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Chinese Obstetrics and Gynecology Journal Club (COGJOC): A Randomized Controlled Trial of a Journal Club to Improve Medical English in Chinese Medical Professionals

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SCHOLARONE™ Manuscripts

- 1 Chinese Obstetrics and Gynecology Journal Club (COGJOC): A Randomized
- 2 Controlled Trial of a Journal Club to Improve Medical English in Chinese Medical
- 3 Professionals
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- Obstetricians and Gynecologists Chicago, IL, April 24-8, 2014
- 19 Word Count: 2,486 of text only

Objective: To assess whether an intensive journal club model based on articles and questions from the journal *Obstetrics and Gynecology* could improve comprehension and written and spoken expression of medical English in a population of Chinese medical professionals.

Methods: A volunteer sample of 52 medical professionals who were residents or postgraduate students at the master and PhD levels at the Heilongjiang University of Chinese Medicine. After a 3-part baseline examination (multiple choice, written, and oral) to assess medical English comprehension, participants were randomized to either 1) an intensive treatment arm with 24 journal club sessions or 2) a self-study group. An intensive journal club met for two hours every other day for 8-consecutive weeks or selfstudy. At the conclusion of the 8-week intervention period participants were re-tested with new questions. Evaluators were blinded to intervention assignments.

Results: Primary outcome measured was the change in score on the multiple choice

examination. Secondary outcomes included change in written and oral scores with grading scales used for Test of English as a Foreign Language (TOEFL) tests. Both groups improved on multiple choice assessment without a statistically significant difference between groups (90% power; n=25 and 27 for self-study and intervention groups, respectively). However, there was a statistically significant difference between groups with respect to both mean improvement in written (difference in means of 3.07 TOEFL score, 95% CI:[1.1,5.0],p=0.003) and speaking scores (difference in means of 1.91 TOEFL score, 95% CI:[0.06, 3.7],p=0.04) favoring the journal club intervention.

Conclusions: Although reading articles and questions from *Obstetrics and Gynecology* was associated with an increased number of correct answers on a multiple choice test

- of medical knowledge in all participants, interacting with colleagues and an English-speaking facilitator in an intensive journal club environment improved both written and
- spoken expression of English medical literature in Chinese medical professionals.
- Trial Registration: ClinicalTrials.gov NCT01844609



INTRODUCTION

English is increasingly becoming the *lingua franca* of medicine. Most international medical conferences are held in English and the journals with the highest impact are published in English. However, many international research institutions have driven growth in participation in international meetings and publication output¹ without necessarily addressing the challenges facing academicians with limited English language capabilities who compete to present at international meetings and publish in these elite international journals. Consequently, there is an acute need for non-English speaking medical professionals to develop written and oral English communication skills to participate in these academic endeavors. Previous studies have suggested that learners succeed when they focus on reading academic texts in their field to learn typical writing patterns^{2,3}.

The purpose of this randomized educational trial was to determine if an intensive journal club based on articles and specifically-designed materials freely accessible through the *Obstetrics and Gynecology* website improves comprehension and written and spoken expression of medical English in a population of Chinese medical professionals.

METHODS

The study population consisted of 52 medical professionals who were residents or postgraduate students at the master and PhD levels at the Department of Obstetrics and Gynecology, Heilongjiang University of Chinese Medicine in Harbin, China, who consented to participate in an 8-week educational intervention. This randomized

Tsui

controlled trial with parallel design was exempt from approval by the Institutional Review Board at the Pennsylvania State University College of Medicine and by the review board of the host institution in China at The First Affiliated Hospital, Heilongijang University of Chinese Medicine. All participants gave written informed consent with potential harms cited as possible stress from taking examinations or participating in a journal club. Participants were eligible if they were Chinese medical professionals specializing in gynecology (in China the practice of obstetrics and gynecology is split and we focused on gynecology specialists in this study). The sole exclusion criterion was self-reported English-speaking fluency. Consenting participants completed a baseline demographics questionnaire and were randomized to either 1) an intensive treatment arm with 24 journal club sessions led by a bilingual (English and Mandarin) medical student (IKT) from the United States (US) over the course of 8 weeks (intensive journal club) or 2) a self-study arm with self-directed learning (self-study). One of the authors (ARK) developed the randomization scheme using permuted blocks of size 2 to randomly assign the consenting participants to the intervention groups using an equal allocation ratio of 1:1 which was unknown to the other authors or participants. Another author (IKT) matched an alphabetized student roster to this randomization list three days prior to the first day of the journal club. No other characteristics about the students were known besides his or her name. Randomization was kept concealed to all study participants until the intervention groups were assigned.

Participants took a 3-part baseline examination (multiple choice, written, and oral) to assess medical English comprehension and expression; this format was modeled off of standardized language exams such as the Test of English as a Foreign Language

(TOEFL). A similar format but different content I post-intervention examination was repeated at end of study. The multiple choice examination consisted of 15 questions, with 5 answer choices each, adapted from the Association of Professors of Gynecology and Obstetrics (APGO) Undergraduate Web-Based Interactive Self Evaluation (uWISE) practice examinations and was read aloud to all participants during a one hour group orientation session. Participants did not have access to questions in a written format. Two additional open-ended questions were selected from one of the *Obstetrics and* Gynecology journal club article's study guide: one was read aloud and students had 10 minutes to provide written responses and the other was read aloud to each student privately as he or she provided an oral response, which was recorded. At the time of baseline testing, no articles had been presented at journal club, though the article selected for the oral examination was one of the first ones listed on the class syllabus that had been distributed in advance. Similarly, the article selected for the post-exam was one of the final journal club articles, though students did not know in advance the identity of the journal club article, all of which were selected from the Obstetrics and Gynecology journal. Following baseline examinations, both groups received a class syllabus with 24 selected gynecology articles and stimulus questions from the Obstetrics and

selected gynecology articles and stimulus questions from the *Obstetrics and Gynecology* journal club website. Articles spanned over 15 unique gynecology topics as identified by the APGO Medical Student Educational Objectives⁴ (see eTable 1).

