

# Insika Yomama - A Cluster Randomised Controlled Trial: An evaluation of a combined psychological and parenting intervention for HIV-positive women depressed in the perinatal period, to enhance child development and reduce maternal depression



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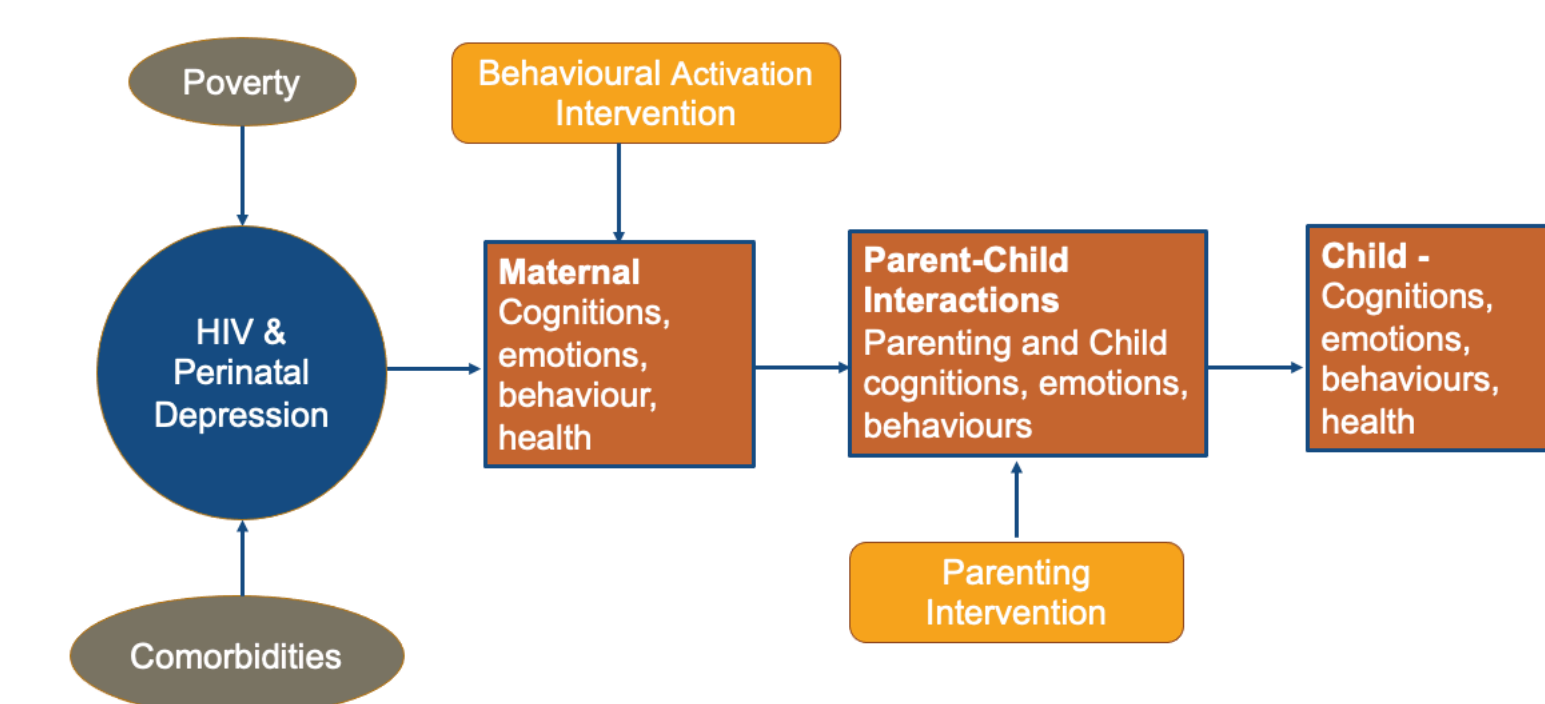
## Background

- High prevalence of perinatal depression amongst HIV-positive women in Sub-Saharan Africa
- Large unmet need for cost-effective, context-sensitive treatments.
- Adverse maternal and child outcomes in context of depression and HIV:
  - Maternal** - Low ARV adherence and clinic attendance, increased viral load, adverse pregnancy outcomes
  - Child** - Reduced cognitive and language development, behavioural problems, growth delays.

