Research Protocol: Evaluation of a New Zealand-wide 'Sleep-On-Side When Baby's Inside' public health campaign

COVER PAGE

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STUDY TITLE	Sleep practices and knowledge about sleep position among women and care providers in late pregnancy.
Short title	Pregnancy sleep practices

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NB: IF YOU ARE INVOLVED IN SPONSORED RESEARCH, THE CVS OF ALL PERSONNEL CONCERNED ARE REQUIRED.
Not applicable

A) Project summary / Abstract *(provides an overview of the study)*

In New Zealand, The 'Sleep-On-Side When Baby's Inside' public health campaign was initiated in June 2018 in response to evidence from an individual participant data meta-analysis which confirmed that going-to-sleep supine (lying on the back) in the third trimester was an independent risk factor for late stillbirth.[1] These findings were biologically plausible, as research from our group and others has shown that supine position is associated with vena-caval compression,[2 3] reduced maternal cardiac output,[4] reduced uterine blood flow,[5] and indicators of hypoxia in the fetus,[6 7] compared with left-side maternal position. In addition, feedback from pregnant women and data from sequential research demonstrated that women could change their going-to-sleep position in response to research evidence.[8] Hence going-to-sleep position met the criteria for a public health campaign with potential to reduce stillbirth.

The multi-disciplinary campaign[9] was supported by the New Zealand Ministry of Health and key professional and consumer bodies. It was developed with an online video and written resources for women and maternity providers. Dissemination of key messages and resources occurred through professional bodies and networks, the campaign website (https://www.sleeponside.org.nz/), journal and media articles, and conference presentations to midwives and doctors.

Over the next six months, we plan to evaluate the campaign by carrying out two surveys. The first survey is for pregnant women in the third trimester. The aim is to evaluate women's knowledge of the 'Sleep-On-Side When Baby's Inside' messages and resources, as well as current going-to-sleep position and whether this position has changed during pregnancy. The second survey is for health professionals who provide care for pregnant women in New Zealand, and is designed to assess health professionals' knowledge about the campaign and the key messages.

We plan to survey pregnant women (sample size of 569 participants) using an internet link to the web-based survey promoted to pregnant women living in New Zealand through Facebook. To support recruitment of an ethnically diverse sample of women from an area of high deprivation and increased risk of stillbirth, an invitation to participate in the survey via an electronic tablet will also be offered face-to-face to pregnant women attending antenatal clinics in the Auckland District Health Board (ADHB) and Counties Manukau Health (CMH) regions over a six-week period by a research assistant.

The survey for health professionals (with the intention to include as many participants as possible) will be disseminated through professional bodies and networks. To support recruitment of eligible health professionals, a research assistant will invite their participation while pregnant women attending antenatal clinics in the ADHB and CMH regions complete the women's survey. General practitioner practices' in the CMH region and wider Auckland region will also be contacted by a research assistant and invited to participate in the survey.

B) Background / Rationale (provides justification for the project)

Late stillbirth and supine position

Late stillbirth (death of an unborn baby at 28 weeks or more of pregnancy) is a tragedy for all involved and a public health problem that is still too common. In New Zealand, about three in every 1000 pregnant women experience a late stillbirth, resulting in the deaths of approximately 160 otherwise normal babies every year.[10] Nearly one-third of these late stillbirths are currently classified as "unexplained". If readily modifiable risk factors could be identified, some of these deaths could be prevented.

Our research group was the first to investigate the relationship between maternal sleep practices and risk of late (≥28 weeks') stillbirth. In 2011, the publication of The Auckland Stillbirth Study (TASS)[11] showed women who reported going to sleep lying on their backs had a 2.5-fold increase in risk of late stillbirth that was independent of

other major risk factors for stillbirth. This led to our larger New Zealand-wide Multicentre Stillbirth Study (MCSS),[12] an Australian[13] and UK based study[14] which each confirmed our original findings. Data from existing case control studies[11 12 14 15] have now been combined in an Individual participant data meta-analysis[1] that has confirmed that the women who go to sleep lying supine have an increased likelihood of late stillbirth [aOR 2.63 (95% CI 1 .72–4.04)], which is independent of other major stillbirth risk factors.