Articles were selected based on website availability and perceived student interest of the journal club facilitator (IKT). Students accessed all material independently from the *Obstetrics and Gynecology* website. The intensive journal club participants attended

 two-hour sessions every other day, which consisted of reading selections of the assigned article aloud and discussing questions from the website's study guide. The self-study group followed the same syllabus but did not attend classes. There were no restrictions on use of translation software, nor was there an accurate way to monitor its potential use. The self-study students were asked to submit written, ungraded answers to 2 questions from the study guide for each article by the day it was to be presented in journal club as a measure of compliance. All data was collected at the host institution in Harbin, China. The journal club ran for 8 weeks from May through July 2013.

The primary outcome measured was the change in score from baseline to post-intervention on the multiple choice examination. Pre-specified secondary outcomes included change in score on the written and oral examinations. Two independent, masked evaluators (WCD and RSL) graded the written and oral examinations based on a rubric adapted from respective TOEFL exams at the study's conclusion, therefore feedback was not provided to the participants mid-study. The evaluators were blinded to the identity of the subject, the group assignment, and whether the exam they were grading was the baseline or end of study exam.

Each evaluator independently graded the written responses on two tasks (language use and topic development) from 0 to 5 for a total maximum score of 10. Masked evaluators assigned written scores to students based on the associated student ID number only; written responses were presented and evaluated in a random order. The spoken responses were graded on three tasks (delivery, language use, topic development) from 0 to 4 for a total maximum score of 12. Masked evaluators assigned speaking scores to students based on their verbalized student ID number only; recorded responses were

presented in a random order and not segregated by treatment group. A higher score indicated a greater comprehension and fluency of written or spoken English, respectively.

The primary outcome for this study was the change in the number of correct answers from baseline to post-intervention on the multiple choice examination. Prior to study initiation, we judged that a difference in the means of 3 points between the two groups was an educationally meaningful difference, based on a 15-point exam. Further, we assumed the standard deviation would be 3 points. Based on these assumptions, a sample size of 23 participants per group provided 90% power to detect a difference of 3 points between the two groups using a two-sided test having a significance level of 0.05. However, we anticipated a 10% attrition rate for the participants during the study; therefore, the total sample size was increased to 52 participants.

Linear mixed-effects models were used to assess differences between and within groups with respect to the primary outcome (change in multiple choice scores) and secondary outcomes (change in writing and speaking scores). Linear mixed-effects models are an extension of regression models that account for the within-subject correlation inherent in longitudinal studies. Inter-rater reliability between the two independent evaluators for the writing and speaking examinations was assessed using the weighted Kappa statistic. All hypothesis tests were two-sided and all analyses were performed using SAS software, version 9.3 (SAS Institute Inc., Cary, NC).

RESULTS

Fifty-two Chinese medical professionals participated in the study with 46 completing all aspects of the study (Fig 1). Recruitment began in March 2013 and ended in May 2013. Participants were recruited from a pool of 60 students by attending OB/GYN physicians at the host institution, and recommended by their attending physicians to participate in this educational summer experience. Six participants failed to complete the study (4 in the intensive group and 2 in the self-study group) for an 11.5% attrition rate. Participants were either lost to follow-up or were unable to complete the course and attend the final day of testing due to conflicting professional duties. Compliance for the self-study group, as measured by electronic submission of two study guide questions per article, dropped from 100% the first week, down to 60% (15 out of 25) by mid-study to 20% (5 out of 25) by the study conclusion at 8 weeks. In comparison, attendance for the intensive group dropped from 100% the first week, down to 96% (26 out of 27) by mid-study to 77% (20 out of 27) by study conclusion.

Results of baseline characteristics between the two cohorts show similar levels of self-reported English proficiency, as well as other demographic characteristics including age, highest degree conferred, and years of formal English instruction (**Table 1**). Both groups improved in mean number of correct multiple choice responses, but there was no statistically significant difference between groups (**Table 2**). However, there was a statistically significant difference between groups with respect to both mean written scores and speaking scores (**Table 2**; For self-study and intensive groups, respectively: mean correct written score (SD) on pre-test 5.52 (2.36) and 4.72 (3.10); mean correct written score (SD) on post-test 4.72 (2.32) and 6.98 (2.20); mean correct speaking

score on pre-test 5.33 (2.37) and 5.63 (2.36); mean correct speaking score on post-test 4.89 (2.70) and 7.11 (2.16)).

There was also a statistically significant improvement within the intensive group across all three language competencies (**Table 3**). There was a statistically significant improvement within the self-directed group on the multiple choice examination, but not for writing or speaking components

For this study, inter-rater reliability of the two independent raters for evaluating pre- and post-examination written scores had a weighted kappa value of 0.67 (95% CI: (0.55, 0.79)) and 0.71 (95% CI: (0.62, 0.81)), respectively. Weighted kappa scores for pre- and post-examination speaking scores were slightly lower at 0.58 (95% CI: (0.45, 0.72)) and 0.57(95% CI: (0.42, 0.72)), respectively.

DISCUSSION

Our study results suggest that a journal club significantly and selectively improves both written and verbal medical English proficiency of Chinese OB/GYN health professionals as assessed by a significant improvement in respective TOEFL scores. This suggests that holding frequent journal clubs may offer one method of increasing oral comprehension and speaking skills in foreign medical professionals. However, other factors such as the students' concurrent clinical training may also play a role in individual content-specific test performance.

One objective of our study was to determine if participating in a journal club would improve knowledge base and comprehension over independently reading journal

articles and answering stimulus questions. A large study by the Royal College of Physicians and Surgeons of Canada demonstrated that out of possible activities, reading medical literature most frequently stimulated self-directed learning activities leading to a greater likelihood of changing practice patterns, in spite of available educational seminars and opportunities for group discussion with peers, as in a journal club setting⁵. The American Medical Association (AMA) even issues a standard certificate based on structured or less-structured learning experiences, of which selfdirected reading is a credible option for continuing medical education⁶. On the other hand, a randomized controlled trial suggested that surgeons who participated in an internet-based journal club improved their critical appraisal skills more than the control group that only read clinical articles, possibly due to the lack of accountability in selfdirected learning'.

Another aim was to objectively quantify a potential difference in reading, oral, and spoken comprehension between the two groups as assessed by multiple choice and modified TOEFL tests. While studies have described the journal club's effectiveness in teaching critical appraisal as measured by subjective self-assessments or self-created pre- and post-tests⁸⁻¹¹, little research has evaluated the journal club method as a vehicle for specifically improving oral and spoken comprehension of medical English. Further, a literature review found no evidence of a randomized trial that quantifies the journal club's impact in an international academic setting, specifically as a tool for teaching medical English and improving oral and written comprehension for non-English speakers, though commentary has explored the benefits of and barriers to organizing journal clubs in developing countries¹².

