Plan of Analysis
Be-Prox. An effectiveness study of a bullying intervention in Norwegian kindergartens

August 2024
Version 2.0

Contents

1. Version history

Version number	Date	Comments
1.0	June 2024	Finalized draft of analysis: - Specified the main research question and objective. - Specified the primary and secondary outcomes. - Included details on the statistical procedures and methods.
2.0	August 2024	Specification to the primary and secondary outcomes. Specification to the statistical procedures.

Data are 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)

Acronym: BeProx
Clinicaltrials.gov: NCT06040437
Main funder: The Research Council of Norway (grant no. 336181).
Published protocol: Submitted to JMIR Research Protocols May 2024, accepted July 2024.
Enrolment started: August 2024.
Data collection started: September 2024.
Scheduled last day of follow up for the main outcomes: July 1st, 2024.
Planned date for breaking the randomization code: August 19th, 2024.
Submittable manuscript: November 15th, 2024.

2. Research question and project synopsis

Research question: Does introducing Be-Prox in Norwegian Early Childhood Education and Care Centres (ECECs) lead to a decrease in negative behavior between peers?

Scientific basis: Intentionally exposing other children to negative behaviour is regarded as aggressive behaviour. 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. While bullying is well-described in school age children, a new and growing body of research now also describes bullying among children in ECECs.

There are limited evidence-based interventions described in the literature directly targeting bullying between peers in ECECs. The Bernanese Program (Be-Prox), designed to systematically prevent and handle negative behaviour and bullying between children in Swiss ECECs is one of few interventions with supported evidence. In a pilot-study, Be-Prox was translated, adjusted, and evaluated for a Norwegian context providing teaching materials and tools for ECECs. In the current study we evaluate the effectiveness of the Be-Prox intervention in Norwegian ECECs to prevent and handle bullying among peers.

Study design: Cluster randomized controlled trial. Randomization was stratified by municipality, private/governmental ECEC and size of the ECEC.

Study participants and site: 709 children 3-5 years at baseline in 39 ECECs in Bjørnafjorden and Narvik municipalities.

Intervention: BeProx program through a 6-module training to ECEC personnel over a period of 9 months.

Comparator: Control, standard care.

Primary outcomes: Sum of negative behavior at the end of the BeProx training in the intervention arm (T1).

Relevance for programs and public health: Be-Prox is a universal program, developed to prevent negative behaviors and bullying between preschool children in the context of ECECs. If proven effective, introducing Be-Prox in Norwegian ECECs could contribute to the prevention of trajectories of aggressive behaviour established early in life and lay foundation for classroom environments both in preschool and school years with less bullying behavior.

In the long run, Be-Prox may promote later healthy peer interactions and relationships. Efforts to reduce the number of children exposing others or being exposed by others to negative behavior as early as preschool years, is in other words, an important measure to promote social participation that may prevent social exclusion later in life.

3. Primary objective
To measure the effect of the Be-Prox intervention in Norwegian ECECs on negative behavior between peers.

3.1 Primary outcomes
Mean of an index of negative behaviors (physical, verbal, relational, object-related, range 0-20) post-intervention:
- exposing peers
- being exposed by peers

4. Secondary objectives
a. To measure the effect of the Be-Prox intervention on the frequency of children exposing peers or being exposed by peers to negative behavior "2-3 times a month"or more.

b. To measure the effect of the Be-Prox intervention on the specific negative acts (physical, verbal, relational and object-related), exposing peers/being exposed by peers.

4.1. Secondary outcomes
- Frequency of children who have exposed peers to negative behaviors 2-3 times a month or more (dichotomized: 1,0) post intervention.
- Frequency of children being exposed to negative behavior by peers 2-3 times a month or more (dichotomized: 1, 0) post intervention.
- Sum of specific negative acts being exposed to/exposing peers to (physical, verbal, relational and object-related acts, range 0-5) post-intervention.
- Frequency of children being exposed to/exposing peers to specific negative acts "2-3 times a month" or more post-intervention.

