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Protocol for Validation of the Global Scales for Early Development (GSED) for Children under 3 Years of Age in Seven Countries

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Complete List of Authors:	<p>Cavallera, Vanessa; World Health Organization, Department of Mental Health and Substance Use Lancaster, Gillian; Keele University School of Medicine Gladstone, Melissa; University of Liverpool Institute of Translational Medicine, Women and Children's Health Black, Maureen; RTI International; University of Maryland School of Medicine McCray, Gareth; Keele University School of Medicine Nizar, Ambreen; The Aga Khan University, Department of Peadiatrics Ahmed, Salahuddin; Projahnmo Research Foundation Dutta, Arup; Center for Public Health Kinetics Anago, Romuald ; Innovations for Poverty Action Brentani, Alexandra; University of Sao Paulo, Pediatrics Jiang, Fan; Shanghai Children's Medical Center Affiliated to Shanghai Jiaotong University School of Medicine Schönbeck, Yvonne; Netherlands Organization for Applied Scientific Research, Department of Child Health McCoy, Dana; Harvard Graduate School of Education Kariger, Patricia; University of California Berkeley School of Public Health Weber, Ann; University of Nevada Reno Raikes, Abbie; University of Nebraska Medical Center College of Public Health Waldman, Marcus; University of Nebraska Medical Center College of Public Health van Buuren, Stef; TNO, Department of Statistics Kaur, Raghbir; World Health Organization Maillard, Pérez; World Health Organization Nisar, Muhammad; The Aga Khan University, Pediatrics and Child Health Khanam, Rasheda; Johns Hopkins University, International Center for Maternal and Newborn Health, Department of International Health, Johns Hopkins Bloomberg School of Public Health Sazawal, Sunil ; Centre for Public Health Kinetics Zongo, Arsène; Innovations for Poverty Action Pacífico Mercadante, Mariana; University of Sao Paulo, Pediatrics Zhang, Yunting ; Shanghai Children's Medical Center Affiliated to Shanghai Jiaotong University School of Medicine Roy, Arunangshu ; Projahnmo Research Foundation Hepworth, Katelyn; University of Nebraska-Lincoln College of Education and Human Sciences</p>

	<p>Fink, Günther ; Schweizerisches Tropen- und Public Health-Institut, Household Economics and Health System Research Unit Rubio-Codina, Marta; Inter-American Development Bank Tofail, Fahmida; International Centre for Diarrhoeal Disease Research Bangladesh, Centre for Nutrition & Food Security Eekhout, Iris; TNO, Child Health Seiden, Jonathan; Harvard Graduate School of Education Norton, Rebecca; World Health Organization Baqui, Abdullah; Johns Hopkins University Bloomberg School of Public Health Zhao, Jin; Shanghai Children's Medical Center Affiliated to Shanghai Jiaotong University School of Medicine Holzinger, Andreas; Innovations for Poverty Action Detmar, Symone; TNO Kembou, Samuel; Innovations for Poverty Action Begum, Farzana; The Aga Khan University, Department of Paediatrics Jehan, Fyezah; The Aga Khan University, Paediatrics and Child Health Dua, Tarun; World Health Organization Janus, Magdalena; McMaster University, Offord Centre for Child Studies</p>
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Authors: Cavallera V, Lancaster G, Gladstone M, Black MM, McCray G, Nizar A, Ahmed S, Dutta A, Anago R, Brentani A, Jiang F, Schönbeck Y, McCoy D, Kariger P, Weber A, Raikes A, Waldman M, van Buuren S, Kaur R, Pérez Maillard M, Nisar I, Khanam R, Sazawal S, Zongo A, Pacifico Mercadante M, Zhang Y, Roy AD, Hepworth K, Fink G, Rubio Codina M, Tofail F, Eekhout I, Seiden J, Norton R, Baqui AH, Zhao J, Holzinger A, Detmar S, Kembou S N, Begum F, Jehan F, Dua T, Janus M.

Affiliations:

Corresponding author: Dr Vanessa Cavallera, MD, MPH, World Health Organization (WHO), Brain Health Unit in Department of Mental Health and Substance Use, Av. Appia 20, 1202 Geneva, Switzerland. cavallerav@who.int

Prof Gillian Lancaster, PhD, MSc, BSc (Hons), Clinical Trials Unit, School of Medicine, Keele University, UK

Prof Melissa Gladstone, MD, International Child Health and Neurodevelopmental Paediatrics, Department of Women and Children's Health, Institute of Translational Medicine, University of Liverpool, Alder Hey Children's NHS Foundation Trust, UK.

Prof Maureen Black, PhD, Department of Pediatrics, University of Maryland School of Medicine, Baltimore, MD, USA and RTI International, Research Park, NC, USA

Dr Gareth McCray, MA, MRes, PhD, Research Associate, the School of Medicine, Keele University, Keele, UK.

Ambreen Nizar, BDS, MSc, Department of Paediatrics, Aga Khan University, Karachi Pakistan.

- 1
2
3 27 Salahuddin Ahmed, MBBS, Projahnmo Research Foundation, Dhaka, Bangladesh
4
5
6 28 Arup Dutta, MBA, Center for Public Health Kinetics, New Delhi, India
7
8
9 29 Romuald Kouadio E Anago, MA, BA, Innovations for Poverty Action (IPA), Abidjan,
10
11 30 Côte d'Ivoire
12
13
14 31 Dr. Alexandra Valeria Maria Brentani, PhD, Dept. of Pediatrics, University of Sao Paulo
15
16 32 Medical School, Brazil
17
18
19 33 Prof. Fan Jiang, MD, PhD, Department of Developmental and Behavioral Pediatrics,
20
21 34 National Children's Medical Center, Shanghai Children's Medical Center, affiliated to
22
23 35 School of Medicine Shanghai Jiao Tong University, China
24
25
26 36 Dr. Yvonne Schönbeck, PhD, Msc, Dept. Child Health, Netherlands Organization for
27
28 37 Applied Scientific Research (TNO), Leiden, The Netherlands
29
30
31 38 Dr Dana McCoy, PhD, Harvard Graduate School of Education, Cambridge, MA, USA
32
33
34 39 Dr Patricia Kariger, PhD CEGA (Center for Effective Global Action), School of Public
35
36 40 Health, University of California, Berkeley, California, USA.
37
38
39 41 Dr Ann Weber, PhD, MPH, School of Public Health, University of Nevada, Reno, NV,
40
41 42 USA
42
43
44 43 Dr Hilary Abigail Raikes, MPH, PhD, University of Nebraska Medical Center, College of
45
46 44 Public Health, Omaha, NE, USA
47
48
49 45 Dr. Marcus Waldman, PhD, University of Nebraska Medical Center, College of Public
50
51 46 Health, Omaha, NE, USA
52
53
54 47 Prof Stef van Buuren, PhD, Department of Child Health, Netherlands Organization for
55
56 48 Applied Scientific Research TNO, Leiden, The Netherlands
57
58
59
60

- 1
2
3 49 Raghbir Kaur, MPH, DMD, MS, Consultant World Health Organization (WHO), Brain
4
5 50 Health Unit in Department of Mental Health and Substance Use, Geneva, Switzerland
6
7 51 Michelle Pérez Maillard, MSc, Consultant World Health Organization (WHO), Brain
8
9 52 Health Unit in Department of Mental Health and Substance Use, Geneva, Switzerland
10
11
12 53 Prof. Muhammad Imran Nisar, MBBS, MSc, Department of Peadiatrics, Aga Khan
13
14 54 University, Karachi Pakistan.
15
16
17 55 Dr. Rasheda Khanam, MBBS, MPH, PhD, International Center for Maternal and
18
19 56 Newborn Health, Department of International Health, Johns Hopkins University
20
21 57 Bloomberg School of Public Health, Baltimore, MD, USA
22
23
24 58 Dr. Sunil Sazawal, MBBS, MPH, PhD, Center for Public Health Kinetics New Delhi,
25
26 59 India
27
28
29 60 Mr. Arsène Zongo, MA, BA, Innovations for Poverty Action (IPA), Abidjan, Côte
30
31 61 d'Ivoire
32
33
34 62 Dr. Mariana Pacifico Mercadante, MD, Dept. of Pediatrics, University of Sao Paulo
35
36 63 Medical School, Brazil
37
38
39 64 Dr. Yunting Zhang, PhD, Child Health Advocacy Institute, National Children's Medical
40
41 65 Center, Shanghai Children's Medical Center, affiliated to School of Medicine Shanghai
42
43 66 Jiao Tong University, China
44
45
46 67 Dr. Arunangshu D. Roy, MBBS, Projahnmo Research Foundation, Dhaka, Bangladesh
47
48
49 68 Katelyn Hepworth, MA, University of Nebraska-Lincoln, College of Education and
50
51 69 Human Sciences, NE, USA
52
53
54 70 Prof Günther Fink, PhD, Swiss Tropical and Public Health Institute, Basel, Switzerland
55
56
57
58
59
60

- 1
2
3 71 Dr Marta Rubio-Codina, PhD, Inter-American Development Bank, Washington, D.C.,
4
5 72 USA
6
7
8 73 Dr. Fahmida Tofail, MBBS, PhD, International Centre for Diarrhoeal Disease Research
9
10 74 Iccdr,b, Dhaka, Bangladesh
11
12
13 75 Dr. Iris Eekhout, PhD, MSc, Department of Child Health, Netherlands Organization for
14
15 76 Applied Scientific Research TNO, Leiden, The Netherlands
16
17
18 77 Jonathan Seiden, EdM, Harvard Graduate School of Education, Cambridge, MA, USA
19
20
21 78 Rebecca Norton, Consultant World Health Organization (WHO), Brain Health Unit in
22
23 79 Department of Mental Health and Substance Use, Geneva, Switzerland
24
25
26 80 Dr. Abdullah H. Baqui, MBBS, DrPH, Johns Hopkins Bloomberg School of Public
27
28 81 Health, Baltimore, Maryland, USA
29
30
31 82 Dr. Jin Zhao, MD, PhD, Department of Developmental and Behavioral Pediatrics,
32
33 83 National Children's Medical Center, Shanghai Children's Medical Center, affiliated to
34
35 84 School of Medicine Shanghai Jiao Tong University, China
36
37
38 85 Andreas Holzinger, MA, BA, Innovations for Poverty Action (IPA), Abidjan, Côte
39
40 86 d'Ivoire
41
42
43 87 Dr. Symone Detmar, PhD, Msc, Department of Child Health, Netherlands Organization
44
45 88 for Applied Scientific Research TNO, Leiden, The Netherlands
46
47
48 89 Dr, Samuel Nzale Kembou, PhD, MA, BA, Innovations for Poverty Action (IPA),
49
50 90 Abidjan, Côte d'Ivoire
51
52
53 91 Farzana Begum, MSc, Department of Peadiatrics, Aga Khan University, Karachi
54
55 92 Pakistan.
56
57
58
59
60

1
2
3 93 Prof. Fyezah Jehan, MBBS, FCPS, MSc, Department of Peadiatrics, Aga Khan
4

5 94 University, Karachi Pakistan.
6
7

8 95 Dr Tarun Dua, MD, World Health Organization (WHO), Brain Health Unit in
9

10 96 Department of Mental Health and Substance Use, Geneva, Switzerland
11
12

13 97 Prof Magdalena Janus, MBBS, FCPS, MSc, Offord Centre for Child Studies, McMaster
14

15 98 University, Hamilton ON, Canada.
16
17

18 99 **Disclaimers:**

20 100 The author is a member of the World Health Organization. The author alone is
21
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23
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25
26 103 Cavallera V, Dua T, Kaur R, Pérez Maillard M and Norton R]
27
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29 104 The views here presented do not represent the Inter-American Development Bank, its
30
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3 109 **ABSTRACT**
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6 110 **Introduction.** Children's early development is affected by caregiving experiences, with
7
8 111 life-long health and wellbeing implications. Governments and civil societies need
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10 112 population-based measures to monitor children's early development and ensure that
11
12 113 children receive the care needed to thrive. To this end, the World Health Organization
13
14 114 (WHO) developed the Global Scales for Early Development (GSED) to measure
15
16 115 children's early development (ages 0-3 years). The GSED includes three measures: 1)
17
18 116 short form (SF) for population-evaluation (caregiver-report), 2) complementary long
19
20 117 form (LF) for programmatic-evaluation (direct assessment), and 3) psychosocial form
21
22 118 (PF) for psychosocial development evaluation (caregiver-report). The primary aim of this
23
24 119 protocol is to validate the GSED SF and LF. Secondary aims are to create preliminary
25
26 120 reference scores for the GSED SF and LF, validate an adaptive testing algorithm, and
27
28 121 assess the feasibility and preliminary validity of the GSED PF.
29
30

31
32
33 122 **Methods and Analysis.** We will conduct the validation in seven countries varying in
34
35 123 geography, language, culture and income through a one-year prospective design,
36
37 124 combining cross-sectional and longitudinal methods with 1248 children per site, stratified
38
39 125 by age and sex. The GSED generates an innovative common metric (Development-score:
40
41 126 D-score) using the Rasch model and a development-for-age z-score (DAZ). We will
42
43 127 evaluate six psychometric properties of the GSED SF and LF: concurrent validity,
44
45 128 predictive validity at six months, convergent and discriminant validity, and test-retest and
46
47 129 inter-rater reliability. We will evaluate measurement invariance by comparing differential
48
49 130 item functioning (DIF) and differential test functioning (DTF) across sites.
50
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53
54 131 **Ethics and dissemination.** This study has received ethical approval from the WHO
55
56 132 (protocol GSED validation 004583 20.04.2020) and approval in each site. Study results
57
58
59
60

1
2
3 133 will be disseminated through webinars and publications from WHO, international
4
5 134 organisations, academic journals, and conference proceedings.
6
7

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10 136 10.17605/OSF.IO/KX5T7; identifier: osf-registrations-kx5t7-v1)
11
12

13 137 **ARTICLE SUMMARY**

14 138 **Strengths and limitations of this study**

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16
17 139 • The study collects validation data (n = 8736 children) for the Global Scales for
18
19 140 Early Development (GSED) in seven countries that vary in geographic, linguistic,
20
21 141 cultural and sociodemographic characteristics. The sampled populations are
22
23 142 chosen to be diverse and are not nationally representative.
24
25
26 143 • The methods for the validation of GSED are systematic across sites and follow
27
28 144 rigorous standard operating procedures based on the best scientific evidence
29
30 145 available.
31
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33 146 • A tablet-based App is used for data collection to make the administration of the
34
35 147 GSED measures user-friendly, to reduce recording and transcribing errors, and to
36
37 148 facilitate adaptive testing.
38
39
40 149 • The GSED SF and LF aims to include items that are culturally neutral and fit the
41
42 150 Rasch model, which assumes that child development milestones are age-ordinal,
43
44 151 to create D-scores. Psychosocial items are included in a separate measure (GSED
45
46 152 psychosocial form [PF]) and cultural-specific items can be supplemented by
47
48 153 countries.
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50
51 154 • The three secondary aims (preliminary reference scores, an adaptive testing
52
53 155 algorithm, and the feasibility and validity of the GSED PF), are exploratory and
54
55 156 will require further research.
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157 INTRODUCTION

158 Prenatal and early postnatal experiences have significant impacts on early childhood
159 development (ECD) and can influence the accrual of health, well-being, and productivity
160 throughout the life-course (1). To promote current and sustainable peace and prosperity,
161 the United Nations has focused the Sustainable Development Goals (SDG) on improving
162 children's outcomes in the early years through multiple targets. The most explicit target
163 for young children is SDG 4 (Education goal), which requires reporting on the
164 "proportion of children under 5 years of age who are developmentally on track in health,
165 learning and psychosocial well-being, by sex" (2).

166 There are few valid measures that can be used globally to assess child development for
167 children under three years of age. Current measures of ECD range from proxy measures
168 (e.g., prevalence of country-level stunting and poverty) to detailed measures of individual
169 performance on developmental tasks (3). The Early Childhood Development Index 2030
170 (ECDI 2030) (4) does not include children below two years of age. A recent review has
171 identified the creation and validation of population-based instruments for assessing very
172 young children as a global priority (5).

173 The Global Scales for Early Development (GSED) build on advances made by analyses
174 of existing global datasets (6), and new data collection (7) that demonstrated the cross
175 cultural applicability of items that measure young children's development. Three research
176 teams (8) joined efforts to develop the GSED in response to the pressing need for
177 instruments and metrics to measure ECD at population and programmatic levels across
178 diverse parts of the world.

