Statistical Analysis Plan for

Phase 2 of the Pelotas Parenting Interventions for Aggression (PIA) trial: follow-ups at ages 5 and 6-7 years.

Trial registration: RBR-2kwfsk at the Brazilian Ministry of Health Register of Clinical Trials (http://www.ensaiosclinicos.gov.br/)

Trial protocol: Murray, et al. The effects of two early parenting interventions on child aggression and risk for violence in Brazil (The PIÁ Trial): protocol for a randomised controlled trial. Trials (2019) 20:253. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6498476/pdf/13063_2019_Article_3356.pdf

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Conflicts of interest: Authors of the study collaborated with the Municipal Government of Pelotas implementing the randomized trial. After finishing the delivery of the interventions within the trial, the Municipal Government implemented in a larger scale at municipal level one of the training programmes evaluated - *ACT: Raising Safe Kids.* That governmental implementation occurred after conclusion of the experimental procedures without participation of the research team.

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1 Introduction

The study aims are to determine, in a three-arm randomised controlled trial, the medium-term impact of two group-based, parent training programmes implemented with mothers with young children. The two training programmes are *ACT: Raising Safe Kids*, which primarily aims to reduce harsh discipline and maltreatment against children, and a *Dialogic Book Sharing* (DBS) programme, which primarily aims to stimulate positive parent child interaction and child cognitive development.

The first phase of the Pelotas Parenting Interventions for Aggression (PIA) trial involved a set of analyses assessing intervention effects on parental and child outcomes measured 4-week post-intervention, and 8-month post-intervention (when children were 4 years of age). All steps of that first evaluation are concluded and a full report is under review for publication.

In a second phase of PIA trial (which this statistical analysis plan describes), outcome data from two additional time points will be examined. These outcomes were measured when children were aged 5 years, during the COVID-19 pandemic in 2020, and in a follow-up when children were aged 6-7 years, in 2021-2022. Consistent with the initial theory of change of the PIA trial, we aim to determine the impact of each training programme on child aggressive behaviour (primary outcome), as well as child mental health (secondary outcomes), child executive functions (secondary outcomes), and parenting practices (secondary outcomes).

2 Hypotheses

2.1 Primary Outcome Hypothesis

1. During the COVID-19 pandemic follow-up, when children were 5 years of age, compared to a control group of children whose carers received no additional intervention, children whose carers received ACT or DBS will evidence significantly less aggressive behaviour.
2. At age 6-7 years follow-up, compared to a control group of children whose carers received no additional intervention, children whose carers received ACT or DBS will evidence significantly less aggressive behaviour.

2.2 Secondary Outcome Hypotheses

1. During the pandemic follow-up (5 years of age), compared to children of families who received no intervention (the control group), children whose carers received DBS will show less emotional, conduct and hyperactivity problems; and their parents will report better parent-child relationships, but will not show different levels of coercive parenting.
2. During the pandemic follow-up (5 years of age), compared to children of families who received no intervention (the control group), children whose carers received ACT will show less emotional, conduct and hyperactivity problems; and their parents will report better parent-child relationship and less coercive parenting.
3. In the follow-up at ages 6-7 years, compared to children of families who received no intervention (the control group), children whose carers received DBS will show less emotional, conduct and hyperactivity problems; will show higher prosocial behaviour, reading motivation

and literacy; and they will perform better on measures of language development and attention shifting.

4. In the follow-up at ages 6-7 years, compared to parents who received no intervention (the control group), parents receiving DBS will report higher frequency of book sharing, and better parent-child relationships and more positive parenting; but they will not report different levels of coercive parenting or child maltreatment.
5. In the follow-up at ages 6-7 years, compared to children of families who received no intervention (the control group), children whose carers received ACT will show less emotional, conduct and hyperactivity problems; they will show higher prosocial behaviour; and they will perform better on measures of language development, attention shifting and self-control.
6. In the follow-up at ages 6-7 years, compared to parents who received no intervention (the control group), parents receiving ACT will report better parent-child relationships, positive discipline, emotional and behavioural regulation, communication and media access control; and they will report less attitudes favourable to corporal punishment, less coercive parenting and less child maltreatment.

