Group Clinical Supervision for midwives in Sydney

**Protocol Number:** V3

**Principal Investigator:** Associate Professor Christine Catling

christine.catling@uts.edu.au

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**Protocol Authors:** Christine Catling and Helen Donovan

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**Proprietary Notice (if applicable)**

Not applicable

**Ethics Statement:**

The study will be conducted in accordance with the *National Statement on Ethical Conduct in Human Research* (2007), the *CPMP/ICH Note for Guidance on Good Clinical Practice* and consistent with the principles that have their origin in the Declaration of Helsinki. Compliance with these standards provides assurance that the rights, safety and well-being of trial participants are respected.

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## Summary

Study title: **Group Clinical Supervision for midwives in Sydney**

***Protocol version 1***

***Primary objective:***

To identify the levels of work-related burnout in midwives

***Secondary objectives:***

To identify the efficacy of Group Clinical Supervision (GCS) for midwives

To identify midwives’ intention to stay in their role/profession and rates of actual turnover

To identify midwives’ perceptions of their workplace culture

***Study design***: Cluster Randomised Controlled Trial

***Planned sample size***: 12 maternity units in the Sydney region and surrounds[[1]](#footnote-2) (~894 midwives)

***Selection criteria***: Maternity sites and their midwifery staff in Sydney and surrounds

***Study procedure:*** Following ethical approval, recruitment of twelve maternity sites and midwives who work at the sites will occur. Six sites will receive the GCS and six will not. All midwives at the intervention sites will be encouraged to attend monthly GCS for up to two years. Every six months, all participating midwives will be asked to complete an online survey with three tools: the Australian Midwifery Workplace Culture Instrument, the Copenhagen Burnout Inventory and the Clinical Supervision Evaluation Questionnaire (CSEQ).

***Statistical considerations***: The study aims to recruit twelve maternity sites. The primary outcome will be levels of midwifery burnout using the Copenhagen Burnout Inventory (CBI). Assuming that 67% of midwives will have moderate or higher levels of burnout, (the finding from the WHELM study) [1], a sample size of 744 with 372 (six maternity sites with 62 participants) per study arm will achieve 80% power to detect a 15% decrease in moderate or greater burnout with an α level of 0.05 and intra-class correlations of 0.03. To compensate for attrition and other potential threats on effect size, the target midwife sample size was increased by 20% to 894 (447 per arm).

***Duration of the Study***: Jan 2022 – Dec 2025

# 1. BACKGROUND AND INTRODUCTION

###  PROPOSED INTERVENTION BACKGROUND

Midwives are essential to maternal wellbeing. Globally, they are pivotal to the reduction of maternal and neonatal morbidity and mortality [8, 9]. In high-resource countries such as Australia, midwives are also critical to ensuring optimal maternal and fetal outcomes. For instance, a Cochrane review of over 17,600 women demonstrated that services offering midwife-led continuity of care resulted in a 24% reduction in preterm birth, compared with standard hospital care [10]. High-level research indicates that midwife-led care is associated with improved physical and psychological outcomes for mothers [11, 12], including less epidurals, episiotomies and instrumental births.

New South Wales faces a predicted shortfall of more than 8000 registered nurses and midwives by 2030 [13]; however, nuanced data regarding midwifery attrition in the workforce is not available that could be examined in order to reverse this trend. Australia appears to be educating a sufficient number of midwives to meet the needs of maternity units [14] but reports of staffing shortages causing workload stress and burnout[[2]](#footnote-3) are rife [15]. The number of births in Australia is increasing due to population growth through migration; the current average of 309,000 births per year is 5.8% higher than 10 years ago [16]. Further, there is now more diversity and complexity around birth due to factors such as rising maternal age and higher rates of obesity. These factors mean more midwives are necessary in the workplace but staffing ratios have not changed to reflect this acuity, contributing to the dissatisfaction of midwives across Australia.