The strengths of the study include its randomized design, its reproducible model, the use of objective journal article study guides from the Obstetrics and Gynecology website, and the standardized TOEFL grading rubric. Articles selected for the intervention spanned over 15 unique topics in gynecology. This provided an appropriate and broad academic context for health professionals to learn both medical vocabulary and grammatical structures. Additionally, both pre- and post-intervention examinations were adapted from uWISE, a professional question bank used by some students to prepare for the National Board of Medical Examiners (NBME) subject examination in obstetrics and gynecology. The grading rubrics for both the written and speaking portions were adapted from respective TOEFL rubrics with comparable score reliability estimates. Weighted kappa scores for the pre-and post-examination written scores were 0.67 and 0.71, respectively and for the pre- and post-examination speaking scores were 0.58 and 0.57, respectively. Score reliability estimates for the TOEFL writing and speaking exams are comparable at 0.74 (Standard Error of the Mean (SEM)=2.76) and 0.88 (SEM=1.62), respectively 13. The preferred TOEFL kappa value between automated and human scoring is 0.70, which represents the threshold at which signal outweighs noise in prediction¹⁴. One of the limitations of our study is the appropriateness of using this multiple choice test to evaluate medical knowledge acquisition and language comprehension. Since the clinical question stems are modeled on US-based examinations that test knowledge of guidelines and treatment, they may not have been an appropriate test vehicle for a population of Chinese medical professionals with limited education in western medicine. These participants have an undergraduate educational background in Traditional

Tsui

Chinese Medicine (TCM), with a curriculum that is 40% western medicine-based.

Though this strengthens the integration of eastern and western medicine, it may have limited the efficacy of our experimental training module. Additional limitations include the disparate journal club attendance and compliance rate of the self-directed control group.

The *Obstetrics and Gynecology* journal club may provide an efficient vehicle for learning both written and spoken English and content-specific medical knowledge. Further research should assess the effect of advanced native student facilitators on medical English improvement in a journal club setting, as this may be a more sustainable model with potentially greater reproducibility than utilizing bilingual U.S. professionals. Future directions may also focus on using the journal club model to teach manuscript preparation for both basic and clinical OB/GYN research to English based medical journals.

ACKNOWLEDGEMENT:

Contributors: Xiao-Ke Wu, Richard S Legro designed the protocol and got funding as "Longjiang Professorship". Ilene K Tsui coordinated the trial and drafted the manuscript. Hongying Kuang and Feng-Juan Han recruited the participants. Allen R Kunselman served as statistician. William C Dodson was a consultant for this educational trial.

Competing interests: None

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Competition) in Heilongjiang Province Universities.(3) "Longjiang Scholarship" chair professor for Dr. Richard S Legro in Heilongjiang Province during the year of 2010-2013. (4) the National Key Discipline of Chinese Medicine in Gynecology during the year of 2009–14

Data sharing statement: We state that all data are available for this international cooperative educational project. For this manuscript, IKT and ARK take responsibility for the integrity of the data and the accuracy of the data analysis.

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Page
1 2
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BMJ Open

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Table 1: Baseline demographic and characteristics of both cohorts as self-reported on questionnaire prior to study randomization.

5 6	Self-Study (n=25)	Intensive (n=27)
Demographic Characteristic	n (%)	n (%)
Students with PhD degree	6 (24)	6 (22)
<5 years of formal English instruction	4 (16)	1 (4)
English proficiency		
Novice	4 (16)	7 (26)
Intermediate	20 (80)	18 (67)
Advanced	1 (4)	2 (7)
Age (years)*	27.3 ± 3.7	26.8 ± 2.8
Female students	22 (88%)	26 (96%)
data reported as mean (standard deviation)		<u> </u>

'data reported as mean (standard deviation)

Table 2: Mean differences in examination score between pre-intervention and postintervention examinations between Self-Study and Intensive journal club groups. (Multiple choice score out of 15 possible points, Writing out of 10 possible TOEFL points, Speaking out of 12 possible TOEFL points).

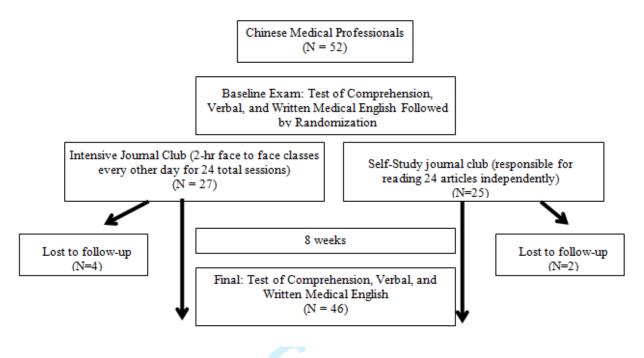
Method	Self-Study Mean (SD) [n=23]	Intensive Study Mean (SD) [n=23]	Difference in means (95% CI)	P-value
Multiple choice	1.04 (2.14)	1.91 (2.02)	0.87 (-0.37, 2.11)	0.164
Writing	-0.80 (3.25)	2.26 (3.30)	3.07 (1.12, 5.01)	0.003
Speaking	-0.43 (3.71)	1.48 (2.39)	1.91 (0.06, 3.77)	0.043

Table 3: Mean differences in examination score between pre-intervention and post-intervention examinations within Self-Study and Intensive journal club groups. (Multiple choice score out of 15

329	possible poin	ts, Writing out of '	10 possible TOE	FL points	s, Speaking	out of 12 poss	sible TOEFL poin	ts).

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	Method	Difference in Self-Study means (95% CI) [n=23]	Improvement in score	P-value	Difference in Intensive Study means (95% CI) [n=23]	Improvement in score	P-value
	Multiple choice	1.04 (0.17, 1.92)	6.9%	0.021	1.91 (1.04, 2.79)	12.7%	<0.001
	Writing	-0.80 (-2.18,	-5.3%	0.245	2.26 (0.89, 3.64)	15.0%	0.002
		0.57)					
	Speaking	-0.43 (-1.75,	-2.8%	0.507	1.48 (0.17, 2.79)	9.9%	0.028
	. 5	0.88)			, , ,		
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Figure 1. Flow chart of study design.



