Be-Prox. An effectiveness study of a bullying intervention in Norwegian kindergartens. A study protocol of a cluster randomized trial

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Ingrid Kvestad[1] PhD; Frode Adolfsen[2] PhD; Renira Corinne Angeles[1] PhD; Oda Lekve Brandseth[1] MA; Kyrre Breivik[1] PhD; Janne Grete Evertsen[2] MA; Irene Kvåle Foer[3] MA; Morten Haaland[1] BA; Birgit Millejord Homloa[4] BA; Gro Hoseth[4] MA; Josefine Jonsson[2] MA; Egil Kjerstad[1] PhD; Henriette Kyrrestad[2] PhD; Monica Martinussen[2] PhD; Annelene Moberg[2] MA; Anita Skogstrand[1] MA; Line Remme Solberg[1] MA; Merete Aasheim[2] PhD

[1]NORCE Norwegian Research Center Bergen NO
[2]UiT The Arctic University of Norway Tromsø NO
[3]Bjørnafjorden municipality Bjørnafjorden NO
[4]Narvik municipality Narvik NO

Corresponding Author:
Ingrid Kvestad PhD
NORCE Norwegian Research Center
Nygårdsgaten 112
Bergen
NO

Abstract

Background: A new and growing body of research describes bullying among children in Early Childhood Education and Care Centres (ECEC). The Bernanese Program (Be-Prox) is designed to systematically prevent and handle bullying between children in Swiss ECECs. The effectiveness of the Be-Prox intervention is not known in a Norwegian ECEC setting.

Objective: To evaluate the effectiveness of Be-Prox program to prevent and handle bullying among peers in Norwegian ECECs.

Methods: ECECs from two Norwegian municipalities will be invited to participate in a cluster randomized controlled trial (RCT) to evaluate the effectiveness of the Be-Prox intervention on peer bullying in Norwegian ECECs. Project ECECs will be randomized to an intervention or control arm after baseline measures have been taken. The Be-Prox intervention will be introduced to ECECs in the intervention arm through 6 modules over a 9-month period immediately following the randomization. ECECs in the control arm will participate in the data collection and offered the Be-Prox intervention the following year. The primary outcome of the effect evaluation is the mean change in negative behaviour from baseline to the end of the Be-Prox training in the intervention arm. Secondary outcomes include child bystander behaviour and teacher's self-efficacy and ECEC authoritative climate. An extensive implementation and process evaluation, and cost-effectiveness analyses will be conducted alongside the RCT. A two-level random intercept multilevel model will be used to detect group mean differences (intervention versus control).

Results: Baseline data collection was conducted in September 2023, and the post-intervention data collection will start in May 2024. From baseline we have data in 709 children from 39 project ECECs in the 2 Norwegian municipalities, and 413 of the personnel. Results from the study will be available late 2024 at the earliest.

Conclusions: The proposed project includes a comprehensive evaluation of the effectiveness of Be-Prox in Norwegian ECECs directly targeting the prevention and handling of bullying, including implementation and cost-effectiveness evaluations. Results from the project have the potential to fill in identified knowledge gaps in the understanding of negative behaviour and bullying between peers in ECECs, and how these may be prevented. If proven efficient, our ambition is to offer Be-Prox to Norwegian ECECs as evidence-based practice to prevent and handle bullying among preschool children. Clinical Trial: The project is registered at ClinicalTrials (ID NCT06040437).

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[1] Regional Centre for Child and Youth Mental Health and Child Welfare, NORCE, Norwegian Research Centre, Bergen, Norway

[2] Regional Centre for Child and Youth Mental Health and Child Welfare, UiT The Arctic University of Norway, Tromsø, Norway

[3] NORCE Norwegian Research Centre AS, Department of Social Science, Health Services and Health Economics Research Group, Bergen, Norway

[4] Bjørnafjorden municipality, Bjørnafjorden, Norway

[5] Narvik municipality, Narvik, Norway

Corresponding author: Ingrid Kvestad, Regional Centre for Child and Youth Mental Health and Child Welfare, NORCE Norwegian Research Centre, Nygårdsgaten 112, 5008 Bergen, inkv@norceresearch.no, phone +47 99400431

Abstract

Background

A new and growing body of research describes bullying among children in Early Childhood Education and Care Centres (ECEC). The Bernese Program (Be-Prox) is designed to systematically prevent and handle bullying between children in Swiss ECECs. The effectiveness of the Be-Prox intervention has not yet been explored in a Norwegian ECEC setting.

Objective

To evaluate the effectiveness of Be-Prox to prevent and handle bullying among peers in Norwegian ECECs.

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ECECs from two Norwegian municipalities were invited to participate in a cluster randomized controlled trial (RCT) to evaluate the effectiveness of the Be-Prox intervention on peer bullying in Norwegian ECECs. Project ECECs were randomized to an intervention or control arm after baseline measures were taken. The Be-Prox intervention was introduced to ECECs in the intervention arm through 6 modules over a 9-month period immediately following the randomization. ECECs in the control arm participated in the data collection and will be offered the Be-Prox intervention the following year. The primary outcome of the effect evaluation is the mean sum of negative behaviour between peers after the Be-Prox training is completed in the intervention arm. Secondary outcomes include child bystander behaviour and teacher's self-efficacy and ECEC authoritative climate. An extensive implementation and process evaluation as well as cost-effectiveness analyses will be conducted alongside the RCT. A two-level random intercept multilevel model will be used to detect group mean differences (intervention versus control).

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The proposed project includes a comprehensive evaluation of the effectiveness of Be-Prox in Norwegian ECECs directly targeting the prevention and handling of bullying, including implementation and cost-effectiveness evaluations. Results from the project have the potential to fill in identified knowledge gaps in the understanding of negative behaviour and bullying between peers in ECECs, and how these may be prevented. If proven efficient, our ambition is to offer Be-Prox to Norwegian ECECs as evidence-based practice to prevent and handle bullying among preschool children.

Trial registration number

The project is registered at ClinicalTrials (ID NCT06040437).