1
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3 **179 The Global Scales for Early Development (GSED)**
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5
6 180 The GSED consist of three open-access measures developed by a WHO-led team¹ to
7
8 181 provide a standardized methodology for measuring the development of children aged 0-3
9
10 182 years (0-36 months) across diverse cultures and contexts (9, 10). They are developed for
11
12 183 three objectives: 1) for population-level evaluation based on caregiver-report, GSED
13
14 184 Short Form (SF); 2) for programmatic evaluation in combination with SF, direct child
15
16 185 assessment, GSED Long Form (LF); and 3) for measuring psychosocial behaviours,
17
18 186 caregiver-reported GSED Psychosocial Form (PF). The development and piloting of the
19
20 187 GSED SF, LF, and PF are described elsewhere (9).
21
22

23
24 188 The GSED SF and LF produce metrics on the same age-ordinal scale and quantify the
25
26 189 same latent construct. The Developmental Score (D-score) (see Box 1) underlies both
27
28 190 measures and reflects children's overall development across multiple domains typically
29
30 191 demonstrated in this age group (e.g., cognitive, motor, language, social-emotional) (6).
31
32

33 192 The GSED PF items, designed to measure non-normative developmental patterns,
34
35 193 including behavioural or regulatory challenges, are not age-ordinal and do not use the D-
36
37 194 Score metric.
38
39

40
41 **Box 1: The Developmental score**
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43
44 The Developmental score (15), or D-score, is a unidimensional latent variable
45
46 measuring child development during the first three years across multiple domains. The
47
48 milestones that make up the D-score conform to the Rasch model (25), thus yielding a
49
50 scale with interval properties with a fixed unit (Figure 1). It is therefore possible to
51
52 calculate a meaningful difference between two D-scores. Similar to height-for-age Z-
53
54 score, given suitable age-conditional references, the D-score can be transformed to a Z-
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56
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58
59 ¹ The full team and contributors are listed in the Acknowledgments.
60

score that accounts for children's age (i.e., Development for Age Z-score, or DAZ).

The DAZ facilitates comparisons across children of different ages.

195 AIMS

196 The primary aim of this study is to validate the GSED measures (11), through testing for
197 measurement invariance and evaluation of the psychometric properties to measure
198 development among children aged 0-3 years (0-36 months) globally (including creation
199 of D-scores and Development for Age Z-score [DAZ]).

200 Specific Objectives:

- 201 a) Fit a Rasch model to the item data to calculate the D-scores and DAZ.
- 202 b) Investigate differential item functioning (DIF) and differential test functioning
203 (DTF) across sites to determine measurement invariance.
- 204 c) Examine psychometric properties of the GSED SF and LF:
 - 205 • Test-retest and inter-rater reliability (score and item level),
 - 206 • Concurrent validity (association between scores on GSED and Bayley Scales
207 of Infant and Toddler Development (Bayley-III) or Griffiths Scales of Child
208 Development administered concurrently) (12),
 - 209 • Convergent validity (strength of association between GSED D-scores and
210 other theoretically-relevant constructs)
 - 211 • Predictive validity (association between GSED scores six months after initial
212 assessment).

213 The secondary aims are to: 1) establish preliminary reference scores² for optimal
214 development on the D-score (GSED SF and LF), 2) develop and validate an adaptive

² The population has not been selected as a representative sample of all children aged 0-3 in each site (as would happen in a countrywide population census). Selection and recruitment of a representative sample

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3 215 testing algorithm, and 3) obtain preliminary validity data on the psychometric properties
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5 216 of the GSED PF.
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8 9 217 **METHODS**

10 11 218 **Design and study sites**

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14 219 The GSED validation study uses a prospective cross-sectional design with a longitudinal
15
16 220 component of age and sex stratified samples of children in seven countries. The countries
17
18 221 are culturally, linguistically and geographically diverse, representing low-income
19
20 222 (Bangladesh, Côte d'Ivoire, Pakistan, United Republic of Tanzania), middle-income
21
22 223 (Brazil and The Republic of China), and high-income (The Netherlands) settings.
23
24
25 224 Samples in each site are not nationally representative; however, they are diverse, e.g.
26
27 225 covering both rural/urban settings.

28
29
30 226 Preparation and feasibility phases are described elsewhere (11), and assess feasibility of
31
32 227 administration of GSED and associated measures including processes for translating and
33
34 228 culturally adapting GSED and other study measures, creating data management systems,
35
36 229 and training teams in data collection procedures.

37 38 39 230 **Patient and Public involvement**

40
41 231 Participants were involved in the study design as the burden of the assessment was
42
43 232 discussed with them in a pilot stage through qualitative data collection. We intend to
44
45 233 disseminate the main results to trial participants and will seek patient and public
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47 234 involvement in the development of an appropriate method of dissemination.
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57 was beyond the scope of this study and not required for validation purposes. We are therefore developing
58 'reference scores' which should not be interpreted as population-sampled norms.
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235 **Study sample**

236 The study sample includes children between 0 to 41 months of age (inclusive) living in
 237 study areas (see Table 1 for inclusion and exclusion criteria).

238 **Table 1. Study sample inclusion and exclusion criteria**

Sample	Inclusion criteria	Exclusion criteria
Total per site N=1248 (as described in sample size section below)	1. Age 0-41 months 2. Family speaks to the child in same language as GSED translation 3. Primary caregiver available to participate	1. Missing gestational age (ultrasound or last menstrual period LMP) 2. Missing birth weight data 3. Acutely unwell at time of assessment (temporary exclusion: to be rescheduled after 7 days)

240 ***Recruitment and consent***

241 In each site the sampling frame consists of a list of potentially eligible caregiver-child
 242 dyads residing in the defined study area. Lists of potential participants vary by site and
 243 may include: participants in local pregnancy surveillance systems, families who have
 244 previously agreed to be contacted for participation, birth registries from hospital/health
 245 centers, or families with children attending local child health/care centers.
 246 Eligible children are sampled from this list using the GSED sampling scheme (Figure 2).
 247 To minimize clustering of correlated scores within households, one child per caregiver
 248 and in multi-family household is selected, guided by age and sex quotas. For siblings or
 249 twins, one is chosen randomly. Target children's primary caregiver (person most familiar
 250 with the child and spends most time with them) is approached for consent and enrollment.
 251 A non-technically worded information sheet is shared and consent to participate is
 252 obtained at first visit. In the Netherlands, participants provide consent online, confirmed
 253 by study staff at first visit. Refusals to participate and dropouts are registered and
 254 replaced.

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3 255 ***Sampling frame and schemes***
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5 256 Sample size for recruitment within each site is 1248 children (total 8736 children) across
6
7 257 seven countries. After consent is provided, children are allocated by sex and age groups
8
9
10 258 using a randomization procedure to one of several sampling schema (e.g., predictive,
11
12 259 reference-score, reliability; Figure 2). See sampling Table S1 in Supplementary file S1
13
14 260 for sampling frame. Out of the full site sample of 1248 children, 504 children per site are
15
16
17 261 randomly selected for re-evaluation 6 months later to assess predictive validity (primary
18
19 262 aim). A second scheme indicates the minimum sub-sample of children needed to
20
21 263 calculate preliminary reference scores (secondary aim) that will facilitate cross-country
22
23 264 comparisons. To maximize precision of parameter estimates, larger quotas are kept for
24
25 265 the youngest age brackets where rates of development are accelerated. A third scheme
26
27 266 addresses inter-rater reliability for 90 children per site using two assessors who
28
29 267 independently assess the same child sequentially or within 24 hours (12)³. Test-retest
30
31 268 (intra-rater reliability) is performed by inviting 50 children per site to return for repeat
32
33 269 assessment with the same rater within 7-10 days.
34
35 270 In the Netherlands, the GSED SF and PF are administered online. A subset of participants
36
37 271 (N=32) are interviewed face-to-face to compare method of administration. To determine
38
39 272 test-retest reliability (intra-rater reliability), the primary caregiver completes the SF and
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41 273 PS form online and then a second time 7-10 days later.
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56 ³ We note that this procedure differs from typical inter-rater reliability (IRR) designs which involve
57 simultaneous scoring of a single assessment. This sequential design was necessitated by logistical
58 constraints. Given that this design captures both variance due to differences in raters *and* differences in
59 occasions, the observed IRR represents a lower bound for the true inter-rater reliability of the assessments.
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3 274 **Data collection**
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6 275 *Measures*
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9 276 *GSED*
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12 277 **GSED SF and LF.** The creation of the GSED SF and LF is described elsewhere (10).
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14 278 Briefly, we constructed an item bank from previously gathered data and compiled cross-
15

16 279 sectional and longitudinal data from 31 countries representing over 73,000 anonymized
17

18 280 children with 109,079 assessments (using 22 established ECD instruments) (6, 13, 14).
19

20 281 Using subject matter expert input and statistical modelling (15), we developed a
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22 282 caregiver-reported measure intended to capture child development at population-level
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24 283 (GSED SF), and a complementary direct-assessment measure to evaluate programmatic
25

26 284 impacts (GSED LF) (10). The measures are created paper-based and app-based (GSED
27

28 285 App) with built-in administration rules and supporting media-files (see below).
29

30 286 The GSED SF includes 139 items representing emerging skills and behaviors within
31

32 287 cognitive, motor, language and social-emotional domains. All items are presented as
33

34 288 questions to the caregiver, with binary response options (Yes/No and “Don’t Know”) that
35

36 289 use start rules based on the child’s age, and stop rules based on age and performance.
37

38 290 Assessors record caregiver’s responses, regardless of the assessor’s observations. In the
39

40 291 Netherlands only, the GSED SF is completed online by caregivers. The GSED SF
41

42 292 administration includes sounds, images, and short video clips that assist in understanding,
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44 293 interpreting and administering the items.
45

46 294 The GSED LF includes 155 items capturing similar domains to the SF but, observed by
47

48 295 the assessor following start and stop rules based on the child’s age and responses. Items
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50 296 are organized into three grids (A, B and C) that enable assessors to measure the child’s
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52 297 performance on similar tasks in succession, making the administration easier for both
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3 298 assessors and children. To further facilitate administration, icons are placed next to each
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5 299 item that inform the assessor whether the item is observed, demonstrated to or by the
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7
8 300 child, listened for or spoken to the child. The GSED LF uses a locally constructed and
9
10 301 low cost kit with basic materials that the child interacts with to demonstrate abilities. The
11
12 302 kit is created by local teams with detailed guidance from WHO. Responses of all LF
13
14 303 items are binary (skill observed/not observed).

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16
17 304 The items in both measures are ordered by difficulty reflecting children's emerging skills.
18
19 305 Based on the analyses from the validation, we will select the items to be included in the
20
21 306 final GSED SF and LF versions available for use.

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24 307 **Psychosocial Form (PF).** Unlike the SF and the LF, the GSED PF has been developed to
25
26 308 index non-normative developmental patterns that provide a window into early
27
28 309 manifestations of children's mental health challenges, including internalizing and
29
30 310 externalizing behaviour problems and dysregulation (e.g., eating and sleeping). Items
31
32 311 capturing developmentally normative information about socio-emotional competencies
33
34 312 are included in the GSED SF and LF, as the SDG 4.2 includes children's psychosocial
35
36 313 well-being. Because few instruments have been developed to capture psychosocial
37
38 314 difficulties for children under 3 years, little existing data are available and the
39
40 315 development of the GSED PF is exploratory. The PF initial prototype was created
41
42 316 through a review of existing measures of infant and toddler mental health and consensus
43
44 317 by subject matter experts. The GSED PF includes 47 items and reflects caregiver
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46 318 perceptions of the behaviors' frequency, using response options: Often; Sometimes;
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48 319 Never/almost never. Items are divided into two age groups: 0-6 and 6-36 months.

50 51 52 53 54 320 *Contextual and demographic measures*

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56
57 321 In addition to the GSED, the validation study includes measures of children's growth and
58
59 322 nutrition, health, environmental and contextual information (see Table 2 for measures and

323 sources). The selection of measures was based on known biological and social
 324 determinants of development (16), the demonstrated validity of the contextual measures
 325 in at least one low- and middle-income country (LMIC), and efficiency for data
 326 collection. See Supplementary File S2 for visit schedules (Tables S2a and S2b).
 327 In three sites (Côte d'Ivoire, The Netherlands and The Republic of China) where
 328 administration of the Home Observation for Measurement of the Environment Inventory
 329 (HOME) is not feasible, household stimulation data and caregiver-child activities are
 330 collected using Family Care Indicators (FCI). In all sites, a concurrent measure of child
 331 development (Bayley-III or Griffiths Mental Development Scales) is administered in a
 332 subsample of children to determine concurrent validity of GSED to a well-established
 333 measure of the same construct.

334 **Table 2: Study measures in addition to GSED**

Construct	What the Measure Captures	Measure	Administration Mode	Time for Administer (Minutes)
Child health and household socioeconomic status (SES)	<ul style="list-style-type: none"> • Eligibility (exclusion - criteria) • Demographic information • Information about acute child health • Delivery and Perinatal conditions • Breastfeeding • Child's health history • Household socio-economic status* • Caregiver education • Maternal health/ chronic illness • COVID-19 exposure 	Eligibility and Contextual Form [Specifically developed for the study]	Caregiver Report	35
Anthropometry	<ul style="list-style-type: none"> • Weight at time of assessment 	Anthropometry Form	Child Assessment	15

	<ul style="list-style-type: none"> • Infant Length/ Child Height at time of assessment • Child's Mid-upper arm circumference at time of assessment • Child's head circumference at time of assessment 			
<i>Family / home environment</i>	<ul style="list-style-type: none"> • Home Environment (HOME only) • Play/ Stimulation / linteractions between the child and other family members in the home (HOME and FCI) 	Home Observation for Measurement of the Environment Inventory (HOME) (26) OR Family Care Indicators (FCI) (27) †	<i>HOME</i> : Caregiver report & Observation <i>FCI</i> : Caregiver Report	<i>HOME</i> : 45 <i>FCI</i> : 15
	<ul style="list-style-type: none"> • Child neglect/abuse • Exposure to violence or conflict 	Childhood Psychosocial Adversity Scale (CPAS)(28) †	Caregiver Report	15
	<ul style="list-style-type: none"> • Family resilience 	Brief Resilience Scale (BRS) (29) †	Caregiver Report	1
	<ul style="list-style-type: none"> • Family social support 	Family Support Scale (FSS) (30) †	Caregiver Report	5
Caregiver health and well-being	<ul style="list-style-type: none"> • Caregiver Depressive Symptoms 	The Patient Health Questionnaire-9 (PHQ-9) (31)	Caregiver Report	5
Child development	<ul style="list-style-type: none"> • Global child development (0-41 months) 	Bayley Scales of Infant and Toddler Development (Bayley-III) (32) OR Griffiths Mental Development Scales(33) ‡	Direct child Assessment	45-60

	<ul style="list-style-type: none"> Global child development (24-41 months) 	Early Childhood Development Index 2030 (ECDI2030) (4) [§]	Caregiver Report	10
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335 * Socioeconomic information on this form comes from the standard DHS multiple assets
 336 index; however, some sites have adapted the socio-economic status items to better fit
 337 their contexts

338 † these measures have been minorly adapted for the purpose of the study

339 ‡ in a sub-sample (N=150)

340 § in a sub-sample (all children of 24 to 41-months within the predictive validity
 341 subsamples in three countries)

342

343 ***Schedule***

344 Data collection is scheduled over one to three visits depending on the study site to
 345 accommodate rules of measure administration order and location. The first
 346 administration of the GSED SF and PF is completed at home (or online in the
 347 Netherlands) to test it in the setting intended for future use (e.g., Multiple Indicator
 348 Cluster Surveys MICS or Demographic and Health Surveys DHS) and prior to
 349 administration of the GSED LF. The GSED LF is administered in a controlled
 350 environment (e.g., clinic) to match the required concurrent validity testing protocols. For
 351 the concurrent validation, the GSED and concurrent measures are administered in the
 352 same location on different days and counter-balanced in order of administration.

353 ***Training and Quality Control***

354 Training of local master trainers is performed by the WHO team for the GSED SF, PF
 355 and LF, using slide presentations, discussion forums, audio-visual aids, and practice
 356 exercises. Local master trainers are responsible for training local field teams using
 357 materials adapted and translated to local languages. Reliable administration of the GSED
 358 measures must be met (inter-rater agreement with a master trainer of $\geq 90\%$) for
 359 certification.

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3 360 To ensure quality assurance, 10% of all the study visits are observed by the study
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5 361 supervisor in person (or through video-recording in the Netherlands), covering each child
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7 362 age band and certified assessors. Supervisors independently complete questionnaires
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9 363 being administered by the assessor and complete a fidelity checklist. Assessors are given
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11 364 feedback based on checklist score. Supervisors review quality assurance findings with the
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13 365 WHO biweekly, along with discussions with the subject matter experts for further
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15 366 resolution, as needed.

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17 367 The GSED application software for data collection has built-in data range and
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19 368 consistency checks. Data managers review and resolve issues daily in consultation with
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21 369 the local field team and/or WHO team.

22 370 **Sample size**

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24 371 Sample size determination was based on the primary aim of assessing the psychometric
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26 372 properties of the GSED. To have sufficient power to estimate measurement parameters
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28 373 (abilities and difficulties) needed to calculate the D-score and DAZ scores at baseline and
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30 374 to detect DIF of 1 logit with a power of $1 - \beta = 0.90$ and a two-sided significance level
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32 375 of $\alpha = 0.05$, a sample of $N=1248$ per site is required. This sample size was calculated via
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34 376 optimization of the sample size at i) each age/sex stratum and ii) overall on 1000
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36 377 simulated datasets generated from parameters suggested by the Rasch GSED model. See
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38 378 Supplementary file S1 for additional details.