First Author	Title	APGO Topic
Hansen, M	Assisted Reproductive Technology and Major Birth Defects in Western Australia	Infertility
Twijnstra, Andries R	Predictors of Successful Surgical Outcome in Laparoscopic Hysterectomy	Gynecological Procedures
Edwards, Digna R. Velez		
Moorman, Patricia G	Effect of Hysterectomy With Ovarian Preservation on Ovarian Function	Gynecological Procedures
Grimm, Christoph	Treatment of Cervical Intraepithelial Neoplasia With Topical Imiquimod: A Randomized Controlled Trial	Cervical Disease and Neoplasia
Gariepy, Aileen M	Reliability of Laparoscopic Compared With Hysteroscopic Sterilization at 1 Year: A Decision Analysis	Family Planning
Dmitrovic, Romana	Continuous Compared With Cyclic Oral Contraceptives for the Treatment of Primary Dysmenorrhea: A Randomized Controlled Trial	Dysmenorrhea
Kaunitz, Andrew M	Levonorgestrel-Releasing Intrauterine System or Medroxyprogesterone for Heavy Menstrual Bleeding: A Randomized Controlled Trial	Abnormal Uterine Bleeding
Diamond, Michael P	Endometrial Shedding Effect on Conception and Live Birth in Women With Polycystic Ovary Syndrome	Infertility
Timmermans, Anne	Endometrial Thickness Measurement for Detecting Endometrial Cancer in Women With Postmenopausal Bleeding: A Systematic Review and Meta-Analysis	Endometrial Hyperplasia and Carcinoma
Tanmahasamut, Prasong	Postoperative Levonorgestrel-Releasing Intrauterine System for Pelvic Endometriosis-Related Pain: A Randomized Controlled Trial	Endometriosis
Badalian, Samuel S	Vitamin D and Pelvic Floor Disorders in Women: Results From the National Health and Nutrition Examination Survey	Pelvic Organ Prolapse
Paraiso, Marie Fidela R	Laparoscopic Compared With Robotic Sacrocolpopexy for Vaginal Prolapse: A Randomized Controlled Trial	Gynecological Procedures
Castle, Philip E	Relationship of Atypical Glandular Cell Cytology, Age, and Human Papillomavirus Detection to Cervical and Endometrial Cancer Risks	Cervical Disease and Neoplasia
Semere, Luwam G	Endometrial Intraepithelial Neoplasia Clinical Correlates and Outcomes	Endometrial Hyperplasia and Carcinoma
Jaakkola, Susanna	Endometrial Cancer in Postmenopausal Women Using Estradiol–Progestin Therapy	Menopause

Dinger, Jürgen	Effectiveness of Oral Contraceptive Pills in a Large U.S. Cohort Comparing Progestogen and Regimen	Family Planning
Tuomikoski, Pauliina	Effect of Hot Flushes on Vascular Function: A Randomized Controlled Trial	Menopause
Penninx, Josien P.M	Bipolar Radiofrequency Endometrial Ablation Compared With Hydrothermablation for Dysfunctional Uterine Bleeding: A Randomized Controlled Trial	Abnormal Uterine Bleeding
Jakobsson, Maija	Loop Electrosurgical Excision Procedure and the Risk for Preterm Birth	Preterm Labor
Parker, William H	Ovarian Conservation at the Time of Hysterectomy and Long-Term Health Outcomes in the Nurses' Health Study	Gynecological Procedures
Hefler, Lukas	The Intraoperative Complication Rate of Nonobstetric Dilation and Curettage	Induced Abortion
Partridge, Edward	Results From Four Rounds of Ovarian Cancer Screening in a Randomized Trial	Ovarian Neoplasms
Connolly, AnnaMarie	Reevaluation of Discriminatory and Threshold Levels for Serum β-hCG in Early Pregnancy	Maternal Fetal Physiology



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			_
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
ntroduction			.2
Background and	2a	Scientific background and explanation of rationale	4
objectives	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	is and the second secon
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	7
nterventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were	
		actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they	7
		were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	8
_ , , , , , , , , , , , , , , , , , , ,	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:	0	Method wood to consists the wooders allegation convenes	_
Sequence	8a	Method used to generate the random allocation sequence	<u>5</u>
generation Allocation	8b 9	Type of randomisation; details of any restriction (such as blocking and block size)	5
concealment	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
mechanism		describing any steps taken to concear the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	
	. •	interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	7
CONSORT 2010 checklist	595		Pac

			2
		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	9/12
diagram is strongly		were analysed for the primary outcome	19
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	8-9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	
		by original assigned groups	15-16
Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	
estimation		precision (such as 95% confidence interval)	15-16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	
		pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	5
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	12-13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12-13
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

^{*}We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Chinese Obstetrics and Gynecology Journal Club (COGJOC): A Randomized Controlled Trial

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SCHOLARONE™ Manuscripts

1	Chinese Obstetrics and Gynecology Journal Club (COGJOC): A Randomized
2	Controlled Trial

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- **Key words**: Medical education, medical English, journal clubs
- 15 Clinicaltrials.gov ID: NCT01844609

ABSTRACT

- Objectives: To assess whether a journal club model could improve comprehension and written and spoken expression of medical English in a population of Chinese medical professionals.
- Setting and Participants: The study population consisted of 52 medical professionals
 who were residents or postgraduate students at the master and PhD levels at the
- Department of Obstetrics and Gynecology, Heilongjiang University of Chinese Medicine
- 24 , China
- 25 Intervention: After a 3-part baseline examination to assess medical English
- comprehension, participants were randomized to either 1) an intensive journal club
- treatment arm or 2) a self-study group. At the conclusion of the 8-week intervention
- participants (nIRB=52) were re-tested with new questions.
- **Outcome measures:** Primary outcome was the change in score on the multiple choice
- examination. Secondary outcomes included change in scores on the written and oral
- examinations with modified grading scales used from the Test of English as a Foreign
- 32 Language (TOEFL).
- **Results:** Both groups improved on multiple choice assessment without a statistically
- significant difference between groups (90% power). However, there was a statistically
- 35 significant difference between groups with respect to both mean improvement in written
- 36 (95%CI:[1.1,5.0],p=0.003) and speaking scores (95%CI:[0.06, 3.7],p=0.04) favoring the
- journal club intervention.
- **Conclusion:** Interacting with colleagues and an English-speaking facilitator in a journal
- 39 club environment improved both written and spoken expression of English medical
- 40 literature in Chinese medical professionals. Implications include using journal clubs as a

- self-sustainable teaching model to improve fluency in medical English for international colleagues.
- 43 Trial Registration ID: NCT01844609
- 44 Strengths and Limitations:
 - Limited sample size of students nominated by clinical professors
- Asked about but did not quantify history of prior formal English language
 instruction in baseline questionnaire
 - Poor compliance rate of written answers to questions from self-study group
 - Pre- and post-test examinations modeled off standardized Tests of English as a Foreign Language (TOEFL) exams
 - Appropriateness of using multiple choice tests modeled on US based
 examinations to evaluate medical knowledge of Chinese medical professionals.