Keywords

Peer bullying in Early Childhood Education and Care; The Bernese Program; Cluster randomized controlled trial

Introduction

According to the Norwegian Kindergarten Act (§ 41-43), Norwegian Early Childhood Education and Care Centres (ECECs) should work systematically to prevent bullying and social exclusion, including adopting a zero-tolerance for violations such as exclusion, bullying, violence, discrimination, and harassments [1].

Intentionally exposing other children to negative behaviour is regarded as aggressive behaviour [2, 3]. Children with difficulties in regulating and understanding emotions are at greater risk of displaying aggressive behaviour [4, 5] as they may often misunderstand the emotions of others and are more inclined to interpret others' intentions as aggressive [6]. Aggression can also be more planful and proactive, of which it is instrumental in reaching a goal such as dominating others [7]. Children struggling to regulate emotions and behaviour require developmental support from adults to function in interactions with their peers [8, 9]. Preventing trajectories of aggressive behaviour early gives better prognosis later in life [10], and social and cognitive skills that children acquire in early childhood lay foundation for later peer interactions and relationships [3, 11]. Efforts to reduce the number of children exposing others or being exposed by others to aggression as early as preschool years, is in other words an important measure to promote social participation that may prevent social exclusion later in life.

A systematic review of universal social and emotional learning interventions for children in ECECs through twelfth grade showed that children who participated in these interventions experienced improved academic achievement, school climate, school functioning, social emotional skills, attitudes, prosocial and civic behaviours, and reduced internalizing and externalizing problems [12]. The findings specifically suggest the value of teaching emotional skills before social skills, contributing with the strongest effects of the social and emotional learning programs [13, 14]. In Norway, Fossum et al. used a randomized-controlled between-group design to identify preventive effects of the Incredible Years Teacher Classroom Management program on pre-schoolers' social competence and behaviour problems [15]. Findings suggested an increase in social competence and a reduction in aggression, internalizing and attention problems among children. Additionally, significant improvements in social competence were observed in a sub-sample of children who exhibited baseline aggressive behaviour scores at or above the 90th percentile [15].

Aggressive behaviour does not constitute bullying in itself. The term peer bullying is conventionally defined as aggressive behaviour which occur *repeatedly* over time and where there is a *power imbalance* between the child exposing others and the child being exposed [16]. While bullying is well-described in school age children, a new and growing body of research also describes bullying among children in ECECs. Estimating the prevalence of bullying among children in ECECs based on previous studies is challenging, however, due to differences in how bullying is defined and operationalized in this age group, differences in informants, instruments used and the modes of data collection [17]. Moreover, the concept of bullying among preschool children in ECECs is debated [2, 18, 19]. Some argue that children in this age group (i.e. under 6 years) seem to aggress towards their peers in a rather indiscriminative way, and do not repeatedly target peers who have less power than themselves, which generally is considered an important criterion to discriminate bullying from aggression [3]. Hence, terms such as "unjustified aggression" [2] and "peer victimization" [20] have been suggested instead of bullying in this age group. Through results from their studies, Alsaker and Valkanover argue that bullying also exists among children in kindergartens [21]. In the Pathways to victimization study, they used the concepts of teacher reported *physical*, *verbal*, *relational* and *object-related* negative acts and categorized children as victims, bullies, bully-victims and non-involved [21].

Studies specifically targeting bullying between preschool peers are few and often limited by a low sample size [9]. In the Pathways to victimization study, 6% of the children were found to be victims

of bullying (i.e., exposed to negative acts by other children at least once a week over a 3-month period), 11% bullies (i.e., exposing others to negative acts), 10% bully-victims (i.e., both exposed and exposing others) and 46.5% not involved [21, 22]. Two Finnish studies found 12.6% of children 3–6-year-old in ECECs were involved in bullying [23] and almost 30% of 4-year-olds [11] as reported by teachers and parents respectively. From a Norwegian context, a scoping review found the prevalence in Norwegian ECECs varied from 6 to 20% in various studies [17]. A recent study including approximately 900 children 1-5 years old from Norwegian ECECs used the concepts of physical, verbal, relational and object-related negative acts to study negative behaviour between peers and found that across age almost half of the children were involved in negative behaviours between peers either as a victim, perpetrator or both 2-3 times a month or more often based on teacher report [24]. The prevalence varied markedly across age and the specific acts however, with the prevalence of all types of negative acts increasing between the 1- and 2-year-olds, after 3 years of age, the prevalence of physical negative acts declined, whereas the verbal and relational acts was attenuated.

There are limited evidence-based interventions described in the literature directly targeting bullying between peers in ECECs [3, 17]. The Bernese Program (Be-Prox) , designed to systematically prevent and handle bullying between children in Swiss ECECs is one of few interventions with supported evidence [25]. In Be-Prox, the aim is to increase understanding and skills among ECEC personnel through a 6-module training. An evaluation of the Be-Prox program in Swiss ECECs found a decrease in the number of children victimized after introducing the intervention, and that the risk of being victimized in the control ECECs was one and a half times higher compared to ECECs where Be-Prox were introduced [26]. In a pilot-study, Be-Prox was translated, adjusted, and evaluated for a Norwegian context providing teaching materials and tools for ECECs in a Norwegian municipality. From this pilot, our experience is that Be-Prox is well accepted among Norwegian ECEC personnel and that the 6 modules are feasible in the effort to prevent and handle negative behaviour and bullying in Norwegian ECECs in accordance with the Norwegian Kindergarten Act [1]. Whether the intervention leads to changes in the frequency of negative behaviour and bullying in a Norwegian context is not known, however. To evaluate the effectiveness of the Be-Prox intervention to prevent and handle bullying in Norwegian ECEC, there is therefore a need for a sufficiently powered randomized controlled trial, preferable including several municipalities in different parts of Norway to increase generalizability of findings.

