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# Systematic Review of Women Leading and Participating in Nephrology Randomized Clinical Trials



Sumiya Lodhi[1,7], Taddele Kibret[2,7], Shreepriya Mangalgi[3], Lindsay Reid[1], Ariana Noel[3], Sarah Syed[2], Nickolas Beauregard[2], Shan Dhaliwal[2], Junayd Hussain[2], Amanda J. Vinson[4], Harriette G.C. Van Spall[5], Manish M. Sood[3], Risa Shorr[6] and Ann Bugeja[3]

[1]Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada; [2]School of Epidemiology and Public Health, Faculty of Medicine, University of Ottawa, Ontario, Canada; [3]Division of Nephrology, Department of Medicine, The Ottawa Hospital and Kidney Research Centre, Ottawa, Ontario, Canada; [4]Division of Nephrology, Department of Medicine, Dalhousie University, Halifax, Nova Scotia, Canada; [5]Department of Health Research Methods, Evidence, and Impact, McMaster University, Hamilton, Ontario, Canada; and [6]Learning Services, The Ottawa Hospital, Ottawa, Ontario, Canada

**Introduction:** Women are underrepresented in the leadership of and participation in randomized controlled trials (RCTs). We conducted a bibliometric review of nephrology RCTs to examine trial leadership by women and participation of women in nephrology RCTs.

**Methods:** A bibliometric review of RCTs published in top medical, surgical, or nephrology journals was conducted using MEDLINE and EMBASE from January 2011 to December 2021. Leadership by women as corresponding authors, women trial participation, and trial characteristics were examined with duplicate independent data extraction. Logistic regression was used to examine associations between trial characteristics and women leadership and trial participation.

**Results:** A total of 1770 studies were screened and 395 RCTs met eligibility criteria. The number (%) of women in corresponding, first, and last authorship positions were as follows: 89 (22%), 109 (28%), and 74 (19%), respectively, without change over time ($P = 0.94$). The median percentage (interquartile range [IQR]) of women trial participants was 39.0% (13.5%) with no difference between women or men lead authors ($P = 0.15$). Men lead authors were statistically less likely to enroll women in RCTs. Women lead authors were less likely to be funded by industry (odds ratio [OR]: 0.30; 95% confidence interval [CI]: 0.14–0.63; $P = 0.002$) or lead international trials (OR: 0.11; 95% CI: 0.01–0.83; $P = 0.03$). Trials with sex-specific eligibility criteria were more likely to have women leaders (OR: 2.56; 95% CI: 1.19–5.49; $P = 0.02$) than those without.

**Discussion:** Gender inequalities in RCT leadership and RCT participation exist in nephrology and did not improve over time. Strategies to improve inequalities need to be implemented and evaluated.

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Gender inequalities persist in academic medicine, where women remain underrepresented in leadership of clinical research, and with fewer opportunities to acquire leading authorship positions.[1-3] Leadership in research is a well-recognized marker of success in the field of medicine and is essential for career advancement in many academic settings. Early evidence suggests that women remain underrepresented in lead authorship positions in publications.[4-7] It is unclear if this trend persists in nephrology. In Canada, women represent approximately 40% of the nephrology workforce, whereas in the United States, approximately 40% of nephrology trainees and 29% of active nephrologists are women.[8-10]

Recent research has also highlighted sex-based and gender-based differences in the epidemiology and pathogenesis of kidney disease, revealing that women exhibit unique risk factors that differ from those seen in men.[11-13] Although RCTs offer a gold standard for evaluating therapeutic interventions and providing high-quality evidence for clinical practice, women

**Correspondence:** Ann Bugeja, Division of Nephrology, Department of Medicine, The Ottawa Hospital and Kidney Research Centre, 1967 Riverside Drive, Ottawa, Ontario K1H 7W9, Canada. E-mail: abugeja@toh.ca

[7]SL and TK are co-first authors who contributed equally.

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remain broadly underrepresented as participants in these studies.[13–16] This underrepresentation of women in RCTs hampers the exploration of sex and gender differences in disease presentation and treatment response, which in turn may limit the generalizability of medical evidence.[15,17,18] Therefore, addressing the underrepresentation is essential to ensuring equitable access to high-quality care and improving our understanding of sex and gender differences in kidney disease.[19,20]

In this meta-epidemiologic study, we aimed to investigate leadership of women by authorship in nephrology RCTs from high impact nephrology and kidney transplant journals, and the representation of women in RCTs by trial participation.

