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Effect of a center-based early childhood care and education program on child nutritional status: A secondary analysis of a stepped wedge cluster randomized controlled trial in rural Sindh, Pakistan

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Running head: Effect of LEAPS on child nutritional status

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Abbreviations:

BMI: body-mass index

BMIZ: BMI-for-age z score

CYL: Community Youth Leaders

ECCE: early childhood care and education

GEE: Generalized Estimating Equation

HAZ: height-for-age z score

HCZ: head circumference z scores

HICs: high-income countries

ICC: intra-cluster correlation coefficient

ITT: intention-to-treat

LEAPS: Youth Leaders for Early Childhood Assuring Children are Prepared for School

LMICs: low- and middle-income countries

LMM: linear mixed effect model

MUAC: mid-upper arm circumference

MUACZ: MUAC-for age z score

NCHD: National Commission for Human Development

OR: odds ratio

SDGs: Sustainable Development Goals

ToT: training of the trainer

WAZ: weight-for-age z score

WHO: World Health Organization

WHZ: weight-for-height z score

95% CI: 95% confidence interval

1 **Abstract**

2 **Background:** High-quality early childhood care and education (ECCE) programs can positively impact
3 children’s development. However, as an unintended consequence, ECCE attendance may also affect
4 children’s nutritional status.

5 **Objective:** We evaluated the effect of a center-based ECCE intervention on child nutritional outcomes in
6 rural Pakistan.

7 **Methods:** This study utilized data from a stepped-wedge cluster randomized controlled trial of a center-
8 based ECCE program that trained female youth to run high-quality preschools for children aged 3.5-5.5
9 years (LEAPS program) in rural Sindh, Pakistan. The program did not include any school meals. A total
10 of 99 village clusters were randomized to receive the LEAPS intervention in three steps, and repeated
11 cross-sectional surveys were conducted to assess the impact on children (4.5-5.5 years old) at four time
12 points. Intention-to-treat analyses with multi-level mixed-effect models were used to estimate the effect of
13 the intervention on child anthropometric outcomes.

14 **Results:** The analysis included 3,858 children with anthropometric data from four cross-sectional survey
15 rounds. The LEAPS intervention was found to have a positive effect on child HAZ (mean difference: 0.13
16 z-scores; 95% confidence interval (CI): 0.02, 0.24). However, there was a negative effect on weight-based
17 anthropometric indicators, -0.29 WHZ (95% CI: -0.42, -0.15), -0.13 BMIZ (95% CI: -0.23, -0.03), and -
18 0.16 MUACZ (95% CI: -0.25, -0.05). An exploratory analysis suggested that the magnitude of the
19 negative effect of LEAPS on WHZ, BMIZ, and WAZ was greater in the survey round during the COVID-
20 19 lockdown.

21 **Discussion:** The LEAPS intervention positively affected child linear growth but had negative effects on
22 multiple weight-based anthropometric measures. ECCE programs in low- and middle-income country
23 settings should evaluate the integration of nutrition-specific interventions (e.g., school lunch, counseling
24 on healthy diets) and infection control strategies to promote children's healthy growth and development.

25 **Clinical Trial Registry:** ClinicalTrials.gov, NCT03764436,

26 <https://clinicaltrials.gov/ct2/show/NCT03764436>

27 **Keywords:** Children, preschool, anthropometry, child development, Pakistan

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30

31 **Introduction**

32 Decades of research have demonstrated the crucial role of the first five years of life in shaping children’s
33 growth and development (1). However, poor child growth and suboptimal developmental outcomes
34 persist in low and middle-income countries (LMICs), with an estimated 149 million children under the
35 age of 5 years being stunted, 45 million wasted, and 250 million failing to reach their full developmental
36 potential (2, 3). Children in LMICs are vulnerable to multiple risk factors that can contribute to both poor
37 growth and developmental outcomes, such as preterm birth, low birth weight, small-for-gestational age,
38 food insecurity, infections, low maternal education, maternal depression, and other exposures within the
39 broader socioeconomic and environmental context (2, 4). The Sustainable Development Goals (SDGs)
40 include multiple targets to improve child undernutrition and development (5), which has led to increased
41 investment in child nutrition and early childhood care and education (ECCE) programs.

42 ECCE encompasses learning opportunities for children outside their homes, such as daycare, preschool,
43 and pre-primary school programs, from birth to eight years old. A large body of research on ECCE in
44 high-income countries (HICs) and LMICs has generally shown positive cognitive and social-emotional
45 developmental outcomes for children (6-9). However, few studies have evaluated the effect of ECCE
46 interventions on child nutrition outcomes in LMICs using experimental and quasi-experimental designs,
47 and the evidence is mostly from studies that included a nutrition intervention. Three studies of ECCE
48 programs that included school meals that varied in terms of the quality and quantity of meals provided
49 found mixed effects on the nutritional status of the children (10-12). For example, a subsidized
50 community nursery program in Colombia was found to have a positive effect on the linear growth of
51 children aged 3-6 years (10), whereas a preschool program in Bolivia had a negative impact on the weight
52 of children under age five years despite the fact that both studies included school meal equivalent to 70%
53 of daily calorie requirements (11). Given that ECCE programs bring children together in groups, it is
54 hypothesized that an increased risk of infectious disease transmission may contribute to the negative
55 effects on morbidity and child weight in some settings. Therefore, research is needed to better understand

56 the impact of ECCE programs on the nutritional status of children in LMICs, particularly in contexts with
57 high risk of infectious diseases and food insecurity where these effects may be most pronounced.