39 379 **Statistical Analysis**

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41 380 To construct the scores for the GSED SF and LF, a Rasch model will be fitted and the
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43 381 item fit statistics (infit and outfit) will be assessed. Any items with unacceptable fit
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45 382 levels will be removed. Items will be screened for whether they exhibit unacceptable
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47 383 levels of measurement non-invariance (i.e., they have approximately equal difficulties)
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49 384 across countries and other contextual variables. Items exhibiting unacceptable DIF (using
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3 385 the logistic regression method) will be discarded sequentially, and the item response
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5 386 models will be refit using the remaining items. The expected a posteriori (EAP) method
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7 387 (17) will be applied to the final model to estimate the latent ability parameter (the D-
8
9 388 score). Systematic deviations from unidimensionality will be tested by performing a
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11 389 principal components analysis on the residuals of the Rasch model. The ability estimates
12
13 390 will be used to estimate preliminary developmental percentile curves against age using a
14
15 391 Generalized Additive Model for Location Scale and Shape (GAMLSS). Following
16
17 392 previous methodology (18) software will be written to calculate DAZ-scores based on the
18
19 393 final dataset in R, and a user-friendly front-end version created in R (ShinyApp) and/or
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21 394 Excel.
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26 395 Reliability (inter-rater and test-retest) for all GSED measures will be analyzed using ICC
27
28 396 (at the score level) and Gwet's AC1 agreement (at the item level) statistics with 95%
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30 397 confidence intervals to determine whether items perform reliably within and between
31
32 398 assessors (19). A cut-off value of 0.4 and above will be used to flag items as adequately
33
34 399 reliable. Those items with agreement between 0.4 and 0.5 will be discussed to determine
35
36 400 if modifications can be made to improve their administration and/or comprehension.
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41 401 DAZ scores from the GSED SF and LF will be used to conduct validity analyses to
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43 402 ensure that the measures are capturing the construct they are purported to measure
44
45 403 (construct validity). Concurrent validity will be assessed by correlating age-corrected
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47 404 Bayley-III or Griffiths Mental Development Scales scores with GSED DAZ scores. We
48
49 405 anticipate that these scores will have low to moderate positive correlations. Convergent
50
51 406 validity will be supported by statistically significant positive correlations (with 95%
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53 407 confidence interval) between the GSED scores and continuous contextual measures with
54
55 408 prior evidence of association with child development. Comparisons between "known
56
57 409 groups" will be made using the following variables: maternal education, home learning
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3 410 opportunities, home environment, socioeconomic status (SES), maternal mental health
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5 411 and child anthropometry, and stunting to determine if scores discriminate between high
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7 412 and low categories for each variable using mean DAZ scores.
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10 413 GSED scores at baseline and follow up will be correlated for predictive validity (positive
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12 414 association between baseline and at 6 months) and mixed-effects linear regression used to
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14 415 adjust for other contextual covariates and baseline scores.
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18 416 **Secondary (Exploratory) Aims**

19 20 21 417 *Reference Scores*

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23 418 We plan to develop a set of preliminary reference scores to facilitate comparison of DAZ
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25 419 scores across countries. From the full validation study sample, a sub-sample of children
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27 420 who have not experienced prior exposure to major known biological and environmental
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29 421 risk factors is selected (i.e., “reference sub-sample”) (Table 3). Such an approach relies
30
31 422 on the assumption that the attainment of basic developmental milestones captured by the
32
33 423 GSED of children who are free of major risk factors is relatively similar globally (20).
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35 424 To develop the reference scores, we will fit GAMLSS (21) to flexibly model both
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37 425 conditional means, conditional standard deviations of scores, and, if necessary,
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39 426 conditional skewness and kurtosis. We will test our assumption that the distribution of
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41 427 scores is equivalent across sites by adding a site indicator at each moment of the
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43 428 distribution, and testing site effects for their statistical significance. Where possible, we
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45 429 will conduct standardization of scores to assist with the interpretation of scores by
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47 430 pooling data across countries. We will report the corresponding parameters of the
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49 431 GAMLSS model at appropriate ages.
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55 432 **Table 3. “Reference” sub-sample exclusion criteria (healthy sub-sample)**

Sample	Exclusion criteria
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<p>Minimum sub-sample of “reference” children per site N=522</p>	<ol style="list-style-type: none"> 1. Below secondary maternal education (<6 years of schooling) 2. Birthweight less than 2500 gr 3. Gestational age < 37 completed weeks (259 days) and \geq 42 completed weeks (294 days) [assessed by ultrasound] 4. Undernutrition (weight for age, length for age, OR weight for height Z score of less than -2 on the WHO Child Growth Standards) at the time of developmental assessment 5. Known severe congenital birth defect 6. History of birth asphyxia OR neonatal sepsis requiring hospitalization 7. Known neurodevelopmental disorder/ disability (Severe visual problems, seizures, hearing impairment) OR other chronic health problems (that is congenital heart disease)
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434 ***Adaptive testing***

435 We will determine whether adaptive testing is a feasible and valid option to measure
 436 child development within the GSED (Box 2). Adaptive testing (22) is an administration
 437 method that continually adapts to the level of the child’s performance, thereby reducing
 438 test administration time. Previous simulations (23) indicated that theoretically substantial
 439 gains in the precision of scores are possible when using adaptive testing even if
 440 administering fewer items.

Box 2: Adaptive testing validation methodology

We investigate the feasibility by applying adaptive testing in addition to the traditional “fixed” GSED administration methods in the sub-sample designated for predictive validity analyses (N=502 per site) in three sites. The adaptive test is executed using tablets that are specially programmed to continually adjust child’s score after each item is administered, and to suggest the next item based on the answers already received (e.g., a more difficult item for a child with a higher score, an easier item for a child with a lower score). Once the program establishes a reliable score, the administration is

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3 terminated. Both the adaptive test and the fixed test are administered with the same
4 sub-sample during two separate visits alternating the order of administration to
5 investigate the difference between the two modes of administration. We will
6 investigate the following: the variance of user experience as a function of the average
7 difficulty of milestones (leniency); the comparison of the D-score distribution under
8 the adaptive testing procedure with the D-score distribution under the fixed GSED
9 administration (using a z-test to assess the equivalence of the two modalities and
10 plotting the results to show the level of concordance); and relation of the difference
11 between the two D-scores to background variables.
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441

442 *Psychosocial Form*

443 The PF measure is in an early stage and will undergo exploratory and confirmatory factor
444 analyses to assess the internal scale structure. Associations between items and factor
445 scores with variables suggesting a high risk of psychosocial stress, such as family
446 resilience, social support, and family and community violence, in addition to GSED SF
447 and LF scores (concurrent validity measures) will be examined.

448 **ETHICS AND DISSEMINATION**

449 The study complies with the International Ethical Guidelines for Biomedical Research
450 Involving Human Subjects (24) and received ethical approval from the appropriate body
451 in each site and within WHO (protocol GSED validation 004583 approved on
452 20.04.2020). The findings of the study will be disseminated following a comprehensive
453 dissemination strategy to reach a diverse range of stakeholders at the local, national and
454 international level.

455 **DISCUSSION**

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3 456 The validation of the GSED SF and LF is a meticulous and systematic global process that
4
5 457 introduces an innovative common metric (the D-score) that countries can use to track the
6
7 458 progress of child development among populations of young children and to measure the
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9 459 impact of programmatic interventions. Additional attention is required on understanding
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11 460 young children's responses to psychosocial challenges within global contexts. The
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13 461 exploration of the GSED PF introduces an important opportunity to capture the non-
14
15 462 normative developmental patterns among young children that are potential precursors to
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17 463 behaviour and psychiatric problems. The GSED validation has several important design,
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19 464 methodological and implementation characteristics that illustrate the rigour required to
20
21 465 validate instruments to measure child development globally. First, it is conducted in
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23 466 seven countries with multiple linguistic, cultural and socioeconomic backgrounds.
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25 467 Second, GSED is implemented through an app-based data collection system that
26
27 468 facilitates the implementation by reducing recording and transcribing errors and other
28
29 469 common pitfalls of paper-based instruments. Third, this study builds on the best practices
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31 470 in validation by including a broad spectrum of psychometric methodologies (concurrent,
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33 471 predictive, convergent, and discriminant validity, test-retest and inter-rater reliability,
34
35 472 differential item functioning, and differential test functioning). Fourth, a secondary aim
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37 473 builds the evidence for the creation of preliminary reference scores for the SF and LF,
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39 474 based on a sub-sample with minimal exposure to major biological risk factors and to the
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41 475 extent possible, minimal social and environmental risk factors. Fifth, we are validating an
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43 476 adaptive testing design that can streamline administration by tailoring and reducing the
44
45 477 number of items required to obtain a valid score. Sixth, we are testing a new measure of
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47 478 young children's non-normative psychosocial development.
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49 479 One notable difference between the GSED SF and LF measures and other instruments of
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51 480 early child development is that the GSED measures are based on a unidimensional model
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3 481 of development through measurement approaches that are universally applicable across
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5 482 cultures. The measures do not follow the common multidimensional approach with
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7 483 separate scores for different domains or contexts. Our validation study intends to
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9 484 demonstrate that this model provides valid, reliable, and interpretable data globally. The
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11 485 GSED SF and LF may exclude some items that measure development in cultural or
12
13 486 setting-specific ways, because the focus is on selecting items that are meaningful for
14
15 487 understanding child development within any given setting. If specific aspects need to be
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17 488 captured locally, to increase cultural relevance we suggest that the GSED measures are
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19 489 lightly adapted with country or culture-specific item props (in agreement with WHO)
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21 490 and/or through the administration of additional measures.
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27 491 There are several limitations to our study. Although we are validating the GSED in seven
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29 492 countries, including one high income setting, three sites are resource-limited
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31 493 (Bangladesh, Pakistan and United Republic of Tanzania). Additional evidence may be
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33 494 needed in high income countries to expand the validity and reliability of the GSED to
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35 495 population-representative samples in additional countries. Second, the GSED has been
36
37 496 created using items that fit a Rasch model demonstrating developmental progress across
38
39 497 ages 0-3 years (9). This univariate model makes strict assumptions designed for global
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41 498 population estimates and may exclude items that do not show strong age gradients or
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43 499 items that measure development in a culturally-specific ways. Third, GSED was
44
45 500 developed to address population and programmatic level evaluations of early child
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47 501 development globally. The GSED is presently not being validated for screening or
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49 502 diagnosing individual children. Finally, our three secondary aims are exploratory, and
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51 503 will require further research, including developing global standards to replace our
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53 504 preliminary reference scores with more specific global norms, as in the Multi-country
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55 505 Growth Reference Standards for children's weight and height. In the future we plan to
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3 506 collect additional data from countries using strict inclusion/exclusion criteria (e.g.,
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5 507 additional considerations around environmental risk and protective factors) to further
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8 508 validate our initial reference scores. Similarly, we plan to conduct further work to explore
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10 509 the functionality, reliability, validity, and invariance of the PF.

11 510 **Conclusion**

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15 511 The validation of the GSED will enable countries to implement the measures with
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17 512 confidence. With valid, reliable, and invariant measures in hand, countries can advance
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19 513 initiatives to ensure that children reach their developmental potential, while reducing or
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21 514 eliminating disparities. Ensuring that all communities have access to policies and
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23 515 programs that provide nurturing care to children and families, with additional support for
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25 516 regions in need, promotes equity and increases the likelihood of achieving the SDGs.
26
27 517 Once validated, the GSED measures will enable countries to adapt, modify, and evaluate
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29 518 their policies and programs to ensure that young children are effectively and equitably
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31 519 reaching their development potential and building the human capital needed for
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33 520 sustainable development.
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3 521 **LIST OF ABBREVIATIONS**
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5 522
6 523 Bayley-III Bayley Scales of Infant and Toddler Development
7 524 BRS Brief Resilience Scale
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9 525 CI Confidence interval
10
11 526 CPAS Childhood Psychosocial Adversity Scale
12 527 DAZ Development for Age Z-score
13
14 528 DHS Demographic and Health Surveys
15 529 DIF Differential item functioning
16
17 530 DTF Differential test functioning
18
19 531 D-score Developmental Score
20 532 EAP Expected a posteriori
21
22 533 ECD Early child development
23
24 534 ECDI 2030 Early Childhood Development Index 2030
25 535 FCI Family Care Indicators
26
27 536 FSS Family Support Scale
28
29 537 GAMLSS Generalized Additive Model for Location Scale and Shape
30 538 GSED Global Scales for Early Development
31
32 539 HAZ Height-for-age z-score
33
34 540 HOME Home Observation for Measurement of the Environment Inventory
35 541 ICC Intraclass correlation coefficient
36
37 542 LF Long Form
38
39 543 LMIC Low- and middle-income country
40 544 MICS Multiple Indicator Cluster Surveys
41
42 545 OSF Open Science Framework
43
44 546 PF Psychosocial Form
45 547 PHQ-9 The Patient Health Questionnaire-9
46
47 548 SDG Sustainable Development Goals
48
49 549 SES Socioeconomic status
50 550 SF Short Form
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52 551 SOPs Standard operating procedures
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54 552 WAZ Weight-for-age z-score
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3 553 **STATEMENTS**
4

5 554 **Ethics approval:** The study complies with the International Ethical Guidelines for
6
7 555 Biomedical Research Involving Human Subjects and received ethical approval from the
8
9 556 appropriate Ethics Review Committee (ERC) at the World Health Organization (WHO)
10
11 557 (protocol ID GSED validation 004583 approved on 20.04.2020) and in each site.
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14 558 **Patient consent:** Written consent is gathered by all study participants. Informed consent
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16 559 forms are written to be easily understood by lay persons, enabling them to understand the
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18 560 aims, procedures and potential risks of participation and have been approved by the
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20 561 WHO ERC. For participants who are illiterate, culturally acceptable options including
21
22 562 witnessed oral consent and a thumbprint in lieu of a signature are accepted by the WHO
23
24 563 and local ERCs.
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28 564 **Data sharing:** Not applicable (protocol paper)
29

30 565 **Author Contributions:** All authors contributed substantively to this work. VC, TD, MG,
31
32 566 MMB, MJ, and PK conceptualized the study protocol and drafted the manuscript; GL,
33
34 567 GMc, DMc, MW, SvB, IE, and JS drafted the statistical analysis plan and determined the
35
36 568 sample size calculations; AN, AR, KH, and AW drafted pieces of the manuscript. SA,
37
38 569 AD, RA, AB, FJ, YS, IN, RK, SS, AZ, MPM, YZ, FT, ARD, AB, JZ, AH, GF, SD, NSK,
39
40 570 FB, FJ, and MRC contributed to the adaptation of the study protocol for feasibility and
41
42 571 on-the-ground implementation. All above authors, in addition to RK, MMP, and RN
43
44 572 reviewed and edited the study protocol and the manuscript. All authors read and approved
45
46 573 the final manuscript submission.
47
48

49
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2
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4

