Validation, and utility for intervention, of a parentally-completed developmental screen for use by low-income families with children at risk of failure to reach their developmental potential.

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October 2022

Thesis Research in Partial Fulfilment of the Requirements for the Degree of Doctor of Psychology

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Abstract

Early childhood poverty and scarcity of resources put children in low-and-middle-income countries at risk of not reaching their developmental potential. However, despite a near-universal interest in risk reduction, effective interventions for developmental delay remain elusive for most vulnerable families. Here, we report four studies, including data from a previous two-year research programme in Colombia, evaluating the quality and design of the CARE instrument. CARE involves the use of parental scaffolding for developmental screening of 24- to 59-month-old children. Our initial study (Study 1) measure different health, wellbeing, and demographic dimensions for the whole sample (N = 1177) through a previous research programme called *Inicio Parejo de la Vida* ('Equal Start in Life'). In this study, we found a correlation between the reading frequency reported at home and developmental-screening risk status for a subsample of children (24- to 36-month-old; n = 116). In Study 2, we undertook a reliability and agreement study for CARE's congruence and diagnostic properties, comparing direct observation using a screening instrument (the Haizea-Llevant) and the parental report. The two further studies presented effects on children's outcomes when parents received CARE (Study 3) and specific interventions with CARE and a dialogical book-sharing protocol in Spanish (Study 4). All participants lived in exclusively Spanish-speaking vulnerable neighbourhoods in Colombia. The results of the aforementioned studies indicate differences in children evaluated as "At risk" or "Not at risk" based on frequency of reading habits as measured by parents (Study 1). Also, for the "At risk" and "Not at risk" classifications, CARE had good psychometric properties and high congruence between the direct screening observation and parental reports (Study 2). The third study indicated the non-significant and limited benefits of no-intervention-delivery of CARE for general risk results between pre-and post-assessments. However, the interventions reported in the fourth study positively affected children's developmental status and language-related skills and will be used as a strong benchmark for sample size calculation in subsequent trials. Finally, it should be noted that the research programme was compromised by measures taken against the COVID-19 pandemic (e.g., closure of day care centres), with several resulting limitations (e.g., sample size) for each study, and possible effects on the analysis of children's developmental potential to consider in future research.

Key words: Early childhood poverty, Developmental potential, Scaffolding, Developmental Screening, Parent–child interactions, Dialogical book sharing.

Acknowledgements

I am infinitely gratefully to my life structure, my wife, Juana, and my kids, Juandi & Any, for all the patience and support dispensed through many issues and against stiff odds from 2016 to 2021. To Graham for being more than a "supervisor" (including a clear explanation about it in the first year) and give me a life lesson about what it means to be a Mentor. To Peter for his incredible generosity in accepting the translation of DBS in Spanish and the material, academic and personal support through all these years. Then, to all functional support from the Universidad de la Sabana por creer en mi y financiar la realización de este Doctorado. Special gratitude to Mikhulu Trust generosity in materials and training support for DBS intervention. Also, families, children and directives in Amiguitos Royal CC and Colsubsidio Nueva Roma CC in Bogotá and, internship students of Pasantía de Cuidado y Desarrollo and from the master's program in the Department of Psychology at Universidad de la Sabana, especially to Maria Alejandra Cristancho and Diana Sanchez. Also, to ASCOFAPSI 2018-2019 grant for research projects and the Doctoral Grant Convocatoria 860 de 2019 from the Colombia's Ministerio de Ciencia, Tecnología e Innovación (Minciencias). Finally, but no less remarkable, thanks to many persons I may forget to mention but without the contingencies that joined us before, nothing of this thesis could be possible: mi Familia Huertas-Ortiz, the Arana-Arana and Arana García; friends like Daza, Laura, Mario, Gordon; my Univalle professors Mariela Orozco Hormaza and Rebeca Puche for the original inspiration to follow an academic career, and everyone who knows that I send my grateful feeling for their anonymous but indispensable place in this thesis. Finally, to my two final examiners for their precise and useful comments.

Declaration

I confirm that this is my own work and the use of all material from other sources has been properly and fully acknowledged.

Juan José Giraldo Huertas

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Glossary and abbreviations

ABC: Average-based change statistics, such as Cohen's *d* or Hays's $\omega 2$.

ABFW: the Child Language Test in Phonology, Vocabulary, Fluency and Pragmatics (Dias, Rondon-Melo, & Molini-Avejonas, 2020).

ADS-1: Abbreviated Development Scale, in Spanish, *Escala Abreviada del Desarrollo* (Ortiz, 1991).

AIN-C: Panama's programme *Atención Integral de la Niñez con Participación Comunitaria*.

ANCOVA: analysis of covariance.

ANOVA: Analysis of variance.

ASQ: Ages and Stages Questionnaire (Steenis, Verhoeven, Hessen & van Baar, 2015).

AUC: Area under the curve in a ROC analysis.

Az: The Area under the fitted curve in a ROC binormal curve.

BSID-III: Bayley Scales of Infant and Toddler Development III.

CARE: Compilation of Activities to Report and Enhance development, designed by the author of the Thesis.

CAS: Complex Adaptive Systems healthcare framework.

CBI: CARE booklet intervention, a parental intervention using CARE for parental report of children skills.

CC: Children's Centre.

CNH: Ecuador's programme *Creciendo con Nuestros Hijos*.

Co-PI: co-investigator.

CPI: commitment to parental involvement (Haine-Schlagel and Escobar-Walsh, 2015).

CSRA: Bolivia's *Consejo de Salud Rural Andino* programme.

DASII: the Developmental Assessment Scales for Indian Infants (Juneja, Mohanty, Jain, & Ramji, 2012).

DBS: Dialogical Book-Sharing**,** a training programme for parents/carers to promote supportive and reciprocal book-sharing with young children, delivered by a trained facilitator.

DDST: the Denver Developmental Screening Test (Frankenburg, 1987; Frankenburg, van Doorninck, Liddell, & Dick, 1976).

DIBELS: The Dynamic Indicators of Basic Early Literacy Skills, a battery of brief fluency measures that can be used for universal screening and progress monitoring in preschool contexts (Nichols, Kim, & Nichols, 2018).

DOT: A direct observation tool.

DS: Developmental screening.

ECD: early childhood development.

ECDI: The Early Childhood Development Index, a 10-question survey used in the Nurturing Care Framework.

EI: Early interventionist in the parental coaching approach.

ENDS: *Encuesta Nacional de Demografía y Salud*—Colombian National Survey of Demographics and Health (Profamilia, 2010).

ERIC: the Early Report by Infant Caregivers (Schafer et al., 2014).

FAMI: the Family, Women, and Infancy Programme (Attanasio et al., 2018).

GDQ: The Questionnaire for Parents and Caregivers General Data.

GMCD: the Guide for Monitoring Child Development (Ertem et al., 2008; Ertem et al., 2018).

GRTR: The *Get Ready to Read!* Screening measure (Whitehurst, 2001).

HBR: home-based record, in which parents maintain a document with information about child health and developmental milestones, which can be shared with experts and other interested parties.

HLL: Haizea-Llevant developmental screening table (Iceta & Yoldi, 2002). The Haizea-Llevant screening table is a developmental version of the Denver Developmental Screening Test.

IBC: Individual-based change statistics, like the SID and the RCI.

IDSC: Indice de Desarrollo sociocognitivo, a socio-cognitive development index score for individual children obtained in the initial analysis of IPV data.

IPV: a research programme named *Inicio Parejo de la Vida* ('Equal Start in Life' in English), with the author of the Thesis in a PI role.

IQ: intelligence quotient.

IQR: Interquartile range.

IT: Information technology.

K*→*S*→*D: a model of the *knowledge → stimulation → development.*

K*⇔I/*S*→*D: a model of *knowledge ⇔ interaction/stimulation → development*.

LBW-T: low-birthweight, term-born.

LMIC: low-and-middle-income countries.

LNF: Letter Naming Fluency, a subscale of the DIBELS.

MESEP-DNP: Metodología para el Empalme de las Series de Empleo, Pobreza y Desigualdad (MESEP) - Methodology for the Splicing of the Employment, Poverty, and Inequality Series, of the National Planning Department -DNP (Departamento Nacional de Planeación) of Colombia.

NASEM: National Academies of Sciences, Engineering, and Medicine in the USA.

NBW: normal-birthweight children.

NET: the Net percentage change index, in our case: 100 x (CARE score – HLL score) / (HLL score).

NGO: Non-government organisation.

PAIPPI: Nicaragua's *Programa de Acompañamiento a la Política de Primera Infancia*.

PC: Principal caregiver.

PCT: A parent-completed tool.

PDQ: Denver Pre-screening Developmental Questionnaire.

PEDS: the Parents' Evaluation of Developmental Status (Glascoe, 2002).

PI: Principal investigator.

PIM: in Brazil the *Programa Primeira Infancia Melhor*.

PP: Parenting programmes (Center on the Developing Child at Harvard University, 2007).

PSF: Phonemic Segmentation Fluency, a subscale of the DIBELS.

PSID: Panel Study of Income Dynamics (McGonagle, Schoeni, Sastry & Freedman, 2012).

Q-RCT: quasi-RCT (Reeves, Wells, & Waddington, 2017).

R-DPDQ: Revised Denver Pre-screening Developmental Questionnaire.

R&A: reliability and agreement studies (Carmines & Zeller, 1979)

RCI: The Reliable Change Index.

RCT: randomised control trials.

RNDA: the Rapid Neurodevelopmental Assessment (Khan et al., 2013).

ROC: The receiver operating characteristic method to assess the performance of a diagnostic test.

RQ#: Research questions numbered in the Thesis.

SD: Standard deviations.

SEI: Sistemas Especializados de Información, a firm for fieldworkers and statistical analyses under contract by the IPV program.

SES: Socioeconomic status.

SID: The Standardised Individual Difference.

ST: the *Smalltalk* programme (Nicholson et al., 2016).

TA: Thesis author.

TDSC: the Trivandrum Developmental Screening Chart (Nair et al., 1991).

USA: United States of America.

USD: United States Dollar.

WHO: World Health Organization.

WRF: Word Reading Fluency, a subscale of the DIBELS.

ZPD: Vygotsky's classic theory of the Zone of Proximal Development (Vygotsky, 1978; Wood, Bruner & Ross, 1976).

Preface: Thesis roadmap and contributions

The present Thesis would not be possible without the contribution of many persons and institutions interested in the interventions to enhance the development of children at risk for poverty and other socioeconomic causes, especially after the COVID-19 pandemic significantly suffered in the years 2020 and 2021. A coronavirus called SARS-CoV-2 began making people sick with flu-like symptoms at the end of December of 2019 in Wuhan (China). The illness it causes is called coronavirus disease-19 or COVID-19, for short. From that moment, all available resources of the WHO (https://www.who.int/emergencies/diseases/novel-coronavirus-2019) and hundreds of institutions struggled to inform and help in an unprecedented worldwide effort against one health-disease common cause. However, for most people, COVID-19 only represent a mild illness, including children who do not receive any specific treatment.

Nevertheless, for many others, COVID-19 represents several diseases in the lungs and respiratory system, finally leading to death. For the July 1st of 2022, the WHO reported 6.334.728 confirmed deaths due to COVID-19 complications. For children, the number of deaths and infections have been fever reported, and they usually seem to have a milder illness. However, some children had more severe symptoms, like the called multisystem inflammatory syndrome in children (MIS-C). MIS-C is a severe condition affecting many-body systems, including the lungs, heart, brain, kidneys, blood vessels, skin, eyes, and gastrointestinal system. These syndrome requires hospital treatment, mostly in young children unvaccinated due to age or, like vulnerable families in Colombia, those who do not receive the COVID-19 vaccines early.

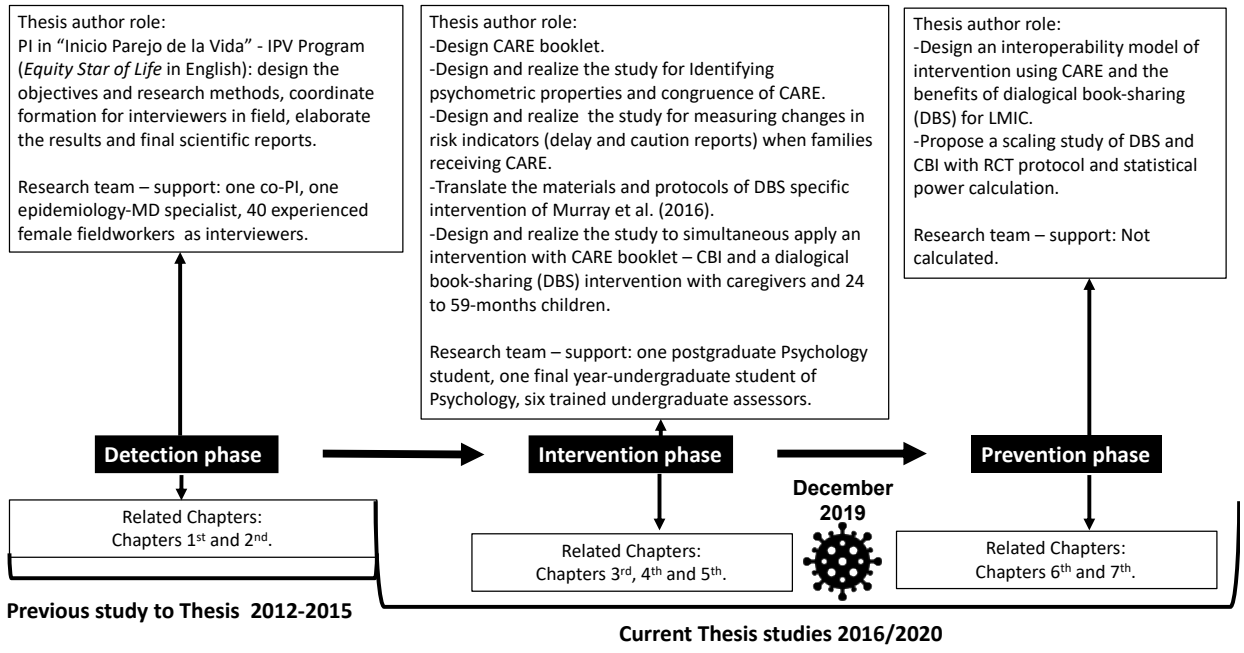
People can catch COVID-19 from others who have the virus even if they have no symptoms. According to a specialist portal (https://kidshealth.org/en/parents/coronavirus.html), infection occurs when an person carrying the virus breathes, talks, sneezes, or coughs, sending tiny droplets into the air. These can land in the nose, mouth, or eyes of someone nearby. Some of the tiniest droplets, called aerosols, can linger in the air for minutes and travel on air currents. Many countries mandated their citizens to wear facemasks out of their homes and preventive closures of pre-school and day care centres, affecting vulnerable and impoverished children who may be exposed to less educative or learning activities than ever before. On the March 6th of 2020, The Ministry of Health and Social Protection confirmed the first case of COVID-19 in Colombia on a 19-year-old female patient (https://www.poverty-action.org/blog/tracking-

colombians%E2%80%99-experiences-with-covid-19-households-face-mounting-challenges-virus). Between the March 16th and the August 31st of 2020, the pre-school and day care centres keep officially closed, but for poorest communities that may last longer (Kenny & Yang, 2021).

As a memory of the effort and sadness for many of us, year by year and chapter by chapter, the following figure (Fig. 1) describes the author's roles and the contribution extend to different teams and supporters, from co-PI to fieldworkers, who make possible this thesis.

Figure 1.

Thesis author role and research team description by Phases and Chapters.



Chapter 1. General Introduction

The proportion of children at risk of not reaching their developmental potential due to poverty and psychosocial deprivation is higher in low-and-middle-income countries (LMICs), than in richer nations: more than 40% of children under 5 years old are at risk in low-income countries (Black et al., 2016). Recent studies (Abdoola, Swanepoel, Van Der Linde, & Glascoe, 2019; Gil, Ewerling, Ferreira & Barros, 2020) indicate elevated rates of developmental delay in children coming from low-income families in LMICs. Recently reports shown that more than a third (35%) of children aged between 0 and 18 months had developmental delay, as revealed by a widely used standardised assessment tool: the Bayley Scales of Infant and Toddler Development III or BSID-III (Abdoola et al., 2019). The real percentage of children with developmental delay could well be even higher, considering cultural barriers for optimal use of the BSID-III scale (Lohaus et al., 2011), especially in the receptive and expressive language subtests (Ranjitkar et al., 2018).

Even with near-universal interest in reducing risks through public health and early education endeavours (Cavallera et al., 2019; Pérez-Escamilla, Cavallera, Tomlinson, & Dua, 2017; Sabanathan, Wills, & Gladstone, 2015), poverty and other risk factors persist among the poorest families in LMICs (Duncan, Magnuson & Votruba-Drzal, 2017). Colombia, a LMIC, has various examples of public health and early education programmes with small or null effects on nutritional or developmental outcomes (Andrew et al., 2016; Bernal, Attanasio, Peña, & Vera-Hernández, 2019). Bernal and Ramirez (2019) indicated that effects of a public policy for integrative services in health and education for families and children, had significant values only for cognitive outcomes but not for nutritional or health ones. Nevertheless, their results and conclusions do not consider biological, nutritional, neurological, or psychological evidence that should be included when systematic and integrative frameworks are used (Blomkvist et al., 2019; Nyaradi et al., 2013). This thesis presents an integrative developmental framework using the concept of nurturing care (Richter et al., 2019), which recently became an official international framework (World Health Organization, United Nations, Children's Fund & World Bank Group, 2018). Previous research and growing citations of the construct indicate that young children have the best chance of maximizing their potential when they are well nourished and responsively cared for, with learning opportunities in many different moments of life (Banerjee et al., 2019). The integrative framework in this thesis is a continuum of decisions and actions for Responsive

Caregiving and Early Learning, two specific components of nurturing care definition. Nurturing Care can be used to enhance the development of at-risk children through monitoring responsive caregiving and stimulating early learning. Responsive Caregiving is related to caregiver nurturance, i.e., routines with both emotional and cognitive support. Early Learning is related to home opportunities for exploring and learning through play, and to various materials like books or toys. World Health Organization and other children wellbeing agencies clearly report the lack of information about Nurturing Care in many LMICs (WHO et al., 2018). Insufficient data and the lack of tools to estimate the burden of risk and poverty (i.e., stunting) demand strategies that are better adjusted to vulnerable populations, and easier for them to access (Daelmans, 2015; Richter et al., 2019). For example, Colombia's data is not available for three out of four indicators of Early learning nor any Responsive caregiving information (UNICEF & Countdown to 2030 Women's, Children's, and Adolescent's Health, 2020). The need for information, action and transformation demands a strategic approach that a Detection-Intervention-Prevention continuum might provide. This important concept is discussed next.

1.1. The Psychology of the Detection-Intervention-Prevention Continuum

The concept of the detection-intervention-prevention continuum was elaborated based on research into the nurturing care construct (Richter et al., 2019), and is founded conceptually in the links between poverty and children's developmental outcomes (Walker et al., 2011). Walker et al (2011) described translational processes related to the effects of family poverty on early brain and biological systems. The translational process for Walker et al. (2011) consists of timing, dose, and differential reactivity. 'Time' refers to sensitive periods in development; 'dose' means co-occurring or cumulative influences of risks and protective factors; and 'differential reactivity' refers to individual, personal, and contextual characteristics that moderate timing and dose levels.

The translational process of Walker et al. (2011) has an echo in the nurturing care framework for the design, implementation, and scaling of early childhood development (ECD; Black et al., 2017; Boggs et al., 2019; Britto et al., 2017; Magwood et al., 2019; Richter et al., 2017; Richter, Lye, & Proulx, 2018). Boggs et al. (2019) identified a design phase with effective "real world" approaches, implemented with measurement of coverage and quality. The scaling process is related to tracking coverage and correct the protocols for a programme's activities (Cavallera et al., 2019). However, these two perspectives (Boggs et al., 2019; Cavallera et al.,

2019) are directed towards a paediatric and medical audience. Are poverty and its associated developmental risks a "disease", which can be seen as an exclusively medical concern? This thesis does not commit to a single answer for that question, but the detection-intervention-prevention continuum aims to go beyond the clinical perspective on poverty and developmental risk by dividing research into three phases: 1) the analysis of the characteristics and prevalence of developmental risk, by designing and using easy-to-handle tools for baseline risk detection; 2) surveying the evidence for the positive effects of interventions; and 3) planning preventive, long-term-work for diminishing the baseline risk.

A barrier to reaching the first phase for an optimal detection-intervention-prevention framework, with attendant high positive effects in LMICs such as Colombia, is the lack of access to detection tools and cost-efficient interventions (Rubio-Codina & Grantham-McGregor, 2020). The potential for scaling up the detection-intervention-prevention process in an LMIC requires a high quality of detection tools, with efficient adaptation of proven interventions that maintain the prevention of pervasive cycles of poverty. An example is the well-known Jamaica program, estimated to cost over $100 per child per year (Walker et al., 2015). The Jamaica studies were conducted at Kingston, Jamaica, to determine the benefits of psychosocial stimulation provided up to age 24 months through weekly home visits and assessments. Results showed founding benefits in the children's development at 7, 15, and 24 months old (Walker et al., 2007, 2010, 2011, 2015, 2018). Also, Walker and collabs used the same home visits method up to age 24 months, to compared the development of low-birthweight, term-born (LBW-T) and normal-birthweight (NBW) children development and determine whether psychosocial stimulation had sustained benefits on cognition and behaviour in LBW-T children at six years of age, and whether LBW-T children still exhibited deficits in cognition and behaviour when compared with NBW children at this age. The Jamaica program, and any home-visit intervention in general, is thus not a cheap option (Walker et al., 2018). Moreover, poverty in LMICs is more than just a limitation on income. Even with high-quality public policy interventions with income benefits, low and null effects have been reported in LMICs like Colombia (Bernal & Ramírez, 2019). The detection-intervention-prevention continuum in LMIC needs both a multidimensional concept of poverty, and the inclusion of developmental screening tools that work with home-based records (Cavallera et al., 2019; Osaki et al., 2019).

The present thesis will focus on the detection and intervention phases, because prevention requires escalating efforts in a way clearly designed by different academic and government agents (Boggs et al., 2019; Cavallera et al., 2019; Magwood et al., 2019). As a starting point in the detection-intervention-prevention continuum, the detection phase tools and design were included in the research programme named *Inicio Parejo de la Vida* ('Equal Start in Life'), henceforth IPV. In the IPV phase, the daily at-home conditions (in particular, reading activities) and levels of risk regarding environmental characteristics of parents and families were studied in children under 6 years old in the central region of Colombia, surrounding the capital city, Bogotá. The IPV researchers (including the present author) designed a survey to describe the socio-demographic characteristics of a sample of children aged under 6 years old, their families, and primary caregivers. The IPV study was a cross-sectional design involving 1177 principal caregiver/child dyads. Conceptually, IPV use a Complex Adaptative Systems (CAS) Framework in Healthcare. The CAS is defined as a "multi-disciplinary approach to understanding the behaviour of diverse, interconnected agents and processes from a system-wide perspective" (McDaniel, Lanham & Anderson, 2009; Paina & Peters, 2012; Perez-Escamilla & Hall-Moran, 2016). But system-wide perspectives, such as the application of the CAS and Bronfenbrenner's theory to public mental health research, need an additional direction: the inclusion of local evidence for specific needs and opportunities to reduce the risk that children in poverty do not reach their full developmental potential. A bottom-up direction should be designed, in addition to approaching strategically to change the proximal process (i.e., the microsystem) through activities like shared book reading. Shared book-reading is a cornerstone activity to any parental engagement approach for mediating long-lasting learning effects in infant and toddler development (Axford et al., 2019). The positive effects in families with advantageous conditions of frequently shared book reading are notable in toddlers' language development and pre-reading and pre-writing skills, as well as gains in childcare, improvements in social understanding, and empathy (Dowdall et al., 2017). Also, book-sharing interventions with wordless books show increased academic and reading-related skills in pre-schoolers, and predict better subsequent language comprehension (Hu, Liu, & Zheng, 2018). The bottom-up direction considers the inclusion of developmental screening tools and home-based records for a complete model of the detection-intervention-prevention continuum. Developmental screening (hereafter referred to as DS) is a strategy for identifying individual alerts and delays in a normal trajectory, using age-appropriate instruments and an inventory of behaviours and skills.

DS can be used alongside physical examination in primary healthcare contexts (i.e., developmental monitoring), and for detection of cases that need detailed surveillance and evaluation for individual development trajectories (Cavallera et al., 2019; Vitrikas, Savard, & Bucaj, 2017). DS has the capacity to access multiple domains, including emotional, social, cognitive, linguistic, and motor development (e.g., Duby et al., 2006; Libertus & Landa, 2013; Rescorla & Alley, 2001), and has been used extensively with children who were born prematurely (Brooks-Gunn et al., 1994; Field et al., 2016; Perra et al., 2015; Schafer et al., 2014). Early DS is not only used for collective or community research (Magnusson, Murphy & Peña-Jackson, 2020) but may also enable the detection of individual conditions for intervened through a long-lasting agenda like the nurturing care framework (Lu et al., 2020; Trude et al., 2021). However, early DS and nurturing care do not work at an individual level without a mechanism or system that connects the social and the individual spheres of actions. A suitable mechanism for that connection is Vygotsky's concept of scaffolding (Mermelshtine, 2017; Vygotsky, 1978; Wood, Bruner & Ross, 1976). While CAS and system-wide perspectives might include an intersubjective definition for parental scaffolding (Ugur, Nagai, Celikkanat & Oztop, 2015), like a teaching-learning process, we adopt a specifically definition to connect caregivers' previous knowledge about child behaviour to novel observations in infants and children's interactions (Obradović, Yousafzai, Finch & Rasheed, 2016).

1.2. Definition of Scaffolding adopted in the Thesis

Scaffolding is a concept frequently related to Vygotsky's theoretical thinking, and applied to multiple kinds of interventions (Xu et al., 2022). However, the first mention of scaffolding with precision to the described intersubjective process of teaching and learning was proposed by Wood, Bruner, and Ross (1976) and resembled the zone of proximal development (henceforth, ZPD) enunciated by Vygotsky (1978, 1987). Although Vygotsky's no clear definitions for ZPD or scaffolding were in the original works, many interpretations and posteriors analysis give an ideal conceptualization for a relation between everyday learning and developmental potential (Xi & Lantolf, 2021). The present thesis limits the discussion about scaffolding, when explicitly referring to the principal caregiver's effort to control the *degrees of freedom* in any task for a child who is able or not to obtain specific outcomes. *Degrees of freedom* are the detectable levels of a task with the required skills to complete it. The adopted definition comes from the six "scaffolding functions" mentioned by Wood et al. (1976) and previously suggested by Bernstein (1967).

Bernstein (1967) describes the *intra*subjective process of new skill mastery, whereas Wood et al. (1976) talks about *the inter*subjective process of teaching and learning (Shvarts & Bakker, 2019). To our proposal, both processes are required in developmental scenarios when parent and child interactions take place, and both may regulate the educational and environmental factors associated with developmental outcomes in vulnerable families and children (Vrantsidis et al., 2020). When parental or principal caregivers scaffolding is guided through behaviours such as prompts, praise, elaboration, and redirection, the intra- and inter-subjective process mediate the intervention effects in high-income countries (Fay-Stammbach, Hawes, & Meredith, 2014; Guttentag et al., 2014; Weisleder & Fernald, 2013) and LMIC as well (Yousafzai et al., 2016). Reaching the complexity of scaffolding behaviours is not spontaneous or frequently observed in LMIC due to home context and family socioeconomic factors (Obradovic´ et al., 2016). Without the effort for interventions interested in exposing and implicitly promoting caregivers' scaffolding interactions, the poor quality of early education opportunities outside the home (UNICEF, 2013, 2014) and the more significant impact of socioeconomic covariates (i.e., wealth, food insecurity, family size) will keep the adverse effects in the early childhood development trajectories of vulnerable families. Early interventions require screening and interaction opportunities during the sensitive period of rapid cognitive development between ages two and four when exploration and motivation skills are higher in children (Liquin & Gopnik, 2022) and their parents or principal caregivers scaffolding may take place on the proximal process at home.

The main interest of this thesis is related to screening for detection of delays and alarms in proximal processes, and the opportunity for positive intervention in the context of parental scaffolding, in children aged 2 to 5 years old in Colombia, an LMIC. The start points for the studies included in this thesis are the data about the daily at-home conditions (in particular, reading activities) and levels of risk regarding environmental characteristics of parents and families were studied in children under six years old in Colombia's central region, surrounding the capital city, Bogotá, and recollected by the IPV research programme between 2012-2014. The IPV researchers (including the author) conduct an initial analysis of IPV data allowing the establishment of a socio-cognitive development index (IDSC) score for individual children. The baseline report (Giraldo-Huertas, Cano, & Pulido-Alvarez, 2017) focused specifically on the general distribution of the IDSC in the IPV sample (N = 1177) but never used it in the specific exploration of scaffolding activities (i.e., reading frequency reported by parents) or the detection of risk and delay levels at a

specific age (i.e., 24–36 months) and investigate their interactions during reading activities at home. The second chapter will use the IPV sample to help answer a research question (RQ#1): Are reports of reading activities by parents related to cautionary signs and the detection of delay in the developmental screening of children?

1.3. Reading habits reported by parents and related to developmental screening levels of Caution and Delay.

Different lines of evidence suggest the remarkable importance of reading habits in the developmental and school outcomes prediction. Recent evidence indicates that interventions to effectively increase the levels of home reading and increasing the pre-school attendance of disadvantaged children compared to that of their advantaged peers could potentially reduce the absolute risk difference equivalent to eliminating a further 2.1% of the socioeconomic gap (Goldfeld et al., 2021). However, after reports of both increasing levels (i.e., levels of home reading and pre-school attendance) disadvantaged children kept an 18.3% (95% CI: 14.0%−22.7%) higher risk of poor reading outcomes compared to their more advantaged peers in absolute terms.

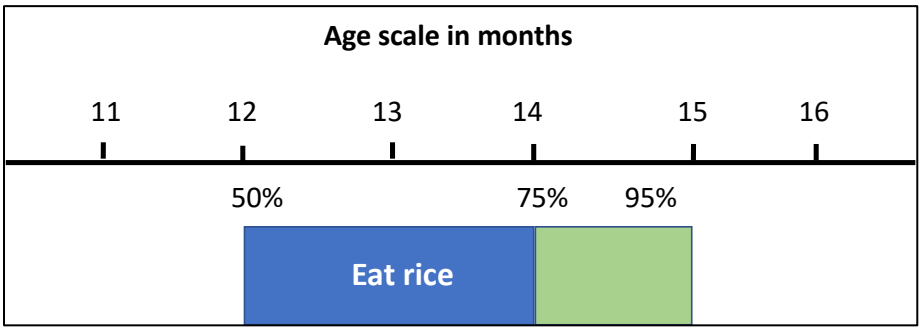
A first step in our intention to design an effective intervention for vulnerable families and children in Colombia require the analysis of reading habits at home and if detectable by the developmental screening tool (i.e., Haizea-Llevant) that originates the posterior intervention using the parental report for specific developmental dimensions or domains. Developmental screening (DS) was the research line used for the IPV programme, even when healthcare intervention shows low levels of application in high-income countries (Hirai et al., 2018) and the robust evidence of the positive effect of using it for primary and early health prevention frameworks (Gross et al., 2021). Recent reports about DS in LMICs also indicates low coverage proportions for children at early or primary health services, representing a considerable barrier for early childhood intervention programmes (Cavallera et al., 2019; Vargas-Barón, 2019). However, when DS is incorporated in the developmental monitoring process by healthcare professionals, the opportunity to identify at-risk children and candidates for early interventions are significantly improved (Barger, Rice, Wolf, & Roach, 2018). Similar improvement in identifying children at-risk results is obtained when parents are developmentally informed, including being given information about a developmental timeline and corresponding milestones to carry out their own DS at home (Teti

et al., 2017). Active learning is a necessity for parents to be developmentally informed about different milestones, and might be an option to optimize parental engagement in higher order thinking about their own behaviour and how it can enhance, for example, their child's vocabulary development (Teepe et al., 2019).

Advancing through the relation between parental reading habits with children and the developmental screening report, it will be included as a guide for analysis a comprehensive, evidence-based milestone chart, describing the "standardization" of behaviour and skill (i.e., items) included at each age. In some cases, the DS standardization identifies the age at which 25%, 50%, 75% and 90% or 95% of reference cohort children 'pass' (positive observation) an item. As an example, Figure 1.1 shows the standardised proportion of children passing the fictitious milestone of an "Eat rice" item, using colours and position as indicators in a graphical chart. A bar might be situated under or above an age-line with symmetric marks for each time unit (i.e., months). Our example situates the "Eat rice" box beginning from 12 months. That means that 50% of children in the sample for standardization were observed eating rice at 12 months of age. The next line in the box, indicates that 75% of children pass the observation (three-quarters of children are observed eating rice), or have the skill at 14 months. Those two limits mark an area with a different colour in the next box. The adjacent colour box for the same skill shows the limit for the 95% sample children eating rice at 15 months of age. The percentiles (50%, 75% and 95%) and graphic conventions (colours) often change with different tools.

Figure 1.1

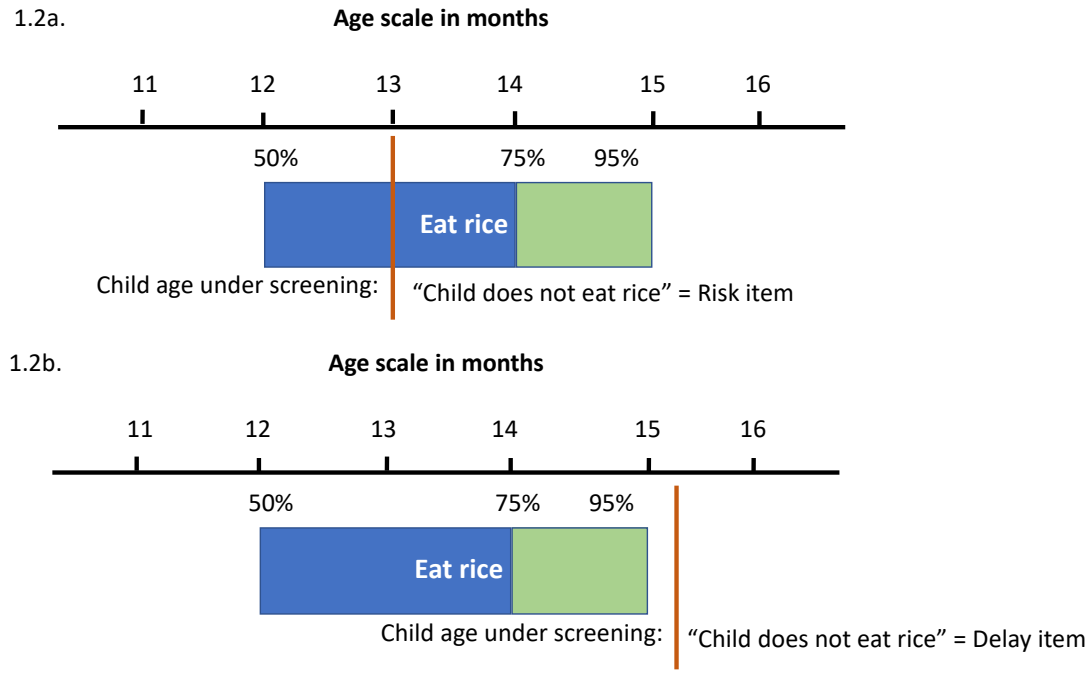
Example of "Eat rice" item in a standardised screening tool.



The graphical conventions used in the DS tools are usually intended to draw attention to risk or delay in reaching developmental milestones (Duby, et al., 2006; Johnson, Wolke, & Marlow, 2008; Libertus & Landa, 2013; Rescorla & Alley, 2001). A risk in reaching a milestone might be present when an item observation is negative (i.e., failed, refused, or absent) and the age of the child falls within the box limits. Using the example of the "Eat rice" item, if a child is 13 months old and does not eat rice during the observation with the screening tool, this item is marked "Fail" or "Refuse" and interpreted as a "Risk" or "Caution" item (Figure 1.2a). A delayed item is considered when the age of the child falls above the upper limit of the box. For the "Eat rice" sample (Figure 1.2b) if a child is over 15 months old and does not eat rice during the observation with the screening tool, this item is marked "Fail" or "Refuse" and interpreted as "Delay". The counting of at-risk and delayed items helps in scoring the overall test, potentially leading to additional evaluations or referrals when an at-risk or developmental-delay status is suggested (Vitrikas et al., 2017). A child with a screening classification of "At risk" is not considered an individual with an atypical trajectory. Delays and Cautions are not "alarm" issues. However, participants that keep the "At risk" condition in more than one observation (e.g., an external developmental screening observation and a parental report) are the target for health and educational interventions in many LMIC (Cavallera et al., 2019; Vargas-Barón, 2019). Discussing how typical or atypical development is related to developmental screening is not a concern of the thesis' conceptual and methodological proposals.

Figures 1.2a. – 1.2b.

Examples of risk and delay "Eat rice" items in a standardised screening tool.



After the analysis of different health, wellbeing, and demographic dimensions for the whole IPV sample (N=1177) and the correlation between the reading frequency reported at home with the risk condition determined by the caution and delays in the DS for a subsample of children (24- to 36-month-old: *n* = 116), the third chapter contains the examination of a potential tool for cheaper and sustainable developmental screening, using a framework for reliability and agreement (R&A) studies. Comparing the outcomes of two DS tools, one by observation (i.e., Haizea-Llevant) and the other with parental reports (i.e., CARE booklet) of a sample of parents and their children in Colombia, the third chapter of this thesis will answer a specific research question (RQ#2): *Are parental reports as valid and accurate as expert reports using developmental screening tools*? If the answer for RQ#2 is sufficiently positive to consider a reliable and valid screening tool the DS tool designed for the parental report, then it will be included for an intervention with parents in a fourth chapter.

