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The role of training and technological innovation in improving early childhood development under home-visiting programmes - a feasibility study

Submission date	**Recruitment status**	[X] Prospectively registered
13/01/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/01/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
11/08/2023	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of preschool is to help children grow and develop in different ways, like thinking, moving, and getting along with others. But many young children in poor countries don't have a good place to learn and play. In Ecuador, most children this age don't go to preschool. The government there started a program in 2018 to visit these children at home and help them learn. The program is called SAFPI. Researchers want to study how well the program works and if it can help these children do better. They will use a special study to see if things like teacher training and technology can make a difference in how the children learn and grow.

Who can participate?
The study involves 48 districts in the Sierra regime of Ecuador which have the SAFPI home-visiting programme running for at least one academic year prior to study recruitment. Within these 48 districts, approximately 341 teachers, 1607 children in age group 3-5 years, and their primary caregivers will be surveyed.

What does the study involve?
The study involves training and continuous professional development to SAFPI teachers in the Reggio Emilia Approach. A digital EdTech application will also be developed and provided to the teachers to enable digital submission of home visiting related monitoring forms. This digital submission will be made under a new Monitoring and Information System (MIS) for the Ministry of Education that will produce service delivery metrics from these monitoring forms and provide weekly motivational nudges and reminders to the SAFPI teachers.

What are the possible benefits and risks of participating?
The benefits include better child development outcomes and an improved SAFPI home-visiting programme infrastructure backed by digital innovation. Specific material benefits will accrue to randomly selected half the participating teachers in terms of training. There are no risks from participating in the study.

Where is the study run from?
The study will be run in Ecuador through the National Ministry of Education.

When is the study starting and how long is it expected to run for?
May 2019 to August 2023.
The study will start recruitment in February 2023 in the 48 districts of Sierra academic regime and run for 4 months. The duration includes baseline data collection in February 2023, the feasibility trial period from March to June 2023.

Who is funding the study?
Economic and Social Research Council (ESRC) (UK)

Who is the main contact?
Prof. Gabriella Conti, gabriella.conti@ucl.ac.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Cluster randomised feasibility study of teacher training and technology-enabled monitoring on childhood development under the SAFPI home visiting programme in Ecuador

Study objectives

Teacher training, technology enabled monitoring and motivational nudges in home-visiting programme (such as the SAFPI in Ecuador) will have positive impacts on early childhood development.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 06/05/2022, UCL IOE Research Ethics Committee (IOE, UCL's Faculty of Education and Society, University College London, 20 Bedford Way, London, WC1H 0AL, UK; +44 (0)20 7679 2000; ioe.researchethics@ucl.ac.uk), ref: UK REC1635
2. Approved 02/09/2022, PUCE Ethics Committee for Research on Human Beings (Dr. Iván Dueñas Espin, President, CEISH
Av. 12 de octubre 1076 y Roca, Quito, edificio administrativo, piso 3, oficina 327, Ecuador; +593 2991700, ext. 2917; igduenase@puce.edu.ec) ref: PV-21-2022, V2

Study design

Cluster randomized feasibility trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Early childhood development

Interventions

Current interventions as of 13/06/2023:

The intervention will be randomised at the district level (cluster) in the Sierra academic regime. 48 Districts have been selected using purposive sampling out of the 60 operational SAFPI service districts. The selection of districts was based on the criteria that the district must have had a SAFPI programme running for at least one academic year. The 48 selected districts will then be stratified by their size in terms of number of teachers per district, and on the number of 'new' teachers per district with no previous experience within the SAFPI programme. After stratification, equal number of districts will be assigned to 2 arms. Randomisation will be done on the computer using Stata.

There are two study arms:
1. Treatment Arm receiving improved SAFPI programme: The teachers in the treatment arm will receive training in the Reggio Emilia Approach (March 2023 to June 2023). We will also develop a customised EdTech application to enable digital monitoring and tracking of services.
2. Control Arm receiving the standard SAFPI programme: The teachers in the control arm will continue delivering the SAFPI programme without any improvements, that is, no training and no access to digital technology.

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Previous interventions:

The intervention will be randomised at the district level (cluster) in the Sierra academic regime. 48 Districts have been selected using purposive sampling out of the 60 operational SAFPI service districts. The selection of districts was based on the criteria that the district must have had a SAFPI programme running for at least one academic year. The 48 selected districts will then be stratified by their size in terms of number of teachers per district, and on the number of 'new' teachers per district with no previous experience within the SAFPI programme. After stratification, equal number of districts will be assigned to 2 arms. Randomisation will be done on the computer using Stata.

There are two study arms:
1. Treatment Arm receiving improved SAFPI programme: The teachers in the treatment arm will receive training in the Reggio Emilia Approach, tablets with internet package and a customised application to enable digital monitoring and tracking of services, and motivational app-based nudges. The treatment will last for 4 months (March 2023 to June 2023).
2. Control Arm receiving the standard SAFPI programme: The teachers in the control arm will continue delivering the SAFPI programme without any improvements, that is, no training, no tablets, no access to digital technology, no motivational nudges.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 11/08/2023:
1. Pre-literacy and Pre-numeracy using Items 2-8 and Items 15-20 of IDELA at baseline (March 2023)
2. Language development using TVIP at baseline (March 2023)
3. Executive functioning using Delay-Choice Test and Items 13-14 of IDELA at baseline (March 2023)
4. Child Development (caregiver report) using ECDI at baseline (March 2023)

