robust Youths" so that we can investigate possible interaction or confounding effects.

When publishing our results, we will report sufficient details of our intervention to allow replication,.

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3.4 Outcomes

3.4.1 Subjective wellbeing

As a measure of *present* global life satisfaction, a version of the Cantril Ladder Scale will be used, one that has been used in the Young in Norway study (Cantril, 1965). Pupils are asked to evaluate their life at the present time, on a scale from 0 (feeling very poor) to 10 (feeling very well).

As a measure of expected *future* global life satisfaction, pupils are asked to estimate how good or bad their life will be in five years from now, on the Cantril Ladder Scale.

Satisfaction with the different life domains will be measured by asking the pupils "how satisfied are you with the following aspects of your life: your parents, your friends, your school, your neighborhood, your health, and your appearance?". Pupils respond to each item on a four-point scale ranging from "not at all" to "very satisfied".

Satisfaction with the different life domains will be measured by asking the pupils "how satisfied are you with the following aspects of your life: your parents, your friends, your school, your neighborhood, your health, and your appearance?". Pupils respond to each item on a four-point scale ranging from "not at all" to "very satisfied".

3.4.2 Social relationships

Relationships with friends will be assessed by asking the pupils: "Do you have a friend whom you can trust and talk to about everything?", with response options "Yes, I am sure", "Yes, I think so", "I don't think so", and "I have no friends, nowadays".

The pupils will be asked two items; "Do you have [a friend] to be with during 1) your leisure time and 2) in the school breaks?" These items will be measured by a four-point scale ranging from "Yes, always" to "No, never".

3.4.3 Loneliness

Loneliness will be assessed by one item on feelings of loneliness in the past week, on a four-point scale from 'affected not at all' to 'affected extremely'.

3.4.4 Mental health

Depressive symptoms will be measured by Kandel and Davies's six-item Depressive Mood Inventory (Kandel & Davies, 1982). This measure was derived from the widely used Hopkins Symptom Checklist (Derogatis et al., 1974) and assesses depressive symptoms during the preceding week on a four-point scale from 'affected not at all' to 'affected extremely'. The scale has been shown to correlate highly with other measures of adolescent depressive symptoms in Norway (von Soest & Wichstrøm, 2014). In addition to this instruments, we will use the five prosocial items from the Strengths and Difficulties Questionnaire (SDQ), a validated instrument that has been used in Norway before (Goodman et al., 1998; Sagatun et al., 2008).

3.4.5 Leisure activities and screen time

The respondents' weekly leisure activities will be assessed with the following items: "In your leisure time, how often do you 1) meet with friends in their homes, 2) hang out with friends [outdoor], 3) exercise or do sports, 4) ride a horse, 5) stay at a youth activity club, 6) play an instrument, 7) do









things together with your family, 8) help at home doing chores, 9) relax on your own most of the evening". The pupils will respond on a six-point scale ranging from "never" to "every day".

The respondents' daily leisure activities and screen time will be assessed with the following items: "In your leisure time, how may hours a day do you 1) watch tv, tv series, and/or YouTube, 2) read books, 3) play computer games, 4) play games on your smartphone, 5) use social media, 6) read/watch news". The pupils will respond on a six-point scale ranging from "no time" to "3 hours or more".

3.4.6 Indicators of socio-economic status

Family socio-economic status will be assessed by a composite score four items from Family Affluence Scale II (Currie et al., 2008; Currie et al., 1997), which include frequency of traveling for family holidays in the previous year, number of computers and cars in the family, and having an individual room at home. The scale ranges from 0 to 9, where a low score indicates low socio-economic status.

3.4.7 Other demographics

Gender will be assessed. Only school grade (grades 5 to 10) but not age will be assessed. In the Norwegian school system, attendance in school grades is strictly organized by birth cohorts, and staying back (repeating a grade) due to poor academic performance is generally not practised. We therefore use school grade as an indicator of age.