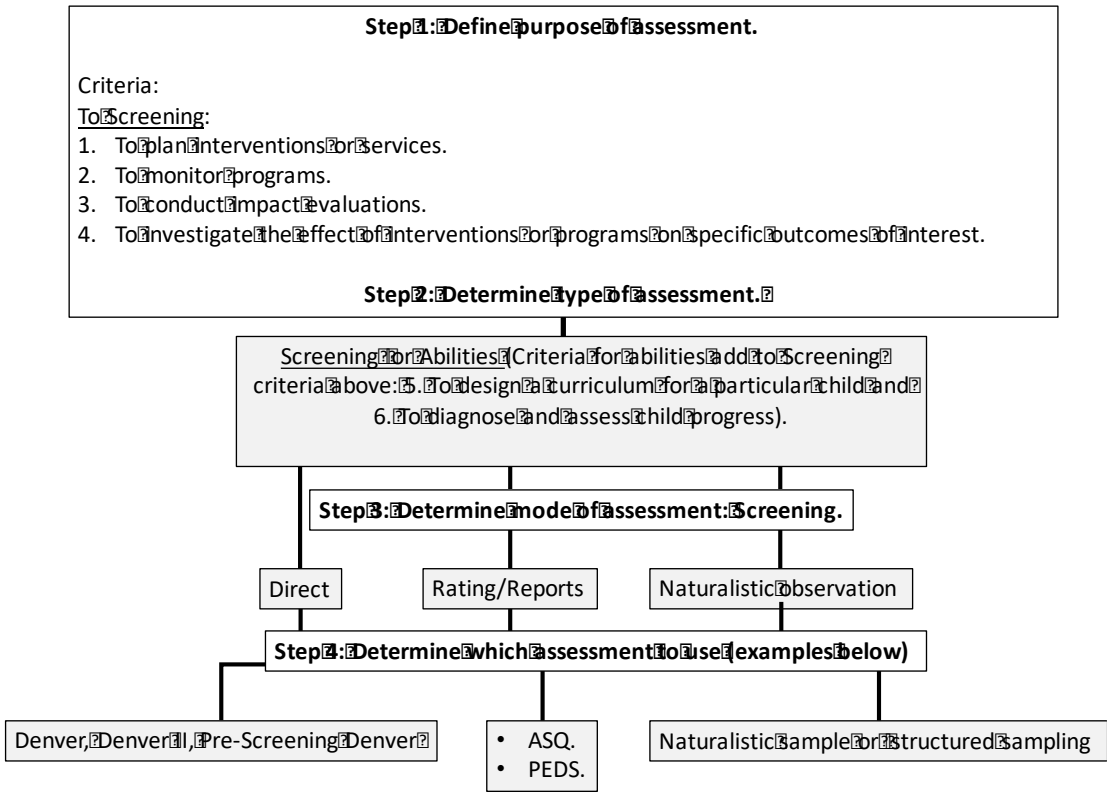
1.4. Identifying psychometric properties and congruence between direct observation and the parental reports.

Developmental screening (DS) with well-designed tools has been deployed to assess the effect of intervention programmes on specific outcomes (Fernald, Kariger, Engle & Raikes, 2009; Tann et al., 2021). Several decision-making steps are required when DS tools are included in interventions, monitoring programmes, assessments, or research (Figure 1.3). Well-designed DS tools also reduce financial and time costs for fundamental research and public health activities, such as assessing early developmental status at an individual level (Johnson, Wolke, & Marlow, 2008), even in LMICs (Tann et al., 2021).

In the last decade, various studies have evaluated DS tools deployed at primary healthcare services in LMICs (Fischer, Morris & Martines, 2014; Fernald, Prado, Kariger & Raikes, 2017; Boggs et al., 2019). The three mentioned studies rated 14 individual-level tests, applying common criteria for validity, reliability, accessibility of application, required training, administration time, cultural adaptability, geographical uptake, and clinical relevance and utility (this last criterion was only considered for the category of individual-level measurement tools; see Table 1.1). Boggs et al. (2019) excluded the costs of the tool (i.e., the budget necessary to buy and use the materials and to train personnel) from the criteria listed by Fischer et al. (2014).

Figure 1.3

Flowchart for decision-making in a Developmental Screening arm.



Note: Source: Fernald et al., (2009), p. 66.

The mentioned reviews of 14 individual-level tests indicated higher ratings of administration time or reliability compared with population-level and ability-level tools (Boggs et al., 2019). Of these, 36% (n = 5) had a higher rating for both administration time and reliability: namely, the Ages and Stages Questionnaire (ASQ), the Denver Developmental Screening Test (DDST), the Guide for Monitoring Child Development (GMCD; Ertem et al., 2008; Ertem et al., 2018), the ICMR Psychosocial Development Screening Test, and the Parents' Evaluation of Developmental Status (PEDS; Glascoe, 2002).

Table 1.1

Rating criteria for accuracy and feasibility in early child development measures tools.

Grading criteria	Definition	Rating	Meaning
A. Does the tool work? Psychometric properties and cultural adaptability of tool			
1. Validity	The degree to which a measure accurately assesses behaviours or abilities that reflect the underlying concept being tested. (16)	3	Validity ideally against educational outcomes up to age 5 with a standardised test, eg, Wechsler, equal to or above widely accepted threshold (eg, >0.7), statistically significant.
		2	Validity somewhat below widely accepted threshold (eg, 0.5–0.7) against another performance-based tool, eg, Bayley III.
		1	Some description/mention of validity but methods unclear or poor quality, below accepted threshold (eg, <0.5).
		0	Inadequate result of validity, no statistical significance.
2. Reliability	How consistently a measure produces similar results for a child or group of children with repeated measurements over a short period of time. (16)	3	Equal to or above widely accepted threshold (eg, >0.7) for measure tested at tool level, rigorous methods of testing, statistically significant ideally with kappa. (supplementary web appendix 1).
		2	Somewhat below widely accepted threshold (eg, 0.5–0.7), rigorous methods of testing but in one continent only.
		1	Some description/mention but methods unclear or poor quality or below accepted threshold (eg, <0.5).
		0	Inadequate discussion of reliability, no statistical.
3. Cultural adaptability	Modification of items, materials and procedures to fit the local context, such as translating items and changing words or pictures to reflect cultural differences. (16)	3	Easy modification of items, materials and procedures.
		2	Minimum to moderate modification of items, materials and procedures.
		1	Moderate to complex modification of items, materials and procedures.
		0	Highly difficult modification of items, materials and procedures.
B. Can the tool be delivered? Practicality of administration			
1. Accessibility	Access to tool, including digital availability and costs to purchase and use the tool with equipment as required. *Note: cost is allocated per child for 100 tests. Note: digital defined here as open access tool available online and app available. Note: cost does not include training costs, some tools may be freely available but require payment for a trainer to train the project team.*	3	Tool, administration, scoring and interpretation, adaptation and training resources all available open access online with no intellectual property restrictions; no cost for tool, no additional equipment; app available.
		2	Tool, administration, scoring and interpretation, adaptation and training resources all available open access online with no intellectual property restrictions, minimal cost to tool and/or equipment (≤US$10 per child), no app available.
		1	Tool, administration, scoring and interpretation, adaptation and training resources all available online, but some intellectual property or other restrictions (eg, requirement for direct involvement tool authors/owners in research), moderate cost to tool and/or equipment (range >US$10 to ≤US$20 per child), no app available.
		0	Not readily available online with intellectual property restrictions, high cost tool and equipment (range >US$20 per child), no app available.
2. Training	Refers to duration of training, skill level of trainer and trainee and certification requirement. *Note: duration of training does not include general field work.*	3	Brief (≤1 hour), minimal (ie, non-specialist worker can train non-specialist worker), no certification requirement.
		2	Moderate (>1 hour to ≤1 day), moderate (ie, non-specialist trainer) but requires more standardisation and training or direct assessments of children's abilities that require moderate training and practice, no certification requirement.
		1	Long (≤2 days), moderate (ie, non-specialist trainer) but requires more standardisation and training or direct assessments of children's abilities that require moderate training and practice, may include certification requirement.
		0	Long (≥3 days), specialist trainer and/or trainee, certification required.
3. Administration time	Estimated time taken to administer the tool in completion, including scoring time. *Note: when range is given an estimated median time for administration will be used.*	3	≤15 min, easy scoring.
		2	>15 to ≤30 min, minimum to moderate scoring.
		1	>30 to ≤60 min, moderate to complex scoring.
		0	>60 min.
4. Geographical uptake	Geographical use of the tool.	3	Used in at least three continents.
		2	Used in two continents only.
		1	Used in one continent only.
		0	Used in one country only.
C. Individual-level tool only			
1. Clinical relevance and utility	Usability of tool for frontline worker for interpretation and response.	3	Easy interpretation, clear threshold for action and structure for counselling response and contextually appropriate referral.
		2	Minimum to moderate interpretation, thresholds for action but unstructured response guidance and/or suggested response unlikely to be feasible in context.
		1	Moderate to complex interpretation, no structured thresholds for action and/or suggested response unfeasible in context.
		0	Highly technical interpretation (eg, with separate manual), no clear threshold for action, specialist referral response.

(Source: Boggs et al., 2019, S24)

The mentioned review studies did not find any screening tool particularly designed for or used in Colombia (Boggs et al., 2019; Fischer et al., 2014). However, Colombia's Ministry of Health uses the Abbreviated Development Scale (ADS-1; in Spanish, *Escala Abreviada del*

Desarrollo; Ortiz, 1991) in various institutional scenarios, including children's centres and public kindergartens around the country. Colombia's Ministry of Health (Ministerio de Salud, 2016) presents the ADS-1 with no published report on its conceptualization, pilot testing, or complete analysis of validity and reliability. A partial validation analysis of the ADS-1 for the language and hearing domain in 4- to 5-year-old children indicated low predictive ability (Sensitivity: 54%, Specificity: 42%) and poor agreement with a gold standard for early detection of language and hearing disorders (the Reynell norm-referenced test) on measuring expressive and receptive language skills (Muñoz-Caicedo, Zapata-Ossa, & Pérez-Tenorio, 2013). We can therefore conclude that to the best of our knowledge, ADS-1 is not a very suitable tool for the Colombian context, following the standards of Boggs et al. (2019). Moreover, the rating exercises report the use of a "developmental domain" approach to the relevant screening tools, but not an analysis of "administration of test", as recommended by several authorities (e.g., Boggs et al., 2019; Fernald et al, 2017). The "administration of test" view requires comparing caregiver reports with direct child observation. Vitrikas et al. (2017) described both a parent-completed DS tool as an instrument for obtaining screening information through parent participation, and (as a separate instrument) a directly administered DS tool when information is based on direct observation of the child by a physician or other expert.

To probe the potential of a screening tool to improve the outlook of at-risk children in conditions of poverty in LMICs, the research described in this thesis presents the design of a parent-administered report of direct observation and activities for children between 24 and 59 months of age. More specifically, it presents the further development of a direct assessment tool conducted by parents and other caregivers called CARE (Compilation of Activities to Report and Enhance development).

1.4.1. **The CARE Booklet**

The idea for the CARE design is associated with the truncated continuity of the *Inicio Parejo de la Vida* (IPV; "Equal Start in Life", in English) research programme. The content of CARE is derived from the Haizea-Llevant developmental screening table (Iceta & Yoldi, 2002). The Haizea-Llevant screening table is a developmental screening version of the Denver Developmental Screening Test or DDST (Frankenburg, 1987; Frankenburg, van Doorninck,

Liddell, & Dick, 1976) and the Denver Pre-screening Developmental Questionnaire (PDQ). The selection criteria for the Haizea-Llevant (HLL) are intended to increase the rigour in items for observation in the Spanish language by adapting cultural/linguistic modifications obtained in the original Llevant study at País Vasco (Fuentes-Biggi, Fernandez & Alvarez, 1992). Also, HLL was selected because the DDST is broadly used and standardised in different countries (Dawson & Camp, 2014; Guevara et al., 2013; Lipkin & Gwynn, 2007), including populated regions in Brazil (Lopez-Boo, Cubides-Mateus & Llonch-Sabatés, 2020) and Colombia (Rubio-Codina & Grantham-McGregor, 2020). While the Denver Developmental Screening Test II consists of 125 tasks or items, the HLL has 97 items, including four areas of functioning: 1. Personal-Social or relating to people and caring for personal needs; 2. Language or about hearing, understanding, and using language; 3. Fine Motor-Adaptive or about eye-hand coordination, manipulation of small objects and problem-solving; and 4. Gross Motor about sitting, walking, jumping and overall considerable muscle coordination.

The main content of CARE includes 47 activities for two age groups (24- to 35-month-old, 36- to 59-month-old) to report developmental milestones in the exact four domains mentioned for the Denver II and with a different title in Spanish but covering the same dimensional or domain skills in the HLL table: Personal-Social, Language and logico-mathematical reasoning, Manipulative or fine motor-adaptive, and Postural or gross motor skills (Table 1.2). Every item in CARE is closely related or identical to one item in the Haizea-Llevant Table (Iceta & Yoldi, 2002) but designed for parental attention (Appendix A). Access to Haizea-Llevant has been free since 1991 because the País Vasco health system included the scale without cost for public consultation in the Central Publications Service of the Basque Government (Fuentes, Rueda & Fernández-Matamoros, 1991).

Table 1.2

CARE and Haizea-Llevant item examples by developmental domains

Original item description in CARE (Spanish)	Item description in CARE (English)	Item description in Haizea-Llevant (English)
Personal-social items		
1. Ayuda a recoger los juguetes.	Help pick up the toys.	Help pick up the toys.
2. Da de comer a los muñecos.	Feed the dolls.	Feed the dolls.
3. Se quita los pantalones.	Take off his pants.	Take off his pants.
Language and logico-mathematical reasoning items		
1. Nombra un objeto dibujado.	Name a drawn object.	Name drawn object.
2. Ejecuta dos órdenes.	Execute two commands.	Execute two commands.
3. Combina dos palabras.	Combine two words.	Combine two words.
Fine motor-adaptive items		
1. Tapa un bolígrafo, lapicero o marcador.	Cap a pen, pencil, or marker.	Cap a pen.
2. Hace una torre de cuatro cubos.	Makes a tower of four cubes.	Makes a tower of four cubes.
3. Coge un lápiz.	Grab a pencil.	Grab a pencil.
Gross motor items		
1. Baja escaleras.	Go downstairs.	Go downstairs.
2. Patea una pelota.	Kick a ball.	Kick the ball.
3. Salta hacia delante.	Jump forward.	Jump forward.

The similarity between HLL and CARE resides in the intention to offer caregivers a tool for controlling in milestone-related tasks and observations the *degrees of freedom* described previously in our adopted definition of scaffolding (Bernstein, 1967; Shvarts & Bakker, 2019; Vrantsidis et al., 2020; Wood et al., 1976). While HLL requires a third person to observe the interactions between caregivers and children, CARE leaves to the caregiver the demand for attention to the *intra*subjective and *inter*subjective processes that are required in developmental scenarios at home, when parent and child interactions take place, and which are regularly

associated with developmental outcomes in vulnerable families and children (Shvarts & Bakker, 2019; Vrantsidis et al., 2020).

Initially, the delivery of CARE was similar to a general home-based record (HBR), which sought some of the benefits described for HBRs in paediatric studies (Mahadevan & Broaddus-Shea, 2020). The practicalities of the Compilation of Activities to Report and Enhance development (CARE booklet) might be linked to those of HBRs in general, for which parents maintain a document with information about child health and developmental milestones that can be shared with experts and other interested parties, allowing comparison with previous reports and the compilation of information about individual trajectories. The first pages of CARE (Appendix A) clarifies its usage for parents and gives instructions on how to interact, observe, and supervise every activity in the pages of CARE for one month after they receive it.

We expect that the content and implementation of CARE, like with other HBRs that are widely used worldwide, will not be applied in universal or standardised ways (Mahadevan & Broaddus-Shea, 2020). Recently, the World Health Organization (WHO) launched several recommendations for home-based records (WHO, 2018), including parental reports, to increase the use of HBRs in maternal and child health services. However, by 2016 only 25 countries, out of 163 reporting some use of HBRs, demonstrated a fully integrated use of HBRs in child health handbooks (Osaki & Aiga, 2019). Despite the low proportion of HBR integration in health systems, their general use and application, for instance in presenting vaccination cards to patients (Shah et al., 1993), can give rise to multiple paediatric and developmental benefits (Mahadevan & Broaddus-Shea, 2020):

(i) increasing caregivers' knowledge about the uses and demand for healthcare services,

(ii) facilitating communication between caregivers and health workers,

(iii) reducing missed opportunities of surveillance or monitoring for healthcare services.

Those functions can be divided into three levels in the expected functions of CARE (Osaki & Aiga, 2019): (level 1) data recording and storage; (level 2) behaviour change communication; (level 3) monitoring and referral (i.e., reports in paediatric and nursing practices). The efficient use of CARE and the characteristics of its functioning as an HBR also demand that users act as providers of information and healthcare services. Users' capacities require knowledge, potential abilities, motivation, and attitudes that enable frequent use of HBRs in home-based practices

(Osaki & Aiga, 2019). Nevertheless, the use of HBRs in maternal, newborn and child health reporting, care seeking and self-care practice in LMICs, after a three-year follow-up, showed a reduced risk of cognitive delay in children (Magwood et al., 2019). Despite the critical role of HBRs in assessing the cognitive development of at-risk children in LMICs, there is limited evidence of the effects on children's cognitive outcomes when the HBR designs are not exclusively focused on child vaccination cards (Mahadevan & Broaddus-Shea, 2020).

Consequently, the fourth chapter in the thesis explores whether recommending the CARE booklet to parents and caregivers to be used in regular observation and registration of routines at home answers a specific question (RQ#3): *Might the delivery of a parent-administrated tool for developmental screening to principal caregivers for a month have any effect on children's developmental outcomes?*

1.5. Measuring changes in risk indicators (Delay and Caution reports) in participant children after parents received CARE compared with a control group.

A recent review of 124 studies of language interventions taught to caregivers in homes and classrooms (Biel et al., 2020) do not found studies that used one training function with scaffolding or prompting strategies. In our view of the importance of "scaffolding" for parental involvement using HBRs and active learning (Axford et al., 2019; Magwood et al., 2019; Mermelshtine, 2017; Veas, Castejon, Miñano & Gilar-Corbí, 2019), the absence of previous specific interventions with active learning as a training function for caregivers creates the opportunity for a short and comprehensive review of parenting programmes.

1.5.1. Parenting Programmes (PP).

Parenting programmes (PPs) are convenient ways to intervene in parent-child interactions, and an indirect way to enhance the home learning environment (Center on the Developing Child at Harvard University, 2007). PPs that focus on enhancing the parent-child interaction may show more promising results compared with those that focus on basic child healthcare, or offer developmental information or community support (Kearney, York, & Deatrick, 2000). Results of PPs focused on parent-child interaction included changes in parental attitudes and behaviours (Fergusson, Grant, Horwood, & Ridder, 2005) and children's socioemotional outcomes (Engle et al., 2011; Walker et al., 2007; Walker et al., 2011), and improvement in children's developmental

outcomes (Olds, Sadler, & Kitzman, 2007). One well-known PP with evaluations of intervention impact on parental behaviour is the Head Start Program (Office of Head Start, 2011). Changes caused by the Head Start Program to parental involvement were specifically aimed at reducing spanking and increasing reading activity and were associated with better school performance of children (Gershoff, Ansari, Purtell, & Sexton, 2016). Although family income manipulation (e.g., cash transfers), nutritional supplementation, and early educational programmes demonstrated significant and sustained effects on child development outcomes, PPs that included components of home environment enhancement and stimulating activities proved to be the most effective in LMICs (Nores & Barnett, 2010; Rasheed & Yousafzai, 2015). Despite this evidence, the coverage, technical and scientific support for PPs in LMICs remains low, and available data on implementation is deficient (Richter et al., 2020; Tanner, Candland, & Odden, 2015). One possible explanation for this is the costs associated with home visits as a privileged way of PPs to intervene in parent-child interaction. A special characteristic of many PPs is the use of home visits as the delivery strategy for intervention in parent-child interactions, as well as in home environment and stimulating activities. Frequency and length of visits have different effects on desirable outcomes and participant success (Gomby, Culross, & Behrman, 1999; McDonald, Moore, & Goldfeld, 2012; Peacock, Konrad, Watson, Nickel, & Muhajarine, 2014; Zercher & Spiker, 2004). However, most studies and reviews of PPs based on home visits agree that these programmes require higher costs in financial and professional resources, have limited potential for large-scale delivery, and have low levels of engaging and retaining families over time (Araujo, López-Boo & Puyana, 2013; Nicholson et al., 2016). These difficulties are seen as "prohibitive" for long term initiatives in Latin American LMICs (Baker-Henningham & López-Boo, 2013). The cost of interventions that exclusively use home visits is not only monetary: high engagement with home visits is associated with particular maternal characteristics (higher IQ, older mothers, mothers who were employed during pregnancy, mothers with greater knowledge of infant development, and mothers with more positive parenting beliefs), rather than other characteristics (i.e., young, unemployed, and/or less well-educated mothers) that are more frequently found in LMICs (Doyle, 2020).

1.5.2. **Parenting Programmes in Latin-American and LMIC.**

Nutrition and behavioural programmes involving parental actions have a higher frequency and history in Latin-American and LMIC (Mejia, Calam & Sanders, 2015), while parenting programmes about information and skills tracking to promote their children's cognitive development and learning through a series of home visits provided by trained professionals or paraprofessionals are a relatively recent initiative in the region and are not universal (Leer & Lopez-Boo, 2019). Only seven programmes with exclusively home-visit strategies for parenting and caregivers to practice early stimulation activities, are recently reported in the Caribbean, Central and South America: three national programmes, in Peru (Cuna Más), Ecuador (Creciendo con Nuestros Hijos, CNH) and Nicaragua (Programa de Acompañamiento a la Política de Primera Infancia, PAIPPI); three regional programmes, in Brazil (Programa Primeira Infancia Melhor, PIM), Jamaica (the Home Visits Programme in Kingston and Saint Andrews) and Panama (Atención Integral de la Niñez con Participación Comunitaria, AIN-C); and one programme in Bolivia implemented at the municipal level in El Alto by an NGO (The Consejo de Salud Rural Andino programme, CSRA). The Jamaica Home Visits Programme is the most influential and long sustained study of them. In this programme, caregivers and children aged 9 to 24 months were selected based on their malnutrition status among other vulnerability and poverty factors, and through 24 months of regular home visits focused on language, socioemotional and motor development stimulation, researchers found a significant effect of 0.8 standard deviations (SD) on children's cognitive development (Grantham-McGregor, Powell, Walker & Himes, 1991). After 11 and 20 years after the first interventions, the cognitive scores (IQ assessment), educational attainment, mental health conditions, and labour earnings are higher in the treated children compared with the control group in different small studies (Walker, Chang, Vera-Hernández, & Grantham-McGregor, 2011). Despite the benefits remarked of low-cost of home-visit programmes compared to interventions that require infrastructure investments for schools or centre buildings (Leer & Lopez-Boo, 2019), the not reported sustainability, costs-benefit balance and logistical difficulties are the key reason for the low number of PPs in LMICs. Centred in long-term effects, only three studies exclusively carried in Jamaica, present results that relate changes in parental behaviour to children under the age of 6 with sustainable effects on their development and skills once they are 9–11 years old (Grantham-McGregor, Powell, Walker, Chang, & Fletcher, 1994; Grantham-McGregor, Walker, Chang, & Powell, 1997; Walker, Chang, Younger, & Grantham-McGregor, 2010). Other PP studies in Latin-America and LMIC do not track the sustainability of

changes and their effect on children's development (Al-Hassan & Lansford, 2011; Cooper et al., 2002; Gardner, Walker, Powell, & Grantham-McGregor, 2003; Wendland-Carro, Piccinini, & Millar, 1999). The greatest methodological problem with Grantham-McGregor, Walker and colleagues' studies is the geo-political and cultural limitations of their participant samples. As mentioned before, all three studies were applied in Jamaica, and therefore their wider applicability may be in question. However, Grantham-McGregor et al.'s results are highly relevant because they show the great potential gains of direct interventions in children's home environments and demonstrate a methodological strategy for realizing PPs to achieve long-lasting and positive effects on children's development (Yousafzai & Aboud, 2014). The Jamaica PP approach helped to inspire small-group interventions and add-ons for community-based or parental group programmes, such as the Smalltalk programme (Nicholson et al., 2016).

1.5.3. **The Smalltalk Intervention Program**

Nicholson et al. (2016) designed, applied, and evaluated the Smalltalk (ST) programme. This programme pursued, as its main goals, the improvement of parents' capacities in socially and economically disadvantaged families in Victoria (Australia), and the enhancement of the home learning environment for their infant and toddler children. The ST program content emphasized two main parenting strategies: 1) quality parent–child interactions; and 2) a stimulating home-learning environment. Nicholson et al. (2016) designed visual (DVD) and printed resources illustrating these parenting strategies. This material was distributed to two intervention groups (*Smalltalk group-only* and *Smalltalk plus* – the latter group receiving the same treatment as the former, with the addition of coaching via home visits), while another group of parents was allocated to the *standard condition* control group. The intervened groups received 2 hours of group sessions with training staff from local government authorities in the state of Victoria. These sessions included information and active skills training in five strategies for enhancing the quality of parent-child interactions (e.g., parent responsiveness, positive verbal exchanges) and five strategies for providing a stimulating home learning environment (e.g., use of books, toys, etc., and daily activities and routines for language and literacy). The *standard condition* group did not receive the visual or printed material, and their sessions were focused on issues relevant to parenting for the children's age group; no elements of the ST program were discussed. The *Smalltalk group-only* and the *Smalltalk plus* groups had two different delivery formats (Infants and

Toddlers), depending on the children's age: 1) infants (aged 6 to 12 months), and 2) toddlers (aged 12 to 36 months). The number of participants by sessions and the duration of the programme varied according to these delivery formats: 1) infants: 6 or more participants for 6 weeks; 2) toddlers: 10-15 participants for 10 weeks. The results of the ST programme were reported by Hackworth et al. (2017) and indicated that:

1. After 32 weeks of intervention, in the infant trial, there were no differences by trial arm for the parent verbal responsivity or home learning activities.
2. After 32 weeks of intervention, in the toddler trial, participants in the *Smalltalk group-only* trial showed improvement compared to the standard program for: a) parent verbal responsivity (effect size 0.16; 95% CI 0.01, 0.36); and b) home learning activities (effect size 0.17; 95% CI 0.01, 0.38).
3. The *Smalltalk plus* group (the same treatment as the *Smalltalk group-only* group with the addition of home visit coaching), did not report significant results.
4. For measurement of other parenting behaviours (parent-reported warmth and irritability, and directly observed parent-child interactions) and the home environment conditions (parent-reported home literacy environment, and household chaos) in the infant trial, several differences were found initially favouring the *Smalltalk plus* group at 12 weeks, but not maintained at 32 weeks. For the toddler trial, these differences favoured the *Smalltalk-plus* group at 12 weeks and were maintained at 32 weeks.

In conclusion, Hackworth et al. (2017) reported some benefits of a parenting intervention focused on the home learning environment for parents of toddlers but not for children. Certain results are key for the research questions addressed in this thesis research:

1. The best age range for a *Smalltalk* type of intervention in parent-child interaction is after 24 months old. The results of Hackworth et al. (2017) are consistent with other reports about the importance of this age range in social and cognitive development for developmentally delayed children (Brown, Finch, Obradović, & Yousafzai, 2017; Casale & Desmond, 2016; Cheng, Palta, Kotelchuck, Poehlmann, & Witt, 2014; Crookston et al., 2011), with interventions before 24 months old seeming more relevant for proximal developmental targets (Slemming, Kagura, Saloojee, & Richter, 2017) such as nutrition (i.e., food supplements) or hygiene and immunization (vaccine supplies).

2. Parent-child interactions and home learning activities are key to enhancing parenting strategies and increasing the probability of changing children's developmental outcomes (Napoli et al., 2021).

The *Smalltalk* results (Hackworth et al., 2017) indicate a need for more structured administration of the DS tool such as the CARE booklet in the home environment. The importance of "scaffolding" and parental involvement suggests that delivering just the DS or HBE *per se* will probably not have significant effects. The absence of previous interventions with active learning as a training function for caregivers (Biel et al., 2020), suggests we attempt a contrast between the CARE intervention and an intervention with proven robust effects, such as the dialogical book-sharing reading intervention for parents and children (Canfield et al., 2020; Vally, Murray, Tomlinson, & Cooper, 2015). In order to compare a CARE intervention with a DBS intervention, a focus in cognitive and social enhancement through parent training, this thesis will attempt to answer a specific research question (RQ#4): *Are significant differences in the developmental outcomes for two intervention groups (DBS intervention and CARE intervention) compared with a control group?*

1.6. Comparing the effects of an intervention with CARE (CARE booklet intervention – CBI) versus a dialogical book-sharing (DBS) intervention in 24- to 59-month-old children

Dialogical Book-Sharing **(**DBS) is a training programme for parents/carers to promote supportive and reciprocal book-sharing with young children, delivered by a trained facilitator. This programme has been trialled in South Africa and found to be highly effective in improving carer book-sharing skills, and to have a significant benefit for child attention, language, and pro-social behaviour (Cooper et al, 2014; Vally et al, 2015; Murray et al, 2016). The programme was also piloted in a UK Children's Centre (Pen Green in Corby) where it was enthusiastically received by both staff and parents (P. Cooper, personal communication, April 23, 2021). The programme involves parents meeting in small groups and receiving instruction from a facilitator over six weekly hour-long sessions. These sessions, which are organized around a 'book of the week', involve a PowerPoint presentation with demonstration video clips to illustrate key learning points, incrementally building up skills. The group session ends with each parent being given the book to

take home to share with their child, with encouragement to do so, if possible, daily for approximately ten minutes per day.

Before and after interventions, independent assessments were made of caregivers' and children's language abilities, executive functioning, attention, prosocial behaviour, theory of mind, and book-sharing behaviour (sensitivity, elaborations, and reciprocity). A recent meta-analysis (Dowdall et al., 2020) reviewed book-sharing interventions in LMICs (two studies in South Africa, one in Brazil, and one in Türkiye) and found small to large size effects on expressive (d = 0.41) and receptive language (d = 0.26), as well as caregiver book-sharing competence (d = 1.01). Also, the impact of the intervention on child language was moderated by intervention dosage, with lower dosage associated with a minimal impact.

Book-sharing in LMICs is often considered a school activity and a task for acquiring knowledge, rather than a pleasant and autonomous learning activity, and it is less likely that caregivers in such environments will read books with toddlers (Chaparro-Moreno, Reali & Maldonado-Carreño, 2017). Consistent with studies of deprived participants in South Africa and the USA, Cooper et al. (2014) showed that their 6 to 8-week book-sharing training program brought about significant benefits in parental sensitivity and reciprocity whilst sharing picture books, as well as to child attention, and receptive and expressive language. Further, recent research (Vally et al, 2015) indicates that the intervention was especially beneficial for children at the most disadvantaged level. The research described in this thesis will involve a comparison of effects for a Dialogical Book-sharing intervention and the CARE booklet intervention used as a home-based record.

All mentioned studies take place in Colombia, two of them before the beginning of the doctoral studies of the author and approved by the institutional committees of the Faculty of Psychology and the General Directorate of Research of the Universidad de la Sabana, which reason why the University of Reading approval was not required. Furthermore, all the research activities related to the Thesis studies are under the legal provision of Resolution No. 008430 of 1993 of the Ministry of Health of the Republic of Colombia, in which standards appear scientific, technical, and administrative for research activity in health contexts. Specifically, the studies derived from the IPV research programme mentioned in the 1st and 2nd Chapters had approval from the School of Medicine and the General Directorate of Research of the Universidad de la Sabana (ACTA 33 del 1 de Febrero de 2013; File: MEM_DIN 002-2013_IPV.pdf). The design of CARE, mentioned

in 3rd and 4th Chapters, had approval from the institutional research committee of the Faculty of Psychology (Proyecto PSI-50-2015: Efectos del uso de un instrumento para valorar el desarrollo socio cognitivo de niños entre 24 y 59 meses de edad administrado por padres y cuidadores, Mayo de 2015; Formato Concepto de la Subcomisión de Investigación sobre calidad científica e Integridad Ética del Proyecto; File: Subcomision_Acta-083 13-05-2015.pdf). The interventions in the 5th Chapter had approval from the institutional research committee of the Faculty of Psychology (Proyecto PSI-67-2019: Estudio ECA -Ensayo Controlado Aleatorio- del entrenamiento a cuidadores principales en el uso del Dialogical-Book-Sharing y el uso de una cartilla de monitoreo en el desarrollo socio-cognitivo de niños entre 3 y 5 años de edad en jardines de dos regiones de Colombia, del Octubre 19 de 2018; Acta 118 del 18-Oct-2018; File: Cont_Act118 18-10-2018.pdf). All files with the description of ethical approvals conform the Appendix B.

In summary, the next chapter presents the results of the IPV programme, which gave rise to the design of CARE, followed by a third chapter about the psychometric characteristics of CARE. A fourth chapter reports the effects on delay and risk indicators in participant children after parents use CARE for screening. The fifth chapter compares a Dialogical Book-Sharing intervention (DBS) and a CARE booklet intervention (CBI) in developmental outcomes of a specific age group (24- to 59-month-old children). To conclude the Thesis, the sixth and seventh chapters discuss an integrated view of the results: firstly, how our methods account for the effects of interventions in LMICs; and secondly, how to improve CARE as a screening tool and as a parent-based intervention. Finally, a model of the detection-intervention-prevention continuum using the concept of interoperability (Pronovost et al., 2018) describes the study's limitations and considerations for future research.

Chapter 2. Children At risk and Reading Frequency in a Low-to-Middle-Income Country (LMIC): The Case of Cundinamarca and Boyacá in Colombia.

Poverty is a considerable barrier to get living wellbeing for more than 40% of children worldwide who are at risk of not reach all their developmental potential (Lu, Black & Richter, 2016; Richter, 2019). However, there has been some success in reducing childhood undernourishment caused by poverty (Kinyoki et al., 2020). Nonetheless, 99% of children worldwide living in poverty or with undernutrition live in the 105 low- and middle-income countries (LBD Double Burden of Malnutrition Collaborators, 2020). Such countries therefore bear the brunt of consequent cognitive, physical, and metabolic developmental impairments, leading to reduced intellectual ability and poor school achievement. Sociodemographic, gestational, nutritional, educative, and parental variables related to different aspects of poverty have an impact on individual children's development (Alkire, Ul Haq, & Alim, 2019; Axford et al., 2019; Bornstein et al., 2017; Lewkowicz, 2011; Richter et al., 2019; Zhang & Han, 2020).

Colombia is a low- and middle-income country (LMIC) in South America with a high indicator of multidimensional poverty for children aged 3 to 5 years (37%) and 0 to 2 years (28.6%; García et al., 2013). García et al. also revealed that about 80% of 3- to 5-year-old Colombian children do not receive preschool education or attend early childhood centres. Some 14.5 million Colombians at the time of this research lived below the country's poverty line, meaning they survived on less than US$88 per month, or $1460 per year (World Bank, 2014). Based on this context, an urgent search for alternatives to institution-based early learning in terms of child support at home might lead us to promote early literacy and reading habits. Robust and reliable evidence about the importance of the home literacy environment has been reported over the last two decades (Goldfeld et al., 2021) and their early effects in children development (Neri et al., 2021). Especially, the literacy environment determines major academic and wellbeing gaps in rural and urban low-SES homes in the USA (Burris, Phillips, & Lonigan, 2019; Tichnor-Wagner, Garwood, Bratsch-Hines, & Vernon-Feagans, 2016). Literacy promotion at home and in early education programmes only succeeds, under conditions of poverty or other vulnerability, when frequent parental interactions (i.e., shared book-reading) occurs (Dexter & Stacks, 2014; Sénéchal & Young, 2008; Tichnor-Wagner et al., 2016). For Latino families as well, the same barriers and benefits for early interventions (i.e., parental literacy, distribution, and cost) exist as previously

mentioned for low-SES families in the USA (Zuckerman, Elansary & Needlman, 2019). To our knowledge, there are no recent studies of home reading conditions in Colombian families.

This chapter describes an analysis of a screening measurement for reading habits in Colombian families with children aged between 24-36 months old. Data were obtained from the *Inicio Parejo de la Vida* ("Equal Start in Life"; IPV) program. The IPV is an initial research support for developmental measurement of 1177 children and their parents, using a screening instrument translated from the Denver Developmental Screening Test (Frankenburg, 1987; Frankenburg et al., 1976) and the Denver Pre-screening Developmental Questionnaire (PDQ): the Haizea-Llevant development screening table (Iceta & Yoldi, 2002). The Haizea-Llevant development screening table allows the collection of individual data about attainment of developmental milestones across four dimensions or domains, and consequently the triggering of caution or risk status when specific milestones are not reached.

The chapter first report general results of the IPV developmental measurements and an aggregate statistical characterization of all 1177 participants. Then, the information collected about the *caution* and *risk* screening indicators are set out, which will be useful as a contrast group for the experimental results in the following chapters, and finally, the correlation between caution and risk indicators.

2.1. Background for "Inicio Parejo de la Vida" Developmental Measurement Study

The IPV study assumes a complex view of development (Bornstein et al., 2017; Lewkowicz, 2011; Richter et al., 2019). A principal idea relating to the complexity of child development implies a view of development as an "immensely complex, dynamic, embedded, interdependent, and probabilistic process" (Lewkowicz, 2011; p. 331). That complexity requires the inclusion of the caregiving context as a significant factor affecting children's cognitive development (Bornstein et al., 2017). The main objective of the IPV study is obtain information about the developmental status of children in a three-year research program, with a sample of 1177 children under 6 years old and their caregivers in two large territorial regions of the Andean geographic-centre in Colombia (Cundinamarca and Boyacá), in urban settings (Giraldo-Huertas, Cano, & Pulido-Alvarez, 2017). Also, through the IPV programme, the caregiving context was observed and measured along with children's skills and learning across different developmental periods (i.e., early childhood/preschool, and middle childhood). The IPV program include a

harmonious concept of Nurturing Care (Richter et al., 2019) entailed in actions and conditions in a home environment sensitive to multiple health, nutritional, emotional, and developmental needs, and responsive to caregivers' and communities' contexts. The complex and systematic view of development adopted in the IPV program allows the expectation of diverse variables related to gestation, nutrition, education, and parental support, with responsive, stimulating opportunities for play and exploration, and protection from adversity (Richter et al., 2019). As a summary, the main interest of IPV concerns how Colombian children's developmental outcomes are related to home routines and interactions with parents and other caregivers.

2.1.1. Methods in IPV program

The research team in the IPV program includes other PI who is an epidemiology MD specialist and a consulting firm that had much experience of large-scale local survey projects (Sistemas Especializados de Información – SEI) for sample selection and adjustment of initially quantitative instruments. The survey field operations (i.e., observations for developmental screening) were performed by 40 female fieldworkers experienced in not developmental studies at SEI, who were trained directly by the IPV PIs, including the author of the Thesis.

