

# PRELIMINARY AND CONFIDENTIAL FINDINGS OF THE OUTCOME EVALUATION

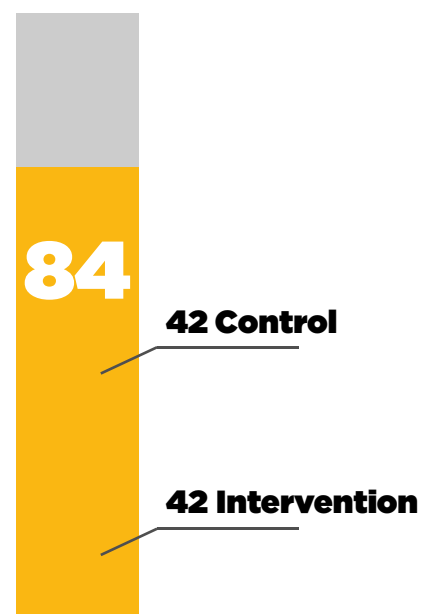
Learning clubs to improve women's health & infant's health and development in Vietnam: a cluster randomised controlled trial to inform scale up (TTS-1803-22331)



## 1. INTRODUCTION

This report presents key confidential and preliminary findings of the primary and some secondary outcomes **of the Learning clubs to improve women's health & infant's health and development in Vietnam: a cluster randomised controlled trial to inform scale up** (TTS-1803-22331) jointly funded by Grand Challenges Canada under the Saving Brains Initiative and by the Australian National Health and Medical Research Council. The Project was implemented in 84 of the 112 communes in Ha Nam province. Among these, 42 communes were randomly assigned by an independent statistician to the control arm providing usual care and the other 42 to the intervention arm, which included usual care plus the Learning Clubs program. All women aged at least 18 years, pregnant and less than 20 weeks' gestation based on the first day of their last menstrual period, living in the selected communes, were eligible. In total, 1245 pregnant women from 84 clusters were recruited to participate.

**112**  
Communes



The Learning Clubs intervention (new name: Early Journey of Life) is a structured program combining perinatal stage-specific information, learning activities and social support. It comprises 20 sessions, in 19 accessible, facilitated groups for women at a community centre (every two weeks from mid-pregnancy and every four weeks after childbirth until the end of the first postpartum year) and one home visit (during the first postpartum week). Evidence-informed content is drawn from interventions that have been established as effective in ameliorating one of the risk factors in randomised controlled trials in other resource-constrained settings and local maternal and child health policies. Content has been translated and culturally adapted for Vietnam and acceptability and feasibility established in pilot testing.

This outcome evaluation was conducted by 2 independent teams, the clinical and educational psychologists from the Green Pine Clinic and the public health workers from the Division of Health Promotion and Education of the Centre for Disease Control, Ha Nam province. The outcome assessors were blind as to which arm of the trial the commune had been assigned to.

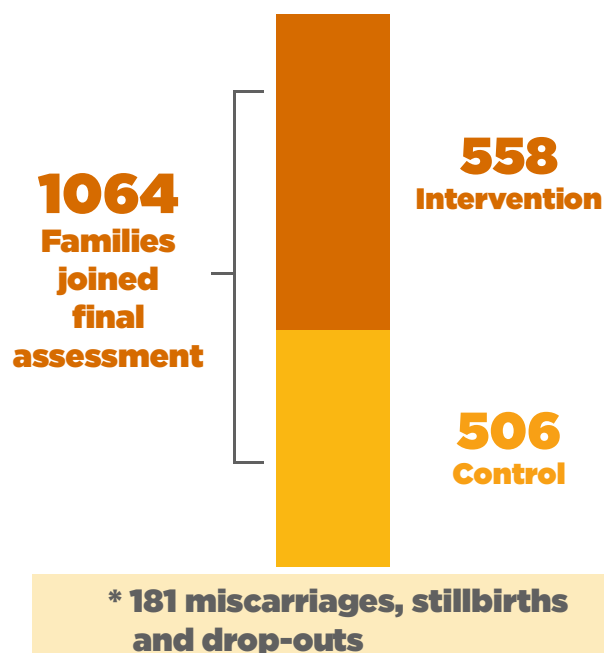


## 2. METHODOLOGY

The assessment of trial outcomes focused on the effectiveness of an 18-month, 20-session structured, facilitated group intervention (Learning Clubs) for women's health and early childhood development in reducing deficient cognitive development among two-year old in rural Vietnam. The primary outcome is the prevalence of deficient cognitive development among two-year-old established using the international gold standard, the Bayley Scale of Infant and Toddler Development version III.

The secondary outcome is the rate of being underweight among children and the mediator indices are parent behavior scores assessed using the HOME inventory and improvement in maternal mental health.

This report presents preliminary findings from the full dataset of the child assessment (N=1064 children) and a sub-set of parent interviews (N=707). The parent assessments are on-going and expected to be completed by mid-November 2020. These preliminary analyses have been conducted on the basis of intention to treat and include data from all participants, whether or not they attended the Learning Clubs program. All analyses presented here are unadjusted. Further analysis will be provided in December 2020 when all outcome assessments, including analysis of blood samples have been completed.