For successful implementation of an intervention to educational systems such as ECECs, evidence should go beyond the solid empirical documentation of the effect of an intervention (evidence-based intervention) and incorporate the empirically based knowledge with the practitioner`s experience-based knowledge and the needs and wishes of the end-users [27]. To be able to say with a reasonable degree of certainty that an intervention will be effectively used in ordinary practice, both positive results from good efficiency studies and evaluation of systems that ensure implementation quality when the intervention is used in ordinary practice is necessary. Therefore, assessment of implementation quality, fidelity- and usefulness of the program of question should be included in the study evaluation [28]. This is referred to as evidence-based practices, and the goal is to base decisions on useful interventions, measures or programs on best available scientific evidence aligned with the view and needs of the practitioners and end-users [29]. More attention is also currently being directed to the economic evaluations of an intervention when implemented to, for instance, the educational system. These evaluations assess alternative program options in terms of cost and consequences. A core question is whether resources on interventions are optimally spent in terms of benefits gained, compared to the current practice [30]. Cost-effectiveness analysis compares the costs (monetary units such as NOK) and benefits (non-monetary units such as prevalence of bullying) of the intervention with the standard practice [31].

The current project aims to evaluate the effectiveness of the evidence-based anti-bullying intervention, Be-Prox in a cluster randomized controlled trial (RCT) in Norwegian ECECs with an

overall aim to ensure a safe and sound ECEC environment for Norwegian children. Our hypothesis is that the Be-Prox intervention will be effectful in preventing and handling bullying among peers in Norwegian ECECs and that it is possible to successfully implement the intervention in Norwegian municipalities.

We will reach the project aim through the following project objectives in Norwegian ECECs:

1. To evaluate the effectiveness of the Be-Prox intervention to prevent and handle bullying among peers.
2. To examine implementation factors that promote or inhibit the effectiveness of the Be-Prox intervention.
3. To examine the cost-effectiveness of the Be-Prox intervention.
4. To generate knowledge on how the Be-Prox intervention can be aligned and implemented in Norwegian municipalities.

Methods

Study design and setting

The fundamental pillar of the project is the *effect evaluation* using a cluster randomized controlled trial (RCT) design with longitudinal follow-ups in two Norwegian municipalities (**Figure 1**). The primary outcome for the effect-evaluation will be measured after the training is complete in the intervention arm (T1). The *implementation and process evaluation* and *economic evaluation* will be conducted alongside this trial benefitting from the stringently conducted RCT in a real-world setting combining the advantages of minimizing selection bias and increasing external validity of the findings [30].

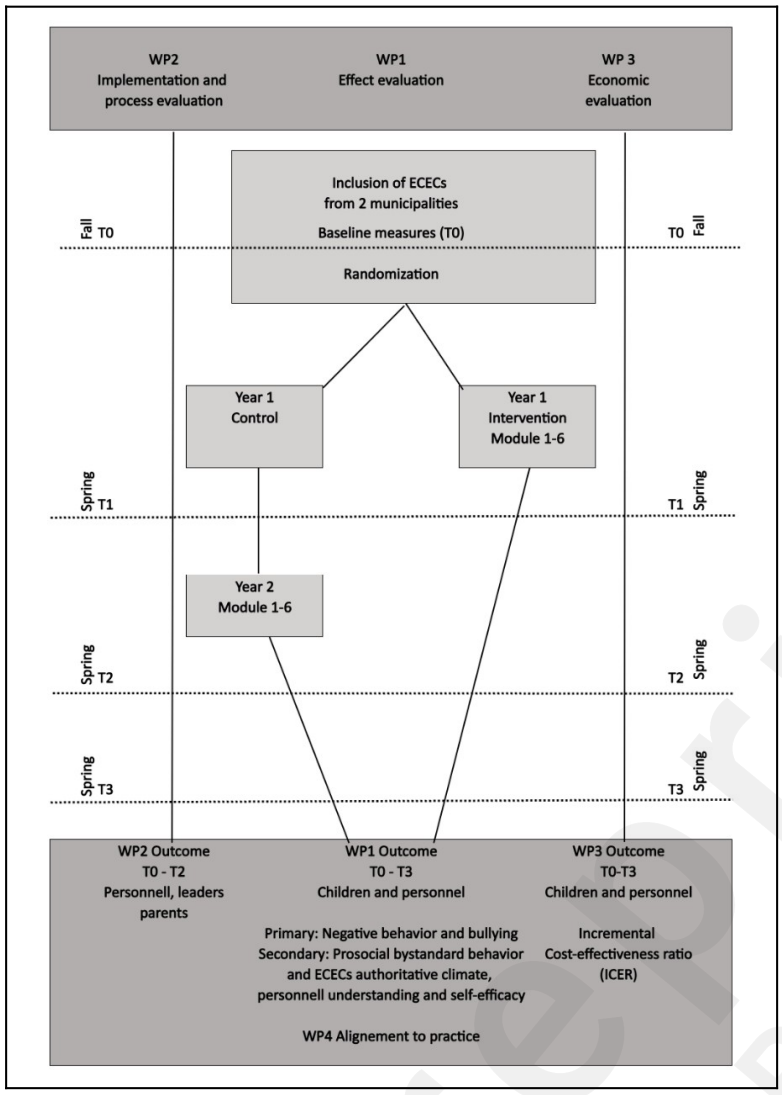

Figure 1. Overview of the Be-Prox study

The study is set in two mid-sized Norwegian municipalities, Bjørnafjorden and Narvik with approximately 25,000 and 19,000 inhabitants and 24 and 28 ECECs, respectively [32]. Both public and private ECEC institutions were invited for participation to the study. The project adopts a pragmatic approach and includes all ECECs that were available and consented to participate.

Participants and recruitment

All ECECs in the two municipalities received information about the project in meetings with the municipality and participants from the project group (**Figure 2**). While all public ECECs were included through the municipality, private ECECs consented for participation on their own after this initial meeting.