2.1.1.1. Participants

The sample was representative of the population of children in the aforementioned central region of Colombia (Cundinamarca and Boyacá *departamentos*). Only one child per household was selected, in a probabilistic, stratified, clustered sample. It was randomly selected by housing units in each city neighbourhood, using cartographic information from Colombia's National Administrative Department of Statistics. In the case of households with more than one child in the age range of interest, random selection was applied. The sample was representative of the set of municipalities in the region (Error rate: 7.5%; reliability: 95%) and was estimated using epidemiologic-population research criteria (Hajian-Tilaki, 2011), such as usually dictated by feasibility in terms of time and resources (Banerjee & Chaudhury, 2010). The final sample was made up of 1177 children (Table 2.1).

Table 2.1

Sample distribution in complete IPV's characterization study (n=1177)

Category	Cundinamarca n (%)	Boyacá n (%)	Total n (%)
Children under 6 y old.	578 (49.1)	599 (50.9)	1177
Sex			
Female	293 (50.7)	284 (47.4)	577 (49.0)
Male	285 (49.3)	315 (52.6)	600 (50.9)
Age group (months-old)			
0 – 6	59 (10.2)	52 (8.7)	111 (9.4)
7 - 13	63 (10.9)	60 (10.0)	123 (10.5)
14 – 20	67 (11.6)	62 (10.3)	129 (10.9)
21 - 27	48 (8.3)	55 (9.2)	103 (8.8)
28 - 36	72 (12.5)	73 (12.2)	145 (12.3)
37 - 71	269 (46.5)	297 (49.6)	566 (48.1)

Note: Cundinamarca and Boyacá are two *Departamentos* (geopolitical administrative units) in Colombia.

2.1.2. Measurement Methods in IPV's Characterization Study

2.1.2.1. Sociodemographic Survey

A structured survey was designed to obtain information about different variables related to socio-demographic and daily parent-child routines of families with children under 6 years old. The final survey included 158 questions grouped in nine categories, answered by the mother or other primary caregiver. The survey time was approximately 1 hour. After answering the survey, the interviewer asked the mother about the availability of the child and their acceptance to participate in the observation of socio-cognitive development.

2.1.2.2. Sociocognitive Development Observation

The observation of socio-cognitive development was designed by the present author and applied using as reference the items from the Haizea-Llevant screening table (HLL) in children aged 0-36 months-old, used in two large studies with a large sample-size (Fernández & Álvarez, 1989; Iceta & Yoldi, 2002). The original HLL instrument was composed of 270 items, but the Llevant study, applied in health programmes in Spain (Fernández & Álvarez, 1989; Iceta & Yoldi, 2002), redesigned and reduced it to 97 items distributed in four main developmental dimensions or domains, like those found in the Denver Developmental Screening Test and the PDQ. Three- to

four-year-old children were assessed using the HLL observation items and additional tasks related to intra-specific representation systems, or core knowledge systems (Spelke, 2000). The tasks are related to socio-cognitive development (Callaghan et al., 2011), five core knowledge systems of representation, described as:

> "1. inanimate objects and their mechanical interactions, 2. agents and their actions directed at goals, 3. sets and their numerical relations of ordering, addition, and subtraction, 4. locations in a continuous spatial arrangement and their geometric relationships and 5. members belonging to a social group in relation to members of another group and to guide social interactions with members inside and outside of the group" (Kinzler & Spelke, 2007, p.257).

The time taken for the application of all these items and tasks after the survey was a maximum of 1 hour and 30 minutes for each family.

2.1.3. Statistical Analysis in IPV's Characterization Study

Verification and debugging of common coding errors (i.e., syntax error, semantic error, logic error, etc.) in the database was carried out by SEI (Sistemas Especializados de Información). Six observations (cases) suffered from extensive loss of information, so were excluded from the sample. An exploratory analysis was then carried out to observe the characteristics and distribution of the data, perform transformations and examine other aspects such as extreme data, inconsistencies, and deviations. Subsequently, with the data derived from the information collected in the surveys and development evaluations, univariate and bivariate descriptive analyses were carried out by SEI for several composed indices, collecting different variables together with the method of Joint Correspondence Analysis (JCA; Camiz & Gomes, 2013). This method indicated five indices, but only two of them were significantly related to other variables in the regression models: 1) the nutritional index, and 2) the socio-cognitive development index (IDSC). The IDSC is a continuous quantitative variable, which can take any value between 1 and 100 (*M*: 49.7; *SD*: 18.0; Min.: 4.2, Max.: 96.3). The analysis of psychometric properties for the IDSC using the observations from the Haizea-Llevant tool and the individual child as the unit of analysis, produced a Cronbach reliability coefficient alpha for each dimension of between .79 and .93.

IDSC was the dependent variable for regression analysis. A linear regression model was constructed using the stepwise backward methodology, where from a saturated model the analysis tool retained the variables with the highest correlation. With the stepwise backward methodology different combinations of variables were tested, with different adjusted results. All those preliminary analyses were reached by the author of the Thesis and the research team, including other co-PI, with the complete sample were processed in the Stata program, because the license was owned by the other PI's employer. Analysis in this chapter was performed exclusively by the Thesis author using SPSS v25, licensed by the author's employer. Both analyses—the Joint Correspondence Analysis (JCA) with the whole sample using Stata, and the pairwise comparison using SPSS—complement each other by adding to the integrated view of a Nurturing Care framework (Richter et al., 2019) an age controlled (24- to 36-month-old) analysis of particular variables (e.g., the reading frequency reported by parents) directed at the instruments (e.g., Haizea-Llevant) and interventions (e.g., Dialogical Book-sharing) that comprise the following chapters.

2.1.4. Results in IPV's characterization study

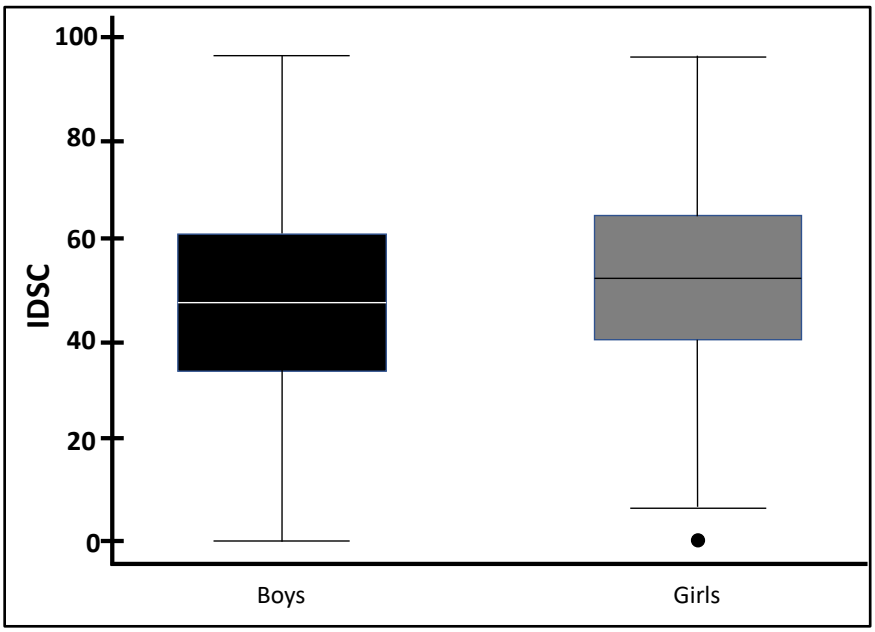
After the mentioned preliminary analysis, the results previous obtained from the complete sample of the IPV program are presented first as a background for the upcoming studies and derived from an academic supervision of the Thesis author in a Public Health Magister Study (Diaz, 2016), for Universidad de los Andes (Colombia). After general results for the entire sample, a new and not published analysis with the 24- to 36-month-old subsample (n = 197) includes sociodemographic description, caution, and delay indicators, reading frequency at home, and various correlations, all limited to this age group.

2.1.4.1. Complete IPV sample results

Across the whole sample (N = 1177) there were significant positive correlations of age (r = .26, p < .001) with the index of socio-cognitive development (IDSC). Also, a Mann-Whitney U test showed that there was a significant difference between boys and girls (U = 1448, p < .001, r = .14); on average, girls obtained 4.7 more points in the IDSC than boys (Fig. 2.1).

Figure 2.1.

Boxplot of socio-cognitive development index (IDSC) according to sex of all participating children (N=1177).



Note: IDSC = Socio-cognitive development index.

The final regression model contained 14 variables measuring different health, wellbeing, and demographic dimensions, which together explained a statistically significant amount of variance in the IDSC (F[37, 229] = 26.27, $p < .001$, $R^2 = .20$). The model obtained by stepwise backward methodology indicate a different combination of variables not only statistically tested, but coherent with a rationale analysis of ecological validation in a nurturing care framework described before in 1st chapter. As example, the rationale includes the consideration of the participants answer about the child's autonomy, with the control group of answers in the option with high level of autonomy: “Children has own opinion and, they can make their own decisions”. A difference between parent-child dyads who performed positively on these variables, and parent-child pairs who did not, with up to 7.5 points of difference in the IDSC. Fourteen variables were related to the IDSC (Table 2.2).

Table 2.2

Variables associated with the Index of Sociocognitive Development (IDSC) of children of under 6 years of age in Cundinamarca and Boyaca, n=1171.

Factor in lineal regression model associated with IDSC	β	*p*-value	Reliability rank (95%) Min to Max.	
Sociodemographic information				
(1) Male	-3.71	.014	-6.66	-0.77
(2) Caregiver with undergraduate or post graduate formation	4.66	.007	1.31	8.0
Prenatal, labour and birth information				
(3) Four or more prenatal care-health check-up	7.54	.022	1.10	13.98
(4) Extended give birth process (>12 hours)	-4.24	.014	-7.63	-0.86
Child nutrition related information				
(5) Gives solid food to child before 6 months-old	-10.4	.032	0.93	20.03
(6) Feeding by someone else	-5.18	.001	-8.31	-2.06
Parent's gestation-time information				
(7) Mother's alcohol frequent consumption during gestation	-14.9	.029	-28.36	-1.56
(8) Father employed during gestation	4.06	.043	0.13	7.98
Preschool attendance information				
(9) Attending an educational or caregiving community home or kindergarten: *YES*.	4.25	.007	1.18	7.31
(10) Attending an educational or caregiving community home or kindergarten: *private kindergarten*.	7.43	<.001	3.76	11.10
Daily activities with parents				
(11) Observed counting activity at home: medium	-6.07	.001	-9.60	-2.54
(12) Observed counting activity at home: low	-5.87	.001	-9.44	-2.30
(13) perform physical activity outdoors with their parents in last seven days	4.29	.001	1.70	6.88
Parents beliefs about children autonomy*				
(14a) "Children has own opinion, but can't take decisions"	-6.44	.018	-11.75	1.13
(14b) "Children has own opinion, but take decisions according to grown stage"	-8.06	<.001	-12.18	3.94
(14c) "Children has not own opinion and can't take decisions"	-11.6	.014	-21.0	2.35

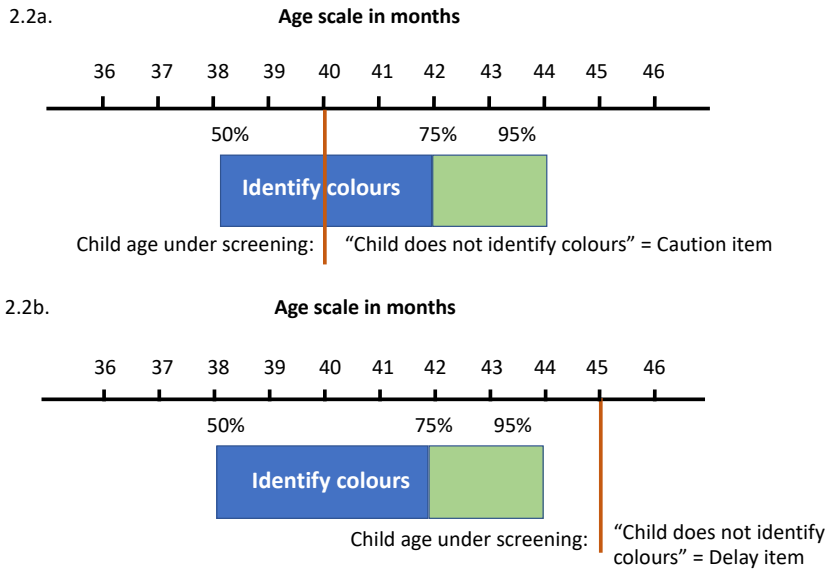
Note: *R-squared* = 0.20. Source: Díaz (2016). *: For the parent's beliefs about the child's autonomy, the control group are answers with the option: "Children has own opinion and, they can make their own decisions" (high level of attributed autonomy).

The higher positive effect (β = 7.54; p = .022) was founded on the quality of gestation and the birth process (i.e., children of mothers who reported more than four prenatal controls and no complications in the process of giving birth). The highest negative effect was for the report of mothers who frequently consumed alcohol during gestation (β = -14.96; p = .029). After the general results as a background for the thesis, the main research question in this chapter is related to the 24- to 36-month-old group (n = 197). To answer the question, we use caution and risk indicators and reading habits reported by parents.

The individual developmental performance score is defined as the number of age-appropriate test items of a domain in HLL that a child can successfully pass or not. For nominal classification, a "Caution" is recorded when an age-appropriate item is not passed. If the child is older than the limit age for the 95% of the standardisation population passing the item, and does not pass it, that item is recorded as a "Delay". As example for a real HLL item ("Identify colours") in the domain of language and logic-mathematical reasoning: if a child is 40 months old and does not identify colours when these are pointed out by the interviewer, this is interpreted as a "Caution" item (Fig. 2.2a); if a child is over 44 months old and does not identify colours during the observation with the HLL, this is interpreted as "Delay" item (Fig. 2.2b).

Figures 2.2a – 2.2b.

Examples of Caution and Delay answers in "Identify colours" item in Haizea-Llevant



The counting of Caution and Delay items enables scoring of the overall test and helps the interpretation of the screening, permitting additional evaluations and referrals as appropriate (Vitrikas et al., 2017). For nominal classification of the results, if the child at least one Delay item or at least two Cautions, he/she would be classified “At risk”. No Delay answers and just one Caution answer would lead to a classification of “Passing”. Henceforth, we classify those participants “Passing” the HLL as “Not at risk”. For developmental domain analysis, values were scored following a recent approach for the Denver II test, using an analysis of the distribution of items in the Haizea-Llevant tool according to age (Drachler, Marshall, & de Carvalho, 2007; Lopez-Boo, Cubides-Mateus, & Llonch-Sabatés, 2020). A quantitative coefficient for continuous variable analysis in the HLL was obtained by scoring the Delayed items as minus one point (-1) and Caution items as zero (0) and totalling the result. A Positive answer or performance in Haizea-Llevant is scored with one point if child’s performance is equal to or better than that of 50% or more of the standardization population for their age.

2.1.4.2. Sociodemographic characteristics of 24-36 months-old group (n=197)

The 24- to 36-month-old group represent 16.7% of the total IPV sample. Their sociodemographic characteristics will be used as a baseline for sample selection in the following chapters (Table 2.3).

Table 2.3

Characteristics of the sample for 24-36 (n=197).

Average age	
30.1 Months (*SD*=3.56)	
Sex of the child	***n (%)***
Female	85 (43.1)
Male	112 (56.9)
Principal caregiver (PC)	
Mother	139 (70.5)
Relative at home	43 (21.8)
Relative out of home	9 (4.56)
Non-relative at home	4 (2.03)
Non-relative out of home	2 (1.01)
PC educational level	
Incomplete elementary	14 (7.11)
Elementary	22 (11.2)
Incomplete high school	41 (20.8)
High school	65 (32.9)
Technician	26 (13.2)
Incomplete undergraduate	10 (5.08)
Undergraduate	14 (7.11)
Postgraduate	5 (2.54)
Maternal Employment	
Employed	174 (88.3)
Unemployed	23 (11.7)
Type of settlement	
Urban	181 (91.8)
No urban	16 (8.12)
Socioeconomic national scale^{+}	
Very low: Less than 4.5 USD by day	40 (20.3)
Low: More than 4.5 USD but less than 10.0 USD by day	113 (57.4)
Moderate low: More than 10.0 USD but less than 15.0 USD by day	42 (21.3)
Medium-low: More than 15.0 USD but less than 20.0 USD by day	2 (1.02)

Notes: $^{+}$: Different sources help to an approximate calculus of this levels (Sanchez-Torres, 2015; MESEP-DNP, 2011)

2.1.4.2.1. Reading Frequency reported by parents and prevalence of possible developmental delay (At risk condition)

The Haizea-Llevant tool application suggested that 59.8% (n = 116) of the 24- to 36-month-old subsample might be at risk. Therefore, according to Haizea-Llevant, those children are candidates to evaluate in detail the presence of any possible developmental delays. Due to the small sample and for pairwise comparison, the reading frequency reported by parents follows Kalb & Van Ours (2014) and Goldfeld et al. (2021) dichotomized distribution for the 24- to 36-month-

old children analysis: 1) One with a maximum of two days per week reported reading (n = 168), and 2) Other with three or more days reported reading (n = 26).

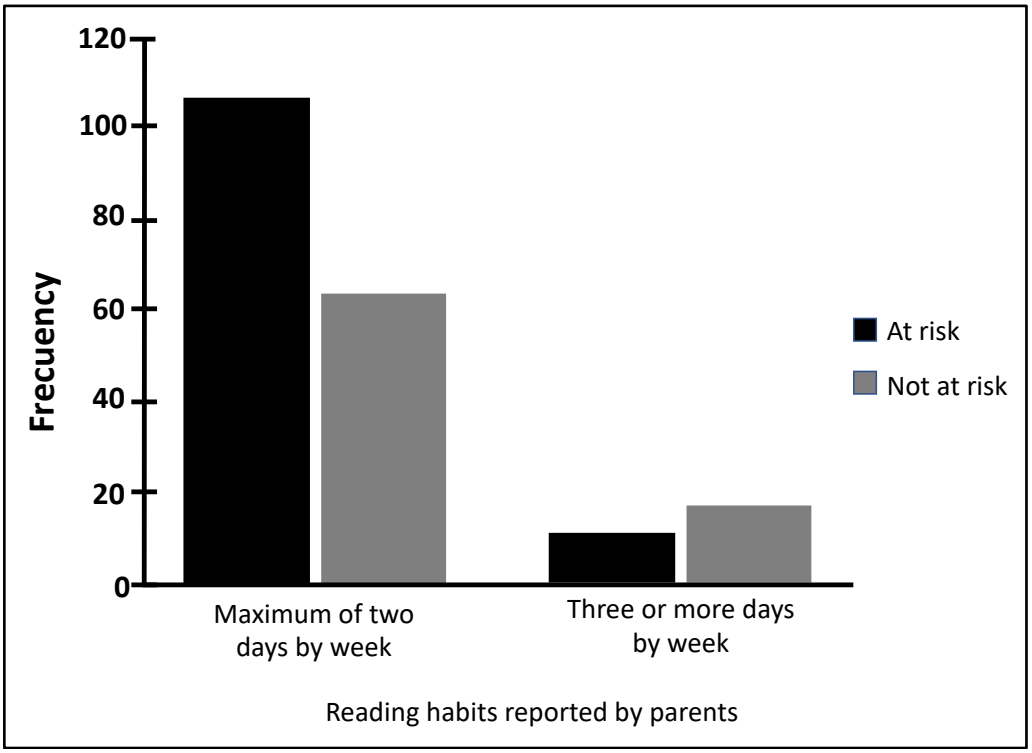
Three children were excluded because their caregivers did not properly answer the question and selected two or more options in the scale. The group with a maximum of two days per week reading reported presented a higher proportion of children at risk (63.1%). In contrast, the group with three or more days per week of reading reported had a lower proportion of children at risk (38.5%).

2.1.4.2.2. Correlation Between "At Risk Condition" with Reading Frequency Reported by Parents.

To determine whether a difference was present in the reading frequency group between At risk or Not at risk condition (Fig. 2.3), a chi-square test was conducted. This statistical procedure was viewed as the optimal one to use because frequency data were present for the reading frequency group and for the At-risk condition. As such, chi-squares are the statistical procedure of choice when both variables are categorical. In addition, the available sample size per cell was more than five. Therefore, the assumptions for utilizing a chi-square were met. The result was statistically significant, indicating a difference in the proportions of children in the "At risk" or "Not at risk" conditions in the aforementioned groups based on reading habits, $\chi(1) = 5.683$, $p < .05$, $\Phi = .171$. The effect size for this finding, Cramer's V, was small (Cohen, 1988).

Figure 2.3

Children 24-36 months old in At risk or Not at risk condition in two groups of reading days by week reported by parents (n=194).



2.1.4.2.3. Caution and Delay Indicators with Reading Frequency Reported by Parents in 24 – 36.

A Mann-Whitney U test showed that there was a significant difference in Caution items using Haizea-Llevant (U = 2070, p = 0.011, r = .20) between the reading reported group of maximum two days reading (*Median*=2) compared to the three or more days reading group (*Median*=1). No differences were founded between these groups for Delay items.

2.2. Conclusion

The first research question (RQ#1) (Are reports of reading daily activities by parents related to caution and delay detection in a children developmental screening?) was addressed by data obtained in the IPV data collection. The IPV data-variables in the model referred to sociodemographic, gestational, nutritional, educative, and parental characteristics that supported

the multidimensional nature of child development (Bornstein et al., 2017; Lewkowicz, 2011; Richter et al., 2019). But our main concern, the Nurturing Care components of Responsive Caregiving and Early Learning (Richter et al., 2019) are clearly identified in the previous IPV analysis included in this chapter.

A clear background for an answer to RQ#1 is in the results daily activities reported by parents in counting and outdoor physical activities that negatively influenced the developmental index score, when medium or low frequency was compared with high frequency. Also, beliefs of parents about autonomy of their children might impact the parent-child interactions at home (Bindman, Pomerantz & Roisman, 2015; Soenens, Deci, & Vansteenkiste, 2017). The positive benefits of more observation and autonomy-supporting interactions between parent and children was evident for children's academic achievements in elementary school as well as high school (Bindman et al., 2015; Soenens et al., 2017). Most importantly, these interaction and daily activities and supportive characteristics of parents are affected by sociodemographic, gestational, nutritional, and educative variables as well. Also, the analysis of reading habits in the specific segment of 24- to 36-month-old children reveals the sensibility to parental activities of children's developmental screening status.

Our results maintain the orientation about the clear evidence for the importance of the home literacy environment for children's development and the beneficial effect expected in early interventions with parents (Goldfeld et al., 2021; Neri et al., 2021). Furthermore, the literacy promotion at home and in early education programmes for increasing the frequency of parental interactions should anticipate the pre-school attendance of disadvantaged children by conditions of poverty or other vulnerability.

However, limitations like the small sample of participants should warn us of any generalization to other age groups, communities, or different income backgrounds. Indeed, another limitation arises from the more than a decade passed from recollecting the data and not including the educational, economic, or social effects of the COVID-19 pandemic. Consequently, the not robust analysis of sociodemographic variables might be excusable on insufficient information about how they could be affected by different kinds of extrinsic and intrinsic reading variables (Suárez-Fernández & Boto-García, 2019). For example, the analysis of reading motivation guided by intrinsic and extrinsic variables requires the measurement of internal satisfaction and the material goals imposed to pass an examination or demand in a job. Also, the genre of the books

modifies the Parental book-sharing styles (Noble et al., 2019; Potter & Haynes, 2000) and, probably, the reading habits of the household (Leyva et al., 2021). Better conclusions might be obtained if the information or experimental controls allow the comparison between narrative and non-narrative books (Noble et al., 2019). Likewise, child temperament and other intrinsic characteristics of children (e.g., extraversion, negative reactivity) should be important to better conclusions about the reported habits at home and the risk of developmental conditions in vulnerable families and communities (Leyva et al., 2021).

A particular interest in the objectives of this thesis is the effect that a parental report might have on child development, adding some understanding that support the use and integration of a particular tool (i.e., CARE) in interventions for caregivers' knowledge about specific developmental milestones and skills to facilitate communication, surveillance or monitoring universally recommended (Mahadevan & Broaddus-Shea, 2020), but for children at risk of not reach all their potential. Also, not all tools for screening have enough considerations for feasible parental use or enough congruence for validation features (Boggs et al., 2019). The following chapter aims to determine if a screening report using a tool administrated by parents can have sufficient psychometric and congruence features to be used in the detection of children at risk of not reaching their developmental potential in an LMIC.

Chapter 3. Agreement and Reliability of Parents' Report and Direct Screening of Developmental Outcomes in Toddlers at Risk in a Low and Middle-Income Country (LMIC).

Attention to screening tools in LMIC settings has grown recently. However, only population-level tools (i.e., instruments for monitoring countries or regional status) have been shown to have acceptable accuracy, reliability, and feasibility for routine use in health and educational systems (Boggs et al., 2019). Individual-level tools (i.e., instruments to measure cases or single participant assessment) are not frequently reported to have utility in planning for direct early interventions. Optimal monitoring to planning and direct early interventions requires screening tools that include concepts coming from the Nurturing Care Framework (Britto et al., 2017; WHO, 2020). The Nurturing Care Framework has inspired a considerable literature for early interventions in LMICs (Trude et al., 2021). Reviews of previous screening and surveillance projects around parenting effects on children development, shown how high nurturing interventions reduce negative effects of scarce and adverse environments (Lu et al., 2020; Tann et al., 2021). However, there is no complete or permanent programme in an LMIC that ensures constant and relevant evidence-based approaches to monitoring and assessment of child development or nurturing status (Milner et al., 2019). Also, several barriers to the identification of developmental delay using tools adapted for LMICs have recently been reported (Faruk et al., 2020) and difficult optimal monitoring and assessment programmes. Along with monitoring, even in high income countries, indicators and information to design interventions and programmes to reduce social and educational inequity are incomplete (NASEM, 2019). The NASEM report showed how, before the COVID-19 pandemic, standard health information systems needed improvements in research and data sources, to fill important gaps in knowledge about child intervention programs to identify promising program features to implement effectively at scale. For example, in the U.S., programmes like the Medicaid program and the Children's Health Insurance Program, with expenditures of more than $90 billion directed at children (Barker & Li, 2020), would not show their positive effects for families and children in poverty without the data from the Panel Study of Income Dynamics (PSID). The original aim in 1968 of the PSID was the study of the dynamics of income and poverty, with an oversample of 1,872 low-income families and a nationally representative sample of 2,930 households designed by the Survey Research

Center at the University of Michigan (McGonagle et al., 2012). The same efforts for having similar PSID information systems are needed in getting accurate information including a call for action through developmental monitoring and screening in LMICs (Goldfeld & Yousafzai, 2018). Increasing developmental monitoring and screening of children's outcomes can optimize early intervention referrals, assessments, and eligibility (Barger, Rice, Wolf, & Roach, 2018). There needs to be a sustainable improvement in numbers of referrals of children for early interventions in such countries, with large numbers of children at risk of not reaching their developmental potential (Black et al., 2016). Improved measurement in early child development (ECD) is feasible, but several coverage and quality characteristics remain unreachable for interventions in LMICs (Milner et al., 2019): namely that interventions are made simpler and more routine and include multi-domain outcome measurement. However, the cost of hove visits to obtain the monitoring and screening of children's outcomes made unsustainable for that kind of long-term initiatives in Latin American LMICs (Baker-Henningham & López-Boo, 2013). That a reason to ponder the parent-completed tools (henceforth PCT) and the direct observation tools (henceforth DOT) administrated by parents.

3.1. Development Screening Tools by Parent Rating and Completion

A parent-completed tool (PCT) is usually a specific questionnaire which elicits past observations of activities and skills in children. Parental report measures have reliable and valid conditions comparable with tools administered by professionals in many health dimensions (Boggs et al., 2019; Chung et al., 2016).

If PCTs are administered as questionnaires, like the Ages and Stages Questionnaire or ASQ (Squires, Bricker, & Potter, 1997), two broad default assumptions follow (Stone, 1993):

1. The research situation *per se* does not influence the nature of the answers given by respondents.
2. The process of answering questions *per se* does not change the respondents' beliefs, opinions, habits etc.

If individual developmental change is a goal, Stone's (1993) assumptions direct us beyond questionnaires limitations to adapt and modify actions or activities related to individual development previously identified using the tool. A PCT, like any questionnaire, is not a flexible enough device to consider the improvement of at-home interactions; nor, consequently, to

privilege the enhancement of parenting strategies and learning activities at home. PCT characteristics do not include intuitive or adaptable components for inclusion in daily activities and proximal process to report time dedication or quality in children and caregivers' interactions.

Also, when it is administered by parents, the inevitable features of any PCT may cause it to be seen as a "test", leading to possible concerns in caregivers about being judged, and the appearance of the assessment as an unnatural scenario (Bennetts, 2017), raising worries about demand characteristics and hence possible distortion in its completion (Kendall et al., 2014). Nonetheless, Vitrikas et al. (2017) considered that PCTs entail two important elements of the patient-centred medical home practices: they engage parents as active participants in their child's health and facilitate the parent-child-physician relationship. However, further research needs to be done to support or reject Vitrikas et al.'s (2017) affirmation.

3.2. Development Screening Tools by Direct Observation

A direct observation tool (henceforth DOT) for development screening helps to screen activities and instructions to determine presence or absence of specific behaviours and skills, according to a child's age. These specific behaviours and skills can be developmental milestones, and different DOTs use different methods to include and validate the "universality" of milestones (Wilkinson et al., 2019). Examples of DOTs include the Denver Developmental Screening Test (DDST; Frankenburg, 1987; Frankenburg et al., 1976), the Kent Inventory of Developmental Skills (Reuter, Katoff, & Gruber, 1996), and the Early Report by Infant Caregivers (ERIC; Schafer et al., 2014). The structure of DOTs, such as the DDST, can help parents and caregivers to maximise opportunities for enhancing individual developmental status through monitoring more effective interactions (Dosman, Andrews, and Goulden, 2012; Fischer et al., 2014). This individual enhancement with DOTs in children in poverty or psychosocial deprivation can be explained using the operation of a general socio-cognitive mechanism such as "scaffolding" in our view described before ("1.7. Definition of Scaffolding adopted in the Thesis", p.21) and more concretely through parental involvement using home-based learning (Magwood et al., 2019; Veas et al., 2019).

But in LMICs, caregiving contexts for optimal developmental conditions are not frequently or consistently measured (Bornstein et al., 2017; Walker et al., 2007), and numerous harmful effects of economic deprivation on children's potential might be mitigated by enhancing parental interactions because of better interventions. Home-visit interventions now need also to take in

account the disruption caused by the COVID-19 outbreak (Guan et al., 2020). Screening and direct interventions need several adaptations to enable remote access. Sanitary and public health measures like social distancing should impact home visits and long-term, scalable actions after the pandemic in LMICs and might include parent-handled reports as remote screening tools. However. remote screening still has some unique challenges associated with obtaining accurate developmental data in early childhood, especially in LMICs and families in poverty conditions (Lu et al., 2020). The Early Childhood Development Index (ECDI), for example, is a 10-question survey used in the Nurturing Care Framework to determine whether children are on track in their cognitive and social-emotional development (Richter et al., 2017; 2019). For global, national, and regional level, ECDI information is fundamental, but high-quality and comparable data for individual developmental status is not fully captured by developmental surveys or questionnaires (McCoy et al., 2016; 2018; Lu et al., 2020). Parental reports are a high-quality, reliable alternative to obtaining individual child information via home visits.

3.3. Parents Report with CARE

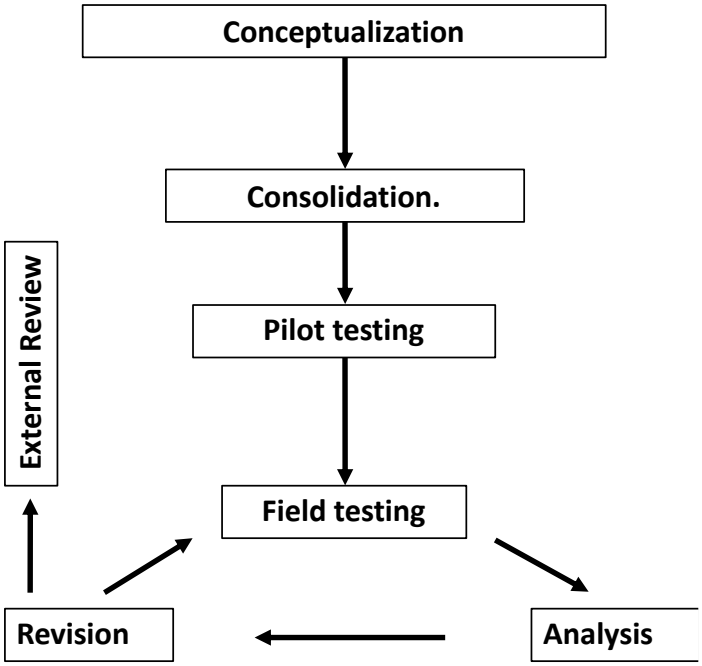
We define 'parent report' in this chapter as information obtained from a parent using CARE®. The Compilation of Activities to Report and Enhance development (CARE) is a booklet created to obtain information of daily activities of interaction between parents or caregivers with children. The main content of CARE includes activities to report developmental milestones in the four domains mentioned previously (Personal-Social, Language and logico-mathematical reasoning, Fine motor-adaptive, and Gross motor skills), for two age groups: 24- to 35-month-old and 36- to 59-month-old. Every item in CARE is closely related to one item in the Haizea-Llevant Table (Iceta & Yoldi, 2002). As described above, the Haizea-Llevant screening table (HLL) is a developmental screening tool derived from the Denver Developmental Screening Test (DDST) and the Denver Pre-screening Developmental Questionnaire (Frankenburg, 1987; Frankenburg et al., 1976).

The HLL items included in CARE and the whole designing process follow the components recommended by Nadeem et al. (2016) for construction and validation of assessment tools. Conceptualization and consolidation phases (Fig. 3.1) were realized in the IPV (*Inicio Parejo de la Vida*, "Equal Start in Life") program described in previous chapter. The present chapter

describes pilot testing of CARE comparing with the HLL, including reliability and agreement analysis.

Figure 3.1.

Components in a flowchart for a tool construction-validation process.



Notes. Source: Nadeem et al. (2016, p. 2). Conceptualization and consolidation phases were described in previous chapters (1st and 2nd Chapters). Present chapter described a pilot testing before a Field testing with CARE.

3.4. Agreement Measurements of Parent Reports and Direct Assessments

Parental reporting and direct assessment are currently the two main methods used to evaluate child development (Miller, Perkins, Dai, & Fein, 2017). Miller et al. (2017) remark on the need to determine reliability and agreement in parental reports in the early detection of developmental delays, comparing these with direct assessments as a quality control procedure. Comparison between parent reports and medical health records or direct testing with equivalent tools (e.g., the Vineland Adaptive Behaviour Scales vs. the Mullen Scales of Early Learning) indicates variable but significant agreement in specific and general measurements of skills (Miller

et al., 2017). Agreements in language production and comprehension, gross motor functioning and fine motor skills were reported in previous research (Miller et al., 2017; Nordahl-Hansen et al., 2014; Sachse & Von Suchodoletz, 2008). Also, no significant main effect of maternal education or other sociodemographic variables was reported for agreement measures (Miller at al., 2017).

In a framework for optimal quality in early childhood assessments, reliability, and agreement (R&A) studies are often expected (Vanbelle, 2017). R&A studies provide information about the quality of measurements, specifically about the ability of a scale to differentiate between the items, despite the presence of measurement error (reliability); and, about the degree of closeness between two assessments made on the same items (agreement). Good levels of R&A are essential for new measurement tools if they are to be included in clinical decision making and subsequent interventions (Vanbelle, 2017). R&A application may relieve technical concerns about the accuracy of parental reporting (Bennetts et al., 2016; Miller et al., 2017). Parents are an important source of information regarding child skill deficits and atypical behaviours, because they are uniquely positioned to observe and interact with children across various daily interactions at home (Jeong, Siyal, & Yousafzai, 2019). Also, for developmental monitoring (i.e., healthcare professionals' practices to make informed clinical judgments about children's developmental progress based on their own criteria) parent reports might be included to help identify children at risk (Barger et al., 2018; Gellasch, 2019). Developmental monitoring practices with parent reports for individual developmental status and later diagnostic testing may be shorter to administer, thereby reducing costs and increasing developmental delay identification in the regular health visits at 9, 18, and 24–30 months (Vitrikas et al., 2017; Gellasch, 2019; Miller et al., 2017).

Unfortunately, even in high-income countries, only a small proportion of children regularly receive developmental monitoring in health systems, preventing the detection of early delays and subsequent interventions (Barger et al., 2018). The COVID-19 pandemic may have exacerbated adversity and imposed still more barriers to the optimization of developmental monitoring (Richter et al., 2020; Trude et al., 2021), making parental reports valuable tools for identifying individual children's developmental status.

The present study aims to evaluate consistency between two sources of information—direct assessment and parent report—when classifying at-risk children and measuring child development in four domains: Personal-Social, Language and logico-mathematical reasoning, Fine motor-

adaptive, and Gross motor skills. The current and following chapters will be used as the pilot testing phase for future field testing of CARE. The aims of the current study are threefold:

1. Examine consistency between CARE and HLL classification and scores in the domains of Personal-Social skills, Language and logico-mathematical reasoning, Fine motor-adaptive and Gross motor skills. We expect to find similar results to prior research showing good agreement between parent report and direct testing of social, language and gross motor skills, but somewhat weaker agreement in fine motor skills (Miller et al., 2017).
2. Explore the diagnostic characteristics and performance of CARE as a tool for developmental screening using parent reports, with item agreement analysis at the individual level between parent reports and direct assessment in particular domains, as set out above.
3. Obtain relevant data to identify the validity of CARE, with feedback of the findings to both academic and institutional administrators engaged in participant enrolment.

It is important to note that the parental administration method does not profess to replace any clinical or scientific intervention and will presumably run in parallel with other previously existing or subsequently developed screening and intervention methods for health and educational systems.