Research from the UK [17] found that midwives who left the profession cited dissatisfaction with staffing levels, workload and conditions, Midwives emphasised that they received limited support from managers and experienced constraints on their ability to provide quality care. The case is similar in Australia, where midwives often report frustrations in their efforts to practice woman-centred care due to an increasingly medicalised environment [18, 19]. The international Work, Health and Emotional Lives of Midwives (WHELM) study, which included Australia, reported that midwives were discontented with the conditions in which were required to practice [1]. They believed that workplace structures compromised the standard of care they were able to deliver, and thereby affected the relationships they established with the women in their care. Midwives in this study also cited issues with heavy workloads, which they attributed to insufficient staffing and unsupportive managers. This led to high levels of personal and work-related distress. These findings are supported in other Australia-based research that similarly indicates that midwives are not provided with the adequate support to effectively provide adequate health care to women [15, 20-22].

Australian research has also demonstrated high levels of stress and burnout among midwives, which have a direct impact on midwives’ dissatisfaction and their stated intentions to leave the profession [23-25]. One study reported that 47% of midwives working in Western Australian hospitals intended to leave the profession, 24% of them within five years [26]. Another Australian study of 1037 midwives reported that 43% had recently considered leaving the profession [19]. Both studies cited midwives’ discontent with their roles. Previous research has also uncovered evidence of a negative culture in Australian midwifery workplaces, reflected in constraints on collaboration, hierarchical practices, and uncaring or ‘toxic’ work environments [3, 27, 28].

Importantly, some studies have shown that adequate resources, support from managers, and feelings of control and empowerment are key factors in supporting the retention of midwives [29, 30]. There is clearly a need to investigate how to support midwives in these key areas to improve satisfaction, maintain quality of care and retain them in the workforce. One possible way of doing this is through the implementation of Group Clinical Supervision (GCS). The NSW Health Education and Training Institute (HETI) endorses and recommends GCS as a means for clinicians, including midwives, to reflect on their care-giving practices and to receive support “to ultimately enhance and maintain the quality and safety of patient care” [31, 32]. HETI recommends that GCS be provided for 1-1.5 hours per month to enhance midwives’ emotional wellbeing and promote working relationships in supportive environments [33]. GCS is already widely applied for mental health professionals due to their stressful work environment [34]. The work environment for midwives is similarly stressful, both physically and emotionally, because they deal with stillbirth and fetal/maternal morbidity on a regular basis, but nonetheless have little access to formalised support structures [35]. This is despite a clear position statement from the Australian College of Midwives recommending GCS be implemented by professional bodies [36], and the ongoing facilitation training of senior clinicians in NSW in GCS in recent years (Johns, 2019, personal communication). It is therefore vital to encourage the implementation of GCS in maternity units to improve the experiences of midwives and, as a result, the wellbeing of childbearing women and their families.

### RATIONALE FOR PERFORMING THE STUDY

The international significance and benefits of the research project will be substantial. This will be the first longitudinal research study to examine the complex relationships between workplace culture, staff attrition, burnout and sustained GCS within midwifery. The outcomes have significant implications for individual midwives, maternity services and wider healthcare systems. Moreover, the project will contribute to the development of a sustainable and committed midwifery workforce, which will be vital for ensuring maternal and infant wellbeing and providing improvements in future maternity care practices.

The project will be of considerable value to maternity managers within health organisations, not only because of its potential to reduce staff turnover costs, but through the creation of new knowledge and the enhanced capacity to build a robust, efficient, collaborative and engaged midwifery workforce. Innovative remedies to stem the midwifery attrition rate amid predicted shortfalls will benefit the Australian community, and, in particular, health organisations, women and their families. This could be life-changing for many women at this significant yet vulnerable time of their lives.

# 2. HYPOTHESES

* Regular GCS will improve midwives’ perceptions of their workplace culture and lower their levels of work-related burnout.
* Midwives with positive perceptions of their workplace culture will be more likely to remain in their profession.
* Maternity units offering regular GCS will have lower levels of midwifery staff attrition than others.