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6

7 577 **COMPETING INTERESTS**
8

9
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11

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13

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19 582 Organization.
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3 681 **FIGURE LEGEND**
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5 682 **Figure 1. Development chart**
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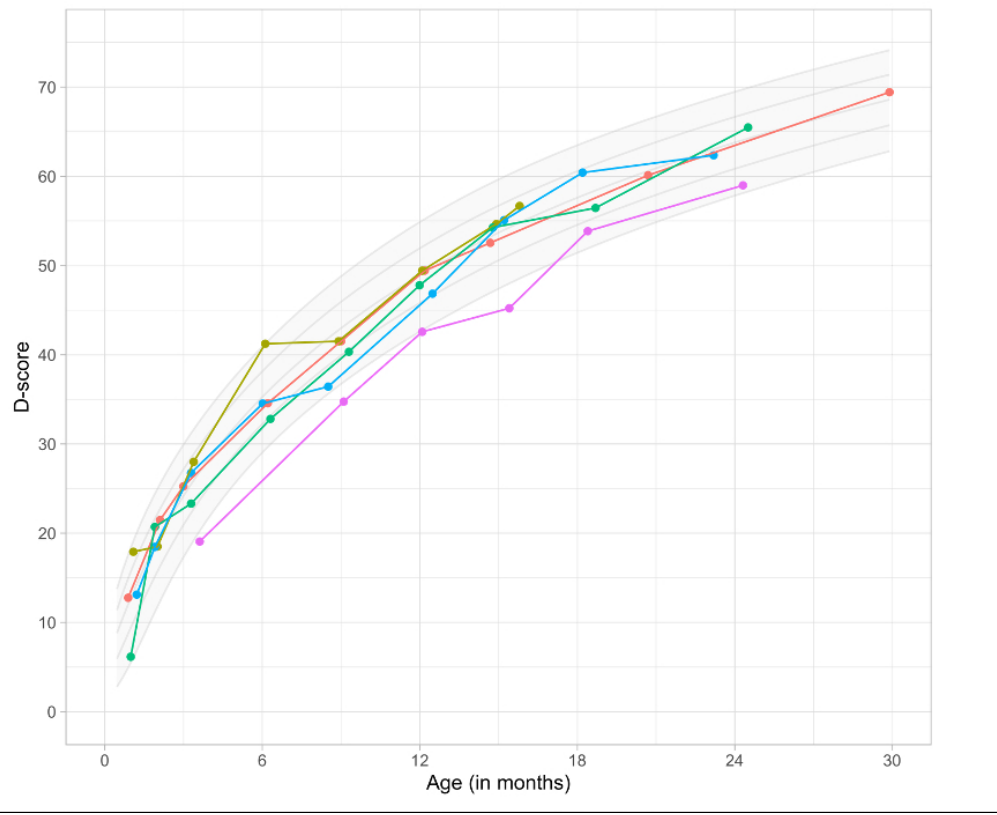
7 683 Reproduced with permission from van Buuren S and Eekhout I (2021) (15)
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12 685 **Figure 2. Study Sampling schema diagram**
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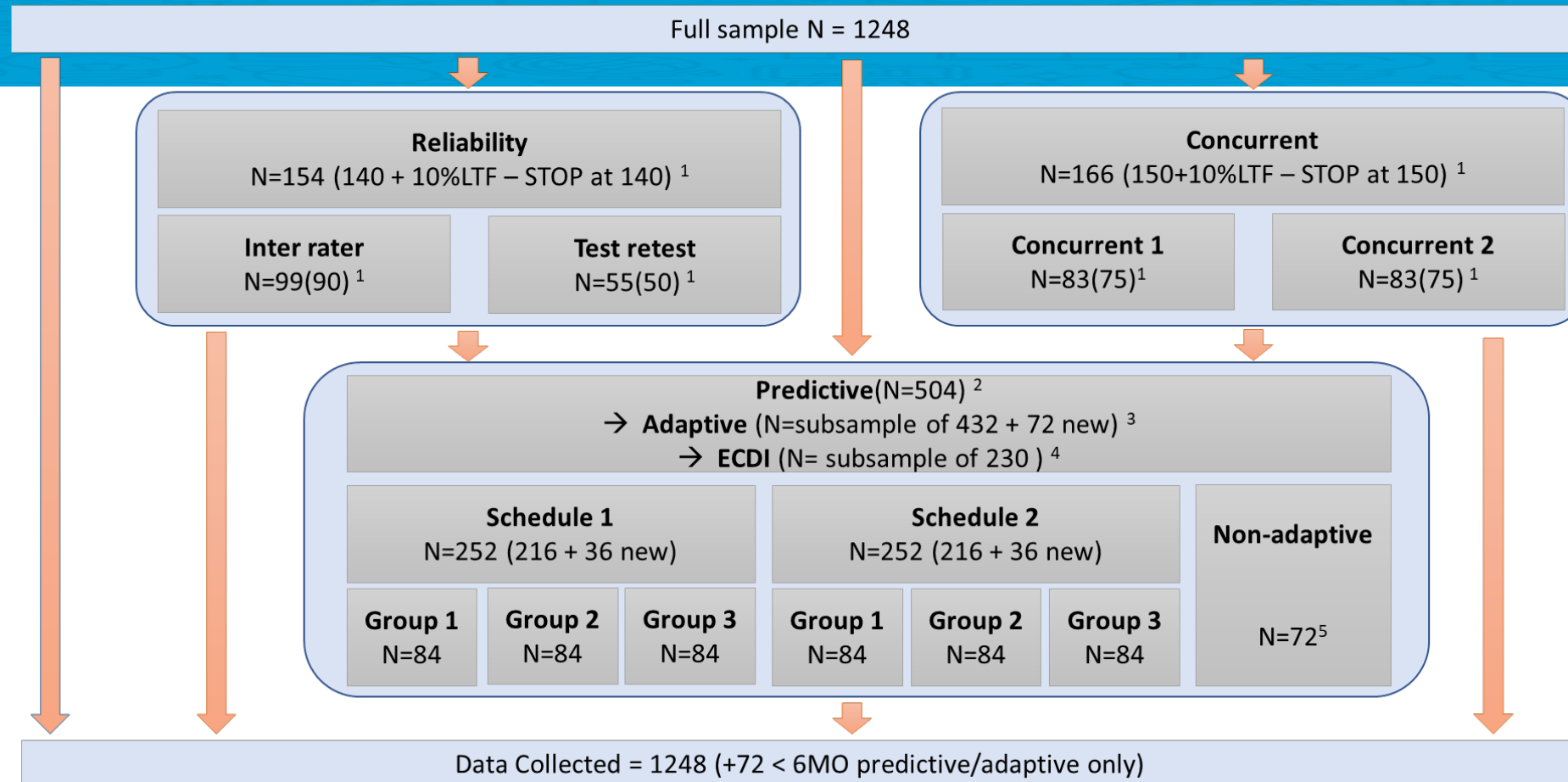
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152x125mm (144 x 144 DPI)

GSED study sample



[1] The number inside parentheses is the number collected and the number outside is the number randomised to account for loss to follow-up

[2] Two additional participants have been added to the predictive to have equal numbers in each experimental group.

[3] 72 new children between 2 weeks and 6 months of age have been added to the adaptive sample to ensure coverage at the lower ages.

[4] ECDI will only be done on N=230 Children between the ages of 2+ years at the time of the predictive data collection.

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[5] The 72 oldest children (36-41 months) from the predictive sample will not be part of the adaptive sample.

Supplementary file 1 – Sample size calculations and sampling frame

The sample size calculation for reliability is based on a confidence interval (CI) approach and the desired accuracy for the lower bound of the CI for the ICC estimates. In an Analysis of Variance (ANOVA) with 2-way random effects on a single score with 2 observations per subject (following Shrout and Fleiss, 1979) (27) and with a two-sided 95% confidence interval and an expected ICC of 0.875, the lower confidence interval for the inter-rater reliability sample (N=90) = 0.852. With the same parameters but an expected ICC of 0.90 the lower confidence interval for the test-retest reliability sample (N=50) is 0.830. We expect the ICC to be higher for the test-retest reliability than the inter-rater reliability as inter-rater estimates contain all the sources of error in the test-retest estimates, plus additional error between assessors (14).

To assess concurrent validity, a sample size of 150 per site produces a two-sided 95% CI 0.15-0.44, when the estimate of Pearson's product-moment correlation is 0.30, with an equal spread of participants tested across age and sex. The CI will be narrower when the data are combined across all seven countries. To assess predictive validity a sample size of 404 produces a two-sided 95% CI 0.65-0.75 when the estimate of Pearson's product-moment correlation is 0.70 between individual scores at baseline and at the 6-month follow-up. Allowing 20% dropout at follow up, a sample size of approximately 500 participants is required.

Table S1. Sampling Frame

Sample size per site by age and sex for total population (n=1248) which includes a minimum subsample of healthy 'reference' children (n=522)

Age (Days)	Sex	Total Sample size	Minimum sub-sample of reference children	Predictive validity sample (6-month follow-up; age at baseline)	Reliability: Inter-rater	Reliability: Test-Retest	Concurrent validity
15-30	Male	40	20	8	2	1	4
	Female	40	20	8	2	1	2
31-61	Male	40	12	8	1	1	2
	Female	40	12	8	2	1	2
62-91	Male	40	10	8	2	1	2
	Female	40	10	8	1	0	4
92-122	Male	36	9	8	2	1	2
	Female	36	9	8	2	1	2
123-152	Male	32	8	8	1	1	2
	Female	32	8	8	2	1	2

153-183	Male	28	8	8	1	0	4
	Female	28	8	8	1	1	2
184-213	Male	25	7	8	2	1	2
	Female	25	7	8	1	0	2
214-244	Male	23	7	8	1	1	2
	Female	23	7	8	2	1	4
245-274	Male	21	6	8	1	1	2
	Female	21	6	8	1	1	2
275-304	Male	19	6	8	2	0	2
	Female	19	6	8	1	1	2
305-335	Male	17	6	8	1	1	4
	Female	17	6	8	2	0	2
336-365	Male	16	6	7	1	1	2
	Female	16	6	7	1	1	2
366-396	Male	14	6	7	2	1	2
	Female	14	6	7	1	1	4
397-426	Male	13	6	7	1	0	2
	Female	13	6	7	2	1	2
427-457	Male	12	5	7	1	1	2
	Female	12	5	7	1	0	2
458-487	Male	11	5	7	2	1	4
	Female	11	5	7	1	1	2
488-517	Male	11	5	7	1	1	2
	Female	11	5	7	2	1	2
518-548	Male	10	5	7	1	0	2
	Female	10	5	7	1	1	4
549-578	Male	9	5	7	2	1	2
	Female	9	5	7	1	0	2
579-609	Male	9	5	7	1	1	2
	Female	9	5	7	2	1	2
610-639	Male	9	5	7	1	1	4
	Female	9	5	7	1	1	2
640-670	Male	9	5	7	2	0	2
	Female	9	5	7	1	1	2
671-700	Male	9	5	7	1	1	2
	Female	9	5	7	2	0	4
701-730	Male	9	5	7	1	1	2
	Female	9	5	7	1	1	2
731-761	Male	9	5	7	2	1	2
	Female	9	5	7	1	1	2
762-791	Male	9	5	6	1	0	4
	Female	9	5	6	2	1	2
792-822	Male	9	5	6	1	1	2
	Female	9	5	6	1	0	2
823-852	Male	9	5	6	2	1	2
	Female	9	5	6	1	1	2

853-883	Male	9	5	6	1	1	2
	Female	9	5	6	2	1	2
884-913	Male	9	5	6	1	0	2
	Female	9	5	6	1	1	2
914-944	Male	9	5	6	2	1	2
	Female	9	5	6	1	0	2
945-974	Male	9	5	6	1	1	2
	Female	9	5	6	2	1	2
975-1004	Male	9	5	6	1	1	2
	Female	9	5	6	1	1	2
1005-1035	Male	9	5	6	2	0	2
	Female	9	5	6	1	1	2
1036-1065	Male	9	5	6	1	1	2
	Female	9	5	6	2	0	2
1066-1096	Male	9	5	6	1	1	2
	Female	9	5	6	1	1	2
1097-1126	Male	9	5	0	0	0	0
	Female	9	5	0	0	0	0
1127-1157	Male	9	5	0	0	0	0
	Female	9	5	0	0	0	0
1158-1187	Male	9	5	0	0	0	0
	Female	9	5	0	0	0	0
1188-1218	Male	9	6	0	0	0	0
	Female	9	6	0	0	0	0
1219-1248	Male	9	6	0	0	0	0
	Female	9	6	0	0	0	0
1249-1279	Male	9	7	0	0	0	0
	Female	9	7	0	0	0	0
TOTAL		1248	522	504	*99	**55	***166

*90 + ~10% Loss to follow up = 99; **50 + ~10% Loss to follow up = 55; ***150 + ~10% Loss to follow up = 166

Supplementary file 2 – Visit schedule

Table S2a. Visit Schedule for the GSED Validation Study (all sites except the Netherlands)

Main Study Only [No Sub-sample]	Inter- Rater Reliability Sub- Sample	Test- Retest Reliability Sub- Sample	Concurrent Sub- Sample 1 [LF First]	Concurrent Sub- Sample 2 [BSID III First]
Visit 1 [At Home]				
Eligibility and Consent	Eligibility and Consent	Eligibility and Consent	Eligibility and Consent	Eligibility and Consent
COVID Questionnaire	COVID Questionnaire	COVID Questionnaire	COVID Questionnaire	COVID Questionnaire
Contextual	Contextual	Contextual	Contextual	Contextual
GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]
GSED Psychosocial form [PF]	GSED Psychosocial form [PF]	GSED Psychosocial form [PF]	GSED Psychosocial form [PF]	GSED Psychosocial form [PF]
HOME Inventory or Family Care Indicators (FCI)	HOME Inventory or Family Care Indicators (FCI)	HOME Inventory or Family Care Indicators (FCI)	HOME Inventory or Family Care Indicators (FCI)	HOME Inventory or Family Care Indicators (FCI)
Anthropometrics*	Anthropometrics*	Anthropometrics*	Anthropometrics*	Anthropometrics*
Visit 2 [At home, clinic, or other setting within 48 hours of visit 1] Note: For Concurrent Sample, the Visit is at the Clinic setting				
Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]
GSED Long form [LF]	GSED Long form [LF]	GSED Long form [LF]	GSED Long form [LF]	BSID III
CPAS	CPAS	CPAS	CPAS	-----
PHQ9	PHQ9	PHQ9	PHQ9	-----
Family support & Resilience Scale	Family support & Resilience Scale	Family support & Resilience Scale	Family support & Resilience Scale	-----
Visit 3 [Setting and timing vary by sub-sample]				
Visit 3 not required	Visit 3 [At home, clinic or other setting where the LF was completed- within 24 hours of the LF]	Visit 3 [At home, clinic or other setting where the LF was completed- this should happen 7 to 10 days after LF]	Visit 3 [Clinic setting within 24- 72 hours of the LF- can be done at same time as Visit 2 – taking child fatigue into consideration]	Visit 3 [Clinic setting within 24- 72 hours of the BSID III - can be done at same time as Visit 2 – taking child fatigue into consideration]
	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]
	GSED Short form [SF]	GSED Short form [SF]	BSID III	GSED Long form [LF]
	GSED Psychosocial form [PF]	GSED Psychosocial form [PF]	-----	CPAS
	GSED Long form [LF]	GSED Long form [LF]	-----	PHQ9
-----	-----	-----	-----	Family support & Resilience Scale

* Anthropometrics may be done either at visit 1 or visit 2

Table S2b: Visit Schedule for the GSED Validation Study (the Netherlands only)

Main Study Only [No Sub-sample]	Inter- Rater Reliability Sub- Sample	Test- Retest Reliability Sub- Sample	Concurrent Sub- Sample 1 [LF First]	Concurrent Sub- Sample 2 [BSID III First]
Session 1 [Online]				
Eligibility and Consent	Eligibility and Consent	Eligibility and Consent	Eligibility and Consent	Eligibility and Consent
Contextual	Contextual	Contextual	Contextual	Contextual
GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]
GSED Psychosocial scale [PS]	GSED Psychosocial scale [PS]	GSED Psychosocial scale [PS]	GSED Psychosocial scale [PS]	GSED Psychosocial scale [PS]
Visit 1 [At clinic within 48 hours of session1]				
Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]
GSED Long form [LF]	GSED Long form [LF]	GSED Long form [LF]	GSED Long form [LF]	BSID III
Anthropometrics	Anthropometrics	Anthropometrics	Anthropometrics	Anthropometrics
Session 2 [Online, Test-Retest of SF/PSY within 7 to 10 days of online session 1]				
Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]
COVID Questionnaire	COVID Questionnaire	COVID Questionnaire	COVID Questionnaire	COVID Questionnaire
-----	-----	GSED Short form [SF]	-----	-----
-----	-----	GSED Psychosocial scale [PS]	-----	-----
CPAS	CPAS	CPAS	CPAS	CPAS
PHQ9	PHQ9	PHQ9	PHQ9	PHQ9
Family support & Resilience Scale	Family support & Resilience Scale	Family support & Resilience Scale	Family support & Resilience Scale	Family support & Resilience Scale
Family Care Indicators (FCI)	Family Care Indicators (FCI)	Family Care Indicators (FCI)	Family Care Indicators (FCI)	Family Care Indicators (FCI)
Visit 2 [At clinic, timing varies by sub-sample]				
Visit 2 not required	Visit 2 [within 24 hours of the LF]	Visit 2 [7 to 10 days after LF]	Visit 2 [within 24- 72 hours of the LF- can be done at same time as Visit 1 – taking child fatigue into consideration]	Visit 2 [within 24- 72 hours of the BSID III - can be done at same time as Visit 1 – taking child fatigue into consideration]
	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]
	GSED Long form [LF]	GSED Long form [LF]	BSID III	GSED Long form [LF]

BMJ Open

Protocol for Validation of the Global Scales for Early Development (GSED) for Children under 3 Years of Age in Seven Countries

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-062562.R1
Article Type:	Protocol
Date Submitted by the Author:	23-Sep-2022
Complete List of Authors:	<p>Cavallera, Vanessa; World Health Organization, Department of Mental Health and Substance Use Lancaster, Gillian; Keele University School of Medicine Gladstone, Melissa; University of Liverpool Institute of Translational Medicine, Women and Children's Health Black, Maureen; RTI International; University of Maryland School of Medicine McCray, Gareth; Keele University School of Medicine Nizar, Ambreen; The Aga Khan University, Department of Peadiatrics Ahmed, Salahuddin; Projahnmo Research Foundation Dutta, Arup; Center for Public Health Kinetics Anago, Romuald ; Innovations for Poverty Action Brentani, Alexandra; University of Sao Paulo, Pediatrics Jiang, Fan; Shanghai Children's Medical Center Affiliated to Shanghai Jiaotong University School of Medicine Schönbeck, Yvonne; Netherlands Organization for Applied Scientific Research, Department of Child Health McCoy, Dana; Harvard Graduate School of Education Kariger, Patricia; University of California Berkeley School of Public Health Weber, Ann; University of Nevada Reno Raikes, Abbie; University of Nebraska Medical Center College of Public Health Waldman, Marcus; University of Nebraska Medical Center College of Public Health van Buuren, Stef; TNO, Department of Statistics Kaur, Raghbir; World Health Organization Maillard, Pérez; World Health Organization Nisar, Muhammad; The Aga Khan University, Pediatrics and Child Health Khanam, Rasheda; Johns Hopkins University, International Center for Maternal and Newborn Health, Department of International Health, Johns Hopkins Bloomberg School of Public Health Sazawal, Sunil ; Centre for Public Health Kinetics Zongo, Arsène; Innovations for Poverty Action Pacífico Mercadante, Mariana; University of Sao Paulo, Pediatrics Zhang, Yunting ; Shanghai Children's Medical Center Affiliated to Shanghai Jiaotong University School of Medicine Roy, Arunangshu ; Projahnmo Research Foundation Hepworth, Katelyn; University of Nebraska-Lincoln College of Education and Human Sciences</p>

	Fink, Günther ; Schweizerisches Tropen- und Public Health-Institut, Household Economics and Health System Research Unit Rubio-Codina, Marta; Inter-American Development Bank Tofail, Fahmida; International Centre for Diarrhoeal Disease Research Bangladesh, Centre for Nutrition & Food Security Eekhout, Iris; TNO, Child Health Seiden, Jonathan; Harvard Graduate School of Education Norton, Rebecca; World Health Organization Baqui, Abdullah; Johns Hopkins University Bloomberg School of Public Health Zhao, Jin; Shanghai Children's Medical Center Affiliated to Shanghai Jiaotong University School of Medicine Holzinger, Andreas; Innovations for Poverty Action Detmar, Symone; TNO Kembou, Samuel; Innovations for Poverty Action Begum, Farzana; The Aga Khan University, Department of Paediatrics Jehan, Fyezah; The Aga Khan University, Paediatrics and Child Health Dua, Tarun; World Health Organization Janus, Magdalena; McMaster University, Offord Centre for Child Studies
Primary Subject Heading:	Public health
Secondary Subject Heading:	Paediatrics
Keywords:	MENTAL HEALTH, Paediatric neurology < NEUROLOGY, Developmental neurology & neurodisability < PAEDIATRICS, PUBLIC HEALTH, EPIDEMIOLOGY, International health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Title: Protocol for Validation of the Global Scales for Early Development (GSED) for Children under 3 Years of Age in Seven Countries

Authors: Cavallera V, Lancaster G, Gladstone M, Black MM, McCray G, Nizar A, Ahmed S, Dutta A, Anago R, Brentani A, Jiang F, Schönbeck Y, McCoy D, Kariger P, Weber A, Raikes A, Waldman M, van Buuren S, Kaur R, Pérez Maillard M, Nisar I, Khanam R, Sazawal S, Zongo A, Pacifico Mercadante M, Zhang Y, Roy AD, Hepworth K, Fink G, Rubio Codina M, Tofail F, Eekhout I, Seiden J, Norton R, Baqui AH, Zhao J, Holzinger A, Detmar S, Kembou S N, Begum F, Jehan F, Dua T, Janus M.