3.4. Method

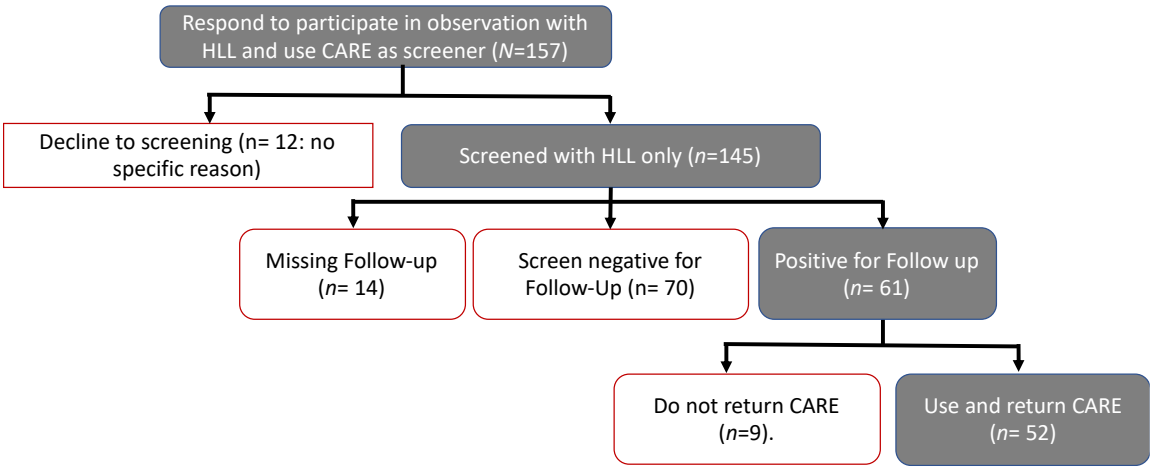
3.4.1. Participants

Participants were dyads of toddlers and principal caregivers recruited at a Children's Centre (CC) pertaining to a community-level social support intervention which was part of a wider government-funded and mandatory nutritional programme (Nores et al., 2019). The study's catchment area included an urban population vulnerable to poverty, in the north-west of Bogotá, Colombia. One hundred and fifty-seven families initially responded to a call to participate in a study of tools for a future cognitive intervention and completed documentation for informed consent (Fig. 3.2). All children were screened using the Haizea-Llevant (HLL) screening table (Iceta & Yoldi, 2002). After a first screening with HLL, 61 dyads were positive for follow-up but nine of them do not return the CARE booklet after a month and two direct calls to parents asking

for a meeting at CC or a home visit. Some 52 caregivers out of these 61 dyads returned the CARE booklet after using it as a screening tool at home.

Figure 3.2

CONSORT diagram for participants called for screened with the Haizea-Llevant screening table and to use CARE at home.



Note. HLL = Haizea-Llevant; CARE = The Compilation of Activities to Report and Enhance development booklet. One-month pass between the positive Follow-up and the caregivers return of CARE booklet used as screening tool.

The sample included all families who satisfied the following criteria: 1) They had at least one pre-school child (aged 59 months or younger); 2) they were currently in a couple, unless it was unfeasible to talk with one partner (e.g., partners who travelled a lot, widows, divorcees); 3) they understood written and spoken Spanish; and 4) they were willing to receive a CARE booklet and use it as a screening tool, to the best of their capabilities. Sociodemographic characteristics of the sample are given in Table 3.1.

Table 3.1

Characteristics of the sample for validation of CARE (n=52).

Sex of the child	***n (%)***
Female	23 (44.2)
Male	29 (55.8)
Age group	
24-35 months old	9 (17.3)
36-47 months old	25 (48.1)
48-59 months old	18 (34.6)
Principal caregiver (PC)	
Mother	29 (55.8)
Relative at home	9 (17.3)
Relative out of home	5 (9.6)
Non-relative at home	2 (3.8)
Non-relative out of home	1 (1.9)
No answer	6 (11.5)
PC educational level	
No school experience	1 (1.9)
Incomplete elementary	6 (11.5)
Elementary	5 (9.6)
Incomplete high school	2 (3.8)
High school	18 (34.6)
Technician	9 (17.3)
Incomplete undergraduate	1 (1.9)
Undergraduate	3 (5.8)
Postgraduate	1 (1.9)
No answer	6 (11.5)
Maternal Employment	
Employed	34 (65.4)
Unemployed	12 (23.1)
No answer	6 (11.5)
Type of settlement	
Urban	39 (75.0)
Non-urban	4 (7.7)
No answer	9 (17.3)
Socioeconomic national scale^{+}	
Level 1 Very low: Between 1488-1606 US Dollar by year or less.	13 (25.0)
Level 2 Low: More than 1606 US Dollar by year but less than one national minimum wage (3.751 USD per year).	19 (36.5)
Level 3 Medium low^{++}: less or more than one or two national minimum wage as household income.	14 (27.0)
No answer	6 (11.5)

Notes: $^{+}$: Income are exchanged to US dollars in Jul/2020; $^{++}$ Different sources that keep validity to present household/income stratification in Colombia, help to an approximate calculus of this levels (Sanchez-Torres, 2015; MESEP-DNP, 2011).

3.4.2. Measures

Each dyad was interviewed and received:

1. Sociodemographic information survey (The Questionnaire for Parents and Caregivers General Data; Giraldo-Huertas, Cano, & Pulido-Alvarez, 2017; Profamilia, 2010).
2. The Haizea-Llevant screening table (Iceta & Yoldi, 2002).
3. The CARE booklet.

3.4.2.1. The Questionnaire for Parents and Caregivers General Data (GDQ).

The GDQ was used in the IPV (*Inicio Parejo de la Vida*—Equal Start in Life) program (Giraldo-Huertas et al., 2017) and contains the 14 variables associated with the socio-cognitive development of children of under six years of age in the geographic region of interest, including items from the ENDS (*Encuesta Nacional de Demografía y Salud*—Colombian National Survey of Demographics and Health; Profamilia, 2010). The GDQ comprises 68 questions in 8 modules which obtain data about the social, demographic and health characteristics of children under six years old and their families (Appendix C). All questions were answered by the mother or primary caregiver of each child. The survey took approximately half an hour per participant.

3.4.2.2. The Haizea-Llevant (HLL) screening table.

The Haizea-Llevant screening table (HLL) mentioned before (Fuentes-Biggi et al., 1992; Iceti & Yoldi, 2002; Rivas, Sobrino, & Peralta, 2010), was used by the research team for individual assessment of children. The individual developmental performance score is defined as the number of age-appropriate test items of a domain in HLL that a child can successfully pass or not. For nominal classification, a "Caution" is recorded when an age-appropriate item is not passed. If the child is older than the limit age for the 95% of the standardisation population passing the item, and does not pass it, that item is recorded as a "Delay". The counting of Caution and Delay items enables scoring of the overall test and the nominal classification of the results, if the child at least one Delay item or at least two Cautions, he/she would be classified "At risk". No Delay answers and just one Caution answer would lead to a classification of "Passing". Henceforth, we classify those participants "Passing" the HLL as "Not at risk". A quantitative coefficient for continuous variable analysis in the HLL was obtained by scoring the Delayed items as minus one point (-1)

and Caution items as zero (0) and totalling the result. A Positive answer or performance in HLL is scored with one point if child's performance is equal to or better than that of 50% or more of the standardization population for their age.

3.4.2.3. The CARE Booklet

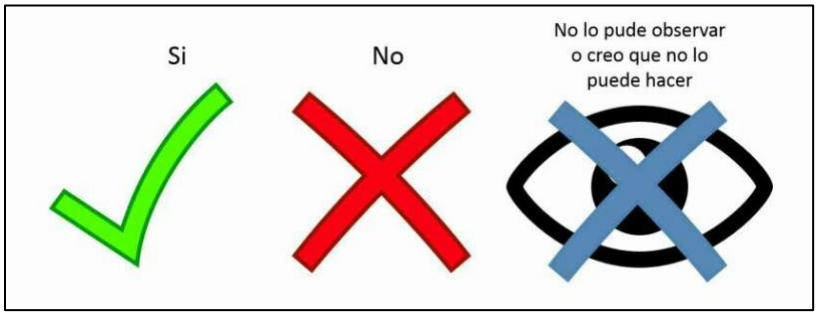
Parents received a CARE booklet to be used as a screening report. The report consists of a mark over an icon (Fig. 3.3.), for which the parent or caregiver chooses *Sí* ("Yes") if the skill or behaviour was observed in interaction with the child, *No* if the skill or behaviour was not observed in interaction with the child, or *No lo pude observar o creo que no lo puede hacer* ("I couldn't observe it or I believe they can't do it") if the parent did not have an opportunity to observe if the skill or behaviour were attainable by the child. The two options falls under the same question because the main intention with the booklet is the report of interactions, not recalls or beliefs about the children's skills. The components of the CARE booklet keep the same domains but vary in the complexity of items between 24-35 months old and 36-47 months old. The content for 36- to 47-month-old children is the same as for 48- to 59-month-olds. The CARE instrument has 47 items in four domains comparable with the HLL observations: a) Personal-Social (11 items), b) Language and logico-mathematical reasoning (20 items), c) Fine motor-adaptive (9 items), and d) Gross motor (7 items). It also includes an exploration of socio-cognitive development in context, in the use of Core Knowledge Systems (Callaghan et al., 2011; Kinzler & Spelke, 2007). The "Core Knowledge" components inquired with CARE are related to spontaneous and autonomous play, counting, geospatial orientation, age-pair interactions, and outdoors activities. The Core Knowledge components used do not differ between each age-group booklet. The nominal classification and agreement analyses do not include the Core Knowledge components, because they are not comparable with any of the HLL contents.

We followed the HLL scoring system for nominal classification with CARE results. However, after direct commentaries from users about misinterpretation in the use of the "I cannot observe it, or I believe he/she cannot do it" option (e.g., "I did not check any option because sometimes he/she can do it, but not always"; "I did not see if he/she can do it, but grandpa said he/she can"; "he/she cannot do it right now, but I watch if before"), decide to include an arbitrary range for the not reported interactions when parents choose it: if the child at least one Delay or at least two Cautions or at least four unanswered items, he/she was classified "At risk". 'No Delay'

answers or less than two Cautions or ≤3 not answered items he/she would be classified as 'Not at risk'. A quantitative coefficient for continuous variable analysis in CARE performance was obtained by scoring the Delayed items with -1 and Caution items with 0. A positive answer or performance in CARE was scored with 1 point.

Figure 3.3.

Report icons of parent-child interaction in CARE booklet.



3.4.3. Procedure

Children who screened positive for risk in a first screening participated in a follow-up HLL screening at Children's Centres (CC). The agreement with the CC for access to their families includes the exclusive follow-up for those who screened positive for risk as a part of the strategic-attention agenda of the CC for the first year of joint activities with the Thesis author and the caregiving personnel. Also, the CC only attends families where at least one family member (e.g., mother, father, grandparents, close relatives) assists with the time and location called for research and caregiving activities. The CC rule about the constant presence of one familiar or close relative excludes single-parent families who can receive similar caregiving services in other facilities and CCs in the same neighbourhood.

The follow-up was performed by three trained assessors in an individual meeting with caregivers and children. During the HLL screening, one of the assessors applied a survey to obtain sociodemographic information. Survey and screening application lasted less than 30 minutes. For children who screened positive in the initial session, a member of the research team contacted caregivers in the CC to administer the follow-up screen using HLL. A licensed psychologist then

checked that assessors had completed all evaluations and proceeded to deliver a copy of the CARE booklet. Parents watched an instructional two-minute video on how to report children's activities using the CARE booklet. Families were instructed to carry out the activities and return the booklet as soon as possible but not less than one month after receiving it. After they had watched the video with the reporting instructions, the CARE booklet was delivered to the caregiver with the following items in a toy bag for each child: five wooden cubes, two hand puppets, a small plastic ball, one maraca, a pre-schooler's set of scissors, six crayons of different colours, and a pen with lid. Specific indications were given to parents to administer all items at home, and they were advised not to worry if their child did not complete them all. All children were screened in their primary language, Spanish.

The review board at the Faculty of Psychology (*Facultad de Psicología*) and the General Directorate of Research (*Dirección General de Investigaciones*) of the Universidad de la Sabana granted ethical approval for the study (Acta CAG #1517 of 19/11/2015). Permission for data collection was granted in agreement with the legal ruling of Resolution Nº 008430 of 1993 of the *Ministerio de Salud de la República de Colombia* (Health Ministry of Colombia), which sets out ethical, scientific, technical, and administrative norms for research activity with human participants. At the time of screening, parents were given an information sheet describing the larger original study. Consent for participation in the research project was indicated by completion of the sociodemographic survey, prior to inclusion in the current study.

3.4.4. Analysis

The analyses used average-based change statistics (ABCs), such as Cohen's *d* or Hays's ω^2, to evaluate changes in distributions, and individual-based change statistics (IBCs), such as the Standardised Individual Difference (SID) or the Reliable Change Index (RCI), to evaluate whether each case in the sample experienced a reliable change (Estrada, Ferrer, & Pardo, 2019; Clifton & Clifton, 2019). The standardization of measurement differences was used to calculate the net percentage change index (i.e., 100 x [CARE score – HLL score] / [HLL score]). Primary analyses included mixed design analysis of variance (ANOVA), with data source (i.e., direct assessment using Haizea-Llevant, parental report using CARE) as a within-subjects factor and screening category group (i.e., "At risk" or "Not at risk") as a between-subjects factor, to examine consistency between Haizea-Llevant and CARE in determining the developmental milestones

reached. Separate mixed design ANOVAs were run for each developmental domain. The decision to use a mixed design ANOVA was based on the need to compare differences between groups split on two factors: a within-subjects factor in which all participants, serving as their own matched pair, were measured in two conditions (i.e., sources of information); and a between-subjects factor in which participants were classified separately based on developmental screening. This analytic approach follows Miller et al.'s (2017) agreement study comparing direct testing and parent reports, while also allowing evaluation of the predictive quality of CARE booklet as a screening tool.

Secondary analyses included chi-square tests of agreement on individual matched pairs of items from both primary study measures, to determine agreement at the level of specific developmental milestones. In cases where assumptions of chi-square testing were violated due to small sample sizes (i.e., less than five cases in a contingency table cell), Fisher's exact test was used.

Using the scoring procedures described above, interviewers' direct observations with HLL and parental reports using CARE were scored by the author and checked independently by a licensed psychologist who was a research team member. Discrepancies in scoring were resolved in face-to-face meetings of the research team and compared against hard copies of the forms, and corrections were made on the forms. Demographic form data were entered into Microsoft Excel, uploaded to a drive-in cloud storage, and checked using a double-data entry procedure.

Within our main results (i.e., participant recruitment and prevalence of developmental delay), the comparative analysis for CARE using parents' report and direct observation included:

1. Effects of demographic variables (e.g., socioeconomic status) on overall agreement.
2. Effects of demographic variables on the various domain scores (Personal-Social, Language and logico-mathematical reasoning, Fine motor-adaptive, Gross motor skills).
3. Overall agreement and congruence between the CARE report classification and interviewers' direct screening classification ("At risk" or "Not at risk"), defined as the degree of correspondence between individuals' judgments or ratings (Price et al., 2017). Inter-rater reliability (Cohen's κ) was calculated and interpreted with the most accepted arbitrary ranges for Cohen's κ (Landis & Koch, 1977): 0.00 - 0.20 indicates slight agreement, 0.21- 0.40 fair agreements, 0.41-0.60 moderate agreement, 0.61-0.80 substantial agreement, and 0.81-1.00 indicates almost perfect agreement.

4. Screening classification ("At risk" or "Not at risk") differences in development domain scores between HLL and parental CARE report. Differences in counting of total "No" answers in CARE reports and "Caution" items (i.e., an age-appropriated item is not passed) in HLL were analysed. Also, differences were reported on mentioned domain scores for both sources of data.
5. ROC curve area under the curve (AUC) analysis. The receiver operating characteristic (ROC) method is a commonly used paradigm in different medical and social areas to assess the performance of a diagnostic test (e.g., Schafer et al., 2014; Zanca et al., 2012). For the present study, the method requires values of two variables for each case: a *truth* variable (sometimes referred to as a 'gold standard') indicating the "At risk" status (HLL data) for each child and a *decision* variable indicating the CARE determination of "At risk" or "Not at risk". The parent report in CARE is used to assign a single rating to each case ("At risk" or "Not at risk"). When the decision in CARE corresponds to the *truth* HLL direct observation status ("At risk") it is called a *true positive*. When the decision in CARE does not correspond (i.e., "Not at risk") to the *truth* HLL direct observation status ("At risk") it is called a *false negative*. False positives correspond to a case when CARE reports an "At risk" condition but HLL indicates "Not at risk". The ROC curve is a plot of true positive fraction in the sample (Sensitivity) and the complement of false positive fraction (Specificity) or 1 – Specificity, for a continuous range of decision values in the decision variable. When ROC uses non-parametric estimation for diagnostic test analyses (e.g., the Wilcoxon test), it is called an "empirical ROC" (Pepe, 2003). An empirical ROC has an empirical area under the curve (AUC). The area under the curve has a value between 0 and 1 showing the performance of the test (CARE), with higher values indicating better test performance and 0.5 indicating randomness. For small sample sizes, the empirical AUC may change dramatically due to small perturbations and differ significantly from the expected AUC (Ma, Song & Huang, 2006). An alternative to the empirical AUC is the binormal AUC (Pepe, 2003). The binormal AUC is more stable than the empirical version for small sample sizes (Ma et al., 2006). In order to present comparable empirical AUC and binormal data, I report the nominal classification analysis using previous sensitivity and specificity calculation in a web page calculation tool (i.e., VassarStats) and using quantitative indices for CARE and HLL classification to plot a binormal ROC curve (Eng,

2014).

6. Item-Level Comparison of Agreement for specific Domains. To determine agreement at the item level, a series of chi-square tests of agreement between parental reports and direct assessment was performed on individual matched item pairs. Inter-rater reliability (Cohen's κ) and phi or Cramer's V from the chi-square tests were reported (Bakker & Wicherts, 2011). A Cramer's V parameter is used to compare the strength of association between any two cross-classification tables: a larger value for Cramer's V can be considered to indicate a strong relationship between variables, with a smaller value for V indicating a weaker relationship (Price et al., 2017).
7. Acceptability and feasibility analysis, which included six characteristics considered to influence implementation feasibility (Boggs et al., 2019): cultural adaptability, accessibility, training, administration time, geographical uptake, and clinical relevance and utility.

In the following analyses, assumptions of normality, homogeneity of variances, and sphericity were met, and no significant outliers were identified in our sample. Otherwise, non-normal distribution of data was analysed with nonparametric tools (i.e., the Kruskal-Wallis's test or Mann-Whitney test). An alpha level of .05 was adopted for all statistical tests. All statistical analyses were conducted using IBM SPSS Statistics for Macintosh, Version 25.0 (IBM Corporation, 2017).

3.5. Results

3.5.1. Participant Recruitment

Following procedures for recruiting parents (N = 157) and the positive screening for following up with the CARE delivery procedure (n = 61), 85.2% of participants returned the CARE booklet after using it as a screener for one month at home (n = 52).

3.5.2. Prevalence of Developmental Delay

After the first pre-screening and only for comparison of direct observations with HLL and parental reports using CARE, not for clinical or developmental characterization, 75% of

participants were classified with HLL as "At risk" (n = 39). The CARE booklet reported that 71% (n = 37) of the sample qualified as "At risk" (Table 3.2). Nominal classification analysis indicated that the sensitivity proportion was high (95%, corresponding to 37 out of 39 at-risk children), as was the specificity value (85%, corresponding to 11 out of 13 not-at-risk children). Also, for nominal classifications, the positive likelihood ratio (LR+) was 6.17 and the negative likelihood ratio (LR-) was 0.06.

Table 3.2

Observed frequencies for prevalence in Haizea-Llevant (HLL) observations and positive and negative predictive values with CARE report

	HLL-Observation	
	At Risk	Not at risk
	f	*f*
At Risk using parents' CARE report	37	2
Positive predictive value (%)	94.9	
Not at risk using parents' CARE report	2	11
Negative predictive value (%)		84.6
Total (Truth prevalence) *f (%)*	39 (75%)	13 25%)

3.5.3. Effect of Demographics on Overall Agreement

Analysing the effect of demographic characteristics in overall agreement requires individual-based change statistics (IBCs) with the net percentage change index (NET). NET is calculated by: (100 x [CARE score – HLL score] / [HLL score]). NET values indicate that the higher the difference score, the higher the probability of not agreement (Table 3.3). Also, negative values indicate lower score for the parental report in CARE compared to observation score using HLL (i.e., an underrated report by the parent). Differences between Haizea-Llevant (HLL) and CARE report were higher in low SES (i.e., the second level) compared to very low SES homes. The medium-low SES was the only level at which the CARE score was lower than the HLL score.

Table 3.3

Raw and net percentage change index (NET) for overall scoring differences between Haizea-Llevant (HLL) and CARE

		Haizea-Llevant overall (raw) scoring		CARE overall (raw) scoring		HLL minus CARE overall NET[+] difference	
SES[++]	n(%)	M	*SD*	M	*SD*	M	*SD*
Level 1 - Very low	13 (25)	0,67	*0,11*	0,68	*0,08*	3,41	*16,2*
Level 2 - Low	19 (36.5)	0,67	*0,19*	0,78	*0,11*	25,94	*40,4*
Level 3 - Medium low	14 (26.9)	0,72	*0,11*	0,70	*0,13*	-0,57	*23,3*
No data	6 (11.5)						

Note. [+] 100 x (CARE score – HLL score) / (HLL score); [++] According to socioeconomic national scale (Sanchez-Torres, 2015; MESEP-DNP, 2011).

Multiple One-way ANOVAs were then run to determine whether any sociodemographic variable influenced overall CARE and HLL score agreement. There was a main effect of SES on overall differences, $F(2, 43) = 6.947$, $p = .002$, $\eta^2 = .12$. *Post hoc* analyses using the Bonferroni adjusted criterion for significance and *t*-test when significant differences were found, indicated that differences in scores were significantly higher in low SES compared with very low SES homes, $t(30) = -2.72$, $p = .011$, $d = .72$, and with medium low SES, $t(31) = 2.98$, $p = .006$, $d = .81$.

No significant effect of other sociodemographic variables in the ANOVA analysis, including whether the child was a boy or a girl using *t*-test, was found on overall scoring differences between data sources (HLL vs CARE) in the total sample.

3.5.4. Effect of Demographics on Domain Scores

To analyse the effects of demographic characteristics for each developmental domain assessed with Haizea-Llevant (HLL) and CARE, individual difference scores were calculated. The net percentage change index (NET) was calculated by subtracting each age-equivalent

standardised individual CARE score from the age-equivalent standardised individual score in the corresponding developmental domain (Table 3.4).

Using raw differences or standardised individual differences (SID), the negative values indicate lower score for the parental report in CARE compared to observation score using HLL (i.e., underrated report by parent). Differences were higher in Personal-Social and Gross motor domains for girls. Language and logico-mathematical reasoning and Fine motor-adaptive domains scorings has higher differences for boys. Working mothers had higher differences in Personal-Social and Fine motor-adaptive for Employed status. Language and logico-mathematical reasoning and Gross motor domains scorings has higher differences for Unemployed status. Also, differences were higher in Personal-Social domain for Medium low SES and in Language and logico-mathematical reasoning for Low SES (i.e., the second level). Fine motor-adaptive and Gross motor domains scorings have higher differences for Very low SES compared with other SES levels.

Table 3.4

Median and data spread (Interquartile range-IQR) for the Net percentage change index (NET) between scores for Haizea-Llevant (HLL) and CARE report by developmental domains.

	Personal-Social domain		*Language and logico-mathematical reasoning*		*Fine motor-adaptive domain*		*Gross motor domain*	
	Median	*IQR*	Median	*IQR*	Median	*IQR*	Median	*IQR*
Sex								
Male	-12.7	*18.9*	-11.2	*16.9*	-15.2	*21.4*	-10.0	*27.6*
Female	-12.8	*12.5*	-8.5	*10.8*	-11.4	*13.4*	-13.3	*11.3*
Working mother status								
Employed	-13.5	*19.6*	-8.6	*16.6*	-13.2	*19.4*	-14.6	*23.2*
Unemployed	-9.4	*13.1*	-16.6	*18.4*	-11.7	*28.0*	-19.9	*38.9*
SES								
Level 1: Very low	-15.4	*27.0*	-7.7	*15.4*	-15.2	*9.7*	-16.1	*9.4*
Level 2: Low	-8.2	*13.1*	-16.8	*15.6*	-8.1	*32.6*	-9.3	*40.7*
Level 3: Medium low	-16.5	*28.8*	-8.6	*9.0*	-8.3	*21.6*	-6.9	*35.5*

A Mann-Whitney test was run on standardised individual differences (SID) and indicated a significant effect of working-mother status, with higher difference for employed (*Median* = -13.2) than unemployed mothers (*Median* = -11.7) on HLL and CARE scorings in the fine motor-adaptive domain, $U = 114.5$, $p = .02$, $r = .33$.

No significant effect of any other sociodemographic variables was found on developmental domains differences between data sources (CARE vs. HLL), suggesting that parents did not significantly differ in their ratings of child skills using CARE compared to direct testing with HLL in the total sample. The non-significant results for the many descriptive differences in Table 3.4 are included to strengthen the analysis in this section (Appendix D).

3.5.5. Overall Agreement between Haizea-Llevant (HLL) and CARE Screening Classification ("At Risk", "Not at Risk")

When comparing the classification outcomes of CARE booklet with the Haizea-Llevant (HLL), the overall agreement was 92% (by accuracy). Cohen's κ was calculated to determine if there was an agreement between the nominal screening classifications ("At risk" or "Not at risk") in HLL and CARE. There was almost perfect agreement between the two classifications data, κ = .810 (95% CI -.973, .988), $p < .0001$.

3.5.6. Screening Classification ("At Risk", "Not at Risk") Differences in Delay and Caution Items Between Haizea-Llevant (HLL) and CARE

Table 3.5 shows descriptive statistics of overall performance on items (i.e., Delays and Cautions) and nominal classification (i.e., "At risk" or "Not at risk") using Haizea-Llevant (HLL) and parents' reports using CARE. In the HLL reports, more items were reported as Cautions than Delays. The same was true for CARE reports in "Not at risk" participants. In contrast, Delays were four times more likely to be reported in "At risk" children when using the CARE report.

Table 3.5

Delays and Cautions for nominal classification groups using Haizea-Llevant (HLL) and CARE

		Items in Delay		Items in Caution	
	n (%)	Median	*IQR*	Median	*IQR*
HLL-Observation					
At risk	39 (0.75)	1.0	2.0	3.0	3.0
Not at risk	13 (0.25)	0.0	0.0	1.0	0.0
Using CARE report					
At risk	39 (0.75)	4.0	3.5	1.0	4.5
Not at risk	13 (0.25)	0.0	0.0	1.0	1.0

A Mann-Whitney tests indicated a significant difference in HLL observations, such that the "At risk" group presented a greater number of Caution items (*Median* = 3) than the "Not at risk" group (*Median* = 1), $U = 66.0$, $p < .001$, $r = .56$. Similarly in CARE report, "At risk" children

presented a greater number of Delay items (*Median* = 4) than the "Not at risk" group (*Median* = 0), $U = 85.5$, $p < .001$, $r = .50$. The results suggest a more sensitive trail in HLL for differences in both nominal classifications (“At risk", “Not at risk”) starting from the items in Caution, than CARE apparently more sensitive to children’s classifications starting from the items in Delay.

3.5.7. Screening Classification (“At Risk”, “Not at Risk”) in Development Domain Scores for Haizea-Llevant (HLL) and CARE

Standardised individual scores were calculated for analysing developmental domains (i.e., Personal-Social domain) and nominal classification (i.e., “At risk” or “Not at risk”) using both HLL and CARE (Table 3.6). Differences were greater in HLL classification in the Personal-Social and the Language and logico-mathematical reasoning domains for “Not at risk” children. Also, same children (HLL classification: “Not at risk” children) had a higher CARE report scoring than their HLL score in the Gross motor domain. Fine motor-adaptive scorings had higher differences for “At risk” children classified using HLL observation. Greater differences with higher CARE report scoring than HLL score were seen for “Not at risk” children in all domains.

Table 3.6

Median and data spread (Interquartile range-IQR) for the Net percentage change index (NET) between scores for Haizea-Llevant (HLL) and CARE report by developmental domains

	Personal-Social domain		*Language and logico-mathematical reasoning*		*Fine motor-adaptive domain*		*Gross motor domain*	
	Median	*IQR*	Median	*IQR*	Median	*IQR*	Media	*IQR*
HLL-Observation								
At risk	0,20	*0,98*	0,00	*1,74*	-0,15	*1,51*	0,00	*1,46*
Not at risk	-0,29	*2,83*	-0,59	*1,25*	0,13	*1,85*	0,73	*0,00*
Using CARE report								
At risk	-0,30	*1,12*	-0,22	*1,06*	-0,02	*0,00*	0,05	*0,00*
Not at risk	0,89	*0,00*	1,03	*0,43*	0,81	*0,00*	0,73	*0,00*

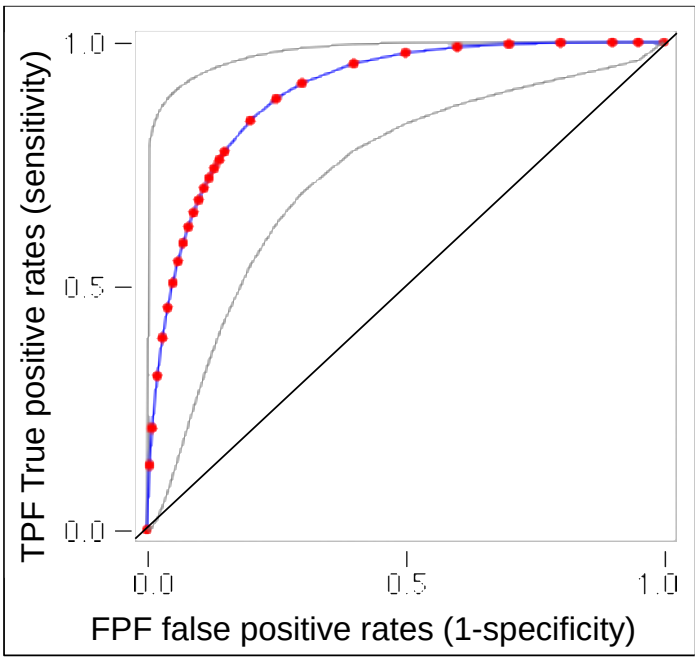
A Mann-Whitney test indicated that scores on the CARE report in the Personal-Social domain were lower for the "At risk" group (*Median* = 0.7) than for the "Not at risk" group (*Median* = 1.0), $U = 82.5$, $p = .001$, $r = .52$. No significant difference was found between "At risk" or "Not at risk" groups on personal-social domain scores for direct testing with HLL. Comparing scores in Language and logico-mathematical reasoning, using a Mann-Whitney test, indicated that on CARE report scores were lower for the "At risk" group (*Median* = 0.7) than for the "Not at risk" group (*Median* = 1.0), $U = 74.0$, $p = .001$, $r = .53$. No significant difference was found between "At risk" or "Not at risk" groups on Language and logico-mathematical domain scores for direct testing with HLL. Also, a Mann-Whitney test indicated that score in Fine motor-adaptive domain on CARE report was lower for the "At risk" group (*Median* = 0.8) than for the "Not at risk" group (*Median* = 1.0), $U = 118.5$, $p = .01$, $r = .42$. No significant difference was found between "At risk" or "Not at risk" groups on fine motor-adaptive domain scores for direct testing with HLL in the total sample (data not shown). Score in Gross motor domain on CARE report, a Mann-Whitney test, indicated that was lower for the "At risk" group (*Median* = 0.80) than for the "Not at risk" group (*Median* = 1.0), $U = 110.5$, $p = .01$, $r = .45$. Likewise, scores in Gross motor domain on direct testing with HLL was lower for the "At risk" group (*Median* = 0.75) than for the "Not at risk" group (*Median* = 1.0), $U = 72.5$, $p = .05$, $r = .30$.

3.5.8. ROC Curve: Area Under the Curve (AUC).

As mentioned before (i.e., 3.4.4. Analysis, p. 60) using quantitative indices for CARE and HLL classification to plot an empirical and a binormal ROC-curve analyses in the total sample ($n = 52$), the area under the curve (AUC) is 0.894 (Trapezoidal Wilcoxon area) with a higher Youden index of 0.860 (Table 3.7). Otherwise, a binormal ROC curve (Fig. 3.4) uses quantitative index for CARE and HLL classification as a *truth* variable indicating the “At risk” status for each child. The Area under the fitted curve (Az) in the binormal curve is 0.899.

Figure 3.4

Receiver operating characteristic (ROC) binormal curve for CARE and Haizea-Llevant classification for the total sample (n=52)



Note. This ROC curves plot use web-based calculator for ROC curves (http://www.jrocfit.org). Grey lines indicate 95% confidence interval of the fitted ROC curve. ROC analysis plot for each possible cut-off points of the relevant CARE scale, the true-positive proportion (sensitivity=95%) against the false-positive proportion (1– specificity). A perfect test would have an area under the curve (AUC) of 1 and the curve would pass through the upper left corner of the plot (100% sensitivity, 100% specificity). In this study, Trapezoidal (Wilcoxon) area / AUC = .89 (Std. error = 0.04) and the Area under the fitted curve (Az) = 0.90 (Std. error = .052).

Youden J indexes (Table 3.7) are reported because they indicate the maximum potential effectiveness of CARE scoring, and act as a common summary measure of the ROC curve (Ruopp, Perkins, Whitcomb & Schisterman, 2008). Using this method defines the optimal cut-point as the point maximizing the Youden function which is the difference between true positive rate and false positive rate over all possible cut-point values.

Table 3.7

Youden J indexes for empirical values in ROC curve

True positive rates (sensitivity)	Specificity (sp)	Distance to Sensitivity-Specificity (1,1) point	Youden's *J* (YJ) index
0.910	0.95	0.103	0.860
0.931	0.90	0.121	0.831
0.943	0.85	0.160	0.793
0.952	0.80	0.206	0.752
0.958	0.75	0.253	0.708
0.964	0.70	0.302	0.664
0.968	0.65	0.351	0.618
0.972	0.60	0.401	0.572
0.976	0.55	0.450	0.526
0.979	0.50	0.500	0.479
0.982	0.45	0.550	0.432
0.985	0.40	0.600	0.385
0.987	0.35	0.650	0.337
0.989	0.30	0.700	0.289
0.991	0.25	0.750	0.241
0.993	0.20	0.800	0.193
0.995	0.15	0.850	0.145
0.997	0.10	0.900	0.097
0.998	0.05	0.950	0.048

The Youden J indexes obtained indicates a high performance of CARE, $YJ = 0.86$ (the larger the better). The maximum value of the *Youden index* is 1 (perfect test) and the minimum is 0 when the test has no diagnostic value (Ruopp et al., 2008) and every value obtained for CARE indicate that all possible cut-point values are positive and optimal in the context of developmental screening.

3.5.9. Item-Level Comparison of Agreement for Specific Domains

Given the small group sizes when the sample was split by demographic variables, item level analyses were conducted on the full sample instead of separately for each screening group. Table 3.8 shows the mean proportions of correct items in the HLL and CARE reports. An important aspect to note is the asymmetry in the number of participants due to the application of HLL to specific ages and the delivery of CARE to the general sample. The asymmetry corresponds to the items in HLL according to the child's age at the moment of the observation. The numbers in CARE are according to the booklet's content by group age: 24-35 months old or 36-47 months old, the same as for 48- to 59-month-olds. Also, the number of items for each developmental domain differs in the correspondence between the tools and not by any relevance or developmental preference-domain criteria. After descriptive data, the agreement at the item level was determined with a series of chi-square tests performed on individual matched item pairs across HLL and CARE scores and developmental domains.

Table 3.8

Media and standard deviation (SD) for assertive observation or reports in Haizea-Llevant (HLL) and CARE by items in developmental domains

	HLL			CARE		
Personal-Social domain	***n***	**M**	***SD***	***n***	**M**	***SD***
Help in House	4	1.00	*0.00*	9	0.67	*0.73*
Feed doll	7	0.86	*0.76*	9	0.89	*0.67*
Remove Garment	12	1.00	*0.00*	9	0.89	*0.67*
When he or she play with dolls, he/she performed a play like a script or short tale with their dolls or toys?	17	0.94	*0.49*	52	0.92	*0.36*
Put on clothing	30	0.56	*1.00*	52	0.77	*0.74*
Did he/she suggest or show when need to go to the toilet?	17	1.00	*0.00*	50	0.88	*0.27*
Did he/she answer if he or she is a boy or a girl?	30	0.78	*0.86*	52	0.90	*0.50*
Dress, no help	26	0.41	*1.02*	52	0.71	*0.85*
Did he/she play with an adult using hand puppets?	31	1.00	*0.68*	52	0.87	*0.41*
Prepare cereal (In Spanish this item is open to more food than cereals)	24	0.64	*0.95*	43	0.84	*0.67*
Draw a person	16	0.44	*0.91*	43	0.53	*0.95*
Language and logico-mathematical reasoning						

Name __ Pictures (6 pictures)	5	0.87	*1.10*	9	0.67	*0.88*
Know 2 actions	5	0.63	*1.10*	9	0.78	*0.71*
Combine words	5	0.40	*1.10*	9	0.56	*0.87*
Name __ Pictures (5 pictures)	9	0.56	*1.05*	9	0.89	*0.33*
Use of 3 Objects	10	0.40	*0.97*	9	0.89	*0.33*
Speech half understandable	12	0.40	*0.90*	26	0.89	*0.33*
Did he/she point the dog correctly? (memorize an image)	19	0.70	*0.96*	35	0.85	*0.59*
When he or she speaks use pronouns?	29	0.28	*0.94*	9	0.97	*0.17*
Did he/she count aloud two consecutive numbers?	27	0.43	*1.02*	52	0.79	*0.71*
Name __ Pictures (10 pictures)	33	0.68	*1.01*	52	0.96	*0.19*
Did he/she use “to be” in a phrase?	33	0.30	*1.00*	52	0.90	*0.50*
Pick longer line	38	0.42	*1.01*	52	0.90	*0.55*
Speech all understandable	37	0.51	*0.99*	51	0.85	*0.62*
Identify colours	36	0.50	*0.96*	43	0.79	*0.82*
Did he/she realize no-connected actions?	39	0.63	*0.97*	43	0.88	*0.55*
Name colours	27	0.54	*0.90*	43	0.79	*0.68*
Opposites - morning/afternoon	23	0.36	*0.93*	43	0.79	*0.68*
Did he/she tell stories?	16	0.62	*0.25*	43	0.63	*0.92*
Did he/she repeat a complete phrase?	12	0.41	*0.51*	43	0.67	*0.83*
Did he/she recognize numbers (Arabic writing numerals)?	12	0.42	*0.52*	43	0.56	*0.92*
Fine motor-adaptive domain						
Put Block in Cup	6	0.94	*0.00*	9	1.00	*0.00*
Tower of 4 cubes	9	0.62	*0.00*	9	1.00	*0.00*
Thumb-finger grasp (grab a pencil)	16	0.54	*1.03*	52	0.88	*0.46*
Copy a circle	30	0.00	*1.02*	52	0.87	*0.61*
Did he/she imitate a bridge with 3 cubes?	37	0.00	*1.01*	52	0.87	*0.57*
Did he/she fold a paper sheet?	30	0.74	*0.82*	44	0.73	*0.69*
Did he/she use scissors to cut a paper sheet?	26	0.59	*0.98*	44	0.77	*0.64*
Copy a square	19	0.53	*1.01*	44	0.64	*0.82*
Did he/she imitate a door with 5 cubes?	19	0.79	*0.84*	44	0.73	*0.69*
Gross motor domain						
Walk down steps	4	0.58	*0.00*	9	1.00	*0.00*
Kick ball forward	4	0.58	*1.00*	9	1.00	*0.00*
Broad jump	17	0.79	*0.87*	52	0.85	*0.58*
Balance Each Foot 5 seconds	28	0.00	*0.92*	52	0.75	*0.75*
Jump up	29	0.25	*0.82*	52	0.79	0.64

Did he/she jump backwards?	22	0.76	*0.46*	52	0.69	0.66
Balance each foot 1 second	18	0.79	*0.57*	44	0.75	0.69

Several chi-square tests indicated, overall, somewhat mixed item-level agreement findings for every domain. The proportion of items with significant agreements was higher in Personal-Social (7 out of 11: 63%) and Language and logico-mathematical reasoning (14 out of 20: 70%) than the proportions in Fine motor-adaptive (5 out of 9: 55.5%) and Gross motor skills (3 out of 7: 42.8%). However, nearly all scores for items accrued in one quadrant of the chi-square contingency table (Appendix E). Under that condition there are key limitations to adequate interpretation for Kappa values for agreement between data sources (Gingrich, 2004). That is a reason to report Cramer's *V*, which is used to compare the strength of association between any two cross-classification tables. The analysis of the Cramer's *V* measurement for agreements of HLL and CARE in each item should be interpreted as a low agreement when value is between .00 - .15, medium agreement between .16 - .45 and a strong agreement between .46 - up (Gingrich, 2004; Price et al., 2017).