# 3. STUDY OBJECTIVES

### 3.1. PRIMARY OBJECTIVES

To identify the levels of work-related burnout in midwives

### 3.2. SECONDARY OBJECTIVES

To identify:

 -the efficacy of Group Clinical Supervision for midwives

 -midwives’ intention to stay in their profession and rates of actual turnover

 -midwives’ perceptions of their workplace culture

# 4. STUDY DESIGN

### 4.1. DESIGN

### The study will involve a three-phase design incorporating a cluster RCT. The CONSORT statement for cluster RCTs will be used to ensure rigour and process. Quantitative and qualitative data will be collected in this study. The quantitative data will be from three validated tools (see below), as well as simple demographic data. Qualitative data will be collected from questions added to the Australian Midwifery Workplace Culture (AMWoC) instrument. The open-ended question is:

### Can you tell us more about your workplace culture?

**Phase 1 – Preparation (January – December 2021):**

* Writing and registration of the protocol for the cluster RCT
* Engagement of a Research Assistant to deliver the intervention (monthly Group Clinical Supervision [GCS])
* Set up and liaison with a stakeholder group consisting of the Principal Investigators (comprising midwifery managers/directors, and Clinical Midwifery Consultants/Research midwives) in participating maternity units within Sydney to help co-create the study
* Creation of a Trials Steering Group (comprising an experienced triallist, the Director of Research in the Faculty of Health, a consumer and a Principal Investigator) to provide supervision of the progress of the study
* Submission of this protocol to the Australian New Zealand Clinical Trials Registry (ANZCTR)
* Ethical clearance – from participating Local Health District (LHD) HRECs and UTS HREC
* Training in GCS facilitation
* Set up REDCap (a secure web application for building and managing online surveys and databases) survey to contain demographic questions and three tools:
	+ The Australian Midwifery Workplace Culture (AMWoC) instrument
	+ The Copenhagen Burnout Inventory
	+ The Clinical Supervision Evaulation Quesionnaire (CSEQ)

**Phase 2 – The RCT (January 2022 – December 2024):**

* Randomisation of maternity units and data management will occur using REDCap
* Recruitment of midwives (n=894) to complete tools (in REDCap) in both study and control sites (around 75 midwives per maternity unit).
* Ongoing provision of monthly GCS in the intervention units for up to two years.
* Six-monthly completion of the tools from participants in the intervention and control sites.
* Debriefing of facilitator/s about their experiences conducting GCS in these settings as needed.
* Regular meetings with the PIs of all sites

**Phase 3 – Analysis (January – December 2025):**

* Quantitative analysis of the research data from midwifery participants on the uptake of GCS and staff turnover, and a comparison between the intervention and control maternity units.
* Thematic analysis of qualitative data from free text in the AMWoC tool.
* Triangulation of qualitative and quantitative data.
* Preparation and dissemination of findings and implications through reports and targeted workshops for NSW Health and LHDs, scholarly articles and other study outputs.
* Further refinement of the AMWoC tool and manuals to support uptake by LHDs.

**Intervention – Group Clinical Supervision**

Phase 2 will implement GCS monthly for up to two years in selected maternity units in Sydney and surrounds. The GCS intervention will be standardised through only two facilitators delivering the intervention (trained in the Role Development Clinical Supervision model). The PI will liaise with maternity unit staff to determine timing, facilities and resource availability. GCS will comprise an hour-long group session for midwives that will encourage them to reflect on their practice in a safe, confidential and supportive environment. GCS will be optional but strongly encouraged for midwives in the intervention maternity units. Control sites will have no GCS, but midwives will be recruited to complete the survey tools.

**Data Collection and Analysis:**

***Cluster RCT (Phase 2):*** Data collection tools will include the AMWoC instrument, the CSEQ, and the Copenhagen Burnout Inventory. Workforce data on midwifery staff turnover will be collected from LHDs. Data collection will take place every six months on all midwives in both arms. Participants will be hospital maternity units (n=12) and midwives working within those units. Participating maternity units will be identified as having little or no GCS implementation. All midwives in the intervention units will be offered access to GCS funded by the study. The primary outcome will be levels of midwifery burnout using the Copenhagen Burnout Inventory (CBI). Assuming that 67% of midwives will have moderate or higher levels of burnout, (the finding from the WHELM study) [1] there will be > 80% power to detect a 15% decrease in moderate or greater burnout using a 5% significance level. The sample size calculation also assumes that an average of 75 midwives per unit will complete the survey, with an intracluster correlation of 0.03. Secondary outcomes will be the efficacy of GCS, perceptions of workplace culture and midwives’ intention to stay in their role/profession and rates of actual turnover.