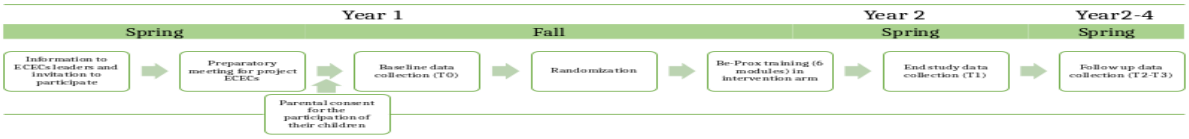

Figure 2. Study procedures in the Be-Prox study

In ECECs consenting to participate (in the following referred to as *project ECECs*), parents of children that turned 3 years in project year 1 (i.e., when ECECs in the intervention arm received the training) and older were asked to consent for the participation of their child to the study. Children were included if they belonged to a project ECEC, turned 3 years in project year 1 or were older, and if at least one parent consented for their participation. Children were excluded if they were under 3 years, and one parent specifically opposed the participation of their child.
All personnel in project ECECs that attended the Be-Prox training as appointed by the head of the ECEC were invited to participate in a general survey and in evaluations of the Be-Prox training. Personnel that did not consent to participation were excluded.
All Be-Prox instructors in both municipalities were invited to fill in a self-evaluation following each Be-Prox training session. When training was completed in ECECs in the intervention arm (T1), all parents of children in the project ECECs were invited for an anonymous survey.

Randomization and allocation to study arms

Project ECECs were randomized to the intervention-or control arm after baseline measures (T0) were completed about one month after the start of the ECEC year following summer holidays (**Figures 1 and 2**). Randomization was stratified by municipality, the size of the ECEC (small/large) and public or private ECEC. Randomization was done by a statistician at UiT, the Arctic University of Norway not otherwise involved in the project. A random number of 0 and 1 was generated using SPSS v.29.0 (SPSS, Inc., Chicago, IL, USA) and assigned to each project ECEC.

Intervention and co-intervention

Be-Prox intervention:

Drawing from an ecological approach focusing on the quality and context of the child`s environment [33], the Be-Prox intervention regards bullying among peers as a social phenomenon that requires both the presence of aggressive children and the passivity of other children and adults to develop into chronic patterns [26, 34, 35]. The aim of the intervention is lower levels of bullying through a positive ECEC environment characterized by shared values and beliefs about behaviour among children and ECEC personnel. Moreover, Be-Prox foster an adult authoritative approach combining a high degree of support towards the children with a high degree of disciplinary structure. ECEC personnel, and in this regard, *all* adults working in the ECEC independent of profession, are therefore the main target group for the Be-Prox intervention [26]. The focus is through a 6-module training to increase understanding and skills in managing bullying among all personnel and encourage positive interactions between the children [35]. The goal is to prevent occurrences of negative behaviour and bullying at an early stage, talk about bullying and victimization, strengthen prosocial resources in the group of children and intervene when negative behaviour and bullying

occurs [26].

Table 1. Be-Prox modules and program elements

Module 1	Mobilize	To raise awareness of negative behaviour and bullying among kindergarten peers.
Module 2	Look at it	Uncover negative behaviour and bullying among kindergarten peers.
Module 3	Let`s talk about it	Discuss negative behaviour and bullying with children, colleagues, and parents.
Module 4	The contract	Involve children in making common rules of behaviour.
Module 5	Act and monitor	Kindergarten personnel are consistent in their follow up of common rules.
Module 6	Strengthening resources	Strengthening resources and prosocial bystander behaviour.
Appendices	I. Collaboration with parents. II. Quality control systems to ensure sustainability of the program.	

The principles of Be-Prox as described above, are introduced to ECEC personnel in 6 modules over a 9-month period [35] (**Table 1**). The Be-Prox training is conducted during personnel meetings throughout the ECEC year (usually modules 1 and 2 in one full day in early fall, then modules 3-6 in approximately 2 ½ hours meetings, 2 in the fall and 2 during spring).

All personnel with more than a 50% position will participate in the training and have access to the Be-Prox homepage with available material and tools. Between the module trainings, there are assignments where the personnel try out and practice activities with the children. These assignments are discussed with colleagues at the start of the next module. After the training is completed, there is a final meeting in the ECEC leader team on implementation of a quality system to ensure sustainability of the program in the ECECs after training is completed.

Preparations:

The leaders of all ECECs participated in a preparatory meeting (April/May in year 1) before the start of data collection, randomization, and training in the intervention arm (**Figure 2**). This meeting included brief information on the project including data collection and randomization procedures, how to structure the training in the ECECs and the importance of investing in the Be-Prox training the first year for successful adoption of the program.

Instructor`s training:

The Be-Prox intervention was delivered to ECECs by local trained instructors in pairs of two. These local instructors were trained and supervised by senior advisors (AS, MH, MA, JE) throughout the intervention period.

Eligible candidates with competence at bachelor or master level and relevant experience were identified within the municipalities to be trained as Be-Prox instructors. The instructor training was held over 6 days: 3 days introduction (August, year 1), two days follow-up (January year 2) and a final digital 3 hours meeting summarizing and discussing the way forward (May/June year 2). The trained instructors (3 pairs in each municipality) are responsible for the Be-Prox training in the ECECs and receive digital supervision from senior advisors at the partners institutions timed according to each module throughout the ECEC year.

Intervention arm:

Preparatory meeting with the ECEC leader team. After filling in the baseline measures (T0), ECECs randomized to the intervention arm continued with the full Be-Prox training over a period of about 9

months.

Co-intervention arm (Control):

Preparatory meeting with the ECEC leader team and baseline measures (T0), identical to the intervention arm. ECECs in the control arm will be offered the Be-Prox training in year 2.

Data-collection

All data in the project are collected by questionnaires created with nettskjema.no, a survey solution developed and hosted by the University of Oslo (nettskjema@usit.uio). Data is stored within the same system, TSD (Services for Sensitive Data) services, designed for storing and post-processing of sensitive data in compliance with applicable regulations [36].

Data on child behaviour is collected by two ECEC personnel who know the children well (as appointed by the ECEC leader). The questionnaire takes approximately 10 minutes to fill in for each child. These personnel received an introductory video on how to fill in the questionnaire. The personnel in all project ECEC will complete questionnaires on child behaviour at baseline (T0) and following the end of the Be-Prox training in the intervention arm (T1). Data will also be collected after one (T2) and two (T3) years following the end of the Be-Prox training in the intervention arm (longitudinal follow-ups) (**Figures 1 and 2**).