58 Child nutritional status is a complex interplay of diet and infectious disease morbidities within a broader
59 social, political, and economic environment (13). Leroy and colleagues, in their systematic review of
60 daycare/ ECCE programs, used a program theory framework to identify pathways by which ECCE
61 programs can directly and indirectly affect child health, nutrition, and developmental outcomes (9, 14).
62 Provision of meals in the ECCE program, nutrition education, parents' social network, and parents'
63 income opportunities are factors that may positively impact child health and nutrition. On the other hand,
64 they note that hygiene and sanitation and increased contact between children in a group setting may
65 elevate the risk of infection transmission and thereby negatively affect their nutritional status. Thus, an
66 ECCE program's overall effect on child nutritional status may be determined by the balance between
67 these positive and negative factors within the school and home environments. Given the high
68 susceptibility of under-five children to infection and subsequent undernutrition, it is important to
69 understand the effect of the ECCE programs in LMICs, where the majority of these programs are run in
70 informal centers that do not provide school meals and nutrition education (9, 15).

71 We evaluated the effect of a center-based ECCE intervention, called LEAPS (Youth Leaders for Early
72 Childhood Assuring Children are Prepared for School), on the nutritional status of children aged 4.5 to
73 5.5 years in rural Sindh, Pakistan. Given the need for early childhood education opportunities and
74 considering the limited resources in LMICs, LEAPS preschools were conceptualized as a low-cost,
75 innovative solution that was strategically situated in rural areas, utilized community spaces, and were
76 operated by trained youth leaders. The LEAPS program was evaluated using a stepped wedge randomized
77 controlled trial design with a primary outcome of children's school readiness. Nevertheless, the trial also
78 provides the opportunity to estimate the causal effect of the program on multiple secondary outcomes,
79 including the nutritional status of children at the population level. Findings from this study will provide

80 critical insights that can inform the need and design of effective ECCE nutrition policies and programs in
81 LMICs.

82 **Methods**

83 **Study setting**

84 The LEAPS trial was conducted in four rural districts of Dadu, Khairpur, Naushahro Feroze, and Sukkur
85 in Sindh, Pakistan, from December 2018 to June 2021. The region has a low enrollment rate in early
86 childhood education among children aged 3 to 5 years at 39% and a high burden of childhood
87 undernutrition including stunting (62%), wasting (13%), and underweight (51%) (16, 17). Studies in the
88 setting have identified multiple risk factors of childhood undernutrition, including low levels of women's
89 literacy, poverty, high levels of food insecurity, and events such as seasonal floods and droughts (17).

90 **Study design**

91 A stepped wedge cluster randomized control trial was conducted to evaluate the impact of the LEAPS
92 intervention (**Figure 1**). The primary outcome of the trial was school readiness at the population level as
93 measured by the International Development and Early Learning Assessment (IDELA) (ClinicalTrials.gov,
94 NCT03764436). Full details of the study methodology can be found in the published protocol (18).
95 Briefly, villages with a primary school run by the National Commission for Human Development
96 (NCHD) were selected for inclusion. Clusters that participated in the prior LEAPS efficacy trial (19),
97 lacked community space for the preschool setup, had a safety concern, or lacked a female youth leader
98 with a minimum of 10 years of education to support the preschool program were excluded. One hundred
99 and nineteen clusters were screened, and 99 village clusters were selected from the four rural districts
100 based on the study inclusion criteria. Village clusters were then block-randomized with a 1:1:1 ratio,
101 stratified by district, to roll out the LEAPS intervention in three steps. All clusters started in the control
102 state (no LEAPS intervention), and in each step, 33 clusters transitioned to the LEAPS intervention.
103 Randomization was done using a computer-generated sequence by a study statistician not directly

104 involved with study implementation. Due to the nature of the intervention, blinding the study participants
105 was not possible. Blinding of the outcome assessors was attempted but blinding was limited due to visible
106 community intervention activities.

107 **Intervention**

108 LEAPS was implemented in collaboration with NCHD and provided educational services for children in
109 areas where the Ministry of Education of Pakistan has limited services. Initially, the LEAPS intervention
110 support team, which consisted of five female trainers with master's degrees, conducted a five-day training
111 of the trainer (ToT) course for 50 NCHD officers. The trained NCHD officers then recruited female youth
112 leaders aged 18-24 years with at least a 10th-grade education through community-based recruitment
113 workshops. The NCHD officers trained these youth leaders on the preschool curriculum and provided
114 them with a "starter kit" to set up a LEAPS preschool with community support. Space for the LEAPS
115 preschool was provided by the local community.