How does sleep position contribute to stillbirth risk?

The relationship between maternal supine position and stillbirth is biologically plausible as supine position in late pregnancy is associated with haemodynamic effects that can compromise fetal wellbeing. It has been known for some decades that supine position reduces inferior vena cava flow.[2] Recent research carried out at The University of Auckland[3] using MRI technology has been able to investigate these haemodynamic effects in detail. When healthy women in the late third trimester lie supine there is a >80% reduction in inferior vena cava blood flow, a 16% reduction in cardiac output and 32% reduction in blood flow at the aortic bifurcation.[3] The consequences are reduced uterine blood flow[5] and reduced fetal oxygenation,[6 16] and the fetus spends more time in a quiet behavioral state (non-reactive fetal heart pattern) and rarely enters a very active behavioral state.[7] This suggests that the fetus responds to the reduced blood supply by reducing oxygen consumption. We speculate that whilst the otherwise healthy fetus can compensate adequately for periods of reduced placental perfusion, a vulnerable fetus may not be able to achieve this and a tipping point is reached where the fetus decompensates.[17]

Can maternal going-to-sleep position be modified?

Women in the third trimester of pregnancy typically change their sleep position several times overnight. The position in which women go-to-sleep has the longest duration compared with positions adopted later in the night[16 18] and is therefore likely to have the greatest potential to impact on the baby. Going-to-sleep position is also modifiable. When we published the Auckland stillbirth case control study in 2011, 43% of controls (women with ongoing pregnancies) reported they went to sleep on their left side.[11] At that time we thought that left side going to sleep position may be preferable to the right side. When we published our New Zealand wide study in 2017, 58% of women reported they went to sleep on their left side,[12] indicating that women had changed their going to sleep position in line with the findings from the Auckland Stillbirth study and advice from their midwives. Current evidence now shows that left and right side have similar physiological effects and equivalent stillbirth risks.[1 7]

In 2014, we carried out a survey of maternal pregnancy sleep practices in CMH,[8] the region with the highest perinatal mortality in New Zealand. We asked 377 women in the third trimester whether they could change their going-to-sleep position, and 85% of respondents reported that they could change their going-to-sleep position if that was better for the health of their baby.[8]

The Sleep-On-Side Public Awareness Campaign

In view of the consistent evidence, the biological plausibility , the fact that pregnant women have changed their going to sleep position and reported that they could change further if it was best for baby we obtained funding from Cure Kids to initiate a Public Awareness Campaign.[9] This campaign was carried out in partnership with the New Zealand Ministry of Health and with participation of key professional bodies, consumer groups, and stakeholders including representatives from the New Zealand College of Midwives, Ngā Māia ki Tāmaki Makaurau (Auckland regional group of Ngā Māia o Aotearoa Māori Midwives), Pasifika Midwives Tamaki Makaurau, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Royal New Zealand College of General Practitioners, New Zealand Nurses Organisation, Nurse Practitioners New Zealand, New Zealand College of Primary Health Care Nurses, Public Health, Parents' Centre New Zealand, Sands New Zealand, Rural Women New Zealand, Rural Health Alliance Aotearoa New Zealand, and Women's Health Action. The campaign was launched in June 2018 (https://www.sleeponside.org.nz/).

The multidisciplinary group developed and piloted a number of resources for pregnant women and for health professionals. This included pamphlets for pregnant women, translated into Te Reo Māori, Samoan, Tongan and

Hindi,[19] and a simple video which is available on the Cure Kids website[20] and on YouTube. Additional resources explaining the campaign and underlying mechanisms were developed for health professionals and disseminated through key professional bodies and stakeholders. Through our partnership with midwives and childbirth educators in development of the campaign, the campaign message of 'Sleep-On-Side when baby's inside' has been widely incorporated into childbirth education classes in New Zealand.