For personnel, we collect survey data at baseline (T0) and after completion of the training in the intervention arm (T1), and one (T2) and two (T3) years after the end of the Be-Prox training in the intervention arm (**Figures 1 and 2**). At each time point, questionnaires take approximately 30 minutes to fill in. During the intervention year, personnel will also fill in questions related to the training modules (fidelity) and the instructors will be requested to anonymously fill in fidelity checklists connected to each training module.

During spring of year 2 (T1), we will invite all parents to fill in an anonymous user satisfaction survey.

Outcomes

Effect evaluation:

Negative behaviour between peers: The frequency of negative behaviour between peers will be rated by ECEC personnel using 4-item scales on physical, verbal, relational and object-related negative acts where one scale is on *exposing peers to negative acts*, and one scale is on *being exposed to negative acts by peers* [21]. These scales are adapted from the Pathways to victimization study, have shown acceptable construct validity [37, 38] and will have the following response categories in the current study: “never/seldom”(0), “once per months” (1), “2-3 times per month” (2), “1 time per week” (3) and “more than once a week” (4) using the last month as the reference period.

In the current study, the scales will be used as sum-scores (i.e., “exposing peers to negative behaviour” and “being exposed to negative behaviour by peers”, range 0-16), itemized by the different negative acts (i.e., physical, verbal, relational, object-related, range 0-4) and as the frequency of children exposing peers/being exposed by peers to negative behaviour more than 2-3 times per month. For each of the eight negative acts, the questionnaire will also include an identical item assessing whether there was a power imbalance involved in the negative acts with the response categories: no (0), yes (1), yes and no (2).

The primary outcomes of the effect evaluation are the mean sum of negative behaviour (range 0-16) exposing peers/being exposed by peers, post-intervention. This is also what forms the basis for the power calculations.

Child bystander behaviour: Bystander behaviour, i.e. trying to help the exposed child, withdraw from the situation or join in on the bullying will be assessed by a 12-item questionnaire adapted from

the Pathways to victimization study [39], with the response categories: “never” (0), “seldom” (1) and “always” (2).

ECECs Personnels’ *self-efficacy:* Personnels’ self-efficacy and the probability that they will intervene will be assessed by adapted items from the *Bullying intervention self-efficacy scale* developed and validated for a German school setting [40, 41]. The original 5 item scale was translated to Norwegian for the current study and wordings changed from school peers to ECEC peers. We also changed the response category from 4 to 7 points on the Likert scale, where high scores indicated high self-efficacy in handling bullying situations.

Authoritative climate: Authoritative climate will be measured through an adapted version of a scale constructed and validated for Norwegian schoolteachers [42]. In the current study, we have included 10 items whereby personnel evaluate the degree of support and control in the ECEC environment on a 7-point Likert scale. From the original 8-item scale, adaption for the current ECEC environment included changing from using “I” to “Adults in our unit” and adding two items related to the ECECs context. In this scale, higher scores indicate a higher degree of authoritative ECEC climate.

Implementation and process evaluation:

To identify factors that promote or inhibit the implementation of the Be-Prox program, the study will investigate issues regarding the personnel’ work environment, intervention fit and organizational readiness for change [43, 44]. Questions where re-phrased to be more relevant to the present study setting, for instance, in addition to questions phrased in first person (I), questions in third person (them), were added. Wordings were also re-phrased to address the current theme “bullying” within this specific ECEC context. Questions related to employees' perception of workload, work-conflict and work-family conflict, and autonomy and leadership, as well as job satisfaction, were adjusted to the present study and included. Factor structure and psychometric properties of the Norwegian versions are supported in previous studies [45, 46]. In addition, question about employee’s intention to quit [47], employee’s perceptions of burnout and engagement [48, 49] will be examined. Questions are rated on a 7-point Likert scale ranging from 1 (Strongly disagree) to 7 (Strongly agree) or assessed from 1 (not at all) to 7 (to a very large extent).

Implementation quality, fidelity- and usefulness of the program will be assessed through checklists to Be-Prox instructors and module-evaluations to personnel. Checklists and module-evaluations were developed for this study based on Be-Prox materials and tools [35] and distribution timed according to each training module, and as well a final evaluation after the last training module.

This study will also explore parents' experiences of how the personnel address negative behaviour and bullying, and parents' confidence and ability to raise concerns about these issues through a user satisfaction survey. Questions are assessed on a 5-point scale ranging from 1 (to a very large extent) to 5 (to a very small extent) and are supported in previous Norwegian studies [50, 51]. The survey will be distributed electronically to the parents after program completion at the end of the first year (T1).

Economic evaluation:

The economic evaluation of Be-Prox will consist of a cost-effectiveness analysis evaluating the cost from a societal and ECEC perspective. A cost-effectiveness analysis compares the cost and consequences of different programs such as anti-bullying interventions and estimates the value of the program [31]. The aim in the current study is to evaluate the cost-consequences for each gained unit-effect of the Be-Prox intervention.

As effectiveness measure in the cost-effectiveness analysis, we will use the primary outcome as outlined above. The cost data for the cost-effectiveness analysis will include both direct and indirect intervention costs. Direct costs include material and labour costs for extra staff or extra labour-hours used to implement the program incurred to the ECECs [31, 52]. Indirect costs include labour costs that are not directly incurred to the kindergarten but compensate for the time used to implement the

program which could have been otherwise spent on other core activities. These costs are a relevant economic cost ("alternative cost") and often constitute the largest part of the overall costs for similar intervention programs. The cost information will be collected from ECEC leaders at T3. Information on time resources and workload connected to the Be-Prox implementation will be collected as part of the fidelity measures.

Demographic variables:

Information on child age and gender and parental country of birth will be collected from parents while asking for consent for child participation (before T0, **Figure 2**). Demographic information in the personnel such as age, gender, nationality, educational background, current position in the ECEC, and years of experience from ECEC work will be collected in the survey at baseline (T0). Based on the leader's report, organizational variables of the ECECs (e.g., number of employees, children and departments, type of organization and structure in the ECEC, previous competence-enhancing courses and measures) will also be examined [45, 53].