116 The youth leaders then enrolled children aged 3.5-5 years who were registered within the NCHD working
117 areas in LEAPS preschools. The program team tried to ensure equal enrolment for boys and girls to
118 promote gender equality. The LEAPS preschool classroom maintained a teacher-to-student ratio of 1:20
119 and followed the NCHD feeder primary school calendar, with six school days per week and each session
120 lasting three hours (8:00-8:30 am to 11:00 am). Each preschool session includes individual and small
121 group activities, indoor/outdoor play, snack time, and free play. Children were advised to bring their own
122 snacks or food from home during school days. In case, they did not bring anything, the school provided
123 them small packets of biscuits during snack breaks. The LEAPS curriculum included 4-5 sessions per
124 school year on healthy eating given to preschool children to promote physical development. Hand
125 washing and hygiene practices were promoted in the LEAPS classrooms. There was no education session
126 on child health, nutrition, and development given directly to the caregivers.

127 Implementation of the LEAPS intervention started in March 2019 (**Supplemental Figure 1**). Due to the
128 COVID-19 pandemic, LEAPS preschools remained closed from March to September 2020 during the
129 lockdown period. At that time, NCHD implemented the LEAPS emergency plan to promote remote
130 learning activities for the youth leaders and provided LEAPS workbooks for children to continue their
131 learning at home. The youth leaders also met children in informal community gatherings to support
132 learning during lockdown.

133 Following the lockdown, LEAPS preschools resumed operations in October 2020 and continued till
134 March 2021. During this time, youth leaders received training in COVID-19 safety protocols. The
135 protocols promoted practices such as handwashing, wearing masks, maintaining social distancing,
136 identifying COVID-19 symptoms, seeking appropriate care, and adhering to guidelines for returning to
137 work after a COVID-19 infection. The study provided essential supplies like masks, sanitizers, and
138 disinfectants to ensure the implementation of safety precautions within LEAPS classrooms.

139 **Data Collection**

140 We used repeated population-based cross-sectional surveys to evaluate the impact of the LEAPS
141 preschool intervention. The surveys were conducted at four different time points, including baseline
142 (January-April 2019), round two (August-November), round three (February-March 2020 and June-
143 August 2020), and endline (December 2020-March 2021) (**Supplemental Figure 1**). Due to COVID-19,
144 round three data collection was interrupted in March-June 2020. The survey included children aged 4.5-
145 5.5 years and their caregivers residing in the study clusters, regardless of their participation status in the
146 LEAPS intervention. Children with severe health conditions or disabilities were excluded. Written
147 informed consent was obtained from the parents, and verbal assent was obtained from the children.

148 Local women who were fluent in Sindhi and had at least a bachelor-level education were trained for ten
149 days as study outcome assessments before the baseline survey. They also received one day of refresher
150 training before each subsequent data collection round. If a cluster had more than 11 children, assessors
151 used a random number generator to select 11 children who met the study inclusion criteria.

152 The assessors collected data on child, parent, and caregiver characteristics, household socio-demographic
153 status, household food security, preschool readiness, child executive function, and child anthropometry
154 (including height, weight, head circumference, and mid-upper arm circumference (MUAC)) during
155 household visits at all four-time points. To measure height and weight, the assessors used portable Shorr
156 boards (Weigh and Measure LLC, USA) and Seca 877 Digital Flat Scales, respectively. Height, weight,
157 head circumference, and MUAC were measured in duplicate. Out of 3858 children surveyed, we had
158 height measurements for 3843 children and weight information for 3844 children; <1% anthropometry
159 information was missing. Head-circumference and MUAC measurements were available for 2153 out of
160 2155 children aged 4.5- 5 years. No data was collected on morbidity or prevalence of infectious diseases
161 in the survey.

162 **Statistical Analysis**

163 First, we evaluated the sociodemographic characteristics of the study participants in each randomization
164 step to assess the balance between groups. To estimate the effect of the LEAPS intervention on child
165 nutritional outcomes, we utilized the intention-to-treat (ITT) analysis approach and followed the Hussey
166 and Hughes analytical framework for analysis of stepped wedge randomized controlled trials (RCTs)
167 (20). The two measures of height, weight, and MUAC were averaged prior to the calculation of z-scores.
168 For children ≤ 60 months old, we estimated child anthropometric z-scores (height-for-age (HAZ), weight-
169 for-age (WAZ), weight-for-height (WHZ), head-circumference-for-age (HCZ), and MUAC-for-age
170 (MUACZ)) using the World Health Organization (WHO) Child Growth Standards (21). We used the
171 WHO Growth Reference for School-Aged Children and Adolescents (5-19 years) to estimate
172 anthropometric z-scores for children > 61 months (22). We also analyzed the binary indicators of stunting
173 (HAZ < -2), wasting (WHZ < -2 for children ≤ 60 months and BMIZ < -2 for children > 61 months), and
174 underweight (WAZ < -2).

175 A linear mixed effect model (LMM) was used to estimate the effect of the LEAPS intervention on
176 continuous anthropometric indices (HAZ, WAZ, WHZ, BMIZ, HCZ, and MUACZ). Multi-level mixed-

177 effect logistic models were used to estimate odds ratios for the binomial stunting, wasting, and
178 underweight outcomes. Our primary ITT models included a random effect for clusters and fixed effects
179 for stratified randomization and survey rounds as recommended by Hussey and Hughes for basic analysis
180 of stepped wedged RCT with repeated cross-sectional samples(20). The assumptions of the model include
181 i) a fixed effect for time accounting for a common underlying secular trend across all clusters, ii) a single
182 term for the treatment, allowing a constant shift in this trend under treatment, iii) a uniform correlation
183 structure, where the correlation between any two observations in the same cluster remains the same
184 regardless of administered treatments and the duration between the periods of the observations given the
185 random sampling of children from clusters in each survey rounds and iv) the data, collected at multiple
186 discrete time points, pertain to different individuals considering children surveyed in different survey
187 rounds are different.

