



CROWN
CORE OUTCOMES IN
WOMEN'S HEALTH



Khalid Khan

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Epidemiology

Editor in Chief, BJOG



@Profkkhan

Comet
Rome
Nov 2014



Barts and The London
School of Medicine and Dentistry

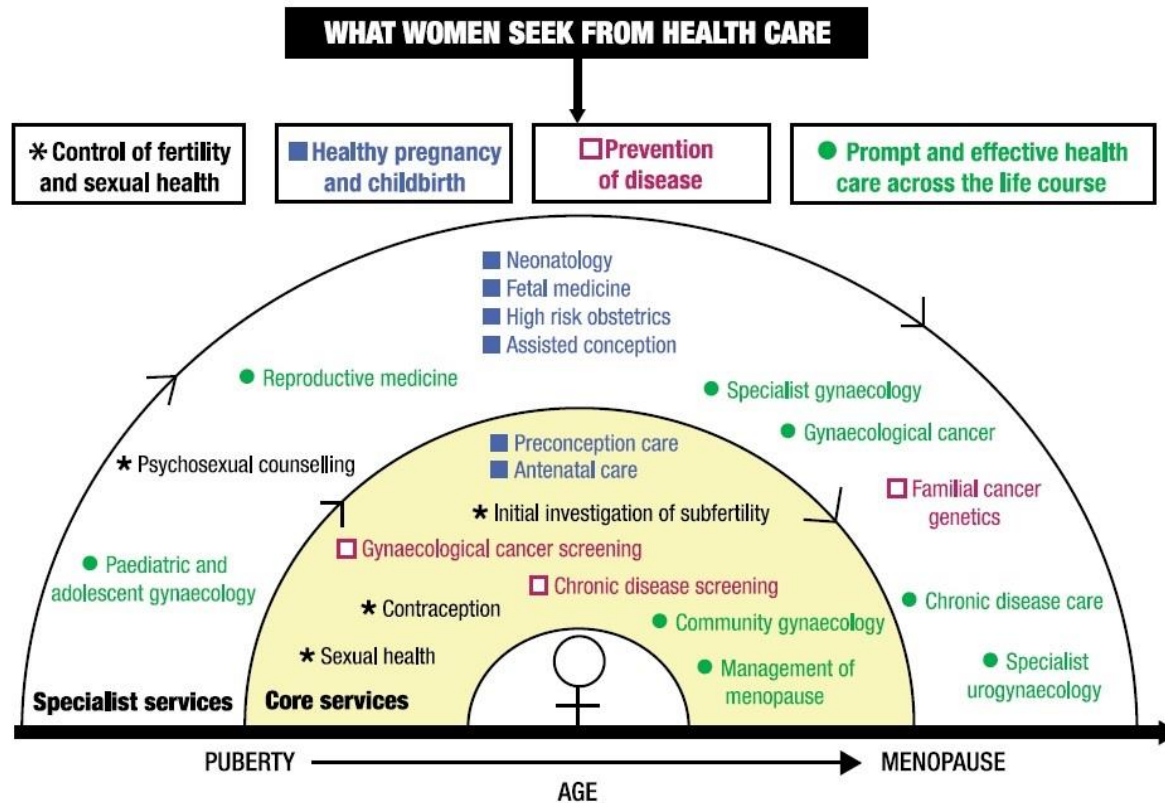
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Why we need COS

CROWN's aims

The progress of CROWN

Get involved



Source: RCOG, Scientific Impact Paper No. 7 (2011), Figure 3 Life course view of a health service for women




Effect of antenatal peer support on breastfeeding initiation: a systematic review

Lucy Ingram BSc (Midwifery), Christine MacArthur PhD, Khalid Khan MBBS,
Jonathan J. Deeks PhD, Kate Jolly MBChB