INTRODUCTION

English is increasingly becoming the *lingua franca* of medicine. Most international medical conferences are held in English and the journals with the highest impact are published in English. However, many international research institutions have driven growth in participation in international meetings and publication output [1] without necessarily offering sustainable solutions for academicians with limited English language capabilities who compete to present at international meetings and publish in these elite international journals, thus limiting global scholarship and exchange with non-native speakers [2]. In Chinese higher education, for example, there is significant pressure to publish in English academic journals for many doctoral science students [3, 4]. But amidst the rapid growth of international publications by Chinese scientists, which

now ranks 5th in the world in volume [5], instruction on writing within specialist disciplines is still lacking and language remains a barrier for many students who wish to convey their discipline-specific concepts in English while avoiding plagiarism and an industry of literacy brokers [6]. Consequently, there is an acute need for non-English speaking medical professionals to develop written and oral English communication skills to participate in these academic endeavors. Previous studies have suggested that needs in learning the English language are better met when applied towards some discipline-specific focus rather than mastering English to achieve language fluency [5]. The purpose of this randomized educational trial was to therefore determine if an intensive journal club based on articles and specifically-designed materials freely accessible through the Obstetrics and Gynecology website improves comprehension and written and spoken expression of medical English in a population of Chinese medical professionals. Ultimately, the policy implication is that this may facilitate opportunities for international colleagues to engage with native English speakers and encourage academic collaboration and innovative methods for teaching English for a specific purpose (ESP).

MATERIALS AND METHODS

The study population consisted of 52 medical professionals who were residents or postgraduate students at the master and PhD levels at the Department of Obstetrics and Gynecology, Heilongjiang University of Chinese Medicine in Harbin, China, who consented to participate in an 8-week educational intervention. Participants had limited experience with Western medicine. This randomized controlled trial with parallel design was exempt from approval by the Institutional Review Board at the Pennsylvania State

University College of Medicine (45 CFR 46.101(b)(1)) and by the review board of the host institution in China at The First Affiliated Hospital, Heilongjiang University of Chinese Medicine based on its classification as educational instruction and strategy research. All participants gave written informed consent with potential harms cited as possible stress from taking examinations or participating in a journal club. Tests results were anonymized and performance was kept strictly confidential so as not to impact the student's professional reputation. Participants were eligible if they were Chinese medical professionals specializing in gynecology (in China the practice of obstetrics and gynecology is split and we focused on gynecology specialists in this study). The sole exclusion criterion was self-reported English-speaking fluency. Consenting participants completed a baseline demographics questionnaire and were randomized to either 1) an intensive treatment arm with 24 journal club sessions led by a bilingual (English and Mandarin) medical student (IKT) from the United States over the course of 8 weeks or 2) a self-study arm with selfdirected learning. One of the authors (ARK) developed the randomization scheme to randomly assign the consenting participants to the intervention groups using an equal allocation ratio of 1:1 which was unknown to the other authors or participants. Another author (IKT) matched an alphabetized student roster to this randomization list three days prior to the first day of the journal club. No other characteristics about the students were known besides his or her name. Randomization was kept concealed to all study participants until the intervention groups were assigned.

Participants took a 3-part baseline examination (multiple choice, written, and oral) to assess medical English comprehension and expression; this format was modeled off of

standardized language exams such as the Test of English as a Foreign Language (TOEFL). A similar format but different content post-intervention examination was repeated at end of study. The multiple choice examination consisted of 15 questions. with 5 answer choices each, adapted from the Association of Professors of Gynecology and Obstetrics (APGO) Undergraduate Web-Based Interactive Self Evaluation (uWISE) practice examinations and was read aloud to all participants during a one hour group orientation session. Sample test questions are provided as supplemental information. Participants then selected one of five multiple choice answers and recorded their responses. Participants did not have access to questions in a written format. Two additional open-ended questions were selected from one of the Obstetrics and Gynecology journal club article's study guide: one was read aloud and students had 10 minutes to provide written responses and the other was read aloud to each student privately as he or she provided an oral response, which was recorded. At the time of baseline testing, no articles had been presented at journal club, though the article selected for the oral examination was one of the first ones listed on the class syllabus that had been distributed in advance. Similarly, the article selected for the post-exam was one of the final journal club articles, though students did not know in advance the identity of the journal club article. Test questions addressed vocabulary, grammatical competence, knowledge of content manner and verbal fluency. Following baseline examinations, both groups received a class syllabus with 24 selected gynecology articles and stimulus questions from the Obstetrics and Gynecology journal club website. Articles spanned over 15 unique gynecology topics as identified by the APGO Medical Student Educational Objectives [7]. Articles were

 selected based on website availability and perceived student interest of the journal club facilitator (IKT). Students accessed all material independently from the *Obstetrics and Gynecology* website. The intensive journal club participants attended two-hour sessions every other day, which consisted of reading selections of the assigned article aloud and discussing questions from the website's study guide. The self-study group followed the same syllabus but did not attend classes. There were no restrictions on use of translation software, nor was there an accurate way to monitor its potential use. The self-study students were asked to submit written, ungraded answers to two questions from the study guide for each article by the day it was to be presented in journal club as a measure of compliance. All data was collected at the host institution in Harbin, China. The journal club ran for eight weeks from May through July 2013.

The primary outcome measured was the change in score from baseline to post-intervention on the multiple choice examination. Pre-specified secondary outcomes included change in score on the written and oral examinations. Two independent, masked evaluators (WCD and RSL) graded the written and oral examinations based on a rubric adapted from respective TOEFL exams at the study's conclusion, therefore feedback was not provided to the participants prior to the study's conclusion. The evaluators were blinded to the identity of the subject, the group assignment, and whether the exam they were grading was the baseline or end of study exam.