Evaluation of the Campaign
The purpose of this study is to evaluate the effectiveness of the 'Sleep-On-Side When Baby's Inside' campaign.

C1) Aims and Objectives

The broad objectives are to assess the success of the 'Sleep-On-Side When Baby's Inside' public awareness campaign among 1) pregnant women in the third trimester, and 2) health professionals providing pregnancy care (including midwives, obstetricians, general practitioners, nurses, childbirth educators). This will be undertaken using two online web-based surveys:

Part A: Survey for pregnant women
We aim to conduct a survey in a multi-ethnic and geographically diverse sample of women in late pregnancy in New Zealand in order to establish:
1. Knowledge about going-to-sleep position.
2. Sources of information accessed about going-to-sleep position.
3. How women felt about information received on going-to-sleep position
4. Current going-to-sleep position
5. Whether going-to-sleep position changed in late pregnancy after advice received

Part B: Survey for health professionals
We aim to conduct a survey amongst health professionals currently providing care for pregnant women living in New Zealand (midwives, obstetricians, general practitioners, nurses, childbirth educators) to establish their:
1. Knowledge about supine going-to-sleep position and association with late stillbirth.
2. Awareness of the 'Sleep-On-Side When Baby's Inside' public awareness campaign and educational resources
3. Provision of 'Sleep-On-Side When Baby's Inside' information to pregnant women.

C2) Hypotheses

Part A: Survey for pregnant women
- Pregnant women in the third trimester will be less likely to report they go-to-sleep supine compared with control women in our previous New Zealand case control studies.
- Pregnant women who have received advice about going-to-sleep position will be less likely to report they go to sleep supine compared with women who have not received information.

Part B: Survey for health professionals
- Knowledge of supine going-to-sleep position and risk of late stillbirth will not differ between professional groups of maternity providers (midwives vs obstetricians)

Secondary aims: To explore maternal knowledge about going-to-sleep position and reported going-to-sleep position by demographic characteristics including ethnicity and geographic location.

D) Methodology

Study design:
Anonymous cross-sectional survey

Participants:

Part A: Survey for pregnant women

Inclusion criteria: Pregnant women over the age of 16 years, with a singleton baby, who are ≥28 weeks' gestation and living in NZ. Exclusion criteria: multiple pregnancy, <28 weeks pregnant, no longer pregnant.

Part B: Survey for health professionals

New Zealand health professionals who are currently providing care for women during pregnancy and living in NZ.

Outcomes Maternal Survey:

Primary Outcome:

- Maternal going to sleep position

Secondary Outcomes:

- Whether going to sleep position has changed after advice
- Correct knowledge about going to sleep position
- Knowledge of 'Sleep-On-Side' resources
- Anxiety about 'Sleep-On-Side' resources
- Going to sleep position and knowledge by maternal demographic characteristics

Outcomes Health Professionals' Survey:

Primary Outcome:

- Correct knowledge about supine going-to-sleep position and late stillbirth risk

Secondary Outcomes:

- Knowledge of 'Sleep-On-Side' resources
- Provision of 'Sleep-On-Side' information to women

Sample size:

Part A: Survey for pregnant women

The sample size for the women's survey is based on a 3.9% (22/569) prevalence of supine going-to-sleep position in the control participants in our last New Zealand-wide stillbirth case control study[12] and a type 1 error of 5% and power of 80%. With 569 participants, we can detect a change in practise of supine going-to-sleep position from a prevalence of 3.9% to 1.3%. We intend to recruit at least 569 women in the third trimester living in New Zealand.

Part B: Survey for health professionals

No specific power calculation was performed for this component of the study, as the intention is to include as many participants as possible for preciseness of estimates.