Study	Methods	Participants and setting	Intervention	Outcomes
Chapman et al. ²³	<ul style="list-style-type: none"> • RCT • 219 AN recruits • Intervention: <i>n</i> = 113 • Control: <i>n</i> = 106 	<ul style="list-style-type: none"> • Predominantly Hispanic women, ≤ 26 wk, eligible for WIC, age ≥ 18 yr, telephone contact for follow-up, considering BF, living in greater Hartford, no other PC, full-term singleton delivery with no congenital abnormalities, no history of maternal HIV infection. NICU infants excluded • UK 	AN early intrapartum, PN PC	BF initiation, BF rates at 1, 3 and 6 mo
Graffy et al. ²⁴	<ul style="list-style-type: none"> • RCT • 720 AN recruits • Intervention: <i>n</i> = 363 • Control: <i>n</i> = 357 	<ul style="list-style-type: none"> • 28–36 wk gestation • Considering BF • Not BF previous child age > 6 wk, English speaking, staying in area until ≥ 4 mo PN • UK 	<ul style="list-style-type: none"> • AN + PN • National Childbirth Trust PC • Intervention: routine care + 1 AN visit + PN telephone support or home visits if requested • Control: routine care 	<ul style="list-style-type: none"> • Primary outcome: prevalence of any BF at 6 wk • Secondary outcome: BF initiation



Effectiveness of strategies incorporating training and support of traditional birth attendants on perinatal and maternal mortality: meta-analysis

 OPEN ACCESS

Amie Wilson *doctoral researcher*¹, Ioannis D Gallos *specialist registrar*¹, Nieves Plana *research fellow*², David Lissauer *clinical lecturer in obstetrics and gynaecology*¹, Khalid S Khan *professor of*

Table 2| Quality assessment of non-randomised controlled trials

	Representativeness	Selection of comparison	Ascertainment of exposure	Demonstration of outcomes	Comparability	Outcome assessment	Length of follow-up	Adequacy of follow-up (%)
Janowitz 1988 ²²	Present*	Present*	Present*	Present*	Present**	Present*	Present*	>90
Greenwood 1990 ²⁴	Present*	Present*	Present*	Present*	Absent or not reported	Present*	Present*	>99
Alisjahbana 1995 ⁹	Present*	Present*	Absent or not reported	Present*	Present**	Present*	Present*	>99
Ronsmans 1997 ²¹	Present*	Present*	Present*	Present*	Absent or not reported	Present*	Present*	>99
Bang 1999 ²⁵	Present*	Present*	Present*	Present*	Absent or not reported	Present*	Present*	>90
Gloyd 2001 ²⁰	Absent or not reported	Present*	Absent or not reported	Present*	Present**	Present*	Present*	>99
Bhutta 2008 ²³	Present*	Present*	Present*	Present*	Present**	Present*	Present*	>99

One star (*)=half the maximum score for a specific quality item; two stars (**)=maximum score for a specific quality item.



GRADE

Quality assessment							Summary of findings				Quality	Importance
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations	No of patients		Effect			
							Atosiban	betamimetics	Relative (95% CI)	Absolute		
Necrotising enterocolitis												
2	randomised trials	serious ¹	no serious inconsistency	serious ²	no serious imprecision	none	0/0 (0%)	0/0 (0%)	RR 0.48 (0.12 to 1.98)	0 fewer per 1000 (from 0 fewer to 0 more)	⊕⊕⊕⊕ LOW	IMPORTANT
								0%		0 fewer per 1000 (from 0 fewer to 0 more)		

¹ Lack of blinding in ritodine group (Goodwin 1996)

² Dosage of atosiban other than registered dosage (Goodwin 1996)

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A ROUGH GUIDE TO SPOTTING

• BAD SCIENCE •

1. SENSATIONALISED HEADLINES



Headlines of articles are commonly designed to entice viewers into clicking on and reading the article. At best, they over-simplify the findings of research. At worst, they sensationalise and misrepresent them.

2. MISINTERPRETED RESULTS



News articles sometimes distort or misinterpret the findings of research for the sake of a good story, intentionally or otherwise. If possible, try to read the original research, rather than relying on the article based on it for information.

