



**PREGNANCY RESEARCH PROJECT**

## The Pregnancy Research Project: A Collaborative Approach to Pregnancy Research

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## BACKGROUND



*“Stillbirth is the most under-studied issue in medicine today”.*

*“No one professional organization takes responsibility for stillbirth.”*

The Lancet (2011) Stillbirth Series Executive Summary

## BACKGROUND

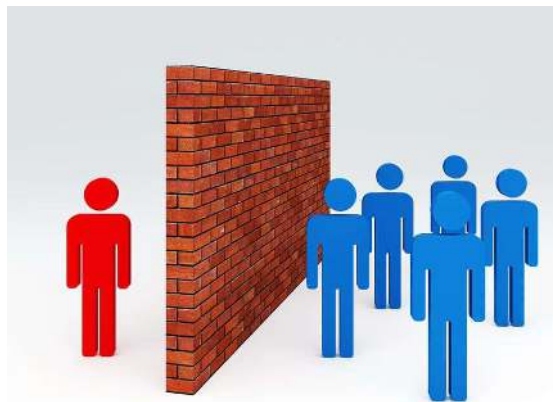


the sudden unexpected death  
data enhancement and awareness act

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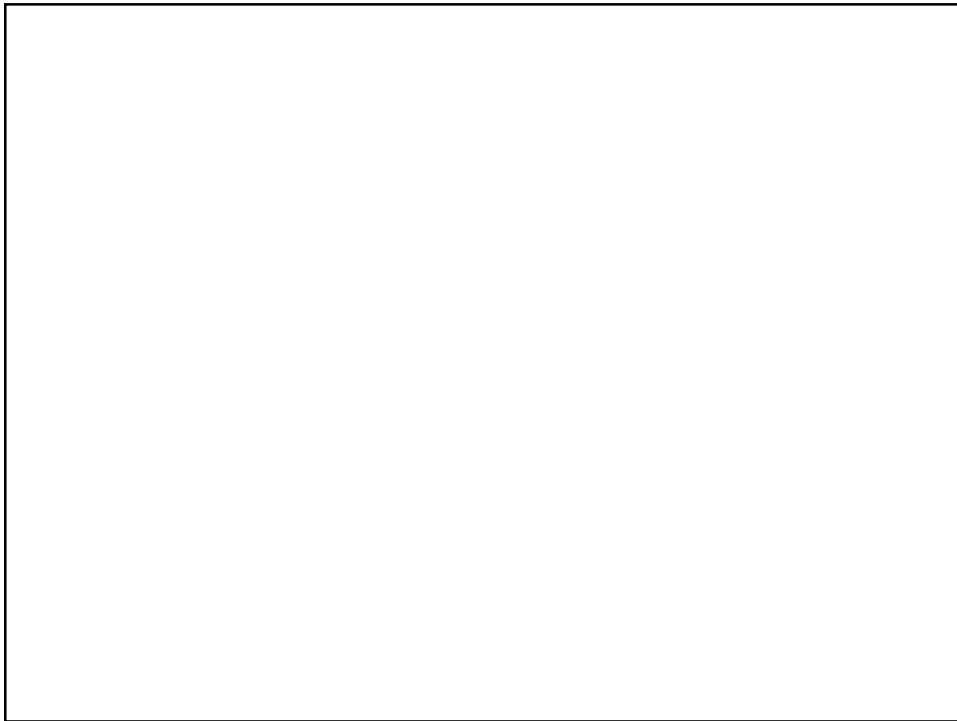
## CHALLENGES







So instead of waiting for the government.....





In 2011 the first Stillbirth Summit brought clinicians, researchers, and families together to “think outside the box”.

One of the results of that meeting was the STARS Study:



The STARS Study



The STARS Study

STARS (Study of Trends and Associated Risks for Stillbirth) Consortium\*

- Partnered with the Star Legacy Foundation and other stillbirth and parental support groups
- This unique partnership allowed bereaved parents to have direct discussions with consortium members regarding common experiences prior to their loss in order to inform the development of the survey

**The goal was to investigate trends and risk factors for stillbirth**

Particular interest in sleep position due to the findings of The Auckland Stillbirth Study (TASS):

- Women with a late stillbirth (28 weeks or more) were 2.5 times more likely to have gone to sleep on their back (supine position)

Stacey et al 2011

\* Members of the STARS consortium listed in alphabetical order: Collins JH, Heazell AEP, Huberty JL, Kliman HJ, McGregor JA, Mitchell EA, O'Brien LM, Parast M, Peesay M, Stacey T, Warland J, Wimmer LJ.