### 3. INNOVATION OUTCOMES

#### Primary Outcome: Child Development

- Children in the intervention arm had on average, statistically significantly **higher Cognitive, Motor and Language Development scores** than those in the control arm.
- The Social-Emotional Development score was higher in the intervention than the control arm, but the difference did not reach statistical significance.

|  | Intervention<br>N=558 | Control<br>N=506 | Difference<br>(Intervention -<br>Control) | P-Value |
|--|-----------------------|------------------|---|---------|
| <i>Bayley Score (Mean)</i>                 |                       |                  |   |         |
| Cognitive Sub-scale Composite score        | 99.62                 | 95.42            | 4.20                                      | <0.001  |
| Motor Sub-scale Composite score            | 103.98                | 101.11           | 2.87                                      | <0.001  |
| Language Sub-scale Composite score         | 99.42                 | 96.85            | 2.57                                      | 0.002   |
| Social-emotional Sub-scale Composite score | 102.3                 | 101.81           | 0.49                                      | 0.74    |

#### Secondary Outcome: Child Anthropometric indices

- The rate of **being severely underweight** (Weight-for-age z score <-2) at 24 months of age among the intervention cohort was **significantly lower** than in the control cohort (2.3% vs. 4.6%, with p-value<0.05)
- There was no statistical significance between the intervention and control group with regard to stunting and wasting indices, but the data have not yet been adjusted for birthweight.

#### Mediator Indicators

- The HOME Inventory, is designed to assess the amount, availability and quality of sources of stimulation, practical and emotional support, structure and safety available to a particular child in their home environment. Although data are only available so far for about half the families in each arm of the trial. The preliminary findings are that the **HOME Inventory scores are significantly higher for the intervention** than the control arms.
- It appears on the basis of this preliminary and unadjusted comparison that the dimensions (reflected in subscale scores) that are significantly different: responsive care, learning materials, parental involvement and variety of activities, each a focus of the Learning Club innovation have been influenced positively.
- There were no differences in the acceptance and organization scores, but we are not able to interpret these until the full dataset is available.

|                                    | Intervention<br>N=325 | Control<br>N=382 | Difference<br>(Intervention -<br>Control) | P-Value |
|------------------------------------|-----------------------|------------------|---|---------|
| <i>HOME Inventory (Mean)</i>       |                       |                  |   |         |
| Total scale score                  | 36.40                 | 34.33            | 2.07                                      | <0.001  |
| Responsivity sub-scale score       | 9.82                  | 9.19             | 0.63                                      | <0.001  |
| Acceptance sub-scale score         | 6.69                  | 6.73             | -0.04                                     | 0.51    |
| Organisation sub-scale score       | 5.52                  | 5.53             | -0.01                                     | 0.83    |
| Learning Materials sub-scale score | 6.57                  | 5.88             | 0.69                                      | <0.001  |
| Involvement sub-scale score        | 4.57                  | 4.22             | 0.35                                      | <0.001  |
| Variety sub-scale score            | 3.25                  | 2.82             | 0.44                                      | <0.001  |

- We are not yet able to calculate changes in the maternal mental health indicators from pregnancy to two years because the data sets will not be merged until the full endline data have been collected and the data set cleaned and checked.

#### 4. CONCLUSIONS

Although these are preliminary and unadjusted comparisons of an as-yet incomplete dataset, they provide promising indications that the Learning Clubs program has been successful in achieving its primary goal which is a significant improvement in the cognitive development of children at the age of two years in a rural province of northern Vietnam. There are also indications that the secondary outcomes of other developmental domains, including language and motor development are significantly better among children in the intervention than the control condition. have been collected and the data set cleaned and checked.

Impact on child growth is less easy to interpret because the outcomes are not yet adjusted for birthweight and gestational age. It appears from these data however, that rates of being severely underweight are significantly lower in the intervention than the control arm.

One mediating mechanism has been investigated and, acknowledging that it is on a subset (about 50%) of the data, the preliminary indication is that the home environment of children in the intervention arm is significantly better in terms of access to learning materials, responsive care, and parental involvement than in the control arm indicating that the Learning Clubs' program has been effective in changing caregiver's behaviours.

Overall we interpret these preliminary analyses as providing highly positive indications that the intervention has been beneficial to early childhood development. At present the data are confidential and cannot be released, but we look forward to informing Grand Challenges Canada of the final outcomes once the full data set has been completely analysed.



For more information about the project, please contact:

Ms. Ha Tran at [ha.tran@rtccd.org.vn](mailto:ha.tran@rtccd.org.vn), the Research and Training Centre for Community Development Vietnam (RTCCD)

Prof. Jane Fisher at [jane.fisher@monash.edu](mailto:jane.fisher@monash.edu), Monash University Australia