3.5.9.1. Agreements in Personal-Social Domain.

For items assessing Personal-Social domain (e.g., "Help in house"), there was more significant agreement than non-agreement between parental report and direct testing (Table 3.9). However, on some items measuring-agreement continuity is expected, because some activities will use the same objects in a trajectory of increasing complexity in interactions with adults or peers (cp. Bayley scales for instance). Items like "Feed doll" and "When he or she plays with dolls, he/she performed a play like a script or short tale with their dolls or toys?" or "Did he/she play with an adult using hand puppets?" are examples of the expected trajectory. The expected trajectory apparently requires more complex developmental skills that affect the agreement level. Another example is "Remove garment" and "Put on clothing" or "Dresses, without help". For those items, parents mostly reported that the child had the skill, but it was not seen on direct testing. Finally, a significant disagreement ($\kappa \leq 0$) between CARE and HLL direct testing was found in "Did he/she suggest or indicate needing to go to the toilet?", showing that this behaviour was more often seen in direct assessment than reported by parents.

Table 3.9

Personal-Social items agreement between observations or reports in Haizea-Llevant (HLL) and CARE.

Item description	X^2	*p*	κ	*Φ or Cramer's V*
4. Help in House	19.7	**< .001**	**.41**	**.80**
5. Feed doll	32.4	**< .001**	**.71**	**.62**
6. Remove Garment	31.1	**< .001**	**.76**	**.83**
7. When he or she play with dolls, he/she performed a play like a script or short tale with their dolls or toys?	6.33	.253	.01	.19
8. Put on clothing	4.44	.306	.03	.23
9. Did he/she suggest or show when need to go to the toilet?	4.91	**.039**	**-.01**	**.34**
10. Did he/she answer if he or she is a boy or a girl?	11.2	**.002**	**.12**	**.44**
11. Dress, no help	4.23	.800	.03	.19
12. Did he/she play with an adult using hand puppets?	3.60	.541	.02	.14
13. Prepare cereal (In Spanish this item is open to more food than cereals)	17.9	**.011**	**.28**	**.34**
14. Draw a person	17.4	**.009**	**.03**	**.34**

Note. Significant *p* values (<.05) in bold.

3.5.9.2. Agreements in Language and Logico-Mathematical Reasoning.

For items assessing language and logico-mathematical reasoning skills (e.g., "Combine words"), there were more items in significant agreement than items with non-agreement between parent report and direct testing (Table 3.10). However, as in the Personal-Social domain, there were items where measuring-agreement continuity was not obtained, e.g., "Did he/she count aloud two consecutive numbers?" and "Did he/she recognize numbers (Arabic numerals)?". Also, perceptual, and contextual discrimination skills were not in agreement (i.e., parents reported that the child could "Pick longer line" and recognize "Opposites - morning/afternoon" more often than

seen on direct assessment). Likewise, some expressive language items had no significant agreement (i.e., “Did he/she use ‘to be’ in a phrase?”; “Did he/she repeat a complete phrase?”).

Table 3.10

Language and logico-mathematical reasoning items agreement between observations or reports in Haizea-Llevant (HLL) and CARE.

Item description	X^2	p	κ	Φ or Cramer's V
1. Name __ Pictures (6 pictures)	28.9	**< .001**	**.45**	**.65**
2. Know 2 actions	28.9	**< .001**	**.37**	**.72**
2. Combine words	27.9	**< .001**	**.37**	**.61**
3. Name __ Pictures (5 pictures)	44.2	**< .001**	**.68**	**.74**
4. Use of 3 Objects	38.6	**< .001**	**.51**	**.66**
5. Speech half understandable	24.1	**< .001**	**.10**	**.57**
6. Did he/she point the dog correctly? (memorize an image)	8.36	**.046**	**.23**	**.27**
7. When he or she speaks use pronouns?	15.0	**.006**	**.16**	**.35**
8. Did he/she count aloud two consecutive numbers?	13.8	**.005**	**.10**	**.40**
9. Name __ Pictures (10 pictures)	6.53	**.049**	**.02**	**.50**
10. Did he/she use “to be” in a phrase?	10.2	.380	.04	.24
11. Pick longer line	7.30	.435	.00	.21
12. Speech all understandable	11.4	.329	.04	.20
13. Identify colours	22.3	**< .001**	**.27**	**.50**
14. Did he/she realize no-connected actions?	30.3	**< .001**	**.29**	**.47**
15. Name colours	21.4	**.001**	**.25**	**.45**
16. Opposites - morning/afternoon	16.4	.092	.15	.37
17. Did he/she tell stories?	14.4	**.008**	**.20**	**.35**
18. Did he/she repeat a complete phrase?	10.0	.752	.06	.23
19. Did he/she recognize numbers (Arabic writing numerals)?	10.3	.671	.09	.23

Note. Significant *p* values (<.05) in bold.

3.5.9.3. Agreements in Fine Motor-Adaptive Domain.

For items assessing fine motor-adaptive skills (e.g., make a "Tower of 4 cubes"), there was almost the same number of items in significant agreement than those without significant agreement between parent report and direct testing (Table 3.11). However, as with previous domains, there were items where measuring-agreement continuity was not obtained (i.e., "Tower of 4 cubes" vs. "Did he/she imitate a bridge with 3 cubes?", and "Copy a circle" vs. "Copy a square").

Table 3.11

Fine motor-adaptive items agreement between observations or reports in Haizea-Llevant (HLL) and CARE.

Item description	X^2	P	κ	Φ or Cramer's V
1. Put Block in Cup	11.5	**.006**	**.21**	**.47**
2. Tower of 4 cubes	5.60	**.037**	**.15**	**.33**
3. Thumb-finger grasp (grab a pencil)	5.26	.221	-.01	.24
4. Copy a circle	2.52	.721	.01	.14
5. Did he/she imitate a bridge with 3 cubes?	1.15	.960	-.03	.07
6. Did he/she fold a paper sheet?	25.4	**< .001**	**.29**	**.42**
7. Did he/she use scissors to cut a paper sheet?	18.4	**.008**	**.19**	**.34**
8. Copy a square	17.8	**.002**	**.12**	**.45**
9. Did he/she imitate a door with 5 cubes?	9.97	.069	.17	.34

Note. Significant *p* values (<.05) in bold.

3.5.9.4. Agreements in Gross Motor Domain.

For items assessing gross motor domain (e.g., making a "Wide jump"), there were more items with no significant agreement than items with significant agreement between parent report and direct testing (Table 3.12). As in previous domains, there were items where measuring-agreement continuity was not obtained (i.e., "Wide jump" and "Jump up").

Table 3.12

Gross motor items agreement between observations or reports in Haizea-Llevant (HLL) and CARE.

Item description	X^2	p	κ	Φ or Cramer's V
1. Walk down steps	20.7	**< .001**	**.27**	**.63**
2. Kick ball forward	14.5	**< .001**	**.34**	**.63**
3. Broad jump	7.90	**.046**	**.09**	**.36**
4. Balance Each Foot 5 seconds	4.11	.357	-.03	.21
5. Jump up	1.33	1.000	.01	.10
6. Did he/she jump backwards?	5.74	.411	.04	.26
7. Balance each foot 1 second	11.1	.215	.12	.30

Note. Significant *p* values (<.05) in bold.

3.5.10. Acceptability and Feasibility in CARE booklet

The rating criteria in Boggs et al. (2019) for mentioned characteristics in screening tools were applied to the CARE reports. Validity and reliability analysis was presented in previous sections. According to the rating criteria of Boggs et al. (2019), CARE presented several characteristics in rating levels between 0 and 3, indicating a good consideration for scalable studies (Table 3.13).

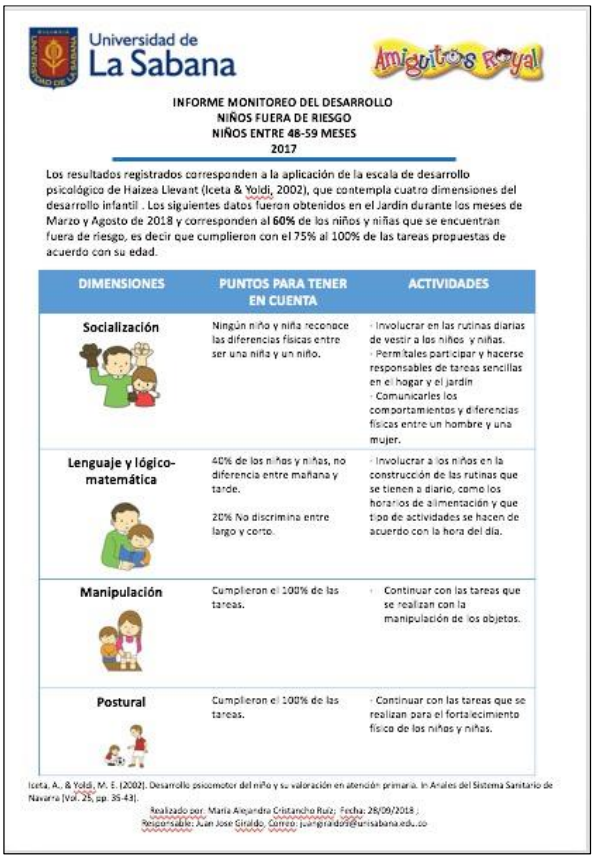
Table 3.13

CARE characteristics according to early child development measurement tool accuracy and feasibility for use in routine programmes criteria by Boggs et al. (2019)

	Boggs level description	Observation about CARE
Cultural adaptability, Rating: 3	Easy modification of items, materials, and procedures.	All items have a particular space for annotations a personalize descripted instructions or activities. The modification of items, materials and procedures will be fitted according inhouse context. Pictures and words are widely understood for specific participants with low academic level.
Accessibility, Rating: 2	Tool, administration, scoring and interpretation, adaptation, and training resources all available open access online with no intellectual property restrictions, minimal cost to tool and/or equipment (≤US$10 per child), no app available.	CARE is online available at https://monitoreoencasa.weebly.com/ The toys and materials delivered with the printed booklet cost less than 7 GBP per child.
Training, Rating: 3	Brief (≤1 hour), minimal (i.e., non-specialist worker can train non-specialist worker), no certification requirement.	Parents only received a less than three minutes video instruction (https://youtu.be/Y5864iGCvG8); research team are undergraduate students and do not receive specialized instruction for cooperation or answer questions coming from parents.
Administration time, Rating: 2	>15 to ≤30 min, minimum to moderate scoring.	CARE is planned to apply at home. A direct question about accumulated time when the booklet is returned to research team indicates less than an hour throughout a 1 month.
Geographical uptake, Rating: 0	Used in one country only.	Only used in Colombia.
Clinical relevance and utility, Rating: 3	Easy interpretation, clear threshold for action and structure for counselling response and contextually appropriate referral.	CARE is intended to use it as referral for clinical surveillance and motive observations an interaction between caregivers and children at home. All individuals had a one-page results, as a guide for educative action (Fig. 3.5a) and understandable by caregivers and CC workers in the individual report returned as feedback to participants (Fig. 3.5b).

Figures 3.5a and 3.5b.

Results of CARE delivered to participants as a guide for action in CCs (3.5a) and individual report (3.5b).



Universidad de La Sabana

Amiguitos Royal

INFORME MONITOREO DEL DESARROLLO
NIÑOS FUERA DE RIESGO
NIÑOS ENTRE 48-59 MESES
2017

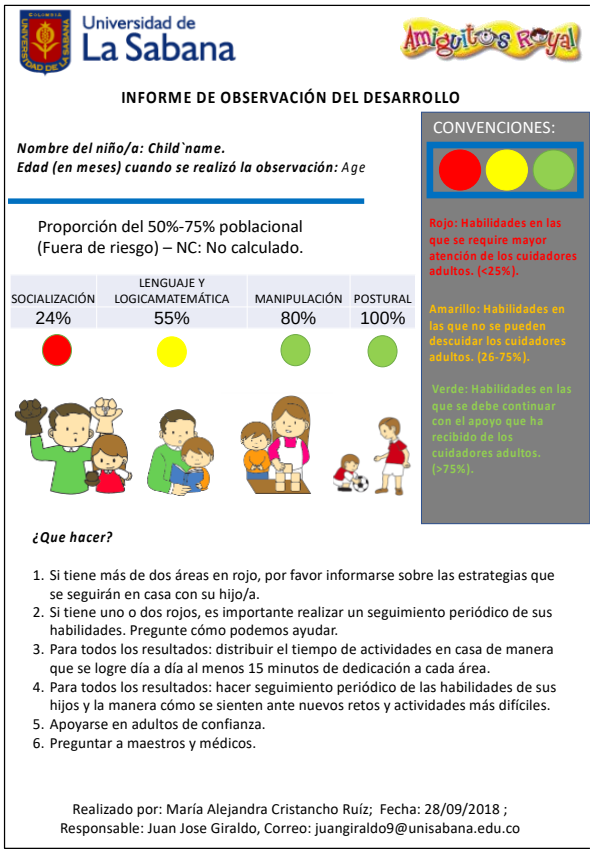
Los resultados registrados corresponden a la aplicación de la escala de desarrollo psicológico de Haizea Llevant (Iceta & Yoldi, 2002), que contempla cuatro dimensiones del desarrollo infantil . Los siguientes datos fueron obtenidos en el Jardín durante los meses de Marzo y Agosto de 2018 y corresponden al **60%** de los niños y niñas que se encuentran fuera de riesgo, es decir que cumplieron con el 75% al 100% de las tareas propuestas de acuerdo con su edad.

DIMENSIONES	PUNTOS PARA TENER EN CUENTA	ACTIVIDADES
Socialización	Ningún niño y niña reconoce las diferencias físicas entre ser una niña y un niño.	· Involucrar en las rutinas diarias de vestir a los niños y niñas. · Permitales participar y hacerse responsables de tareas sencillas en el hogar y el jardín · Comunicarles los comportamientos y diferencias físicas entre un hombre y una mujer.
Lenguaje y lógico-matemática	40% de los niños y niñas, no diferencia entre mañana y tarde. 20% No discrimina entre largo y corto.	· Involucrar a los niños en la construcción de las rutinas que se tienen a diario, como los horarios de alimentación y que tipo de actividades se hacen de acuerdo con la hora del día.
Manipulación	Cumplieron el 100% de las tareas.	· Continuar con las tareas que se realizan con la manipulación de los objetos.
Postural	Cumplieron el 100% de las tareas.	· Continuar con las tareas que se realizan para el fortalecimiento físico de los niños y niñas.

Iceta, A., & Yoldi, M. E. (2002). Desarrollo psicomotor del niño y su valoración en atención primaria. In Anales del Sistema Sanitario de Navarra (Vol. 25, pp. 35-43).

Realizado por: María Alejandra Cristancho Ruiz; Fecha: 28/09/2018 ;
Responsable: Juan Jose Giraldo, Correo: juangiraldo9@unisabana.edu.co

Fig. 3.5a



Universidad de La Sabana

Amiguitos Royal

INFORME DE OBSERVACIÓN DEL DESARROLLO

Nombre del niño/a: Child`name.
Edad (en meses) cuando se realizó la observación: *Age*

Proporción del 50%-75% poblacional
(Fuera de riesgo) – NC: No calculado.

SOCIALIZACIÓN	LENGUAJE Y LOGICAMATEMÁTICA	MANIPULACIÓN	POSTURAL
24%	55%	80%	100%

CONVENCIONES:

Rojo: Habilidades en las que se require mayor atención de los cuidadores adultos. (<25%).

Amarillo: Habilidades en las que no se pueden descuidar los cuidadores adultos. (26-75%).

Verde: Habilidades en las que se debe continuar con el apoyo que ha recibido de los cuidadores adultos. (>75%).

¿Que hacer?

1. Si tiene más de dos áreas en rojo, por favor informarse sobre las estrategias que se seguirán en casa con su hijo/a.
2. Si tiene uno o dos rojos, es importante realizar un seguimiento periódico de sus habilidades. Pregunte cómo podemos ayudar.
3. Para todos los resultados: distribuir el tiempo de actividades en casa de manera que se logre día a día al menos 15 minutos de dedicación a cada área.
4. Para todos los resultados: hacer seguimiento periódico de las habilidades de sus hijos y la manera cómo se sienten ante nuevos retos y actividades más difíciles.
5. Apoyarse en adultos de confianza.
6. Preguntar a maestros y médicos.

Realizado por: María Alejandra Cristancho Ruíz; Fecha: 28/09/2018 ;
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Fig. 3.5b

3.6. Discussion

The CARE booklet featured in this study was designed to monitor and support parents' interactions, to enhance their children's development and help identify developmental difficulties. The previous phases of this study include the conceptualization and consolidation of CARE components related to the Haizea-Llevant developmental screening table (HLL). The monitoring component of CARE is central to the current study, in particular an examination of its sensitivity and specificity in a small sample of vulnerable families in Colombia. The sample of families and

children recruited from a community Children's Centre in Colombia's capital, Bogotá, was similar to those for which similar screening tools are designed and standardised in LMIC populations (Faruk et al., 2020).

First, a positive characteristic of CARE is in the level of engagement shown for a measurement tool relating to a cognitive intervention. Following a meta-analysis for commitment of parental involvement (Haine-Schlagel & Escobar-Walsh, 2015), completion of tasks in cognitive interventions had a range of 19% to 89% in participants. The effective users of the CARE booklet in this study were the 85.2% of receivers who used it for one month at home. The literacy levels in parents were not controlled, but the under elementary school condition for caregivers of 12 participants of our sample (23%) apparently was not an issue for use and engagement with CARE. The high level of CARE report use has considerable positive implications for the whole monitoring, screening, and surveillance cycle to track a child's developmental progress (Faruk et al., 2020), known as the detection-intervention-prevention continuum.

Second, concerning the prevalence of developmental delay, our procedure to recruit participants after initial screening may have affected the high level of delay found (75%), raising concerns of generalizations for more wide-ranging recruitment in an experimental field procedure using CARE as a screening tool. However, recent studies reported low delay prevalence in developmental screening (Ozturk-Ertem et al., 2019) and the higher prevalence in our study must be interpreted with caution. If excluding participants from receiving the CARE booklet after first screening can lead to recruitment bias, it is also an opportunity for methodological improvement and overgoing the several barriers to adaptation of screening tools for LMIC (Faruk et al., 2020). Indeed, other screening studies included samples that did not share comparable sociodemographic characteristics to our participants, such as lower socioeconomic status (Murphy et al., 2020). The following sections comprise a discussion of results in comparison to the stated aims of the current study.

3.6.1. Consistency Between CARE and HLL Classification and Scores in Developmental Domains

Overall, the results suggest that parental observation of different child abilities reported in the CARE booklet did not differ significantly from direct assessment using HLL, and results were generally stable across screening classification groups. Also, the effects of demographic variables

on agreement between parent report and direct assessment of child are fundamental for decisions on future research and interventions since the onset of the COVID-19 pandemic. Differences for lower socioeconomic status and working-mother status between observations with HLL and parental reports with CARE indicate a need for better tracking of interactions related to parenting employment and individual developmental trajectories when those demographic conditions are present in LMIC populations and founded in South America's work-life balance studies (Campaña, Gimenez-Nadal, & Molina, 2020). Language and mathematical reasoning and Fine motor skills were the two skill areas most affected by SES conditions in our data, in common with previous studies of early childhood (Justice et al., 2019). Some barriers connected with caregivers serving as informants of their own interactions' quality relate to parental distress around parent–child interactions. CARE developmental screening might diminish parental stress or other contingent conditions associated with dysregulated parent–child interactions and reported in vulnerable or impoverished conditions in rich countries (Justice et al., 2019). However, SES is not defined solely by economic poverty, and more research is needed to clarify the issue of scarcity in child-parent interactions in conditions not only reported in countries with high economies like Justice et al. (2019) studies.

CARE reports agreement with HLL direct observations indicates an appropriate form of conducting developmental screening for children at risk of not reach their potential. However, the present study has a technical advantage over other comparisons with agreement analyses, including Miller et al. (2017): 100% of items in the parental reports (the CARE booklet) were comparable with the items included in the direct screening measurement. Indeed, Miller et al. (2017) only compared 12 out of 381 items (3.15%) for the Vineland Adaptive Behavior Scales (Survey Interview Form; Sparrow, Cicchetti, & Balla, 2005) and 12 out of 91 items (13.2%) for the Mullen Scales of Early Learning (Mullen, 1995). The good agreement shown in our results suggests that not only the similarity in items makes the parents reports contains reliable information of child abilities. When comparing agreement between "At risk" classification and scores on CARE and HLL, across the domains of Personal-Social skills, Language and logico-mathematical reasoning, Fine motor-adaptive and Gross motor skills, CARE demonstrated discriminatory potential that was as good as that provided by the HLL direct observations.

While HLL is a better detector than CARE for Cautions, parental reports with CARE demonstrated better discrimination for Delays. Furthermore, all developmental domains had

differences in nominal classifications in the "At risk" and "Not at risk" groups using CARE, but only in the gross motor skills dimension using HLL. A next step in the optimal design process for CARE should be a comparison with other tools to establish wide discriminatory characteristics in a Field Testing-Analysis-Revision framework (Nadeem et al., 2016).

3.6.2. Item Level Consistency Between CARE and HLL

Overall, the proportion of items in agreement between observations with HLL and parental reports with CARE were higher for Personal-Social and for Language and logico-mathematical reasoning compared to the proportions for Fine motor-adaptive and Gross motor skills. One straightforward answer to explain this discrepancy would be the time dedicated to observation of interactions. CARE gives parents one month to screen their children constantly on four developmental dimensions. These continuing observations with the screening activities in CARE relating to fine motor-adaptive and gross motor skills could well give rise to the observed disagreement with the short-term observations using HLL, given the accumulation of time and opportunities for reporting motor interactions at home. However, there is no information about the effective proportion of the whole month dedicated to exclusively observations of the selected skills at home. A recent study in a LMIC (Scherer et al., 2019) shows higher levels of observed responsive caregiving behaviours in mothers associated with higher maternal education attainment, lower number of children and greater socioeconomic assets between other significant variables. The complexity for such association clearly exposes the need for a more invasive methods to capture the rushing to complete CARE or a more controlled intervention that next chapters describe.

Otherwise, a significant disagreement ($\kappa \leq 0$) between CARE and HLL direct testing was found in “Did he/she suggest or indicate needing to go to the toilet?”, with this behaviour more often seen in direct assessment than reported by parents. The autonomy levels expected in the test environment are different in the Children’s Centre compared to the child’s home. Therefore, in this specific case, the parental report about the autonomy of their child and assigned to going to the toilet, like other social items, result from parents if a child cannot perform age-appropriate tasks without having observed these in detail at home (Miller et al., 2017). Also, such items will be subject to parents’ interpretation according to the cultural context (Schiariti, Simeonsson, & Hall, 2021). Specifically, cultural contexts are included and analysed under the so-called “standard

model" of consecutive *knowledge → stimulation → development* (Bornstein, 2015; Britto et al., 2017; Cuartas, Rey-Guerra, McCoy, & Hanno, 2020).

The *knowledge → stimulation → development* (*K→S→D*) model acts like a "cascade" of processes and outcomes, involving parenting attributions and supportive parenting, and concluding in the child's externalizing behaviour. In the *K→S→D* model, the testing of any child's skills by observation has specific challenges for parents and even for professional experts in child development, despite their favourable knowledge and attitudes (Jain, Solomon, & Ramachandran, 2021) and appropriate healthcare organizational setup (Sheeran, Zhao, Buchanan, & Xenos, 2020). Child noncompliance, reduced attention, and interest in calls for interaction, and the unfamiliar framework for direct reports at home might affect the success of testing. Recent research confirms the relevance of responsive parental behaviour and child's interactive engagement for positive developmental trajectories in children with significant cognitive and motor developmental delay (Van Keer, Bodner, Ceulemans, Van Leeuwen, & Maes, 2020). The level of attention from parents, and the initiation of interactions by children, might explain why the frequency, continuity, and quality of interactions at home affect positive parental reports when interaction is not complex, but disagrees with external observation when complexity in interactions is higher and is not capable of full reporting through the screening measurements. In our data, the disagreement levels were specifically noted in fine and gross motor skills, as we expected and was suggested before by Miller et al. (2017).

CARE screening may demand attention to behaviours, skills and performances that routinely are included in at-home interactions and excluded in the report. The attentional demands of routine interactions between parents and children were recently included in an analysis of associations between high levels of cognitive stimulation in the home and increased screening scores for children in low-SES conditions (Slemming, Cele, & Richter, 2021). Moreover, the *K→S→D* model implies that parents might recall whether a skill milestone had effectively been reached, before confirming this through observation. If the CARE delivery is not enough for changing parental knowledge of stimulating interactions and consequently affecting children's outcomes, a pre-post study might indicate the need for a new design, beyond CARE delivery as an intervention in screening tools. The following chapters will explore whether changing the recall component through the delivery of the CARE booklet for parental reports might positively affect individual trajectories in the developmental dimensions selected in the parental screening study.

3.6.3. Diagnostic Characteristics and Performance of CARE as a Tool for Developmental Screening

ROC analysis results indicated that CARE is a satisfactory tool for screening diagnostics and might help to build a quantitative index for better and faster classification of an "At risk" status in children aged 24–59 months. Our data offers complete diagnostic performance for a screening tool, surpassing the limitations of other tools designed and developed in LMICs (Faruk et al., 2020), such as the Child Language Test in Phonology, Vocabulary, Fluency and Pragmatics (ABFW; Dias, Rondon-Melo, & Molini-Avejonas, 2020), the Developmental Assessment Scales for Indian Infants (DASII; Juneja, Mohanty, Jain, & Ramji, 2012), and the Rapid Neurodevelopmental Assessment (RNDA; Khan et al., 2013). There is no ROC analysis of ABFW, DASII or RNDA to compare with our data. However, the sensitivity and specificity (95% and 85% respectively) of CARE were higher than for another tool validated against the Denver Developmental Screening Test, namely, the Trivandrum Developmental Screening Chart (TDSC; Nair et al., 1991). The TDSC had an overall sensitivity and specificity of 66.7% and 78.8%, respectively. The diagnostic characteristics of CARE therefore appear highly trustworthy compared to other screening tools designed for long observation periods by parents. However, due to the limitations set out in the next section, we cannot say that CARE might be better than the Guide for Monitoring Child Development (GMCD) or other tools targeted at early ages or specific developmental domains, such as social-emotional or self-help subscales (Faruk et al., 2020).

3.6.4. Pilot Validity of CARE for Research and Intervention with Institutional Community Participants

The CARE booklet, and other screening tools administered by parents, might act like home-based records (HBRs). Such records do not replace clinical or scientific intervention but can run in parallel with other existing or subsequent screening tools for optimal health and educational system interventions (Mahadevan & Broaddus-Shea, 2020). The CARE booklet shows similar conditions for delivery as HBRs, with rigorous reliability and agreement results. Also, CARE content and design had enough cultural adaptability to follow the Nurturing Care Framework, and could be administrated in programmes like the Family, Women, and Infancy Programme (FAMI)

for rural families in Colombia (Attanasio et al., 2018; Milner et al., 2019). FAMI is a government-funded parenting programme in rural Colombia, with tracking components derived from a Nurturing Care Framework (Milner et al., 2019). The FAMI programme was delivered for vulnerable families with group sessions and home visits, implemented by local women who had no previous child development training. The FAMI intervention team (Attanasio et al., 2018) devised their own structured measurement for quality of intervention delivery: feasibility, fidelity, and acceptability. However, FAMI and other home-visit interventions now need also to take in account the disruption caused by the COVID-19 outbreak (Guan et al., 2020). Likewise, the accessibility of CARE might be diminished by the fact that after the COVID-19 pandemic there is no digital app for it available. A first step considering the relevance of Boggs et al. but forgetting the focus on vulnerable and limited resources for families in poverty is in an online information-delivery through a beta webpage with a digital version of CARE (https://monitoreoencasa.weebly.com/). The availability of CARE in electronic format limits the delivery for the focused families in the present study. However, it will contribute to even easier access and optimal conditions for training and administration time in families and health systems having non-limited connection or access to the internet.

Finally, as a preliminary conclusion, CARE may be an efficient, cost-effective screening instrument for children between aged 24- to 59-month-old who are at risk of not reaching all their cognitive potential because of social and economic limitations. The clinical relevance and utility of the accurate and efficient classification obtained with tools like CARE could be included in health systems and surveillance routines for developmental screening in the detection of delay and could potentially be useful for identification and electronic records as implemented in paediatric and nursing practices, like reported by Vitrikas et al. (2017) and Gellasch (2019). Developmental monitoring and screening processes in LMICs should use tools like CARE for detecting and increasing early intervention referrals, assessments and eligibility for the children who need it most. CARE not only shows the desired sensitivity-specificity values, but also provides information on cultural adaptation with respect to the communities that use Children's Centres for vulnerable families in Colombia. The reported diagnostic and screening characteristics also most likely resulted in the high level of acceptance of the screening process (75%), which is crucial for the success of a large-scale surveillance programme. However, attention to the limitations of this

study and the possibility for further research is needed to evaluate its potential for population screening and monitoring, and its cost-effectiveness as a public health measure.

3.7. Limitations in CARE Screening and Diagnostics Characteristics

The optimal diagnostic characteristics of CARE are obtained for the optimized cut-off from the scoring values of HLL in the ROC and will not necessarily replicated if a different marking method or sample of participants are assessed. For example, the lack of data about the clinical status of parents using CARE helps to maintain the consideration of parental discrepancy in reports as an essential source of information, given the assuming norm that parents are uniquely positioned to observe and interact with children in various situations at home (Bennetts et al., 2016; Jeong et al., 2019; Miller et al., 2017). However, the results of the item analysis require an explanation of certain disagreements and inconsistencies. The data appear overall to have no systematic pattern of disagreement in the consideration of items by domains (i.e., proportion of items with significant agreements, personal-social: 63%, language and logico-mathematical reasoning: 70%, fine motor-adaptive: 55.5%, gross motor skills: 42.8%), but some disagreements (e.g., "Copy a circle": κ = .01, p = .72; "Copy a square" κ = .12, p < .01) show a truncated continuity in the screening process by parents when the nature of the activities increases the complexity in some domains.. The mentioned $K \rightarrow S \rightarrow D$ model explain the probability of memory and recall use for parent's report, but do not resolve this issue in future and scalable applications of CARE. As indicated before, this a pilot phase of CARE for optimizing the design following the components of Nadeem et al. (2016) and several other limitations in the present study might be addressed before subsequent field testing.

Also, like any other screening test, CARE only allows for a 'snapshot' of a child at one time point, limiting the ability to capture the full range of a child's functioning. Our standardised developmental screening tool, the Haizea-Llevant (HLL) has its own limitations to capturing the whole individual child's functioning. The last reported use and correction was normed a decade ago (Rivas, Sobrino, & Peralta, 2010) and it is thus less up to date than other early developmental screening tools (Boggs et al., 2019). Consequently, the CARE snapshot might lead to interpreting a false classification or disagreement at item level (compared to the HLL observation) as "parental error" (Miller et al., 2017, p. 12). Miller and colleagues (2017) argued that it cannot be systematically ascertained whether a child's behaviour during the evaluation was typical of his or

her home behaviour. An alternative to the "error" explanation is a hypothesis related to the effects of the psychology of scarcity (Camerer et al., 2018; Shah, Mullainathamn & Shafir, 2012; Shah, Mullainathan, & Shafir, 2018; Shah, Shafir & Mullainathan, 2015). This argument might be called the "scarcity of parental interactions" argument as opposed to the error argument (Miller et al., 2017). For the other kind of disagreements, "when a parent reports that a child has a skill, yet the skill is not seen on direct assessment" (Miller et al., 2017; p. 12), parents might use two strategies to report using CARE: a) recall or memory of interaction events, and b) direct subsequent observations of their interactions with children. A limitation on analysing these disagreements is in the lack of more invasive research and evaluation techniques in this study, with a clear suggestion of including home-visit observations or home-recorded videos.

3.8. Limitations in the Study Design and Next Chapters

Further research is necessary to evaluate if limitations related to the sample size and sampling methodology, and data analysis itself (e.g., ROC with different scoring values in HLL observations) might invalidate the use of CARE as a screening tool with the potential to activate alerts for the early cognitive delay and lead clinicians and families onto further specialized and controlled developmental evaluations. Consequently, the overall results and item analysis of the current study should be interpreted with caution. All suggested patterns of agreement and disagreement in the data should be considered exploratory.

Most notably, the final sample and the small within-group numbers demonstrate the effects of demographic variables and item-level results that might be corrected with a large and randomized sample. However, all statistical assumptions in the tests (e.g., One-way ANOVA, Chi-Square), like normality and minimum cell sample, are rigorously checked for the results. Future research is needed to examine specific skills that are under- or over-reported and the influence of parents' and interviewers' characteristics on the agreement between parent reports and direct testing.

Finally, screening and diagnostics using parent reports as part of long-reach monitoring for social and cognitive developmental status require an examination of engagement and attrition levels of the participants. Previous literature reported parental engagement by an average completion rate across all cognitive intervention sessions (Haine-Schlagel & Escobar-Walsh, 2015). The average rate is for 49% of participants to abandon the process before cognitive

interventions, with a range from 19% to 89%. Haine-Schlagel and Escobar-Walsh's (2015) research indicates that in our case, the 14.9% not returning CARE forms (i.e., attrition) for a non-clinical intervention is very good but would still reward future inquiry about this issue. Recent studies dedicated to Spanish-monolingual U.S. Latino parents' engagement in an evidence-based program focused on promoting sensitive, responsive parenting for socioeconomically disadvantaged families (So et al., 2020) indicated distinct barriers (e.g., employment challenges, health-related challenges) and facilitators (e.g., knowing other mothers in the group, interest in the program topics), none of which were explored in the current study with CARE. Also, the applied acceptability criteria (Boggs et al., 2019) do not include the parents view on the design or other characteristics for CARE that might increase the engagement and the positive return of the booklet that only reach the 85% of the initial follow-up group.

The next chapters examine whether direct observation at home affects individual development status, and what differences might appear when CARE is not only delivered as a screening tool but structured as an intervention. The following chapter will provide a preliminary idea of whether instruments like CARE affect children's outcomes simply by giving caregivers indications to observe and report a broad spectrum of developmental interactions, as do the Guide for Monitoring Child Development (GMCD) and other tools used in global programmes (Faruk et al., 2020). Independent of the positive or negative results when analysing only the standard delivery of the tool, examined in the next chapter, a comparison with a structured intervention of dialogical book-sharing will be analysed later in the thesis.

Chapter 4. Effects in Developmental Outcomes when Parents Receipt a Screening Report Tool in Children at Risk in a Middle-Low-Income Country.

As we have seen, scaffolding, and learning processes in parent-child interaction are fundamental to improving the life chances of children and can reduce the impact of environmental factors in children at risk in LMIC (Walker et al., 2011). Psychological research has a clear role to play in detection and intervention guided by early screening and "scaffolding" (Barbot et al., 2020). However, recent evidence indicates a gap between capacity-building practices and the research with positive results about caregiver-implemented interventions in child outcomes (Romano & Schnurr, 2020). Particularly and even with policies that indicate the need for enhancement of parenting knowledge and skills for better parent-child interaction, public and socio-political systems still considering more important providing affordable and accessible quality childcare (Nores et al., 2019; Teti, Cole, Cabrera, Goodman, & McLoyd, 2017). Teti et al. (2017) highlighted some characteristics of parenting that benefit children regardless of the specific family conditions in which parent-child interaction takes place. These are: protection, developmentally informed and mindful, and nurturance with developmentally appropriate control. However, as noted in the Introduction, being "developmentally informed" is not a natural or spontaneous condition in parents on any developmental dimension. Also, maternal knowledge apparently works well in countries like the USA, predicting supportive parenting for lower levels of externalizing problems when their children reach puberty (Bornstein, Putnick, & Suwalsky, 2018). But in LMICs, a similar relation between maternal knowledge and children's developmental outcomes has not been robustly established (Cuartas et al., 2020). A normative model of parenting that assumes the *Knowledge → stimulation → development* process as "universal" (e.g., Bornstein, 2015; Britto et al., 2017; Cuartas et al., 2020) in fact has limited empirical support.

For instance, a Colombian sample of 1277 low-income mothers and their children under the age of five showed varying levels of knowledge about child development and caregiving in mothers reports of practices at home associated with irregular outcomes in children (Cuartas et al., 2020). Cuartas et al.'s analysis of the *knowledge → stimulation → development* model (*K→S→D*) with a Colombian sample used a structural equation model (SEM) for targeted maternal knowledge about child development, based on caregiving information obtained in previously designed surveys

(e.g., Attanasio et al., 2014; MacPhee, 1981) when children were 9- 26 months old with growth in same children's cognitive, receptive language, and gross motor skills at ages 27-46 months. Moreover, Cuartas et al. (2020) did not find associations between maternal stimulation and children's expressive language or fine motor development, in contrast with one U.S.-based study only (Bornstein, Putnick, & Suwalsky, 2018).

