

Integrating Early Stimulation and Play at Scale: Study Protocol for “MAHAY Mikolo”, a Multi-arm Cluster-randomized Controlled Trial

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Research Article

Keywords: Early Childhood Development, Early Stimulation, Implementation Science, Time-use, Program Take-up, Play Materials

Posted Date: May 10th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-402243/v1>

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Version of Record: A version of this preprint was published at BMC Public Health on February 9th, 2022.
See the published version at <https://doi.org/10.1186/s12889-022-12640-z>.

1 **Integrating Early Stimulation and Play at Scale: study protocol for “MAHAY Mikolo”, a multi-**
2 **arm cluster-randomized controlled trial**

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17 **Keywords:** Early Childhood Development, Early Stimulation, Implementation Science, Time-use,
18 Program Take-up, Play Materials

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20 **Abstract word count:** 344 out of 350 words maximum

21

22 **ABSTRACT**

23 *Background:* Hundreds of millions of children living in poverty worldwide are not reaching their full,
24 developmental potential. Programs to promote nurturing and responsive caregiving, such as those in
25 which community health workers (CHWs) conduct home visits to support optimal early child

26 development (ECD), have been effective in small trials, but have not achieved similar success at
27 scale. This study will explore two approaches to scale-up: converting a home-visiting model to a
28 group-based model; and integrating the ECD curriculum into an existing government program. The
29 objectives of the study are to: 1) Measure how the integration of ECD activities affects time and task
30 allocation of CHWs and CHW psychosocial wellbeing; 2) Examine how the integration of ECD
31 activities affects caregiver-child dyad participation in standard health and nutrition activities; and 3)
32 Explore how the availability of age-appropriate play materials at home affects caregiver-child dyad
33 participation rates in a group-based ECD program.

34 *Methods:* We will randomize 75 communities in rural Madagascar into three arms: 1) [C], which is
35 the status quo (community-based health and nutrition program); 2) [T], which is C + ECD group
36 sessions [T]; and 3) [T+], which is T with the addition of an enhanced play materials package for
37 home use. All children between 6-30 months old at the time of the intervention launch will be eligible
38 to participate in group activities. The intervention will last 12 months and is comprised of fortnightly
39 group sessions in which the CHWs provide caregiver-child dyads with information relating to ECD;
40 CHWs will also include structured time for caregivers to practice the play and child stimulation
41 activities they have learned about. We will administer monthly surveys to measure CHW time use
42 and task allocation, and we will leverage administrative data to measure caregiver-child dyad
43 participation in the group sessions.

44 *Discussion:* The results from the trial will provide the evidence base required to implement an
45 integrated package of nutrition, health and ECD promotion activities at scale in Madagascar, and
46 findings may also be relevant in other low-income countries.

47 *Trial registration:* This trial has been registered on the AEA RCT Registry (AEARCTR-0004704,
48 <https://www.socialscisceregistry.org/trials/4704>, registered on November 15, 2019).

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Administrative information

Title	Integrating Early Stimulation and Play at Scale: study protocol for “MAHAY Mikolo”, a multi-arm cluster-randomized controlled trial
Trial registration	This trial has been registered on the AEA RCT Registry (AEARCTR-0004704). Registered on November 15, 2019. https://www.socialscienceregistry.org/trials/4704
Protocol version	March 22, 2021
Funding	Funding for this study was provided by the Strategic Impact Evaluation Fund (SIEF) and the Early Learning Partnership (ELP) Grant. Implementation is funded by the National Nutrition Office in Madagascar (implementing agency (PNNC/ONN)).
Author details	University of California, Berkeley (Lia C. H. Fernald, Caitlin Hemlock, Maria Dieci), The World Bank (Emanuela Galasso), Centre Médico-Educatif ‘Les Orchidées Blanches’, Madagascar (Lisy Ratsifandrihamanana), Programme National de la Nutrition Communautaire, Madagascar (Mathilde Col, Norotiana Rakotomalala), Ann M. Weber (University of Nevada, Reno)
Name and contact information for the trial sponsor	SIEF (Alaka Holla, Program Manager, aholla@worldbank.org); ELP (Amanda Devercelli, adevercelli@worldbank.org).
Role of sponsor	The funders did not have role in the study design or data collection, or the decision to submit the protocol for publication.

55 **BACKGROUND**

56 Hundreds of millions of children around the world live in poverty, and as a result, are at risk
57 of not reaching their developmental potential. Living in poverty increases exposure to multiple risk
58 factors, such as poor nutrition, unstimulating home environments, inadequate water and sanitation,
59 and environmental hazards, all of which can then lead to lower early child development (ECD)
60 outcomes and educational attainment early in life, as well as worse labor market outcomes later in
61 life (1–3). Investments to promote developmental outcomes in early childhood -- often in the form of
62 parenting support/education and nutrition supplementation -- can put children on a higher lifetime
63 income trajectory, and can potentially crowd-out negative effects of early adverse events (1,4). A
64 recent review of the effectiveness of parenting programs showed that, on average, participation in
65 parenting programs resulted in improvements in child development outcomes (5). Specifically, there
66 were benefits for measures of cognitive development (standardized mean difference (SMD) 0.36,
67 95% CI 0.22-0.49, 19 studies), motor development (SMD 0.13, 95% CI 0.07-0.19, 9 studies), and
68 psycho-social development (standardized mean difference [SMD] 0.35, 95% CI 0.14-0.56, 13
69 studies). However, programs that have been effective in small program settings have not consistently
70 achieved similar successes at scale.

71 A recent study in Madagascar (MAHAY) investigated the impact of an adaptation of a
72 parenting program originating in Jamaica, the *Reach Up and Learn* program (6). The program
73 included fortnightly home visits by a dedicated community health worker (CHW) focusing on early
74 child development (ECD) outcomes. Although the MAHAY program was carefully implemented and
75 rigorously supervised, it failed to demonstrate significant effects on child outcomes. Researchers
76 hypothesized that one of the reasons the intervention was not as effective as anticipated was that
77 CHWs had to visit a large group of eligible children spread over a wide geographic area, resulting in
78 long travel times and threats to personal safety. Another possible reason for the small effect sizes of
79 the program on child development was the limited engagement by caregivers, possibly from lack of
80 time or interest in topics covered. Furthermore, the caregivers may not have been able to act on

81 suggestions made by CHWs because they did not have time or resources, or because they lacked
82 materials, such as toys, and thus could not engage in the CHW suggestions regarding play.

83 A group adaptation of the previously tested MAHAY home visits was designed to address the
84 issues that emerged in the MAHAY study. The revised, group-based program (MAHAY Mikolo,
85 “*know how to take care*”) targets existing implementation issues that arose in the home-visit model
86 by increasing coverage while reducing the amount of travel time spent by the CHWs given the greater
87 efficiency possible with groups compared with one-on-one visits. The MAHAY Mikolo program
88 incorporates behavioral nudges into the ECD group sessions to improve parental skills, promote peer
89 support and encourage sustained caregiver-child play in between the fortnightly meetings. A
90 subgroup of program communities will also receive boxes of age-appropriate toys and books to
91 promote sustained play between group sessions and for daily practice at home. The group-based
92 program has the potential to be integrated into Madagascar’s ongoing national reproductive, maternal
93 and child health and nutrition program and rolled out gradually by the National Nutrition office
94 (ONN) in Madagascar. Yet, there are important knowledge gaps about the potential costs or benefits
95 of such an integration before scaling it up. A recent special issue in the *Annals NY Academy of*
96 *Science* highlighted the importance of program implementation, and understanding issues such as
97 fidelity, coverage, dosage, quality of delivery, and participants’ acceptance and enactment of program
98 content, for program success (7). The proposed evaluation builds from these lessons and assesses the
99 feasibility of a group-based program by addressing key implementation research and policy
100 questions.