Recruitment process:

Part A: Survey for pregnant women

1. **Internet link to the survey**
   The survey will be promoted and disseminated to pregnant women through Facebook via a specially designed study-specific University of Auckland recruitment webpage. An invitation containing the internet link to the recruitment webpage for the online survey will also be emailed to eligible women via key health professional and consumer networks to support participation of women throughout New Zealand (including in small centres and rural areas). Participants will access the survey in their own home, or a venue of their choosing, and complete the survey at their convenience.
2. **Face-to-face invitation to the survey**
   Face-to-face invitation to participate in the web-based survey from the research assistants to pregnant women, will take place at antenatal clinics in the Auckland District Health Board (community and hospital clinics) and

CMH (community and hospital clinics and self-employed midwifery practices) regions over a six-week period. The purpose of the face-to-face invitation is to recruit an ethnically diverse sample of women. Recruitment of women from the CMH region is important, as many women reside in areas of high deprivation and stillbirth rates are higher than elsewhere in New Zealand.

Face-to-face invitation process

a) Health professionals who provide pregnancy care will receive information about the purpose of the survey for pregnant women by one of the named investigators (R. Cronin or L. McCowan).
b) Mechanisms for introduction of eligible pregnant women to one of the research assistants will be arranged to suit needs of individual clinics, practice settings, health professionals and clinic staff. Following the introduction, the research assistant will explain the purpose of the study to the women, and if the women wish to participate, the research assistant will obtain verbal consent to proceed.
c) The research assistants will have a tablet, laptop, and modem, which will link to the specially designed study-specific University of Auckland recruitment webpage. If the woman is agreeable, she will be invited to read the specific participant information online via the research assistant's tablet or laptop and decide whether she wishes to take part in the survey (see Appendices, Part A).
d) If the woman wishes further time to consider participating and/or to consult with friends and whanau, she will be provided with the internet link to the University of Auckland recruitment webpage, or can choose to undertake the survey via the research assistant's tablet or laptop at a future pregnancy appointment.

Part B: Survey for health professionals

1. Internet link to the survey

Eligible health professionals will be emailed an invitation containing the internet link to the specially designed study-specific University of Auckland recruitment webpage from their health professional organisations and networks. The survey will be accessed at a time and in a setting of the health professionals' choice on their own electronic device.

2. Face-to-face invitation to the survey

To support recruitment of eligible health professionals, a researcher or research assistant will contact general practitioner practices in the CMH and wider Auckland region, and general practitioners and practice nurses will be invited to participate. If agreed, the researcher or research assistant will visit the practice and provide paper-based copies of the online survey or email the internet link to the specially designed study-specific University of Auckland recruitment webpage.

Data collection:

The surveys are included as appendices to this application.

Part A: Survey for pregnant women

Variables being collected include: date of commencement of survey, weight and height, pregnancy number, current weeks of gestation, highest education level, country of birth, ethnicity, rurality, DHB of residence, marital status, maternity provider type, current anxiety,[21] weeks of pregnancy when first saw Doctor/Midwife, maternal bed type and sharing, sleep position and reasons for choosing this, advice received about sleep position and sources of information, changes to going-to-sleep position, knowledge re 'Sleep-On-Side' resources, anxiety after completing interview,[22] opinion re provision of advice about late pregnancy going-to-sleep position to all pregnant women.

Part B: Survey for health professionals

Variables being collected include professional background, work location, health region of professional work, provision of going-to-sleep position advice, awareness of Sleep-On-Side resources, and knowledge of supine going-to-sleep position and risk of stillbirth, opinion re whether sleep position advice should be given.

Analysis plan:

Part A: Survey for pregnant women

Descriptive statistics will be used to describe the study population and summarise data such as demographic characteristics, going to sleep position and sleep knowledge in late pregnancy. Scores for our anxiety scale will be compared in each participant at the beginning and end of the survey. Multivariate logistic regression will be performed to identify factors independently associated with supine going-to-sleep position in late pregnancy. Statistical significance will be defined at the 5% level and analysis carried out using SAS version 9.3 (SAS Institute Inc., Cary, NC, USA).