188 Aligned with the trial protocol, we also conducted a per-protocol analysis by excluding 8 clusters that
189 were randomized but did not roll out a LEAPS intervention either due to a lack of eligible children or
190 insufficient space to establish a preschool in the community. There was no difference in baseline
191 characteristics for clusters that were excluded from the per-protocol analysis as compared to clusters that
192 were included in the analysis (**Supplemental Table 1**). Additionally, we examined as-treated effect of the
193 intervention among children who attended LEAPS preschools in the intervention clusters as compared to
194 children in the control clusters adjusted for child age, sex, birth order, number of children in the
195 household, mother's education levels, father's education levels, family structure (nuclear/extended),
196 household food insecurity level and the household wealth index.

197 As outlined in the protocol, we conducted the following sensitivity analyses to examine modeling
198 assumptions of the basic stepped wedged RCT model proposed by Hussey and Hughes (20) i) adding a
199 fixed effect for clusters to model intra-cluster correlation ii) incorporated a random effect interaction
200 between cluster and times to adjust for potential effect modification between clusters and time if any , iii)
201 included a random effect interaction between treatment and cluster to adjust for potential effect

202 modification between treatment and clusters if any, iv) utilized a generalized estimating equations (GEE)
203 model to account for variable cluster sizes, and v) employed a multivariable model adjusted for child age,
204 sex, and birth order, the number of children in the household, mother's education levels, father's
205 education levels, family structure (nuclear/extended), household food insecurity index, and the household
206 wealth index to account for potential imbalances in baseline characteristics.

207 Additionally, we conducted an exploratory analysis to examine potential effect modification by COVID-
208 19, by modeling interaction between the treatment and survey rounds, where round two represents the
209 pre-COVID period and round three represents the COVID lockdown period. We also conducted
210 exploratory subgroup analyses to examine potential modification of the treatment effect by child age (<5
211 years and ≥ 5 years), sex (male and female), household wealth (< median and \geq median), and household
212 food security (food secure, mild to moderate food insecure and severe food insecure). The likelihood ratio
213 test was used to assess the statistical significance for models that explored effect modification.. All
214 analyses were conducted using Stata 15.0 Special Edition statistical software.

215 **Ethics**

216 The study obtained ethical approval from the Aga Khan University Ethics Review Committee, the
217 Pakistan National Bioethics Committee, and the Harvard T.H. Chan School of Public Health Institutional
218 Review Board. Our study adhered to ethical principles governing human research. Written informed
219 consent was obtained from parents, while children were asked to assent verbally in the local language,
220 Sindh.

221 **Funding**

222 Dubai Cares and Saving Brains, Grand Challenges Canada funded the study. The funders had no role in
223 the study design, implementation, data collection, or interpretation of study findings.

224 **Results**

225 The flow of the randomized LEAPS intervention roll-out and population-based surveys is presented in
226 **Figure 1**. The population-based surveys included a total sample of 3,858 children aged between 4.5 and
227 5.5 years from 99 study clusters across the four survey rounds, which were conducted between December
228 2018 and June 2021. A total of 1,089 children were included in the baseline survey, 1,004 in round two,
229 906 in round three, and 859 in the endline survey. **Table 1** presents characteristics of children in the
230 baseline pre-intervention survey stratified by the steps by which villages clusters were randomized to
231 receive the LEAPS intervention. The baseline characteristics of children were similar for villages
232 randomized to receive LEAPS in the first, second or third step in terms of the child's mean age, gender,
233 birth order, parents, household characteristics and anthropometric measures at baseline. The coverage of
234 the LEAPS intervention among surveyed children in which the intervention was to be implemented was
235 78% (248 out of 320) in round two, 59% (343 out of 518) in round three, and 72% (613 out of 857) in the
236 endline survey (**Supplemental Table 2**). The distribution of anthropometric measures among intervention
237 and control children by survey rounds is presented in **Supplemental Table 3**.

238 **Table 2** shows the effect of the LEAPS intervention on children's anthropometric measures. The LEAPS
239 intervention had a positive effect on linear growth and increased HAZ by 0.13 z-scores (95% CI: 0.02,
240 0.24). However, there were significant negative effects on BMIZ, WHZ, and MUACZ, with mean
241 differences of -0.13 z-scores (95% CI: -0.23, -0.03), -0.29 z-scores (95% CI: -0.42, -0.15), and -0.16 z-
242 scores (95% CI: -0.25, -0.05), respectively. There was no statistically significant effect of LEAPS on
243 WAZ, HCZ, or the risk of stunting, wasting, and underweight (p-values > 0.05).