3. CONFLICT OF INTERESTS



Many companies employ scientists to carry out and publish research - whilst this does not necessarily invalidate research, it should be analysed with this in mind. Research can also be misrepresented for personal or financial gain.

4. CORRELATION & CAUSATION



Be wary of confusion of correlation & causation. Correlation between two variables doesn't automatically mean one causes the other. Global warming has increased since the 1800s, and pirate numbers decreased, but lack of pirates doesn't cause global warming.

5. SPECULATIVE LANGUAGE



Speculations from research are just that - speculation. Be on the look out for words such as 'may', 'could', 'might', and others, as it is unlikely the research provides hard evidence for any conclusions they precede.

6. SAMPLE SIZE TOO SMALL



In trials, the smaller a sample size, the lower the confidence in the results from that sample. Conclusions drawn should be considered with this in mind, though in some cases small samples are unavoidable. It may be cause for suspicion if a large sample was possible but avoided.

7. UNREPRESENTATIVE SAMPLES



In human trials, researchers will try to select individuals that are representative of a larger population, if the sample is different from the population as a whole, then the conclusions may well also be different.

8. NO CONTROL GROUP USED



In clinical trials, results from test subjects should be compared to a 'control group' not given the substance being tested. Groups should also be allocated randomly. In general experiments, a control test should be used where all variables are controlled.

9. NO BLIND TESTING USED



To prevent any bias, subjects should not know if they are in the test or the control group. In double-blind testing, even researchers don't know which group subjects are in until after testing. Note, blind testing isn't always feasible, or ethical.

10. 'CHERRY-PICKED' RESULTS



This involves selecting data from experiments which supports the conclusion of the research, whilst ignoring those that do not. If a research paper draws conclusions from a selection of its results, not all, it may be cherry-picking.

11. UNREPLICABLE RESULTS



Results should be replicable by independent research, and tested over a wide range of conditions (where possible) to ensure they are generalisable. Extraordinary claims require extraordinary evidence - that is, much more than one independent study!

12. JOURNALS & CITATIONS



Research published to major journals will have undergone a review process, but can still be flawed, so should still be evaluated with these points in mind. Similarly, large numbers of citations do not always indicate that research is highly regarded.

EXTREME RESULTS

TYPE II ERROR



- Form a consortium among all gynaecology-obstetrics and related journals to promote core outcome sets in all areas of our specialty.
- Encourage researchers to develop core outcome sets using robust consensus methodology involving multiple stakeholders, including patients.
- Strongly encourage the reporting of results for core outcome sets.
- Organise robust peer-review and effective dissemination of manuscripts describing core outcome sets.
- Facilitate embedding of core outcome sets in research practice, working closely with researchers, reviewers, funders and guideline makers.

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Core Outcomes for Clinical Trials: Moving Ahead

Timothy Rowe, MB BS, FRCSC

Editor-in-Chief



At the recent World Congress of the Royal College of Obstetricians and Gynaecologists in Liverpool, I met Professor Khalid Khan, the Editor-in-Chief of the British Journal of Obstetrics and Gynaecology. We had an amicable discussion about the present and future concerns of publishing in our specialty (he's a big fan of Twitter, by the way), but one subject of discussion resonated and continues to do so. It was the subject of clinical outcomes for studies submitted to journals of obstetrics, gynaecology, and reproductive medicine, and how the heterogeneity of the outcomes of RCTs makes comparison between and combination of results across studies difficult—and sometimes impossible.

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Core Outcome Measures in Effectiveness Trials

Links

Here you can find links to useful and relevant websites. If there is a link that you would like to recommend for this list, please [contact us](#).