Affiliations:

Corresponding author: Dr Vanessa Cavallera, MD, MPH, World Health Organization (WHO), Brain Health Unit in Department of Mental Health and Substance Use, Av. Appia 20, 1202 Geneva, Switzerland. cavallerav@who.int

Prof Gillian Lancaster, PhD, MSc, BSc (Hons), Clinical Trials Unit, School of Medicine, Keele University, UK

Prof Melissa Gladstone, MD, International Child Health and Neurodevelopmental Paediatrics, Department of Women and Children's Health, Institute of Translational Medicine, University of Liverpool, Alder Hey Children's NHS Foundation Trust, UK.

Prof Maureen Black, PhD, Department of Pediatrics, University of Maryland School of Medicine, Baltimore, MD, USA and RTI International, Research Park, NC, USA

Dr Gareth McCray, MA, MRes, PhD, Research Associate, the School of Medicine, Keele University, Keele, UK.

Ambreen Nizar, BDS, MSc, Department of Paediatrics, Aga Khan University, Karachi Pakistan.

- 1
2
3 27 Salahuddin Ahmed, MBBS, Projahnmo Research Foundation, Dhaka, Bangladesh
4
5
6 28 Arup Dutta, MBA, Center for Public Health Kinetics, New Delhi, India
7
8
9 29 Romuald Kouadio E Anago, MA, BA, Innovations for Poverty Action (IPA), Abidjan,
10
11 30 Côte d'Ivoire
12
13
14 31 Dr. Alexandra Valeria Maria Brentani, PhD, Dept. of Pediatrics, University of Sao Paulo
15
16 32 Medical School, Brazil
17
18
19 33 Prof. Fan Jiang, MD, PhD, Department of Developmental and Behavioral Pediatrics,
20
21 34 National Children's Medical Center, Shanghai Children's Medical Center, affiliated to
22
23 35 School of Medicine Shanghai Jiao Tong University, China
24
25
26 36 Dr. Yvonne Schönbeck, PhD, Msc, Dept. Child Health, Netherlands Organization for
27
28 37 Applied Scientific Research (TNO), Leiden, The Netherlands
29
30
31 38 Dr Dana McCoy, PhD, Harvard Graduate School of Education, Cambridge, MA, USA
32
33
34 39 Dr Patricia Kariger, PhD CEGA (Center for Effective Global Action), School of Public
35
36 40 Health, University of California, Berkeley, California, USA.
37
38
39 41 Dr Ann Weber, PhD, MPH, School of Public Health, University of Nevada, Reno, NV,
40
41 42 USA
42
43
44 43 Dr Hilary Abigail Raikes, MPH, PhD, University of Nebraska Medical Center, College of
45
46 44 Public Health, Omaha, NE, USA
47
48
49 45 Dr. Marcus Waldman, PhD, University of Nebraska Medical Center, College of Public
50
51 46 Health, Omaha, NE, USA
52
53
54 47 Prof Stef van Buuren, PhD, Department of Child Health, Netherlands Organization for
55
56 48 Applied Scientific Research TNO, Leiden, The Netherlands
57
58
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60

- 1
2
3 49 Raghbir Kaur, MPH, DMD, MS, Consultant World Health Organization (WHO), Brain
4
5 50 Health Unit in Department of Mental Health and Substance Use, Geneva, Switzerland
6
7 51 Michelle Pérez Maillard, MSc, Consultant World Health Organization (WHO), Brain
8
9 52 Health Unit in Department of Mental Health and Substance Use, Geneva, Switzerland
10
11
12 53 Prof. Muhammad Imran Nisar, MBBS, MSc, Department of Peadiatrics, Aga Khan
13
14 54 University, Karachi Pakistan.
15
16
17 55 Dr. Rasheda Khanam, MBBS, MPH, PhD, International Center for Maternal and
18
19 56 Newborn Health, Department of International Health, Johns Hopkins University
20
21 57 Bloomberg School of Public Health, Baltimore, MD, USA
22
23
24 58 Dr. Sunil Sazawal, MBBS, MPH, PhD, Center for Public Health Kinetics New Delhi,
25
26 59 India
27
28
29 60 Mr. Arsène Zongo, MA, BA, Innovations for Poverty Action (IPA), Abidjan, Côte
30
31 61 d'Ivoire
32
33
34 62 Dr. Mariana Pacifico Mercadante, MD, Dept. of Pediatrics, University of Sao Paulo
35
36 63 Medical School, Brazil
37
38
39 64 Dr. Yunting Zhang, PhD, Child Health Advocacy Institute, National Children's Medical
40
41 65 Center, Shanghai Children's Medical Center, affiliated to School of Medicine Shanghai
42
43 66 Jiao Tong University, China
44
45
46 67 Dr. Arunangshu D. Roy, MBBS, Projahnmo Research Foundation, Dhaka, Bangladesh
47
48
49 68 Katelyn Hepworth, MA, University of Nebraska-Lincoln, College of Education and
50
51 69 Human Sciences, NE, USA
52
53
54 70 Prof Günther Fink, PhD, Swiss Tropical and Public Health Institute, Basel, Switzerland
55
56
57
58
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60

- 1
2
3 71 Dr Marta Rubio-Codina, PhD, Inter-American Development Bank, Washington, D.C.,
4
5 72 USA
6
7
8 73 Dr. Fahmida Tofail, MBBS, PhD, International Centre for Diarrhoeal Disease Research
9
10 74 Iccdr,b, Dhaka, Bangladesh
11
12
13 75 Dr. Iris Eekhout, PhD, MSc, Department of Child Health, Netherlands Organization for
14
15 76 Applied Scientific Research TNO, Leiden, The Netherlands
16
17
18 77 Jonathan Seiden, EdM, Harvard Graduate School of Education, Cambridge, MA, USA
19
20
21 78 Rebecca Norton, Consultant World Health Organization (WHO), Brain Health Unit in
22
23 79 Department of Mental Health and Substance Use, Geneva, Switzerland
24
25
26 80 Dr. Abdullah H. Baqui, MBBS, DrPH, Johns Hopkins Bloomberg School of Public
27
28 81 Health, Baltimore, Maryland, USA
29
30
31 82 Dr. Jin Zhao, MD, PhD, Department of Developmental and Behavioral Pediatrics,
32
33 83 National Children's Medical Center, Shanghai Children's Medical Center, affiliated to
34
35 84 School of Medicine Shanghai Jiao Tong University, China
36
37
38 85 Andreas Holzinger, MA, BA, Innovations for Poverty Action (IPA), Abidjan, Côte
39
40 86 d'Ivoire
41
42
43 87 Dr. Symone Detmar, PhD, Msc, Department of Child Health, Netherlands Organization
44
45 88 for Applied Scientific Research TNO, Leiden, The Netherlands
46
47
48 89 Dr, Samuel Nzale Kembou, PhD, MA, BA, Innovations for Poverty Action (IPA),
49
50 90 Abidjan, Côte d'Ivoire
51
52
53 91 Farzana Begum, MSc, Department of Peadiatrics, Aga Khan University, Karachi
54
55 92 Pakistan.
56
57
58
59
60

1
2
3 93 Prof. Fyezah Jehan, MBBS, FCPS, MSc, Department of Peadiatrics, Aga Khan
4

5 94 University, Karachi Pakistan.
6
7

8 95 Dr Tarun Dua, MD, World Health Organization (WHO), Brain Health Unit in
9

10 96 Department of Mental Health and Substance Use, Geneva, Switzerland
11
12

13 97 Prof Magdalena Janus, MBBS, FCPS, MSc, Offord Centre for Child Studies, McMaster
14

15 98 University, Hamilton ON, Canada.
16
17

18 99 **Disclaimers:**

20 100 The author is a member of the World Health Organization. The author alone is
21
22 101 responsible for the views expressed in this publication and they do not necessarily
23
24 102 represent the decisions, policy or views of the World Health Organization. [Applies to
25
26 103 Cavallera V, Dua T, Kaur R, Pérez Maillard M and Norton R]
27
28

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3 109 **ABSTRACT**
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6 110 **Introduction.** Children's early development is affected by caregiving experiences, with
7
8 111 life-long health and wellbeing implications. Governments and civil societies need
9
10 112 population-based measures to monitor children's early development and ensure that
11
12 113 children receive the care needed to thrive. To this end, the World Health Organization
13
14 114 (WHO) developed the Global Scales for Early Development (GSED) to measure
15
16 115 children's early development (ages 0-3 years). The GSED includes three measures: 1)
17
18 116 short form (SF) for population-evaluation (caregiver-report), 2) complementary long
19
20 117 form (LF) for programmatic-evaluation (direct assessment), and 3) psychosocial form
21
22 118 (PF) for psychosocial development evaluation (caregiver-report). The primary aim of this
23
24 119 protocol is to validate the GSED SF and LF. Secondary aims are to create preliminary
25
26 120 reference scores for the GSED SF and LF, validate an adaptive testing algorithm, and
27
28 121 assess the feasibility and preliminary validity of the GSED PF.
29
30

31
32
33 122 **Methods and Analysis.** We will conduct the validation in seven countries (Bangladesh,
34
35 123 Brazil, Côte d'Ivoire, Pakistan, The Netherlands, The Republic of China, United
36
37 124 Republic of Tanzania), varying in geography, language, culture and income through a
38
39 125 one-year prospective design, combining cross-sectional and longitudinal methods with
40
41 126 1248 children per site, stratified by age and sex. The GSED generates an innovative
42
43 127 common metric (Development-score: D-score) using the Rasch model and a
44
45 128 development-for-age z-score (DAZ). We will evaluate six psychometric properties of the
46
47 129 GSED SF and LF: concurrent validity, predictive validity at six months, convergent and
48
49 130 discriminant validity, and test-retest and inter-rater reliability. We will evaluate
50
51 131 measurement invariance by comparing differential item functioning (DIF) and differential
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53 132 test functioning (DTF) across sites.
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3 133 **Ethics and dissemination.** This study has received ethical approval from the WHO
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5 134 (protocol GSED validation 004583 20.04.2020) and approval in each site . Study results
6
7 135 will be disseminated through webinars and publications from WHO, international
8
9 136 organisations, academic journals, and conference proceedings.

10
11
12 137 **Registration details:** Open Science Framework (OSF) <https://osf.io/> on 19/11/2021 (DOI
13
14 138 10.17605/OSF.IO/KX5T7; identifier: osf-registrations-kx5t7-v1)

17 18 139 **ARTICLE SUMMARY**

19 20 140 **Strengths and limitations of this study**

- 21
22 141 • The study collects validation data (n = 8736 children) for the Global Scales for
23
24 142 Early Development (GSED) in seven countries that vary in geographic, linguistic,
25
26 143 cultural and sociodemographic characteristics.
- 27
28 144 • The methods for the validation of GSED are systematic across sites and follow
29
30 145 rigorous standard operating procedures based on the best scientific evidence
31
32 146 available.
- 33
34 147 • A tablet-based App is used for data collection to make the administration of the
35
36 148 GSED measures user-friendly, to reduce recording and transcribing errors, and to
37
38 149 facilitate adaptive testing.
- 39
40 150 • The GSED SF and LF aims to include items that are culturally neutral and fit the
41
42 151 Rasch model, which assumes that child development milestones are age-ordinal,
43
44 152 to create D-scores while psychosocial items are included in a separate measure
45
46 153 (GSED psychosocial form [PF]) and cultural-specific items can be supplemented
47
48 154 by countries.
- 49
50 155 • The three secondary aims (preliminary reference scores, an adaptive testing
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52 156 algorithm, and the feasibility and validity of the GSED PF), are exploratory and
53
54 157 will require further research.
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158 INTRODUCTION

159 Prenatal and early postnatal experiences have significant impacts on early childhood
160 development (ECD) and can influence the accrual of health, well-being, and productivity
161 throughout the life-course (1). To promote current and sustainable peace and prosperity,
162 the United Nations has focused the Sustainable Development Goals (SDG) on improving
163 children's outcomes in the early years through multiple targets. The most explicit target
164 for young children is SDG 4 (Education goal), which requires reporting on the
165 "proportion of children under 5 years of age who are developmentally on track in health,
166 learning and psychosocial well-being, by sex" (2).

167 There are few valid measures that can be used globally to assess child development for
168 children under three years of age. Current measures of ECD range from proxy measures
169 (e.g., prevalence of country-level stunting and poverty) to detailed measures of individual
170 performance on developmental tasks (3). The Early Childhood Development Index 2030
171 (ECDI 2030) (4) does not include children below two years of age. A recent review has
172 identified the creation and validation of population-based instruments for assessing very
173 young children as a global priority (5).

174 The Global Scales for Early Development (GSED) build on advances made by analyses
175 of existing global datasets (6), and new data collection (7) that demonstrated the cross
176 cultural applicability of items that measure young children's development. Three research
177 teams (8) joined efforts to develop the GSED in response to the pressing need for
178 instruments and metrics to measure ECD at population and programmatic levels across
179 diverse parts of the world.

180 **The Global Scales for Early Development (GSED)**

181 The GSED consist of three open-access measures developed by a WHO-led team¹ to
182 provide a standardized methodology for measuring the development of children aged 0-3
183 years (0-36 months) across diverse cultures and contexts (9, 10). They are developed for
184 three objectives: 1) for population-level evaluation based on caregiver-report, GSED
185 Short Form (SF); 2) for programmatic evaluation in combination with SF, direct child
186 assessment, GSED Long Form (LF); and 3) for measuring psychosocial behaviours,
187 caregiver-reported GSED Psychosocial Form (PF). The development and piloting of the
188 GSED SF, LF, and PF are described elsewhere (9).

189 The GSED SF and LF produce metrics on the same age-ordinal scale and quantify the
190 same latent construct. The Developmental Score (D-score) (see Box 1) underlies both
191 measures and reflects children's overall development across multiple domains typically
192 demonstrated in this age group (e.g., cognitive, motor, language, social-emotional) (6).

193 The GSED PF items, designed to measure non-normative developmental patterns,
194 including behavioural or regulatory challenges, are not age-ordinal and do not use the D-
195 Score metric.

Box 1: The Developmental score

The Developmental score (11), or D-score, is a unidimensional latent variable measuring child development during the first three years across multiple domains. The milestones that make up the D-score conform to the Rasch model (12), thus yielding a scale with interval properties with a fixed unit (Figure 1). It is therefore possible to calculate a meaningful difference between two D-scores. Similar to height-for-age Z-score, given suitable age-conditional references, the D-score can be transformed to a Z-

¹ The full team and contributors are listed in the Acknowledgments.

score that accounts for children's age (i.e., Development for Age Z-score, or DAZ).

The DAZ facilitates comparisons across children of different ages.

196 **AIMS**

197 The primary aim of this study is to validate the GSED measures (13), through testing for
198 measurement invariance and evaluation of the psychometric properties to measure
199 development among children aged 0-3 years (0-36 months) globally (including creation
200 of D-scores and Development for Age Z-score [DAZ]).