## Intervention & Enhanced Standard of Care (ESoC)

- Intervention:**
- 10-home based sessions delivered by lay-counsellors (4 antenatal, 6 postnatal), 1 booster at 16 months
  - Therapy** – Two evidence-based interventions:
    - Behavioural Activation** for depression
    - Parenting programme** adapted from UNICEF/WHO Care for Child Development
- ESoC**
- 4 Counselling Support and Advice Calls delivered by lay-counsellor (2 antenatal, 2 postnatal)
  - ESoC Package** – Support, brief advice and information provision about referrals and health services.

## Basic Model of Intervention

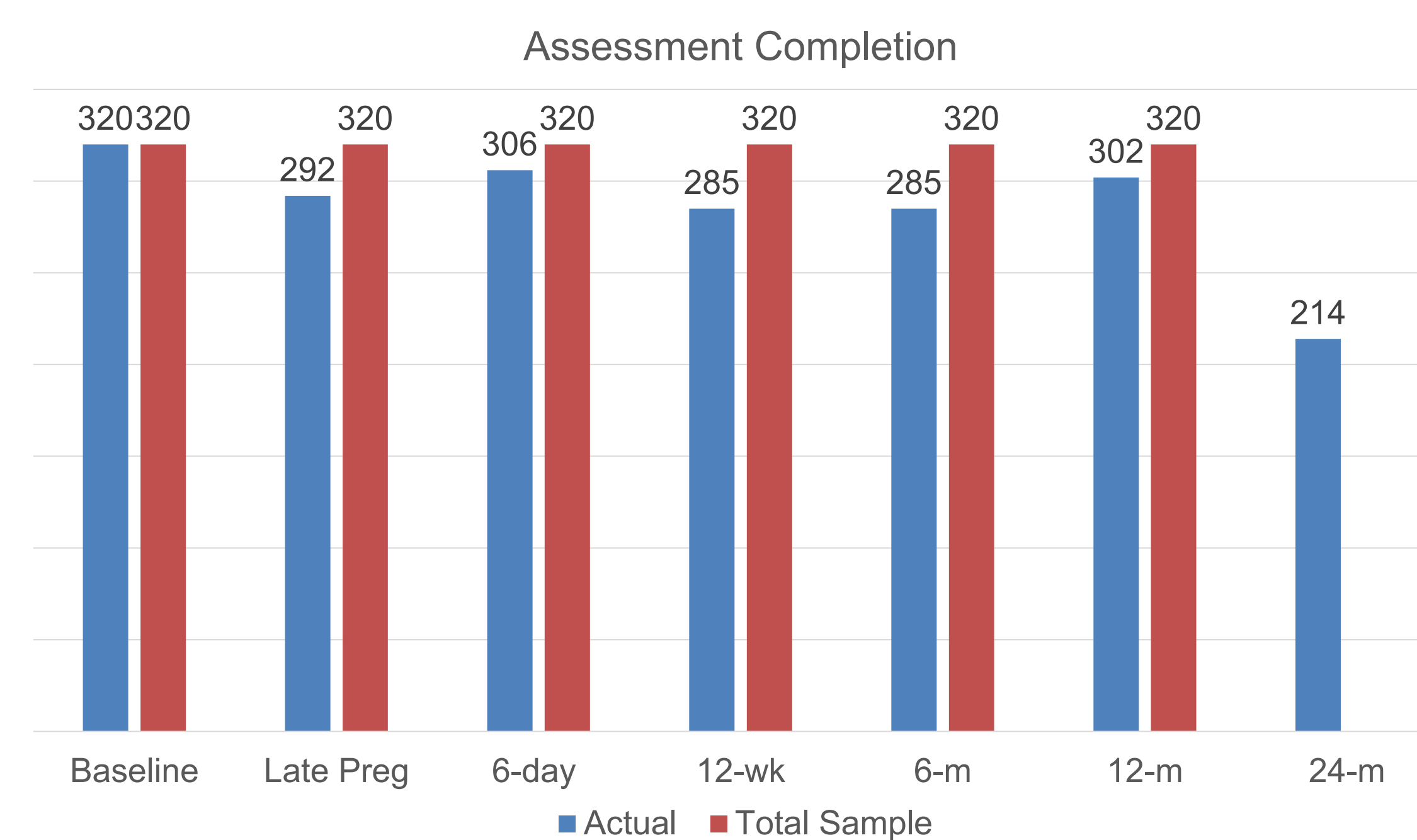


## Objectives – To identify if the intervention compared to ESoC:

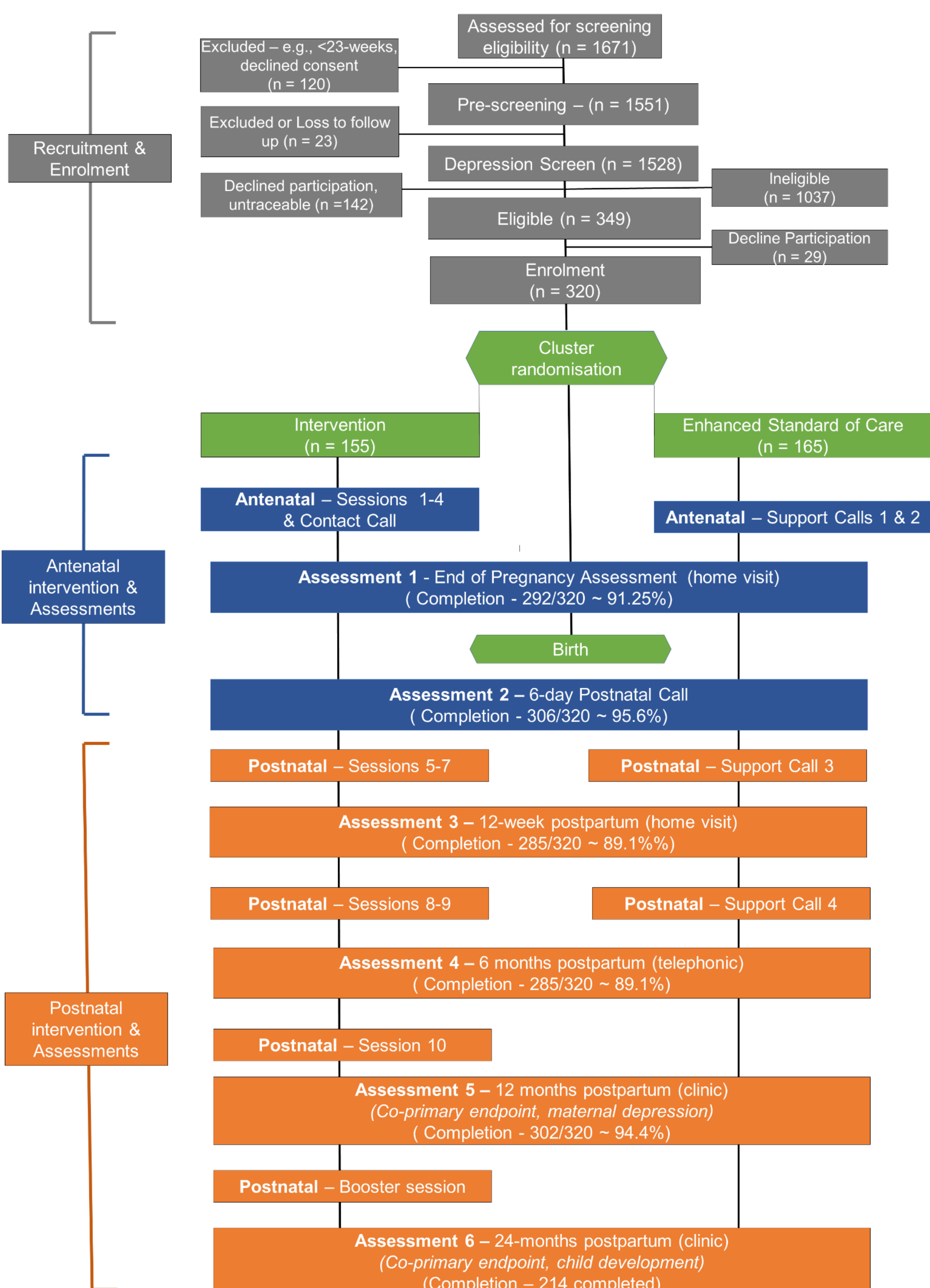
- Primary:**
- Reduces maternal perinatal depression at 12-months
  - Improves child cognitive development at 24-months
- Secondary:**
- Improves maternal depression over trial period.
  - Improves maternal anxiety over trial period.
  - Increases maternal adherence to Antiretroviral over the trial period.
  - Increases rates of exclusive breastfeeding to six months postnatal.
  - Improves adherence to infant immunisation during first 24-months
  - Reduces diarrhoea over the postnatal period
  - Improve the quality of infants' cognitive and emotional stimulation within the home environment at 12 and 24 months.
  - Reduces child behavioural difficulties at 12 and 24 months.
  - Improves child language development at 24 months.
  - Improves child growth at 24 months.