3 Trial Methods

3.1 Trial design

The study is a three-arm randomized controlled trial (RCT) nested within an ongoing birth cohort study. The 2015 Pelotas Birth Cohort Study, has followed 4,275 children from birth. The cohort includes the entire population of children born in the calendar year 2015 in the city of Pelotas, southern Brazil. Based on data collected on the cohort when children were aged 24-months, a sub-sample of mother-child pairs were recruited for the PIÁ trial, when children were between 2-3 years old. Interventions were delivered by the Pelotas municipal government staff in local educational facilities, under the supervision of the research team.

A first assessment of the effects of the interventions (ACT and DBS) was completed, and the results are under review for publication. Those analyses used data assessed at Baseline, 4-weeks post-intervention, and at 8-month follow-up. Given the initially stated expectation for both interventions to show effects across the life-course, ultimately potentially leading to a reduction in the use of violence in adulthood, the present *Phase 2 of the PIÁ trial* aims to evaluate the effects of interventions at two further time points: 1) the COVID-19 pandemic period, when children were 5 years of age; and 2) when children started elementary school, and were assessed at ages 6-7 years. To estimate the impacts of DBS and ACT on these outcomes, Phase 2 of the trial will use outcome data collected at those time points, as well as baseline data collected in Phase 1.

The pre-analysis plan will be preregistered on the Open Science Framework. Ethical approvals for the PIÁ trial were obtained from the Research Ethics Committees of the Federal University of Pelotas/Faculty of Medicine (#2.602.769). All mothers provided written informed consent to participate in the trial. Additionally, all 2015 Pelotas Birth Cohort assessments were approved by a Research Ethics Committee of the Federal University of Pelotas, including the Phase 2 follow-ups of the PIÁ trial subsample when cohort children were aged 5 and 6-7 years (School of Physical Education at age 0-4 years: #26746414.5.0000.5313; Faculty of Medicine at age 5 years: #31179020.7.0000.5313; Faculty of Medicine at age 6-7 years: #51789921.1.0000.5317). All caregivers provided written informed consent at each cohort follow-up.

3.2 Randomisation

Randomisation of mother-child pairs to either one of the two interventions (ACT and DBS) or control condition, was undertaken at the research centre immediately after baseline assessment, minimising for the following dichotomous variables: age of child (<3 years and ≥3 years), child sex (male and female), child aggression score at age 2 years (<4 and ≥4), and harsh parental discipline score at age 2 years (<6 and ≥6). The probability that individuals are allocated to each of the three arms of the trial was 33.3%.

3.3 Sample size

The sample at the beginning of the trial comprised mothers from the 2015 Pelotas Birth Cohort Study with children 2-3 years old, who were in the poorest 30% of the population (based on family income when children aged 24-months), and who reported that their children showed average-high levels of child aggression at age 24-months (based on Physical aggression scale from the ELDEQ study).

Power calculation carried out before the randomization: With alpha set at 0.025 due to two pair-wise comparisons (i.e. between DBS and control, and between ACT and control), and beta at 0.20, each of the three arms in the trial required a minimum of 104 participants (allowing for 10% attrition to the follow-up assessment) to detect a mid-range effect size of d = 0.45. Therefore, a minimum of 312 participants were needed for the study. In Phase 1 of PIÁ trial 369 participants were included in the study, assessed at baseline, and randomized to one of the two intervention groups or control.

For Phase 2 of the trial, the actual number of participants assessed in the follow-up during the COVID-19 pandemic (age 5 years) was 252 (68.3%), via an online questionnaire responded by mothers. The change in data collection method and especially the disruption of the pandemic contributed to increased drop-out in this follow-up, especially among families at the lower end of the socio-economic spectrum. At age 6-7 years, 365 (98.9%) participants were followed-up in person at the research center. A post-hoc power calculation to detect a mid-range effect size of d = 0.45 was carried out, with alpha set at 0.05 and beta at 0.20, and showed a 0.82 power at the age 5 years assessment, and a 0.94 power at the age 6-7 years assessment for both the Control vs. ACT and Control vs. DBS comparisons.

3.4 Blinding

To prevent assessment bias, assessments of children and caregivers were carried out blind to group allocation. The statistician will be provided with individual intervention allocations at the time of database lock, in the form of a categorical variable with three values (1= A, 2 = B, 3 = C) remaining blind to which of A, B, and C refers to the ACT group, the DBS, and the Control group. The statistician will then compare A-B, B-C, and C-A, in order to generate trial results comparing ACT-control and DBS-Control, while remaining blind to intervention status. After primary intention to treat analyses have been completed comparing outcomes in this way, the statistician will be unblinded in order to complete additional per-protocol analyses, sensitivity analysis, moderation analyses, and potential mediation analyses, comparing ACT-Control and DBS-Control.