201 Specific Objectives:

- 202 a) Fit a Rasch model to the item data to calculate the D-scores and DAZ.
- 203 b) Investigate differential item functioning (DIF) and differential test functioning
204 (DTF) across sites to determine measurement invariance.
- 205 c) Examine psychometric properties of the GSED SF and LF:
 - 206 • Test-retest and inter-rater reliability (score and item level),
 - 207 • Concurrent validity (association between scores on GSED and Bayley Scales
208 of Infant and Toddler Development (Bayley-III) or Griffiths Scales of Child
209 Development administered concurrently) (14),
 - 210 • Convergent validity (strength of association between GSED D-scores and
211 other theoretically-relevant constructs)
 - 212 • Predictive validity (association between GSED scores six months after initial
213 assessment).

214 The secondary aims are to: 1) establish preliminary reference scores² for optimal
215 development on the D-score (GSED SF and LF), 2) develop and validate an adaptive

² The population has not been selected as a representative sample of all children aged 0-3 in each site (as would happen in a countrywide population census). Selection and recruitment of a representative sample

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3 216 testing algorithm, and 3) obtain preliminary validity data on the psychometric properties
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5 217 of the GSED PF.
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8 9 218 **METHODS**

10 11 219 **Design and study sites**

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13
14 220 The GSED validation study uses a prospective cross-sectional design with a longitudinal
15
16 221 component of age and sex stratified samples of children in seven countries. The countries
17
18 222 are culturally, linguistically and geographically diverse, representing low-income
19
20 223 (Bangladesh, Côte d'Ivoire, Pakistan, United Republic of Tanzania), middle-income
21
22 224 (Brazil and The Republic of China), and high-income (The Netherlands) settings.
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25 225 Samples in each site are not nationally representative; however, they are diverse, e.g.
26
27 226 covering both rural/urban settings.

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30 227 Preparation and feasibility phases are described elsewhere (13), and assess feasibility of
31
32 228 administration of GSED and associated measures including processes for translating and
33
34 229 culturally adapting GSED and other study measures, creating data management systems,
35
36 230 and training teams in data collection procedures.
37
38

39 231 **Patient and Public involvement**

40
41 232 Caregivers of children 0-41 month-olds were involved in the study design as the burden
42
43 233 of the assessment was discussed with them in a pilot stage through qualitative data
44
45 234 collection. We intend to disseminate the main results to trial participants and will seek
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47 235 patient and public involvement in the development of an appropriate method of
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49 236 dissemination.
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57 was beyond the scope of this study and not required for validation purposes. We are therefore developing
58 'reference scores' which should not be interpreted as population-sampled norms.
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3 237 **Study sample**
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5 238 The study sample includes children between 0 to 41 months of age (inclusive) living in
6
7 239 study areas (see Table 1 for inclusion and exclusion criteria). The small sample of
8
9 240 children from 36-41 months aims to ensure that parameters are estimated with adequate
10
11 241 precision for children at the top of our age range (36 months).
12
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14

15 242 **Table 1. Study sample inclusion and exclusion criteria**

Sample	Inclusion criteria	Exclusion criteria
Total per site N=1248 (as described in sample size section below)	<ol style="list-style-type: none"> 1. Age 0-41 months 2. Family speaks to the child in same language as GSED translation 3. Primary caregiver available to participate 	<ol style="list-style-type: none"> 1. Missing gestational age (ultrasound or last menstrual period LMP) 2. Missing birth weight data 3. Acutely unwell at time of assessment (temporary exclusion: to be rescheduled after 7 days)

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30 244 ***Recruitment and consent***

31
32 245 In each site the sampling frame consists of a list of potentially eligible caregiver-child
33
34 246 dyads residing in the defined study area. Lists of potential participants are created in
35
36 247 compliance with ethical review boards approved processes; they vary by site and may
37
38 248 include: participants in local pregnancy surveillance systems, families who have
39
40 249 previously agreed to be contacted for participation, from hospital/health center registries,
41
42 250 or families with children attending local child health/care centers. Sites using registries
43
44 251 will rely on hospital or health center staff (unaffiliated with GSED) to contact families
45
46 252 and obtain consent for sharing their information with the GSED team. A sample listing of
47
48 253 the pre-consented families will be provided to the GSDE team for recruitment. Sites
49
50 254 recruiting families from local child health/care centers will rely on advertisements or
51
52 255 flyers with information about the project, participation requirements, GSED team contact
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3 256 information for questions, and a scan code or website link for interested families to
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5 257 provide basic eligibility information and consent to be contacted for enrollment.
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8 258 Eligible children are sampled from this list using the GSED sampling scheme (Figure 2).
9
10 259 To minimize clustering of correlated scores within households, one child per caregiver
11
12 260 and in multi-family household is selected, guided by age and sex quotas. For siblings or
13
14 261 twins, one is chosen randomly. Target children's primary caregiver (person most familiar
15
16 262 with the child and spends most time with them) is approached for consent and enrollment.
17
18 263 A non-technically worded information sheet is shared and consent to participate is
19
20 264 obtained at first visit. In the Netherlands, participants provide consent online, confirmed
21
22 265 by study staff at first visit. Refusals to participate and dropouts are registered and
23
24 266 replaced.

29 267 ***Sampling frame and schemes***

30
31 268 Sample size for recruitment within each site is 1248 children (total 8736 children) across
32
33 269 seven countries. After consent is provided, children are allocated by sex and age groups
34
35 270 using a randomization procedure to one of several sampling schema (e.g., predictive,
36
37 271 reference-score, reliability; Figure 2). See sampling Table S1 in Supplementary file S1
38
39 272 for sampling frame. Out of the full site sample of 1248 children, 504 children per site are
40
41 273 randomly selected for re-evaluation 6 months later to assess predictive validity (primary
42
43 274 aim). A second scheme indicates the minimum sub-sample of children needed to
44
45 275 calculate preliminary reference scores (secondary aim) that will facilitate cross-country
46
47 276 comparisons. To maximize precision of parameter estimates, larger quotas are kept for
48
49 277 the youngest age brackets where rates of development are accelerated. A third scheme
50
51 278 addresses inter-rater reliability for 90 children per site using two assessors who
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3 279 independently assess the same child sequentially or within 24 hours (14)³. Test-retest
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5 280 (intra-rater reliability) is performed by inviting 50 children per site to return for repeat
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7 281 assessment with the same rater within 7-10 days. For concurrent validity, to assess the
8
9 282 GSED against the Bayley-III, a sample size of N = 150 per country produces a two-sided
10
11 283 95% confidence interval 0.15-0.44, when the estimate of Pearson's product-moment
12
13 284 correlation is 0.3, with an equal spread of participants tested across age and sex.
14
15 285 In the Netherlands, the GSED SF and PF are administered online. A subset of participants
16
17 286 (N=32) are interviewed face-to-face to compare method of administration. To determine
18
19 287 test-retest reliability (intra-rater reliability), the primary caregiver completes the SF and
20
21 288 PS form online and then a second time 7-10 days later.
22
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26 289 **Data collection**

27 290 *Measures*

28 291 *GSED*

29 292 **GSED SF and LF.** The creation of the GSED SF and LF is described elsewhere (10).
30
31 293 Briefly, we constructed an item bank from previously gathered data and compiled cross-
32
33 294 sectional and longitudinal data from 31 countries representing over 73,000 anonymized
34
35 295 children with 109,079 assessments (using 22 established ECD instruments) (6, 15, 16).
36
37 296 Using subject matter expert input and statistical modelling (11), we developed a
38
39 297 caregiver-reported measure intended to capture child development at population-level
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41 298 (GSED SF), and a complementary direct-assessment measure to evaluate programmatic
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56 ³ We note that this procedure differs from typical inter-rater reliability (IRR) designs which involve
57 simultaneous scoring of a single assessment. This sequential design was necessitated by logistical
58 constraints. Given that this design captures both variance due to differences in raters *and* differences in
59 occasions, the observed IRR represents a lower bound for the true inter-rater reliability of the assessments.
60

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3 299 impacts (GSED LF) (10). The measures are created paper-based and app-based (GSED
4
5 300 App) with built-in administration rules and supporting media-files (see below).
6
7 301 The GSED SF includes 139 items representing emerging skills and behaviors within
8
9 302 cognitive, motor, language and social-emotional domains. All items are presented as
10
11 303 questions to the caregiver, with binary response options (Yes/No and “Don’t Know”) that
12
13 304 use start rules based on the child’s age, and stop rules based on age and performance.
14
15 305 Assessors record caregiver’s responses, regardless of the assessor’s observations. In the
16
17 306 Netherlands only, the GSED SF is completed online by caregivers. The GSED SF
18
19 307 administration includes sounds, images, and short video clips that assist in understanding,
20
21 308 interpreting and administering the items.
22
23 309 The GSED LF includes 155 items capturing similar domains to the SF but, observed by
24
25 310 the assessor following start and stop rules based on the child’s age and responses. LF
26
27 311 items must either be observed incidentally or by eliciting the behaviour or both,
28
29 312 depending on the item. Items are organized into three grids (A, B and C) that enable
30
31 313 assessors to measure the child’s performance on similar tasks in succession, making the
32
33 314 administration easier for both assessors and children. To further facilitate administration,
34
35 315 icons are placed next to each item that inform the assessor whether the item is observed,
36
37 316 demonstrated to or by the child, listened for or spoken to the child. The GSED LF uses a
38
39 317 locally constructed and low cost kit with basic materials that the child interacts with to
40
41 318 demonstrate abilities. The kit is created by local teams with detailed guidance from
42
43 319 WHO. Responses of all LF items are binary (skill observed/not observed).
44
45 320 The items in both measures are ordered by difficulty reflecting children’s emerging skills.
46
47 321 Based on the analyses from the validation, we will select the items to be included in the
48
49 322 final GSED SF and LF versions available for use.
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3 323 **Psychosocial Form (PF).** Unlike the SF and the LF, the GSED PF has been developed to
4
5 324 index non-normative developmental patterns that provide a window into early
6
7 325 manifestations of children's mental health challenges, including internalizing and
8
9 326 externalizing behaviour problems and dysregulation (e.g., eating and sleeping). Items
10
11 327 capturing developmentally normative information about socio-emotional competencies
12
13 328 are included in the GSED SF and LF, as the SDG 4.2 includes children's psychosocial
14
15 329 well-being. Because few instruments have been developed to capture psychosocial
16
17 330 difficulties for children under 3 years, little existing data are available and the
18
19 331 development of the GSED PF is exploratory. The PF initial prototype was created
20
21 332 through a review of existing measures of infant and toddler mental health and consensus
22
23 333 by subject matter experts. The GSED PF includes 47 items and reflects caregiver
24
25 334 perceptions of the behaviors' frequency, using response options: Often; Sometimes;
26
27 335 Never/almost never. Items are divided into two age groups: 0 to <6 and 6 to <36 months.

336 *Contextual and demographic measures*

337 In addition to the GSED, the validation study includes measures of children's growth and
338 nutrition, health, environmental and contextual information (see Table 2 for measures and
339 sources). The selection of measures was based on known biological and social
340 determinants of development (17), the demonstrated validity of the contextual measures
341 in at least one low- and middle-income country (LMIC), and efficiency for data
342 collection. See Supplementary File S2 for visit schedules (Tables S2a and S2b).
343 In three sites (Côte d'Ivoire, The Netherlands and The Republic of China) where
344 administration of the Home Observation for Measurement of the Environment Inventory
345 (HOME) is not feasible, household stimulation data and caregiver-child activities are
346 collected using Family Care Indicators (FCI). In all sites, a concurrent measure of child
347 development (Bayley-III or Griffiths Mental Development Scales) is administered in a

348 subsample of children to determine concurrent validity of GSED to a well-established
 349 measure of the same construct.

350 **Table 2: Study measures in addition to GSED**

Construct	What the Measure Captures	Measure	Administration Mode	Time for Administer (Minutes)
Child health and household socioeconomic status (SES)	<ul style="list-style-type: none"> • Eligibility (exclusion - criteria) • Demographic information • Information about acute child health • Delivery and Perinatal conditions • Breastfeeding • Child's health history • Household socio-economic status* • Caregiver education • Maternal health/ chronic illness • COVID-19 exposure 	Eligibility and Contextual Form [Specifically developed for the study]	Caregiver Report	35
Anthropometry	<ul style="list-style-type: none"> • Weight at time of assessment • Infant Length/ Child Height at time of assessment • Child's Mid-upper arm circumference at time of assessment • Child's head circumference at time of assessment 	Anthropometry Form	Child Assessment	15
<i>Family / home environment</i>	<ul style="list-style-type: none"> • Home Environment (HOME only) • Play/ Stimulation / interactions between the child and other family members in the 	Home Observation for Measurement of the Environment Inventory (HOME) (18) OR Family Care Indicators (FCI) (19) †	<i>HOME</i> : Caregiver report & Observation <i>FCI</i> : Caregiver Report	<i>HOME</i> : 45 <i>FCI</i> : 15

	home (HOME and FCI)			
	<ul style="list-style-type: none"> Child neglect/abuse Exposure to violence or conflict 	Childhood Psychosocial Adversity Scale (CPAS)(20) [†]	Caregiver Report	15
	<ul style="list-style-type: none"> Family resilience 	Brief Resilience Scale (BRS) (21) [†]	Caregiver Report	1
	<ul style="list-style-type: none"> Family social support 	Family Support Scale (FSS) (22) [†]	Caregiver Report	5
Caregiver health and well-being	<ul style="list-style-type: none"> Caregiver Depressive Symptoms 	The Patient Health Questionnaire-9 (PHQ-9) (23)	Caregiver Report	5
Child development	<ul style="list-style-type: none"> Global child development (0-41 months) 	Bayley Scales of Infant and Toddler Development (Bayley-III) (24) OR Griffiths Mental Development Scales(25) [‡]	Direct child Assessment	45-60
	<ul style="list-style-type: none"> Global child development (24-41 months) 	Early Childhood Development Index 2030 (ECDI2030) (4) [§]	Caregiver Report	10

351 * Socioeconomic information on this form comes from the standard DHS multiple assets
 352 index; however, some sites have adapted the socio-economic status items to better fit
 353 their contexts

354 [†] these measures have been minorly adapted for the purpose of the study

355 [‡] in a sub-sample (N=150)

356 [§] in a sub-sample (all children of 24 to 41-months within the predictive validity
 357 subsamples in three countries)

358

359 ***Schedule***

360 Data collection is scheduled over one to three visits depending on the study site to

361 accommodate rules of measure administration order and location. The first

1
2
3 362 administration of the GSED SF and PF is completed at home (or online in the
4
5 363 Netherlands) to test it in the setting intended for future use (e.g., Multiple Indicator
6
7 364 Cluster Surveys MICS or Demographic and Health Surveys DHS) and prior to
8
9 365 administration of the GSED LF. The GSED LF is administered in a controlled
10
11 366 environment (e.g., clinic) to match the required concurrent validity testing protocols. For
12
13 367 the concurrent validation, the GSED and concurrent measures are administered in the
14
15 368 same location on different days and counter-balanced in order of administration.

19 369 ***Training and Quality Control***

21 370 Training of local master trainers is performed by the WHO team for the GSED SF, PF
22
23 371 and LF, using slide presentations, discussion forums, audio-visual aids, and practice
24
25 372 exercises. Local master trainers are responsible for training local field teams using
26
27 373 materials adapted and translated to local languages. Reliable administration of the GSED
28
29 374 measures must be met (inter-rater agreement with a master trainer of $\geq 90\%$) for
30
31 375 certification.

35 376 To ensure quality assurance, 10% of all the study visits are observed by the study
36
37 377 supervisor in person (or through video-recording in the Netherlands), covering each child
38
39 378 age band and certified assessors. Supervisors independently complete questionnaires
40
41 379 being administered by the assessor and complete a fidelity checklist. Assessors are given
42
43 380 feedback based on checklist score. Supervisors review quality assurance findings with the
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45 381 WHO biweekly, along with discussions with the subject matter experts for further
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47 382 resolution, as needed.

51 383 The GSED application software for data collection has built-in data range and
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53 384 consistency checks. Data managers review and resolve issues daily in consultation with
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55 385 the local field team and/or WHO team.

386 **Sample size**

387 Sample size determination was based on the primary aim of assessing the psychometric
388 properties of the GSED. To have sufficient power to estimate measurement parameters
389 (abilities and difficulties) needed to calculate the D-score and DAZ scores at baseline and
390 to detect DIF of 1 logit with a power of $1 - \beta = 0.90$ and a two-sided significance level
391 of $\alpha = 0.05$, a sample of $N=1248$ per site is required. Given the rapidity of development of
392 children at this age, the latent trait is longer than tends to be found in educational tests which
393 focus on a narrower ability range. The easiest item in our tool “Does your child smile?” has a
394 difficulty of -13.2 logits (1.1 on the D-score scale) and the most difficult item has a difficulty of
395 8.4 logits (88.86 on the D-Score scale), a 21.6 logit span. Thus, a one logit difference is not
396 particularly large, given the length of the latent trait. This sample size was calculated via
397 optimization of the sample size at i) each age/sex stratum and ii) overall on 1000
398 simulated datasets generated from parameters suggested by the Rasch GSED model. See
399 Supplementary file S1 for additional details.