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Previous primary outcome measure from 13/06/2023 to 11/08/2023:

1. Pre-literacy and Pre-numeracy using Items 2-8 and Items 15-20 of IDELA at baseline
2. Language development using TVIP at baseline
3. Executive functioning using Delay-Choice Test and Items 13-14 of IDELA at baseline
4. Child Development (caregiver report) using ECDI at baseline

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Previous primary outcome measure:

1. Pre-literacy and Pre-numeracy using Items 2-8 and Items 15-20 of IDELA at baseline and after 4 months
2. Language development using TVIP at baseline and after 4 months
3. Executive functioning using Delay-Choice Test and Items 13-14 of IDELA at baseline and after 4 months
(added 30/01/2023)
4. Child Development (caregiver report) using ECDI at baseline and after 4 months

Key secondary outcome(s))

Current secondary outcome measures as of 11/08/2023:
1. Motor skills using Items 21-24 of IDELA at baseline (March 2023)
2. Socio-emotional development using Items 1 and Items 9-12 of IDELA, caregiver reported Strength and Difficulties Questionnaire, and scoring of child's self-portrait at baseline (March 2023)
3. Altruism or preference for egalitarianism using adapted Dictator Game at baseline (March 2023)
4. Intervention take-up: teachers' attendance in training sessions
5. Teachers' knowledge of early childhood development measured through a list of true/false statements at baseline (March 2023)
6. Teachers' motivation and job satisfaction measured through a list of likert scale rated statements at baseline (March 2023)
7. Teachers' burnout using Maslach Burnout Inventory for Educators at baseline (March 2023)
8. Biological mothers'/primary caregivers' self-efficacy using likert scale rated list of statements at baseline (March 2023)
9. Home learning environment using shorter adapted versions of FCI and HOME at baseline (March 2023)
10. Biological mother/Primary caregiver - child interactions through coding of 5 minute video of toy-based play at baseline (March 2023)

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Previous secondary outcome measures from 13/06/2023 to 11/08/2023:

1. Motor skills using Items 21-24 of IDELA at baseline and after 4 months
2. Socio-emotional development using Items 1 and Items 9-12 of IDELA, caregiver reported Strength and Difficulties Questionnaire, and scoring of child's self-portrait at baseline and after 4 months
3. Altruism or preference for egalitarianism using adapted Dictator Game at baseline and after 4 months
4. Intervention take-up: teachers' attendance in training sessions
5. Teachers' knowledge of early childhood development measured through a list of true/false statements at baseline and after 4 months
6. Teachers' motivation and job satisfaction measured through a list of likert scale rated statements at baseline and after 4 months
7. Teachers' burnout using Maslach Burnout Inventory for Educators at baseline and after 4 months
8. Biological mothers'/primary caregivers' self-efficacy using likert scale rated list of statements at baseline and after 4 months
9. Home learning environment using shorter adapted versions of FCI and HOME at baseline and after 4 months
10. Biological mother/Primary caregiver - child interactions through coding of 5 minute video of toy-based play at baseline and after 4 months

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Previous secondary outcome measures:

1. Motor skills using Items 21-24 of IDELA at baseline and after 4 months
2. Socio-emotional development using Items 1 and Items 9-12 of IDELA, caregiver reported

Strength and Difficulties Questionnaire, and scoring of child's self-portrait at baseline and after 4 months
3. Altruism or preference for egalitarianism using adapted Dictator Game at baseline and after 4 months
4. Intervention take-up: teachers' attendance in training sessions and teachers' usage of the tablet based cutomised application. Both will be measured in real time throughout the intervention period.
5. Teachers' knowledge of early childhood development measured through a list of true/false statements at baseline and after 4 months
6. Teachers' motivation and job satisfaction measured through a list of likert scale rated statements at baseline and after 4 months
7. Teachers' burnout using Maslach Burnout Inventory for Educators at baseline and after 4 months
8. Biological mothers'/primary caregivers' self-efficacy using likert scale rated list of statements at baseline and after 4 months
9. Home learning environment using shorter adapted versions of FCI and HOME at baseline and after 4 months
10. Biological mother/Primary caregiver - child interactions through coding of 5 minute video of toy-based play at baseline and after 4 months

Completion date
31/08/2023

Eligibility

Key inclusion criteria
1. All SAFPI teachers in study districts. Study districts are included if they have had an operating SAFPI programme for at least one academic year prior to study recruitment
2. Children aged 3 - 5 years enrolled in the SAFPI programme
3. Biological mother or primary caregiver of the child

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
3 years

Upper age limit
5 years

Sex
All

Key exclusion criteria
No exclusion criteria except that teachers and biological mothers/primary caregivers are able to provide informed consent. That biological mothers/primary caregivers can provide informed consent on behalf of their child.

Date of first enrolment
07/02/2023

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
Ecuador

Study participating centre
Ministry of Education
Av. Amazonas N34-451 y Av. Atahualpa
Quito
Ecuador
170507

Sponsor information

Organisation
Economic and Social Research Council

ROR
https://ror.org/03n0ht308

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
Social Science Research Council, ESRC, SSRC, UKRI ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated will be published as a supplement to the results publication. In this case, the data will be anonymised. The participants will be made aware of this in the information leaflet and the informed consent. The participants will also be informed of their right to withdraw and/or ask for deletion of their data. In the case of withdrawal and/or deletion of data, participants will also be made aware that any data that has already been analysed and process for publication, cannot be excluded.

IPD sharing plan summary
Published as a supplement to the results publication