

Short term functional motor outcomes during high risk infant follow up through telerehabilitation

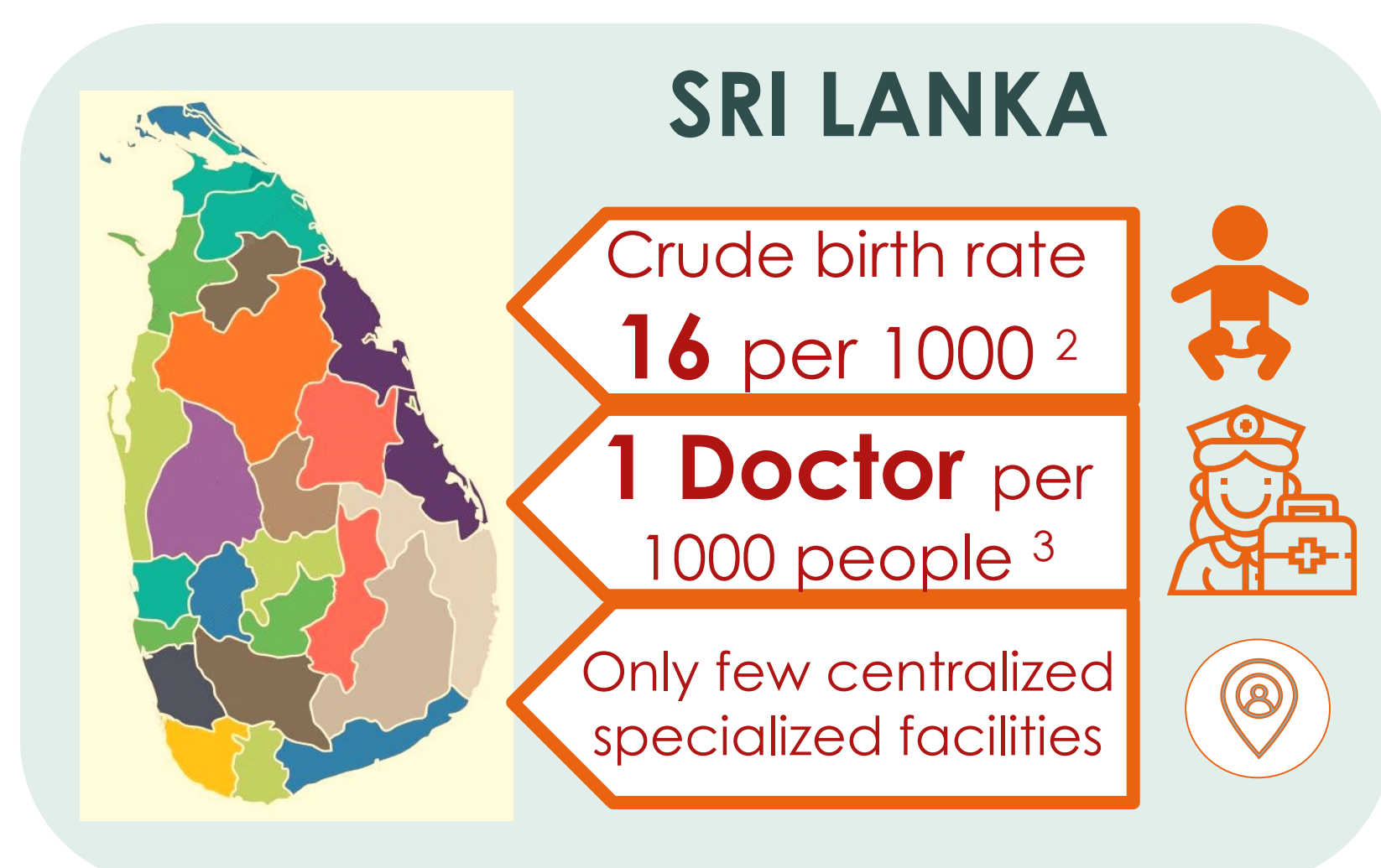
A protocol paper for a randomized control clinical trial

Vipulaguna DV¹, Madushika HT², Kumarendran B², Sumanasena SP²

¹Postgraduate Institute of Medicine, Sri Lanka, ² University of Kelaniya, Sri Lanka, ³University of Jaffna, Sri Lanka



Cerebral Palsy is a leading cause of disability among children
Regional prevalence of cerebral palsy (CP) is **3.4 per 1000** children ¹



High-risk infant follow-up (HRIF) programs provide the early identification, neurodevelopmental follow up and necessary referrals for neurodevelopmental delays and impairments to high-risk infants.