Star Legacy Foundation  
Dedicated to Stillbirth Research and Education



The STARS Study



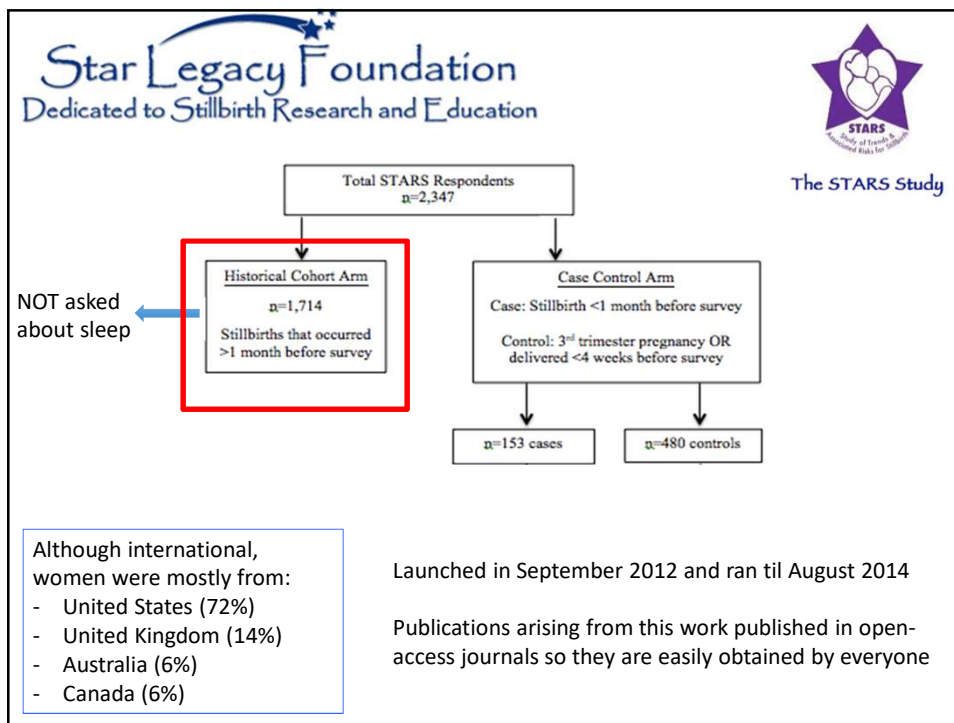
Web-based survey to investigate potentially modifiable risk factors in a large, international population.

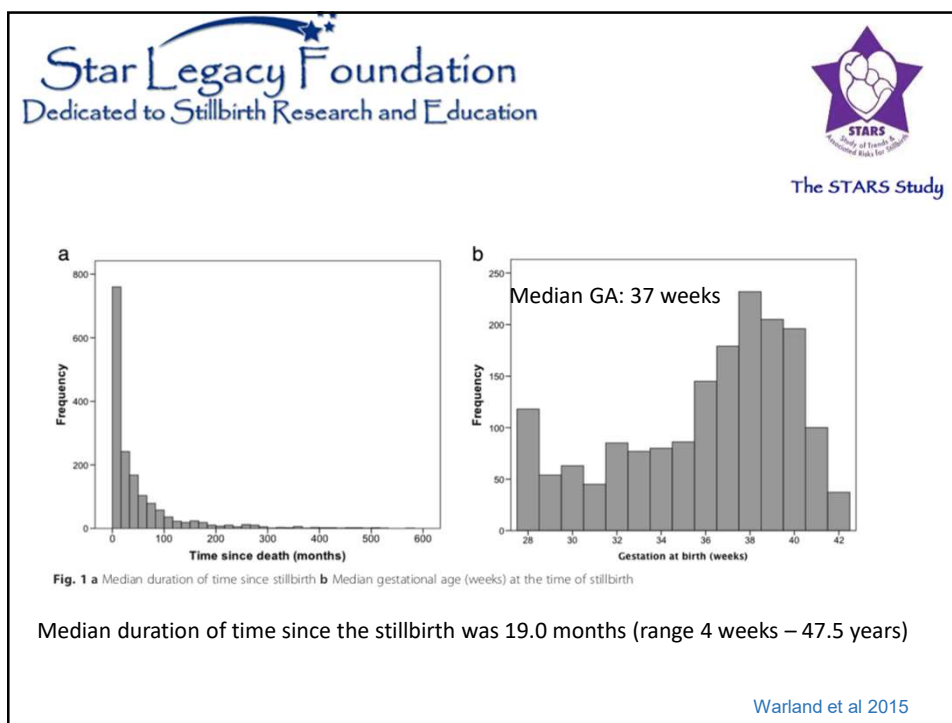
In contrast to most previous studies, our approach asked mothers directly about their behaviors, experiences, and symptoms during pregnancy.