101 The overall objective of the study is to examine the effects of integrating ECD group sessions
102 into the existing, at-scale, community health and nutrition programs administered by the government
103 in Madagascar. The specific objectives of the study are to test how integrating ECD group activities
104 affects the time and task allocation of CHWs and if adding these new activities may change the
105 allocation of times towards health and nutrition activities, whether participation rates in health and

106 nutrition activities are affected in communities where the ECD activities are offered, and if there is
107 an additional benefit to providing age-appropriate toys and play materials for use at home on the take-
108 up of ECD activities. To achieve these objectives, we will use a cluster randomized controlled trial
109 design with three arms: a control group, with the status quo community-based health and nutrition
110 program; a treatment arm with fortnightly group ECD sessions, based on Reach Up and Learn
111 curriculum and supportive behavioral nudges, added to the status quo; and an enhanced treatment
112 arm, where the intervention in the treatment arm is layered with the provision of individual toy boxes
113 including age-appropriate toys.

114

115 *Research Questions*

116 The primary questions we aim to address through this research are:

117 *CHW Time and Task Allocation*

- 118 • *Primary Question 1: How does the integration of ECD activities into existing health and*
119 *nutrition responsibilities affect the time use and task allocation of CHWs?*
- 120 • *Secondary Question 1: How does the integration of ECD activities affect measures of CHW*
121 *psychosocial wellbeing?*

122 The role of CHWs has expanded considerably over the past 50 years, particularly in low and
123 middle income countries (8,9). CHWs are frontline workers tasked with bringing a wide variety of
124 public health services to their communities, and crucially bridging the gap between remote
125 communities and the formal health care system in a hub and spokes model. A large and growing body
126 of evidence documents the positive effects of CHW-run programs on population health (8).
127 Understanding the impact of the demands of the CHW role on the health and wellbeing of the workers
128 is an important dimension of research that has received limited attention.

129 CHWs are often time constrained, and thus it is crucial to understand how the addition of new
130 ECD responsibilities will affect the time spent by CHWs on regular tasks relating to health and

131 nutrition programming. There may be economies of scope through joint delivery. Specifically, by
132 relying on an existing infrastructure and using the same CHWs, there may be substantial cost savings
133 to having the two sets of program components delivered separately. On the other hand, these
134 components may interfere or crowd each other out if the time, mental space and attention of the
135 CHWs limits the implementation of multiple tasks. Crowd-out has been documented in the context
136 of school meals and school-based nutrition interventions in other LMIC settings (10,11).

137 The evidence on the positive effects of CHWs on health knowledge and outcomes in their
138 target communities has been shown in a variety of contexts (8), but there has also been evidence of
139 more troubling outcomes such as service delivery gaps (12,13), infrequent home visits (14), and
140 insufficient time spent on core health promotion activities (15,16). These intermediate outcomes that
141 relate to how program demands impact the quality and composition of the time spent working by
142 CHWs are crucial to measure how CHW programs impact downstream health knowledge and
143 outcomes.

144 One important pathway that affects CHWs' ability to effectively delivery primary health
145 services to their communities is CHW workload. Existing literature on CHW time use has found
146 evidence of workload strain. In one study in India, high administrative burdens resulted in CHWs
147 spending time on administrative reporting tasks such as filling out paper registries instead of direct
148 service provision (11). Other papers in different settings have found that a source of strain for many
149 CHWs is a lack of compensation commensurate with the demands of their jobs (17,18). This study
150 will add to the evidence base of how increasing the scope of CHW workload affects their time and
151 task allocation, not only on the different tasks that are related to the overall package of activities, but
152 also the potential reallocation away from the CHW's income generating activities or household
153 caregiving or family chores.

154 Our secondary objective is to measure how expanding the CHW workload through the
155 addition of ECD group sessions affects CHWs psychosocial wellbeing over the course of the program

156 implementation. We have a unique setting in that we will repeatedly measure the changes in time
157 demands on CHWs through the integration of ECD group sessions over a 12-month period.
158 Measuring changes in CHW stress and psychosocial wellbeing over this period will provide some of
159 the first quantitative evidence for the broader implications of a change in job responsibilities on health
160 worker wellbeing.

161

162 *Caregiver-Child Dyad Participation*

- 163 • *Primary Question 2: How does the integration of ECD activities affect participation by*
164 *caregiver-child dyads in all activities led by CHWs?*
- 165 • *Secondary Question 2: How is the treatment effect on caregiver-child dyad participation in*
166 *health and nutrition activities moderated by key household and community characteristics?*

167 In addition to understanding time use among CHWs, this study also seeks to examine caregiver
168 behavior and how the addition of ECD activities may affect participation of caregiver-child dyads.
169 Attendance at the ECD sessions is likely to be time consuming, competing with caregivers'
170 productive activities and housework/caregiving duties, thereby negatively affecting take-
171 up/participation of nutrition health activities. Conversely, the introduction of ECD group sessions
172 may increase the caregivers' potential interest and knowledge, because of its novelty and supporting
173 nudges. Consequently, one could expect increased take-up of nutrition/health activities for existing
174 caregiver-child dyads or new registration for health and nutrition programs of caregiver-child dyads
175 who are in the community. The main outcome of interest will be an index of participation in the
176 standard nutrition and maternal/child health activities. We will also examine how participation in the
177 CHW-led activities may be affected by key household-level (e.g. maternal education), and
178 community-level (e.g. remoteness) characteristics. A previous study found that there was some
179 suggestive effects of heterogeneity of ECD outcomes by child age and maternal education (6);
180 measuring intermediate outcomes could be helpful in further understanding pathways in ECD.

181

182 *Age-Appropriate Play Materials*

- 183 • *Primary Question 3: How does the availability of age-appropriate materials/activities for home-*
184 *based play affect caregiver-child dyad participation in ECD activities?*

185 Toys, books and other age-appropriate play materials are crucial for young children to use in
186 play because of the ways that these items promote engagement and promote learning. In addition to
187 clear benefits of these items to promote children’s development, toys and books are also critical to
188 sustain mothers’ interest in ECD activities by creating opportunities for home-based play. A recent
189 meta-analysis including 13 RCTs showed medium-to-large benefits of stimulation interventions for
190 improving the home caregiving environment, which includes having materials such as books and toys
191 for children to play with (19). A key component of our behavioral theory of change (the Integrated
192 Behavioral Model) goes beyond motivation and knowledge and focuses on the idea that
193 environmental constraints, such as a home without appropriate play materials, should not hinder the
194 application of the new knowledge (20). Another pillar of our design is that the behavior
195 (developmentally-appropriate play and stimulation) should be salient to the individual, which is the
196 reason we are focusing on the provision of toys, books and materials for participants to take home as
197 a way to enhance engagement. Finally, we intend for the experience performing the behavior to
198 become habitual so that true behavior change can occur and aim to promote habits with a combination
199 of a toy box that is provided at home to each target child, as well as a rotating set of developmentally
200 appropriate toys and books that participants can take home and use in between group sessions.