Early cognitive and active motor interventions during infancy are effective in the infants at high risk of CP ^{4,5,6}

Telerehabilitation is an alternative method of delivering conventional rehabilitation services by provision of services to patients at a remote location using information and communication technologies.



General Objective

To compare the short term functional motor outcomes of early interventions between telerehabilitation and conventional follow up in infants in HRIF program in multidisciplinary clinic at Ayati Centre, Sri Lanka

Secondary Objectives

- To compare daily functional performances between telerehabilitation and conventional follow up in children enrolled to development surveillance-early intervention program in multidisciplinary clinic at Ayati Centre, Sri Lanka
- To compare cost effectiveness between telerehabilitation and conventional follow up in children enrolled to development surveillance-early intervention program in multidisciplinary clinic at Ayati Centre, Sri Lanka

Study Design

Single Centre exploratory single blind three armed randomized controlled trial with 1:1:1 allocation

Study setting

Two neonatal units- postnatal wards, special care baby units and neonatal intensive care units in Tertiary care unit. The follow up of HRIF program occur in multidisciplinary clinic at Ayati Centre, Sri Lanka

Duration

This study will continue for 6 months duration.

Study population

All the neonates born in specified study setting and having high risk of adverse neurodevelopmental outcomes are selected using a checklist. Each eligible newborn will undergo two video assessments at two consecutive time points two weeks apart for GMA. All the neonates with **abnormal GMA in writhing period** (cramped synchronized, poor repertoire and chaotic movements) will be eligible to recruit to HRIF program.

Sample size

PASS 7.0 software used for sample size calculation. All analyses will be undertaken using SPSS-21 software with significance set at $p < 0.05$. Participant data will be stored and managed according to universal privacy and confidentiality standards. Sample size was calculated with the power of 0.91 and alpha value of 0.05. Sample size for each group is 25, making the total **sample size 75**.

Randomization

The children will be randomized to 3 groups using blocked randomization method to ensure equal sample sizes in each group. Block size will vary during randomization to minimize bias.

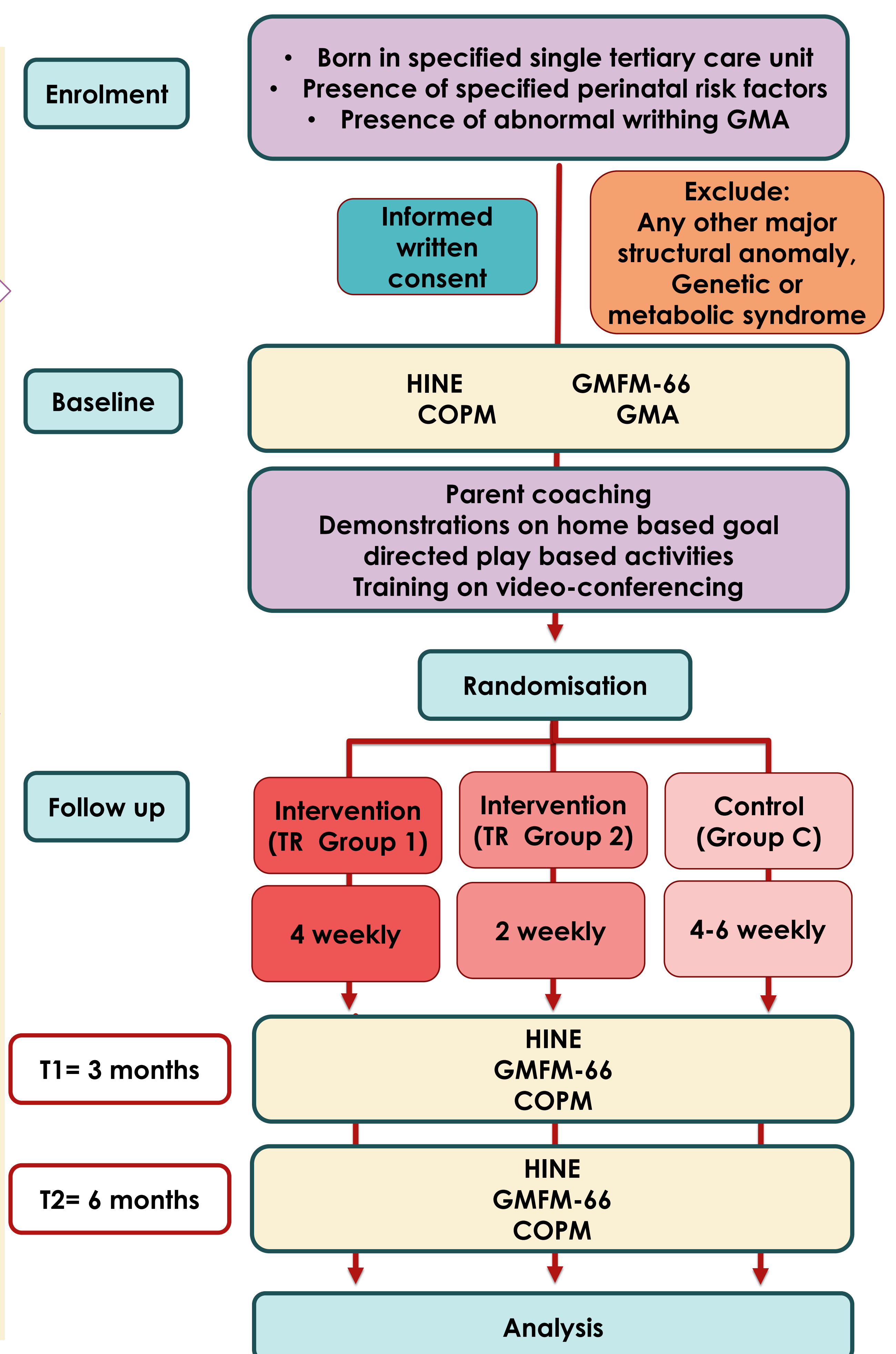
Investigator (DP2) assessing 3month PTA and 6 month PTA outcomes measures would be blinded to group allocations. Investigators involved in delivering therapy and parents however are not blinded.