Each evaluator independently graded the written responses on two tasks (language use and topic development) from zero to five for a total maximum score of 10. Masked evaluators assigned written scores to students based on the associated student ID number only; written responses were presented and evaluated in a random order. The

 written or spoken English, respectively.

spoken responses were graded on three tasks (delivery, language use, topic development) from zero to four for a total maximum score of 12. Masked evaluators assigned speaking scores to students based on their verbalized student ID number only; recorded responses were presented in a random order and not segregated by treatment group. A higher score indicated a greater comprehension and fluency of

Prior to study initiation, we judged that a difference in the means of three points between the two groups was an educationally meaningful difference, based on a 15-point exam. Further, we assumed the standard deviation would be three points.

Based on these assumptions, a sample size of 23 participants per group provided 90% power to detect a difference of three points between the two groups using a two-sided test having a significance level of 0.05. However, we anticipated a 10% attrition rate for the participants during the study; therefore, the total sample size was increased to 52 participants.

Linear mixed-effects models were used to assess differences between and within groups with respect to the primary outcome (change in multiple choice scores) and secondary outcomes (change in writing and speaking scores). Linear mixed-effects models are an extension of regression models that account for the within-subject correlation inherent in longitudinal studies. Inter-rater reliability between the two independent evaluators for the writing and speaking examinations was assessed using the weighted Kappa statistic. All hypothesis tests were two-sided and all analyses were performed using SAS software, version 9.3 (SAS Institute Inc., Cary, NC).

RESULTS

Fifty-two Chinese medical professionals participated in the study with 46 completing all aspects of the study. Recruitment began in March 2013 and ended in May 2013. Participants were recruited from a pool of 60 students at the host institution and introduced by their attending physicians to this educational summer experience. Six participants failed to complete the study (4 in the intensive group and 2 in the self-study group) for an 11.5% attrition rate. Participants were either lost to follow-up or were unable to complete the course and attend the final day of testing due to conflicting professional duties. Compliance for the self-study group, as measured by electronic submission of two study guide questions per article, dropped from 100% the first week, down to 60% (15 out of 25) by mid-study to 20% (5 out of 25) by the study conclusion at 8 weeks. In comparison, attendance for the intensive group dropped from 100% the first week, down to 96% (26 out of 27) by mid-study to 77% (20 out of 27) by study conclusion. The facilitator (IKT) sent email reminders directly to students and also asked attending physicians to encourage participation of students to mitigate further noncompliance. All students completed the post-test, regardless of compliance level and their results were included in the final analyses. Results of baseline characteristics between the two cohorts show similar levels of selfreported English proficiency, as well as other demographic characteristics including age, highest degree conferred, and years of formal English instruction (Table 1). Of note, study participants are overwhelmingly female because culturally, practicing obstetricians and gynecologists remain predominantly female in China and therefore the department's population represents that distribution. Both groups improved in mean number of correct multiple choice responses, but there was no statistically significant

difference between groups (Table 2). However, there was a statistically significant difference between groups with respect to both mean written scores and speaking scores (Table 2; For self-study and intensive groups, respectively; mean correct written score (SD) on pre-test 5.52 (2.36) and 4.72 (3.10); on post-test 4.72 (2.32) and 6.98 (2.20); mean correct speaking score (SD) on pre-test 5.33 (2.37) and 5.63 (2.36); on post-test 4.89 (2.70) and 7.11 (2.16)). There was also a statistically significant improvement within the intensive group across all three language competencies (Table 3). There was a statistically significant improvement within the self-directed group on the multiple choice examination, but not

Table 4 listed articles selected from the Obstetrics and Gynecology Journal. Articles spanned 15 unique gynecology topics as identified by the APGO Medical Student Educational Objectives

For this study, inter-rater reliability of the two independent raters for evaluating pre- and post-examination written scores had a weighted kappa value of 0.67 (95%CI:(0.55,0.79)) and 0.71 (95%CI:(0.62,0.81)), respectively. Weighted kappa scores for pre- and post-examination speaking scores were slightly lower at 0.58 (95%CI:(0.45,0.72)) and 0.57(95%CI:(0.42,0.72)), respectively.

DISCUSSION

for writing or speaking components

Our study results suggest that a journal club significantly and selectively improves both written and verbal medical English proficiency of Chinese OB/GYN health professionals as assessed by a significant improvement in respective TOEFL scores. This suggests

Tsui

that holding frequent journal clubs may offer one method of increasing oral comprehension and speaking skills in foreign medical professionals. However, other factors such as the students' concurrent clinical training may also play a role in individual content-specific test performance.

One objective of our study was to determine if participating in a journal club would improve knowledge base and comprehension over independently reading journal articles. A large study by the Royal College of Physicians and Surgeons of Canada demonstrated that out of possible activities, reading medical literature most frequently stimulated self-directed learning activities leading to a greater likelihood of changing practice patterns, in spite of available educational seminars and opportunities for group discussion with peers, as in a journal club setting [8]. On the other hand, a randomized controlled trial suggested that surgeons who participated in an internet-based journal club improved their critical appraisal skills more than the control group that only read clinical articles, possibly due to the lack of accountability in self-directed learning [9]. In regards to writing skills, a few studies have reported previous strategies used by nonnative scholars to write for English publications which include using a mentoring service provided by the journal, attending a writer's workshop provided by a professional society, recruiting visiting scholars or commissioning fee-for-service editors [2, 5]. Though these solutions are beneficial, there is still a need for students to cultivate transferrable and sustainable writing skills themselves that are adapted to fit the local context and constraints of their academic needs. Part of the continuing difficulties in language acquisition in Chinese higher education is that historically, there has been a division between science and technology teaching and English language teaching,

further limiting opportunities for collaboration. A journal club as a vehicle for language acquisition seeks to combine both disciplines.

Another aim was to objectively quantify a potential difference in reading, oral, and spoken comprehension between the two groups as assessed by multiple choice and modified TOEFL tests. While studies have described the journal club's effectiveness in teaching critical appraisal as measured by subjective self-assessments or self-created pre- and post-tests [10-13], little research has evaluated the journal club method as a vehicle for specifically improving oral and spoken comprehension of medical English. Further, a literature review found no evidence of a randomized trial that quantifies the journal club's impact in an international academic setting, specifically as a tool for teaching medical English and improving oral and written comprehension for non-English speakers, though commentary has explored the benefits of and barriers to organizing journal clubs in developing countries [14].