201

202 **DESIGN**

203 *Study Setting*

204 Our study will take place in 75 communities in two regions (Amoron’i Mania and Haute
205 Matsiatra) out of four regions currently covered by the existing community-based health and nutrition

206 program (Figure 1). The region of Itasy was excluded from our sample frame due to an ongoing LNS
207 supplementation program and Vakinankaratra was excluded due to weak institutional capacity in that
208 region. The study population is composed of CHWs serving these communities at the time of
209 randomization, and caregivers with children between 6 and 30 months of age.

210

211 *Eligibility Criteria*

212 Our sampling frame draws from the universe of communities participating in the national health
213 and nutrition program as of September 2020 in the regions of Amoron'i Mania and Haute Matsiatra.
214 Districts with extreme problems of accessibility (an issue for frequent monitoring) were ineligible
215 and excluded (Figure 2). From this universe of 1,185 potential communities in eight districts, the
216 following inclusion criteria are used to select communities, for operational feasibility:

- 217 ● No other ECD programs present in the community or neighboring communities;
- 218 ● At least 40 children monitored at the nutrition center in the target age range of 6-30 months
219 (monitored is defined as attending at least one growth monitoring session between July 2019
220 to August 2020);
- 221 ● Stable supervisory presence. Local NGOs are contracted to monitor and supervise all
222 community health workers and help to strengthen linkages with local structures such as the
223 community health committees and primary care facilities. Each NGO supervisor is in charge
224 to up to 9 communities, which they visit twice a month. We defined stable presence as not
225 having had NGO turnover within the last year.

226

227 *Recruitment*

228 Local agents (the government Regional Nutrition Office and the local NGOs) will carry out
229 the initial recruitment of communities by introducing the ECD curriculum structure and scope. At
230 this time, CHWs will indicate whether they would be willing to participate in a two-week training

231 session and implement the ECD group sessions in their community for a one-year period and
232 participate in monthly surveys. If a CHW declines to participate, a replacement community will be
233 chosen. Informed consent for the administration of the survey will be collected by the local agents
234 after this introduction to the planned activities and will be collected again more formally by the survey
235 firm at baseline, after the training has occurred.

236

237 *Study arms*

238 **Control: Status quo health and nutrition program**

239 The standard of care program is a community-based health and nutrition program managed by U-
240 PNNC (Unité - Programme de Nutrition Communautaire). The program has a package of activities
241 that address maternal and child health and nutrition (MCH&N) issues:

- 242 • Health: child health monitoring, integrated management of non-severe child illness,
243 pregnancy monitoring
- 244 • Nutrition: growth promotion, breastfeeding promotion and complementary feeding education,
245 monitoring of pregnant and lactating women, oral rehydration therapy for treatment of severe
246 diarrhea and management of moderate and acute malnutrition

247 Activities are carried out at the community level by two CHWs, who are elected by the
248 community.

249

250 **Treatment (T): Status quo health and nutrition program + Fortnightly group ECD sessions,**
251 **based on Reach Up and Learn curriculum and behavioral supporting nudges**

252 Community mobilization/information campaign: At the onset of the program, the ECD
253 activities will be presented to the treatment communities during community mobilization campaigns
254 by the program supervisors and the CHWs, supported by local authorities. The mobilization will start
255 with an introduction that raises awareness about the importance of ECD and explains the objectives
256 of the program. It will be followed by a description of the eligibility, enrollment, structure/content of

257 the sessions, and time commitment by the caregiver-child dyads. The dissemination will be supported
258 by photos and videos of the sessions carried out during pre-tests, as well as supporting materials used
259 during the sessions. We may consider selecting individuals within each neighborhood who would be
260 best placed to spread information about the intervention to encourage adherence and elicit possible
261 interest in enrollment.

262 Household recruitment: During these mobilization campaigns, NGO supervisors will collect
263 names from all eligible households who are interested in participating in the ECD sessions. To be
264 eligible for the ECD curriculum, households must have a child between 6-30 months, have a primary
265 caregiver that is willing to participate in the group activities and live in the selected community.
266 Households or caregiver-child dyads could also register with the CHWs or NGO supervisor during
267 the two weeks following the mobilization campaign.

268 On average, there are about 100 age-eligible mother-child dyads registered in the health and
269 nutrition program in the target communities, and the interventions will be provided for less than half
270 of this eligible number (maximum 40). If there is more demand than can be accommodated for a
271 given age group at a community, all interested households will be entered into a non-public lottery.
272 The research team will randomly draw 10 households from this list to offer a spot in the ECD
273 program, with the remainder being added to a wait list, and will send the final list to the NGO
274 supervisor. Households who are on the wait list will be informed that they have been added to a wait
275 list due to limited space in the program. If enrolled participants do not attend three consecutive ECD
276 sessions (out of the 12 session planned over a period of six months), randomly selected households
277 from the waitlist will be offered to join. There are no additional screening criteria.

278 ECD group sessions: The program will consist of fortnightly group sessions (one to one and
279 a half hour on average) of 10 caregiver-child dyads per six-month age group, for a total of 12 sessions
280 per age group over a period of six months. With four age groups of 10 children each (from 6 to 30
281 months old), coverage can reach up to 40 children at any given time. Each session is expected to

282 require half a day of the CHW's time for preparation, administration, filling out of registries and clean
283 up.

284 The Reach Up and Learn ECD stimulation curriculum was adapted to a group setting based
285 on the previous MAHAY experience. A session will start by (i) reviewing the previous sessions
286 activities and themes, with a few questions to reinforce the message, followed by (ii) a discussion
287 among program participants. The CHW will then introduce a them and message for the session. (iii)
288 a pledge will then be recited by all caregivers and CHWs, highlighting the importance of the
289 caregiver's commitment. (iv) Caregivers will be grouped in two or three to discuss the stimulation
290 activities they did with their own child since the last session. Children and caregivers will spend in
291 total 20 to 30 minutes on 3-4 play activities using age-appropriate toys. Then, they will all learn a
292 new song to sing with or to the child. (v) The session will end with feedback on the messaging and
293 the distribution of a reminder sheet with the main messages, play activities, lyrics of the song, a list
294 of activities to do at home before the next session, followed by (vi) a closing song-

295 The age-appropriate play materials used during the group ECD sessions have been adapted
296 from the Reach Up and Learn program's list. They have been adapted to the materials available in
297 Madagascar and have been built by a team of volunteer youth groups (scouts) (Tily Eto Madagasikara,
298 TEM). The maintenance of the toys and materials used during the group sessions will also be provided
299 by the scouts who live locally within the communities where the program is operational.

300 Behavioral nudges will be incorporated into the ECD group sessions to promote peer support
301 and encourage sustained caregiver-child play in between the fortnightly meetings. These nudges will
302 include a little paper booklet (memory aids) that recap the main lessons of the session with pictures
303 and short messages, the lyrics of the song learnt and the activities done during the session, and provide
304 suggestions for small feasible actions that can be taken at home to promote learning and child
305 development. Caregivers are instructed to fill in the check-boxes listing the activities they have
306 completed with their child at home and bring back the memory aid to the subsequent group session

307 to share their progress in pairs. These memory aids complement the ECD sessions through light-touch
308 reminders to play, and they can be used to reinforce concepts in between sessions and teach other
309 family members so they can also put the lessons into practice. At the end of the curriculum, each
310 caregiver-child dyad that attended each session will have a complete set of memory aids that recap
311 all the ECD lessons learned. A recent study in Zambia suggests that low-cost visual reminders in the
312 home about target activities to promote child development and nutrition may have positive effects,
313 particularly for the most vulnerable (21).