244 Per-protocol analyses which included 91 clusters, showed similar results as our primary ITT analysis
245 (**Supplemental Table 4**). An as-treated analysis that analyzed children who attended LEAPS preschools
246 in the intervention clusters compared to control children showed similar direction, but generally larger
247 effect sizes compared to our primary ITT analysis (**Supplemental Table 5**). The negative effect of
248 LEAPS on WHZ increased, with a mean difference of -0.35 z scores (95% CI: -0.50, -0.20) in the as-

249 treated analysis.. All sensitivity analyses that assessed different modeling assumptions were also
250 generally consistent with results from the primary ITT analyses (**Supplemental Tables 6-14**). However,
251 there was a statistically significant negative effect of the LEAPS intervention on wasting in the GEE
252 model sensitivity analysis (odds ratio: 1.31; 95% CI: 0.99-1.74; p-value: 0.04).

253 We also conducted an exploratory analysis to examine the potential of effect modification of the LEAPS
254 intervention on nutritional status by the COVID-19 lockdown. Overall, we found that the negative effect
255 of the LEAPS intervention on acute undernutrition indicators appeared to be stronger during the COVID-
256 19 lockdown (**Table 3**). Before COVID, in survey round two the effect of the LEAPS intervention on
257 BMIZ was 0.07 (95% CI: -0.07, 0.02), but during the COVID-19 lockdown in survey round three the
258 effect was -0.33 (95% CI: -0.47, -0.19) (p-value for interaction <0.001). Similarly, the effect of LEAPS
259 on WHZ and WAZ was more negative during the COVID lockdown period compared to before COVID
260 (p-values for interaction <0.05). We also observed that the effect of LEAPS on the risk of being
261 underweight was higher during the COVID lockdown (OR: 1.53; 95% CI: 1.05, 2.23) than before COVID
262 (OR: 0.95; 95% CI: 0.66, 1.35; p-value for interaction 0.05). We did not observe evidence of effect
263 modification on HAZ, MUACZ, HCZ, stunting, or wasting by the COVID lockdown period.

264 Exploratory subgroup analyses showed significant effect modification of the effect of the LEAPS
265 intervention on some anthropometric measures by child sex, age group, household socioeconomic status,
266 and household food insecurity status (**Supplemental Table 15-18**). We found larger positive effects of
267 LEAPS on stunting and HCZ among males as compared to female children (p-values for effect
268 modification < 0.05). In contrast, the negative effect of LEAPS on MUACZ appeared to be stronger
269 among females as compared to male children (p-value < 0.05). We also found greater improvement in
270 HAZ and an effect on stunting among under-five children as compared to children older than five years
271 (p-values < 0.05). The negative effect of LEAPS on BMIZ was also more pronounced among children
272 under five as compared to those over five (p-value 0.001). Additionally, the negative effect of LEAPS on
273 wasting appeared to be stronger among children from high-income households compared to children from

274 low-income households (p-value: 0.03). We also observed a stronger positive effect of LEAPS on HCZ
275 indicator among children from food-insecure households compared to children from food-secure
276 households (p-value: 0.01))

277 **Discussion**

278 Our study examined the effect of LEAPS, a center-based ECCE intervention, on the nutritional status of
279 children aged 4.5 to 5.5 years in rural Pakistan. We found a positive impact of the LEAPS intervention on
280 child HAZ, a marker of linear growth generally reflective of long-term nutrition status. However, we also
281 observed a significant negative effect on weight-based anthropometric indicators, including WHZ,
282 MUACZ, and BMIZ. Further, our exploratory analyses indicated that the negative effect of the LEAPS
283 intervention on weight-based indicators appeared to be more pronounced during the COVID-19 lockdown
284 period.

285 In this study, we found contrasting effects of LEAPS intervention on child anthropometric outcomes with
286 positive effects on linear growth but negative effects on multiple weight-based indicators. Prior research
287 has also shown mixed results on the effectiveness of center-based ECCE programs on child
288 anthropometry outcomes (10, 12, 23-25). The complex relationship between linear and ponderal (weight)
289 growth involves shared risk factors, but the response of linear growth and weight to these risk factors may
290 differ (26-28). On an individual level, reductions in WHZ or BMIZ among children are often considered a
291 short-term response to inadequate dietary intake or infection and are generally characterized to precede
292 linear growth faltering (26). However, catch-up linear growth can occur, particularly among preschool-
293 aged children. In this study, we did not follow up with the same cohort of children over time. Therefore,
294 we cannot evaluate the effect of the intervention effect on individual growth trajectories. Nevertheless,
295 based on the Leroy et al framework, each of the components that positively or negatively affect growth
296 may differentially affect a child's height and weight at the population level(9, 13). For example, weight-
297 based indicators may be more sensitive to infections through cleanliness, hygiene, and exposure
298 pathways, while height/length-based indicators may be more sensitive to long-term changes in child's diet

299 through school meal or feeding, health and care practices at home through nutrition education targeted
300 towards caregivers or social interaction.