***Workforce data (Phase 2)***: De-identified workforce data from LHD Human Resource departments will be accessed for the hospital maternity units to ascertain midwifery attrition rates/turnover.

***Data analysis (Phase 3)*:** Data will be analysed using SPSS on an intention-to-treat approach. All analyses will be adjusted for the effect of clustering using generalised estimating equations and will also be adjusted for the variable used in stratification. The qualitative data within the AMWoC survey will be analysed thematically. Triangulation of quantitative and qualitative data will provide further insights into the relationship between GCS, midwifery workplace culture and staff turnover

### 4.2. EXPECTED PARTICIPANT NUMBERS

The study aims to recruit twelve (12) maternity sites to the cluster RCT. Within these sites, we hope to recruit around 75 midwives per site (n=894).

### 4.3. DURATION OF THE STUDY

The duration of the study is from January 2021 – December 2025. The expected time period for participant recruitment is from January 2021 – December 2024.

### 4.4. ENDPOINTS

PRIMARY ENDPOINTS

The primary endpoint will be when the study sample has shown after at least two years of the delivery of the intervention, that burnout levels of midwives has decreased significantly (ie 10% difference from baseline). This will be determined by analysis of the Copenhagen Burnout Inventory.

SECONDARY ENDPOINTS

Secondary endpoints will be a reduced turnover (<20%). Turnover rates of nurses has been defined internationally and comprises a range – from 10% in England (Morris 2006), 13.9% in the US (Nursing Solutions Inc 2011) and 19.9% in Canada (O’Brien-Pallas, et al 2010). Given the lack of studies related to midwifery, we can assume a similar rate of turnover would occur for midwives, and using the higher rate of 19.9% from Canada (O’Brien-Pallas 2010), we have set a ‘high’ turnover rate at >20%. This is excluding staff transferring to other areas within the maternity unit, absences because of voluntary retirement, medical, educational or maternity reasons.

We will study rates of midwifery attrition from HR data and compare rates to the same time period in earlier years), and efficacy from the GCS intervention using the CSEQ tool.

### 4.5. CENTRES

There will be 12, predominantly Sydney-based maternity sites recruited for this cluster RCT with around 75 midwives per site. The maternity sites are Sydney-based for logistical reasons as the GCS facilitator will be delivering the monthly sessions face-to-face. All procedures will be the same per site ie. the number of GCS sessions that are offered.

# 5. STUDY PARTICIPANTS

### 5.1. INCLUSION CRITERIA

Inclusion criteria include:

1. The maternity site is within the Sydney and surrounds area. This will include selected maternity units at the following Local Health Districts: Western Sydney, South Western Sydney, Sydney, Northern Sydney, South East Sydney, Nepean Blue Mountains and Illawarra Shoalhaven. Units are selected due to their geographical position to assist feasibility of the face-to-face intervention.
2. Participating midwives consent to completing the REDCap survey every six months for the period of the study.
3. Participating midwives within the intervention sites agree to attend GCS sessions (as much as is practicable, but at least twice in the preceding six-month period).
4. Participating midwives can be employed as casual, full-time or part-time.

### 5.2. EXCLUSION CRITERIA

Exclusion criteria include:

1. Maternity sites that have established on-site monthly GCS offered to all midwives.
2. Those sites that do not consent to the requirements of the study.
3. Midwives that hold senior roles such as clinical midwifery consultants, midwifery educators and midwifery managers are not offered the GCS sessions.
4. Midwives that are employed from agencies.