314 Transitions across age groups: The study period will cover two cycles of the 12 ECD group
315 sessions. After six months, previous participants of the first three age groups will be offered to
316 “graduate” to the next age group’s curriculum, and new participants will be added to the youngest
317 age group. At this time, if there are participants who decide not to move to the subsequent age group
318 cycle at the transition point, wait list participants will be randomly offered a spot in the age group.

319 Fidelity: CHWs and their NGO supervisors will receive training before the launch of the
320 interventions. Training will include discussion of notion of child development, the importance of
321 early stimulation, the content of the curriculum, with emphasis of role-play content, and assessments
322 of comprehension. An in-person three-days coaching is planned at the onset of the activities and
323 refresher sessions to reinforce concepts and ensure consistent quality across implementers are planned
324 every 4-6 months. In addition, coaches from the ECD team in Madagascar will be available by phone
325 monthly for monitoring and support, and CHWs will have access to phones for technical support.

326 The NGO supervisors will administer a monthly group session checklist, adapted from the
327 Reach-Up material to assess the quality of the sessions being carried out. Finally, we will develop a
328 brief tracking tool to be used by CHWs to record any changes in toy/play material inventory (losses,
329 deterioration in quality) over time.

330

331 **Treatment Plus (T+): Status quo health and nutrition program + Fortnightly group ECD**
332 **sessions, based on Reach Up and Learn curriculum and behavioral supporting nudges +**
333 **individual toy boxes with age-appropriate toys for home-based play**

334 After six months of program operation, half of the ECD communities will be randomly
335 allocated to receive an enhanced play materials and activities package for home use to complement
336 the Reach Up and Learn curriculum (T+) (Figure 2). To promote sustained play between group
337 sessions and daily practice, participating families will receive age-appropriate toy/books boxes at the
338 start of the 6-month cycle. This toy box is composed of one developmentally-appropriate toy given
339 as a gift to the caregiver-child dyad and kept at home. In addition, caregiver-child dyads will be able
340 to borrow a toy and a book from the ECD group session play activities every two weeks to increase
341 play variety and to practice activities learned with the CHWs. Caregivers will learn how to use the
342 toys to play with their children, with lessons at each meeting providing scaffolding to encourage
343 developmental growth. The 6-month delay in implementing T+ increases the power to detect CHW
344 time cost differences from integrating ECD group activities (T) with the health and nutrition program,
345 while maintaining sufficient power to detect differences in take up related to the enhanced play
346 materials (T+) by the caregivers (see section *Power Calculations*).

347

348 *Data collection*

349 There are four primary data sources that will be used to collect outcome data and key
350 covariates: administrative census data, CHW phone surveys and shadowing, community surveys, and
351 administrative participation data; each of these are discussed below.

352 **Administrative census data**

353 A census of all households with pregnant women and children aged 0-5 years was conducted
354 in January 2021 ahead of study activities by U-PNNC as part of the standard MCH&N activities. The
355 census will be used to a) understand underlying characteristics of the study communities and b)

356 identify households with age-eligible children for participation. Households with age-eligible
357 children were given a unique ID and additional information will be gathered including community
358 location, maternal education, number of children 0-5 years old, number of pregnant women and a
359 measure of household wealth.

360 **Monthly CHW surveys and shadowing**

361 Phone surveys will be conducted at baseline and monthly with 150 CHWs (two for each of
362 the 75 study communities) by trained enumerators. In addition to the phone/in person monthly survey,
363 enumerators will record all the activities and time spent by CHW on key work activities, including
364 different aspects of the ECD sessions (if in the treatment arms) during shadowing sessions. Originally
365 planned to be administered every other month, it will start as soon as the COVID-19 restrictions for
366 fieldwork are lifted. The data collected from these shadowing visits are meant to triangulate and
367 validate the self-report time use surveys administered over the phone/in person. The time shadowing
368 will be carried out by a trained enumerator accompanying the CHW during a workday (7am to 6pm).

369 **Community surveys**

370 Surveys will be conducted with two key informants (e.g. mayor, community chief, teachers,
371 doctor, religious leaders, etc.) in each community on a monthly basis to obtain information about key
372 community infrastructure, ongoing programs and events, the frequency and duration of local
373 economic/weather/other shocks, and information on market access, and prices of key commodities.
374 Key informants are identified by the CHWs in collaboration with the supervisors. Data collected from
375 these surveys will be used to control for community-level time-varying socio-economic shocks during
376 the study period that may affect our key outcomes of interest.

377 **Administrative monitoring data**

378 The main data source for caregiver-child dyad participation and engagement at the community
379 health center will be administrative data from a digital tool used to monitor health and nutrition
380 program activities (CommCare application) as part of their monitoring information system.

381 Individual data on participation in program activities are collected by the CHW on a paper monitoring
382 registry, as well as an ECD-specific monthly monitoring registry. The NGO supervisor during one of
383 the monthly visits to the community, enters the individual participation data contained in the registries
384 onto the CommCare application using the unique caregiver-dyad identification number provided by
385 the census.

386

387 *Outcomes*

388 The following primary and secondary outcomes will be collected:

- 389 • *CHW time allocation* (Primary outcome), measured through a 24-hour recall of time spent on
390 program related tasks (group nutrition sessions, home visits, treatment of illnesses,
391 administrative tasks, ECD group sessions, and toy maintenance), household chores,
392 productive activities, caregiving and rest/social activities. This will be measured at baseline
393 and monthly for 12 months through phone-surveys.
- 394 • *CHW psychosocial wellbeing* (Secondary outcome), measured through the monthly phone
395 surveys. Motivation and depression will be measured at baseline and every four months using
396 the short-form CES-D (22) and motivation scales (23) adapted to the Malagasy context and
397 the Rosenberg Self-Esteem Scale (24). Perceived stress will be measured monthly using the
398 Perceived Stress 7-Item Scale (PSS-7) (25).
- 399 • *Caregiver-child dyad participation in health and nutrition activities* (Primary outcome),
400 measured through the administrative data monthly. The range of program activities that are
401 collected range from monthly attendance to group promotion sessions and growth monitoring
402 sessions, indicators of whether they received home visit in last month, and whether they
403 received vitamin A supplementation, deworming and vaccinations (age-specific).
- 404 • *Caregiver-child dyad participation in ECD sessions* (Primary outcome), measured through
405 the administrative data monthly. Information ranges from number of ECD sessions attended

406 by caregiver-child dyad in last month and whether the children transitioned from one age
407 group to the subsequent one.

408

409 *Power Calculations*

410 **CHW Time Allocation**

411 We assumed repeated observations (baseline and 11 post implementation), with an auto-
412 correlation coefficient of 0.7 (high) or 0.5 (low) for the correlation between follow-up measurements
413 of CHW time allocation. We will control for baseline outcomes with an ANCOVA specification. We
414 adjusted for the clustering design effect on sample size with an adjustment of $(1 + \rho(m - 1))$, where ρ
415 is the intra-cluster correlation (ICC) and $m = 2$ CHW within community or cluster. We assume an
416 ICC of 0.2 and 0.3 on the activities performed by CHWs within a cluster, where an ICC=0.2 is
417 benchmarked on previous MAHAY CHW outcomes (26).