Part B: Survey for health professionals

*D*escriptive statistics will be used to describe the study population including professional grouping and geographic location. Knowledge of going to sleep position and risk of late stillbirth and knowledge of educational resources will be explored by geographic location and professional groupings using logistic regression.

The statistical analysis will be carried out by Robin Cronin under the supervision of Associate Professor John Thompson.

E) Ethics and safety

Participant safety: not applicable

Informed consent; completing the web based anonymous survey implies consent

Confidentiality; data will be stored on a secure website. Identifying personal details are not collected.

Safety monitoring; not applicable

Relevant consultation:

We have consulted with Ngā Māia ki Tāmaki Makaurau (Auckland regional group of Ngā Māia o Aotearoa, Māori Midwives) who endorse this as an important study with the potential to improve health outcomes for Māori. Megan Tahere, Ngā Māia ki Tāmaki Makaurau Māori Midwives Chairperson, and Ngatepaeru Marsters, Pasifika Midwives Aotearoa, have been members of the large New Zealand multidisciplinary 'Maternal Sleep Position Awareness Campaign Team' that worked collaboratively on the 2018 'Sleep-On-Side When Baby's Inside' public health campaign, as well as Lisa Paraku (Ngāti Tamaterā, Ngāti Porou), the consumer representative on the Perinatal and Maternity Mortality Review Committee and committee member of Sands Wellington-Hutt Valley. These team members had input into development of the surveys. The campaign team continue to provide consultation on this project.

Health and Disability Ethics Committee (HDEC) approval <u>not</u> required. We have submitted an application to the Auckland Health Research Ethics Committee (AHREC) and this was approved 25.09.2019. We have also obtained locality approval for CMH 11.10.2019, and have applied for locality approval at the Auckland District Health Board.

Data Storage / Data Protection / Data Privacy: Storage of the survey results will be on a University of Auckland password protected server. Access will be limited to the Principal and Co-investigators and their delegates. Personal details of the participants will be unable to be linked to their survey responses.

By checking the boxes below I confirm that I Agree:	
☒	I have read "Health Research and Privacy: Guidance notes for health researchers and ethics committees"*
☒	I have signed a confidentiality agreement (available from the Research Office) and uploaded it with the research application on the online Research Registry. This confidentiality agreement is relevant to any staff with access to the research data.

☒	I will only transfer Health Information** by email to those within the regional secure network (any Middlemore, Waitemata or ADHB email) who are members of the research team.
☒	I will encrypt or password-protect any data storage devices (e.g. USB flash drives) used to store health information.
☒	I will password-protect any files containing Health Information.
☒	I will keep any hardcopy Health Information that relates to identifiable individuals for 10 years and then destroy it in a secure bin.
*http://www.hrc.govt.nz/sites/default/files/Research%20involving%20personal%20health%20information.pdf **Note: anonymised information which cannot be linked to identifiable individuals is not regarded as Health Information by the Health Information Privacy Code (1994).	

F) Project Management

Participating site(s) and persons;

- CMH Women's Health, Professor Lesley McCowan, Mrs Robin Cronin; trained research assistants
- ADHB National Women's Health, Professor Lesley McCowan, Mrs Robin Cronin; trained research assistants

Responsibilities / tasks of each;

- Professor Lesley McCowan is the principal investigator of the study.
- Mrs Robin Cronin is a co-investigator and will be responsible for the day-to-day running of the study at both sites and for supervising the trained research assistants.
- Trained research assistants will be responsible for introducing the survey to eligible pregnant women in community and hospital antenatal clinics following introduction by health professionals.

Data ownership;
Professor Lesley McCowan and Mrs Robin Cronin

Risk management of project.
Professor Lesley McCowan and Mrs Robin Cronin

G) Timetable

Outline from planning to completion and write up.