The pupils will be asked whether both their parents are born in a country other than Norway, and whether they have one or two homes.

3.4.8 Pupils' knowledge of other health promoting programs

Pupils will be asked whether their class/school has completed one of the following teaching programs: 1) SAM, and 2) Robust Youths. Response options are "yes" and "no".

3.4.9 Data on feasibility and acceptability

The teachers who will be teaching the interventions will be asked: "Based on your experiences, which of the five elements in the 5Ways@School do you think was 1) most useful for the pupils?, easiest for you to teach, and 3) most challenging for you to teach? The teachers will respond to these questions by choosing any of the five elements of the 5Ways@School: Take notice, Be active, Keep Learning, Connect, and Give.

The teachers will respond on a four-point scale from "agree completely" to "disagree completely" to the following items: 1) I was well motivated to teach the 5Ways@School, 2) I enjoyed teaching the 5Ways@School, 3) Teaching life skills through the 5Ways@School is a natural part of my job as a teacher, 4) I got sufficient information and/or training before I started teaching the 5Ways@School, 5) I think the pupils learned something new and useful, 6) There was too little activities in the 5Ways@School, 7) There was too much activities in the 5Ways@School, 8) I followed the teaching manual to a high degree, 9) I completed all the six lessons in the 5Ways@School, 10) I had to abbreviate one or more lesson(s), 11) I think that the 5Ways@School should be part of the ordinary school curriculum in 5h to 7th grade, and 12) I think that the 5Ways@School should be part of the ordinary school curriculum in 8th to 10th grade.

We will lso investigate the experiences of school nurses, school leaders, and parents through focus group interviews.

Participating pupils will be given a questionnaire with the following items: 1) I enjoyed learning about 5Ways@School, 2) I learned something new, that I can make use of, 3) The teaching was easy to understand, 4) The teaching was boring, 5) The teaching was interesting, 6) There was too little









activities, 7) There was too much activities, 8) The teaching made me sad, afraid, or angry, 9) The teaching made me happy, 10) I will practise more of the five ways in the future, 11) I think all pupils should learn about the five ways. The pupils will respond on a four-point scale from "agree completely" to "disagree completely".

3.5 Project timeline

- October 2022-October 2023: Develop and pilot the intervention.
- November 2023- November 2024: Collect data and run the intervention.
- 2025-2027: Analyse and publish results.

3.6 Participant timeline

The time schedule of enrolment, interventions and assessments for participants is shown in Figure 2.

Figure 2. Schedule of enrolment, intervention, and assessments.

	Enrolment	Allocation	Post-allocation				
TIMEPOINT	Nov. 2023	Nov. 2023	Nov. 2023	Jan. 2024	Feb. 2024	May 2024	Nov. 2024
ENROLMENT:							
Informed consent	Х						
Allocation		Х					
INTERVENTION – FIRST GROUP			-				
INTERVENTION – SECOND GROUP:				-			
ASSESSMENTS:							
Questionnaires on health & wellbeing			х	х	х	х	х
Socio-demographics			x		х		
Feasibility & fidelity				X (1st group)	X (2nd group)		

3.7 Sample size

During the study period, there will be approximately 3,300 pupils in grade 5 to 10 in the public schools in Moss, who will be invited to participate. We have a conservative estimate of 70 % participation, i.e., about 2,300 participants. All pupils in 157 school classes in Moss municipality will be invited to participate in our study. The average number of pupils in a school class in Moss is 21, and we assume that 15 pupils per class (i.e., 70 %) participate.

Estimating statistical power in a clustered trial that is not randomized can be challenging, as we need to account for the correlation within clusters and the variation between clusters, as well as the variation in the outcome measure(s). Our approach to determine statistical power was to run a power analysis available at <u>http://psychstat.org/crt2arm</u> with the following assumptions:





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- Sample size (i.e., number of participating pupils per class): 15
- Effect size: 0.16
- Number of clusters (i.e., number of school classes); 157
- Intra-class correlation: 0.05
- Significance level: 0.05
- Power curve: No power curve
- H1: Two-sided test

This analysis resulted in a power of 0.8411. The assumption that our intervention might have an effect size of 0.16 is based on previous studies, see (Tanner-Smith et al., 2018; Taylor et al., 2017; Werner-Seidler et al., 2017).