Relevant web links

Core outcome networks / groups / collaborations

- Outcome Measures in Rheumatology (OMERACT)
- Harmonizing Outcome Measures for Eczema (HOME)
- Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)
- Women and Babies Health and Wellbeing : Action through Trials (WOMBAT)
- Prevention of Falls Network (PROFANE)
- European Wound Management Association Patient Outcome Group (EWMA)
- Acute Dialysis Quality Initiative (ADQI)
- European Society of Cutaneous Lupus Erythematosus (EUSCLE)
- International Myositis Assessment and Clinical Studies Group (IMACS)
- Pediatric Rheumatology International Trials Organization (PRINTO)
- Core Outcomes in Women's Health (CROWN)
- ICF Research Branch
- Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT)

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1 - 50 of 178 << First | < Previous | Next > | Last >>

	Title	Type	SJR	H index	Total Docs. (2013)	Total Docs. (3years)	Total Refs.	Total Cites (3years)	Citable Docs. (3years)	Cites / Doc. (2years)	Ref. / Doc.	Country
1	Human Reproduction Update	j	Q1 4,341	106	61	163	5.888	1.400	137	9,68	96,52	UK
2	Human Reproduction	j	Q1 2,641	156	387	1.363	12.495	6.245	1.191	4,91	32,29	UK
3	American Journal of Obstetrics and Gynecology	j	Q1 2,263	153	469	1.778	11.865	5.876	1.355	4,16	25,30	USA
4	Obstetrics and Gynecology	j	Q1 2,188	150	572	1.685	7.937	5.159	1.177	3,97	13,88	USA
5	BJOG: An International Journal of Obstetrics and Gynaecology	j	Q1 2,000	112	381	1.050	7.022	2.754	624	4,28	18,43	UK
6	Gynecologic Oncology	j	Q1 1,959	108	510	1.394	14.095	4.960	1.183	3,97	27,64	USA
7	Molecular Human Reproduction	j	Q1 1,891	91	91	224	5.340	912	214	3,71	58,68	UK
8	Clinics in Perinatology	j	Q1 1,825	52	60	182	3.400	550	159	2,71	56,67	UK
9	Ultrasound in Obstetrics and Gynecology	j	Q1 1,745	93	284	865	6.041	2.192	654	3,37	21,27	UK
10	Archives of Disease in Childhood: Fetal and Neonatal Edition	j	Q1 1,728	84	185	457	2.150	1.026	317	3,21	11,62	UK
11	Fertility and Sterility	j	Q1 1,712	143	704	2.896	23.028	9.066	2.587	3,56	32,71	USA
12	Reproduction	j	Q1 1,641	85	151	494	9.620	1.838	485	3,32	63,71	UK
13	Placenta	j	Q1 1,640	82	221	649	8.047	2.176	575	3,48	36,41	UK
14	Contraception	j	Q1 1,569	71	268	714	6.854	1.785	536	3,17	25,57	USA
15	Perspectives on Sexual and Reproductive Health	j	Q1 1,566	66	54	172	851	266	89	3,47	15,76	UK



The CROWN Initiative: journal editors invite researchers to develop core outcomes in women's health



Appendix 1

The CROWN Initiative includes the following journals, in alphabetical order (correct on 13th May 2014, up to date list available at www.crown-initiative.org):