3.5 Interim analysis

There are no planned interim analyses.

3.6 Final analysis

The final analyses will be performed after all data from the two new time points under analysis are coded, cleaned and the database locked. At the time of database lock the statistician will request to receive the individual level intervention information from the trial manager, according to the procedures described in item 4.4.

3.7 Outcome assessments and other measures

Table 1 shows outcome constructs and measures that will be analysed for the present *Phase 2 of the PIA Trial*.

Table 1. Study Outcomes and Measures

Outcome Domain	Outcome	Outcome Measure	Intervention (Training programme)	Baseline (1 Week Prior to Intervention)	COVID-19 pandemic follow-up (2 years Post Intervention)	Age 6-7 years follow-up (3-4 years Post Intervention)
Child aggression (primary outcome)	**Child aggression**	**Physical aggression score** Étude longitudinale du development des enfants du Québec (ELDEQ study) questionnaire. Physical aggression - 4 items: 1, 2, 3 and 13	ACT and DBS	✓ p1_eldeq_9items	✓ p4_eldeq_4items	✓ p5_eldeq_4items
Child mental health (secondary outcome)	**Child mental health**	**Inattention-Hyperactivity scale** Strengths and Difficulties Questionnaire (SDQ) - 5 items: 2, 10, 15, 21, and 25	ACT and DBS	✓ p1_sdq_hype	✓ p4_sdq_hype	✓ p5_sdq_hype
		Emotional problems scale Strengths and Difficulties Questionnaire (SDQ) - 5 items: 3, 8, 13, 16 and 24	ACT and DBS	✓ p1_sdq_emot	✓ p4_sdq_emot	✓ p5_sdq_emot
		Conduct problems scale Strengths and Difficulties Questionnaire (SDQ) - 5 items: 5, 7, 12, 18 and 22	ACT and DBS	✓ p1_sdq_condu	✓ p4_sdq_condu	✓ p5_sdq_condu
		Peer problems scale Strengths and Difficulties Questionnaire (SDQ) - 5 items: 6, 11, 14, 19 and 23	ACT and DBS	✓ p1_sdq_peerp		✓ p5_sdq_peerp
Child development (secondary outcome)	**Child language**	**Language assessment** Wechsler Intelligence Scale for Children, 4th edition (WISC)	ACT and DBS	✓ p1childlang		✓ p5_wisc_lang

Outcome Domain	Outcome	Outcome Measure	Intervention (Training programme)	Baseline (1 Week Prior to Intervention)	COVID-19 pandemic follow-up (2 years Post Intervention)	Age 6-7 years follow-up (3-4 years Post Intervention)
		Child motivation to read Child's interest in looking at books/magazines – 1 item	DBS	✓ p1bs3_c_attention		✓ p5_motiv_read
		Child Literacy Child being able to read some words – 1 item	DBS	✓ p1childlang		✓ p5_literacy
	Child attention and executive functions	**Cognitive flexibility** EYT Card Sorting task - Attention shifting	ACT and DBS	✓ p1childlang		✓ p5_card_shift
		Self-control Stroop task	ACT	✓ p1moffittsum		✓ p5_stroop_self
	Child prosocial behaviour	**Prosocial scale** Strengths and Difficulties Questionnaire (SDQ) - 5 items: 1, 4, 9, 17 and 20	ACT and DBS	✓ p1_sdq_pros		✓ p5_sdq_pros
Parenting (Secondary outcome)	**Positive parenting**	**Encouragement** Parenting and Family Adjustment Scales (PAFAS) positive encouragement subscale – 2 items: 8 and 9	ACT and DBS	✓ p1pafasposen		✓ p5_pafas_posen
		Parent-child relationship PAFAS parent-child relationship subscale – 5 items: 10, 11, 12, 13 and 14	ACT and DBS	✓ p1pafaspcrelat (all 5 items)	✓ p4_pafas_pcrelat (2 out of 5 items)	✓ p5_pafas_pcrelat (all 5 items)
		Positive discipline ACT scale – 5 items from parental behavior section: 1, 3, 4, 5, and 8	ACT	✓ p1pafasposen		✓ p5_ACT_posdisc