The strengths of the study include its randomized design, its reproducible model, the use of objective journal article study guides from the *Obstetrics and Gynecology* website, and the standardized TOEFL grading rubric. The breadth of articles provided an appropriate and broad academic context for health professionals to learn both medical vocabulary and grammar. Additionally, both pre- and post-intervention examinations were adapted from uWISE, a professional question bank used by some medical students to prepare for the National Board of Medical Examiners (NBME) subject examination in obstetrics and gynecology. The grading rubrics for both the written and speaking portions were adapted from respective TOEFL rubrics with comparable score reliability estimates. Weighted kappa scores for the pre-and post-

Tsui

examination written scores were 0.67 and 0.71, respectively and for the pre- and post-examination speaking scores were 0.58 and 0.57, respectively. Score reliability estimates for the TOEFL writing and speaking exams are comparable at 0.74 (Standard Error of the Mean [SEM]=2.76) and 0.88 (SEM=1.62), respectively [15]. The preferred TOEFL kappa value between automated and human scoring is 0.70, which represents the threshold at which signal outweighs noise in prediction [16].

One of the limitations of our study is the appropriateness of using this multiple choice test to evaluate medical knowledge acquisition and language comprehension. Since the clinical question stems are modeled on US-based examinations that test knowledge of guidelines and treatment, they may not have been an appropriate test vehicle for a population of Chinese medical professionals with limited education in western medicine. These participants have an undergraduate educational background in Traditional Chinese Medicine (TCM), with a curriculum that is 40% western medicine-based. Though this strengthens the integration of eastern and western medicine, it may have limited the efficacy of our experimental training module. Additional limitations include the disparate journal club attendance and compliance rate of the self-directed control group.

The *Obstetrics and Gynecology* journal club may provide an efficient vehicle for learning both written and spoken English and content-specific medical knowledge. Further research should assess the effect of advanced native student journal club facilitators on medical English improvement, as this may be a more sustainable model with potentially greater reproducibility than utilizing bilingual U.S. professionals. Future directions may also focus on using the journal club model to teach manuscript preparation for both basic and clinical OB/GYN research in English based medical journals and more

broadly, to also evaluate the effect of interactive educational activities on learning outcomes within professional contexts

CONFLICT OF INTEREST

The corresponding author also notes no support from any organization for the submitted work and no financial relationships from any organizations. **AUTHOR'S CONTRIBUTIONS:** IKT designed study, prepared data collection tools and surveys, conducted journal club, collected data, and drafted and revised the paper.

WCD designed study, served as blind evaluator of data and drafted and revised the paper. ARK wrote the statistical analysis plan, cleaned and analyzed the data and revised the paper. HK and FJH were international contacts in the setting where the research was conducted and helped to enroll participants and implement the journal club. RSL designed study, served as blind evaluator of data and drafted and revised the paper. He is guarantor. XW designed study, served as international contact at research setting and helped to enroll participants in the journal club.

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Tsui

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- Poster Presentation at the 62nd Annual Meeting of the American Congress of
- Obstetricians and Gynecologists Chicago, IL, April 24-8, 2014
- Data sharing: No additional data available.

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Tsui

journal club on house-staff reading habits, knowledge, and critical appraisal skills. A randomized control trial. JAMA 1988;260(17):2537-41.

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Figure 1. Flow chart of study design.



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Table 1: Baseline demographic and characteristics of both cohorts as self-reported on

questionnaire prior to study randomization.

	Self-Study (n=25)	Intensive (n=27)
Demographic Characteristic	n (%)	n (%)
Students with PhD degree	6 (24)	6 (22)
<5 years of formal English instruction	4 (16)	1 (4)
English proficiency		
Novice	4 (16)	7 (26)
Intermediate	20 (80)	18 (67)
Advanced (but not fluent)	1 (4)	2 (7)
Age (years)*	27.3 ± 3.7	26.8 ± 2.8
Female students**	22 (88%)	26 (96%)

*data reported as mean (standard deviation)

Table 2: Mean differences in examination score between pre-intervention and postintervention examinations between Self-Study and Intensive journal club groups. (Multiple choice score out of 15 possible points, Writing out of 10 possible TOEFL points, Speaking out of 12 possible TOEFL points).

Method	Self-Study Mean (SD) [n=23]	Intensive Study Mean (SD) [n=23]	Difference in means (95% CI)	P-value	
Multiple choice	1.04 (2.14)	1.91 (2.02)	0.87 (-0.37, 2.11)	0.164	
Writing	-0.80 (3.25)	2.26 (3.30)	3.07 (1.12, 5.01)	0.003	
Speaking	-0.43 (3.71)	1.48 (2.39)	1.91 (0.06, 3.77)	0.043	

Ta394 int
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Table 3: Mean differences in examination score between pre-intervention and post-intervention examinations within Self-Study and Intensive journal club groups. (Multiple choice score out of 15 possible points, Writing out of 10 possible TOEFL points, Speaking out of 12 possible TOEFL points).

Method	Difference in Self-Study means (95% CI) [n=23]	Improvement in score	P-value	Difference in Intensive Study means (95% CI) [n=23]	Improvement in score	P-value
Multiple choice	1.04 (0.17, 1.92)	6.9%	0.021	1.91 (1.04, 2.79)	12.7%	<0.001
Writing	-0.80 (-2.18, 0.57)	-5.3%	0.245	2.26 (0.89, 3.64)	15.0%	0.002
Speaking	-0.43 (-1.75, 0.88)	-2.8%	0.507	1.48 (0.17, 2.79)	9.9%	0.028

Table 4: List of articles selected from the Obstetrics and Gynecology Journal. Articles spanned 15 unique gynecology topics as identified by the APGO Medical Student Educational Objectives