301 There are multiple pathways through which ECCE interventions may have a positive effect on linear
302 growth (9). Studies conducted in Colombia (10) and Guatemala (29) demonstrated that providing school
303 meals can have a direct positive effect on children's dietary intake and linear growth. Unlike these
304 programs, the LEAPS intervention did not provide school meals but instead may have indirectly
305 improved child's linear growth through changes in the home environment. At LEAPS preschools,
306 children received a few short lessons on a healthy diet and good hygiene practices in school; however, it
307 seems unlikely due to the low intensity and lack of direct communication with the caregivers that this
308 component of LEAPS resulted in significant behavior change and contributed to effects on nutritional
309 status. However, our qualitative interviews with caregivers of the preschool children revealed that many
310 mothers interacted with other mothers and teachers for the first time outside their homes when their
311 children began attending LEAPS preschools and expressed greater aspirations for improving their
312 children's health and development. Prior literature also supports that mother's social networks can
313 positively impact their children's nutrition status through changes in caregiving practices by health
314 knowledge and resource sharing (30, 31). Therefore, while ECCE programs are generally focused on
315 promoting development outcomes and readiness for primary school, they may also indirectly support
316 health and growth of children through effects on caregivers' practices or directly through school lunch or
317 supplementation interventions. Research in LMICs should evaluate the effectiveness of ECCE programs
318 as a platform for interventions to promote broader health, nutrition, and development of preschool
319 children.

320 On the other hand, the negative effects of the LEAPS intervention on weight-based anthropometry
321 indicators, such as WHZ and BMIZ, could be either due to short-term changes in the child's diet or
322 increased infectious disease morbidities (9). We do not anticipate any acute change in child diet within
323 LEAPS preschools as children only stayed at school for 2 hours during the school days, while increased

324 morbidities in the preschools are possible considering increased risks of infection among children at this
325 age as well as the increased risk of transmission of infectious diseases in group settings. Unfortunately, in
326 our study, we did not collect data on morbidity or infections in the population-based surveys.
327 Nevertheless, multiple studies have found that children attending center-based ECCE programs have two
328 to three times higher risk of infections, especially respiratory tract infections, otitis media, and diarrhea,
329 as compared to children receiving home-based care (25, 32-36). There is a well-documented cyclical link
330 between nutrition and infection in children; importantly, infection can lead to undernutrition through
331 reduced nutrient intake and absorption, increased metabolism, and greater energy expenditure (37-39).
332 Moreover, in rural Pakistan, children under five are particularly vulnerable to the infection-malnutrition
333 cycle due to multiple existing risk factors such as high level of food insecurity, infectious diseases burden,
334 and low vaccination coverage (17, 36). Therefore, when implementing center-based ECCE programs in
335 contexts where food insecurity and infections are prevalent, it seems important to consider and evaluate
336 school-based nutrition interventions such as school meals and nutrition education as well as supplemental
337 infection control strategies, such as immunization, standard infection control protocols, illness
338 notification, isolation of sick children, disinfection of surface areas (36, 40-42). The LEAPS program did
339 not specifically include these components. Most infection control guidelines for preschools have been
340 developed and evaluated in high-income settings, and therefore, research is necessary to adapt and
341 evaluate tailored infection control strategies for contexts in LMICs (40-42).

342 In an exploratory analysis, we also found that the negative effects of LEAPS appeared to be stronger on
343 weight-based anthropometry indicators in the survey conducted during the COVID-19 lockdown period.
344 Despite the closure of preschools, children in the LEAPS intervention group continued to gather
345 informally to support learning, which potentially increased their exposure to and transmission of
346 infections compared to children who stayed at home (43). In contrast, the lockdown and restricted
347 movement may have further reduced the risk of infection transmission among the children in the control
348 areas during COVID lockdown. Therefore, the relative difference in infectious disease risk between

349 children in LEAPS intervention and control villages may have been greater during the COVID-19
350 lockdown period. A population-based observation study in the UK found lower incidence and
351 hospitalization rates for common childhood infections such as influenza, pneumonia, meningitis, mumps,
352 and measles during the period of COVID lockdowns, school closures, and restricted travel (44). Further,
353 COVID-19 had a negative impact on food security during lockdown periods and increased food insecurity
354 was associated with increased wasting among children in Pakistan where there was low social support and
355 safety net programs (45, 46). As a result, increased nutritional vulnerability during the COVID-19
356 lockdown, in combination with the cyclical relationship with infection, may have contributed to a stronger
357 negative effect on acute undernutrition (37-39).

358 A major strength of our study was the use of a randomized design that allowed for the determination of
359 the causal effect of LEAPS intervention on the nutritional status of the children. However, our study also
360 had several limitations. First, inherent in the stepped wedge randomized control trial design, more clusters
361 were exposed to the intervention towards the end of the study than in its early stages which may have
362 confounded the effect of the intervention with any underlying temporal trend (47). To address this
363 potential issue, we used a random effect for the cluster to account for inter- and intra-cluster correlation
364 and fixed effects for stratified randomization by strata and survey rounds in our primary ITT analysis. We
365 also conducted a sensitivity analysis using random effect interaction between cluster and times and
366 random effect interaction between treatment and cluster, which yielded consistent estimates with our
367 primary ITT analysis. As a result, there is limited potential for temporal trends to impact our study
368 findings. Second, the evaluation used population-based cross-sectional surveys that included children who
369 did not attend the LEAPS preschool (22% in round 2, 41% in round three, and 29% in the end line); we
370 likely underestimated the magnitude of the effect of the LEAPS intervention on nutritional outcomes if all
371 children in village clusters had, in fact, attended the LEAPS program. Third, we did not collect morbidity
372 and dietary data, and therefore, we were not able to evaluate mediation pathways through which LEAPS
373 may have impacted the nutritional status of preschool children. Of note, the LEAPS program evaluation