The survey included:

- questions about established risk factors (e.g. smoking, reduced movements)
- questions relating to emerging risk factors (e.g. sleep position, gut instinct and an increase in fetal activity in the days immediately prior to the fetal demise).

Several questions in the survey were raised by bereaved parents at the 2011 Stillbirth Summit and had not been previously addressed in large-scale studies





Warland et al. *BMC Pregnancy and Childbirth* (2015) 15:172  
DOI 10.1186/s12884-015-0602-4

BMC  
Pregnancy & Childbirth

The STARS Study

RESEARCH ARTICLE Open Access

CrossMark

## An international internet survey of the experiences of 1,714 mothers with a late stillbirth: the STARS cohort study

Jane Warland<sup>1\*</sup>, Louise M. O'Brien<sup>2</sup>, Alexander E. P. Heazell<sup>3</sup>, Edwin A. Mitchell<sup>4</sup> and the STARS consortium

**Common themes reported by participants:**

1. Changes in fetal movements (63% of women)
2. Gut instinct that something was wrong (68% of women)
3. Perception that demise occurred at night (40% of women)
4. Cord accident (27% of families were told a cord accident was the cause of death)
5. 55% of families disagreed with the cause of death told by clinicians



Common themes reported by participants:

1. Changes in fetal movements (63% of women)

**Table 2** Frequency of unusual fetal movement

	N (%)
N = 1,714	
No change in fetal movement	480 (28.0 %)
A little bit less movement	273 (15.9 %)
Significantly less movement	522 (30.5 %)
A little bit more movement	136 (7.9 %)
Significantly more movement	146 (8.5 %)
Don't remember	103 (6.0 %)
Missing	54 (3.2 %)

Response to question "Once you were aware of your baby's usual pattern of movements was there any time that your baby's movements were unusual?"

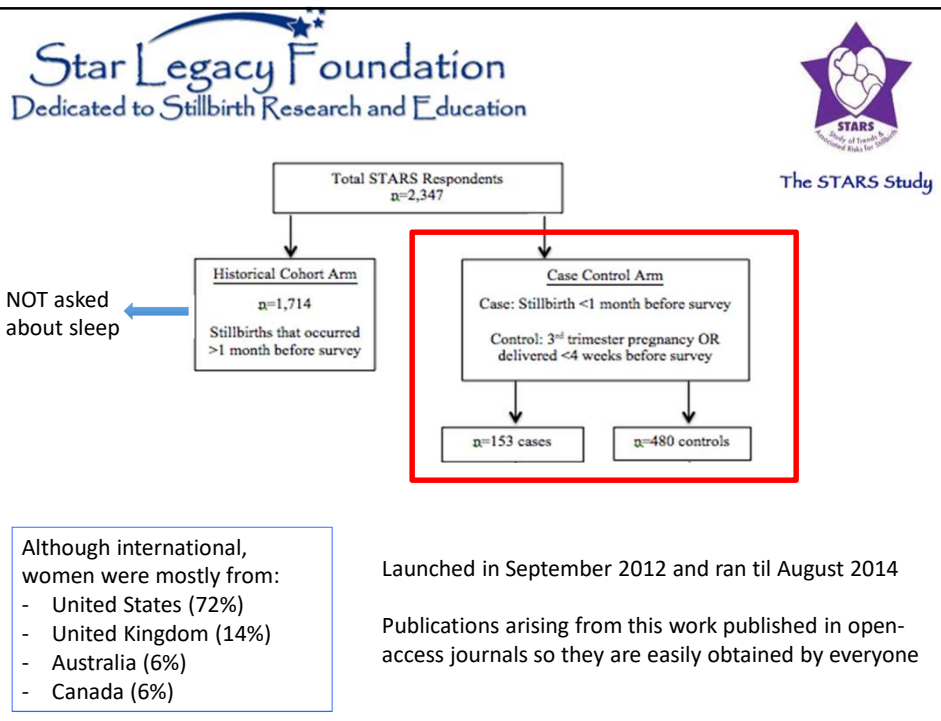


The STARS Study

*"only decreased the week before birth. The day before he died he was especially busy and moving like crazy"*

Significantly more women who reported increased movements, compared to those who reported reduced movements, did not worry about it (14 % vs. 6%,  $p=0.001$ ) and fewer (61% vs. 76%,  $p<0.001$ ) sought professional advice.

