Does a tailored instant messaging program for parents improve early child development? A randomized controlled trial among pre-k children in Uruguay during the school year

Submission date	Recruitment status	Prospectively registered
23/07/2024	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
25/07/2024	Completed	Results
Last Edited	Condition category	Individual participant data
23/07/2024	Other	[] Record updated in last year

Plain English summary of protocol

Background and study aims

Evidence suggests that small aids in the form of instant messaging can facilitate changes in parenting practices, which are crucial factors in enhancing child development and School Readiness.

General objective: To evaluate an instant messaging intervention program aimed at promoting parenting practices and child development in preschool children.

Who can participate?

The participants in this study are parent-child dyads in pre-K (around 4 years old).

What does the study involve?

The FODI (Fortalecimiento Oportuno del Desarrollo Infantil) Program lasts 21 weeks, during which families receive three weekly messages, through digital notifications. These messages contain information aimed at promoting positive parenting practices that can improve the cognitive development of their children.

Participants will be randomly assigned to one of three groups:

- Tailored treatment: personalized messages containing the names of the participants and adjusted according to developmental levels measured using INDI;
- General treatment: personalized messages containing the names of the participants but not necessarily adjusted to the developmental level; and
- Active control group: generic messages related to health and cultural curiosities, with no content aimed at stimulating development.

What are the potential benefits and risks of participating?

The tailored treatment of the FODI messaging program is expected to have a positive impact on parenting practices (compared to the general and active control conditions).

Likewise, the tailored treatment is expected to have a positive effect on cognitive development

or aspects of it.

There are no anticipated risks for participation in this study, but in case of discomfort, parents and children can withdraw from the study at any time.

Where is the study run from?

Espacio Interdisciplinario - Universidad de la República (Uruguay)

When does the study start and how long is it expected to last? October 2021 to December 2024

Who is funding the study?

Universidad de la República and Fundación ReachingU (Uruguay)

Who is the main contact?

Dr. Alejandro Vásquez-Echeverría, alejandro.vasquez@pedeciba.edu.uy

Study website

https://indi.ei.udelar.edu.uy/programa-fodi/

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Prof Alejandro Vásquez-Echeverría

Contact details

José Enrique Rodó 1843 - Espacio Interdisciplinario - Universidad de la República. Montevideo Uruguay 11200 +598 24089010 alejandro.vasquez@pedeciba.edu.uy

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

RU 072024

Study information

Scientific Title

Do pre-k children benefit from a tailored instant messaging program designed to improve parenting practices and child development, as compared to a non-tailored and control condition? A randomized controlled trial during the school year

Study objectives

- 1. The treatment of the messaging program (FODI) (in the general and tailored conditions) will have a positive impact on parenting practices, compared to the active control group, and the effect will be greater in the tailored condition
- 2. The treatment (in the general and adjusted conditions) will have a positive effect on cognitive development or on any of its components, compared to the active control group, and the effect will be greater in the tailored condition
- 3. Quartiles 1 and 4 of the tailored condition (but not quartiles 2 and 3) will show greater impact on development and parenting practices as compared to the general condition
- 4. Parenting practices will exhibit a mediating effect between treatment (tailored and general conditions) and development

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 25/05/2022, Faculty of Psychology Research Ethics Committee - UdelaR (Dr. Tristán Narvaja 1674, Montevideo, 11200, Uruguay; +598 24008555; comiteeticainv@psico.edu.uy), ref: 25052022

Study design

Single centre experimental intervention with an active (strong) control group

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Home, Internet/virtual, Other

Study type(s)

Prevention, Quality of life, Treatment, Efficacy

Participant information sheet

https://forms.gle/B5qUYiPWTaNzWcTf8

Health condition(s) or problem(s) studied

Child development/Parenting practices

Interventions

The Program duration is 21 weeks, during which families receive three messages per week, through instant messaging. The messages contain information intended to promote parenting practices that could enhance their children's cognitive development.

Stratified randomization was performed by baseline cognitive ability quartile at the individual

level. A total of 1274 participants were assigned, with one-third allocated to each of the following conditions: general treatment, tailored treatment and active control.

- 1. Tailored treatment: personalized messages containing the names of the participants and adjusted according to developmental levels measured using the INDI scale;
- 2. General treatment: personalized messages containing the names of the participants but not necessarily adjusted to the developmental level; and
- 3. Active control group: generic messages related to health and cultural curiosities, with no content aimed at stimulating development

Intervention Type

Behavioural

Primary outcome measure

Measured before and after the program implementation, unless noted otherwise:

- 1. Child development is assessed using the Spanish adaptations of the following tests:
- 1.1. School Readiness-Child Development Inventory (INDI; Vásquez-Echeverría et al., 2022)
- 1.2. Bracken School Readiness Assessment (BSRA-3, Bracken, 2007)
- 1.3. Theory of mind Task Battery: ToMTB (Hutchins & Prelock, 2014)
- 1.4. Wechsler Preschool and Primary Scale of Intelligence (WPPSI-4, Wechsler, 2014), specifically the Cancellation and Picture Naming subtests.
- 1.5. Preschool Self-Regulation Assessment (Smith-Donald et. al, 2007), specifically the Pencil tap subtest
- 2. Parenting Practices are evaluated using the Inventory of Characterization of the Home Environment for the Promotion of Child Development (not published yet).
- 3. Sociodemographic information is collected at baseline using an ad-hoc scale including parents' age, parent's educational level, number of members in the household, number of siblings the child has, diagnosed difficulties/disabilities if any, type of technical treatment if any, etc.

Secondary outcome measures

- 1. Motor development outcomes measured using the School Readiness-Child Development Inventory (INDI; Vásquez-Echeverría et al., 2022) before and after intervention
- 2. Social-emotional development outcomes measured using INDI before and after intervention
- 3. Attitudes toward learning outcomes measured using INDI before and after intervention

Overall study start date

29/10/2021

Completion date

31/12/2024

Eligibility

Key inclusion criteria

For parents:

- 1. Being the primary caregiver of a child in pre-K
- 2. Having a phone that supports WhatsApp

For children:

- 1. Being in pre-K (around 4 years old)
- 2. Attending one of the schools selected for the project

Participant type(s)

Healthy volunteer, Carer

Age group

Mixed

Sex

Both

Target number of participants

1300

Total final enrolment

1280

Key exclusion criteria

- 1. Children with severe disabilities as reported by teachers and parents
- 2. Twin siblings (in these cases one sibling was randomly selected)

Date of first enrolment

01/03/2024

Date of final enrolment

26/06/2024

Locations

Countries of recruitment

Uruguay

Study participating centre

Interdisciplinary Center for Cognition for Education and Learning

José Enrique Rodó 1839 bis Montevideo Uruguay 11200

Study participating centre

Faculty of Psychology

Tristán Narvaja 1674 Montevideo Uruguay 11200

Sponsor information

Organisation

Espacio Interdisciplinario - Universidad de la República

Sponsor details

José Enrique Rodó 1843 Montevideo Uruguay 11200 +598 24089010 ei@ei.udelar.edu.uy

Sponsor type

University/education

Website

https://www.ei.udelar.edu.uy//

Funder(s)

Funder type

Charity

Funder Name

Fundación ReachingU

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed the current study are not expected to be made available due to Uruguayan legislation of data protection concerning INDI.

IPD sharing plan summary

Not expected to be made available