The normative *knowledge → stimulation → development* process (*K→S→D*) requires active learning in parents to optimize engagement in higher-order thinking about their own behaviour and vocabulary development (Teepe et al., 2019). Nonetheless, a recent review (Biel et al., 2020) found that out of 124 studies about language interventions delivered to caregivers in homes and classrooms, not one study that used a training function included scaffolding or prompting strategies. In the author's view, emphasis on the importance of "scaffolding" for parent involvement using home-based records (e.g., the CARE booklet) and active learning (Axford et al., 2019; Magwood et al., 2019; Mermelshtine, 2017; Veas, Castejon, Miñano, & Gilar-Corbí, 2019) is a *sine qua non*.

The absence of previous specific interventions with active learning as a training function for caregivers implies a need for an open and comprehensive exploration of effects in the delivery phase. Likewise, booklets with developmental information (i.e., home-based records) can improve health and behavioural outcomes in disadvantaged women, new mothers, and their children (Dagvadorj et al., 2017). The measurement of the effects on children's developmental outcomes of delivering a booklet with child interaction activities and relevant developmental-related information to parents, seems very close to interventions framed in terms of parental coaching (Romano & Schnurr, 2020; Windsor, Woods, Kaiser, Snyder, & Salisbury, 2019) but have fundamental differences with interventions that provide prompts, guidance, and scaffolding delivered to parents and caregivers (Biel et al., 2020). The main difference is about several child-oriented skills demanded to parents before engaging in the coaching interventions and explained in next section.

This chapter does not question the importance of using developmental screening for measurement and intervention in early development delays, reported for more than 20 years in paediatric and surveillance practices (Barger et al., 2018; Guevara et al., 2013; Macy, 2012), and recently in randomized trials and controlled interventions (Nicholson et al., 2016; Olds, Sadler, & Kitzman, 2007). The question raised here is about the effect of delivering information to parents

so that they know the benefits of early interactions with children, but not guide them how to act according to it. Only a few studies have investigated caregiver-implemented interventions that test such strategies' impact on multiple developmental outcomes with children, aged 15 to 23 months with significant disabilities (e.g., Windsor et al., 2019), and there is little experimental research on alternative intervention strategies, such as parental coaching models (Romano & Schnurr, 2020).

4.1. Parental Coaching in Early Interventions

Parental coaching models are interventions characterized by capacity-building approaches, and tend to be complex, multifaceted, and oriented to caregivers who require early intervention (Romano & Schnurr, 2020). The coach or an early interventionist (EI) in the parental coaching approach needs to acquire several child-oriented skills before engaging in the intervention with parents: observing child behaviour, child assessment, in-depth knowledge of child development, and fluency in evidence-based interventions addressing multiple developmental domains. The coaching for caregivers conducted by an EI will guide their interactions with family members and EI colleagues (Friedman et al., 2012; Romano & Schnurr, 2020). The list of requisites for coaching skills includes the domain of intervention strategies and the ability to demonstrate and guide practices to improve interactions in families (Windsor et al., 2019). The CARE booklet delivery does not follow a coaching model. Instead of coaching expectations, CARE delivery and use as a parent report is intended to motivate caregivers to explore and report a broad spectrum of developmental interactions. The motivated caregiver replaces recalled or absent developmental knowledge with practical knowledge (knowledge in action) and simply stimulates children with interactions in the normative $K \rightarrow S \rightarrow D$ process, through mechanisms previously mentioned (Magwood et al., 2019; Mermelshtine, 2017; Teepe et al., 2019). If results on delivery are not enough to consistently change parental actions, some additional design changes to the intervention will be considered for the next step in this thesis.

This chapter aims to identify if it is possible to find any effect on children's developmental outcomes after delivery of a tool for screening development. Thus, our research question is (RQ#3): *Might the delivery of a parent-administrated tool for developmental screening to principal caregivers for a month have any effect on children's developmental outcomes*?

4.2. Design and Method

4.2.1. Study Design and Participants

The enrolled parent-child dyads were drawn from two childcare foundations administering nutritional or basic-care programmes in Bogotá, Colombia. Some 139 children and their families were initially available in two Children's Centres (CC) as potentially eligible. The target population in this study included all families that satisfied the following criteria:

1. They had preschool children (aged 59 months or younger).
2. They were parents in couples unless unfeasible (e.g., divorced, widowed, partner travelling frequently).
3. They understood written or spoken Spanish; and
4. They were willing to receive a CARE booklet from participating in the complete set of activities at home for one month or free-reporting interactions in a blank booklet after one month to the best of their abilities.

Parents of children with self-reported behavioural or developmental disorders were excluded from this study. The parents' consent to enter the study was sought if the child met entry criteria. One hundred and thirty-nine sets of parent-child dyads agreed to participate from two childcare foundations or Children Centres (CC) in Bogotá. Despite the opportunity to work with the enrolled parent-child dyads from the two CC, the assistance to the first two meetings giving essential information about the study and the allocation process and the lack of sociodemographic information for at least three variables leave sixty-nine parent-child dyads excluded in one of the CC. While clear arguments are for the not convenient use of unequal allocation in randomised trials, in our case, scientifically advantageous and consistent ethical study design should be addressed (Hey & Kimmelman, 2014). First, substantial advantages for the subsequent interventions in knowing and having initial encounters with children like an early phase of the trials is the aim of the study in the present chapter. Also, the research team's costs and safety conditions may be a second circumstance where our uneven allocation may be justified. Finally, the excluded CC is in a distant and insecure area of the city (Nueva Roma, Bogotá), and the assessors commented on the reported risk for some families to assist when the first two meetings were scheduled. On the active CC, seventy families were present for the allocation session. Allocation to the CARE users' group or the control group was made using a quasi-random

assignment method (alternating between experimental and control groups). Participants were assigned using controlled clinical trial procedures (Lefebvre et al., 2019), and an independent research assistant talked with participants to inform them of their group allocation. Critically, allocations were unknown to assessors on the developmental screening observation when the decision to exclude one of the two initial CC was not already taken and the exposed ethical and operative arguments sustaining the selection of one CC, and the final distribution rate (1:1.6) for the present study was not rationalised: 27 (38.6%) to the CARE users' group and 43 (61.4%) to the control group (Table 4.1). Assessments were conducted at baseline and after one month of assessment when parents were ready to return the CARE booklet. The final sample (n = 70) had persistent and clear indications of multidimensional poverty (Aguilar & Sumner, 2019). This meant that participants in the sample with a lower socioeconomic status on the national socioeconomic scale and with low levels of multiple variables alongside income, including health or nutritional deficiency, non-constant attendance at nursery or preschool, and material scarcity in some standards of living (e.g., essential home utilities).

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Table 4.1

Sociodemographic description of children and mothers in CARE and Control groups (n=70).

		CARE users (n=27)	Control (n=43)	Total (n=70)
Children		***n* (%)**	***n* (%)**	**n (%)**
	Sex			
	Girls	12 (44.4)	18 (41.9)	30 (42.9)
	Boys	15 (55.6)	25 (58.1)	40 (57.1)
	Age group			
	24-35 months old	1 (3.70)	1 (2.33)	2 (2.86)
	36-47 months old	11 (40.7)	21 (48.8)	32 (45.7)
	48-59 months old	15 (55.6)	21 (48.8)	36 (51.4)
Mother				
	Education level			
	No school experience	3 (11.1)	2 (4.65)	5 (7.14)
	Incomplete elementary school	2 (7.41)	4 (9.30)	6 (8.57)
	Elementary school complete	2 (7.41)	2 (4.65)	4 (5.71)
	Incomplete college	8 (29.6)	13 (30.2)	21 (30.0)
	Complete college or High school	6 (22.2)	13 (30.2)	19 (27.1)
	Apprenticeship certificate or Technician	1 (3.70)	1 (2.33)	2 (2.86)
	Incomplete undergraduate studies	2 (7.41)	5 (11.6)	7 (10.0)
	Undergraduate degree	1 (3.70)	1 (2.33)	2 (2.86)
	Postgraduate	0	1 (2.33)	1 (1.43)
	No answer	2 (7.41)	1 (2.33)	3 (4.29)
	Maternal Employment			
	Working mother	17 (63.0)	29 (67.4)	46 (65.7)
	Non-working mother	8 (29.6)	3 (6.98)	11 (15.7)
	No answer	2 (7.41)	11 (25.6)	13 (18.6)
	Socioeconomic national scale [+]			
	Very low: Less than 4.5 USD by day	3 (11.1)	9 (20.9)	12 (17.1)
	Low: More than 4.5 USD but less than 10.0 USD by day	12 (44.4)	19 (44.2)	31 (44.3)
	Moderate low: More than 10.0 USD but less than 20.0 USD by day	10 (37.0)	13 (30.2)	23 (32.9)
	No answer	2 (7.41)	2 (4.65)	4 (5.71)

Notes: [+]: Different sources help to an approximate calculus of this levels (Sanchez-Torres, 2015; MESEP-DNP, 2011).

4.2.2. Measures

Every dyad was interviewed and assessed with:

1. The Questionnaire for Parents and Caregivers General Data.
2. The Haizea-Llevant screening table.
3. The CARE® booklet.

All these instruments have been previously described in Chapter 3. Changes in assessment procedures compared with Chapter 3 methodology are explained next.

4.2.3. Assessment procedure

Procedure was similar as described in Chapter 3 but for the experimental and the control group, with six trained undergraduate assessors who made the assessments. Being blind to the group to which the child belonged, the assessors first administered the structured questionnaire, alongside the first HLL observation. After this first observation, parents received the CARE booklet and the complementary materials in a toy bag, or they received a blank booklet for free reporting of interactions at home. Parents who received CARE were encouraged to use it as a whole-month report with daily tracking. Parents read each activity in the booklet, prepared the material or scenario for observation or interaction, and reported the result (*Sí*, "Yes," if the skill or behaviour was observed in interaction with the child; *No* if the skill or behaviour was not observed in interaction with the child; *No lo pude observar o creo que no lo puede hacer*, "I can't observe it or I believe he/she can't do it") in the corresponding place.

As an essential condition in the experimental design, the difference between experimental (CARE booklet users) and control groups consisted in the booklet that they received: the experimental group received a CARE booklet, and the control group received a blank booklet. The parents in the control group only receive the instruction to "write or sketch" any activity observed or undertaken with their children during the month. This method for the control group could be described as a placebo, because it "is used here to mean an inert treatment, given as if it was a real treatment" without any ethical conflict (McQuay & Moore, 2005; p. 155).

At this point, only the principal investigator knew who belonged to the experimental or control group. One month after parents had received the CARE booklet, research assistants (i.e., undergraduate internship students) called and reminded them to return their booklet. The second

HLL observation (post-test) was made only when the CARE booklet or blank booklet was returned. The assessments took less than 40 minutes per child. Each child in the experimental and control group was assessed twice during the study period: at baseline (pre-test, before using CARE), and end-line (post-test, at least one month after starting to use CARE).

4.2.4. Data Analysis

All statistical analyses were conducted using IBM SPSS Statistics for Macintosh, Version 25.0 (IBM Corporation, 2017). As a first step in analysis, we conducted a Kolmogorov-Smirnov test to confirm the assumption of normality. The normality test allowed us to choose parametric or non-parametric equivalents for all between (i.e., CARE vs Control) and within (i.e., Pre vs Post assessment) group comparisons. The analyses used average-based change statistics (ABC) (such as Cohen's *d* or Hays's ω^2) and individual-based change statistics (IBC), such as the Standardised Individual Difference (SID) in the same way descripted and used in previous chapter.

To account for the potential differential impacts of receiving the CARE booklet or not on the outcomes of interest, the main analyses were conducted in two ways. First, one-way analysis of covariance (ANCOVA) was used to evaluate the relations between the intervention and post-measurement of delays and cautions, while controlling for pre-measurement of delays and cautions. Then, Mann-Whitney tests were used to examine differences between groups in Haizea-Llevant's assessments of child milestones reached in four developmental dimensions: a) Fine motor-adaptive, b) Gross motor, c) Language and logico-mathematical reasoning, and d) Personal-Social. Using the Haizea-Llevant chart table to view cut-offs and predictive percentile distributions (50% and 75% population distribution areas) by item as a function of age, every register of the observation phases was scored. Once every answer and observation were scored, the intervention group (CARE users) was compared with the control group. In this chapter the hypothesis derived from a specific question (RQ#3) is that the use of a screening developmental report tool by parents would affect the children's outcomes, being statistically different in the intervention group (CARE users) compared to the control group. A significance level of 5% was used and all tests were two-tailed.

4.3. Results

Table 4.2 presents descriptive statistics for children's Delays and Cautions, overall and between groups. In this sample, the control group had a higher number of items in Delay (*Median* = 1), than the CARE group (*Median* = 0) at the pre-delivery assessments, $U = 37.5$, $p = .008$, $r = .32$. However, there were no significant differences between groups on any measure at post-delivery assessments of Delay and Caution items.

Table 4.2

Group mean (SD) in Delays and Cautions items at initial and follow-up assessments in CARE and Control groups (n=70).

Group	CARE users n=23		Control n=47		Total n=70	
	Pre M(*DE*)	Post M(*DE*)	Pre M(*DE*)	Post M(*DE*)	Pre M(*DE*)	Post M(*DE*)
Age in months: mean (SD)	47.2 (7.*2*)	50.4 (6.*7*)	46.9 (7.*1*)	48.3 (6.*6*)	47.0 (7.*2*)	49.1 (6.*7*)
General screening using HLL:						
Items in Delay. *	0.56 (0.*9*)	1.44 (*1.1*)	1.56 (*2.0*)	1.56 (*1.6*)	1.17 (1.*7*)	1.51 (*1.4*)
Items in Caution.	2.33 (*1.5*)	1.89 (*1.3*)	2.28 (*1.6*)	1.93 (1.*6*)	2.30 (*1.6*)	1.91 (*1.5*)

Notes. HLL: Haizea-Llevant; a high number of items in Delay or Caution indicates a higher risk of loss developmental potential.
* = ANOVA or Kruskal-Wallis differences between groups in Pre assessment, $p<0.05$.

4.3.1. ANCOVA for Pre- and Post-Items with Delays and Cautions in CARE and Control Group

An ANCOVA was conducted to compare delays and cautions reported using HLL items in a group of CARE users and a control group while controlling for pre-test results. Excluding normality assumption in favour of the rigor and advantages of ANCOVA over any non-parametric method (van Breukelen, 2006; Olejnik & Algina, 1984; Ghasemi & Zahediasl, 2012; Vickers, 2005), Levene's test and all required assumptions were met. There was no significant difference in the screening indicators between groups. Post-assessment there were no significant effects caused using CARE when compared to the Control group, in either Delays, $F(2,69) = 1.172$, $p = .28$, or Cautions, $F(2,69) = 0.025$, $p = .87$.

4.3.2. Differences on Pre-Post Haizea-Llevant's Domains Scores

Table 4.3 presents descriptive statistics for scores on Haizea-Llevant assessments of child milestones reached in four developmental dimensions. In order to determine whether use of CARE impacted the outcomes in children, several ANCOVA and Mann-Whitney tests were conducted to examine relations between the intervention and differences in pre- and post-assessments for Fine motor-adaptive, Gross motor, Language and logico-mathematical reasoning, and Personal-Social items.

Table 4.3

Group mean (SD) scores (Max=1) at initial and follow-up assessments in Haizea-Llevant's (HLL) developmental dimensions

Group	CARE users n=23		Control n=47	
	Pre	Post	Pre	Post
HLL Domains				
a. Fine motor-adaptive	.62 (*.33*)	.74 (*.30*)	.80 (*.26*)	.79 (*.26*)
b. Gross motor	.75 (*.36*)	.81 (*.31*)	.69 (*.31*)	.65 (*.34*)
c. Language and logico-mathematical reasoning	.54 (*.29*)	.58 (*.29*)	.62 (*.22*)	.63 (*.27*)
d. Personal-Social dimension	.45 (*.38*)	.42 (*.33*)	.38 (*.29*)	.51 (*.33*)

The CARE group showed better performance in post-assessment than in baseline values for Fine motor-adaptive, Gross motor and Language and logico-mathematical reasoning items. In contrast, the CARE group showed worse performance in post-tested Personal-Social items compared to pre-assessment. However, one-way ANCOVAs indicated that there was not any significant difference in the dimensions for the screening score between groups. Using net change index, individual-based change statistics (*IBC*) reveal that significative differences in the CARE users' group (Median = -.27) for scores on Personal-Social items were lower than in the control group (Median = .39), $U = 162.0$, $p = .008$, $r = .32$.

4.4. Discussion

A plain answer to the RQ#3 (Might the delivery of a parent-administrated tool for developmental screening to principal caregivers for a month have any effect on children's developmental outcomes?) is in concordance with the non-significant and limited benefit of the delivery for general risk results between pre- and post-assessments in CARE users compared with a control group: a booklet with developmental informed activities to parents report about activities observed or undertaken with their children during a month, is not enough for found statistical significant changes in children outcomes. Therefore, the simple delivery of a booklet as an intervention may not be effective, in distinction perhaps to the fuller regimes of intervention discussed above. Nonetheless, is not possible to generalize the results of using CARE as a screening tool without inclusion of all variables used in more than 20 years of paediatric monitoring and surveillance with positive and robust results in children development (Barger et al., 2018; Guevara et al., 2013; Macy, 2012). Also, our results do not pretend to avoid the absence of statistical or empirical power to discuss the positive effect of early interventions in childhood and before six years of age, especially in unfavourable environments (Gardner et al., 2003, Gertler et al., 2014; Grantham-McGregor et al., 2007). The results encouraged our next study to formulate precise strategies for skills that favour parental sensitivity for development interactions, even in conditions of extreme knowledge limitations in parents (Hackworth et al, 2017; Murray et al., 2016). Likewise, we do not reject the normative model of parenting that assumes the *Knowledge → Stimulation → Development* process as "universal", but solely wish to point out its limitation in comprehending different levels and types of parental knowledge about child development and caregiving (Cuartas et al., 2020).

If CARE booklet is considered as a home-based record (HBR), our results suggest that delivery of HBRs may not be sufficient for significant positive changes in individual developmental trajectories. The persistence of environmental and learning conditions in vulnerable, impoverished populations in LMICs may maintain negative effects on development even with a wider scope of developmental knowledge for parents about their interactions with children. The ineffective results of delivering CARE without a proper intervention are consistent with recent calls for optimising the implementation for coverage and engagement of HBRs in LMICs (Mahadevan & Broaddus-Shea, 2020). However, it is not a call for incentives for the

parental coaching models (Romano & Schnurr, 2020). A recent systematic review of the effectiveness of home-based records (HBR) on mothers' non-health outcomes like mother-child bonding levels (Carandang et al., 2022) characterises the HBR as a mechanism to improve communication within and outside the household. Inside LMIC families, HBR might clarify pregnancy-related and childcare-related misconceptions among family members (Hagiwara et al., 2013; Osaki et al., 2019). The HBR could be an effective communication tool with healthcare providers outside households. However, Carandang et al. (2022) interpretation of their results turned that characteristic into a barrier due to the lack of satisfactory explanations regarding and personalised guidance on using home-based records. A valuable conclusion to our results and the discussed literature is an additional reflection to consider the effectiveness of CARE, leading to the design of a structured intervention with the booklet. The CARE intervention might be compared with established HBR interventions to create a comparative baseline for future improvement.

As a major limitation of the study reported in the current chapter, we did not have a follow-up period. The study was planned this way mainly because of financial constraints and that is also a justification for the not 1:1 random assignment to treatment arms. Fortunately, it was observed that CCs and families are sharing information about interventions and materials, and there was a chance with adequate funding to scale a posterior intervention. Also, related to the limited number of participants, we did not assess specific variables that may indirectly impact the outcomes, such as feelings of self-efficacy in caregivers (Albanese, Russo & Geller, 2019), or the time dedicated to interactions. Future studies also need to consider the importance of the activities that the control group reports, and analyse any patterns or characteristics associated with significative changes in that group.

The next chapter will set out an intervention designed to examine whether any effect of CARE on children's developmental outcomes is possible with a dedicated plan of parental training, like dialogical book-sharing programmes for parents and children (Canfield et al., 2020; Vally et al., 2015).

Chapter 5. A Pilot Trial of Parent Training using Two Interventions for Low Resource Families in a Spanish speaking Low-Middle income country.

While progress has recently been made in the early identification of developmental delay in children using screening tools adapted to local cultures (Boggs et al., 2019; Gladstone et al., 2010; Marlow, Servilii, & Tomlinson, 2019; Worku et al., 2018), it remains the case that more than 40% of children under 5-years-old in low income countries are at risk of not reaching their developmental potential because of psychosocial deprivation associated with poverty (Black et al., 2016; McFarland, 2017; Murtaza et al., 2019). Effects of poverty and economic deprivation include compromised academic achievement and long-lasting negative effects on general wellbeing (Gubbels, van der Put, & Assink, 2019). Currently, the COVID-19 pandemic increases the risk to vulnerable children cut off from educational services, which is likely to widen the achievement gap between them and their more economically secure counterparts (Busso & Camacho-Muñoz, 2020). Poverty entails not just monetary insecurity. It has a multidimensional impact (Alkire & Foster, 2007), including health and nutrition deficiency, limited access to nursery or preschool education, and poor material standards of living (including essential services such as electricity, sanitation, and drinking water (Aguilar & Sumner, 2019). Multidimensional analysis of poverty includes a wide consideration of sociodemographic effects on early developmental screening and interventions in LMICs (Pitchik et al., 2021).

Early developmental screening of children living in low-income homes, followed by programs which encourage parents to support their preschool child's cognitive development, has been shown to produce beneficial effects (Faruk et al., 2020; Worku et al., 2018). Also, family support programs for home literacy practices and engagement in tracking child development milestones have had positive effects on children aged 5 when parents are encouraged and trained to support their child's development (Edmunds, 2020), confirming the moderating effects that families have for the relationship between poverty and child developmental and academic outcomes (Engle & Black, 2008). However, not all findings have been positive. A longitudinal study recently indicated that after early interventions, positive changes were reported in parenting skills and developmental effects when children were aged 6, 12 and 36 months, but no statistically reliable results were found when participant children were assessed at 5 years old (Orri et al., 2019). Contradictions about the permanence of positive changes in outcomes for at-risk preschool

children following parental interventions make imperative the identification of early intervention programs that are effective and deliverable in low-resource contexts.

5.1. Parental Interventions in LMIC

Two recent meta-analyses of early parenting interventions (Jeon, Pitchik & Yousafzai, 2018; Pedersen et al., 2019) found medium-sized positive effects on children's early cognitive (Cohen's d = 0.42) and linguistic (d = 0.47) development. Jeon et al. (2018) demonstrated that parent- and family-focused interventions (including psychoeducation, parent- and family-skills training, behavioural and psychosocial interventions) had some benefits in LMIC populations. Twenty-eight of the studies reviewed (88% of all studies included in the metanalysis) showed a significant positive effect of the intervention on a myriad of outcomes, including child and youth mental health and wellbeing, as well as on parenting behaviours and family functioning (Jeon et al., 2018).

However, only a limited number of studies have examined the impact of early parenting interventions on the cognitive performance of children living in poverty; and most of them have reported only limited data about early learning or intervention conditions (Richter et al., 2019). Some intervention studies that have focused on the development of children's language and communicative skills by providing direct training to parents have shown significant benefits in LMIC contexts (Cooper et al., 2014; Dowdall et al., 2020; Murray et al., 2016; Vally et al., 2015). The intervention used in these studies involved training parents in Dialogic Book-Sharing (DBS) with their children. A recent meta-analysis of DBS trials from around the world (Dowdall et al., 2020) reported a range of small, medium, and large effects on child expressive (d = 0.41) and receptive language (d = 0.26), as well as on caregiver book-sharing competence (d = 1.01). The impact of the intervention on child language was moderated by intervention dosage, with low dosage associated with a minimal impact.

5.2. DBS Interventions in LMIC

The Dowdall et al. (2020) review included two studies in South Africa, one in Brazil, and one in Türkiye. The DBS interventions reported by Dowdall and colleagues encompassed low and high dosage intensity (i.e., Low is under 60 minutes in total and High is more than 60 minutes), while the time between assessments varied from 4 weeks to 4 years after pre-assessments. To our

knowledge, Brazil is the only South American country with a recent evaluation of a medium or high dosage and 36 weeks between pre- and post-assessment DBS intervention (Weisleder et al., 2018), and a comparison with another intervention in participant engagement (Martins et al., 2020). The early reading programme reported in Brazil (Weisleder et al., 2018) had more variance in time and content compared with the DBS interventions described in Cooper et al. (2014), Murray et al. (2016) and Vally et al. (2015): parent-child dyads were assessed at enrolment and nine months later, at the end of the school year. The programme followed *Reach Out and Read* and the *Video Interaction Project* (Mendelsohn et al., 2018) strategies for families under intervention, borrowing children's books on a weekly basis and in focusing on reading aloud in monthly parent workshops. Weisleder et al. (2018) found that parents in the intervention group engaged in significantly greater cognitive stimulation (d = 0.43) and higher quantity and quality of reading interactions (d = 0.52–0.57) than controls. Also, at a 9-month follow up, children in the intervention group scored significantly higher than controls on receptive vocabulary (d = 0.33), working memory (d = 0.46), and IQ (d = 0.33).

An 8-week DBS programme aiming to promote parental sensitivity and improve child cognitive development and social understanding is currently being conducted in Brazil (Martins et al., 2020; Murray et al., 2019). The DBS intervention is being compared to a no-intervention control group, and also to an alternative intervention, *ACT: Raising Safe Kids* (a 9-week programme aiming to reduce harsh parenting and maltreatment and improve positive parenting practices). Outcome data have yet been reported, but a difference in level of engagement has recently been documented (64.2% completed the ACT programme and 76.6% completed the DBS; P. Cooper, personal communication, April 23, 2021). No DBS intervention in a South American Spanish-speaking country has been reported. Indeed, there have been very few randomised control trials (RCT) in Spanish-speaking LMICs of the impact of early family or centre-based interventions on child development (Nores, Bernal & Barnett, 2019).

5.3. Centre-Based Interventions in Colombia

Recently, a Colombian intervention study was reported as the only RCT in an LMIC evaluating the impact of high-quality centre-based care (the 'aeioTu' intervention programme) provided to infants and toddlers (Nores et al., 2019). This RCT found heterogeneous effects, with large positive effects on child language, motor, and cognitive development. Positive effects were

especially pronounced in girls whose mothers had a relatively higher level of education. One problem with centre-based interventions, like the 'aeioTu' intervention programme, is the requirement of a high level of education for professional workers-caregivers, not commonly found in LMIC. Further, the aeioTu program's child-to-teacher ratio is low (8:2), the intervention is lengthy (130 to 150 days), and all children in this study received 70% of their daily nutritional requirements (breakfast, two snacks, and lunch) from the centre, which is mandatory in all public childcare public programs in Colombia.

While the results of the aeioTu trial are impressive, there is a need in LMIC contexts for rapid and reliable options which are much cheaper and easier to deliver than the aeioTu intervention. Recent literature on strategies for improving the interaction skills between caregivers and children (Biel et al., 2020) highlights the need to apply and evaluate interventions that provide prompts, guidance and scaffolding delivered to teachers or parents. One such centre-based and parents' approach in need of evaluation is the CARE booklet-intervention.

5.4. The CARE Booklet-Intervention: from Centre-Based to Parental Engagement Interventions

Previous chapters described the components and functional value of the CARE booklet as a screening tool. CARE acts as a guide for parents on how they can assess and track their child's developmental progress, and how they can provide scaffolding activities to promote their child's development. However, the strict delivery of CARE as a screening tool for parent administration is not sufficient as an intervention. This was seen in the relatively non-significant and limited benefit of the delivery for general risk results between pre- and post-assessments in CARE users compared with a control group reported in the previous chapter.

The consideration of the DBS structured protocol for effective and robust results, combined with the opportunity to use a centre-based approach with low-income families in Colombia, might help to give structure to the CARE booklet-intervention (CBI). The CARE booklet assessing children's characteristics is like home-based records (HBRs). An HBR such CARE regular and frequently running in parallel with a CBI intervention for optimal health and educational systems is not only desirable (Mahadevan & Broaddus-Shea, 2020): it could increase confidence in parental activities at home. The CBI could work well at home when interactions might be a parental task or burden. Constant recall and demand for interactions at home might increase parental stress and

the possibility of parental burnout. Recent studies in the prevalence of parental burnout (Roskam et al., 2021) show that cultural and social values like individualism and number of hours spent paying attention to children play a significant role in many LMICs, including Colombia.

Specific societal values also play a role in Roskam and colleagues' research. Colombia had the highest scores on the "Indulgence" scale, meaning, according to the researchers, that participants (N = 95) allow relatively free gratification of basic and natural human drives related to enjoying life and having fun. CBI might transform parental "demand" for interactions with their children into activities reported in the booklet, not for evaluation of parenting, but intended as a support device. Parent support in CBI sessions had three principal messages: active learning is central to individual child development; social interactions are fundamental to caregiver-child engagement; and (paraphrasing Lave, 1988) development is not an independent process among other processes but, like learning, it is an aspect of any interactive process in the world. It is not a matter of how much children change and develop but a matter of how, when and with whom they interact. The child might develop what they were not expected to report and might not perform according to the kind of development they were expected to show. CBI's scaling to community-based and regional proposals, is intended to enhance home-based development into communities of development-relevant interactions.

However, before any hypothesis about indulgence and parental stress, is necessary to know if the CBI and mediating sociodemographic factors might change children's outcomes, as the DBS intervention has been shown to do. The present study reports findings from a pilot quasi-RCT study of two parent-training intervention programmes for families in poverty with preschool children: a DBS with materials from previous studies translated into Spanish (Cooper et al., 2014; Murray et al., 2016; Vally et al., 2015) and the CARE booklet intervention. Given the promising results of DBS in LMICs, it is also of interest to evaluate the impact of a DBS intervention in a small sample of families living in a Spanish-speaking LMIC. While sample size limitations might preclude a direct comparison between the two interventions, the intention was to compare both interventions with a no-intervention control group and determine the two interventions' impact on a range of developmental, cognitive, and linguistic variables. This pilot study could be a starting point for more extensive study of prompting, guiding, or scaffolding tools such as the CARE booklet, scaling this to significant samples of participants (parents and caregivers with toddlers and preschool children). We hypothesized that both interventions would have a beneficial effect

on children's cognitive development and language abilities, but it is necessary to note the exploratory conditions for our pilot study and consequent analysis of results.

5.5. Method

The study essentially followed the protocol for a randomised controlled trial (RCT), but the control group was selected based on not attending the randomised session and is therefore the study classified as a pilot quasi-RCT (Q-RCT; Reeves, Wells, & Waddington, 2017). The trial manager functions were shared between the thesis author and a postgraduate psychology student. A Spanish screening tool derived from the Denver II test, the Haizea-Llevant (HLL) observation table, was used to identify children between 24- to 59-month-old at high risk of not reaching their potential development. A member of the research team, blind to group assignment, conducted the assessment. They also employed further standardised measures administered at baseline and post-intervention.

5.5.1. Participants: inclusion and exclusion criteria

Participants were eligible for the study if they:

1. Had at least one child between 24 and 60 months of age.
2. Had completed the recruitment process and the general developmental screening report (HLL table).
3. Had a classification of "At risk" according to the HLL screening table, defined as the child presenting ≥1 Delay or ≥2 Cautions.
4. Were able to complete written records in Spanish.

Participants were excluded if they do not comply any of the four mentioned criteria for inclusion.

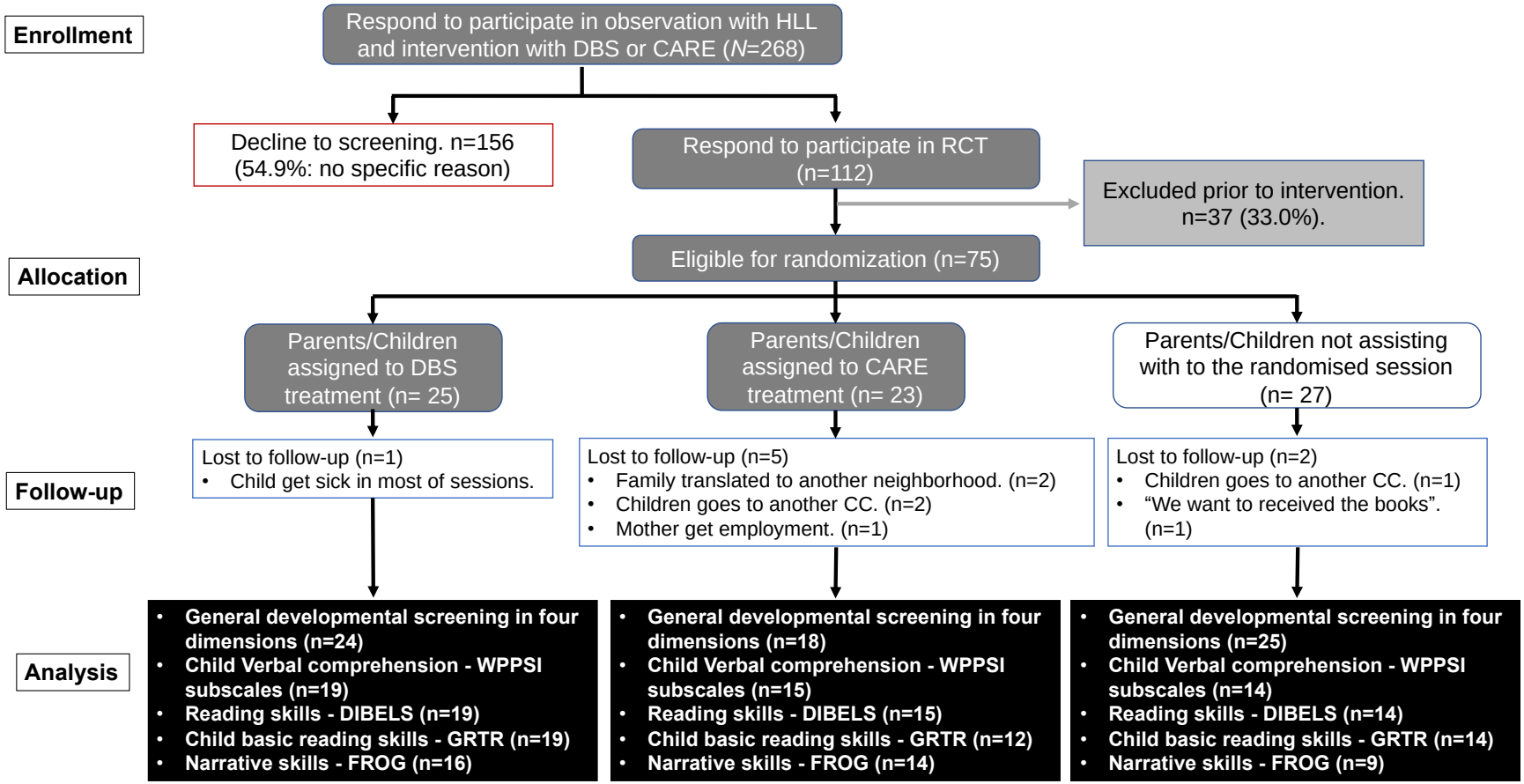
If the child met the entry criteria and the parents consented to participation, the baseline assessment was conducted. Some 268 families were identified by the screening process (see the CONSORT flowchart in Fig. 5.1), but 156 families (54.9%) declined to enter the study and were not followed up further. Thus, 112 families agreed to participate, but 37 of these were excluded for not attending the briefing meetings. This left 75 families who were invited to attend a

randomisation session, but 27 missed this session. For the remaining 48 families, allocation to the DBS or the CARE training was made from a random numbers table.

Participants for DBS and CARE were randomised in blocks of six using a computer-generated number sequence that was created a priori on the random.org website. An independent research assistant informed participants of their group allocation (Fig 5.1). The 48 families were randomised to one of two conditions (DBS group-only, n = 25; CARE® group-only, n=23), and the remaining 27 (those who did not attend the allocation meeting) were assigned to the control group.

Figure 5.1

DBS and CARE booklet intervention pilot-study CONSORT Flow.



We cannot establish if they did not attend the allocation session should affect our results. Consequently, we assumed the main reason they did not attend was that they were not available on the date of the meeting, and there is no reason to assume that any material features defining this group that would bear on child outcome. The lack of demographic differences between the groups supports this assumption. The final sample (N = 75) was demographically homogeneous, and according to the CC records and data analysis, all participants fell under the definition of multidimensional poverty (Aguilar & Sumner, 2019). This means that they had low socioeconomic status, with multiple factors affecting them alongside lower income for national scale, health or nutritional deficiency, lack of continuous attendance at nursery or preschool services, and material scarcity in some standards of living (e.g., essential home utilities). Sociodemographic characteristics are shown in Table 5.1.

Table 5.1

Sociodemographic description of children and mothers in the allocated groups and the whole sample.