Fewer women with increased movements, compared to those with reduced movements, were either admitted or had some type of monitoring (23% vs. 33%,  $p=0.002$ ).



## RESEARCH ARTICLE

## Open Access



The STARS Study

## Stillbirth is associated with perceived alterations in fetal activity – findings from an international case control study

Alexander E. P. Heazell<sup>1,2\*</sup>, Jane Warland<sup>3</sup>, Tomasina Stacey<sup>4</sup>, Christin Coomarasamy<sup>5</sup>, Jayne Budd<sup>1</sup>, Edwin A. Mitchell<sup>5</sup> and Louise M. O'Brien<sup>6</sup>

In the case-control arm, median duration of time since the stillbirth was 13 days (range 1–29 days)

Women with stillbirth were:

- less likely to check fetal movements (aOR 0.54, 95%CI 0.35– 0.83)
- less likely to be told to do so by professionals (aOR 0.55, 95%CI 0.36-0.86)

Pregnancies ending in stillbirth were more frequently associated with changes in fetal movements in the preceding two weeks:

- significant reduction in fetal activity (aOR 14.1, 95%CI 7.27–27.45)
- sudden single episode of excessive fetal activity (aOR 4.30, 95% CI 2.25–8.24).

Cases described their perception of activity differently to healthy controls e.g. vigorous activity was described as “frantic”, “wild” or “crazy” compared to “powerful” or “strong”.



The STARS Study

“They told me all mothers have worries”, stillborn mother’s experiences of having a ‘gut instinct’ that something is wrong in pregnancy: Findings from an international case-control study

Jane Warland, PhD<sup>a,\*</sup>, Alexander E.P. Heazell, PhD<sup>b,c</sup>, Tomasina Stacey, PhD<sup>d</sup>, Christin Coomarasamy<sup>e</sup>, Jayne Budd<sup>b,c</sup>, Edwin A. Mitchell, PhD<sup>e</sup>, Louise M. O'Brien, PhD<sup>f</sup>

In the case-control arm, median duration of time since the stillbirth was 13 days (range 1–29 days)

Gut instinct occurred in response to a change in fetal movements for 40% of case and 26% of controls

It had been present for the whole pregnancy for 21% of cases and only n=1 control

Occurred in the night before birth in 23% of cases and 11% of controls.

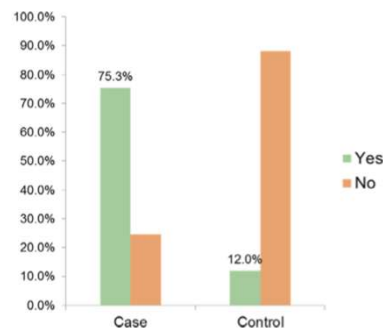


Fig. 2. Percentage response to question “During this pregnancy did you ever have a ‘gut instinct’ that something was not right?” 110 (75.3%) of the 146 stillborn cases (stillbirth less than 3 weeks prior) and only 28 (12.0%) of 234 live born controls (livebirth less than 3 weeks prior) answered yes to this question. OR 22.5 (95% CI 13.0–38.8,  $p=0.001$ ).

Received: 18 September 2018 | Revised: 15 December 2018 | Accepted: 17 December 2018  
 DOI: 10.1111/birt.12416

ORIGINAL ARTICLE

WILEY **Birth**

**Maternal sleep practices and stillbirth: Findings from an international case-control study**

Louise M. O'Brien PhD<sup>1</sup> | Jane Warland PhD<sup>2</sup> | Tomasina Stacey PhD<sup>3</sup> | Alexander E. P. Heazell MBChB, PhD<sup>4,5</sup> | Edwin A. Mitchell MBChB<sup>6</sup> | on behalf of the STARS Consortium\*

**The STARS Study**

In the case-control arm, median duration of time since the stillbirth was 13 days (range 1–29 days)

Queried about sleep practices before pregnancy, in the previous month, and previous night (or night before stillbirth)

No differences in sleep before pregnancy in cases or controls

Stillbirths had significantly higher odds of long sleep duration >9 hours 1.8 (1.1-2.8) and significantly higher odds of NON-restless sleep 1.7 (1.0-3.0) and significantly higher odds of good/very good sleep quality OR 1.69 [95%CI 1.0-2.8]

Significantly LESS likely to wake up on the last night (aOR 2.03 [95% CI 1.24-3.34]).

