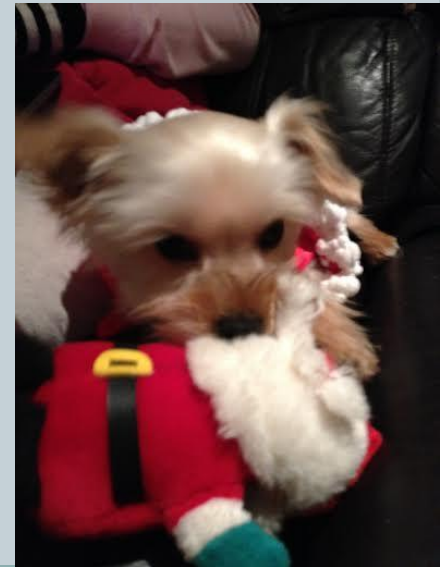


# My experience as a Cochrane Fellow on a systematic review of interventions for nausea and vomiting in early pregnancy and its recent update

ANNE MATTHEWS  
DUBLIN CITY UNIVERSITY, IRELAND



# Outline



- My route to the HRB Cochrane Fellowship & review
- The review process
- Outputs
- Outcomes
- Update 2013
- Reflections
- Acknowledgements

# My route to the Fellowship and review



- All-Ireland meeting in DCU in January 2007
  - Enhanced my interest in Cochrane
  - Information HRB/R&D Cochrane Fellowship Schemes
- Provisional query to Cochrane PCG- the effectiveness of complementary therapies for “morning sickness”
  - **Warm response** to my offer to do a review that already existed (2003)
  - Invitation to consider involvement in an update

# Fellowship & Review process



- Application process opened, setting out criteria
- I put together review team
- Registered the title April 2007
- Submitted application May 2007
- Received a fellowship June 2007
- Submitted draft protocol Feb 2008
- Submitted revised protocol July 2008
- Protocol published Oct 2008
- Submitted review to editorial process Dec 2009
- Finalised review – accepted July 2010
- Published September 2010
- Update completed and submitted November 2013

# Clinical question

What interventions are effective and safe for nausea and vomiting in early pregnancy?

**Source:** Matthews A, Dowswell T, Haas DM, Doyle M, O'Mathúna DP. [Interventions for nausea and vomiting in early pregnancy](#). *Cochrane Database of Systematic Reviews* 2010, Issue 9. Art. No.: CD007575. DOI: 10.1002/14651858.CD007575.pub2..

# Methods

- We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator. This contains trials identified from:
  - quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL); weekly searches of MEDLINE; hand searches of 30 journals and the proceedings of major conferences; weekly current awareness alerts for a further 44 journals; monthly BioMed Central email alerts.
- The search strategy identified 66 reports of 55 studies: 27 were included, 22 excluded, 2 were ongoing and 4 were waiting further assessment.
- We describe outcomes at approximately 3 days after treatment commenced, as being a clinically meaningful time point.
- We judged the 'Risk of Bias' of included studies.

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## Data extraction form

### Interventions for nausea and vomiting in early pregnancy

Report ID* (from PCG list)	First author; year	Review author ID* DH/DOM/AM/MD/TD	Date
4	Belluomini 1994	am	14 June 2009

Eligibility		Yes/no
Confirm eligibility for review	Any intervention for nausea, vomiting and retching in early pregnancy (excluding trials of interventions for <u>only</u> hyperemesis gravidarum- see definition)	Yes
	Recruitment to a trial took place up to 20 weeks' gestation	Yes- 12 weeks or less by study completion
	Study design was an RCT	Yes
Summary: Reason for exclusion:		

Methods	
Study design	A randomized blinded study
Total study duration.	2+ years
Dates of study	Jul 1990- October 1992
Country	US, California
Funding source	Supported in part by the Loewy Fund of California Pacific Medical Center, SF, California

Risk of bias (Table)	Quote/Description (in words from text-verbatim)	Decision (adequate/inadequate/un clear) (+ comment when required)
Sequence generation*	Randomized block design	
Allocation sequence concealment*		

# Description of eligible studies

- Twenty-seven trials were included, with a total of 4,041 participants/women.
- Studies were found of the following treatments:
  - Acupressure (P6, including acustimulation; auricular) with placebo or vitamin B6
  - Acupuncture with sham treatment and no treatment
  - Moxibustion (Traditional Chinese Medicine) with Chinese drugs
  - Ginger with placebo, vitamin B6 or drugs
  - Vitamin B6 with placebo
  - Anti-emetic medications with placebo



## Results- symptom relief

- No statistically significant effect for P6 acupressure versus placebo or vitamin B6; results for auricular acupuncture difficult to interpret.
- No statistically significant differences between groups in the acupuncture study.
- In Moxibustion versus Chinese drugs study– both groups showed improvement, but the study is poorly reported.
- Ginger: two studies favoured ginger over placebo; some studies favoured ginger over vitamin B6 and some favoured vitamin B6
- Results favoured vitamin B6 over placebo.
- Across the range of anti-emetics drugs studied, Debendox (Bendectin) was favoured over placebo.