- 1 Acta Obstetrica et Gynecologica Scandinavica
- 2 American Journal of Obstetrics & Gynecology
- 3 American Journal of Perinatology
- 4 Archives of Gynecology and Obstetrics
- 5 Australian and New Zealand Journal of Obstetrics and Gynaecology
- 6 Best Practice & Research: Clinical Obstetrics & Gynaecology
- 7 Birth: Issues in Perinatal Care
- 8 BJOG: An International Journal of Obstetrics and Gynaecology
- 9 BMC Pregnancy and Childbirth
- 10 BMC Women's Health
- 11 Climacteric
- 12 Clinical Obstetrics and Gynecology
- 13 Clinics in Perinatology
- 14 Cochrane Menstrual Disorders and Subfertility Group
- 15 Cochrane Pregnancy and Childbirth Group
- 16 Contraception
- 17 Current Opinion in Obstetrics and Gynecology
- 18 European Journal of Obstetrics & Gynecology and Reproductive Biology
- 19 Fertility and Sterility
- 20 Fetal Diagnosis and Therapy
- 21 Ginekologia Polska
- 22 Gynecological Surgery
- 23 Gynecologic Oncology
- 24 Gynecologic Oncology Reports
- 25 Human Fertility
- 26 Human Reproduction
- 27 Human Reproduction Update
- 28 Hypertension in Pregnancy
- 29 International Journal of Fertility and Sterility
- 30 International Breastfeeding Journal
- 31 International Journal of Gynecology & Obstetrics
- 32 International Urogynecology Journal
- 33 Journal of Family Planning and Reproductive Health Care
- 34 Journal of Gynecologic Oncology
- 35 Journal of Lower Genital Tract Disease
- 36 Journal of Midwifery & Women's Health
- 37 Journal of Obstetrics & Gynaecology
- 38 Journal of Obstetrics and Gynaecology Canada
- 39 Journal of Obstetric, Gynecologic & Neonatal Nursing
- 40 Journal of Perinatal and Neonatal Nursing
- 41 Journal of Perinatal Medicine
- 42 Maturitas
- 43 MCN The American Journal of Maternal Child Nursing
- 44 Menopause Review (Przegląd Menopauzalny)
- 45 Menopause: The Journal of The North American Menopause Society
- 46 Neurourology and Urodynamics
- 47 Obstetrics & Gynecology
- 48 Paediatric and Perinatal Epidemiology
- 49 Placenta
- 50 Prenatal Diagnosis
- 51 Reproductive Health
- 52 The Breast Journal
- 53 The European Journal of Contraception and Reproductive Health Care
- 54 The Obstetrician & Gynaecologist (TOG)
- 55 Twin Research and Human Genetics
- 56 Ultrasound in Obstetrics & Gynecology



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[The CROWN Initiative: Journal Editors Invite Researchers to Develop Core Outcomes in Women's](#)

1. [Health.](#)

[No authors listed]

Int J Fertil Steril. 2014 Oct;8(3):225-6. Epub 2014 Nov 1. No abstract available.

PMID: 25379148 [PubMed] [Free PMC Article](#)

[Related citations](#)

[The CROWN Initiative: Journal Editors Invite Researchers to Develop Core Outcomes in Women's](#)

2. [Health: The Core Outcomes in Women's Health \(CROWN\) Initiative.](#)

Khan K.

J Perinat Neonatal Nurs. 2014 Oct-Dec;28(4):247-9. doi: 10.1097/JPN.0000000000000052. No abstract available.

PMID: 25347100 [PubMed - in process]

[Related citations](#)

[The CROWN initiative: journal editors invite researchers to develop core outcomes in women's](#)

3. [health: The Core Outcomes in Women's Health \(CROWN\) Initiative.](#)

Khan K.

Ginekol Pol. 2014 Sep;85(9):717-8. No abstract available.

PMID: 25322547 [PubMed - in process]

[Related citations](#)

[\[The CROWN initiative: Journal editors invite researchers to develop core outcomes in women's](#)

4. [health.\]](#)

Khan KS.

J Gynecol Obstet Biol Reprod (Paris). 2014 Oct 7. pii: S0368-2315(14)00228-2. doi: 10.1016/j.jgyn.2014.09.002. [Epub ahead of print] French. No abstract available.

PMID: 25304097 [PubMed - as supplied by publisher] [Free Article](#)