Sample size estimations

A two-level random intercept multilevel model will be used to detect group mean differences (intervention versus control) on post-test scores. Pre-test scores aggregated at the cluster level will be included as covariances to increase power [54]. Based upon interclass correlations (ICC) and cluster sizes from the pilot study, power calculation using the Optimal Design Software (Version 3.01) [55] show that with a .05 level of significance, power = .80, expected ICC at kindergarten level at .12, a cluster size = 45 (children) and pre-test cluster level covariate explaining 30% of the post-test score, 39 kindergartens are needed to detect effect sizes equal or larger than Cohen's $d = 0.30$ representing a medium effect [56]. Given the potential risk of drop-out during the trial and potential contamination bias, we have decided to recruit at least 44 of the 52 available kindergartens.

Statistical analyses

For the effect evaluation (primary outcomes), two-level random intercept multilevel models will be used to detect group mean differences in negative behaviour (intervention versus control) on post-test scores. Pre-test scores aggregated at the cluster level will be included as covariates to increase power [54]. Multilevel growth curve analyses will be conducted to explore whether potentially positive gains from the RCT are maintained at 1 and 2 years after the end of the intervention. Multilevel analyses will also be used in other analyses when data clustering must be accounted for. Missing data will be handled with multiple imputation (MI) and Full Information Maximum likelihood (FIML) [57].

Demographic information provides important descriptions of the samples and can also facilitate measurements of potential effect modifications (e.g., by age, gender, position, and educational background).

The implementation evaluation will examine whether implementation fidelity and quality (e.g., mean evaluation of the Be-Prox trainings received by employees, mean evaluation for the training delivered by the Be-Prox instructors) predict the effectiveness of the Be-Prox intervention (i.e., the difference in frequency of negative behaviours between baseline and T1). Multilevel models with ECEC as a cluster variable will be used. The parents' experiences will also be analysed with multilevel analyses (with ECEC as cluster variable), to investigate which factors predict satisfaction with how the personnel address negative behaviour and bullying. The effect of the Be-Prox intervention on the employees' attitudes and experiences of the work environment (e.g. total workload, attitudes towards EBP, autonomy) will be evaluated using two-level random intercept multilevel models which will compare changes in the control and intervention groups through time (T0, T1, and T2).

The economic evaluation will calculate the cost-effectiveness of the intervention based on estimates from the incremental cost-effectiveness ratio (ICER). The ICER indicates the additional investments needed for the intervention to gain one extra unit of effect compared with control ECECs with no intervention, which can be interpreted as the monetary cost for one less child victim/offender [30]. When ICERS are estimated, we will use non-parametric bootstrapping with 4000 replications to estimate 95% confidence intervals (CIs) around cost differences and the uncertainty surrounding ICERs. To account for the clustering of data bootstrap replications will be stratified by ECECs. Bootstrapped cost-effect pairs will be plotted on a cost-effectiveness plane and used to calculate cost-effectiveness acceptability curves (CEA). CEA displays the probability that a treatment is cost-effective compared with control ECECs with no treatment. We will also carry out deterministic and probabilistic sensitivity analyses to establish the uncertainty of the cost-effectiveness results.
We will also use other statistical approaches such as simple descriptive statistics, regression analyses, factor analysis and structural equation model to answer secondary RQs in the project.

User involvement

User knowledge is essential in the process of building knowledge for evidence-based practice [27]. In the current project the perspectives of the end-users will be incorporated through parent representatives and antibullying professionals in the reference group meeting yearly. The project will also involve ECEC practitioners in the planning of the study and interpretations of results and alignment to practice.

Ethical considerations

The study will be conducted in accordance with the ethical principles set forth in the Declaration of Helsinki. All participants were thoroughly informed about the study purpose and procedures and consent was collected through the nettskjema.no. Participation in the study is voluntarily and consent can be withdrawn at any time. Data will be handled according to recommendations from the Norwegian Data Protection Service (ref.nr. 705199) with public interest as the legal basis for processing personal data (i.e., Art. 6 (1)(e) of the General Data Protection Regulation). All data will be collected and stored within systems designed for storing and post-processing of sensitive data in compliance with applicable regulations (i.e., nettskjema.no and TSD). Only a restricted number of members from the project team will have access to raw data. The remaining project members will have access to anonymized data only. A Data Protection Impact Assessment (DPIA) has been conducted by the Norwegian Agency for Shared Services in Education and Research (SIKT) and the Data Protection Officer at NORCE, in collaboration with the principal investigator (IK) and co-principal investigator (MA). The processing of personal data was evaluated to be in line with the personal data protection regulations. The project is registered at ClinicalTrials (ID NCT06040437).

Results

Baseline data collection was conducted in September 2023, and the post-intervention data collection started in May 2024. From baseline we have data in 708 children from 39 project ECECs in the 2 Norwegian municipalities, and 413 of the personnel constituting a response rate of 70 and 80% of all available participants respectively. Results from the study will be available late 2024 at the earliest and published in peer-reviewed international and national journal as well as presented at relevant conferences.

Discussion

The proposed project includes a comprehensive evaluation of the effectiveness of Be-Prox in

Norwegian ECECs directly targeting the prevention and handling of bullying. The evaluation includes a stringent RCT design in a real-world municipality setting with alongside implementation and cost-effectiveness evaluations.

Be-Prox is one of few interventions described in the literature with scientific evidence for an effect on negative behaviour and bullying between peers in kindergartens [9, 25]. Through the existing project outputs, we will be able to measure whether such an effect also can be found in Norwegian ECECs. Including a wider range of outcome measures, we will be able to examine important mechanisms involved, such as the effect on negative behaviour as such or on bullying as conventionally defined, the mediation by personnel factors and the potential modification by age and gender. Hence, findings from the current project will represent an important contribution to the research field both in providing scientific evidence to whether Be-Prox is effective beyond Switzerland and on important mechanisms involved.