# 6. STUDY PROCEDURES

### 6.1. STUDY FLOW CHART

Diagram of the study design



GCS=Group Clinical Supervision

### 6.2. INVESTIGATION PLAN

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Set up** | **Intervention** | **Ongoing consultation** |
| Initial stakeholder (PI) group meeting/ethics process | Meetings with midwives at the participating maternity sites | GCS sessions for up to two years, held **every month** at each site | Stakeholder group meetings – held every year/as needed and at the end of the study | Meetings with site PIs held every two months/as necessary until the end of the study |
| Inclusion / exclusion criteria | √ | √ | √ |  |  |
| Consent from participating maternity sites  | √ |  |  |  |  |
| REDCap survey sent to midwifery participants every 6 months |  |  | √ |  |  |

GCS = Group Clinical Supervision session

### 6.3. STUDY PROCEDURE RISKS

There is a possibility that midwifery participants may become emotionally distressed should they recount difficult aspects of their work during the GCS sessions. The GCS Facilitator is an experienced health care professional (midwife) and will attend extra training to support the participant should this occur. A specific distress protocol will be in place for the Facilitator to follow. The participant will be offered the opportunity to leave the GCS session if s/he wishes, and the Facilitator will follow up with her/him the following day. Telephone numbers for, and encouragement to attend the Employee Assistance Program (EAP) will be given to any participant that shows signs of distress during the sessions.

There is a possibility that a workplace will establish their own GCS sessions during the course of the study. This possibility will be mitigated as much as possible through liaising with the Directors of Nursing and Midwifery to ascertain their plans for future programs. Should this occur, it would be taken into account in the analysis of that maternity site, and participating midwives would be asked to define their attendance levels at non-study GCS within the REDCap surveys.

There is a possibility for the GCS facilitators to become distressed. Monthly debriefing (and more often if necessary) will occur with an external experienced GCS facilitator to mitigate the development of issues in relation to this possibility.

### 6.4. PARTICIPANT RECRUITMENT AND SCREENING

Potential participants will comprise all midwives (except those in management/senior roles or agency midwives) from the participating maternity sites within Sydney and surrounds. Engagement with the Directors of Nursing and Midwifery and the Midwifery Unit Managers of antenatal, postnatal and intranatal areas of the maternity units will be undertaken. These stakeholders will then contact the employed midwives via email and through staff meetings to inform them about the study. The study research assistant will also hold multiple sessions at the maternity sites to discuss the study with midwives. Advertisements for the study will also be placed in maternity site tearooms.

### 6.5. PARTICIPANT ENROLMENT

Potential participants will be enrolled into the study after the informed consent process has been completed and the participant has been assessed to meet all the inclusion criteria and none of the exclusion criteria.

### 6.6. INFORMATION AND CONSENT

The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2018) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-E6(R2).

Contact will be made with the LHD Directors of Nursing and Midwifery via the Ministry of Health Nursing and Midwifery Office. Interest in participation will be ascertained, and liaison regarding and sign-off on the relevant site-specific ethics forms for the HREC will be gained. Potential participants (midwives) will be approached as per the description in point 6.4 above. If interested, they will be given a Participant Information Sheet and Consent form to read and sign. These will then be collected by the RA, and stored securely as outlined in section 14 of this document.

### 6.7. RANDOMISATION PROCEDURE

The method of randomisation to be used will be computer generated via the REDCap randomisation module. Once the recruitment of twelve maternity sites has occurred, they will be randomised to either the intervention or the control arm. Those in the intervention arm will receive monthly GCS in their maternity units, and those in the control arm will not.

### 6.8. END OF STUDY

The end of the study will occur on 31st December 2025, which coincides with the conclusion of the yearly funding from the NHMRC. The end of the data collection period will be 31st December 2023.

### 6.9. PARTICIPANT WITHDRAWAL

Should a cluster (maternity site) wish to withdraw from the study, this will be dealt with individually, however, this is not anticipated. Already collected data will be used for analysis, as will the data from all non-identifiable participants within that site. We have included an adequate sample size to withstand site withdrawal.

Individual midwifery participants within the randomised sites will be able to decline further involvement in the study at any point. Midwives who have participated in the GCS sessions and submitted online surveys and later ask to withdraw will be informed that any previously submitted data will be used for analysis, as their data will have been de-identified and not possible to retrieve.

# 7. OUTCOMES

### 7.1. DEFINITION OF OUTCOMES

**Work-related burnout in midwives** (primary outcome):

The degree to which the midwifery participants state their burnout level using the Copenhagen Burnout Inventory over the study duration.