# Results- adverse effects & secondary outcomes

- Only some studies reported adverse maternal or fetal/neonatal effects
- Maternal effects
  - Some participants had side-effects for acupressure bands (placebo and treatment groups)
  - Some participants taking ginger had heartburn
- Fetal/neonatal effects
  - No studies found significant differences in adverse neonatal outcomes - studies did not have sufficient power to show such differences
- Secondary outcomes-
  - Few studies reported on quality of life (though results were not easily interpreted) and none on economic costs

## Conclusion

- Little strong or consistent evidence for any intervention; it is not therefore necessary to acknowledge that it is possible to identify with confidence, effective and safe interventions.
- The results of many studies were difficult to interpret and they were difficult to pool due to differences in participants, interventions, comparisons and outcomes.
- No studies had the statistical power to provide convincing evidence regarding relatively rare adverse outcomes
- Very little information was reported on the psychological, social or economic effects of nausea and how this was affected by different interventions.
- The methodological quality of studies was mixed.
- Inadequate information was often provided on randomisation procedures and blinding.

# Implications for future research

- There is a need for specific and justified outcomes in research on interventions for nausea and vomiting in pregnancy.
- A range of instruments has been used to measure outcomes – the Pregnancy Unique Quantification of Emesis and Nausea (PUQE) scale developed by clinician-researchers may address this.
- There is a need to systematically measure and report adverse effects, quality of life and cost outcomes.
- There were no studies of dietary or other behavioural interventions, though these are commonly recommended; only one study measured adherence to dietary and other advice within a study of another intervention- this should be included in studies of all interventions, since this may also affect symptom relief.

# Outputs 2010 review



- Published review September 2010
- Podcast (with Cochrane assistance)
- Cochrane Journal Club October 2010
- 100s of citations and mentions in print and electronic media – nationally, globally, based on press release
- Several radio interviews: BBC 5 live- led to BBC Scotland, NI and London (Vanessa Feltz show, with Anne Diamond)- led to RTE Morning Ireland; 4fm Dublin
- Several summaries updated based on review findings
- Posters annually at All-Ireland and UK/Ire meetings

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## News

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### Morning sickness: still no relief

9 September 2010

#### HRB funded researchers find no evidence of an effective remedy

Anne Matthews from the School of Nursing in Dublin City University explains,

'Most women experience nausea and vomiting in early pregnancy, and, for many, it is the first sign of pregnancy. If you go online, you will find lots of advice based on "what worked for me" and pregnant women buy many over-the-counter remedies, especially complementary therapies, which they might consider to be "safer" than drugs, particularly in early pregnancy.

We looked at sixty years of evidence for various remedies and unfortunately, nothing really stood out as effective.'

The full press release from Wiley is available at the link below. There is also a link to an interview on Morning Ireland on RTE Radio 1, and a Podcast with the Cochrane Collaboration.

#### Links:

[Wiley press release](#)

[Morning Ireland interview](#)

[Cochrane Collaboration podcast](#)

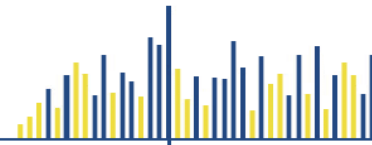
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# Morning Ireland



Morning Ireland

News At One

## Thursday, 9 September 2010

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### this morning...

After months of uncertainty and confronted by increasingly nervous international investors, the Cabinet has approved a way forward for Anglo Irish Bank. It involves splitting the company in two; creating an Asset Recovery Bank to manage its bad

loans and a Funding Bank which will hold deposits. The Labour Party's Finance spokesperson

Joan Burton gives us her view. We speak to our Europe Correspondent, Tony Connelly about the reaction in Europe and the Minister for Finance Brian Lenihan joins us in studio to discuss his plan for the bank.

The Fine Gael parliamentary party is continuing its special meeting in Waterford today. We speak to two TDs who were on opposite sides of the leadership challenge earlier this year. Fine Gael party leader Enda Kenny also joins us live to discuss Anglo, the state of his party and the upcoming political term.

The Chief Executive of the Barnardos children's charity Fergus Finlay has formally declared his interest in running for the Presidency. He has written to Labour TDs, Senators and members of the party's National Executive, seeking a nomination. Fergus Finlay tells us why he thinks he should be the

### Morning Ireland Features

### Pregnancy: wouldn't it make you sick?



Scientists have discovered what many pregnant women already knew -- that there's very little you can do about morning sickness.