418

419 Using Stata Corp sampsi command, we performed sample size calculations with 80% power
420 for an expected effect size of 0.5 SD in a bivariate comparison. A conservative sample size is 25
421 clusters per study arm (Table 1).

422

423 **Caregiver-child dyad participation/take up**

424 Assuming participation comparisons between a minimum of 25 treatment and 25 control
425 communities (50 clusters), we modeled the minimum detectable effect (MDE) size using the software
426 package, Optimal Design (OD) Plus Version 3.01, for clustered randomized trials with repeated
427 measures. We will have administrative data for 40 eligible caregiver-child dyads per community
428 participating in the MCH&N programs at each of 12 time points. We assume an ICC ranging from
429 0.1 to 0.3 for participation of caregiver-child dyads in activities. Under these assumptions, we are
430 powered for MDEs ranging between 0.31 SD (ICC=0.1) and 0.47 SD (ICC=0.3).

431

432 *Sampling, stratification and randomization*

433 In order to capture efficiency gains from adjusting from observable differences in the design
434 of the randomized experiment, we conducted stratified sampling (27). We partitioned the covariate
435 space into 16 strata, with stratification criteria that included region (Amaron'i Mania and Haute
436 Matsiatra), remoteness of the community (above/below the median Euclidean distance to the closest
437 health center), population size of the catchment area (above/below median number of children in the
438 6-30 months old age range), and CHW education level (above/below secondary level of educational
439 attainment).

440 Within each of the 16 strata, we sampled six or 12 communities (one sextuplet drawn from
441 each of seven smaller strata and two sextuplets drawn from each of nine large strata) to create a set
442 of 25 sextuplets that are comparable along the stratification dimensions. Next, we randomly drew
443 three communities selected from each sextuplet and then assigned it to one of the three possible arms
444 (two treatment and one control group) for a total of 75 communities in the final sample. This sampling
445 approach ensures that each community has a cluster of comparable communities within its assigned
446 stratum and allows for up to three back up communities for the potential need for replacement in case
447 of refusal or drop-out by participating communities (27,28). All sampling and randomization were
448 done by key research personnel using standard and reproducible computer-assisted software packages
449 in Stata 16.

450 The random generation sequence and the random assignment of (i) communities to treatment
451 arms and of (ii) households in case of over-subscription in T and T+ will be performed by the research
452 team. Due to the nature of the interventions, it is impossible to blind participants to their intervention
453 group assignment. Interviewers will not be blinded as they will ask participants about their program-
454 related experiences. However, the data will be masked to group assignment during the data analysis
455 phase to blind the data analysts.

456

457 *Data Management*

458 Data collection will be conducted by the National Statistical Institute (INSTAT), which has
459 extensive experience in collecting household survey data in Madagascar. We will collect data with
460 Computer Assisted Personalized Interviews (CAPI) on Android tablets using Survey Solutions, a free
461 software platform.

462 For both survey and administrative data, subject key (identifiers and subject numbers) will be
463 kept in a secure separate location. Individual-level data collected from the census and administrative
464 sources will be shared with the research team for the purposes of analysis with each individual having
465 a unique respondent ID code. All documentation regarding the participants, including the consent
466 forms and questionnaires, will be identified using appropriate participant codes. All records will be
467 accessible only to approved survey firm personnel and research team members in password-protected
468 files. Researchers will also make no attempts to identify any individual caregivers or children through
469 a combination of any of the variables provided through this administrative data. In the event of a
470 breach of confidentiality, we also consider the potential harm to subjects to be minimal as we are not
471 collecting sensitive data.

472 *Statistical methods for primary and secondary outcomes*

473 **General analytic approach**

474 Primary analyses will be conducted on an intention-to-treat (ITT) basis.

475 Identification of causal impacts will rely on the random assignment of treatment at the
476 community level. The main impact of the program activities will be measured through a series of
477 pair-wise comparisons of mean outcomes between the study arms. However, it is possible that by
478 chance alone we will find a covariate imbalance between communities in different treatment arms
479 that could confound our estimates. Therefore, we will measure theoretically significant covariates at
480 the caregiver-child dyad level, CHW and community levels to include in a regression framework.

481 The potential for contamination or spillover effects for CHWs and caregiver-child dyads
482 across communities for the program is low, as communities are self-contained and provide services
483 to mothers and children registered in the local community.

484 **Parameters of interest**

485 Here, we describe the parameters of interest and introduce notation. Treatment, randomly
486 assigned at the community level, is represented by two arms: group ECD sessions (T), and group
487 ECD sessions + enhanced play materials (T+). The status quo, or control arm, is denoted by C. In
488 notation terms, the full set of potential assignment variants is given by $t = [C, T, T+]$. A set of individual
489 (CHW and/or caregiver-child dyad, depending on the outcome) level covariates, X , and community-
490 level covariates, V , will be used to adjust for imbalance that may occur by chance in the
491 randomization process. We also include the baseline value of the outcome of interest (Y_0) to improve
492 precision in our models. Below, we report the parameters of interest for the primary and secondary
493 research questions (reproduced below). Parameters that differ in outcome but not in notation by
494 research question are combined for simplicity.

495

496 *Primary Question 1: How does the integration of ECD activities into existing health and nutrition*
497 *responsibilities affect the time use and task allocation of CHWs?*

498 *Secondary Question 1: How does the integration of ECD activities affect measures of CHW*
499 *psychosocial wellbeing?*

500 *Primary Question 2: How does the integration of ECD activities affect participation by caregiver-*
501 *child dyads in all activities led by CHWs?*

502

503 The estimands are pair-wise comparisons of each intervention arm with the control arm, for
504 CHW or caregiver-child dyad outcomes. These comparisons are represented by the following
505 equation:

506

$$507 \quad E[Y|D=d, Y_0, X, V] - E[Y|C, Y_0, X, V], \text{ where } d = [T, T+] \quad (1)$$

508

509 *Primary Question 3: How does the availability of age-appropriate materials/activities for home-*
 510 *based play affect caregiver-child dyad participation in ECD activities?*

511 To understand how integration of toy boxes affects time/task allocation of CHWs or
 512 caregiver-child participation, we will do one pairwise comparison between the two intervention arms
 513 for this outcome. This comparison is represented by the equation below:

514

$$515 \quad E[Y|D=T, Y_0, X, V] - E[Y|D=T+, Y_0, X, V] \quad (2)$$

516

517 *Secondary Question 2: How is the treatment effect on caregiver-child dyad participation in health*
 518 *and nutrition activities moderated by key household and community characteristics?*

519 In order to estimate how the treatment effect obtained in Equation (1) for caregiver-child dyad
 520 participation is moderated by key individual and community-level characteristics, M, we use the
 521 following estimand:

$$522 \quad (E[Y|D=d, Y_0, X, V, M=1] - E[Y|C, Y_0, X, V, M=1]) -$$

$$523 \quad (E[Y|D=d, Y_0, X, V, M=0] - E[Y|C, Y_0, X, V, M=0]), \text{ where } d = [T, T+] \quad (3)$$

524 **Empirical specification**

525 We have two primary estimating equations, which we discuss below. The first (Eq. 4) is our
 526 main specification for comparisons between each intervention arm and the control group (Primary
 527 Questions 1 & 2, Secondary Question 1). These models will be used to estimate the impact on CHW
 528 outcomes (time use and motivation) and caregiver-child dyad outcomes (participation and
 529 engagement). All specifications will control for the method of randomization by including strata
 530 indicator variables, month fixed effects to account for time-varying unobservable (to the researcher)

531 factors, and correcting standard errors for clustering at the community level. For clarity, we reproduce
532 one set of equations here, but they can be applied to either CHW-level or caregiver-child dyad-level
533 analysis.