**The efficacy of GCS for midwives**:

The efficacy of the GCS sessions, as stated by the midwifery participants.

**The intention for midwives to stay in their role/profession and rates of actual staff turnover**:

The proportion of midwifery participants who state they considered leaving their profession in the last six months (compulsory question within the AMWoC tool below), and the staff turnover and sick leave rates within the maternity sites (from HR data).

**The perceptions of their workplace culture**:

 The perceptions of workplace culture as defined from the midwifery participants – through completion of the Australian Midwifery Workplace Culture (AMWoC) tool.

# 8. STATISTICAL CONSIDERATIONS

### 8.1. SAMPLE SIZE OR POWER CALCULATION

### The study aims to recruit twelve maternity sites. The primary outcome will be levels of midwifery burnout using the Copenhagen Burnout Inventory (CBI). Assuming that 67% of midwives will have moderate or higher levels of burnout, (the finding from the WHELM study) [1], a sample size of 744 with 372 (six maternity sites with 62 participants) per study arm will achieve 80% power to detect a 15% decrease in moderate or greater burnout with an α level of 0.05 and intra-class correlations of 0.03. To compensate for the attrition and other potential threats on effect size, the target midwife sample size was increased by 20% to 894 (447 per arm).

### 8.2. PROVIDE A DETAILED ANALYSIS PLAN

Data will be analysed using SPSS on an intention-to-treat approach. All analyses will be adjusted for the effect of clustering using generalised estimating equations and will also be adjusted for the variable used in stratification. The qualitative data within the AMWoC survey will be analysed thematically. Triangulation of quantitative and qualitative data will provide further insights into the relationship between GCS, midwifery workplace culture and staff turnover.

# 9. DATA COLLECTION

### 9.1. PARTICIPANT REGISTRATION

Not applicable. Data collected from midwifery participants will be non-identifiable.

### 9.2. FORMS AND PROCEDURE FOR COLLECTING DATA

Participating midwives will complete the REDcap online survey every six months. Once completed, these are automatically submitted electronically. The Research Assistant will collect HR data every six months from all participating sites and enter the numbers of exiting midwives and levels of sick leave (from the maternity site).

### 9.3. DATA COLLECTION FORMS AND SCHEDULE FOR COMPLETION

The Data Collection Forms of all participating sites and midwives will be completed by one Research Assistant for consistency. These comprise the REDCap survey (online) which is completed by midwives every six months from all sites (intervention and control arms). Every six months the survey portal will be open for 4 weeks to allow time for midwives to do this.

The study will be completed at the end December 2025, and data collection will be complete by December 31st 2023, with all data collection forms (surveys) completed by that date.

###

### 9.4. DATA FLOW

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# 10. QUALITY CONTROL AND ASSURANCE

### 10.1. CONTROL OF DATA CONSISTENCY

Data will be collected via REDCap from midwifery participants. These surveys will be sent to the participants every six months and one person, the Research Assistant (with guidance from the PI) will be responsible for ensuring data consistency.

### 10.2. AUDITS

### Not applicable

### 10.3. PROTOCOL AMENDMENTS

### Not applicable

# 11. ETHICS

### 11.1. INVESTIGATOR AUTHORISATION PROCEDURE

The required authorisation prior to commencing the trial is granted from the lead HREC (Royal Prince Alfred Hospital), as well as site specific approval from all participating sites (n=12). Because this study is sponsored by UTS, this will also necessitate UTS Ethics Committee clearance. Both LHD HREC and UTS HREC necessitate approved versions of the participant information and consent forms and advertising material.

### 11.2. PARTICIPANT PROTECTION

The PI will ensure that the study is completed in accordance with the guidelines set out in the [*National Statement on Ethical Conduct in Human Research*](http://www.nhmrc.gov.au/guidelines/publications/e72)(2007) (the *National Statement*) and the [*CPMP/ICH Note for Guidance on Good Clinical Practice*](http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm)and any other relevant legislation/guidelines. Section 6.3 of this form describes the risks to participants and the strategy that will be put in place if necessary.