Dr. Anne Matthews, of the School of Nursing at Dublin City University, said it was unclear whether ginger, peppermint tea, dry crackers or any of the other foods commonly used by women to relieve nausea and vomiting in early pregnancy, actually worked.

She also said more research was needed into the benefits of acupressure, acupuncture and other alternative therapies.

Dr. Matthews was lead researcher in the study funded by a [Cochrane Fellowship](#) from the Health Research Board in Ireland.

To listen to Aine Lawlor's interview with Dr. Matthews, [click here](#)

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# NEWS HEALTH

7 September 2010 Last updated at 23:47 GMT



## More 'needs to be done' to combat morning sickness

By Clare Murphy  
Health reporter, BBC News

**More needs to be done to establish which are safe and effective ways to relieve morning sickness, experts say.**

There is reluctance to use pharmaceutical products in pregnancy due to Thalidomide, the 1960s anti-nausea drug which led to birth defects.

But there is little evidence to suggest that alternative therapies have any real impact, the international group of researchers Cochrane found.

Campaigners say women who suffer receive a "Cinderella service".

Despite its name, the vomiting and nausea of morning sickness can occur at any time of the day and affect about half of pregnant women.

About two in 100 will experience it so badly they need to be hospitalised.

**Ginger biscuits**



Morning sickness is a common problem in pregnancy

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# Morning Sickness Treatments

## Review Shows Little Evidence

Jennifer P. Hellwig, MS, RD, ELS

There are currently no reliably safe and effective treatments for morning sickness—that's the conclusion of a group of Cochrane researchers who conducted a systematic review of the available evidence on pharmaceutical and alternative treatments for morning sickness. The review, published in September in the *Cochrane Database of Systematic Reviews*, included 27 randomized controlled trials, which together involved 4,041 women who were up to 20 weeks pregnant. Benefit was measured by various scales commonly used to gauge the severity of nausea at a time as close as possible to 3 days after treatment. In six studies of acupressure and two of acupuncture, there were no significant differences in benefit compared with control groups. One study of acustimulation did, however, report some improvement over 3 weeks. There was limited evidence of an

effect of ginger in relieving nausea, as there was for vitamin B<sub>6</sub>, antihistamines and antiemetic (antivomiting) drugs, including the antenatal drug Debendox. In addition, some of the treatments caused adverse effects, including drowsiness in those taking antiemetics. Ginger caused heartburn in some people. "A number of the studies we looked at appeared to show benefits, but in general the results were inconsistent and it was difficult to draw firm conclusions about any one treatment in particular," said lead researcher Dr. Anne Matthews, of the School of Nursing at Dublin City University in Dublin, Ireland. "We were also unable to obtain much information about whether these treatments are actually making a difference to women's quality of life." The researchers point to the need for additional and more rigorous trials in this area.

Irish Medical News | Still no effective treatment for morning sickness - Still no effective treatment for morning sickne... - Mozilla Firefox

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## Still no effective treatment for morning sickness

Tuesday, 14 September 2010 16:33 | Written by Priscilla Lynch |

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There are currently no reliably safe and effective treatments for morning sickness, according to Cochrane researchers led by an Irish university who conducted a systematic review of the available evidence.

Due to concerns that pharmaceutical medicines may damage their unborn children, women are increasingly turning to non-drug treatments, including complementary and alternative therapies, to treat these symptoms, noted the Cochrane researchers.

However, there is less evidence that alternative therapies work and they tend to be less well-regulated, they said.

The review included 27 randomised controlled trials, which together involved 4,041 women who were up to 20-weeks pregnant. Benefit was measured by various scales commonly used to gauge the severity of nausea at a time as close as possible to three days after treatment.

In six studies of acupressure and two of acupuncture there were no significant differences in benefit compared to

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# Update in 2013



- An easier process (for me)
- Updates to the process
- Same level of support
- Results: 37 studies, 5079 women
- Conclusions largely unchanged; similar methodological problems, little meta-analysis possible
- Currently under editorial review

# Supports that enabled the whole process



- Pregnancy and Childbirth group's support and specific input(s)
- Training within Cochrane generally and under Fellowship scheme in particular
- Publisher Wiley- staff support
- Thanks, I am happy to answer any questions.

# In conclusion: minding your review involves



- Managing relationships
- Managing your time
- Making a commitment
- Making connections
- Needs consistent attention but very rewarding



# Acknowledgements



- Co-authors on the review: Therese Dowswell, David Haas, Dónal O'Mathúna (Fellowship supervisor), Mary Doyle
- Health Research Board, for the Cochrane Fellowship
- Pregnancy and Childbirth Group: Therese, Sonja, Lynn, those involved in editorial process, consumer involvement.
- Mike Clarke, Cochrane trainers/ experts