534 Let the outcomes of interest will be represented by Y_{ijt} , where the subscript refers to CHW
535 (caregiver-child dyad) i , in community j , at time t .

536 The main ITT impact of each intervention arm on the outcome of interest is estimated as
537 follows:

538

$$539 \quad Y_{ijt} = \alpha + \beta_1 T_j + \beta_2 T_{+j} + \gamma Y_{ij0} + \delta_1 X_{ijt} + \delta_2 V_{jt} + \theta_s + \lambda_t + \varepsilon_{ijt} \quad (4)$$

540

541 where T_j or T_{+j} are indicators for the random assignment of community j to treatment, Y_{ij0} are
542 baseline outcomes for CHW (or caregiver-child dyad) i (ANCOVA specification), X_{ijt} are CHW-
543 level (or caregiver-child level) covariates (e.g. age, gender, education level), are V_{jt} time-varying
544 community-level characteristics (e.g. shocks, prices/wages), θ_s are strata fixed effects
545 (randomization triplet fixed effects), λ_t is a set of month fixed-effects, and ε_{ijt} are error terms
546 clustered at the community level.

547 β_1 and β_2 represent the average impact of being assigned to T or T+ over 12- and 6-month
548 periods, respectively, relative to the control group. Testing primary question 1 and primary question
549 2 is equivalent to testing whether ($H_0 : \beta_1 = 0$ and ($H_0 : \beta_2 = 0$)).

550

551 To address Primary Question 3, we restrict the sample to the communities that are offered any
552 ECD intervention (T or T+) and estimate the following equation:

553

$$554 \quad Y_{ijt} = \alpha + \beta_2 T_{+j} + \gamma Y_{ij0} + \delta_1 X_{ijt} + \delta_2 V_{jt} + \theta_s + \lambda_t + \varepsilon_{ijt} \quad (5)$$

555

556 These analyses will occur in a restricted sample of only communities where $T = 1$ or $T+ = 1$.
557 Here, testing ($H_0: \beta_2=0$) is allows to test whether being assigned $T+$ provides any additional benefit
558 over and above T .

559 **Subgroup analyses**

560 For Secondary Question 2, subgroup analysis will be carried out by documenting the
561 differential impact of the two interventions along key household and community-level characteristics.
562 We will estimate heterogeneity on the pooled treatment arms interacting the characteristic of interest
563 with the treatment variable, as well as explore the use of recent developments in machine learning
564 methods (29).

565 **Missing data**

566 Multiple imputation by chained equations will be used for missing covariate and baseline
567 outcome information. Sensitivity analyses will be performed with and without imputation (30).

568 **Interim analyses**

569 Since the ECD curriculum is designated for a specified time period per age group and the
570 intervention does not present any risk to the enrolled population or beneficiaries of the intervention,
571 there are no formal rules for stopping this trial. Data will be reviewed and analyzed monthly,
572 including monitoring the implementation and fidelity of the intervention. If any adverse event,
573 whether related to the intervention or not is reported to the local NGO or U-PNNC, the research team
574 and relevant regulatory bodies will be notified to examine the severity or seriousness of the event.

575

576 *Provisions for post-trial care*

577 There are no anticipated direct benefits or harms for participation in the trial or after the trial
578 has ended. All caregivers that participated in the session, as well as other community members will
579 continue to have access to receive the benefits of the government nutrition program (standard of care

580 provided to the control arm), and the treatment arm will continue to receive standard of care after the
581 intervention has ended. Incorporation of results from the current study will feed back into the redesign
582 of the integrated package by U-PNNC to be further tested or scaled up in the next phase of the project.

583 We used the SPIRIT checklist to design the structure of the protocol. (30)

584 **DISCUSSION**

585 The overall objective of the study is to examine the effects of integrating ECD group sessions
586 into the existing, at-scale, community health and nutrition programs administered by the government
587 in Madagascar. To achieve these objectives, we will use a cluster randomized controlled trial design
588 with three arms: a control group, with the status quo, a community-based health and nutrition
589 program; a treatment arm with the addition of fortnightly group ECD sessions, based on Reach Up
590 and Learn curriculum and supportive behavioral nudges, to the status quo; and an enhanced treatment
591 arm, where the intervention in the treatment arm is layered with the provision of individual toy boxes
592 including age-appropriate toys. The results from the trial will provide the evidence base required to
593 implement an integrated package of nutrition, health and ECD promotion activities at scale in
594 Madagascar, and findings may also be relevant in other low-income countries.

595

596 *Trial status*

597 As of March 2021, all participants have been recruited, the baseline survey has been
598 conducted, and the interventions has been assigned and implemented, and will conclude in February
599 2022.

600

601 *Declarations*

602 ***Ethics approval and consent to participate:*** This study was reviewed and approved by UC Berkeley's
603 Committee for the Protection of Human Subjects (UCB CPHS). The protocol number is 2019-08-

604 12476. All participants that were surveyed provided informed consent prior to data collection. Any
605 modifications to the protocol will be communicated to the relevant parties, including UCB CPHS.

606 ***Consent for publication:*** N/A

607 ***Competing interests:*** None.

608 ***Funding:*** The project is funded by the Strategic Impact Evaluation Trust Fund (SIEF), and the Early
609 Learning Partnership (ELP). The SIEF funding covers study design, survey data collection and
610 analysis. The ELP funding supports enhanced training and monitoring activities that will measure
611 implementation fidelity and ensure the provision of a high-quality parenting support intervention for
612 all study communities. Implementation costs are covered by the National Nutrition Program (U-
613 PNNC) in Madagascar. The funders did not have role in the study design or data collection.

614 ***Availability of data and materials, plans to give access to the full protocol, participant level-data
615 and statistical code:*** In accordance with the World Bank’s Open Data and Knowledge Initiative, the
616 deidentified data collected in the study will be made publicly available at the data repository at the
617 World Bank, which is expected to be within 24 months of the final data collection date. Metadata and
618 critical documents (i.e. protocols and questionnaires) will conform to the standards of the Data
619 Documentation Initiative and will be made available within one year of the end of data collection.

620 ***Authors’ contributions:*** EG is the chief investigator and led the conceptualization, methodology, and
621 supervision of the study. LCHF and AW also contributed to the conceptualization and methodology
622 of the study. LR led the design, pre-testing and adaptation of the Reach Up curriculum, as well as the
623 training of the CHWs. AW and EG led the sample size calculations and randomization, with
624 contributions from MC and MD. CH, MD, and MC are involved in project administration and
625 contributed the writing, reviewing and editing of the manuscript, with significant contributions from
626 AW, LCHF, and EG. NR and VR are involved in the design and project administration.

627

628 **Acknowledgements:**

629 We are grateful for the contributions of the Association ECD-Mizarasoa, Christian Tsirery as
630 well as the Human Centered Design team and Scouts in Madagascar.