Outcome Domain	Outcome	Outcome Measure	Intervention (Training programme)	Baseline (1 Week Prior to Intervention)	COVID-19 pandemic follow-up (2 years Post Intervention)	Age 6-7 years follow-up (3-4 years Post Intervention)
	Media access control	**Media access control** ACT scale – 7 items from electronic media section: 1, 2, 3, 4, 5, 6 and 7	ACT	✓ p1_ACT_media		✓ p5_ACT_media
	Book-sharing practices	**Frequency of book-sharing by the mother** How many times the mother read or looked at a book with the child during last week – 1 item	DBS	✓ fw24reading		✓ p5_bookshare_mother
	Harsh parenting	**Coercive** PAFAS coercive subscale – 4 items: 4, 5, 6 and 7	ACT and DBS	✓ p1pafascoer	✓ p4_pafas_coer	✓ p5_pafas_coer
		Emotional and Behavioral regulation ACT scale – 5 items from parental style section (2, 5, 6, 7 and 8) plus 2 items from parental behavior section (2 and 6)	ACT	✓ p1pafascoer		✓ p5_ACT_emotbeha
		Communication ACT scale - 3 items from parental style section: 4, 10 and 11	ACT	✓ p1pafascoer		✓ p5_ACT_commu
	Attitudes about punishment	**Attitudes about physical punishment** Maternal beliefs regarding using physical violence to educate – 1 item	ACT	✓ p1_aapp		✓ p5_aapp
	Maltreatment	**Child maltreatment** Juvenile Victimization Questionnaire (JVQ)	ACT and DBS	✓ p1jvqanymalt		✓ p5_jvq_anymalt

The following additional data were collected prior to baseline, as part of cohort assessments:

- Maternal education measured in the perinatal assessment, and complemented with pre-natal data when perinatal was missing [abmateduc]
- Socioeconomic status measured when children were 24 months of age [fw24income]
- Frequency of reading-storytelling to child when children were 24 months of age [fw24reading]
- Participation in Primeira Infância Melhor (PIM) home-visiting programme, which aims to promote general Early Child Development [h_pim_participation]
- Child language when children were 24 months (to be used for missing language data at baseline)
    - Total language score: [fw24meanlanguage]
    - Expressive language score [fw24meanexpressilanguage]
    - Receptive language score [fw24meanreceplanguage]

The following additional data were collected at baseline:

- Child age [p1cage, p1cagecat]
- Child sex [p1sex]
- Neighbourhood - randomization area [p1area]
- Mother relationship status [p1partner]
- Child attendance at preschool [p1school]
- Child callous unemotional traits [p1icufinal]
- Intimate partner violence [p1vpifinalcat]
- Maternal depression [p1epdsfinal]
- Maternal problem drinking [p1auditfinalcat]
- Child impulse control – Go/No-Go Score [p1cgng]
- Filmed Book-Sharing Maternal Sensitivity [p1bssensitivity_z]
- Combined child aggression [p1zagg]
- Combined positive parenting [p1zpparent]
- Parental Stress Index [p1psifinal]

The following additional data were collected about intervention adherence (ACT and DBS):

- Mother completed the intervention (no/yes) [p3adherence]
  This was defined as attending 7+ out of 9 of the ACT intervention sessions and 6+ out of the 8 book sharing sessions in the DBS intervention group.

The following additional data were collected about fidelity of ACT facilitators:

- Mother completed the ACT intervention and received it from a high-fidelity facilitator (no/yes) [p3act_fidelity]

The following additional data were collected about experiences during COVID-19 pandemic:

- Major family income loss during pandemic (no/yes) [h_pandemic_income_loss]
- 6 months or more without classes during pandemic years of 2020 and 2021 (no/yes) [h_pandemic_school_loss]

During the intervention phase, the number of sessions attended was recorded, and carer report of compliance and assessment of intervention quality and usefulness is also recorded at post treatment. Fidelity of facilitator implementation of the two parent-training programmes is also assessed by the research supervisors of each intervention.

4 Statistical principles

4.1 Significance level

All confidence intervals presented will be 95% and two-sided.

4.2 Multiple comparisons

No formal adjustment for multiple testing will be made, given the endpoints are associated with each other and an adjustment would over-correct (Schulz et al 2005). The primary outcome, along with secondary and tertiary/exploratory analyses, will be reported and interpreted together. For secondary outcomes, no single confidence interval will be interpreted in isolation and all findings will be considered together to obtain the full picture of the intervention effects on the different outcome measures.