Date	**Research Steps**	
August 2019	Development of women's and health professionals' surveys.	
Sept 2019	Writing and submitting ethics applications to AHREC, and locality approval to CMH and ADHB.	
Oct 2019	Respond and update to requested changes from AHREC, CMH and ADHB Build online web-based survey using Qualtrics survey tools available free through the University of Auckland site license. https://www.software.auckland.ac.nz/itssoftware/sitelicensesrecordlist.php Establish the New Zealand web-based surveys accessed via a specially designed study-specific University of Auckland webpage. Begin recruitment via the webpage throughout New Zealand for both surveys.	
Nov 2019	Establish appropriate relationships with antenatal clinic health professionals and staff at CMH and ADHB in order to be appropriately introduced to pregnant women in the third trimester of pregnancy. Begin recruitment at CMH and ADHB.	
Dec 2019	Continue recruitment at CMH and ADHB	
Jan 2020	Continue recruitment at CMH and ADHB.	

Feb 2020	Continue recruitment at CMH and ADHB (if 500 pregnant women have not been recruited). Continue recruitment of health providers of pregnancy care until the women's survey is completed.	
March – May 2020	Data cleaning and analyses	
May – Dec 2020	Dissemination of study results at conferences and study days Write up manuscript for journal	

F) Resources

The implications for resource utilisation should be minimal. We will discuss mechanisms with individual health practitioners and antenatal clinic staff about how best to identify pregnant women who may be eligible to participate. A health professional or member of the antenatal clinic staff will introduce the research assistants to the eligible women. Completing the interview will occur while the women are waiting for an antenatal appointment. The research assistants may require a seat in the waiting room but could also stand. The research assistants will have their own tablet and modem to connect to the internet.

G) Research Output

A. The effectiveness of the 'Sleep-On-Side when Baby's Inside' campaign will be evaluated. This will provide feedback to the multi-disciplinary stakeholder group as to 1) how effective the campaign has been and 2) if and where further education may be required for New Zealand pregnant women and maternity providers.
B. Dissemination of Results: Results of the study will be presented at local conferences such as the Perinatal Society of Australia and New Zealand, Perinatal Society of Australia and New Zealand, The New Zealand College of Midwives, and at District Health Board research days e.g. CMH Research Week and ADHB National Women's Health Annual Clinical Report Day. The results will also be published in an appropriate medical or midwifery journal and presented at appropriate international scientific meetings.

ADDITIONAL INFORMATION

- CV template (standardised NZ RS&T-CV) can be accessed via the Ministry of Business, Innovation & Employment website: http://www.msi.govt.nz/get-funded/research-organisations/2012-investment round/appdocs/
- Egyptian Group for Surgical Science & Research: http://www.ess-eg.org/pages/groups/surgical/publications/1-how.pdf
- Epiet (2005) How to Write a Study Protocol: http://www.docstoc.com/docs/432932/How-to-write-a-clinical-study-protocol
- Guideline for Good Clinical Practice E6(R1), ICH Harmonised Tripartite Guideline Section 6 'Clinical Trial Protocol and Protocol Amendments. http://www.ich.org/cache/compo/276-254-1.html
- Manar Mohamed Moneer – How to Write a Study Protocol: http://www.nci.cu.edu.eg/lectures/monday2006/23-4/How%20to%20Write%20a%20Protocol.pdf
- New Zealand Health and Disability Ethics Committee application form: can be accessed via their website http://www.ethics.health.govt.nz/ or directly via the Online Forms for New Zealand Research website https://www.ethicsform.org/Nz/SignIn.aspx
- Singh, S, et al (2005) NTI bulletin: http://medind.nic.in/nac/t05/i1/nact05i1p5.pdf
- WHO Recommended format for a research protocol: http://www.who.int/rpc/research_ethics/guide_rp/en/index.html

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Appendices:

Part A: Participant Information Sheet and Sleep Survey for Pregnant Women

NZ_Maternal_SOS_Survey_15_9_2019.docx

Part B: Participant Information Sheet and Sleep Survey for Health Professionals

NZ_Health_Prof_SOS_Survey_15_9_2019.doc