		DBS (n=25)	CBI (n=23)	Control (n=27)	Total (n=75)
Children		***n (%)***	***n* (%)**	***n* (%)**	***n (%)***
	Gender				
	Girls	12 (48.0)	11 (47.8)	16 (59.3)	39 (52.0)
	Boys	13 (52.0)	12 (52.2)	11 (40.7)	36 (48.0)
	Age group				
	24-35 months old	4 (16.0)	0	0	4 (5.3)
	36-47 months old	14 (56.0)	13 (56.5)	17 (63.0)	44 (58.7)
	48-60 months old	7 (28.0)	10 (43.5)	10 (37.0)	27 (36.0)
Mother					
	Education level				
	No school experience	0	0	0	0
	Incomplete elementary school	0	0	0	0
	Elementary school complete	0	1 (4.3)	2 (7.4)	3 (4.0)
	Incomplete college	0	1 (4.3)	2 (7.4)	3 (4.0)
	Complete college or High school	7 (28.0)	7 (30.4)	5 (18.5)	19 (25.3)
	Apprenticeship certificate or Technician	3 (12.0)	5 (21.7)	10 (37.0)	18 (24.0)
	Incomplete undergraduate studies	0	0	0	0
	Undergraduate degree	1 (4.0)	1 (4.3)	2 (7.4)	4 (5.3)
	Postgraduate	0	0	0	0
	No answer	14 (56.0)	8 (34.9)	6 (22.2)	28 (37.3)
	Reading engagement at home				
	Never	0	4 (17.4)	5 (18.5)	9 (12.0)
	Once or twice per week	6 (24.0)	6 (26.0)	5 (18.5)	17 (22.7)
	Three to four times per week	0	2 (8.7)	7 (25.9)	9 (12.0)
	Daily or more per week	6 (24.0)	3 (13.0)	3 (11.1)	12 (16.0)
	No answer	13 (52.0)	8 (34.8)	7 (25.9)	28 (37.3)

Maternal Employment				
Working mother	9 (36.0)	12 (52.2)	12 (44.4)	33 (44.0)
Non-working mother	5 (20.0)	3 (13.0)	8 (29.6)	16 (21.3)
No answer	11 (44.0)	8 (34.8)	7 (25.9)	26 (34.7)
Socioeconomic national scale^{+}				
Very low: Less than 4.5 USD by day	4 (16.0)	4 (17.4)	6 (22.2)	14 (18.7)
Low: More than 4.5 USD but less than 10.0 USD by day	9 (36.0)	11 (47.8)	9 (33.3)	29 (38.6)
Moderate low: More than 10.0 USD but less than 20.0 USD by day	1 (4.0)	0	5 (18.5)	6 (8.0)
No answer	11 (44.0)	8 (34.8)	7 (25.9)	26 (34.7)

Notes: $^{+}$: Different sources help to an approximate calculus of this levels (Sanchez-Torres, 2015; MESEP-DNP, 2011).

Both CARE and DBS participants were asked to complete an intervention session each week for six weeks. Assessments were conducted at baseline and again not more than 2 weeks after the last session.

5.5.2. Interventions

The training program was delivered to the parent who identified as the principal caregiver of their child. The dialogical book-sharing (DBS) intervention promoted supportive and reciprocal book-sharing with young children. The CARE booklet intervention (CBI) promoted the use of a printed booklet for written reports of different activities at home in four developmental dimensions commonly used for early screening. Both interventions involved parents meeting in small groups (4-6 persons) and receiving instruction from a trained facilitator over six weekly one-hour sessions. In both interventions dosage per session was less than 50 minutes, to fit in with the high number of other scheduled activities in the Children's Centre.

5.5.2.1. The DBS intervention.

The DBS intervention focused on instructing parents in how to share picture books with young children. It was emphasized that each child could review the book material at their own pace, and parents were encouraged to provide opportunities for more complex conceptual

elaboration, such as reflection on the meaning of events and their causes, and the characters' emotions, intentions, and perspectives (Dowdall et al., 2020).

The Thesis author (TA) received training in a dialogic book-sharing program (Murray et al, 2016). TA translated and filmed the training materials, including demonstrating videos, into Spanish. TA then delivered the DBS intervention to participants. Each intervention session involved a PowerPoint presentation focusing on a particular aspect of sensitive book-sharing. Embedded within the session were brief video clips of local Spanish-speaking parents demonstrating optimal practices of the session content. Mothers and children for the embedded videos came from high socioeconomic status with higher educational levels than participants (e.g., PhD in Psychology). In addition, they received one of the books used in the DBS intervention for observations at home for five or more minutes in dialogical sharing scenarios. The selection of clips was made according to the similarity with the original in English expressions and practices. For the DBS intervention, at the end of each session the parent was given the 'book of the week' to take home. Each parent also had a brief opportunity to share this book with their child, during a special period of one-to-one support and direction provided by the facilitator. Support for the parents in each session followed the primary components of a previous pilot (Cooper et al., 2014), such as active child participation, interest-sharing guidance, pointing and naming, active questioning, and linking with the weekly book. At the beginning of the second session, and of each subsequent session, a record was taken of the number of times each parent had shared the book of the week with their child since the previous session, and any difficulties they had encountered.

5.5.2.2. The CARE Booklet Intervention (CBI).

The CBI is a specific training for parents using the CARE booklet. CBI is clearly derived from the DBS structure and guidance. The CBI use a weekly group of presentations and one-on-one assistance from a trained facilitator through 6 sessions that are run once a week for 6 weeks (Table 5.2). The aim of the 6 sessions is to provide caregivers with the skills and disposition to use of CARE to obtain information about daily interactions to enhance their toddler's development through regular monitoring of these interactions.

Table 5.2

Session by week description of dialogical book-sharing (DBS) and CARE booklet interventions.

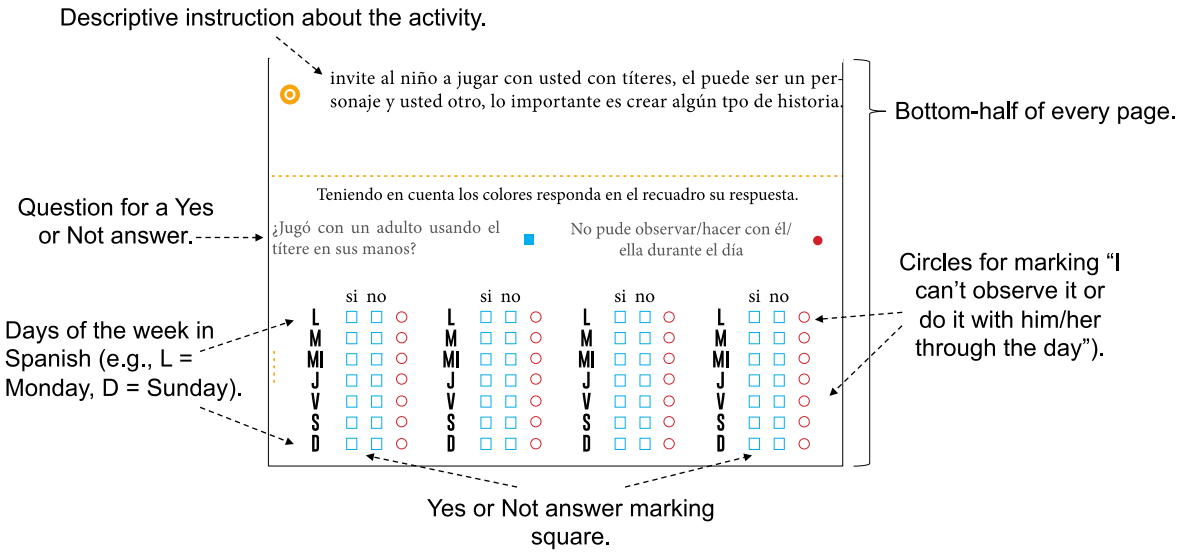
Session order	DBS intervention	CARE intervention (CBI)
Session 1	Introduction: Explaining the benefits to child development of booksharing, stressing the importance of establishing a book-sharing routine. Outlining basic principles of dialogic reading (following the child's lead, pointing, and naming, asking 'who/what/where' questions).	Introduction: Explaining the benefits of using the CARE and the importance of establishing an interaction and report routine.
Session 2	Elaborating and Linking: Elaborating on the child's focus of interest. Making links between the book content and the child's own experience.	Socialization activities: Review of activities for socialization dimension.
Session 3	Numbers and comparisons: Introducing counting and making comparisons. Using relative concepts, such as bigger, smaller, higher, lower.	Language and logical-mathematical reasoning: Review of activities for language and logical-mathematical reasoning.
Session 4	Emotions: Talking about the feelings of the book characters. Naming feelings and contextualizing them. Linking the book characters' feelings to the child's own emotional experience.	Object manipulation activities: Review of activities for object fine motor manipulation.
Session 5	Intentions: Discussing book characters' desires, intentions, and beliefs. Highlighting how this drive the book characters' behaviour.	Postural development activities: Review of activities for postural and gross motor development
Session 6	Relationships: Discussing the relationships between the book characters and how emotions and intentions operate within relationships.	Socio-cognitive development in context: Review and highlight the importance of (a) Household and daily activities, like playing musical instruments, painting, and writing, playing in open spaces; (b) Relationship with others; (c) Use of numbers in daily activities, (d) Geo-spatial orientation in daily activities.

The CARE booklet for CBI had different section in every activity with an area for daily marking, below instructions for how to report interactions daily for four weeks (Fig. 5.2). The primary components in the CBI did not have to do with the obligation for marking or constant reporting. The act of engaging in interactions with children was more important and was clearly remarked in every session. High frequency and quality for shared time playing together and

performing the activities was the declared goal. Each session, depending how many people make up the group (no more than 5 - 6 caregivers and children), runs for about 40 minutes. Within each session, after an initial teaching session with the whole group, the facilitator provides each caregiver and child pair with individual support in the CARE booklet content. Following an introductory session that outlines the structure of the programme, the sessions that follow will focus on a particular domain of development (Personal-Social, Language and logico-mathematical reasoning, Fine motor skills, and Gross motor skills) and the items included in CARE for each one. The CBI make use of group presentations accompanied by slide materials (bullet points with key messages, pictures, and videos) focusing and like the DBS intervention, embedded within each session were brief video clips of local Spanish-speaking parents demonstrating good practice of the session content. These can be shared with the group electronically using a laptop, tablet, or projector. Each weekly session, specific activities were presented for parents to carry out and report using the CARE booklet.

Figure 5.2

Area for daily marking in every activity of CARE booklet.



At the beginning of the second session, and each subsequent session, the facilitator checked if that week's daily records had been used, and if any difficulties had been encountered. It was not possible to determine any significant changes week by week, because caregivers' written, and verbal accounts of their daily reporting were frequently inconsistent.

One facilitator, a final year-undergraduate student of Psychology at Universidad de la Sabana, was trained by the Thesis author to deliver the CBI.

5.5.2.3. Description of input from the Children Centre local services.

All the children participating in the study received 70% of their daily nutritional requirements (breakfast, two snacks, and lunch) in the Children's Centre (CC). Also, all children (N = 75), including every participant dyad in all three groups (i.e., parents-child in DBS intervention, CBI, and Control), receive a daily mixture of services in the CC delivered by undergraduate interns (e.g., physiotherapy, general health advice), supervised by professional specialists and regularly programmed though play activities (e.g., singing nursery rhymes, painting). One of these services for all participants included reading-aloud practice with children, which was mandatory in the CC since its management explored a new structured curriculum of preschool activities. Nevertheless, unfortunately, no information about reading practices at CC is collected or analysed like in recent studies on book-sharing (Torr, 2020).

Like other procedures in previous chapters involving the CARE booklet, the parents in the control group only received the instruction to "write or sketch" in a blank paper booklet any activity that they had carried out with their children that month. This method for the control group is a placebo (McQuay & Moore, 2005). Before the post-trial measurements for the control group, the blank booklet was collected.

5.5.3. Outcome measures

Outcomes were assessed at a post-intervention session conducted the following week after the sixth session. The number of groups for each intervention (more than four) forces to have two additional weeks as the starting point and, consequently, post-intervention assessment sessions in the 7th and the eighth weeks following the baseline assessment. However, the Control group was assessed seven weeks after the baseline assessment session. Two graduate psychologists who conducted assessments, blind to group membership, were trained in the specific measures used. The following measures were administered at baseline and follow-up. The complete set of assessments took 60-90 minutes.

5.5.3.1. Primary outcomes.

a. *General developmental screening report (Haizea-Llevant screening table).* As previously described, the Haizea-Llevant screening table (HLL) is a developmental

screening version of the Denver Developmental Screening Test (Frankenburg, 1987; Frankenburg et al., 1976) and the Denver Pre-screening Developmental Questionnaire (PDQ). The HLL for the current study's age range has 57 items and four dimensions: i) Fine motor (12 items); ii) Gross motor (9 items); iii) Language and logico-mathematical reasoning (22 items); and iv) Personal-Social (14 items). For individual assessment classification, the developmental performance score was defined as the number of age-appropriate test items of a dimension that a child successfully passed. For nominal classification, a "Caution" was counted when an age-appropriated item was not passed. If the child was older than the limit age for the 95% of population passing the item, and did not pass it, the item was counted as a "Delay". The counting of caution and delayed items is used to determine risk or developmental delay status (Vitrikas et al., 2017). For nominal classification, children with ≥1 Delay or ≥2 Cautions would be classified "At risk". Scoring no Delays or just one Caution is not considered to be indicative of risk. For general screening and analysis of development across different dimensions, both Delays and Cautions were counted. The method used is consistent with the use of the instrument described in previous chapters.

b. *Child verbal comprehension.* We used the Wechsler Preschool & Primary Scale of Intelligence – Fourth Edition (WPPSI-IV), specifically, the verbal comprehension full scale for ages 2;6-3;11, comprising the Receptive Vocabulary, Information, and Picture Naming subscales.

5.5.3.2. Secondary outcomes.

a. *Literacy skills:* Fluency was assessed, using the Dynamic Indicators of Basic Early Literacy Skills (DIBELS, 8th Edition). The DIBELS is a battery of brief fluency measures that can be used for universal screening and progress monitoring in preschool contexts (e.g., Nichols, Kim, & Nichols, 2018). Letter Naming Fluency (LNF), Phonemic Segmentation Fluency (PSF), and Word Reading Fluency (WRF) were assessed. Recently a wide regional study with 1st graders in USA (N=11086), report 5.5% missing values in pre-test and 4.3% post-test scores for an application of the following subtests: sound fluency, phoneme segmentation fluency, letter naming

fluency, nonsense word fluency, oral reading fluency, and retell abilities (Kim et al., 2021). Therefore, low values and even floor performance is expected for some subtest.

b. *Child basic reading skills:* The *Get Ready to Read!* (GRTR) screening measure, which is supported by the US National Center for Learning Disabilities (Whitehurst, 2001), was used. It is a brief, user-friendly measure that assesses children's print knowledge, letter knowledge, and early reading skills. It has established validity in indexing emergent literacy skills within the preschool classroom (Phillips, Lonigan, & Wyatt, 2009; Whitehurst, 2001).

c. Narrative skills measured using the Frog Story (*Frog, where are you?* Mayer, 1969). This is a 24-picture story book without words. Botting's (2002) procedure was followed, with the child asked to look at every page of the book and then to tell the story. The Frog Story's analysis also followed Botting (2002) and included the narrative structure (i.e., formal opening, orientation to characters and setting, explicit mention of the theme, a resolution, and a formal ending), the length (counting both number of words and number of propositions), and the use of narrative devices (i.e., mentalizing terms, negatives, causatives, hedges, and words spoken by a character).

Child age and gender, principal caregiver's education level, reported reading engagement at home, mother's employment status, and SES using Colombian household stratification statistics were used as covariates.

5.5.4. Data analysis

All statistical analyses were conducted using IBM SPSS Statistics for Macintosh, Version 25.0 (IBM Corporation, 2017). Due to the small sample in each group of participants (< 30) and the nature of the research as a pilot design study (Conn et al., 2010), analysis consisted of pairwise comparisons between each intervention group and the control group (i.e., DBS vs Control and CBI vs Control).

Again, due to the small sample, as a first step in analysis, we conducted two-way ANCOVAs for a parametric check of interactions between factors (i.e., DBS vs Control and CBI vs Control) and sociodemographic variables (i.e., child age, gender, principal caregiver's education level, reported reading engagement at home, mother's employment status, and

socioeconomic stratification) controlled by pre-intervention scores on each assessment. Then, after the two-way ANCOVA procedure, the interaction (i.e., group * sociodemographic variable) was removed, and the ANCOVA (i.e., one way) was rerun with only main effects for intervention groups and pre-intervention scores, including all the measurements (i.e., primary, and secondary outcomes) and the Cautions and Delay items in the four developmental domains observed in the primary outcome measurements. The unequal sample size in each group prevents the exhaustive pairwise analysis to complete the two-way and one-way ANCOVAs, including post-hoc procedures, like the Schefft's test, to find out which pairs of means are significant (Westfall, 1997; Westfall & Young, 1993). Instead of the exhaustive pairwise analysis, the effect size is reported following the principles and recommendations of Lakens (2013) and Pek & Flora (2018) for eta-squared ($\eta 2$) and partial eta-squared (η^2_p) interpretation, that express the amount of variance accounted for by one or more independent variables. The following rules of thumb are used to interpret values for $\eta 2$ and η^2_p: .01= small effect size, .06 = medium effect size, .14 or higher = large effect size.

5.6. Results

5.6.1. Initial and Follow-Up Group Outcomes

Group mean and standard deviation (*SD*) scores for all variables at the initial and follow-up assessments are shown in Table 5.3. Overall, primary outcomes presented positive improvements in the intervention groups (DBS and CBI), with fewer Delays and Cautions in the general post-screening, and high indices in the WPPSI-IV subtest post-measurements (i.e., Receptive Vocabulary, Information, and Picture Naming). The control group also showed improvements, except in Delays (higher in post-screening) and lower values in the WPPSI-IV Picture Naming subtest post-measurement compared with the pre-tested values. Likewise, overall improvements were observed in all secondary outcome post-test scores with one exception: the CARE group had lower scores in the basic reading skills post-test results with GRTR (*Get Ready to Read*) compared with the pre-test values.

Table 5.3

Group mean and Standard Deviation (SD) for counting and scores at initial and interim follow-up assessments for primary and secondary outcomes.

Group	DBS N=25		CBI N=23		Control (Only CC services) N=27	
	Initial	**Follow-up**	**Initial**	**Follow-up**	**Initial**	**Follow-up**
Age in months: mean (SD)	42.8 (8.03)	44.8 (7.27)	46.6 (6.64)	47.3 (6.50)	45.2 (6.90)	46.7 (7.04)
Primary Outcomes:						
General screening HLL: Items in Delay	3.00 (2.04)	1.48 (1.83)	2.04 (1.69)	1.04 (1.52)	1.67 (1.52)	2.37 (1.47)
General screening HLL: Items in Caution	3.76 (2.42)	3.68 (2.34)	3.26 (2.38)	1.96 (2.06)	3.30 (2.95)	2.33 (2.17)
Child Verbal comprehension: WPPSI-IV Receptive Vocabulary	9.23 (4.35)	11.0 (4.48)	9.18 (5.25)	13.0 (3.84)	11.3 (5.08)	13.2 (5.31)
Child Verbal comprehension: WPPSI-IV Information	7.41 (3.89)	10.7 (4.47)	8.00 (4.52)	11.5 (4.32)	12.1 (3.43)	12.6 (3.30)
Child Verbal comprehension: WPPSI-IV Picture naming	7.86 (4.95)	9.53 (4.34)	7.95 (4.29)	10.9 (3.01)	11.8 (2.65)	9.86 (4.83)
Secondary Outcomes:						
DIBELS: Letter Naming Fluency (LNF)	0.04 (0.20)	0.05 (0.23)	0.00 (0.00)	0.07 (0.26)	0.00 (0.00)	0.07 (0.27)
DIBELS: Phonemic Segmentation Fluency (PSF)	0.08 (0.41)	0.11 (0.46)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
DIBELS: Word Reading Fluency (WRF)	2.42 (7.32)	9.47 (11.3)	0.57 (1.43)	10.4 (19.4)	3.67 (7.66)	12.07 (20.3)
Child basic reading skills: GRTR – Get ready to read items	6.42 (4.01)	7.26 (4.09)	9.00 (3.20)	8.50 (2.71)	7.0 (4.42)	7.50 (4.91)
Frog: Structure.	13.7 (14.1)	36.3 (24.5)	25.3 (16.0)	37.1 (22.0)	22.9 (17.3)	35.6 (26.0)
Frog: Length.	64.7 (86.6)	110.1 (64.1)	64.7 (71.6)	159.3 (113.9)	96.1 (73.6)	115.4 (72.2)
Frog: Narrative devices.	2.19 (4.59)	4.63 (5.23)	1.33 (3.15)	7.71 (8.17)	4.21 (5.07)	4.89 (4.46)

Note: HLL: Haizea-Llevant.

5.6.2. Sociodemographic effects on pre-post assessments for DBS and Control Group

Two-way ANCOVA analysis indicated statistically significant interactions between the DBS intervention and mother's education level and family socioeconomic status, on post-test measurements of HLL Caution items and on WPPSI-IV's Receptive Vocabulary and Picture Naming subtests, while controlling for pre-test values (Table 5.4). Likewise, child age and gender and mother's education level had moderating effects on certain secondary outcomes (DIBELS Letter Naming and Word Reading scores, the *Get Ready to Read* items and the Frog Story narrative devices) when the DBS group was compared with the control group. The measurements without a significant moderating effect of sociodemographic variables (i.e., the Delay items in the HLL, the WPPSI-IV Information subtest, the DIBELS Phonemic Segmentation Fluency score, and the Frog Story structure and length scores) were analysed to obtain the main effects of the DBS intervention compared to Control group in post-test measurements, controlling for pre-test measurement values. Exhaustive pairwise analysis is not completed after the two-way ANCOVA, excluding *post-hoc* procedures, like the Scheffé's test (Westfall, 1997; Westfall & Young, 1993). Instead, partial eta-squared (η^2_p) is reported (Lakens, 2013; Pek & Flora, 2018): .01= small effect size, .06 = medium effect size, .14 or higher = large effect size.

Table 5.4

Two-way ANCOVAs results for sociodemographic significative interactions with post measurements by DBS intervention or Control condition and pre-measurements values

Co-variable*	Measurement (DV)	*df* interaction	*df* Error	Adj. R^2	*F*	η^2_p
	Primary Outcomes:					
Mother's Education level	General screening HLL: Items in Caution	2	23	.612	6.73***	.369
Mother's Education level	WPPSI-IV Receptive Vocabulary	2	13	.638	6.14**	.486
SES	WPPSI-IV Picture Naming	1	18	.378	4.69**	.207
	Secondary Outcomes:					
Child: age	Letter Naming Fluency (LNF)	15	10	.430	6.24***	.757
Child: age	Word Reading Fluency (WRF)	15	9	.484	4.12**	.696
Mother's Education level	GRTR – Get ready to read items	2	13	.564	6.17**	.487
Child: gender	Frog: Narrative devices.	1	17	.528	4.66**	.215

Notes: *Co-v in interaction with "intervention*Pre-measurement".
DV = Dependent variable: Post-measurements; HLL= Haizea-Llevant; SES= Socioeconomic status. ** p < .05 *** p < .01

5.6.3. Sociodemographic effects on pre-post assessments for CBI and Control Group

Two-way ANCOVA analysis indicated a statistically significant interaction between the CBI with child gender and family socioeconomic status, on post-test measurements of HLL Caution items and on the WPPSI-IV Picture Naming subtest, controlling for pre-test measurement values (Table 5.5). Likewise, child gender, mother's education level and reading engagement at home had moderating effects on secondary outcomes (DIBELS Letter Naming Fluency and the *Get Ready To Read* items) when the CBI group was compared with the control group. The measurements without a significant moderating effect of sociodemographic variables (i.e., HLL Delay items, the WPPSI-IV Receptive Vocabulary and Information subtests, DIBELS Phonemic Segmentation and Word Reading Fluency, and the Frog Story structure, length, and narrative devices) were analysed to obtain the main effects of the CBI compared to the control group in

post-test measurements, controlling for pre-test measurement values. Exhaustive pairwise analysis is not completed after the two-way ANCOVA, excluding *post-hoc* procedures, like the Scheffé's test (Westfall, 1997; Westfall & Young, 1993). Instead, partial eta-squared (η^2_p) is reported (Lakens, 2013; Pek & Flora, 2018): .01= small effect size, .06 = medium effect size, .14 or higher = large effect size.

Table 5.5

Two-way ANCOVAs results for sociodemographic significative interactions with post measurements by CBI or Control condition and pre-measurements values

Co-variable[+]	Measurement (DV)	*df* interaction	*df* Error	Adj. R^2	*F*	η^2_p
Primary Outcomes:						
Child: gender	General screening HLL: Items in Caution	1	45	.464	4.18**	.085
SES	WPPSI-IV Picture Naming	1	15	.261	6.47**	.301
Secondary Outcomes:						
Child: gender	Letter Naming Fluency (LNF)	1	23	.522	5.22**	.185
Mother's Education level	Letter Naming Fluency (LNF)	3	13	.320	4.12**	.488
Reading engagement at home	GRTR – Get ready to read items	3	11	.638	4.16**	.532

Notes: [+]Co-v in interaction with "intervention*Pre-measurement".
DV = Dependent variable: Post-measurements; HLL= Haizea-Llevant; SES= Socioeconomic status.
** p < .05

5.6.4. Primary and secondary outcomes comparison in pre-post assessments for DBS and Control Group

One-way ANCOVAs were conducted to compare the effectiveness of the DBS intervention on the post-test variables whilst controlling for pre-test measurement values. Levene's test and normality checks were carried out and the assumptions were met. Eta-squared (η^2) is reported

(Lakens, 2013; Pek & Flora, 2018; interpretation values: .01= small effect size, .06 = medium effect size, .14 or higher = large effect size).

There was a significant difference between DBS intervention and control groups on HLL Delay items, F (1, 49) = 6.50, p = .014, partial η^2 = .117, and Caution items, F (1, 49) = 5.91, p = .019, partial η^2 = .108. No differences were found in other measurements when DBS and control groups were compared.

5.6.5. Primary and secondary outcomes comparison in pre-post assessments for CARE and Control Group

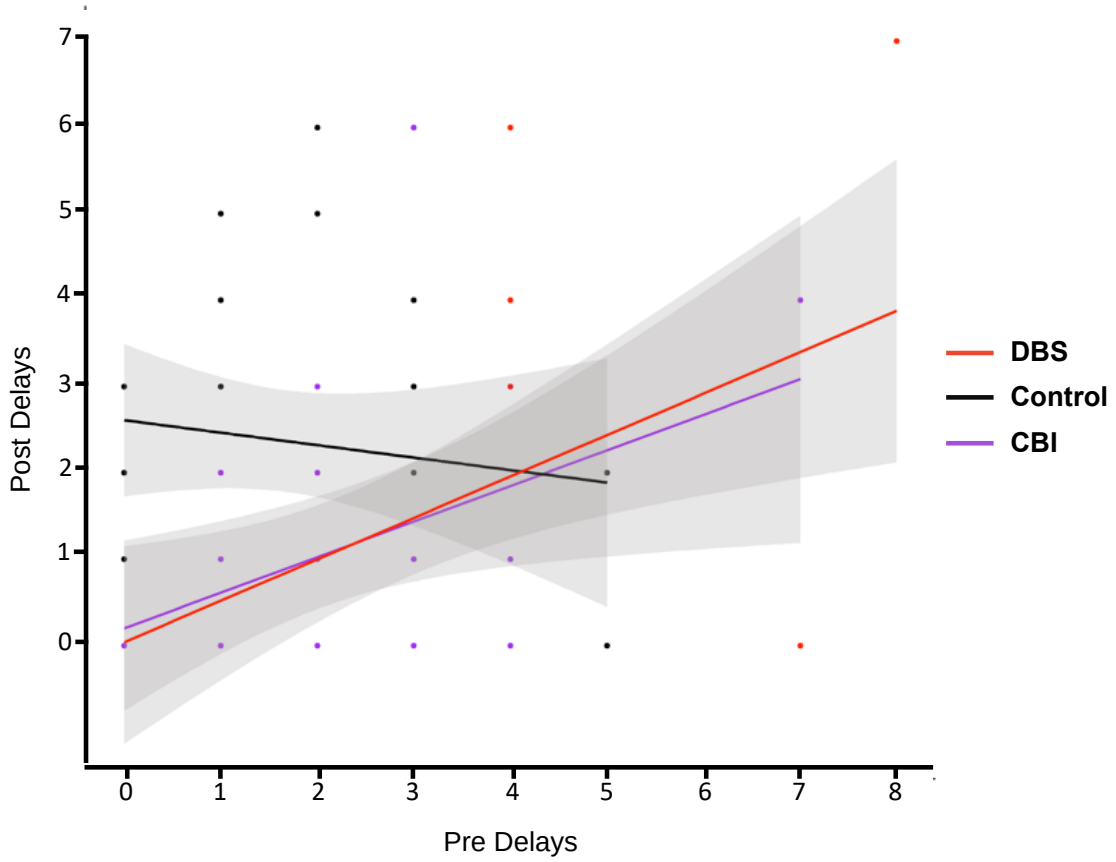
One-way ANCOVAs were conducted to compare the effectiveness of the CBI in the post-test measurements whilst controlling for pre-test measurements values. Levene's test and normality checks were carried out and the assumptions were met. Eta-squared (η^2) is reported (Lakens, 2013; Pek & Flora, 2018; interpretation values: .01= small effect size, .06 = medium effect size, .14 or higher = large effect size).

There was a significant difference between the CBI and control groups on the HLL Delay items, F (1, 47) = 10.45, p = .002, partial η^2 = .182, and the Frog Story's narrative devices scores, F (1, 17) = 4.87, p = .041, partial η^2 = .223. No differences were found in other measurements when CARE and control groups were compared.

ANCOVA results in both comparisons (DBS vs Control and CBI vs Control) indicate that mean post-tested Delay items in HLL observations differed between the parental training conditions and the control group, with a positive association between the pre-test and post-test counts of Delays. Children in both DBS and CBI conditions displayed adjusted post-test Delays means that were higher than the mean for the control group. Fig. 5.3 below shows the significant nature of the association for each of the conditions (i.e., DBS and CARE) compared to the Control group.

Figure 5.3.

Scatterplot with regression lines for interactions between pre and post Delays in Haizea-Llevant for DBS, Control and CARE groups.



Note. This Figure demonstrate a positive effect of the DBS and the CBI interventions in diminishing the post Delays. The solid lines in colours represent the regression slopes for the DBS (Red) and the CBI (Violet) groups. The black line corresponds with the regression slope in the control group and indicates a negative relation for the pre and post Delays. The grey shadow areas for each line represent the standard error for each trendline-data.

5.6.6. General Screening (Haizea-Llevant) Developmental Dimensions Comparison in Pre-Post Assessments for DBS and Control Group

Group mean and standard deviation (*SD*) scores for the four developmental dimensions in Haizea-Llevant (HLL) screening at the initial and follow-up assessments are shown in Table 5.6. Overall, primary outcomes presented positive improvements in the intervention groups (i.e., DBS

and CBI), with fewer Delays and Cautions in all four HLL dimensions. Fine motor-adaptive Cautions and gross motor skills Cautions were higher in the follow-up assessment for the DBS group.

Table 5.6

Group mean and standard deviation (SD) for initial and follow-up Delays and Cautions in developmental dimensions in Haizea-Llevant assessment.

	DBS Training N=25		CARE Training N=23		Control (Only CC services) N=27	
Developmental Dimension	Initial	Follow-up	Initial	Follow-up	Initial	Follow-up
Personal-Social:						
Delays	0.68 (0.69)	0.20 (0.41)	0.43 (0.51)	0.30 (0.56)	0.96 (0.76)	0.85 (0.86)
Cautions	1.00 (0.87)	0.84 (0.75)	1.00 (0.90)	0.52 (0.73)	1.30 (0.99)	0.89 (1.01)
Language and logico-mathematical reasoning:						
Delays	0.96 (0.79)	0.80 (0.87)	0.52 (0.67)	0.43 (0.73)	0.11 (0.32)	0.56 (0.64)
Cautions	1.80 (1.38)	1.48 (1.05)	1.17 (1.34)	0.74 (1.05)	1.30 (1.59)	0.85 (1.23)
Fine motor-adaptive:						
Delays	0.64 (0.70)	0.24 (0.60)	0.57 (0.84)	0.09 (0.29)	0.30 (0.67)	0.56 (0.58)
Cautions	0.48 (0.77)	0.48 (0.71)	0.52 (0.79)	0.35 (0.65)	0.19 (0.56)	0.22 (0.42)
Gross motor:						
Delays	0.72 (0.79)	0.24 (0.72)	0.52 (0.67)	0.22 (0.60)	0.30 (0.54)	0.41 (0.57)
Cautions	0.48 (0.65)	0.88 (0.78)	0.57 (0.66)	0.35 (0.57)	0.52 (0.70)	0.37 (0.56)

One-way ANCOVAs were conducted to compare the effectiveness of DBS intervention in post-test measurements for the four developmental dimensions in the HLL screening, controlling for pre-test measurements values. Levene's test and normality checks were carried out. There was a significant difference between the DBS and control groups in the HLL's Personal-Social skills Delays, F (1, 49) = 9.31, p = .004, partial η^2 = .160, in favour of the DBS group. in contrast, HLL gross motor skills Cautions showed a significant decrease in the Control group, F (1, 49) = 7.86, p = .007, partial η^2 = .138. No differences were found in other dimensions when DBS and control groups were compared.

5.6.7. General Screening (Haizea-Llevant) developmental dimensions comparison in pre-post assessments for CBI and Control Group

Likewise, one-way ANCOVAs were conducted to compare the effectiveness of CBI in post-test measurements for the four developmental dimensions in the HLL screening (HLL), whilst controlling for pre-test measurement values. Levene's test and normality checks were carried out. There was a significant difference between the CARE and control groups in HLL fine motor-adaptive Delays, $F(1, 47) = 10.8$, $p = .002$, partial $\eta^2 = .187$, in favour of the CBI group. No differences were found in other dimensions when the CBI and control groups were compared.

5.6.8. Effect sizes correction in significant one-way ANCOVA.

The ANCOVA procedure in SPSS by default calculates effect size using partial eta squared (η^2_p). The η^2_p statistic belongs to the *r* family of effect sizes (Lakens, 2013), and describes the proportion of variance that is explained by group membership (e.g., bivariate correlations: $r = 0.5$ indicates that 25% of the variance in one variable is explained by the variance in another variable). Several sources (e.g., Leech, Barrett, & Morgan, 2005; Pek & Flora, 2018) recommend the use of corrections for bias, even if corrections do not always lead to a completely unbiased effect size estimation. In the *r* family of effect sizes, the correction for eta squared (η^2) is known as omega squared (ω^2).

Calculating the omega squared (ω^2) statistic for the significant ANCOVA results in our study was done using the following formula:

$$\omega^2 = \frac{SS'_B - (K-1)MS'_W}{SS'_T + MS'_W}$$

where SS'_B is the sums of square for the adjusted treatment (independent variable), K - 1 represents the between-groups degrees of freedom, MS'_W is the error mean square and SS'_T is the total sum of squares, all reported by default in the SPSS output for the ANCOVA procedure.

The resulting ω^2 calculation in reports of significant comparisons between DBS vs control groups and CARE vs control groups are shown in Table 5.7. The ω^2 ranges in value from 0 to 1 and is interpreted as the proportion of variance of the dependent variable related to the factor (independent variable), partially holding constant the covariate: that is, the proportion of total variance in the dependent variable accounted for by the independent variable, controlling for the

effect of the covariate. Cohen (1988) provided benchmarks applied to ω^2 when partial η^2 is corrected: small effects > .01, medium effects > .06, and large effects > .14.

Table 5.7

Interpretation of corrected partial η^2 for ANCOVAs in DBS vs Control and CBI vs Control comparisons.

Reported significant ANCOVA comparison **DBS vs Control group**	ω^2	Cohen (1988) benchmarks' range effects interpretation
All Delay items in Haizea-Llevant	0.04	Small
All Caution items in Haizea-Llevant	0.02	Small
Personal-Social dimension Delays (HLL)	0.08	Medium
Gross motor dimension Cautions (HLL)*	0.07	Medium
CARE vs Control group		
All Delay items in Haizea-Llevant	0.07	Medium
FROG's narrative Devices	0.06	Medium
Fine motor-adaptive dimension Delays (HLL)	0.11	Medium

Note. * = Favouring Control group.

As can be seen from Table 5.7, significant effect sizes, ranging from small to medium, were evident for the DBS condition in four child development outcomes, in three of them favouring the intervention group; and for CBI there were significant medium-sized effects for three items. On only one item (all HLL Delay items) was there a notable effect size for both intervention conditions.

5.7. Discussion

This study was a pilot Q-RCT of parent training for two interventions with preschool children at risk of not reaching their developmental potential. Findings in the dialogical book sharing (DBS) and CARE booklet intervention (CBI) were in line with our prediction that the parental training interventions would enhance children's developmental status and language-related skills. Also, follow-up in both CBI and DBS intervention groups revealed significant positive results in both primary and secondary outcomes compared to the control group that had received local services only. This includes the effect of the decrease in HLL Delay items for the post-test measurements in the DBS and CBI groups compared with the control group. Interestingly,

specific results from both interventions (i.e., DBS, CBI) seems to profile a complementary effect. In the ANCOVAs (giving overall effects interpretation only as an informative benchmark for sample size calculation in any subsequent RCT), small to medium-sized effects were found in three developmental domains (two with DBS and another with CBI). Despite the descriptive results and mean differences for counting and scores at initial and interim follow-up assessments for primary and secondary outcomes (Table 5.3.), the ANCOVAs do not reveal significant changes when each intervened groups are pairwise compared with the Control group assessments (Appendix F).

Overall results and intervention effects are consistent with the theoretical and empirical basis of systematic reviews for DBS programmes in other languages than Spanish (Dowdall et al., 2020), and show a relevant reduction in developmental screening Delays and Cautions. Moreover, specific changes in the specific dimensions of Personal-Social and Gross motor skills suggest further inquiries into the extended benefits of the large effects in caregivers' book-sharing competences compared to controls (cf. Dowdall et al., 2020) A next step in the analysis of parent and caregiver effects in the Spanish-translated DBS might include parental social and play sensitivity, where significant positive effects have previously been reported (Murray et al., 2016). Our results indicate that benefits may be found in social skills, as well as verbal and language gains in children after parental interventions.

The consideration of sociodemographic variables in two-way ANCOVA analysis is informative for any future RCT. Mother's education levels and socioeconomic status, even in very low-income families in LMICs, had a moderating effect for children's developmental and language skills (as measured by HLL Caution items and the WPPSI-IV Receptive vocabulary and Picture Naming subtests) in DBS intervention compared with the control group. The report of sociodemographic covariation with the pre- and post-test interactions when DBS and control groups were compared, should be considered as a matter of particular interest to include in further exploration of moderation analyses with diverse social and cultural variables. Any subsequent RCT requires a deep evaluation of conditions at home and local services related to a formal introduction to writing, and training in cognitive skills and performance with narrative devices. Likewise, child age could have effects in similar DBS interventions. The relationship between child age and the measurement of basic early literacy skills (DIBELS) could be restricted by the proportion of 24-35 months old participants (16%) in the DBS intervention group, but the results

agree with previous DBS interventions with younger participants (Cooper et al., 2014). Also, child gender had a small effect on the differences between DBS and control groups in the Frog Story narrative devices score. However, due to our small sample, we cannot firmly establish if gender is a factor related to narrative abilities, in the same way that 4–11-year-old girls have been found to generate more complex narratives than boys (Ögel-Balaban & Hohenberger, 2020).