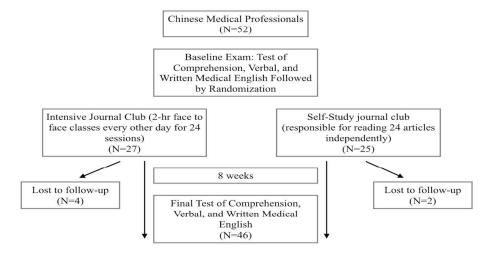
First Author	Title	APGO Topic
Hansen, M	Assisted Reproductive Technology and Major Birth Defects in Western Australia	Infertility
Twijnstra, Andries R	Predictors of Successful Surgical Outcome in Laparoscopic Hysterectomy	Gynecological Procedures
Edwards, Digna R. Velez	Periconceptional Over-the-Counter Nonsteroidal Anti- inflammatory Drug Exposure and Risk for Spontaneous Abortion	Spontaneous Abortion
Moorman, Patricia G	Effect of Hysterectomy With Ovarian Preservation on Ovarian Function	Gynecological Procedures
Grimm, Christoph	Treatment of Cervical Intraepithelial Neoplasia With Topical Imiquimod: A Randomized Controlled Trial	Cervical Disease and Neoplasia
Gariepy, Aileen M	Reliability of Laparoscopic Compared With Hysteroscopic Sterilization at 1 Year: A Decision Analysis	Family Planning
Dmitrovic, Romana	Continuous Compared With Cyclic Oral Contraceptives for the Treatment of Primary Dysmenorrhea: A Randomized Controlled Trial	Dysmenorrhea
Kaunitz, Andrew M	Levonorgestrel-Releasing Intrauterine System or Medroxyprogesterone for Heavy Menstrual Bleeding: A Randomized Controlled Trial	Abnormal Uterine Bleeding
Diamond, Michael P	Endometrial Shedding Effect on Conception and Live Birth in Women With Polycystic Ovary Syndrome	Infertility
Timmermans, Anne	Endometrial Thickness Measurement for Detecting Endometrial Cancer in Women With Postmenopausal Bleeding: A Systematic Review and Meta-Analysis	Endometrial Hyperplasia and Carcinoma
Tanmahasamut, Prasong	Postoperative Levonorgestrel-Releasing Intrauterine System for Pelvic Endometriosis-Related Pain: A Randomized Controlled Trial	Endometriosis
Badalian, Samuel S	Vitamin D and Pelvic Floor Disorders in Women: Results From the National Health and Nutrition Examination Survey	Pelvic Organ Prolapse
Paraiso, Marie Fidela R	Laparoscopic Compared With Robotic Sacrocolpopexy for Vaginal Prolapse: A Randomized Controlled Trial	Gynecological Procedures
Castle, Philip E	Relationship of Atypical Glandular Cell Cytology, Age, and Human Papillomavirus Detection to Cervical and Endometrial Cancer Risks	Cervical Disease and Neoplasia
Semere, Luwam G	Endometrial Intraepithelial Neoplasia Clinical Correlates and Outcomes	Endometrial Hyperplasia and Carcinoma
Jaakkola, Susanna	Endometrial Cancer in Postmenopausal Women Using Estradiol–Progestin Therapy	Menopause

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60

Effectiveness of Oral Contraceptive Pills in a Large Dinger, Jürgen Family Planning U.S. Cohort Comparing Progestogen and Regimen Effect of Hot Flushes on Vascular Function: A Tuomikoski, Menopause Pauliina Randomized Controlled Trial Bipolar Radiofrequency Endometrial Ablation Penninx, Josien Abnormal Uterine Compared With Hydrothermablation for Dysfunctional P.M Bleeding Uterine Bleeding: A Randomized Controlled Trial Loop Electrosurgical Excision Procedure and the Risk Jakobsson, Maija Preterm Labor for Preterm Birth Ovarian Conservation at the Time of Hysterectomy Gynecological Parker, William H and Long-Term Health Outcomes in the Nurses' Procedures Health Study The Intraoperative Complication Rate of Nonobstetric Hefler, Lukas Induced Abortion Dilation and Curettage numized ______.riminatory a _____.Early Pregnant_____. Results From Four Rounds of Ovarian Cancer Partridge, Edward Ovarian Neoplasms Screening in a Randomized Trial Connolly, Reevaluation of Discriminatory and Threshold Levels AnnaMarie for Serum β-hCG in Early Pregnancy

Figure 1. Flow chart of study design



flowchart of the study

A 23 year-old G2P1 with 6 weeks amenorrhea presents with lower abdominal pain and vaginal bleeding. Her temperature is 102.0°F (38.9°C) and the cervix is 1 cm dilated. Uterus is 8-week size and tender. There are no adnexal masses. Urine pregnancy test is positive. What is the most likely diagnosis?

- A. Threatened abortion
- B. Missed abortion
- C. Normal pregnancy
- D. Septic abortion
- E. Ectopic Pregnancy

A 23 year-old G1P0 at 6 weeks gestation undergoes a medical termination of pregnancy. One day later, she presents to the emergency room with bleeding and soaking more than a pad per hour for the last 5 hours. Her blood pressure on arrival is 110/60; heart rate 86. On exam, her cervix is 1 cm dilated with active bleeding. Hematocrit on arrival is 29%. Which of the following is the most appropriate next step in the management of this patient?

- A. Admit for observation
- B. Repeat hematocrit in 6 hours
- C. Begin transfusion with O-negative blood
- D. Give an additional dose of prostaglandins
- E. Prepare her for a dilation and curettage

A 24 year-old G1P1 comes to the office requesting contraception. Her past medical history is unremarkable, except for a family history of endometrial cancer. She denies alcohol, smoking and recreational drug use. She is in a monogamous relationship. She wants to significantly decrease her risk of having a gynecological malignancy. Of the following, what is the best method of contraception for this patient?

- A. Female condoms
- B. Male condoms
- C. Copper containing intrauterine device
- D. Combined oral contraceptives
- E. Cervical cap



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	3
Introduction			.2
Background and	2a	Scientific background and explanation of rationale	4
objectives	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were	
		actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they	
		were assessed	7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			<u></u>
Sequence	8a	Method used to generate the random allocation sequence	5
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	
concealment		describing any steps taken to conceal the sequence until interventions were assigned	-
mechanism	40	Miles and the second of the se	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to	5
Dlinding	110	interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results			
Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	
diagram is strongly		were analysed for the primary outcome	19
recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	8-9
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	14
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	
		by original assigned groups	15-16
Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	4 = 40
estimation		precision (such as 95% confidence interval)	15-16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	222
		pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	5
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	12-13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12-13
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

^{*}We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.