Interpretation of results will take account of consistency across outcomes as well as clinical plausibility based on prior knowledge.

4.3 Analysis Populations

The intention- to- treat (ITT) population will be used for all analyses. This population includes all participants who were enrolled and randomised. Subjects will be analysed based on the groups to which they were originally allocated.

The per-protocol population will be used for a sensitivity analysis on the primary endpoints and secondary outcomes. This population is a subset of the ITT population which excludes subjects who were allocated to but did not complete the ACT and DBS interventions. All ITT subjects in the control group will be included.

Given the considerable drop-out rate at the 5-year follow-up, during the COVID-19 pandemic, a complete case analysis approach may be required for this time point only, but careful consideration will be given to baseline differences between participants who dropped out of the study and those who were assessed, and to intergroup differences in drop-out rates, to ensure the appropriate approach is selected to obtain unbiased estimates of treatment effect (Bell et al., 2013).

4.4 Outliers

It is planned that all data will be included in the relevant analyses. However, an assessment to identify any outliers will be performed. If it is deemed necessary any subjects excluded from the summaries and/or statistical analyses will be documented along with the reason for exclusion in the report.

5 Trial population

The consort diagram comprising the number of people screened/approached, eligible, randomised, received their allocated intervention, withdrawing/lost to the follow-up, will be produced. Reports of compliance/attendance will also be listed and summarised.

6 Efficacy Analysis

6.1 General analysis considerations

For continuous outcomes, adjusted means and standardised mean differences between groups along with 95% confidence intervals will be presented. For binary outcomes, adjusted odds ratios and 95% confidence intervals will be presented.

For all analyses, the relevant assumptions will be checked. Alternative models may be used if necessary. If the normality assumption does not hold then a transformation such as log transformation, or an alternative distribution will be investigated. If there is no suitable transformation then a non-parametric testing method will be utilised.

6.1.1 Descriptive statistics

The primary endpoints will be listed, and summarised by intervention group, and timepoint.
Demographic and baseline characteristics will be listed and summarised by intervention group. Categorical data will be summarised by numbers and percentages. Continuous data will be summarised by mean, SD, median, minimum and maximum values. The number and percent of missing data per outcome, group and time point will be summarised.

6.1.2 Missing data

If more than 1/3 of items on a questionnaire or measure are missing then the result will be considered missing for that person for that timepoint, otherwise prorated scores will be calculated and considered non-missing. For composite baseline proxies of endpoints, prorated scores will be calculated on the individual measures and the composite will then be derived from the imputed components.

The amount and pattern of missing data will be examined and will be addressed using multiple imputation where appropriate.

Due to technical difficulties language measures at baseline are missing for about one third of the participants. For the main analyses, multiple imputation will be used for these missing data, including model-specific covariates and language measures collected at age 24 months (pretrial cohort measure). In final regression models, the imputed child language scores will be used as a proxy of baseline scores for some outcomes, and as an additional covariate for some outcomes (details in Table 1 and Table 2). For analyses of child language outcome at age 6-7 years, a complete case analyses will also be conducted (as a sensitivity analyses), in which the baseline measure of child language without imputation will be used instead of the imputed measure.

6.2 Primary analyses

Intervention effects will be assessed separately at two time points (during the COVID-19 pandemic period when children were aged 5 years, and at age 6-7 years follow-up), and will be adjusted for: baseline scores, child age and sex, maternal education and depression, neighbourhood (as random effect), and additional, outcome-specific covariates shown in Table 2.

A mixed effects model will be fitted for each outcome at each follow-up. Intervention, timepoint, intervention by timepoint interaction, covariates as listed above, and baseline values, will be fitted as fixed effects, neighbourhood and subject will be fitted as random effects, with repeated measures within a subject being accounted for. If the necessary assumptions of the models do not hold, suitable alternative models will be explored. Intention-to-treat analysis will be used to examine intervention effects. As noted in 4.3, for the 5-year follow-up, during the COVID-19 pandemic, careful consideration will be given to baseline differences between

participants who dropped out of the study and those who provided data, and to intergroup differences in drop-out rates, to ensure the appropriate modelling approach is selected to obtain unbiased estimates of treatment effect (Bell et al., 2013).