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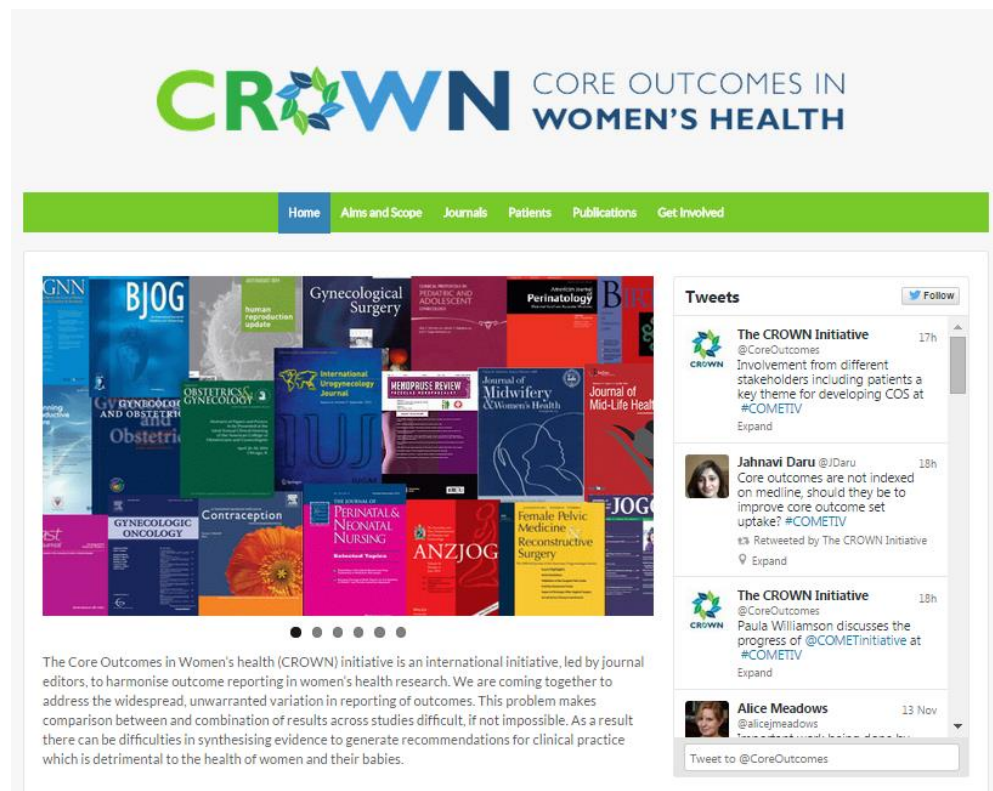
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www.crown-initiative.org





CROWN CORE OUTCOMES IN
WOMEN'S HEALTH


Home Aims and Scope Journals Patients Publications Get Involved


The Core Outcomes in Women's health (CROWN) initiative is an international initiative, led by journal editors, to harmonise outcome reporting in women's health research. We are coming together to address the widespread, unwarranted variation in reporting of outcomes. This problem makes comparison between and combination of results across studies difficult, if not impossible. As a result there can be difficulties in synthesising evidence to generate recommendations for clinical practice which is detrimental to the health of women and their babies.

Tweets [Follow](#)

 **The CROWN Initiative** @CoreOutcomes 17h
Involvement from different stakeholders including patients a key theme for developing COS at #COMETIV
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 **Jahnvi Daru** @JDaru 18h
Core outcomes are not indexed on medline, should they be to improve core outcome set uptake? #COMETIV
Retweeted by The CROWN Initiative
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 **The CROWN Initiative** @CoreOutcomes 18h
Paula Williamson discusses the progress of @COMETInitiative at #COMETIV
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 **Alice Meadows** @alicejmeadows 13 Nov
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CROWN
CORE OUTCOMES IN
WOMEN'S HEALTH

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Journal editors supporting core outcomes in Women's Health
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Federico Prefumo
@FedericoPrefumo FOLLOWS YOU

Sarah Wallace
@SarahJWallace
Speech Pathologist, PhD Candidate, Aphasia United Secretariat.

Paul R. Swift
@PaulRSwift
I am a local historian with a keen interest in the history of Nottingham's Hospitals.

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- Future Publish Core Outcome Sets

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If you are an editor, researcher, clinician or patient we would love to hear from you.



Louisa Waite
Project Coordinator
crown@rcog.org.uk

Please contact Louisa regarding joining the CROWN Initiative, publishing our latest editorial or to provide feedback regarding our website or social media.



James M N Duffy
NIHR Doctoral Fellow
james.duffy@balliol.ox.ac.uk

Please contact James with any queries related to core outcomes research in Women's Health.



www.crown-initiative.org

crown@rcog.org.uk

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