4.4. Other outcomes
Post-hoc – based on results consider including data on power-imbalance on each item.

4.5. Assessment of compliance
In the intervention arm; staff attendance to each training module as a measure of dose.

4.5. Predefined subgroup analyses
All outcomes listed above will be presented by child sex (male/female), and by age (3-4-5).

5. Planned tables and figures
5.1 Tables
Table 1: Baseline characteristics, stratified by intervention and control arm:
- Child
  - Age
  - Sex

- Ethnicity

Table 2: Overview of ECEC, stratified by intervention and control arm:
- ECEC
  - Size
  - Privat/governmental
  - Proportion with special education
- Staff
  - Average age
  - Level of education
  - Years of experience

Table 3: Child negative behavior (primary and secondary outcomes)

Supplemental tables
S-Table1: compliance/dose – staff attendance to Be-Prox training
S-Table2: Child negative behavior by sex and age

5.2. Figures
Figure 1: Trial flow-chart.

Figure 2: Forest plot negative acts by study arms

6. Statistical analyses
Baseline characteristics and overview of the ECECs (table 1 and 2):
Baseline characteristics and overview of the ECECs will be presented stratified by intervention arms.

Intention-to-treat approach:
Our primary analysis will use an intention-to-treat approach where all children from the randomized ECECs and whose primary outcome is known will be included.

Main analyses:
We will use Analyse of Covariance (ANCOVA) aggregated at cluster level to compare the primary outcome (post-intervention scores) adjusting for baseline score.

Example of Stata command:
Mixed outcome treatment baseline_covariate II cluster_id:

For sensitivity purpose, we will use GEE – Generalized Estimating Equations – models.

Example of Stata command:
Xtgee outcome treatment baseline_covariate, family (gaussian) link(identity) corr(exchangeable) robust i(cluster_id)

At both time points, each child has two scores provided by two independent ECEC staff. A mean of these two scores will be calculated and used as outcomes/covariates in the analyses. In sensitivity analyses, we will calculate ICCs to check the correlations between baseline and post-intervention scores.

For secondary analysis, the negative behavior variables will be dichotomized as exposed/exposing others to negative behavior or not 2-3 times a months or more (1,0), and logistic regression approaches (e.g. melogit command in Stata) will be used to detect whether the program has an effect on the frequency of children who have been involved in negative behavior (either as a victim or perpetrator).

For the analysis on item level, we will use methods customized for ordinal or multi-nomic regressions or dichotomize the variables in exposed/exposing others to the negative acts 2-3 times a month or more often or not (0,1) and use logistic regression approaches.

If relevant between-group baseline differences in any of the variables are observed (Table 1 and 2), we will consider adjusting the effect estimates for these potential confounding variables in the regression models and present the adjusted effect in the main text of the manuscript.

Outcome distribution:
We do not expect outcomes to be normally distributed. Deviation from normal distribution is less of a problem when there are more than 100 observations. Still, we will check the residuals and evaluate how much data deviate from linearity and use statistical methods well suited for analyzing non-normal and semi-continuous data.

Subgroup analyses:
Demographic information provides important descriptions of the samples and can also facilitate measurements of potential subgroup effects/effect modifications (e.g., by age and gender). In the subgroup analyses, we will adjust for variables expected to be associated with the outcomes. In these sub-group analyses, we will include interaction terms to test the statistical significance of the effect modifier.

Handling of missing data:
Missing data will be handled with multiple imputation (MI) and Full Information Maximum likelihood (FIML).

Analyses of compliance:
We will describe the attendance to Be-Prox training modules in the intervention arm using descriptive statistics.

6.1. Other analyses that will be considered
Based on results from the primary analyses, we may perform per-protocol analyses. These will be presented as post-hoc secondary findings underlining their limitations in terms of determining causality.