400 **Statistical Analysis**

401 To construct the scores for the GSED SF and LF, a Rasch model will be fitted and the
402 item fit statistics (infit and outfit) will be assessed (26). Any items with unacceptable fit
403 levels will be removed. Items will be screened for whether they exhibit unacceptable
404 levels of measurement non-invariance (i.e., they have approximately equal difficulties)
405 across countries and other contextual variables. Items exhibiting unacceptable DIF (using
406 the logistic regression method) will be discarded sequentially, and the item response
407 models will be refit using the remaining items. The expected a posteriori (EAP) method
408 (27) will be applied to the final model to estimate the latent ability parameter (the D-
409 score). Systematic deviations from unidimensionality will be tested by performing a
410 principal components analysis on the residuals of the Rasch model. The method uses a

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3 411 prior normal distribution with a mean set equal to the average proficiency at the child's
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5 412 age and a standard deviation of 5. The ability estimates will be used to estimate
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7 413 preliminary developmental percentile curves against age using a Generalized Additive
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9 414 Model for Location Scale and Shape (GAMLSS). Note that this application of EAP
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11 415 estimates underestimates the true variability in the population because EAP estimates – as
12
13 416 any measurement – are always imprecise. In daily practice, analysts will compare other
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15 417 EAP estimates to the reference. To support this type of application, we create the
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17 418 references from the EAP estimates and accept a (perhaps slight) underestimate of the true
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19 419 variability in child development in the population. Following previous methodology (28)
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21 420 software will be written to calculate DAZ-scores based on the final dataset in R (29), and
22
23 421 a user-friendly front-end version created in R (ShinyApp) (30) and/or Excel.
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26 422 Reliability (inter-rater and test-retest) for all GSED measures will be analyzed using ICC
27
28 423 (at the score level) and Gwet's AC1 agreement (at the item level) statistics with 95%
29
30 424 confidence intervals to determine whether items perform reliably within and between
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32 425 assessors (31). A cut-off value of 0.4 and above will be used to flag items as adequately
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34 426 reliable. Those items with agreement between 0.4 and 0.5 will be discussed to determine
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36 427 if modifications can be made to improve their administration and/or comprehension.
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38 428 DAZ scores from the GSED SF and LF will be used to conduct validity analyses to
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40 429 ensure that the measures are capturing the construct they are purported to measure
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42 430 (construct validity). Concurrent validity will be assessed by correlating age-corrected
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44 431 Bayley-III or Griffiths Mental Development Scales scores with GSED DAZ scores. We
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46 432 anticipate that these scores will have low to moderate positive correlations. Convergent
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48 433 validity will be supported by statistically significant positive correlations (with 95%
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50 434 confidence interval) between the GSED scores and continuous contextual measures with
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52 435 prior evidence of association with child development. Comparisons between "known
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3 436 groups” will be made using the following variables: maternal education, home learning
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5 437 opportunities, home environment, socioeconomic status (SES), maternal mental health
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7 438 and child anthropometry, and stunting to determine if scores discriminate between high
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9 439 and low categories for each variable using mean DAZ scores.

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12 440 GSED scores at baseline and follow up will be correlated for predictive validity (positive
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14 441 association between baseline and at 6 months) and mixed-effects linear regression used to
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16 442 adjust for other contextual covariates and baseline scores.

20 443 **Secondary (Exploratory) Aims**

23 444 *Reference Scores*

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25 445 We plan to develop a set of preliminary reference scores to facilitate comparison of DAZ
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27 446 scores across countries. From the full validation study sample, a sub-sample of children
28
29 447 who have not experienced prior exposure to major known biological and environmental
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31 448 risk factors is selected (i.e., “reference sub-sample”) (Table 3). Such an approach relies
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33 449 on the assumption that the attainment of basic developmental milestones captured by the
34
35 450 GSED of children who are free of major risk factors is relatively similar globally (32).
36
37 451 To develop the reference scores, we will fit GAMLSS (33) to flexibly model both
38
39 452 conditional means, conditional standard deviations of scores, and, if necessary,
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41 453 conditional skewness and kurtosis. We will test our assumption that the distribution of
42
43 454 scores is equivalent across sites by adding a site indicator at each moment of the
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45 455 distribution, and testing site effects for their statistical significance. Where possible, we
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47 456 will conduct standardization of scores to assist with the interpretation of scores by
48
49 457 pooling data across countries. We will report the corresponding parameters of the
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51 458 GAMLSS model at appropriate ages.

52 459 **Table 3. “Reference” sub-sample exclusion criteria (healthy sub-sample)**

Sample	Exclusion criteria
Minimum sub-sample of “reference” children per site N=522	<ol style="list-style-type: none"> 1. Below secondary maternal education (<6 years of schooling) 2. Birthweight less than 2500 gr 3. Gestational age < 37 completed weeks (259 days) and \geq 42 completed weeks (294 days) [assessed by ultrasound] 4. Undernutrition (weight for age, length for age, OR weight for height Z score of less than -2 on the WHO Child Growth Standards) at the time of developmental assessment 5. Known severe congenital birth defect 6. History of birth asphyxia OR neonatal sepsis requiring hospitalization 7. Known neurodevelopmental disorder/ disability (Severe visual problems, seizures, hearing impairment) OR other chronic health problems (that is congenital heart disease)

460

461 ***Adaptive testing***

462 We will determine whether adaptive testing is a feasible and valid option to measure
 463 child development within the GSED (Box 2). Adaptive testing (34) is an administration
 464 method that continually adapts to the level of the child’s performance, thereby reducing
 465 test administration time. Previous simulations (35) indicated that theoretically substantial
 466 gains in the precision of scores are possible when using adaptive testing even if
 467 administering fewer items.

Box 2: Adaptive testing validation methodology

We investigate the feasibility by applying adaptive testing in addition to the traditional “fixed” GSED administration methods in the sub-sample designated for predictive validity analyses (N=502 per site) in three sites. The adaptive test is executed using tablets that are specially programmed to continually adjust child’s score after each item is administered, and to suggest the next item based on the answers already received (e.g., a more difficult item for a child with a higher score, an easier item for a child

with a lower score). Once the program establishes a reliable score, the administration is terminated. Both the adaptive test and the fixed test are administered with the same sub-sample during two separate visits alternating the order of administration to investigate the difference between the two modes of administration. We will investigate the following: the variance of user experience as a function of the average difficulty of milestones (leniency); the comparison of the D-score distribution under the adaptive testing procedure with the D-score distribution under the fixed GSED administration (using a z-test to assess the equivalence of the two modalities and plotting the results to show the level of concordance); and relation of the difference between the two D-scores to background variables.

468

469 ***Psychosocial Form***

470 The PF measure is in an early stage and will undergo exploratory and confirmatory factor
471 analyses to assess the internal scale structure. Associations between items and factor
472 scores with variables suggesting a high risk of psychosocial stress, such as family
473 resilience, social support, and family and community violence, in addition to GSED SF
474 and LF scores (concurrent validity measures) will be examined.

475 **ETHICS AND DISSEMINATION**

476 The study complies with the International Ethical Guidelines for Biomedical Research
477 Involving Human Subjects (36) and received ethical approval from the appropriate body
478 in each site [Bangladesh – Projahnmo Research Foundation Institutional Review Board;
479 Brazil – University Hospital, São Paulo (HU-USP); Cote d’Ivoire – Comité National
480 D’Ethique des Sciences de la Vie et de la Sante (CNESVS); Pakistan – The Aga Khan
481 University Ethics Review Committee; The Netherlands – Institutional Review Board
482 TNO, Netherlands Organisation for Applied Scientific Research; The Republic of China

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3 483 – IRB of Shanghai Children’s Medical Center Affiliated to Shanghai Jiao Tong University
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5 484 School of Medicine; United Republic of Tanzania – Zanzibar Health Research Institute]
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8 485 and within WHO (protocol GSED validation 004583 approved on 20.04.2020). The
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10 486 findings of the study will be disseminated following a comprehensive dissemination
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12 487 strategy to reach a diverse range of stakeholders at the local, national and international
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15 488 level.

17 489 **DISCUSSION**

20 490 The validation of the GSED SF and LF is a meticulous and systematic global process that
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22 491 introduces an innovative common metric (the D-score) that countries can use to track the
23
24 492 progress of child development among populations of young children and will enable
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26 493 countries to adapt, modify, and evaluate their policies and programs to ensure that young
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28 494 children are effectively and equitably reaching their development potential and building
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30 495 the human capital needed for sustainable development. Additional attention is required on
31
32 496 understanding young children’s responses to psychosocial challenges within global
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34 497 contexts. The exploration of the GSED PF introduces an important opportunity to capture
35
36 498 the non-normative developmental patterns among young children that are potential
37
38 499 precursors to behaviour and psychiatric problems. The GSED validation has several
39
40 500 important design, methodological and implementation characteristics that illustrate the
41
42 501 rigour required to validate instruments to measure child development globally. First, it is
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44 502 conducted in seven countries with multiple linguistic, cultural and socioeconomic
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46 503 backgrounds. Second, GSED is implemented through an app-based data collection
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48 504 system that facilitates the implementation by reducing recording and transcribing errors
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50 505 and other common pitfalls of paper-based instruments. Third, this study builds on the best
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52 506 practices in validation by including a broad spectrum of psychometric methodologies
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54 507 (concurrent, predictive, convergent, and discriminant validity, test-retest and inter-rater
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3 508 reliability, differential item functioning, and differential test functioning). Fourth, a
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5 509 secondary aim builds the evidence for the creation of preliminary reference scores for the
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7 510 SF and LF, based on a sub-sample with minimal exposure to major biological risk factors
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9 511 and to the extent possible, minimal social and environmental risk factors. Fifth, we are
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11 512 validating an adaptive testing design that can streamline administration by tailoring and
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13 513 reducing the number of items required to obtain a valid score. Sixth, we are testing a new
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15 514 measure of young children's non-normative psychosocial development.

16
17 515 One notable difference between the GSED SF and LF measures and other instruments of
18
19 516 early child development is that the GSED measures are based on a unidimensional model
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21 517 of development through measurement approaches that are universally applicable across
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23 518 cultures. The measures do not follow the common multidimensional approach with
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25 519 separate scores for different domains or contexts. Our validation study intends to
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27 520 demonstrate that this model provides valid, reliable, and interpretable data globally. The
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29 521 GSED SF and LF may exclude some items that measure development in cultural or
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31 522 setting-specific ways, because the focus is on selecting items that are meaningful for
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33 523 understanding child development within any given setting. If specific aspects need to be
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35 524 captured locally, to increase cultural relevance we suggest that the GSED measures are
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37 525 lightly adapted with country or culture-specific item props (in agreement with WHO)
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39 526 and/or through the administration of additional measures.

40
41 527 There are several limitations to our study. Although we are validating the GSED in seven
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43 528 countries, including one high income setting, three sites are resource-limited
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45 529 (Bangladesh, Pakistan and United Republic of Tanzania). Additional evidence may be
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47 530 needed in high income countries to expand the validity and reliability of the GSED to
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49 531 population-representative samples in additional countries. Second, the GSED has been
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51 532 created using items that fit a Rasch model demonstrating developmental progress across
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3 533 ages 0-3 years (9). This univariate model makes strict assumptions and may exclude
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5 534 items that do not show strong age gradients or items that measure development in a
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7 535 culturally-specific ways. Third, GSED was developed to address population and
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9 536 programmatic level evaluations of early child development globally. The GSED is
10
11 537 presently not being validated for screening or diagnosing individual children. Finally, our
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13 538 three secondary aims are exploratory, and will require further research, including
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15 539 developing global standards to replace our preliminary reference scores with more
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17 540 specific global norms, as in the Multi-country Growth Reference Standards for children's
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19 541 weight and height. In the future we plan to collect additional data from countries using
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21 542 strict inclusion/exclusion criteria (e.g., additional considerations around environmental
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23 543 risk and protective factors) to further validate our initial reference scores. Similarly, we
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25 544 plan to conduct further work to explore the functionality, reliability, validity, and
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27 545 invariance of the PF. Lastly, as the GSED SF and LF scores are meant to be interpreted
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29 546 and used for population-level measurement, we plan to expand the work towards
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31 547 understanding of how the GSED package could be modified and validated to be able to
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33 548 identify individual children at risk of developmental delays and disorders.
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3 550 **LIST OF ABBREVIATIONS**

4 551

5 552 Bayley-III Bayley Scales of Infant and Toddler Development

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7 553 BRS Brief Resilience Scale

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9 554 CI Confidence interval

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11 555 CPAS Childhood Psychosocial Adversity Scale

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13 556 DAZ Development for Age Z-score

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15 557 DHS Demographic and Health Surveys

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17 558 DIF Differential item functioning

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19 559 DTF Differential test functioning

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21 560 D-score Developmental Score

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23 561 EAP Expected a posteriori

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25 562 ECD Early child development

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27 563 ECDI 2030 Early Childhood Development Index 2030

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29 564 FCI Family Care Indicators

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31 565 FSS Family Support Scale

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33 566 GAMLSS Generalized Additive Model for Location Scale and Shape

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35 567 GSED Global Scales for Early Development

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37 568 HAZ Height-for-age z-score

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39 569 HOME Home Observation for Measurement of the Environment Inventory

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41 570 ICC Intraclass correlation coefficient

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43 571 LF Long Form

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45 572 LMIC Low- and middle-income country

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47 573 MICS Multiple Indicator Cluster Surveys

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49 574 OSF Open Science Framework

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51 575 PF Psychosocial Form

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53 576 PHQ-9 The Patient Health Questionnaire-9

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55 577 SDG Sustainable Development Goals

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57 578 SES Socioeconomic status

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59 579 SF Short Form

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580 SOPs Standard operating procedures

581 WAZ Weight-for-age z-score

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3 582 **STATEMENTS**
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5 583 **Ethics approval:** The study complies with the International Ethical Guidelines for
6
7 584 Biomedical Research Involving Human Subjects and received ethical approval from the
8
9 585 appropriate Ethics Review Committee (ERC) at the World Health Organization (WHO)
10
11 586 (protocol ID GSED validation 004583 approved on 20.04.2020) and in each site
12
13 587 [Bangladesh – Projahnmo Research Foundation Institutional Review Board; Brazil –
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15 588 University Hospital, São Paulo (HU-USP); Cote d’Ivoire – Comite National D’Ethique
16
17 589 des Sciences de la Vie et de la Sante (CNESVS); Pakistan – The Aga Khan University
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19 590 Ethics Review Committee; The Netherlands – Institutional Review Board TNO,
20
21 591 Netherlands Organisation for Applied Scientific Research; The Republic of China – IRB
22
23 592 of Shanghai Children’s Medical Center Affiliated to Shangai Jiao Tong University
24
25 593 School of Medicine; United Republic of Tanzania – Zanzibar Health Research Institute].
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30 594 **Patient consent:** Written consent is gathered by all study participants. Informed consent
31
32 595 forms are written to be easily understood by lay persons, enabling them to understand the
33
34 596 aims, procedures and potential risks of participation and have been approved by the
35
36 597 WHO ERC. For participants who are illiterate, culturally acceptable options including
37
38 598 witnessed oral consent and a thumbprint in lieu of a signature are accepted by the WHO
39
40 599 and local ERCs.
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43

44 600 **Data sharing:** Not applicable (protocol paper)
45
46

47 601 **Author Contributions:** All authors contributed substantively to this work. VC was the
48
49 602 lead author in drafting the manuscript in addition to the technical contributions to the
50
51 603 study protocol conceptualization and development. TD led the conceptualization of the
52
53 604 study, MG, MMB, MJ, and PK contributed significantly to the conceptualization of the
54
55 605 study design and methodology, drafted sections of the protocol and related manuscript;
56
57 606 GL, GMc, [focus on psychometric properties], DMc, JS [focus on preliminary reference
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3 607 scores] MW [focus on testing of psychosocial form], SvB and IE [focus on adaptive
4
5 608 testing] came to consensus on statistical analysis plan, determined the sample size
6
7 609 calculations, and drafted the related parts of the manuscript relevant to their specific
8
9 610 expertise ; AN, AR, KH, and AW drafted substantial pieces of the manuscript related to
10
11 611 sampling frame, study measures and implementation. SA, AD, RA, AB, FJ, YS, IN, RK,
12
13 612 SS, AZ, MPM, YZ, FT, ARD, AB, JZ, AH, GF, SD, NSK, FB, FJ, and MRC contributed
14
15 613 to the adaptation of the study protocol for feasibility and on-the-ground implementation,
16
17 614 focusing on manuscript write up related to site-specific descriptions. All above authors, in
18
19 615 addition to RK, MMP, and RN reviewed and edited the study protocol and the
20
21 616 manuscript. All authors read and approved the final manuscript submission.
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4