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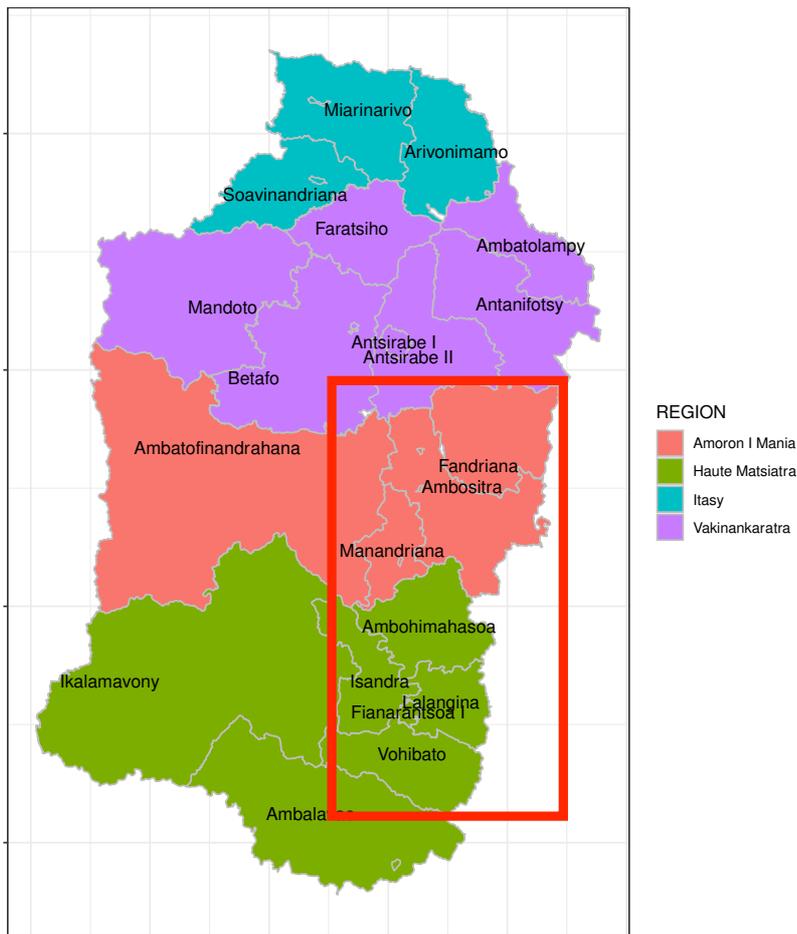
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721 Figure 1. Map of districts in Madagascar.

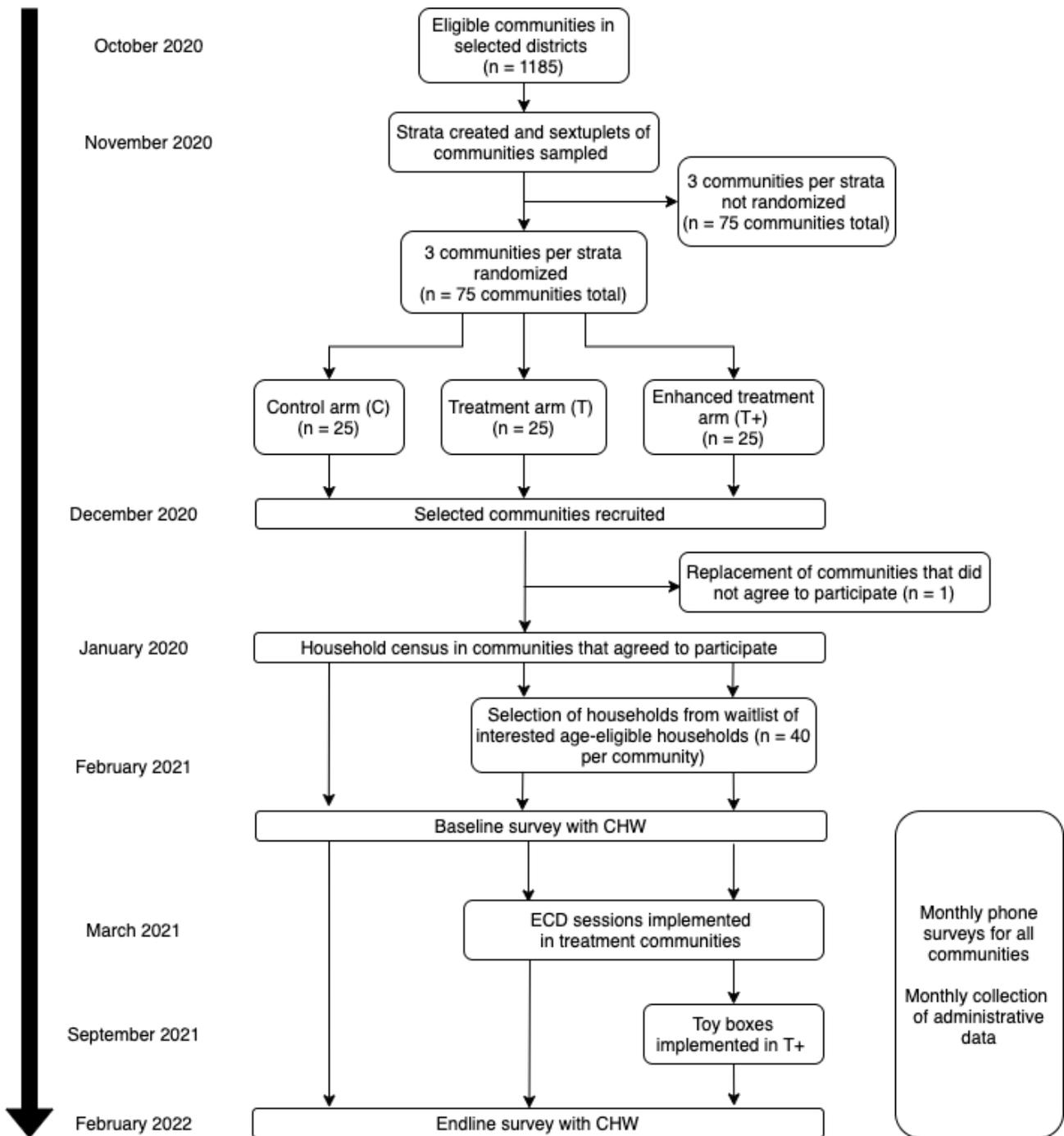


722

723 Note: Study will take place in the regions of Haute Matsiatra and Amoron i' Mania, excluding the
724 districts of Ikalamavony and Ambatofinandrahana.

