

Official title: Randomized Controlled Trial of a Risk Reframing Tool to Change Mothers'  
Parenting Associated With Children's Risky Play

NCT number: 03374683

Document date: Dec 31, 2018

Document type: Statistical Analysis Plan

For complete methods, refer to: Brussoni, M., Ishikawa, T., Han, C., Pike, I., Bundy, A., Faulkner, G, & Mâsse, L. (2018). Go Play Outside! Effects of a risk-reframing tool on mothers' tolerance for, and parenting practices associated with, children's risky play: study protocol for a randomized controlled trial. *Trials*, 19, 173

## **Measurement occasions and follow-up**

Participants will complete a questionnaire package at three time points: baseline (T1), 1 week post intervention (T2) and 3 months 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 will assess long-term effectiveness once participants have had several months to reflect on the intervention and implement change. Survey data will be collected and managed using REDCap. Baseline data collection includes socio-demographic data: age, ethnicity, marital status, education, employment, home dwelling type, household income and number of children in the household. Participants will also complete measures to assess primary and secondary outcomes at each time point.

## **Outcome measures**

The primary outcome measure is increase in the total score on the Tolerance of Risk in Play Scale (TRiPS), a 31-item measure examining adults' tolerance of risk during children's play, which has been psychometrically validated [1]. The scale is based on Sandseter's six category model of risky play [2]. Goodness-of-fit statistics for TRiPS have been found to be in the acceptable range [1]. Examination of logical item hierarchy indicated that items that were relatively difficult to endorse (e.g. 'Would you let the child play near the edge of steep cliffs?') were located higher on the hierarchy than those that were easier to endorse (e.g. 'Would you let the child play in the backyard supervised?'). The Person Separation Index was 2.63, indicating that the measure separated persons into more than two distinct groups, such as more and less risk tolerant. The Person Reliability Index was 0.87 indicating that the instrument was able to consistently differentiate between those scoring high versus low. Self-perceived risk tolerance was highly positively associated with scores on TRiPS, and the mean score increased with age of the child [1].

The secondary outcome measure is self-reported behaviour change. Behaviour change is being measured by their self-reported progress on attaining the goal they set for themselves within the RR tool. Participants will be reminded of their goal and asked: 'Did you accomplish your goal?' with 'Yes' and 'No' response options.

## **Adherence to intervention**

Adherence to the risk-reframing (RR) digital tool will be measured by examining the percentage of content viewed, time spent online and task completion [3]. Adherence to the in person RR tool will be measured by examining workshop attendance and task completion.

## **Statistical analysis**

Analysis strategy (including verification of model assumptions) will follow Singer and Willet's guidelines [4]. All participants allocated to one of the three conditions will be included in the analysis, regardless of deviation from protocol, missed follow-up observations, or withdrawal. To test our hypotheses that mothers completing either version of the RR tool will have significantly greater increase of tolerance for risk in play, we will compare the two intervention conditions with the control condition. For modelling purposes, we will use mixed-effects models using a correlation structure that assumes model change over time. Selection of the most appropriate model will depend on the distributional form of the data, whether the change is linear and nonlinear and model selection will be based on residual analyses. To test our hypotheses that a higher proportion of mothers in either version of the RR tool will report attainment of behaviour-change goals (secondary outcome measure), we will use logistic regressions.

## **Missing data**

We will use multiple imputation to manage missing data and will report and justify our imputation strategies. Imputed data for multiple imputation will be analysed as part of a sensitivity analysis.

## **Statistical software**

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

## **References**

- [1] Hill A, Bundy AC. Reliability and validity of a new instrument to measure tolerance of everyday risk for children. *Child Care Health Dev.* 2014;40:68–76.
- [2] Sandseter EBH. Characteristics of risky play. *J Adventure Educ Outdoor Learn.* 2009;9:3–21. Taylor & Francis.
- [3] Donkin L, Christensen H, Naismith SL, Neal B, Hickie IB, Glozier N. A systematic review of the impact of adherence on the effectiveness of etherapies. *J Med Internet Res.* 2011;13:e52.
- [4] Singer JD, Willet JB. *Applied longitudinal analysis.* New York: Oxford University Press Inc.; 2003.