Does a tailored instant messaging program for parents improve early child development? A randomized controlled trial among prekindergarten children in Uruguay during the summer recess

Submission date 16/02/2024	Recruitment status No longer recruiting	Prospectively registered
		[_] Protocol
Registration date	Overall study status	Statistical analysis plan
23/02/2024	Completed	[_] Results
Last Edited 14/08/2024	Condition category Other	Individual participant data
		[X] 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.

This study aims 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-kindergarten (pre-K), ie aged around 4 years

What does the study involve?

The FODI (Fortalecimiento Oportuno del Desarrollo Infantil) Program lasts 26 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:

a. Tailored treatment: personalized messages containing the names of the participants and adjusted according to developmental levels measured using INDI;

b. General treatment: personalized messages containing the names of the participants but not necessarily adjusted to the developmental level; and

c. Active control group: generic messages related to health and cultural curiosities, with no content aimed at stimulating development.

What are the possible 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? Universidad de la República (Uruguay)

When is the study starting and how long is it expected to run for? October 2021 to November 2024

Who is funding the study? Universidad de la República (Uruguay) and Fundación ReachingU.

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

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers RU_052022

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 summer recess

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, Comité de ética en investigación de la Facultad de Psicología - Faculty of Psychology Research Ethics Committee - UdelaR (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 26 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 401 participants were assigned, with one-third allocated to each of the following conditions: general treatment, tailored treatment and active control.

a. Tailored treatment: personalized messages containing the names of the participants and adjusted according to developmental levels measured using the INDI scale;

b. General treatment: personalized messages containing the names of the participants but not necessarily adjusted to the developmental level; and

c. Active control group: generic messages related to health and cultural curiosities, with no content aimed at stimulating development.

Intervention Type

Behavioural

Primary outcome measure

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.

These assessments are administered both before and after de program implementation.

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.

Social-emotional development outcomes measured using INDI before and after intervention.
Attitudes toward learning outcomes measured using INDI before and after intervention.

Overall study start date

29/10/2021

Completion date 30/11/2024

Eligibility

Key inclusion criteria

Participants in this study are parent/tutor-child dyads. The criteria considered were:

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 500

Total final enrolment 401

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 01/08/2023

Date of final enrolment 26/09/2023

Locations

Countries of recruitment Paraguay

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 - UdelaR** Tristán Narvaja 1674 Montevideo Uruguay 11200

Sponsor information

Organisation Espacio Interdisciplinario - Universidad de la República

Sponsor details José Enrique Rodó 1839 bis Montevideo Uruguay 11200 +598 2408 9010 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 high-impact peer-reviewed journals

Intention to publish date

15/04/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during 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