## METHODS

### Protocol and Registration

This meta-epidemiologic study was registered in Open Science Framework and reported according to adapted Preferred Reporting Items for Systematic Reviews and Meta-analyses reporting guidelines.[21,22]

### Eligibility Criteria

We included RCTs published between January 1, 2011, and December 31, 2021, in high-impact journals from general medicine, nephrology, and kidney transplantation. RCTs were selected based on the population studied, including acute kidney injury, chronic kidney disease, kidney failure, electrolyte disorders, glomerulonephritis, hemodialysis, peritoneal dialysis, kidney transplantation, and polycystic kidney disease. We defined high-impact general medicine journals as the top 5 by impact factor. Similarly, we defined high-impact nephrology journals as the top 4 by impact factor and high impact transplantation journals as the top 2 by impact factor (Annals of Surgery and American Journal of Transplantation). We included English-language RCTs, with participants aged 18 years or older. We excluded RCTs with fewer than 50 participants, children, kidney-pancreas transplantation, renal cell carcinoma, phase 1 or 2 trials, secondary analyses, protocol reports, and RCTs unrelated to general nephrology and kidney transplantation.

The references were screened manually in duplicate and in accordance with the predetermined eligibility criteria and duplicate citations were eliminated. All citations were screened by title and abstract by 3 members of the study team, then full-text review was performed before data extraction of the final included studies by at least 2 individuals. Data extraction forms were piloted by 4 members of the research team using 5 studies. Reviewers were not blinded to the abstracts, full texts, or their study authors and institutions.

### Data Source and Search

The search strategy was devised by the research team, including a health information specialist (RS), utilizing MEDLINE, and EMBASE databases to identify publications from January 1, 2011, to December 31, 2021 (Supplementary Item S1). MeSH terms were employed to capture essential components of the research inquiry.

### Data Abstraction and Management

Nine members of the study team independently extracted the following information: year of publication, journal impact factor for the year of publication, and total number of authors. The journal impact factor at the time of publication was obtained from www.scijournal.org.[19] Author names, including shared authorship, were obtained from the author section of the study publication, with the corresponding author being defined as the study lead author. Gender was investigated for first, last, and lead author positions. Although sex and gender are not synonymous, we assumed women to mean female sex and men to mean male sex in this study. The gender and job title of the corresponding (lead) author was determined via web search of academic networking sites (e.g., ResearchGate), university and hospital websites in conjunction with the authors' credentials and published institution information. Photographs and pronoun descriptors on institutional and social media websites were also used to configure gender. Genderize.io was further utilized to verify the gender of authors.[23] Authors' genders were classified as "uncertain" when gender identification was uncertain. Any discrepancies were resolved by consensus. (Supplementary Item S2)

### Data Analysis

Analyses were informed by previous bibliometric reviews of cardiovascular trials.[5,24] Descriptive analyses were reported, including median and IQR for continuous variables and numbers and percentages for categorical variables. Categorical variables were compared between groups using the Chi-square test and the nonparametric Mann-Whitney U test was used for continuous variables. Temporal trends were assessed using the Kruskal-Wallis and Jonckheere-Terpstra proportion trend tests. We examined study characteristics associated with women in first, last, and corresponding authorship positions using logistic regression. We further examined the association of women as trial leaders and the proportion of women enrolled in RCTs, adjusting for trial characteristics (unit of randomization, obtained consent, region of coordinating center, study eligibility criteria, sex-specific eligibility criteria, type of intervention,

number of centers, scope of trial, type of funding, sex-specific subgroup analysis, and primary population of study participants) independently associated with this outcome. We defined ideal enrolment of women in RCTs as 50% with a prespecified sensitivity analysis for a threshold of 25%. Although some studies use the participation to prevalence ratio, 50% is likely a reasonable estimate for representation because kidney disease as a whole is generally equal for men and women.[16,25] Our results are presented as ORs with corresponding 95% CIs and 2-tailed *P*-values, with an alpha of 0.05. Data was analyzed using SPSS (version 20; IBM Corporation, Armonk, NY).

## RESULTS

### Study Selection

Our comprehensive search yielded 3368 articles and 1598 duplicates were removed. Through title and abstract screening, we excluded 1261 articles based on eligibility criteria, leaving 509 articles for full-text evaluation. We identified 395 studies that met the eligibility criteria for our review (Supplementary Figure S1).