Not enough position data.....


**Lessons learned from STARS:**

**The STARS Study**

- Women want to tell their stories (even decades later)
- We learned from listening to the stories
- We want to drill down deeper on some issues given the STARS findings:
  - significantly increased fetal movement
  - Intuition
- Some questions were asked of control women after delivery (e.g., gut instinct) that would have been better asked during pregnancy before the outcome was known
- A lot of hands-on work that could have been automated and more efficient
- Technical glitches from Survey Monkey made it challenging for analyses
- Would be good to have documented medical data
  - many women don't have things like BP written down, tests taken

Need to work with partners to maximize response







**PREGNANCY RESEARCH PROJECT**

The Pregnancy Research Project will now build on the STARS study by obtaining more details in several key areas:

- sleep practices
- fetal movements
- maternal intuition

The Pregnancy Research Project collects data on:

- other stressors
- depressive symptoms
- paternal demographics
- imaging data (number and frequency of ultrasounds)
- details about previous pregnancies and their outcomes
- more detailed autopsy information

**PREGNANCY RESEARCH PROJECT**

You are eligible to participate if:

- You are at least 18 years of age or older
- You have had a stillbirth (pregnancy loss at or after 20 weeks gestation) at any time in the past
- You have delivered a living baby within the last five (5) years
- You are currently pregnant at 12 weeks gestation or more

The currently pregnant control group allow us have a comparison whereby outcomes are not known at the time of survey responses so that recall bias can be minimized.

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**— PREGNANCY RESEARCH PROJECT —**

The Pregnancy Research Project is a research study bringing together patients and researchers to advance knowledge and discover preventions and treatments for poor pregnancy outcomes.

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ENROLL TO PARTICIPATE

- Complete the online project questionnaire
- Allow us to gather information from your medical records

ENROLL NOW



**FOR WOMEN**  
Learn how you can support the Pregnancy Research Project.  
LEARN MORE

**FOR HEALTH PROFESSIONALS**  
Learn how you can support the Pregnancy Research Project.  
LEARN MORE


**FAQS**  
Answers to frequently asked questions.  
READ FAQS

THE PREGNANCY RESEARCH PROJECT IS A PARTNERSHIP OF:

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**PREGNANCY RESEARCH PROJECT**



After reading the consent page with all the legal stuff.....

**By clicking this link you agree to participate in this study.**

..... you are linked to a REDCap database on a secure server behind Michigan Medicine HIPAA compliant firewalls



**REDCap**  
Research Electronic Data Capture

Pregnancy Research Project - Welcome

Resize font:  [Returning?](#)



**STAR LEGACY FOUNDATION**  
*In association with*




**Thank you for giving us the opportunity to learn from your experiences!**


If you decide to share your experience with us today, answer for one pregnancy only. Later, after you have finished, you can always come back and answer the survey again for other pregnancies that you would like to share with us.

It can take between **30 - 45 minutes** to complete the survey today, depending on your experiences and what you choose to share with us.






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At the end of the survey women are invited to share their prenatal and delivery records


- this requires separate consent and women will need to sign a Release of Information form which will be sent to their care provider
- medical records will provide objective information captured in real time during the pregnancy such as;
  - frequency and results of ultrasounds
  - number of presentations to healthcare providers (and why)
  - routine vital signs
  - results of autopsy (stillbirths)



At the Stillbirth Summit in 2017 we polled attendees re: medical records, and in both mothers who had experienced a stillbirth as well as those who had not, there was an overwhelmingly positive response in favor of sharing documented evidence from health care providers if this could avert another tragic outcome for a family.




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Option to check a box to participate in other research – efficient way to connect families to researchers and vice versa.



We want this to be a living database which will continue to grow and ultimately be the largest, most robust dataset of its kind – which will allow to to find some answers at a population level that smaller studies cannot.

We plan to expand to other languages; while anyone anywhere in the world can take part in the survey, the medical record portion is currently only available to those in the US. That's something we are working on.

Designed to be collaborative; de-identified data will be ultimately opened up to other researchers through Star Legacy Foundation (with appropriate permissions)





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## OPPORTUNITIES FOR PARTNERSHIP

- \* Enroll in the study
- \* Encourage friends, family to enroll
- \* Share information where pregnant women are (clinics/organizations)
- \* Brochures/social media ads/newsletters (available from Star Legacy)
- \* Partnerships available
- \* Add the link/embedded code to your website



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*Thank you!*



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