For the CARE booklet intervention (CBI), the results support using it as a social pragmatic approach for parental reports that gives confidence in activities and interactions at home. Reduction in overall delays, and a medium-sized effect on narrative devices and fine motor-adaptive skills, confirm the CBI as a feasible alternative to fill the gap in interventions that provide prompts, guidance, and scaffolding delivered to parents and caregivers (Biel et al., 2020). However, two-way ANCOVA analysis should be used for future RCT direction, to consider effects of child gender, socioeconomic status, mother's education levels and the frequency of reading engagement at home, which all had interaction effects on the developmental, language and reading differences between children of parents receiving CBI compared and children of the control group.

According to Dowdall et al. (2020), dosage intervention has significant effects in previous DBS studies, implying for our intervention a chance to have a more positive impact on children if the intervention dosage is increased. Indeed, considering that improvements took place in comparison with a control group who received centre-based services for nutritional and regular day care activities, the results for both interventions are remarkable. To our case, the dosage might be related to the absence of direct effects in Language and mathematical reasoning at the developmental screening for DBS and CBI compared to the control group. Effects reported in general language and mathematical milestone items are not consistent with the general findings of meta-analysis for parental intervention results in psychosocial stimulation interventions (Jeon et al., 2018; Pedersen et al., 2019). They found that the impact of the intervention dosage had clear and robust moderation effects on child language outcomes, with low dosage associated with a minimal impact.

5.8.Limitations and future research

All effect sizes in a pilot study should be interpreted with caution because there are several limitations arising from the small sample size. The present DBS and CBI study requires a major sample size for a rigorous and detailed mapping of the effects that similar procedures had with

poor low-income families in LMIC, including a sociodemographic variation control for future *post hoc* analysis after the two-way ANCOVA procedures.

The comparison with centre-based interventions, like the aeioTu program (Nores et al., 2019) might not be convenient, but DBS and CBI are suitable alternatives to consider when taking into account the child-to-adult dyadic ratio and the length of the intervention. A formal comparison between our parent-based intervention with a centre-based intervention like that reported by Nores et al. requires a precise background in the scientific literature related to comparisons of interventions in Spanish-speaking and LMIC conditions, and so far, there has been no such study.

Also, parents of children allocated to the control (local services only) group were assigned to the control condition by virtue of not presenting themselves on the day of DBS and CBI randomised allocation, and, as such, cannot be regarded as a true random control group. However, such parental choice reflects a real-life clinical and research situation. Future RCT studies should be completely coherent with randomised allocation and sufficient sample size to avoid such potential biases, and to increase statistical power to generalize the detected differences between groups.

Another limitation of our study probably resides in our measure of development. The Haizea-Llevant observation table (HLL) is meant as a screening tool and not a diagnostic tool. A high number of Delay and Caution items in HLL developmental dimensions should strictly not be interpreted as a delay relative to benchmarks in comparison with children of the same age. A developmental dimensions report is not the same as a diagnosis of a specific developmental delay. Therefore, these results were framed in terms of children being “At risk” of loss of developmental potential.

The generalizability of our findings may be affected using a sample from a community-based services-program. Participation in the nutritional program offered in the participant children care centre is voluntary. Parents who had concerns about their child's development might have been more inclined to stay in the programme than parents who found their children to be on track. This could have inflated our estimates of the prevalence of risk for developmental delay. On that point, as indicated, we need formal diagnostics with developmental evaluations to corroborate any delayed condition. However, our sample has relatively similar proportions of sociodemographic conditions as the broader group of participants with have previously been seen as at risk of developmental delay (Edmunds, 2020; Richter et al., 2019). For these reasons, it seems reasonable

to assume that our sample does not overestimate the risk for developmental delay in this low-income LMIC population.

A great limitation in this study is related to the absence of direct observational assessment of the parent skills (e.g., social and play carer sensitivity) which in previous DBS interventions have been shown to produce significant positive changes in infants' cognitive and socioemotional outcomes (Murray et al., 2016). This absence was due to scarce financial resources for the Q-RCT.

Likewise, the commitment of parental involvement (CPI) in previous stages of recruitment was not assessed. Haine-Schlagel and Escobar-Walsh (2015) indicated in a meta-analysis the potential benefits for intervention research when the CPI and associated factors are reported: most studies indicate how parents face environmental and personal challenges to participate actively and conclude that levels of engagement is better understood with the declaration of parental involvement issues. Measures of CPI fall into three main categories: global participation levels, specific participation behaviours, and completion of tasks. Regarding task completion, which indicates attendance at all sessions, the average completion rate in all sessions analysed by Haine-Schlagel and Escobar-Walsh was 49%, with a range of 19% to 89%. One possible explanation for the low engagement in optional participants for the present study (54.9% at first call) could be in the sociodemographic characteristics and the opportunity of adherence for participants.

Comparing our sample and experimental procedure with an RCT of a play-assisted intervention for children living with foster families in extreme poverty (Worku et al., 2018), two characteristics could affect the CPI in our cases. First, like other home-visit interventions, before the COVID-19 pandemic, the family's tendency was to not cancel visits in the Worku et al. intervention. In contrast, our families received all assessments and interventions by arriving at the childcare centre (CC). We included a stipend for participants to travel between home and CC, but the proportion of working mothers in our sample is high (52.2% in the CBI group) and this is a main barrier to increase the levels of CPI when travel to CC is required. Second, Worku and colleagues' (2018) intervention was conducted in a foster family's programme (i.e., SOS-villages), where children live with assigned foster families and are always cared for by an SOS-village mother or an "aunt". The mother or "aunt" always is near when the intervention take place, automatically increasing the CPI levels. In future, direct measures of behaviour and competence of parents need to be included to demonstrate objective and generalisable difficulties in CPI.

The present study has highlighted the significant practical and methodological difficulties in undertaking an RCT of an intervention for parents in low-income conditions with preschool children at risk of not reaching all their developmental potential. Future studies oriented towards improving the interaction skills between caregivers and children (Biel et al., 2020) might consider the use of a low-cost and widely applicable scaffolding guided booklet (e.g., the CARE booklet intervention) and a well-recognized intervention, the DBS. Our general findings on different developmental screening and language competences point to the need for further work on parent training approaches. This should include RCTs of sufficient sample size and methodological rigour to confirm and extend these tentative findings, and to more clearly demonstrate whether parent training with scaffolding guides and book-sharing approaches have a specific beneficial effect on relevant skills and competences of children at risk. One kind of interventions includes screening or early developmental monitoring (Cavallera et al., 2019; Goldfeld & Yousafzai, 2018) to assess and intervene in the most vulnerable populations.

Finally, this pilot is the first result of an intervention using a specific DBS protocol (Dowdall et al., 2017) in the Spanish language. Results make a definitive instrumental and scientific contribution in the literature that covers the effects and reports of interventions in book-sharing around the world (Grolig, Cohrdes, Tiffin-Richards & Schroeder, 2020; Noble et al., 2019) and should be effectively used with screening strategies delivered to homes under COVID-19 pandemic confinement, such as the CARE booklet intervention.

Chapter 6. General Observations about Interventions in LMICs

Before the final discussion about the specific contributions of this thesis to the research questions (RQ#1 – RQ#4), this chapter revisits the sections of the introduction that were dedicated to a wide range of supporting themes, but now viewing them through the lens of the results and the prospect for interventions in LMIC. The themes under discussion include the Nurturing Care approach, the detection-intervention-prevention continuum, and the Complex Adaptative Systems (CAS) framework for health and research systems in LMICs such as Colombia.

The Nurturing Care approach is the conceptual starting point for the research described in this thesis was a research programme carried out in 2012–2014 and, even though the latter was not clearly described in the literature until recently (e.g., Richter et al., 2019; WHO et al., 2018). The program, called *Inicio Parejo de la Vida* ("Equal Start in Life", henceforth IPV) was designed as the detection phase in a detection-intervention-prevention continuum for improvement of developmental outcomes in children from vulnerable and impoverished families. The protocols, instruments and measurement tools were intended to form the baseline for detection of changes in developmental status, after a planned intervention phase that never took place. The then government decided in 2014 – in a unilateral decision without consulting the IPV researchers – to cease the funding obtained in a ground-breaking call for eight-year proposals on child health research from Colciencias (the Colombian national research council, which has since been taken back under direct control of the Ministry of Science, Technology, and Innovation, or Minciencias). The immediate effect of this withdrawal of funds was the limitation for developmental monitoring and home visits for diagnostics and interventions with vulnerable families.

IPV leaves a lesson for intervention programs in LMICs: even with financial and political support from governments and policymakers, there is no assurance of intervention and prevention phases in the expected continuum after the detection of risk in regionally scaled processes. The lack of support in the public sector for scaling up the interventions when aiming for long-term financial sustainability (Cavallera et al., 2019) suggests an alternative avenue for maintenance of the detection-intervention-prevention continuum through non-governmental and community organizations. Participants in Cavallera and colleagues' study were members of existing networks interested in innovations to improve healthy development (e.g., Saving Brains® and Grand Challenges Canada®), but stakeholders from civil society and private sectors do not easily find

frameworks available to guide them in successful scalability for every phase in the detection-intervention-prevention continuum.

Thus, the detection-intervention-prevention continuum in LMICs needs both a multidimensional concept of poverty, and the inclusion of developmental screening tools that work with home-based records (Cavallera et al., 2019; Osaki et al., 2019). The present thesis will focus on the detection and intervention phases, because prevention requires escalating efforts in a way clearly designed by different academic and government agents (Boggs et al., 2019; Cavallera et al., 2019; Magwood et al., 2019). The CARE booklet might act as a device for detecting risk in children. The parental administration of CARE is a cheaper and sustainable method for developmental screening in LMICs, even without clear frameworks for scaling up parental-intervention projects (Cavallera et al., 2019). However, the lack of frameworks for scaling up projects in LMICs is not the main concern of this thesis, which is focused on a system-wide perspective for understanding the behaviour of diverse, interconnected agents and processes – the Complex Adaptive Systems (CAS) healthcare framework (McDaniel et al., 2009; Paina & Peters, 2012; Perez-Escamilla & Hall-Moran, 2016).

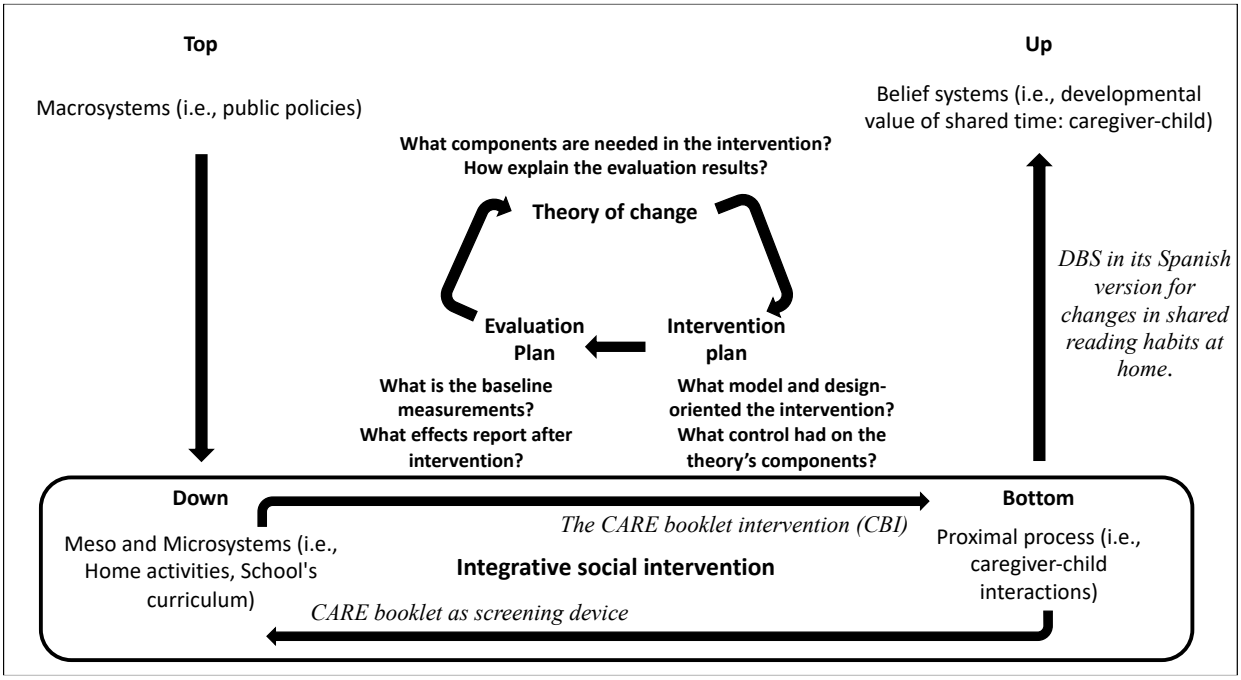
The Complex Adaptive Systems (CAS) allows a discussion in this chapter about two main categories in which parental support interventions can be classified: top-down and bottom-up. The application of Bronfenbrenner's theory to public mental health research described and apply the top-down and bottom-up interventions (Eriksson, Ghazinour, & Hammarström, 2018). I have insisted through the different chapters of the thesis that integration of both types of models is required for long-lasting and scalable impacts on children's development (Cavallera et al., 2019), including parental scaffolding, knowledge about developmental skills, and belief interventions (Cuartas et al., 2020). The Dialogical Book-Sharing (DBS) programme and the CARE Booklet Intervention (CBI) directly respond to a CAS orientation when use the obtained information with the CARE booklet as a measurement device. Then, focusing on diverse mesosystems and microsystems (e.g., daily at-home activities and preschool play-time dedication), DBS and CBI could engage parents and might encourage beliefs about the developmental value of some previously unconsidered interventions and practices at home.

However, several limitations to better parental engagement require a broad view of early family-centred intervention, integrating proximal processes and micro/meso-systems such as children's centres and schools (Guralnick, 2020; Hamilton et al., 2013). Integrative interventions

explicitly declare the effectiveness on children's developmental outcomes and academic success of enhancing within-family interaction patterns, ideally carried out in inclusive community-based programs (Guralnick, 2020). We interpret an integrative social programme, when designed with an initial family-centred framework, connecting institutional activities (i.e., children centres) with principal caregiver-child interactions at home. Integrative social interventions imply an effort to enclose proximal processes and systems related to contexts of change. Positive results for an integrative plan and evaluation might suggest a way of scaling social effects in small groups to a broad population. Scaling the model includes social and educative perspectives with enlightening guidelines for home and school contexts. A better understanding of demands on family interactions requires models of general intervention structures with specific components oriented more to integrating proximal process routines with meso- and micro-systems than to budgetary efforts or investments in achieving vertical scalability (i.e., laws or political regulations). The barriers to achieving consistent results in developmental interventions will often lie in their affordability, and scalability can imply changing the logic and methods as well (Margoni & Shepperd, 2020). The affordability and scalability in integrative social interventions is explicitly assessed and demonstrated in the elaboration of the CARE booklet, the study of agreement and reliability of parents' report and direct screening using the booklet, and the comparison of the booklet intervention (CBI) with the successful DBS in its Spanish version. Every component used specific questions to maintain a dynamic intervention design for updating goals and improving effects (Fig. 6.1).

Figure 6.1.

Integrative social interventions replicable framework with the CARE booklet, the booklet intervention (CBI) and the DBS intervention in its Spanish version.



The theory of change included in this model extends to proximal processes and micro- and meso-systems in a general developmental framework for interventions. Proximal processes include relevant factors that in daily interactions with adults and peers can change children's developmental trajectories (Bornstein et al., 2017). Also, the present integrated social intervention includes sustainable development and optimal conditions as a consequence of the bottom-down cycle. Sustainability is clearly expressed in two dimensions for the nurturing care concept (Walker et al., 2011): responsive caregiving and early learning. Responsive caregiving is related to caregiver nurturance, including everyday routines with emotional and cognitive support. Early learning is related to at-home and out-of-home opportunities to explore and learn through play and exposure to different materials such as books and toys. Both types of activities can be planned and anticipated before birth and extended to various opportunities for structural and contingent care in different contexts and with different agents. The general model for bottom-down cycles focuses on a more integrative perspective, including tools for responsive caregiving and early preschool

interventions, such as the CARE booklet as a screening device, and the DBS and CBI interventions.

Despite the relevance of the topic, there is a surprising shortage of conceptual and multinational data based on research about interventions and conditions that limit or promote the development of the individual potential of children in LMIC populations (Black et al., 2017; Bornstein et al.; 2017; Gladstone et al., 2018). The proposed model, inserted into a bottom-down framework, demands an effort to establishing a valid baseline with information about the developmental status of at-risk children in LMICs. The integrative bottom-down social intervention model will include, as an initial application in an LMIC, developmental screening to include families and caregivers. Further research should assess the variability of developmental trajectories according to other contextual variables, such as parenting abilities, attachment, and linguistic interactions. The relevance of contextual variables has been incorporated in holistic models for school readiness (Gaynor, 2017), but not in integrative or empirical developmental models. Also, children's educational variables, type of instruction, and active and collaborative learning might be included in line with previous models, which highlight that the possibilities and quality of interactions between children and their proximal environment are key for understanding cognitive development (Burger, 2010; Cipriano-Essel et al., 2013; Fitzpatrick et al., 2014; Jeong, McCoy, & Fink, 2017). An integrative intervention reveals the need for maintaining an applied strategy to enhance interactions between parents or caregivers, to moderate the negative consequences of poverty and economic inequality in LMIC children, following a science-based intervention framework. The integrative model in this thesis follows pilot designs with a small sample of participants to ensure longer-term sustainability for a future cycle of interventions and recommendations to scale early child development interventions in LMICs (Cavallera et al., 2019). This included, for the first time, the reporting of the protocol of a previous Dialogical Book Sharing intervention (Cooper et al., 2014; Dowdall et al., 2020; Murray et al., 2016; Vally et al., 2015) in Spanish.

As conclusion, the current thesis is a firm base for detecting and tracking the children who survive the high neonatal mortality rate in LMICs but suffer from various forms of developmental delay due to poor nutrition, poverty, or interpersonal conflict (Faruk et al., 2020). The purpose of this pre-final chapter was to relate all the exploratory pilots in previous chapters to the psychological relevance of the bottom-down framework, supported by current recommended

practices in collaborative transdisciplinary services (Rausch, Bold, & Strain, 2020) and early childhood educational interventions (Melhuish & Gardiner, 2019). The next and final chapter is dedicated to a general discussion of how to obtain a better CARE screening instrument and a better CBI.

Chapter 7. General Discussion.

As a summary of previous chapters, this chapter integrates all components and results of a quasi-experimental design proposed to measure the diagnostic characteristics and effects of delivery of a screening tool administered by parents (CARE) to families with children at risk of not reaching their developmental potential. It also analyses the effects of the CBI intervention using the CARE screening tool, following a well-established protocols of dialogical book sharing (DBS; Dowdall et al., 2017), on children's developmental outcomes. All chapters included a specific discussion and limitations section, but this chapter includes a general discussion on how to have a better CARE and CBI programme. Currently, the COVID-19 outbreak has inspired global efforts to reduce the effects of the closure of Children's Centres (CC) and other preschool institutions, and a key factor in mitigating the effects of isolation on children is parents' and caregivers' constant interactions with them (Guan et al., 2020). The CARE booklet's potential for developmental screening diagnostic, and the effects of both the CBI effects and the Spanish version of the DBS, should be considered in Colombian CC seriously affected by poverty before and after the COVID-19 outbreak.

Specifically, the results that answer RQ#1 (Are reports of reading activities by parents related to cautionary signs and the detection of developmental delay in the developmental screening of children?) indicates the extent to which, years before the effects of the pandemic (including closure of CC), different reading habits at home might have impacted on children's risk conditions (Bao et al., 2020; Dowdall et al., 2020; Mendelsohn et al., 2018) and allow the promotion of early interventions with parents that have been previously designed and adapted to contexts of extreme vulnerability (Erdemir, 2022). In our case, this includes Spanish-speaking families expecting significant effects in young children's abilities when interventions moderate the economic family conditions (Shen & Del Tufo, 2022). Our results reported in Chapter 2 indicate that if a parent or caregiver increase the frequency of reading from a maximum of two days to three or more days, it could directly affect the developmental status of a child (i.e., differences in children "At risk" or "Not at risk" for groups based on reading habits, $\chi(1) = 5.683$, $p < .05$, $\Phi = .171$). Changing parents' home-reading skills can change children's outcomes and should be a priority in countries like Colombia (Kalil & Ryan, 2020; Mendelsohn et al., 2020; Mermelshtine,

2017; Shen & Del Tufo, 2022). However, our limitations include a lack of analysis of multimodal interactions between parents, children and books as causes of lower frequency of reading habits at home (Davidson, Danby, Ekberg & Thorpe, 2020). CARE designs are hampered by the limitation of not including external observations of parents and children's interactions, not only for reading, but also of the developmental dimensions regularly included in screening tools not administered by parents.

Consequently, with the concern for screening tools not administered by parents, the results that respond to RQ#2 (*Are report of parents with CARE as valid and accurate as reports of expert users of developmental screening tools?*), shows in a small sample (n = 52) good psychometric properties and congruence between the direct screening observation and the parental report using CARE (i.e., overall agreement was 92% by accuracy; agreement between HLL and CARE classifications "At risk" or "Not at risk": Cohen's κ = .810 [95% CI -.973, -.988], p < .0001). Specifically, this thesis examined the consistency between child classifications in CARE and in a Spanish screening tool (the Haizea-Llevant tool; HLL). It analysed the diagnostic characteristics and performance of CARE as a tool for developmental screening using parental report, including item agreement analysis in particular developmental dimensions. Overall, our results suggested high consistency between the two, as well as identifying certain sociodemographic variables that affected the parental observation reported in the CARE booklet, compared with direct assessment using HLL. The detection of these sociodemographic moderators indicates the need for better tracking of interactions related to parenting employment and individual developmental trajectories that have previously been reported in LMIC populations (Campaña, Gimenez-Nadal, & Molina, 2020). However, the inter-measure congruence that was found also suggests that the CARE report is an appropriate tool for child developmental screening, compared to previous agreement-design analysis (Miller et al., 2017). The congruence encompasses the item-level detection in different developmental dimensions, which was higher in Personal-Social and Language and logico-mathematical skills compared to Fine motor-adaptive and Gross motor skills. Additionally, a ROC analysis indicated that CARE is a satisfactory tool for screening diagnostics that might help to build a quantitative index for better and faster classification of "At risk" status in children of 24- to 59-month-old (AUC - binormal curve = 0.89). Our data offer complete diagnostic performance for a screening tool of a kind (Sensitivity = 95%; Specificity = 85%; LR+ = 6.17, LR- = 0.06), that has not been regularly reported in other screening tools designed for LMICs (Faruk et al., 2020).

The inter-measure agreement and diagnostic characteristics of CARE, used as a screening tool, allows a consideration of its inclusion in strategies for optimal health and educational systems interventions (Mahadevan & Broaddus-Shea, 2020) and indicates a similarity with home-based records (HBRs): like them, it is intended to run in parallel with other previously existing or subsequent screening tools and/or interventions. A next step is to consider the elaboration of an online tool with the digital version of CARE and compare it with the physical, printed delivery method considered in this thesis.

However, several limitations not yet commented on imply the need for future studies before the implementation of scalability strategies using CARE as a screening tool. Limitations include the sample size and the mentioned caution for the diagnostic characteristics of CARE compared with the scoring values of HLL in the ROC curve: the similarity of items and the consecutive procedures for observations and reports will not keep the cut-off values in a replication if a different marking method or sample of participants are assessed.

Also, the examination of current analysis for nominal classification and agreement of parents in CARE will change with the inclusion of the reported components of "Core Knowledge" cognition in children. The intra-specific representation or Core Knowledge Systems (Callaghan et al., 2011; Kinzler & Spelke, 2007) considered with CARE are embedded in daily, spontaneous, interactive activities such as play, counting, geospatial orientation, age-pair interactions, and outdoor scenarios, but the format and misinterpretation about the marking in CARE reported by parents limit the inclusion in the performed analysis. Likewise, a misinterpretation in the parental marking for "I can't observe it, or I believe he/she can't do it" implies the arbitrariness of the scoring response analysis presented and requires the kind of rigorous adjustment expected in quantitative analysis of screening tools (Boggs et al., 2019). The consideration of "I can't observe it, or I believe he/she can't do it" responses only affect the nominal classification for comparison with the Haizea-Llevant observation. Deeper quantitative analysis is necessary to establish and answer the question of whether the frequency of responses marked with "I can't observe it, or I believe he/she can't do it" is moderated by parents' screening abilities and also their frequency of interactions with children. Future studies need the controlled attention to the use of the "I can't observe it, or I believe he/she can't do it" option, corrected for diagnostic comparison in the thesis (i.e., added to "No" response criteria) but not analysed here for lack of interest in screening and monitoring studies about this option (Dosman et al., 2012; Fischer et al., 2014). The future analysis

for how parents choose the "I can't observe it or I believe he/she can't do it" option requires: it was for one observation "no" (i.e., a parental belief or recall) or after many observations with "no" (i.e., a parental interaction knowledge). CARE screening might demand attention to behaviours, skills and performances that routinely are included in at-home interactions but do not have previous antecedents for assessment in the consulted scientific literature.

While the amount of attention demanded for parents at home using CARE should be established in future studies, RQ#3 (Might the delivery of a parent-administrated tool for developmental screening to principal caregivers for a month have any effect on children's developmental outcomes?) had a clear answer supported by the non-significant and limited benefit of the delivery for general risk results between pre- and post-assessments in CARE users compared with a control group (i.e., Post-assessment CARE user vs Control group: Delays, $F(2,69) = 1.172$, $p = .28$; Cautions, $F(2,69) = 0.025$, $p = .87$): delivery to parents of a screening tool with relevant information about interaction activities for developmental enhancement was not enough for changes in their children's outcomes. The called "standard model" of consecutive *knowledge → stimulation → development* (*K→S→D*) (Bornstein, 2015; Britto et al., 2017; Cuartas et al., 2020) has limited evidence in a Colombian context: specifically, Cuartas et al. did not find associations between maternal stimulation and children's expressive language or fine motor development in a sample of 1277 low-income mothers and their children under the age of five. Otherwise, Slemming et al. (2021) using longitudinal data from the South African Birth to Twenty Plus study, found associations between high levels of cognitive stimulation at home and screening scores (Revised Denver Pre-screening Developmental Questionnaire, or R-DPDQ) for children in the low-SES group. Comparing Colombian (Cuartas et al., 2020) and South African (Slemming et al., 2021) data about plain stimulation and activities related to child development, helps us to understand the negative results in children's outcomes when parents received a screening tool. LMIC parents and caregivers require more than knowledge about household care or sociodemographic conditions: they need knowledge based on interactions that modulate stimulation and allow developmental changes.

The *K→S→D* model in the light of our results and the successful implementation of screening and home-based records resulting in improved maternal and child health outcomes (Mahadevan & Broaddus-Shea, 2020) suggests a new model: reciprocal stimulating interactions with knowledge are conducive to development, or *knowledge ⇔ interaction/stimulation →*

development (*K*⇔I/*S*→*D*). The implications of the *K*⇔I/*S*→*D* transform the Mahadevan & Broaddus-Shea (2020) declared benefits of tools like CARE but in developmental domains:

(i) to increase caregivers' knowledge about use and demand for interactions and milestones to preserve developmental potential,

(ii) to facilitate communication between caregivers and institutional or community-based systems for developmental wellbeing,

(iii) to reduce missed opportunities of surveillance or monitoring for preservation of individual developmental potential and consequent interventions.

The answer given here to RQ#3 is not a negative judgement of developmental screening or parental reports. On the contrary, the positive results of screening efforts to track a child's developmental progress in LMIC are clear and robust (Faruk et al., 2020). Indeed, one limitation of this answer concerns the methodology for making a link between *knowledge* and *interaction/stimulation* components. Coaching methods for parents have recently been considered (Romano & Schnurr, 2020; Windsor et al., 2019), but the large list of pre-requisites for coaching skills might create an additional burden to the complicated duties of parenting, converting successful interactions with their children into a seemingly impossible task, and possibly causing parental burnout (Roskam et al., 2021). Moreover, the *interaction/stimulation* required of parents using CARE can help parents to use scaffolding mechanisms to identify cognitive tracks (Boyer, 1998; Heintz, 2013) for developmental enhancement in their children. Cognitive tracks are associated with the emergence of cultural phenomena and core cognition. Heintz (2013) describe cognitive tracks as certain causal chains that are "more likely to occur than others," merged in with cultural developmental systems. The CARE items described some paths for relevant cognitive tracks in a developmental context, called developmental milestones. But we need controlled studies for coaching vs non-coaching perspectives, studies like the CARE booklet intervention (CBI). The derived hypothesis about why only the provision of knowledge or screening tools does not provide the stimulation necessary to change individual children's trajectories and outcomes, leads us to the next question (i.e., RQ#4).

Finally, the answer for RQ#4 (Are significant differences in the developmental outcomes for two intervention groups (DBS intervention and CARE intervention) compared with a control group?) are highly satisfactory among potential and notable flaws and a small-sample size. The

pilot Q-RCT of parent training with the two interventions gave us a strong benchmark for sample size calculation in any subsequent RCTs and comparing effects in children's developmental status and language-related skills (i.e., DBS vs Control: HLL Delay items, $F(1, 49) = 6.50$, $p = .014$, partial $\eta^2 = .117$; Caution items, $F(1, 49) = 5.91$, $p = .019$, partial $\eta^2 = .108$; CARE booklet intervention - CBI vs Control: HLL Delay items, $F(1, 47) = 10.45$, $p = .002$, partial $\eta^2 = .182$; Frog Story's narrative devices scores, $F(1, 17) = 4.87$, $p = .041$, partial $\eta^2 = .223$). The translation and application of a brief version in Spanish of a successful DBS protocol (Cooper et al., 2014; Murray et al., 2016) was a structural guide for the CARE booklet intervention (CBI). The CBI's main goal goes far from simple developmental screening or the delivery of knowledge about child milestones to parents: CBI relieves the social expectations about caregiving responsibilities (Gladstone et al., 2018), identifying the available cognitive tracks when interactions are followed using daily items. The social expectations in an LMIC like Colombia, where the community cultural background is not oriented to the exclusive importance of early childhood caregiving, instead of domestic chores, working, studying, or other responsibilities that often lead mother's attention away from the child (Gladstone et al., 2018), can seem like a burden. According to two central ideas states by participant parents, CBI asserts: 1) There is no need for label to mothers' interactions with children as a "responsibility"; 2) There is no need for the name to label the scarcity or poverty associated with developmental risk in children as "disease". The CBI results suggest the use of a rigorous RCT protocol and scalability for comparison with centre-based interventions, such as the aeioTu program in Colombia (Nores et al., 2019). Expectations about what an integration of DBS and CBI could achieve if continually administered to families with at-risk children in LMICs, admit the idea of communities of practices (Lave and Wenger, 1991) for learning about developmental enhancement and screening tracking (Mahadevan & Broaddus-Shea, 2020). Definitions of communities of practices regularly describe a context where child learning is the epicentre for instructional conversations, reciprocal teaching, cognitive apprenticeship, and practice-based and problem-based learning processes (Duncan, Jones & Carr, 2008; Matusov, 2001; Wenger, 1998). CBI identifies the caregiver as a learner who mediates the interactions for child development enhancement in a community of practice.

To form and maintain the communities of practices that DBS and CBI shape for caregivers as learners, a complete model of the detection-intervention-prevention continuum described in other recently reported LMIC initiatives (Boggs et al., 2019; Fischer et al., 2014; Magwood et al.,

2019) might be scaled in an applied context. Major levels of support and intervention suggests consideration of an interoperability model (Pronovost et al., 2018). Although the original model of interoperability arose in the context of technology-based information-transfer (Pronovost et al., 2018), considering data exchange over three levels, focuses on the transformation of developmental care via three levels of parent-child interaction-driven support and institutional support in Children's Centres (CCs):

(i) facility-to-facility (macro-tier)

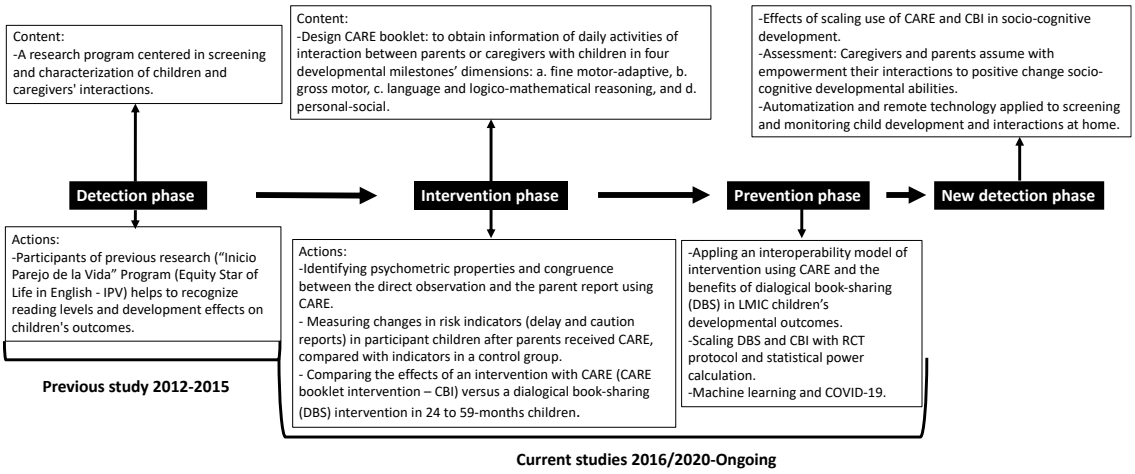
(ii) intra-facility (meso-tier)

(iii) support at the point of care (micro-tier).

To optimize the description of our model, we use information from multiple sources, devices, and organizations across the integrative dimension of developmental care, that enable the identification of interventions at the right time, to the right party, for the right child. A future interdisciplinary research question (IRQ), *How detection-intervention-prevention continuum might use institutional support in Children's Centres, including CARE and DBS interventions as strategies and source of data for an interoperability model?* opens more avenues of inquiry for medium and long-time exploration. Could the closer support and monitored interventions directed at communities of practices for interactions on cognitive tracks be a principal means for LMICs to change the developmental trajectories of at-risk children? The plan overview contained in this thesis is the first section in an integrative framework using the model of the detection-intervention-prevention continuum. Further phases consider the DBS and CBI designs in a scalable and rigorous RCT. The exploration of effects in the previous regional-baseline efforts to recognize the socio-cognitive situation in a sample of Colombian children should extend the reach of our results in a new detection phase (Fig. 7.1), including a dedicated new horizon after the COVID-19 pandemic and machine learning technologies.

Figure 7.1.

Integrative social intervention framework applied in the thesis and further phases.



Previous to a new detection phase, a parallel interoperability design might conform a prevention phase. Interoperability is a well-known concept for data exchange in healthcare systems (Haux, 2018; Friedman, Rubin, & Sullivan, 2017). An original and basic interoperability model is based on an IT information-transfer context that recognizes a specific definition for interoperability (Provonost et al., 2018). To optimize our proposal, the data exchange requires the mentioned three levels: macro-tier (e.g., Children's Centre -to- Children's Centre), meso-tier (e.g., within Children's Centre for caregivers' decisions and communication) and micro-tier (e.g., at the point of care: Children's Centres and homes). We use information from multiple sources, devices, and organizations across the detection-intervention-prevention continuum. The principal processes in the micro-tier level are interactions in the point of care between caregivers and children. Those interactions could be reported using CARE, like a fully integrated home-based record tool, but including an intervention (CBI) and multiple health and developmental focus systems (Mahadevan & Broaddus-Shea, 2020). The most recent laws in Colombia supporting the institutional functions of the public services responsible for wellbeing in families and children (i.e., *Ley 1804 de 2016*, *Ley 2025 de 2020*) demand close attention for vulnerable and impoverished communities. CARE and CBI provide the results that can guarantee a strategy to increase principal caregivers' knowledge about the use of wellbeing practices, facilitate communication between caregivers and

institutional agents, and reduce missed opportunities of monitoring for early education and healthcare services.

The COVID-19 pandemic exposed the need in many LMICs for non-invasive methods in tracking and reporting early developmental interactions. During the closure of outdoor parks, kindergartens, and care centres worldwide, there were difficulties in screening and monitoring child development. Moreover, LMICs in Latin America, such as Colombia, have no reported studies of the effects of the pandemic on socio-cognitive development and interactions between primary caregivers and children at home (Araújo et al., 2021). Therefore, CARE as a screening tool, along with the DBS and CBI interventions, are viable options for mitigating the pandemic's effects on child development due to the closure of children's centres and other positive spaces. This thesis provides an integrative perspective on evidence-based early interventions and structured tools to enhance children's outcomes, through daily routines and reports of specific caregiver-child interactions. Furthermore, it offers a chance to implement a supervised learning algorithm (i.e., random forest) and automatization process for a call to collaborative efforts that involve engineers, clinicians and researchers working in psychology in the developing and testing of innovative developmental supports for vulnerable families (Johnson & Stead, 2022).

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Appendix List and Links

Appendix A. CARE booklet examples for three age groups: 24- to 35-month-old, 36- to 47, 48 – to 59-month-old. Link: https://drive.google.com/drive/folders/1xo75LHtlrVfT7Ft6d_yXFseyz4c6NGeb?usp=sharing

Appendix B. All files with the description of ethical supports and approvals 2013-2018. Link: https://drive.google.com/drive/folders/1hPeOHhxemEXGkXXMhk4eQvTyMcov7LXG?usp=sharing

Appendix C. The Questionnaire for Parents and Caregivers General Data (GDQ). Link: https://docs.google.com/document/d/1z5NPw-E_RUDvX2xMXjpp-cjIki67e5Lv/edit?usp=sharing&ouid=116683195880010919841&rtpof=true&sd=true

Appendix D. Complementary tables for no significant effect of sociodemographic variables on developmental domains differences between data sources (CARE vs. HLL). Link: https://docs.google.com/document/d/1rPPC2Gg3iIxD8dNTMI7po94U_bU49gvu/edit?usp=sharing&ouid=116683195880010919841&rtpof=true&sd=true

Appendix E. Complementary chi-square contingency tables on developmental domains differences between data sources (CARE vs. HLL). Link: https://drive.google.com/drive/folders/1ed2ra-IUKmz5lAwa4IpJeZrWzx3WGN6G?usp=sharing

Appendix F. ANCOVAS for dialogical book sharing (DBS) and CARE booklet intervention (CBI) analysis. Link: https://docs.google.com/spreadsheets/d/1gKEcTSQX-TORHXzETX0-TGufJKFJdt29/edit?usp=sharing&ouid=116683195880010919841&rtpof=true&sd=true