Study data will be collected in paper based forms and managed using SPSS-21 software. All analyses will be undertaken using SPSS-21 software with significance set at $p < 0.05$. Participant data will be stored and managed according to universal privacy and confidentiality standards.

Ethical approval was obtained from ERC- Faculty of Medicine, University of Kelaniya.

Findings from this trial will be disseminated through peer-reviewed publications and at National and International forums.

CONSORT flow chart



References

- Khandaker, Gulam, Mohammad Muhi, Tasneem Karim, Hayley Smithers-Sheedy, Iona Novak, Cheryl Jones, and Nadia Badawi. 2019. 'Epidemiology of Cerebral Palsy in Bangladesh: A Population-Based Surveillance Study'. *Developmental Medicine and Child Neurology* 61 (5): 601-9. <https://doi.org/10.1111/dmcn.14013>.
- <https://fhs.health.gov.uk/index.php/en/statistics>
- <https://data.worldbank.org/>
- Novak, I. *et al.* A systematic review of interventions for children with cerebral palsy: State of the evidence. *Developmental Medicine and Child Neurology* (2013). doi:10.1111/dmcn.12246
- Aj, S., Orton, J., Lw, D. & Boyd, R. Early developmental intervention programs post hospital discharge to prevent motor and cognitive impairments in preterm infants What 's new Dates Text of review Synopsis. 1-56 (2009). doi:10.1002/14651858.CD005495.pub4.www.cochranelibrary.com
- Morgan, C. *et al.* Effectiveness of motor interventions in infants with cerebral palsy: a systematic review. *Dev. Med. Child Neurol.* **58**, 900-909 (2016).
- A Wade^{1*}, Jonathan Karmon¹, Adam G Elshaug^{1,2}, Janet E Hiller. A systematic review of economic analyses of telehealth services using real time video communication
- Gulmans, J., Vollenbroek-Hutten, M., Gemert-Pijnen, L. van & Harten, W. van. A web-based communication system for the integrated care setting of cerebral palsy: experienced contribution to parent-professional communication. *Int. J. Integr. Care* **12**, (2012).
- Free, C. *et al.* The Effectiveness of Mobile-Health Technologies to Improve Health Care Service Delivery Processes: A Systematic Review and Meta-Analysis. *PLoS Med.* **10**, e1001363 (2013).
- Wootton, R., Bahaadinbeigy, K. & Hailey, D. Estimating travel reduction associated with the use of telemedicine by patients and healthcare professionals: proposal for quantitative synthesis in a systematic review. *BMC Health Serv. Res.* **11**, 185 (2011).
- Novak, I. *et al.* Early, Accurate Diagnosis and Early Intervention in Cerebral Palsy: Advances in Diagnosis and Treatment. *JAMA Pediatr.* **171**, 897-907 (2017).