6.3 Sensitivity analyses

The main sensitivity analyses including primary and all secondary endpoints, for both 5 years and 6-7 years follow-ups, will be conducted using the per-protocol population - a subset of the ITT population which includes subjects who were allocated to and did complete the ACT (n for intervention arm = 79) and DBS (n for intervention arm = 95) interventions.

A second sensitivity analysis, restricted to ACT assessments, will be conducted with a subsample who completed the ACT intervention and did so with a high-fidelity facilitator (n for intervention arm = 45). In this analysis the primary outcome and a subset of secondary outcomes (PAFAS Coercive subscale: 5 years and 6-7 years follow-up; ACT Emotional and Behavioural regulation scale: 6-7 years follow-up; ACT Communication scale: 6-7 years follow-up; ACT Positive discipline scale: 6-7 years follow-up; and ACT electronic media scale: 6-7 years follow-up) will be evaluated.

A third sensitivity analysis will be conducted specifically for the primary outcome Child aggression, for both 5 years and 6-7 years follow-ups. Given relatively high frequency of losses in some model specific covariates described in Table 2 (rightmost column), this sensitivity analysis will estimate intervention effects adjusting for generic covariates only (central column in Table 2).

A fourth sensitivity analysis will apply specifically for the secondary outcome child language measured at 6-7 years follow-up. Due to technical difficulties language measures at baseline are missing for about one third of the participants. For the main analyses, multiple imputation will be used for these missing data at baseline, including model-specific covariates and language measures collected at age 24 months (pretrial cohort measure). As a sensitivity analyses, a complete case analyses will be conducted for this outcome.

Table 2. Study Covariates for each Outcome

Outcome Domain	Outcome	Generic Study Covariates (measured at baseline, or pre-baseline from cohort)	Additional Covariates (measured at baseline, or pre-baseline from cohort)
Child aggression (primary outcome)	Child aggression	• Baseline measure • Child age • Child sex • Maternal education • Maternal depression • Neighbourhood	• Child maltreatment • PAFAS coercive parenting • Combined child language • Child Go-No Go Task • Child callous-unemotional traits
Child mental health (secondary outcome)	Hyperactivity	• Baseline measure • Child age • Child sex • Maternal education • Maternal depression • Neighbourhood	• Child maltreatment • PAFAS coercive parenting • Combined positive parenting
	Emotional problems	• Baseline measure • Child age • Child sex • Maternal education • Maternal depression • Neighbourhood	• Child maltreatment • PAFAS coercive parenting • Combined positive parenting
	Conduct problems and Peer problems	• Baseline measure • Child age • Child sex • Maternal education • Maternal depression • Neighbourhood	• Child maltreatment • PAFAS coercive parenting • Combined positive parenting

Outcome Domain	Outcome	**Generic Study Covariates** (measured at baseline, or pre-baseline from cohort)	**Additional Covariates** (measured at baseline, or pre-baseline from cohort)
Child development (secondary outcome)	Child language and child literacy	• Baseline measure • Child age • Child sex • Maternal education • Maternal depression • Neighbourhood	• Child maltreatment • Child preschool attendance • Reading-storytelling at 24 months • Combined positive parenting
	Child attention and executive functions	• Baseline measure • Child age • Child sex • Maternal education • Maternal depression • Neighbourhood	• Child maltreatment • PAFAS coercive parenting • Combined positive parenting
	Child prosocial behaviour	• Baseline measure • Child age • Child sex • Maternal education • Maternal depression • Neighbourhood	• Child maltreatment • PAFAS coercive parenting • Combined positive parenting
Parenting (secondary outcome)	Positive parenting and Frequency of book-sharing	• Baseline measure • Child age • Child sex • Maternal education • Maternal depression	• Maternal problem drinking • Reading-storytelling 24 months • Combined child aggression • Intimate partner violence • Pelotas Parenting Stress Index

Outcome Domain	Outcome	Generic Study Covariates (measured at baseline, or pre-baseline from cohort)	Additional Covariates (measured at baseline, or pre-baseline from cohort)
		• Neighbourhood	
	Harsh parenting	• Baseline measure • Child age • Child sex • Maternal education • Maternal depression • Neighbourhood	• Maternal problem drinking • Combined child aggression • Intimate partner violence • Pelotas Parenting Stress Index • Attitudes about physical punishment • Child maltreatment
	Parental attitudes about corporal punishment	• Baseline measure • Child age • Child sex • Maternal education • Maternal depression • Neighbourhood	• Combined child aggression • Intimate partner violence • PAFAS coercive parenting
	Maltreatment	• Baseline measure • Child age • Child sex • Maternal education • Maternal depression • Neighbourhood	• Maternal problem drinking • Combined child aggression • Intimate partner violence • Pelotas Parenting Stress Index • Attitudes about physical punishment • PAFAS coercive parenting

