Official title: Early Childhood Outside (ECO) Early Childhood Educator (ECE) Tool - Randomized Controlled Trial Study

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Study Protocol

Objectives

Our study objective is to develop and evaluate a web-based intervention that influences early childhood educators' (ECEs) and early learning child care (ELCC) administrators' perceptions and practices in support of children's outdoor play in ELCCs.

Design

This study is guided by the 6-step Intervention Mapping process (Michie et al., 2008) to plan, develop and evaluate the web-based intervention as described in Objectives. Upon receiving ethics approval from the University of British Columbia and Children's and Women's Health Centre of British Columbia Research Ethics Board (H19-01230; H19-03644), we began with Step 1 to understand the problem. This was done by establishing and working with study partners from various disciplines; and, conducting a literature review and a need assessment of the target population through focus groups – to explore key issues, needs and challenges from different perspectives. A logic model of the problem was developed to establish intervention goals. Step 2 involved developing a logic model of change to identify what needs to change and for whom. This linked the behavioral and environmental change objectives to specific outcomes that helped meet the intervention objectives. Then we selected the optimal applications and technology to deliver the intervention (Step 3) to produce the intervention (Step 4). In Step 5, we developed the intervention implementation and mobilization plan to make sure this web-based intervention reaches the target audiences. For the final step (Step 6), we will conduct a single-blind randomized control trial to test the efficacy of the web-based intervention.

Methods

We used a single-blind (researchers and outcome assessors), two-parallel-group randomized controlled trial design to evaluate the efficacy of the intervention. Consenting, randomization, survey administration and follow-ups was managed strictly online. We recruited 563 ECEs and ELCC administrators at baseline through a variety of online means, including Facebooks Ads and mass emails through our partner networks. Participants were randomized into the intervention or the control group by the REDCap, an electronic data capture intervention, hosted by the BC Children's Hospital Research Institute. Participants had equal likelihood of assignment to each group using a basic randomization method. The control group read Position Statement on Active Outdoor Play, a 4-page document on research and recommendations for action in addressing barriers to outdoor play (Tremblay et al., 2015). The intervention group fook the web-based intervention to influence ECEs and ELCC administrators' perceptions and practices in support of children's outdoor play in ELCCs.

The primary outcome is increased tolerance of risk in children's play, as measured by the Teacher Tolerance of Risk in Play Scale. The secondary outcome is self-reported attainment of a self-developed behavior change goal at either two follow-up time point.

For complete study protocol, refer to: Brussoni M, Han CS, Jacob J, Munday F, Zeni M, Walters M, Cheng T, Schneeberg A, Fox E, Oberle E. A web-based risk-reframing intervention to influence early childhood educators' attitudes and supportive behaviors toward outdoor play: Protocol for the outsideplay study randomized controlled trial. JMIR Research Protocols; 2021;10(11):e31041. [doi: 10.2196/31041]

Statistical Analysis Plan

Statistical software
The latest version of R (R Foundation for Statistical Computing, Vienna, Austria) and Stata (StataCorp LLC, College Station, TX, USA) was used for statistical analysis and graphics.

Power
For a sample size of 206 ECEs and ELCC administrators in total, a linear mixed model examining the impact of intervention relative to control, including an interaction with time, was calculated to have 80% power at a P=.05 level of significance to detect a difference of 0.75 between the intervention and control conditions on the T-TRiPS when the SD is 1.82, and the correlation between repeated observations is 0.75. From our previous work (Brussoni et al., 2021), we anticipated requiring 324 complete baseline requirements among ECEs and ELCC administrators who would then be randomized into the 2 conditions. We assumed a 75% retention rate at the 1-week postintervention follow-up time point (n=242) and an 85% retention rate at our 3-month postintervention follow-up time point, which would result in a final sample of 206 ECEs, corresponding to 103 in each condition.

Measurement occasions and follow-ups
Participants completed a questionnaire package at three time points: baseline (T1), 1-week post-intervention (T2) and 3-month post-intervention (T3). Long-term change is unlikely if participants do not make initial changes, thus, the 1-week follow-up was selected to assess short-term effectiveness, while still providing participants sufficient time to make their initial planned changes. The 3-month follow-up assessed long-term effectiveness once participants have had several months to reflect on the intervention and implement change. Survey data were collected and managed using REDCap. Baseline data collection includes socio-demographic data: sex, age, ethnicity, spoken language, years working in the early learning childcare field, years working in the current ELCC center, role in the current ELCC center, province of employment, whether the center is licensed, number of children at the center, number of staffs at the center, whether the center has a designated outdoor space for children, quality of the center's outdoor space for children, hours children spent playing outdoors at the center, and whether the participant feels supported by colleagues in general.

We assessed the primary outcome measure at baseline, 1-week, and 3-month post-intervention. We could only assess the secondary outcome measure at 1-week and 3-month post-intervention because at baseline participants could not have accomplished a goal they had not yet set.

Outcome measures
Our primary outcome measure is change in the total score on the Teacher Tolerance of Risk in Play Scale (T-TRiPS), a validated, reliable 26-item measure with dichotomous yes/no responses on items that reflect Sandseter's (Sandseter, 2009) six categories of risky play (great heights, high speed, dangerous tools, dangerous elements, rough-and-tumble, disappear/get lost) (Ihrig, 2020). The T-TRiPS is a modified version of the TRiPS for parents (Hill & Bundy, 2014) measuring teachers' perception of risk. We assessed the psychometric properties of T-TRiPs in our sample using Rasch analysis, using mirt package in R software (Chalmers, 2012). Items with local dependence will be dropped and model fit amongst the remaining items will be assessed: root mean square error of approximation, standardized root mean square residual, Tucker–Lewis index, comparative fit index, and empirical reliability. Theta standardized scores will be obtained for the analysis and a higher standardized score indicates higher tolerance of risk in play.
Our secondary outcome measure is self-reported behavior change, measured by participants' self-reported progress on attaining the goal they set for themselves. At each follow-up time point,

participants will be reminded of their goal and asked “Did you accomplish your goal?” with dichotomous yes/no responses.

Descriptive Analysis

To compare the raw outcome differences between conditions at each time point, for continuous outcomes (TRiPS scores), we used 1-way ANOVA or Kruskal-Wallis H test (if variance is not equal between conditions). For categorical outcomes (goal attainment), we used the chi-square test. Significance level was set at P=.05.

For complete results, refer to: Brussoni M, Han CS, Lin, Y, Jacob J, Munday, F, Zeni M, Walters M, Oberle E. Evaluation of the Web-Based OutsidePlay-ECE Intervention to Influence Early Childhood Educators’ Attitudes and Supportive Behaviors Toward Outdoor Play: Randomized Controlled Trial. JMIR; 2022; 24(6):e36826. [doi: 10.2196/36826]

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