### Study Characteristics

Eligibility criteria were reported in 97.0% of the studies, and sex-specific eligibility criteria were reported in 28.9% of the RCTs. Only 12.7% of the trials included a sex-specific subgroup analysis. The first and corresponding authors were predominantly men (70.4% and 76.7%, respectively), and most corresponding authors were nephrologists (80.3%). There were no RCTs that outlined numbers approached or declined for enrollment (Table 1).

### Gender of Lead Author Based on Journal of RCT Publication

In Table 2, we summarize the lead authorship positions published in 11 medical journals. The median (IQR) impact factor over the 10-year period was 8.44 (8.88). The American Journal of Kidney Diseases has the highest proportion of women in lead authorship (38%) positions, followed by the Clinical Journal of the American Society of Nephrology (26.1%). Women lead authorship was low among journals with the highest impact factors (Journal of the American Medical Association, New England Journal of Medicine, and Lancet).

### Temporal Trends of Women as Lead Author

The number (%) of women in lead authorship positions was 89% (22.5%), without change over time ($P = 0.94$) (Figure 1a). There was no statistically significant

**Table 1.** Characteristics of randomized control trials ($n = 395$)

| Trial Characteristic | *n* (%) |
|---|---|
| Unit of randomization | |
| Individual | 373 (94.4) |
| Cluster | 22 (5.6) |
| Was informed consent obtained for study enrollment? | |
| Yes | 366 (92.7) |
| No | 29 (7.3) |
| Region of Coordinating Center | |
| North America | 158 (40.0) |
| Europe | 106 (26.8) |
| Not reported | 59 (14.9) |
| Asia | 57 (14.4) |
| Australia | 9 (2.3) |
| Other[a] | 6 (1.5) |
| Were study eligibility criteria reported? | |
| Yes | 383 (97.0) |
| No | 12 (3.0) |
| Was sex-specific eligibility criteria reported? | |
| No | 281 (71.1) |
| Yes | 114 (28.9) |
| Type of intervention | |
| Drug | 269 (66.8) |
| Procedure | 61 (15.4) |
| Health service | 45 (11.4) |
| Device | 17 (4.3) |
| Program | 3 (0.8) |
| Number of centers | |
| More than one | 288 (73.0) |
| One | 107 (27.0) |
| Scope of trial | |
| National | 301 (76.2) |
| International | 94 (23.8) |
| Type of funding | |
| Public | 155 (39.2) |
| Industry | 154 (39.0) |
| Industry and Public | 51 (12.9) |
| Missing | 35 (8.8) |
| Did the trial include a gender-specific subgroup analysis? | |
| No | 345 (87.3) |
| Yes | 50 (12.7) |
| Number of authors | |
| 0-5 | 39 (9.9) |
| 6-10 | 145 (36.8) |
| > 10 | 211 (53.4) |
| Gender of first author | |
| Man | 278 (70.4) |
| Woman | 109 (27.6) |
| Uncertain | 8 (2.0) |
| Gender of co-first author | |
| Not applicable | 324 (82.0) |
| Man | 40 (10.1) |
| Woman | 28 (7.1) |
| Uncertain | 3 (0.8) |
| Gender of last author | |
| Man | 315 (79.7) |
| Woman | 74 (18.7) |
| Uncertain | 6 (1.5) |
| Gender of corresponding author | |
| Man | 303 (76.7) |
| Woman | 89 (22.5) |

(Continued on following page)

**Table 1.** (Continued) Characteristics of randomized control trials ($n = 395$)

| Trial Characteristic | *n* (%) |
|---|---|
| Uncertain | 3 (0.8) |
| Job title of corresponding author | |
| Nephrologist | 317 (80.3) |
| Non-Nephrologist | 78 (19.7) |
| What was the primary population of study participants? | |
| Chronic Kidney Disease | 128 (32.4) |
| Dialysis | 127 (32.2) |
| Kidney Transplantation | 79 (20.0) |
| Glomerulonephritis | 25 (6.3) |
| Acute Kidney Injury | 19 (4.8) |
| Miscellaneous[b] | 17 (4.3) |
| Year of publication | |
| 2011–2013 | 106 (26.8) |
| 2014–2016 | 94 (23.8) |
| 2017–2019 | 105 (26.6) |
| 2020–2021 | 90 (28.2) |

Other[a] refers to Australia, New Zealand, and South America.
Uncertain refers to inability to determine gender by web search.
Miscellaneous[b]: electrolyte disorders ($n = 6$), kidney failure ($n = 2$), and polycystic kidney disease ($n = 9$).
There were no randomized controlled trials that outlined numbers approached or declined for enrollment.

difference in the proportion of women authors who were in lead, first, or last author (Figure 1b).