3.8 Recruitment

The teaching programme will take place at school, during ordinary teaching hours. The Head of education in Moss municipality has decided to use the teaching programme in the interdisciplinary topic of public health and life skills for all pupils in 5th to 10th grade. All pupils in these grades will consequently be exposed to the teaching programme. All pupils in 5th to 10th grade in the public schools in Moss will be invited to complete questionnaires, except pupils attending a special education school (N=18).

Teachers who deliver the intervention will be invited to complete questionnaires.

Some teachers, school nurses, school leaders, and parents will be invited to participate in focus group interviews.

3.9 Data collection methods

We will collect quantitative data by asking the pupils to complete web-based questionnaires at school, in the same way that many of them are used to complete as part of the Ungdata survey. We will use "Nettskjema" to collect data. "Nettskjema" is a digital survey system developed by the University Center for Information Technology (USIT) at the University of Oslo. Responses from the questionnaire will be sent directly and encrypted (asymmetric encryption) to USIT's Services for Sensitive Data (TSD). TSD is developed to store and analyse sensitive research data in accordance with Norwegian and European data protection laws and the Health Research Act.

"Nettskjema" will also be used to collect questionnaire data from teachers who deliver the intervention. Here, no personal identifying information will be collected from the teachers.

Researchers will take written notes during the focus group interviews. Here, no personal identifying information will be collected or included in written notes.

3.10 Data management

Data will be stored and analysed in TSD, which is a platform for collecting, storing, analysing and sharing sensitive data in compliance with the Norwegian privacy regulation. TSD offers virtual servers and backup- and storage systems with very high safety standards.

Students and teachers will be invited sign in through their digital Feide school account. Feide is the national solution for secure login and data sharing in education and research in Norway.

With Feide, pupils, students, researchers and teachers get safe and correct access to a number of different digital services with one username and password. TSD will ensure that every Feide username will be automatically encrypted with an encryption key unique to this project, and the encrypted username will act as the student's or teacher's serial number in the data file. The data file is located on a secure server at TSD and will not contain identifiers such as names, Feide usernames







or national ID numbers. The project manager and staff (named in point 1.7) will be given access to the data file to analyse data on TSD's server. The researchers will not be able to identify individual students or teachers on the basis of the data file.

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3.11 Statistical Analysis Plan

To analyse the effect of the intervention we will use multilevel regression. In these analyses individual measurements at the five timepoints are nested within pupils (level 2), which in turn are nested within classes (level 3), in turn nested within schools (level 4). We will use linear multilevel regression for all continuous outcome measures, and logistic multilevel regression for categorical outcome variables.

Multilevel models are ideally suited for clustered and longitudinal data, where the common assumption of independence of measures does not hold. The models also perform well with missing data, and can be used to investigate both general trends, and factors underlying the variability observed at various levels in the hierarchy.

Based on previous research we hypothesize that the effects of the intervention will be greater for individuals who score lower on wellbeing measures and/or higher on mental health symptoms at baseline. We will therefore stratify our sample based on the participants' wellbeing scores and their mental health symptoms score and perform subgroup analysis. We also hypothesize that the effects of the intervention will be greater for younger participants, and we will therefore perform subgroup analysis based on school grade (as a proxy for participants' age).

To explore the moderation effects by SES, gender, age in years, ethnicity, baseline level of mental health symptoms, loneliness, wellbeing level, and leisure activities level, we will add interaction terms to the model. When these terms are significant, we will stratify the analyses for specific subgroups.

