Semillas de Apego - Pre-Analysis plan amendment

Progress by March 2020, disruptions due to COVID-19, and proposed strategies.
April 20, 2020

This note summarizes an amendment to the empirical analysis and data collection due to the COVID-19 pandemic. It applies to the following registries:

- AEA Registry # 2868
- Clinical Trials Registry NCT03502252

1. Progress up to March 2020.
Between March 2018 and November 2019, we implemented the program over 4 sequential cohorts with 1,375 subjects in total; 713 assigned to the treatment arm (52% of participants) and 662 to the control arm. These figures imply that we enrolled 85 subjects above our initial target of 1,280 subjects (a 7% difference). We also completed all three waves of data collection (baseline, followups 1 and 2) for Cohorts 1 and 2, as well as the baseline and first followup for Cohorts 3 and 4.

2. Disruptions due to COVID-19.
The COVID-19 pandemic disrupted in-person field work for final follow-ups for Cohort 3 and 4. We already postponed field-work to collect the final follow-up for Cohort 3, which was scheduled to take place between the 13th and the 30th of April, and cannot guarantee that we will be able to collect the final followup for Cohort 4 as scheduled, starting in mid June.

We plan to collect the remaining data for Cohorts 3 and 4 as soon as it is safe for our team to travel to the field site and for the subjects to interact with us. However, there is a chance that the pandemic does not subside and that we will not be able to collect the data in the near future, especially considering the vulnerability of the population and the lack of public and medical services in the municipality.

In fact, children and families in our study are already experiencing hardships and additional sources of stress due to the nation-wide lockdown. Closure of all ECDC in the municipality implies that children lost access to the food provided by the centers, and families now have to take care of their children throughout the day, often in overcrowded and precarious housing. As a result, children are now much more reliant on their caregivers and families for healthy child-parent attachments

to meet their development needs. However, caregivers are under severe stress. The threat and uncertainty generated by the pandemic, the loss of income, and the additional child-rearing responsibilities throughout the day can overwhelm caregivers and compromise their ability to respond to the emotional needs of their children, leaving them more vulnerable to toxic stress, neglect, malnourishment, and violence. These are precisely some of the factors (beyond the direct of violence) that motivate the theoretical design of our curriculum.

We thus anticipate that the COVID-19 pandemic will affect our study in different ways. First, there is a possibility that we will not be able to collect the final followup data for C3 and C4. Second, even if we are able to collect this data, it will not be entirely comparable to that of Cohorts 1 and 2 as it will be collected at a later time, but more importantly because the pandemic can attenuate or cancel any positive impacts for subjects in the treatment arm of Cohorts 3 and 4. Both scenarios compromise our ability to assess the impact of the program in the final followup. As specified in the original PAP, this is the more interesting and relevant time frame for our analysis since it is where we expect impacts on early-childhood development and where we can analyze the persistence of the program's impacts on maternal mental health in a context of protracted conflict and concurrent trauma.

3. Proposed strategies and amendment to the pre-analysis plan.
We are adopting the following two strategies to respond to the COVID-19 pandemic and modifying PAP as follows.

First, the empirical analysis of the impact evaluation will be based on the data collected for Cohorts 1 and 2 (N=572) . As discussed above, we completed all activities for these two cohorts before the onset of the pandemic. Therefore, these two cohorts provide the cleanest sample for the analysis (not affected by the pandemic) and allow us to assess both the effects of the program in the short run (at first followup) and medium run (at second followup). The downside of this strategy is that we will have a lower statistical power. Using the same parameters from the original power calculations, we estimate to have a statistical power of 0.63 to identify effect of 0.3 standard deviations without accounting for any gains due to covariate adjustment.

Second, we are currently administering a short (20 minute) phone-survey with subjects in Cohorts 3 and 4 to observe participant's current circumstances; i.e. at the start the pandemic and lockdown in our study site. The survey includes our standard questionnaires/scales on 3 out of the 4 main dimensions of our study: maternal mental health, stress in the child-parent relationship, and

frequency of quality of child-rearing interactions. Unfortunately, we won't be able to assess Early Childhood Development since this requires a battery of in-person tests. In addition, the survey includes a short module on different dimensions that are being affected by COVID-19 (food, income, housing, public services) and how families are responding. The survey is being implemented between the 8th and 22nd of April, and was deemed exempt by the IRB at Universidad de los Andes.

Third, we plan to collect the final followup data for Cohorts 3 and 4 when the pandemic subsides. We will then use the entire data for all four cohorts as an extension of our analysis; specifically to assess whether the results of the main analysis (any non-significant effects) are explained by a lack of statistical power. If we cannot collect this data in an appropriate time frame, we will conduct this analysis by pooling the data collected in person for Cohorts 1 and 2 with the data collected over the phone for Cohorts 3 and 4.

Fourth, we will use the data from the phone survey and from the final followup of Cohorts 3 and 4 (if it is possible to collect it) for two additional analysis: 1) To understand how families are being affected by the onset of the pandemic and how they are coping with this crisis; and 2) To analyze whether subjects who participated in the program are better able to navigate and respond to this crisis, or whether the crisis attenuated the positive effects that we are observing following a descriptive analysis for the first two cohorts. This will allow us to assess the impacts and effectiveness of the program, but also its ability to repair the negative effects of violence on maternal mental health and early childhood development, but also on whether it allows families to better respond and cope with other shocks and vulnerability.

Finally, we will also use within-treatment variation in the time at which subjects in the treatment arm were invited to participate in the program. Recall that we rolled-out the program over 4 sequential Cohorts and that in treated ECDC we randomly assigned families to participate in 1 of the 4 cohorts. This rollout allows us to estimate the short and medium run effects of the program by comparing subjects from earlier cohorts (who completed the program 1 or 8 months ago), with those from latter cohorts (who completed the baseline and were ready to start the program). This strategy has the advantage of higher statistical power, as it is not based on the cluster assignment, and therefore allows us to further investigate whether the results of the main analysis are driven by the lower statistical power of the cluster-based analysis over 2 cohorts.

4. Additional ammendent.
We collected the final followup 8 months after the program's conclusion instead

of the 12-month followup that was originally planed and registered. We made this change for all Cohorts so that we could better track the children and families in the study and lower attrition rates. In the 12-month followup, over 60% of the children would have already transitioned out of the ECDC. By contrast, at the 8th-month followup, 80% of children would still be enrolled in the ECDD, while still allowing an appropriate period of time for the positive effects of the program on early childhood development to materialize.