374 included four cross-sectional surveys, and therefore, morbidity data would have been limited to a short
375 duration maternal morbidity symptom recall, which would not adequately capture the incidence of
376 infection during the LEAPS program. As a result, cohort evaluation of ECCE programs that include data
377 on morbidity incidence, diet changes, and other potential mediators noted by Leroy, et al. should be
378 conducted. Fourth, while LEAPS effects on continuous HAZ, WHZ, and BMI were found, there was no
379 statistically significant effect on the binomial outcomes of stunting, wasting, and underweight, although
380 the measures of effect were in the same direction as the continuous outcomes. This difference was likely
381 due to reduced statistical power for binomial as compared to continuous outcomes. However, these
382 findings are important considering the linear relationship of child HAZ with child developmental
383 outcomes (48, 49). Lastly, our study was conducted in rural Pakistan where the burden of infectious
384 disease and food insecurity is high. Therefore, our findings may not be fully generalizable to other
385 settings and to center-based ECCE programs that include supplementary nutrition or infection control
386 interventions.

387 Overall, center-based ECCE programs play an important role in promoting early child development and
388 school readiness; however, these programs may also have unintended positive or negative effects on child
389 nutrition status. In our study, we found that the LEAPS intervention had positive effects on linear growth
390 but negative effects on weight-based anthropometric measures. Based on these findings, implementation
391 research should be conducted to evaluate integrated strategies including infection control measures,
392 provision of nutritious meals, and engagement of caregivers in diet counseling to promote health and
393 good nutrition in center-based ECCE programs in LMIC settings. Finally, ECCE programs should not
394 only be considered as an intervention to promote development and school readiness, but also as a
395 potential platform to promote the broader health, nutrition, and well-being of preschool children.

396 **Conflicts of interest**

397 The authors declare no conflict of interest.

398 **Contributors**

399 AKY conceptualized the study. AYK, CRS, SS, and SB developed study design, implementation
400 strategies, and data collection materials. SS coordinated the implementation of the study, training, data
401 collection, and quality assurance. NBA conducted the formal analysis and wrote the paper. CRS and
402 AKY supervised manuscript development, data analysis and contributed to the revisions. NBA had the
403 primary responsibility for the final content. All authors reviewed and approved the final manuscript.

404 **Data Sharing**

405 Data described in the manuscript, code book, and analytic code may be made available upon reasonable
406 request to the study principal investigator, Aisha K. Yousafzai (email: ayousafzai@hsph.harvard.edu).

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544

Figure 1. Study flowchart

Table 1. Baseline characteristics of the study participants who were randomized to receive LEAPS intervention in three steps, rural Sindh, Pakistan

	Baseline		
	Clusters randomized to receive LEAPS intervention in Step 1	Clusters randomized to receive LEAPS intervention in Step 2	Clusters randomized to receive LEAPS intervention in Step 3
<i>Cluster characteristics</i>			
Number of clusters (n)	33	33	33
<i>Child Characteristics</i>			
Number of children (n)	361	366	362
Female (n, %)	182 (50.4%)	188 (51.4%)	156 (43.1%)
Age in years (mean, SD)	5.0 (0.4)	5.0 (0.4)	5.1 (0.4)
Birth order (mean, SD)	3.6 (2.3)	3.9 (2.6)	3.7 (2.4)
<i>Child nutritional statuses</i>			
Height-for-age z score	-1.55(1.28)	-1.36(1.03)	-1.34(1.05)
Weight-for-height z score	-0.61(0.96)	-0.71(1.09)	-0.69(0.86)
Weight-for-age z score	-1.45(0.91)	-1.38(0.88)	-1.30(0.85)
BMI-for-age z score	-0.65(0.95)	-0.77(1.09)	-0.65(0.86)
MUAC-for age z score	-0.93(0.80)	-0.99(0.78)	-0.96(0.77)
Head circumference z scores	-1.31(1.10)	-1.14(0.94)	-1.04(1.13)
<i>Mother's Characteristics</i>			
Mother is the primary caregiver (n, %)	357 (98.9%)	361 (98.6%)	355 (98.1%)
Mother's age (mean, SD)	33.4 (6.6)	34.0 (6.5)	33.6 (6.5)
Mother's education level			
No formal schooling (n, %)	302 (83.7%)	309 (84.4%)	296 (81.8%)
Some primary school (n, %)	19 (5.3%)	17 (4.6%)	18 (5.0%)
Completed primary school (Grade 5) (n, %)	40 (11.1%)	40 (10.9%)	48 (13.3%)
Mother's primary occupation			
Housewife (n, %)	286 (79.2%)	280 (76.5%)	288 (76.5%)