# 12. SAFETY

### 12.1. ADVERSE EVENT REPORTING

This is not a medicine or device-related trial, so there are no adverse events anticipated in relation to the procedures used in this research. Risks associated with the trial are reported in section 6.3. We will implement measures to mitigate any potential distress for the midwife participants or the GCS facilitators. Links for sources of support and contact details for the Employee Assist Program will be placed on a specific page within the REDCap platform.

### 12.2. SERIOUS ADVERSE EVENT REPORTING

Not applicable.

### 12.3. DATA SAFETY AND MONITORING BOARD (DSMB)

Not applicable

### 12.4. EARLY TERMINATION

The possible circumstance for early termination of the study would be that the PI was incapacitated in some way, through illness. In this case, the RA would inform participants, correspond with the HREC and complete a final study report.

# 13. BLINDING AND UNBLINDING

This cluster RCT will not be blinded to its participants/researchers. However, the statistical analysis will be blinded ie. the statistician will not be aware of the sites that have had the study intervention when performing the statistical analysis.

# 14. CONFIDENTIALITY AND STORAGE AND ARCHIVING OF STUDY

Data confidentiality will be maintained throughout the study. This includes all participant’s identities and responses. Confidentiality and data storage will be in line with Element 4: collection, use and management of data and information within the National Statement (2018). This comprises all digital information (REDCap surveys) completed by the midwifery participants. All data from REDCap will be downloaded into an Excel computer software file for cleaning and storage.

The qualitative answers to questions on the survey will be saved in MS word and placed in an NVivo database.

Format of stored data will include hardcopy documents and electronic data. All paper data (PISC forms from the Principle Coordinating Investigators from the maternity sites) will be stored in a locked filing cabinet in Associate Professor Christine Catling’s locked office in UTS Building 10 on the 11th floor.

All electronic research data will be stored in special files on a password activated computer and stored on a password protected UTS network. All data from the site midwifery participants will have no identifying feature to ensure privacy confidentiality and beneficence.

Data will be stored for five years beyond the last publication within a UTS approved archival system.

This is a low risk study for midwives completing the survey. No personal data will be collected and hence the survey data will remain anonymous. All participants will be allocated a unique identifier to ensure confidentiality, privacy and beneficence. Participants will be informed that they may discontinue the survey at any time without discrimination.

Study participants will be assigned a study code in the Excel database for data management purposes. Data generated will not be re-identifiable (all potentially identifiable details will be changed to protect the identity of the participant). Any paper notes taken by the investigators will be shredded using an industrial grade shredder located within the UTS campus immediately after the notes have been transcribed into Word. Data will be aggregated for analysis and publications will not contain any information that may identify an individual participant or acute care clinical unit (setting).

# 15. TRIAL SPONSORSHIP AND FINANCING

The National Health and Medical Research Council (NHMRC) is funding the 5-year study. This covers the costs of one full-time researcher (Ass Prof Christine Catling) and a part-time research assistant.

# 16. INDEMNITY

16.1. COMPENSATION

Not applicable.

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# 18. APPENDICES

1. Advertisements to potential participants (midwives in all 12 sites)

1a. Flyer for midwives in intervention arm

1b. Flyer for midwives in control arm

2. Data collection sheet (REDCap survey items)

 2a. Data collection sheet for intervention arm

 2b. Data collection sheet for control arm

3. Cluster Guardianship Information

4. Cluster RCT Consent Form

1. This includes selected maternity units at the following Local Health Districts: Western Sydney, South Western Sydney, Sydney, Northern Sydney, South East Sydney, Nepean Blue Mountains and Illawarra Shoalhaven. [↑](#footnote-ref-2)
2. "Burnout is a syndrome conceptualized as resulting from chronic workplace stress that has not been successfully managed. It is characterized by three dimensions: 1) feelings of energy depletion or exhaustion; 2) increased mental distance from one’s job, or feelings of negativism or cynicism related to one's job; and 3) reduced professional efficacy” (WHO, ICD-11 for Mortality and Morbidity Statistics, 2020). [↑](#footnote-ref-3)