A significance level of p = 0.05 will be used. For the analyses we will use Stata v. 18, IBM SPSS Statistics v. 25.0, and R 3.5.3.

3.12 Qualitative Analysis

Researchers will take written notes during the focus group interviews, and we will conduct a content analysis by two independent researchers. At first, the researchers will do the analysis independently; then their analyses will be compared and consensus will be reached.

4 Ethics and dissemination

4.1 Potential harms and benefits for the participants

The *5Ways@School* intervention will be built from existing teaching material currently used among adults at Norwegian Healthy Lifestyle Centres. Experiences from teaching the Five Ways to Wellbeing at Healthy Lifestyle Centres have been positive, and no harm among adult participants has been reported. To our knowledge, no harm has been reported when using the Five Ways among children and youth in other countries. Based on former studies, we expect the participants to experience benefits from the intervention, and we believe the risk of adverse reactions to the teaching programme is very low. Likewise, we believe the risk of adverse reactions to the questionnaires is similarly low. Nevertheless, we will investigate whether some pupils can have negative reactions, either to the teaching programme or the questionnaires, and we will provide them with support from the teacher or the school nurse if needed. The teachers who administer the







intervention, who know the pupils in their class well, will identify if pupils need further support and will refer them to school nurses if needed.

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Teachers who deliver the intervention will be invited to complete questionnaires, and some teachers, school nurses, school leaders, and parents will be invited to participate in focus group interviews. We do not consider such participation to be harmful.

In total, we consider the cost-benefit ratio to be favourable for all participants.

4.2 Research ethics approval

Ethical approval is obtained by the Regional Ethic Committee (reference number 491440).

4.3 Protocol amendments

Important protocol modifications will be communicated from the PI to the Head of education in Moss, who will inform affected pupils, parents, and teachers. Likewise, the PI will inform the team of supervisors, contributing organisations, and other stakeholders.

4.4 Consent or assent

In the first phase of the study, no information will be collected from the pupils taking part in the pilot. At the end of each pilot teaching session, we will ask the teachers to give us feedback on what parts of the teaching session went well and what parts should be adjusted.

In phase two of the study, informed consent will be sought from the parents before the pupils are invited to complete questionnaires. Consent from one parent will be considered adequate. If a pupil has one consenting parent and one assenting, the assenting parent will be respected and the pupil will not participate. Given consent from their parent(s), the pupils will be invited to participate and asked for informed consent. Parents and/or pupils may at any timepoint choose to withdraw their consent, and we will then delete the information we have collected from the pupil in question.

Before focus group interviews we will give written information to participants, stating that participating is voluntary and that they may choose not to participate. As stated earlier, only adults will be invited to focus group interviews.

4.5 Confidentiality

The participants' confidentiality will be protected by strict procedures, ensuring that personal information will be de-identified. By de-identified, we refer to data where personal identifying information is removed. To prevent the possibility of data re-identification, school name and school class membership will not be included in the final dataset (only gender and school grade). Data will not be disclosed to others or transferred to countries outside of Norway.

4.6 Declaration of interests

The principal investigators and the members of the supervisor team declare no financial and other competing interests.

4.7 Access to data

Only the PI, PhD student, and supervisors listed in paragraph 1.5 "Roles and responsibilities" will have access to the de-identified, final trial dataset.







4.8 Dissemination policy and publishing plan

We will follow open science and replicability practices. The project will commit to unrestricted open access to the published output of the research, and publications will be in accordance with the ICMJE recommendations and the CONSORT statement.

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Planned scientific communications: 4 peer-reviewed, international publications, 2 conference participations, 1 PhD dissertation, 1 intervention manual.

Non-scientific dissemination from the beginning of the project using radio, TV, newspapers, and project's webpage, and through social media. The trial results will be communicated via reports to participants, parents, local politicians, and to the municipality's administration. The teaching material will be made available for other municipalities.

We grant public access to the full research protocol, and to the statistical code (upon request).

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