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6

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19 625 Organization.
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5 727 **Figure 1. Development chart**
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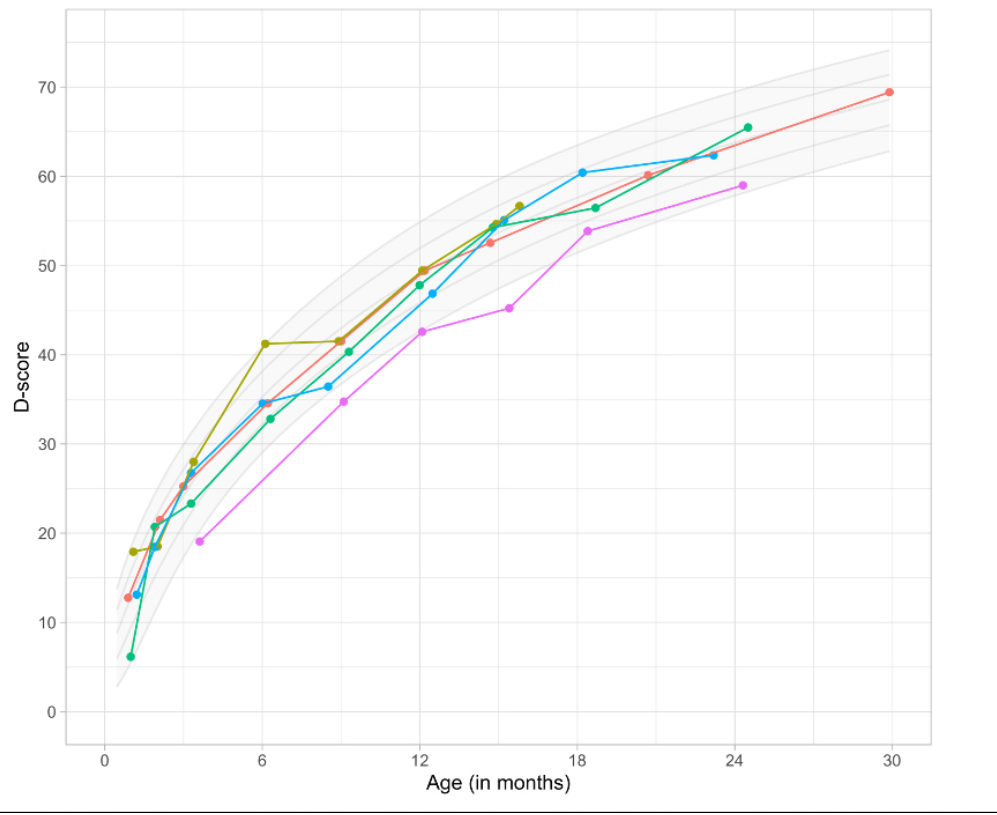
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8 728 Reproduced with permission from van Buuren S and Eekhout I (2021) (11)
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12 730 **Figure 2. Study Sampling schema diagram**
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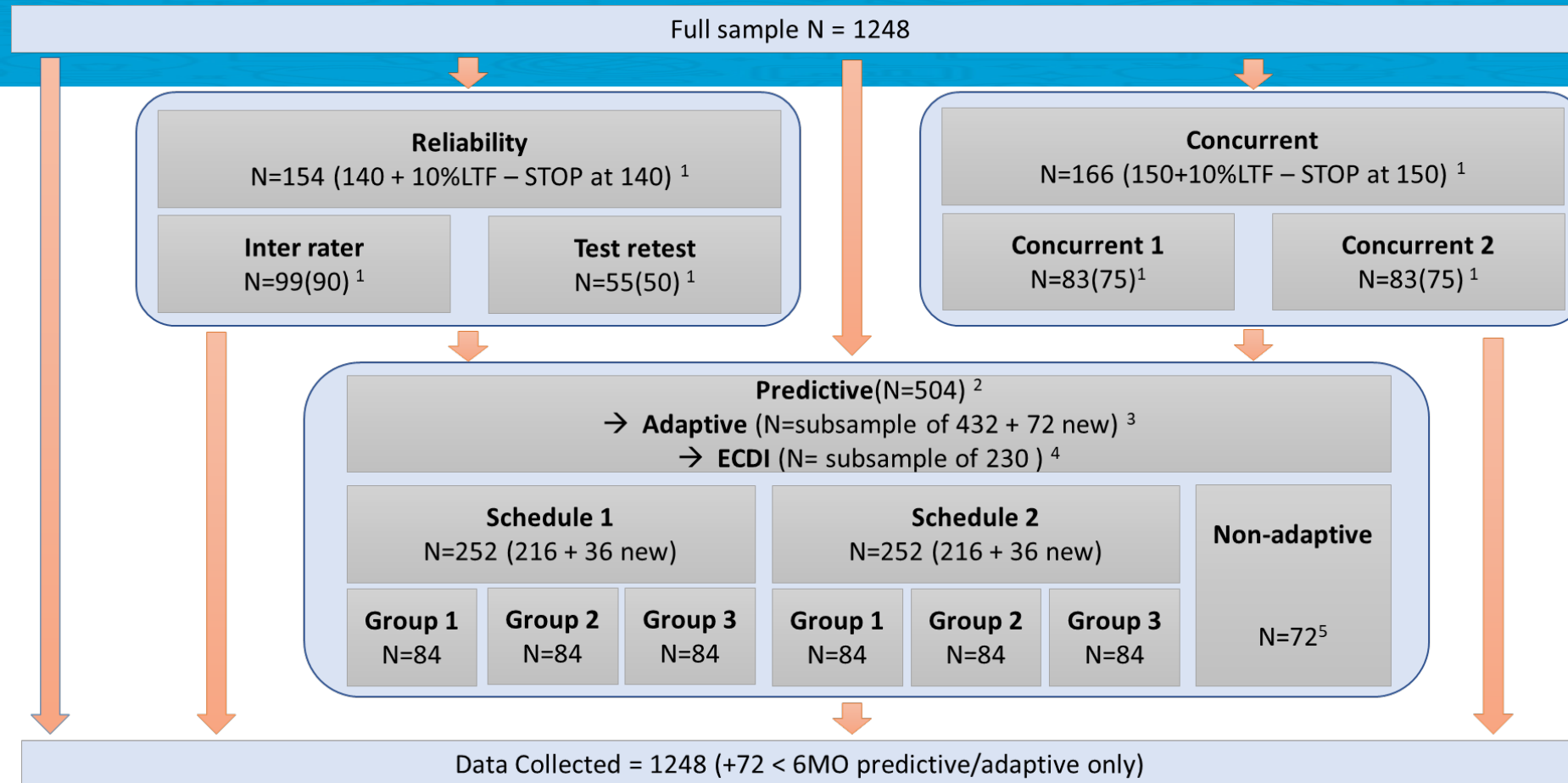
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152x125mm (144 x 144 DPI)

GSED study sample



[1] The number inside parentheses is the number collected and the number outside is the number randomised to account for loss to follow-up

[2] Two additional participants have been added to the predictive to have equal numbers in each experimental group.

[3] 72 new children between 2 weeks and 6 months of age have been added to the adaptive sample to ensure coverage at the lower ages.

[4] ECDI will only be done on N=230 Children between the ages of 2+ years at the time of the predictive data collection.
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[5] The 72 oldest children (36-41 months) from the predictive sample will not be part of the adaptive sample.

Supplementary file 1 – Sample size calculations and sampling frame

The sample size calculation for reliability is based on a confidence interval (CI) approach and the desired accuracy for the lower bound of the CI for the ICC estimates. In an Analysis of Variance (ANOVA) with 2-way random effects on a single score with 2 observations per subject (following Shrout and Fleiss, 1979) (27) and with a two-sided 95% confidence interval and an expected ICC of 0.875, the lower confidence interval for the inter-rater reliability sample (N=90) = 0.852. With the same parameters but an expected ICC of 0.90 the lower confidence interval for the test-retest reliability sample (N=50) is 0.830. We expect the ICC to be higher for the test-retest reliability than the inter-rater reliability as inter-rater estimates contain all the sources of error in the test-retest estimates, plus additional error between assessors (14).

To assess concurrent validity, a sample size of 150 per site produces a two-sided 95% CI 0.15-0.44, when the estimate of Pearson's product-moment correlation is 0.30, with an equal spread of participants tested across age and sex. The CI will be narrower when the data are combined across all seven countries. To assess predictive validity a sample size of 404 produces a two-sided 95% CI 0.65-0.75 when the estimate of Pearson's product-moment correlation is 0.70 between individual scores at baseline and at the 6-month follow-up. Allowing 20% dropout at follow up, a sample size of approximately 500 participants is required.

Table S1. Sampling Frame

Sample size per site by age and sex for total population (n=1248) which includes a minimum subsample of healthy 'reference' children (n=522)

Age (Days)	Sex	Total Sample size	Minimum sub-sample of reference children	Predictive validity sample (6-month follow-up; age at baseline)	Reliability: Inter-rater	Reliability: Test-Retest	Concurrent validity
15-30	Male	40	20	8	2	1	4
	Female	40	20	8	2	1	2
31-61	Male	40	12	8	1	1	2
	Female	40	12	8	2	1	2
62-91	Male	40	10	8	2	1	2
	Female	40	10	8	1	0	4
92-122	Male	36	9	8	2	1	2
	Female	36	9	8	2	1	2
123-152	Male	32	8	8	1	1	2
	Female	32	8	8	2	1	2

153-183	Male	28	8	8	1	0	4
	Female	28	8	8	1	1	2
184-213	Male	25	7	8	2	1	2
	Female	25	7	8	1	0	2
214-244	Male	23	7	8	1	1	2
	Female	23	7	8	2	1	4
245-274	Male	21	6	8	1	1	2
	Female	21	6	8	1	1	2
275-304	Male	19	6	8	2	0	2
	Female	19	6	8	1	1	2
305-335	Male	17	6	8	1	1	4
	Female	17	6	8	2	0	2
336-365	Male	16	6	7	1	1	2
	Female	16	6	7	1	1	2
366-396	Male	14	6	7	2	1	2
	Female	14	6	7	1	1	4
397-426	Male	13	6	7	1	0	2
	Female	13	6	7	2	1	2
427-457	Male	12	5	7	1	1	2
	Female	12	5	7	1	0	2
458-487	Male	11	5	7	2	1	4
	Female	11	5	7	1	1	2
488-517	Male	11	5	7	1	1	2
	Female	11	5	7	2	1	2
518-548	Male	10	5	7	1	0	2
	Female	10	5	7	1	1	4
549-578	Male	9	5	7	2	1	2
	Female	9	5	7	1	0	2
579-609	Male	9	5	7	1	1	2
	Female	9	5	7	2	1	2
610-639	Male	9	5	7	1	1	4
	Female	9	5	7	1	1	2
640-670	Male	9	5	7	2	0	2
	Female	9	5	7	1	1	2
671-700	Male	9	5	7	1	1	2
	Female	9	5	7	2	0	4
701-730	Male	9	5	7	1	1	2
	Female	9	5	7	1	1	2
731-761	Male	9	5	7	2	1	2
	Female	9	5	7	1	1	2
762-791	Male	9	5	6	1	0	4
	Female	9	5	6	2	1	2
792-822	Male	9	5	6	1	1	2
	Female	9	5	6	1	0	2
823-852	Male	9	5	6	2	1	2
	Female	9	5	6	1	1	2

853-883	Male	9	5	6	1	1	2
	Female	9	5	6	2	1	2
884-913	Male	9	5	6	1	0	2
	Female	9	5	6	1	1	2
914-944	Male	9	5	6	2	1	2
	Female	9	5	6	1	0	2
945-974	Male	9	5	6	1	1	2
	Female	9	5	6	2	1	2
975-1004	Male	9	5	6	1	1	2
	Female	9	5	6	1	1	2
1005-1035	Male	9	5	6	2	0	2
	Female	9	5	6	1	1	2
1036-1065	Male	9	5	6	1	1	2
	Female	9	5	6	2	0	2
1066-1096	Male	9	5	6	1	1	2
	Female	9	5	6	1	1	2
1097-1126	Male	9	5	0	0	0	0
	Female	9	5	0	0	0	0
1127-1157	Male	9	5	0	0	0	0
	Female	9	5	0	0	0	0
1158-1187	Male	9	5	0	0	0	0
	Female	9	5	0	0	0	0
1188-1218	Male	9	6	0	0	0	0
	Female	9	6	0	0	0	0
1219-1248	Male	9	6	0	0	0	0
	Female	9	6	0	0	0	0
1249-1279	Male	9	7	0	0	0	0
	Female	9	7	0	0	0	0
TOTAL		1248	522	504	*99	**55	***166

*90 + ~10% Loss to follow up = 99; **50 + ~10% Loss to follow up = 55; ***150 + ~10% Loss to follow up = 166

Supplementary file 2 – Visit schedule

Table S2a. Visit Schedule for the GSED Validation Study (all sites except the Netherlands)

Main Study Only [No Sub-sample]	Inter- Rater Reliability Sub- Sample	Test- Retest Reliability Sub- Sample	Concurrent Sub- Sample 1 [LF First]	Concurrent Sub- Sample 2 [BSID III First]
Visit 1 [At Home]				
Eligibility and Consent	Eligibility and Consent	Eligibility and Consent	Eligibility and Consent	Eligibility and Consent
COVID Questionnaire	COVID Questionnaire	COVID Questionnaire	COVID Questionnaire	COVID Questionnaire
Contextual	Contextual	Contextual	Contextual	Contextual
GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]
GSED Psychosocial form [PF]	GSED Psychosocial form [PF]	GSED Psychosocial form [PF]	GSED Psychosocial form [PF]	GSED Psychosocial form [PF]
HOME Inventory or Family Care Indicators (FCI)	HOME Inventory or Family Care Indicators (FCI)	HOME Inventory or Family Care Indicators (FCI)	HOME Inventory or Family Care Indicators (FCI)	HOME Inventory or Family Care Indicators (FCI)
Anthropometrics*	Anthropometrics*	Anthropometrics*	Anthropometrics*	Anthropometrics*
Visit 2 [At home, clinic, or other setting within 48 hours of visit 1] Note: For Concurrent Sample, the Visit is at the Clinic setting				
Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]
GSED Long form [LF]	GSED Long form [LF]	GSED Long form [LF]	GSED Long form [LF]	BSID III
CPAS	CPAS	CPAS	CPAS	-----
PHQ9	PHQ9	PHQ9	PHQ9	-----
Family support & Resilience Scale	Family support & Resilience Scale	Family support & Resilience Scale	Family support & Resilience Scale	-----
Visit 3 [Setting and timing vary by sub-sample]				
Visit 3 not required	Visit 3 [At home, clinic or other setting where the LF was completed- within 24 hours of the LF]	Visit 3 [At home, clinic or other setting where the LF was completed- this should happen 7 to 10 days after LF]	Visit 3 [Clinic setting within 24- 72 hours of the LF- can be done at same time as Visit 2 – taking child fatigue into consideration]	Visit 3 [Clinic setting within 24- 72 hours of the BSID III - can be done at same time as Visit 2 – taking child fatigue into consideration]
	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]
	GSED Short form [SF]	GSED Short form [SF]	BSID III	GSED Long form [LF]
	GSED Psychosocial form [PF]	GSED Psychosocial form [PF]	-----	CPAS
	GSED Long form [LF]	GSED Long form [LF]	-----	PHQ9
-----	-----	-----	-----	Family support & Resilience Scale

* Anthropometrics may be done either at visit 1 or visit 2

Table S2b: Visit Schedule for the GSED Validation Study (the Netherlands only)

Main Study Only [No Sub-sample]	Inter-Rater Reliability Sub-Sample	Test-Retest Reliability Sub-Sample	Concurrent Sub-Sample 1 [LF First]	Concurrent Sub-Sample 2 [BSID III First]
Session 1 [Online]				
Eligibility and Consent	Eligibility and Consent	Eligibility and Consent	Eligibility and Consent	Eligibility and Consent
Contextual	Contextual	Contextual	Contextual	Contextual
GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]	GSED Short form [SF]
GSED Psychosocial scale [PS]	GSED Psychosocial scale [PS]	GSED Psychosocial scale [PS]	GSED Psychosocial scale [PS]	GSED Psychosocial scale [PS]
Visit 1 [At clinic within 48 hours of session1]				
Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]
GSED Long form [LF]	GSED Long form [LF]	GSED Long form [LF]	GSED Long form [LF]	BSID III
Anthropometrics	Anthropometrics	Anthropometrics	Anthropometrics	Anthropometrics
Session 2 [Online, Test-Retest of SF/PSY within 7 to 10 days of online session 1]				
Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]
COVID Questionnaire	COVID Questionnaire	COVID Questionnaire	COVID Questionnaire	COVID Questionnaire
-----	-----	GSED Short form [SF]	-----	-----
-----	-----	GSED Psychosocial scale [PS]	-----	-----
CPAS	CPAS	CPAS	CPAS	CPAS
PHQ9	PHQ9	PHQ9	PHQ9	PHQ9
Family support & Resilience Scale	Family support & Resilience Scale	Family support & Resilience Scale	Family support & Resilience Scale	Family support & Resilience Scale
Family Care Indicators (FCI)	Family Care Indicators (FCI)	Family Care Indicators (FCI)	Family Care Indicators (FCI)	Family Care Indicators (FCI)
Visit 2 [At clinic, timing varies by sub-sample]				
Visit 2 not required	Visit 2 [within 24 hours of the LF]	Visit 2 [7 to 10 days after LF]	Visit 2 [within 24- 72 hours of the LF- can be done at same time as Visit 1 – taking child fatigue into consideration]	Visit 2 [within 24- 72 hours of the BSID III - can be done at same time as Visit 1 – taking child fatigue into consideration]
	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]	Abbreviated Eligibility [Coversheet]
	GSED Long form [LF]	GSED Long form [LF]	BSID III	GSED Long form [LF]