

Title: Supporting Indigenous Smokers To Assist Quitting (SISTAQUIT®): a cluster randomised controlled trial to change health provider behaviour and support Indigenous Australian pregnant women to stop smoking: protocol and recruitment to date

Authors: *Gillian S Gould, PhD, MA, MBChB (University of Newcastle, Australia), Joley Foster BEd (University of Newcastle, Australia), Parivash Eftekhari PhD, PharmD (University of Newcastle, Australia), Tabassum Rahman MSS (University of Newcastle, Australia), SISTAQUIT Research Group, Nicole Ryan PhD, BSc (University of Newcastle, Australia).

Background: Of Indigenous Australian women 43% smoke in pregnancy. The SISTAQUIT intervention, co-developed with Indigenous communities, aims to improve health provider (HP) delivery of smoking cessation care (SCC) to pregnant Indigenous women who smoke.

Objective: describe protocol and recruitment for SISTAQUIT cluster randomised controlled trial (cRCT).

Methods: Pragmatic Hybrid Type-1 effectiveness multi-site cRCT with outcome and process measures. N=22 Aboriginal Medical Services (AMS) and other health services were randomised to intervention or usual care (intervention later). Services recruit ~15 pregnant Indigenous women who smoke, ≥ 16 yrs old, ≤ 32 wks gestation.

Intervention includes: interactive webinar for HPs; printed educational resources (treatment manual, flipchart for HPs) and booklet with embedded videos for women; oral NRT and Smokerlyzer for breath carbon monoxide (CO).

On-site research facilitators collect data via REDCap. Primary outcome is CO-validated smoking abstinence at 4-wks. Secondary measures include: abstinence to 6-mths postpartum; birth outcomes; baby respiratory symptoms; HP attitudes/behaviours; recruitment/retention rates; NRT provision.

Results: Recruitment to January 2020 includes 22 services (19 AMS and 3 others) in 5 states - majority are in rural and remote areas, 83 HPs, 52 women and 10 babies. Recruitment challenges include lengthily community consultations, service staff changes and lower than expected pregnancies mainly in remote areas.

Conclusion: To our knowledge, this is the first national behavioural trial providing SCC within the pregnant Indigenous setting and to follow mothers' and babies' health. Results will inform practice and policy for SCC during Indigenous pregnancies.

Word count (with spaces) = 1748