6.4 Moderator effects

Table 3 shows the potential moderators of intervention impact that will be tested for a subset of main outcomes. To assess the effect of potential moderators, the same model will be fitted as described in section 7.2 with the addition of the moderator of interest and moderator*intervention interaction, and p-values for interaction terms will be presented. Moderators will be tested for both interventions, unless specified otherwise in Table 3.

6.5 Mediator effects

If relevant effects of ACT or DBS are found on the outcomes described in Table 1, a detailed mediation analysis plan will be registered in a supplemental file, which will receive a Digital Object Identifier, and this supplement will be linked to the originally published statistical analysis plan before mediation analyses are conducted.

Table 3. Moderators for each Outcome

Outcome Domain	Outcome	Principal Outcome Measure for Moderator Analyses	Moderators
Child aggression (primary outcome)	Child aggression	**Physical aggression score** Étude longitudinale du development des enfants du Québec (ELDEQ study) questionnaire. Physical aggression - 4 items: 1, 2, 3 and 13 **(5 years and 6-7 years follow-ups)**	• Baseline measure of outcome • Child sex • Child age • Child callous-unemotional traits • Maternal education • Intimate partner violence • PAFAS coercive parenting • Participation in PIM programme • 6 months or more without classes during pandemic • Major income loss during pandemic
Child development (secondary outcome)	Child language	**Language assessment** Wechsler Intelligence Scale for Children, 4th edition (WISC) **(6-7 years follow-up)**	• Baseline measure of outcome • Child sex • Child age • Maternal education • Maternal depression • Intimate partner violence • Filmed book-sharing task – sensitivity (DBS only) • Participation in PIM programme • 6 months or more without classes during pandemic • Major income loss during pandemic
Parenting (Secondary outcome)	Positive parenting	**Encouragement** Parenting and Family Adjustment Scales (PAFAS) positive encouragement subscale – 2 items: 8 and 9 **(6-7 years follow-up)**	• Baseline measure of outcome • Child sex • Child age • Maternal education • Maternal depression • Intimate partner violence • Participation in PIM programme • 6 months or more without classes during pandemic
		Parent-child relationship PAFAS parent-child relationship subscale – 5 items: 10, 11, 12, 13 and 14 **(5 years and 6-7 years follow-ups)**	

Outcome Domain	Outcome	Principal Outcome Measure for Moderator Analyses	Moderators
			• Major income loss during pandemic
	Harsh parenting	**Coercive** PAFAS coercive subscale – 4 items: 4, 5, 6 and 7 **(5 years and 6-7 years follow-ups)**	• Baseline measure of outcome (ACT only) • Child sex (ACT only) • Child age (ACT only) • Maternal education (ACT only) • Maternal depression (ACT only) • Intimate partner violence (ACT only) • Participation in PIM programme (ACT only) • 6 months or more without classes during pandemic (ACT only) • Major income loss during pandemic (ACT only)
		Emotional and Behavioral regulation ACT scale – 5 items from parental style section (2, 5, 6, 7 and 8) plus 2 items from parental behavior section (2 and 6) **(6-7 years follow-up)**	

7 Changes from protocol defined statistical analysis

The PIA Trial protocol stated that longer-term outcomes would be investigated as the birth cohort was followed into late childhood, adolescence, and adulthood. Nevertheless, the original protocol did not specify which outcomes would be assessed at future follow-ups (after age 4 years follow-up). Thus, preregistration of this analysis plan is necessary, describing specific associations to be tested at two time points beyond the original protocol plan: COVID-19 pandemic follow-up when children were 5 years of age; and age 6-7 years follow-up.

8 Planned publication of findings

This analysis plan encompasses evaluation of effects of PIA Trial interventions on outcomes measured at two different time points, during the COVID-19 pandemic follow-up, and at ages 6-7 years. Given the different contexts of these two follow-ups, and the different sample sizes in each, there is a need to interpret and discuss findings accordingly and we plan to publish results from each follow-up in separate papers – one for outcomes measured during the pandemic period (age 5 years) and another for outcomes measured at age 6-7 years follow-up.

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