## Current Status of the trial:

- Therapy** - All therapy sessions completed, except a few outstanding booster sessions due February 2023.
- ESoC** - All ESoC calls completed.
- Assessments** – All assessments, including the 12-months, have been completed (94% retention). The 24-month assessment is underway with over 2/3 completed.
- Trial Evaluation Components** – Therapy Fidelity Evaluation Completed, Qualitative Evaluation and Health Economics Analysis in progress.



## Participant Flow



## Therapy Adaptation to telephonic delivery during COVID-19

### Adaptation

- Therapy package condensed and adapted to telephonic delivery following lockdown
- Most telephonic sessions were postnatal sessions.

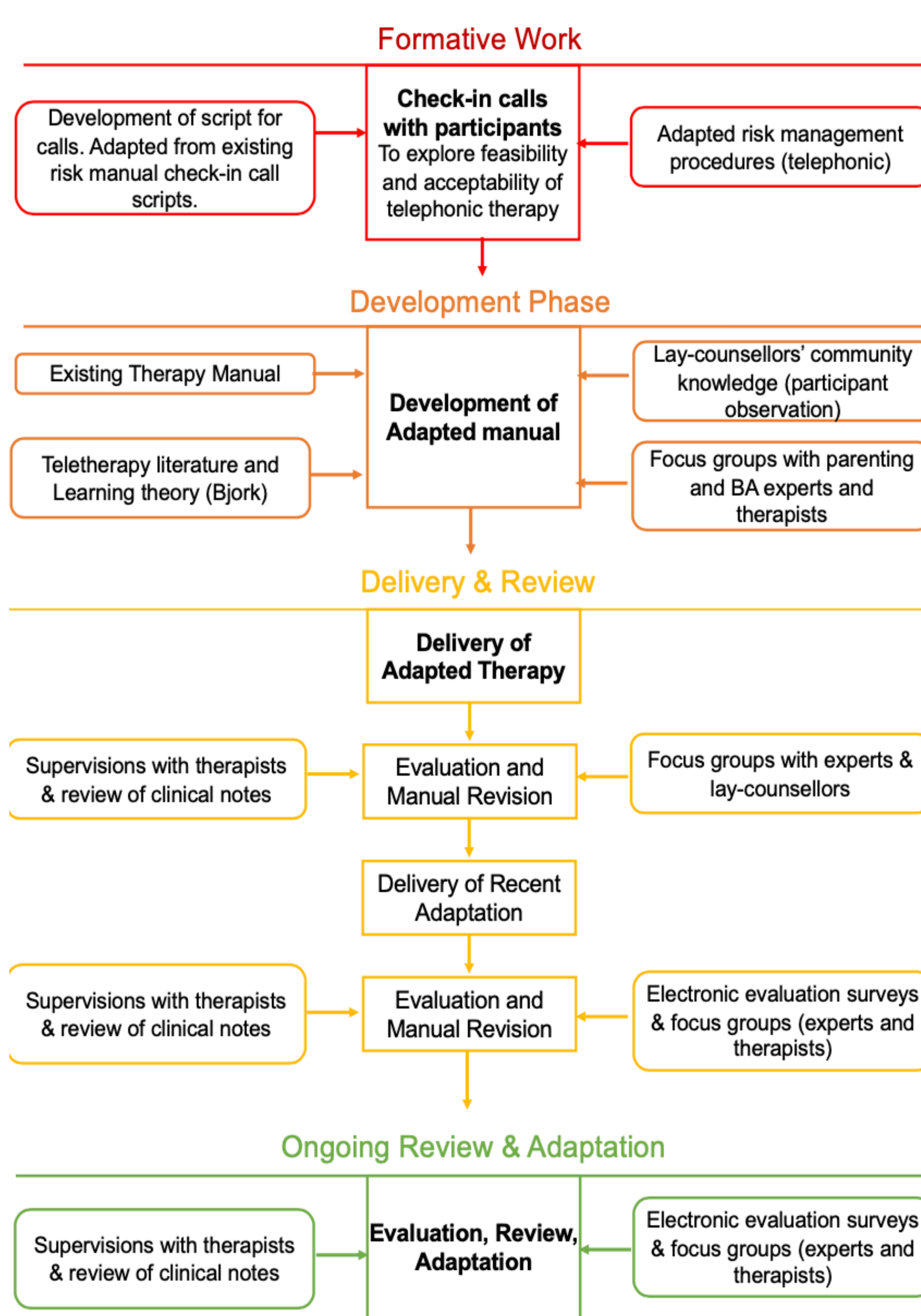
### Advantages:

- High level of uptake (therapy retention rates remained high, 111 participants had at least 1 telephone session).
- Acceptable
- Therapy principles maintained (fidelity to the original therapy manual was high)
- Flexibility – time, location, reduced transport costs for therapists.
- Some participants found telephone therapy more palatable than in-person therapy.
- Some difficult to reach and/or participants who had moved outside the study area were re-engaged.

### Challenges:

- Acceptability of telephone therapy linked to having had prior in-person sessions (enhanced learning and relationship-building environment)
- Structural – e.g., network, airtime, sound quality, privacy.
- Some therapy elements difficult to deliver – e.g., some parenting modules; lack of direct observation of the mother-infant interactions; handouts were not delivered.

**Future** - Potential for use and testing in future trials



## Conclusion

### Trial Contributions:

- First cluster RCT to holistically address both maternal and child health in the context of HIV and depression in Sub-Saharan Africa.
- Novel therapy package based on two evidenced based interventions to reduced depression and promote child development through parenting.
- First cluster RCT to use task-shifting (lay-counsellors) to deliver an intervention to promote maternal and child health in the context of depression and HIV.

### Preliminary findings:

- High levels of co-morbidities of health and psycho-social risks with HIV and depression, including poverty, domestic violence, food insecurity, TB, and substance abuse.
- Evaluation of the fidelity of the delivered therapy package suggest high compliance with the therapy manual.
- Initial qualitative findings underline the need for psychological interventions in the community given a large unmet need.