From the described project we will also obtain comprehensive data on negative behaviour and bullying between preschool peers in a large population-based sample from Norwegian ECECs. Data will be collected on multiple levels, including children, parents, personnel, and ECEC leaders. The concept of bullying in this age group is debated [2, 3], and data from the current project can contribute to an increased understanding of the concept of bullying among ECEC children.

The importance of the project outputs is underlined by the additions to the Norwegian Kindergarten Act in 2021 introducing the right for all children to a safe and sound ECEC environment [1]. Although, increasingly also in Norway, there is a consensus that bullying exists among preschool children in ECECs, few interventions are available directly targeting bullying behaviour in this setting [17]. The lack of evidence-based practice represents a challenge for Norwegian ECECs as well as the municipalities responsible for ECECs being run in accordance with applicable laws and regulations. Going beyond measuring the effect of Be-Prox to prevent and handle bullying; the current project also incorporates essential factors for successful implementation and to whether Be-Prox is a cost-effective alternative. In this regard, project outputs will provide practitioners and decision-makers with information on whether the intervention fulfils its purpose, and in addition inform on whether Be-Prox may be implemented in practice and at what cost. If effectiveness is proven with an effect size that is judged to be of practical significance, Be-Prox can be offered to ECECs and municipalities nationwide.

The negative consequences for children being exposed to bullying are well-described [58], and the available evidence suggests that this can also be generalized to ECEC children [59]. Research findings point to the importance of preventing trajectories of aggressive behaviour early [10] and that social skills acquired in early childhood lay foundation for later relationships [3]. Reducing the number of children experiencing and/or exposing others to negative acts or bullying may therefore be an important measure in a common effort to promote social participation and prevent social exclusion among the rising generation. In this regard the project is not only answering to the UN Convention on the Rights of the Child stating the right for all children to be protected from all forms of physical and mental violence [60], but also to several of the Sustainable Development Goals (SDGs), including SDG 3 to ensure healthy lives and promote well-being at all ages and SDG 4 to ensure inclusive and equitable quality education to all [61].

Strength and limitations

To the best of our knowledge, this is one of few RCTs investigating the effect of an antibullying intervention in Norwegian ECECs. Strengths of the study include being a well-powered cluster randomized trial enrolling a large sample of children 4 to 6 years old and adopting a pragmatic approach in a real-world setting increasing the external validity of our findings. The study setting of two Norwegian municipalities representing different geographical areas (western and northern Norway) should also be considered a study strength. The project adopts an interdisciplinary approach, with project group members from different disciplines (e.g., psychology, kindergarten,

pedagogy, and economics) and representing different work areas such as kindergarten authorities at municipality level, scientists, and senior advisors. The project set up, with the evaluation of effect, implementation, process and economics facilitate a large data collection with the potential to not only increase the knowledge of peer bullying in Norwegian kindergartens, but to what extent the Be-Prox intervention may be implemented in Norwegian municipalities and to what cost.
Limitations to the study include the risk of loss of follow-ups both of project ECECs, children and personnel and loss of power to identify meaningful effects. Moreover, since control ECECs are offered the Be-Prox intervention in year 2 of the project, it is not possible to measure long-term effects of the intervention using the RCT-design. We will however, through state-of-the art statistical methods measure associations between the Be-Prox intervention and relevant outcomes in a longitudinal design.

Conclusion

Results from the project have the potential to fill in identified knowledge gaps in the understanding of negative behaviour and bullying between peers in ECECs, and how these may be prevented. If proven efficient, our ambition is to offer Be-Prox to Norwegian ECECs as evidence-based practice to prevent and handle bullying among preschool children in accordance with the Norwegian Kindergarten Act [1]. In a broader context, the findings will have the potential to inform future strategies for combating bullying in kindergartens, and how, through a systematic measure, promote social participation and avoid social exclusion later in life, thereby contributing to a safer and more inclusive learning environment for children in Norway.

National and international collaboration

The study is a collaboration between two regional centres in Norway working with mental health problems among children and adolescents: RKBU west/NORCE and RKBU north/UiT and two Norwegian municipalities; Bjørnafjorden and Narvik. The project is also conducted in close collaboration with the developer of the Be-Prox intervention, Professor emerita Francoise Alsaker from the Department of Psychology, University of Berne, Switzerland.

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Data availability statement

The data sets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

Conflict of interest

None declared

Authors contributions

All listed authors fulfil ICMJE criteria for authorship. Specific contributions are as follows: Study conception: IK, FA, KB, EK, HK, MM, MA; Study design: IK, FA, RCA, KB, JE, IKF, MH, BMH, GH, EK, HK, MM, AM, KM, AS, LRS, MA; Statistical planning: IK, KB; Implementation and process evaluation planning: FA, JE, HK, MM, AM, AS, MA; Economic analysis planning: RCA, EK; Data collection: IK, FA, RCA, KB, EK, HK, MM, AM, LRS, MA; Article write up: IK, MA; Article review: FA, RCA, OLB, KB, JE, IKF, EVJJ, MH, BMH, GH, EK, HK, MM, AM, KM, AS and LRS

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Supplementary Files

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Figures

Overview of the Be-Prox study.