	Baseline		
	Clusters randomized to receive LEAPS intervention in Step 1	Clusters randomized to receive LEAPS intervention in Step 2	Clusters randomized to receive LEAPS intervention in Step 3
Handicraft (n, %)	56 (15.5%)	57 (15.6%)	57 (15.6%)
Daily paid worker (n, %)	12 (3.3%)	21 (5.7%)	21 (5.7%)
<i>Father's Characteristics</i>			
Father is the primary provider (n, %)	354 (98.1%)	361 (98.6%)	354 (97.8%)
Father's education level			
No formal schooling (n, %)	160 (44.3%)	169 (46.2%)	162 (44.8%)
Completed primary school (Grade 5) (n, %)	66 (18.3%)	52 (14.2%)	67 (18.5%)
Completed middle school (Grade 8) (n, %)	19 (5.3%)	29 (7.9%)	10 (2.8%)
Completed lower secondary school (Grade 10) (n, %)	97 (26.9%)	88 (24.0%)	100 (27.6%)
Father's primary occupation			
Farmer (n, %)	112 (31.0%)	106 (29.0%)	108 (29.8%)
Daily paid worker (n, %)	71 (19.7%)	79 (21.6%)	87 (24.0%)
Industrial worker (n, %)	81 (22.4%)	69 (18.9%)	47 (13.0%)
<i>Household Characteristics</i>			
Family size (mean, SD)	10.7 (5.2)	10.6 (6.3)	12.3 (9.2)
Number of children in household (mean, SD)	5.0 (2.3)	5.2 (2.5)	5.0 (2.3)
Joint /extended family (n, %)	244 (67.6%)	220 (60.1%)	240 (66.3%)
Nuclear family (n, %)	117 (32.4%)	146 (39.9%)	122 (33.7%)
Household wealth quintiles (mean, SD)	2.9 (1.3)	3.1 (1.5)	3.0 (1.5)
Households having private, reliable source of drinking water (n, %)	348 (96.4%)	352 (96.2%)	344 (95.0%)
Households having latrine with flush system (n, %)	97 (26.9%)	126 (34.4%)	142 (39.2%)
Food secure household (n, %)	175 (48.5%)	183 (50.0%)	172 (47.5%)
Mild to moderate food insecure household (n, %)	125 (34.6%)	139 (38.0%)	145 (40.1%)
Severely food insecure household (n, %)	61 (16.9%)	44 (12.0%)	45 (12.4%)

Table 2. Intention-to-treat (ITT) effect of LEAPS intervention on anthropometric indicators for children aged 4.5-5.5 years in rural Sindh, Pakistan (N=3843)

Outcome	LEAPS intervention effect	P value	ICC*
Continuous outcomes		Mean Difference (95% Confidence Interval)	
Height-for-age z score (HAZ)	0.13 (0.02, 0.24)	<0.05	0.07
BMI-for-age z score (BMIZ)	-0.13 (-0.23, -0.03)	<0.01	0.06
Weight-for-age z score (WAZ)	-0.00 (-0.09, 0.09)	0.96	0.07
Weight-for-height z score (WHZ)	-0.29 (-0.42, -0.15)	<0.001	0.06
MUAC-for age z score (MUACZ)	-0.16 (-0.25, -0.05)	<0.01	0.06
Head circumference z scores(HCZ)	0.08 (-0.06, 0.22)	0.24	0.07
Binary outcomes		Odds Ratio (95% Confidence Interval)	
Stunted (HAZ < -2)	0.93 (0.73, 1.18)	0.54	0.07
Wasted (WHZ < -2 / BMI Z < -2)	1.34 (0.94, 1.91)	0.11	0.10
Underweight (WAZ < -2)	1.06 (0.83, 1.36)	0.62	0.06

*ICC= Intra cluster correlation coefficient

Table 3. Effect of LEAPS intervention on children’s nutrition statuses before COVID, during COVID lockdown and effect modification by COVID 19 lockdown period

Outcome	Effect of LEAPS before COVID in Round 2	Effect of LEAPS during COVID lockdown in Round 3	Effect modification by COVID 19 lockdown period [Interaction term Intervention x Round]	P value for effect modification
Continuous outcomes		Mean Difference (95% Confidence Interval)		
Height-for-age z score (HAZ)	0.00 (-0.16, 0.17)	0.10 (-0.07, 0.26)	0.09 (-0.07, 0.26)	0.37
BMI-for-age z score (BMIZ)	0.07 (-0.07, 0.20)	-0.33 (-0.47, -0.19)	-0.40 (-0.57, -0.22)	<0.001
Weight-for-age z score (WAZ)	0.05 (-0.09, 0.18)	-0.16 (-0.30, -0.03)	-0.21 (-0.37, -0.04)	<0.05
Weight-for-height z score (WHZ)	-0.09 (-0.29, 0.11)	-0.48 (-0.66, -0.30)	-0.39 (-0.64, -0.14)	<0.01
MUAC-for age z score (MUACZ)	-0.15 (-0.30, -0.01)	-0.19 (-0.33, -0.06)	-0.04 (-0.23, 0.15)	0.65
Head circumference z scores (HCZ)	-0.11 (-0.31, 0.09)	0.11 (-0.08, 0.30)	0.22 (-0.03, 0.48)	0.08
Binary outcomes		Odds Ratio (95% Confidence Interval)		
Stunted (HAZ < -2)	1.22 (0.86, 1.73)	0.85 (0.60, 1.21)	0.69 (0.44, 1.09)	0.12
Wasted (WHZ < -2 / BMI Z < -2)	1.22 (0.76, 1.95)	1.76 (1.02, 3.05)	1.45 (0.73, 2.85)	0.29
Underweight (WAZ < -2)	0.95 (0.66, 1.35)	1.53 (1.05, 2.23)	1.62 (1.01, 2.59)	0.05