725

726 Figure 2. Flow of study implementation



727

728

729

730

731

732

733 Table 1. Sample size calculations: number of clusters per study arm

	Autocorrelation coefficient	
	High (0.7)	Low (0.5)
ICC = 0	15	19
ICC = 0.2	18	23
ICC = 0.3	20	25

734

Figures

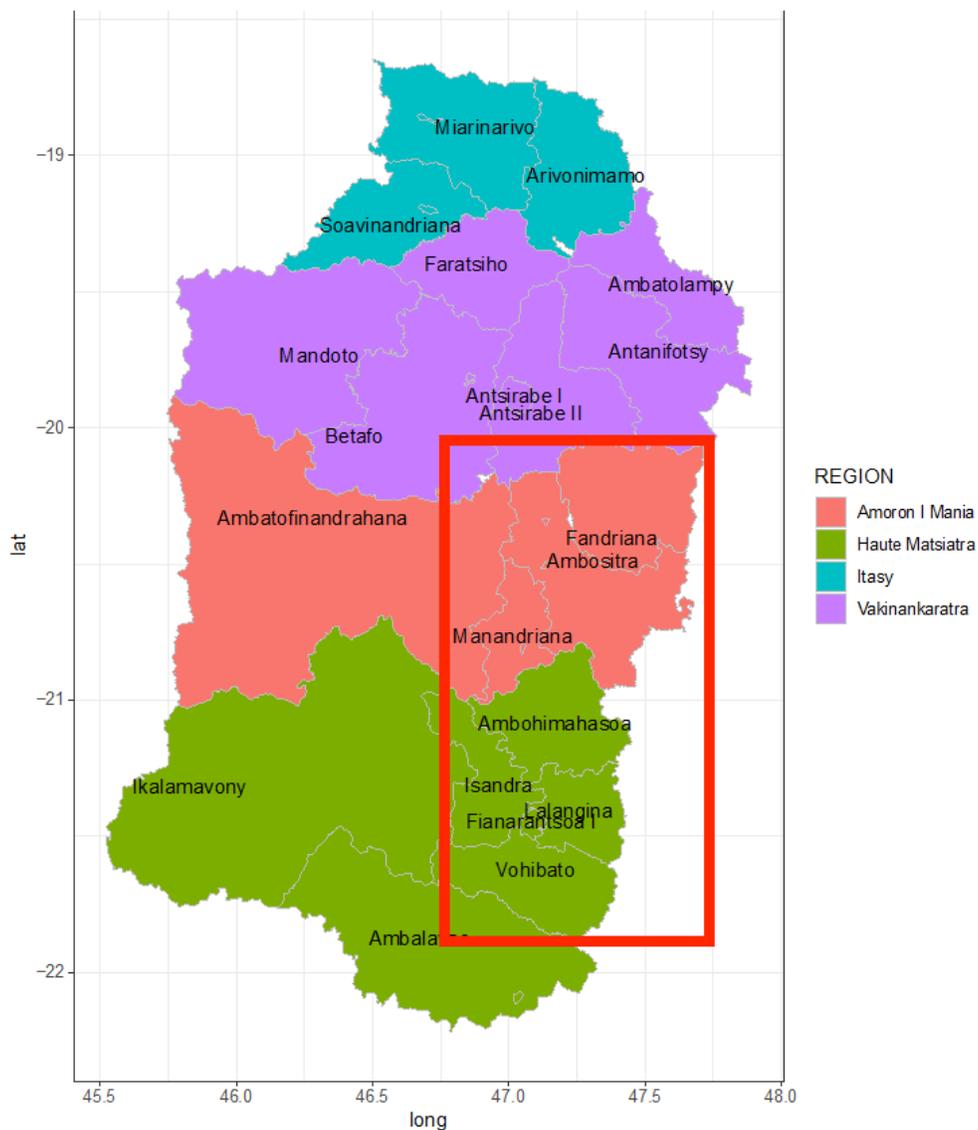


Figure 1

Map of districts in Madagascar. Note: Study will take place in the regions of Haute Matsiatra and Amoron i'Mania, excluding the districts of Ikalamavony and Ambatofinandrahana. Note: The designations employed and the presentation of the material on this map do not imply the expression of any opinion whatsoever on the part of Research Square concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. This map has been provided by the authors.

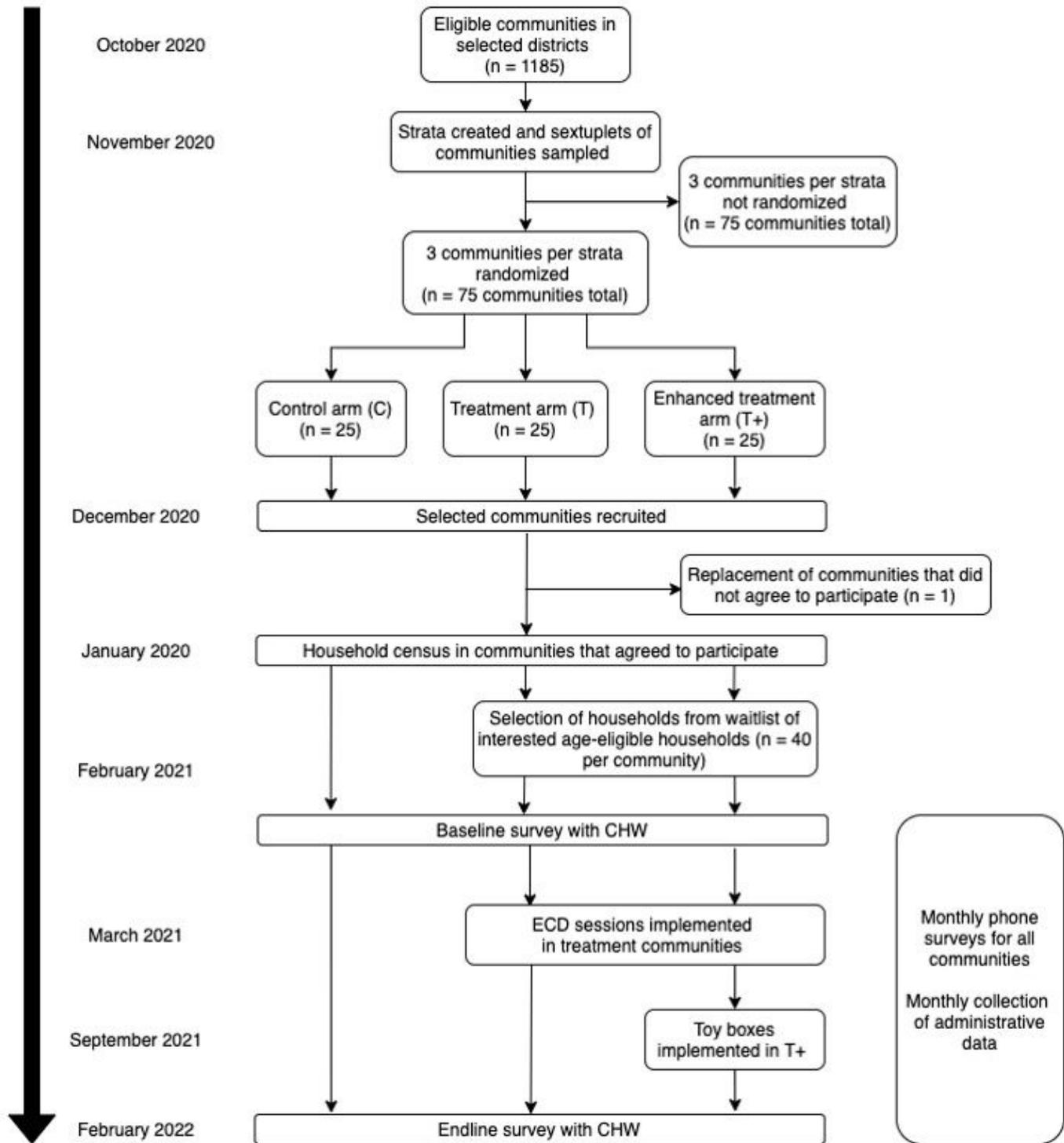


Figure 2

Flow of study implementation

Supplementary Files

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- [MAHAYMikolocompletedSPIRITchecklist.docx](#)