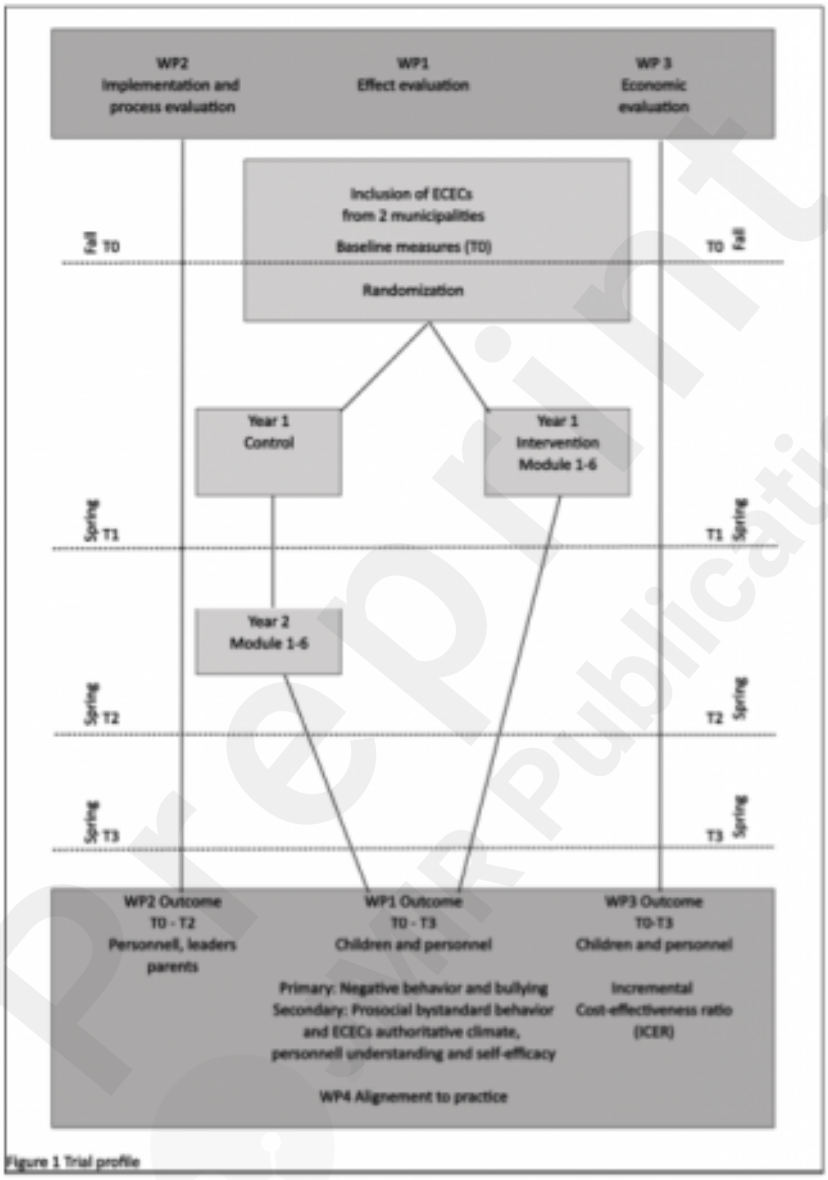
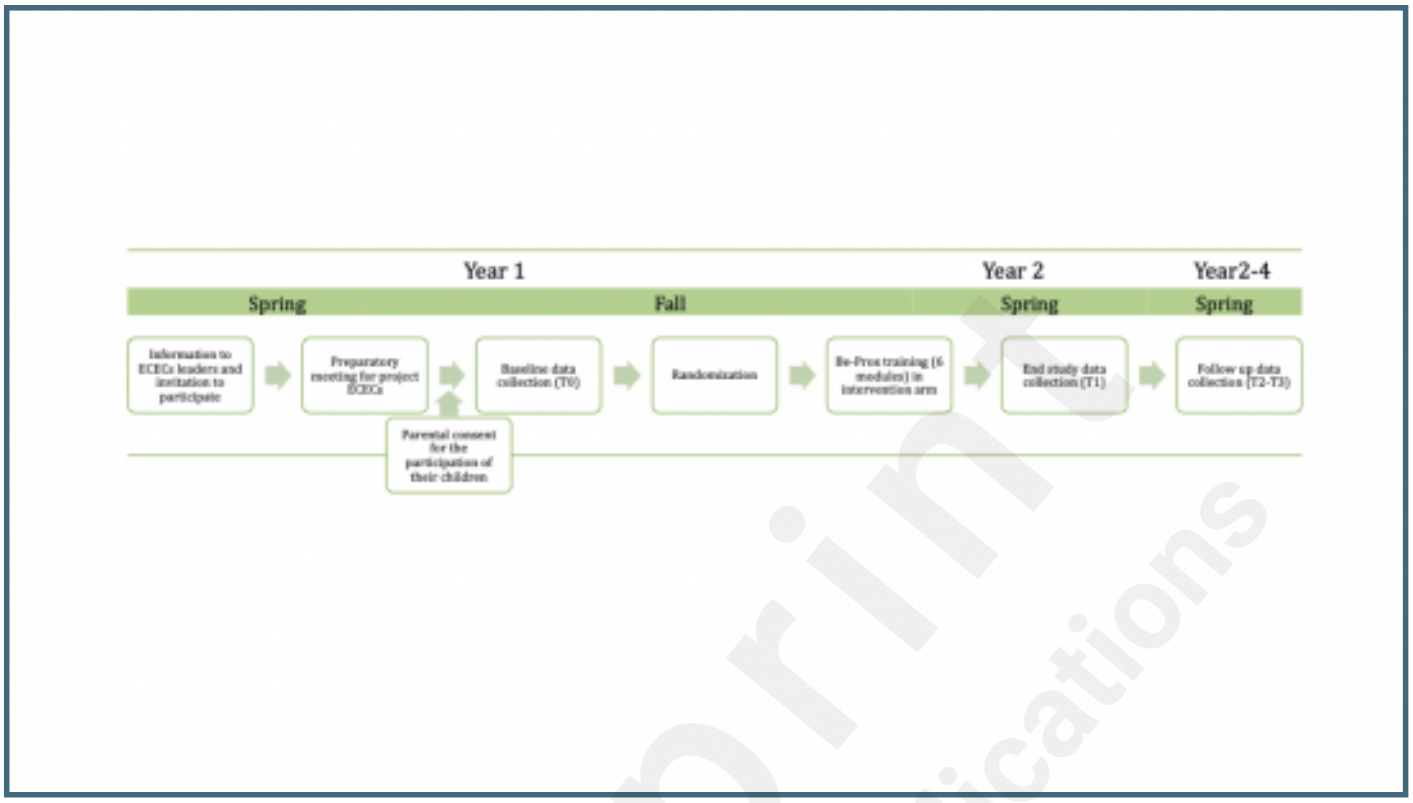


Figure 1 Trial profile

Study procedures in the Be-Prox study.



Multimedia Appendixes

External peer-review from the Research Council of Norway.
URL: http://asset.jmir.pub/assets/9f12fff683d011513a102d51e6f609f5.pdf