## Temporal Trends of Participation of Women in RCTs

The median percentages (IQRs) of women trial participants across 4 time periods (2011–2013, 2014–2016, 2017–2019, and 2020–2021) were 40.2% (12.4%), 38.6% (16.3%), 39.2% (13.7%), and 37.5% (13.1%), respectively, without statistically significant differences over the 10-year study period ($P = 0.37$) (Figure 2a). Among RCTs with women as lead author, the median percentages (IQRs) of women participants were 41.9% (10.4%), 39.6% (14%), 39.4% (17.5%), and 40.4% (10.5%) from 2011 to 2013, 2014 to 2016, 2017 to 2019, and 2020 to 2021, respectively (Figure 2b). The median percentage of women participants was 40.2% across the whole study period and did not change with time with women as lead author ($P = 0.43$). The median percentage (IQR) of women trial participants was 39.0% (13.5%) and did not differ between women and men lead authors.

## RCT Characteristics Associated With Women as Lead Author

Women in the lead authorship position were less likely to be funded by industry alone than those funded by the public sector alone (OR: 0.30; 95% CI: 0.14–0.63; $P = 0.002$). Other trial characteristics did not show statistically significant associations with the corresponding (lead) authorship position in RCTs (Table 3).

RCTs led by women nephrologists *per se* were less likely to have industry funding alone than public funding alone (OR: 0.29; 95% CI: 0.12–0.74; $P = 0.01$) and less likely to have led RCTs with an international scope than a national scope (OR: 0.11; 95% CI: 0.01–0.83; $P = 0.03$). Women nephrologist leaders were more likely to have sex-specific eligibility criteria than not (OR: 2.56; 95% CI: 1.19–5.49; $P = 0.02$) (Supplemental Table S1).

## Trial Characteristics Associated With the Enrollment of Women Participants in RCTs

Women were less likely to be enrolled in trials where the lead author was a man using a 50% threshold of enrollment (Clopper-Pearson binomial: 0.82; 95% CI: 0.78–0.86). No difference was noted with a threshold of 25% enrollment for women with men as lead authors (Clopper-Pearson binomial: 0.08; 95% CI: 0.05–0.11).

# DISCUSSION

Our study demonstrates a gender disparity in nephrology because only 33% of lead authors are women, with no improvement over the last decade.

**Table 2.** Women by authorship position and journal, $n = 395$

| Journals | RCTs, *n* | RCTs with women first authors, *n* (%) | RCTs with women last authors, *n* (%) | RCTs with women as corresponding authors, *n* (%)[a] |
|---|---|---|---|---|
| American Journal of Kidney Diseases | 79 | 25 (31.6) | 24 (30.4) | 30 (38.0) |
| American Journal of Transplantation | 48 | 16 (33.3) | 9 (18.8) | 12 (25.0) |
| Annals of Internal Medicine | 3 | 1 (33.3) | 2 (66.7) | 1 (33.3) |
| Annals of Surgery | 3 | 2 (66.7) | 0 | 1 (33.3) |
| British Medical Journal | 3 | 2 (66.7) | 0 | 1 (33.3) |
| Clinical Journal of the American Society of Nephrology (CJASN) | 69 | 25 (36.2) | 17 (24.6) | 18 (26.1) |
| Journal of the American Medical Association (JAMA) | 20 | 4 (20.0) | 2 (10.0) | 3 (15.0) |
| Journal of the American Society of Nephrology | 70 | 17 (24.3) | 8 (11.4) | 12 (17.1) |
| Kidney International | 36 | 6 (16.7) | 4 (11.1) | 2 (5.6) |
| Lancet | 17 | 4 (23.5) | 1 (5.9) | 3 (17.6) |
| New England Journal of Medicine | 47 | 7 (14.9) | 7 (14.9) | 7 (15.0) |

RCT, randomized controlled trial.
[a]The gender for the corresponding author of 4 RCTs was uncertain.

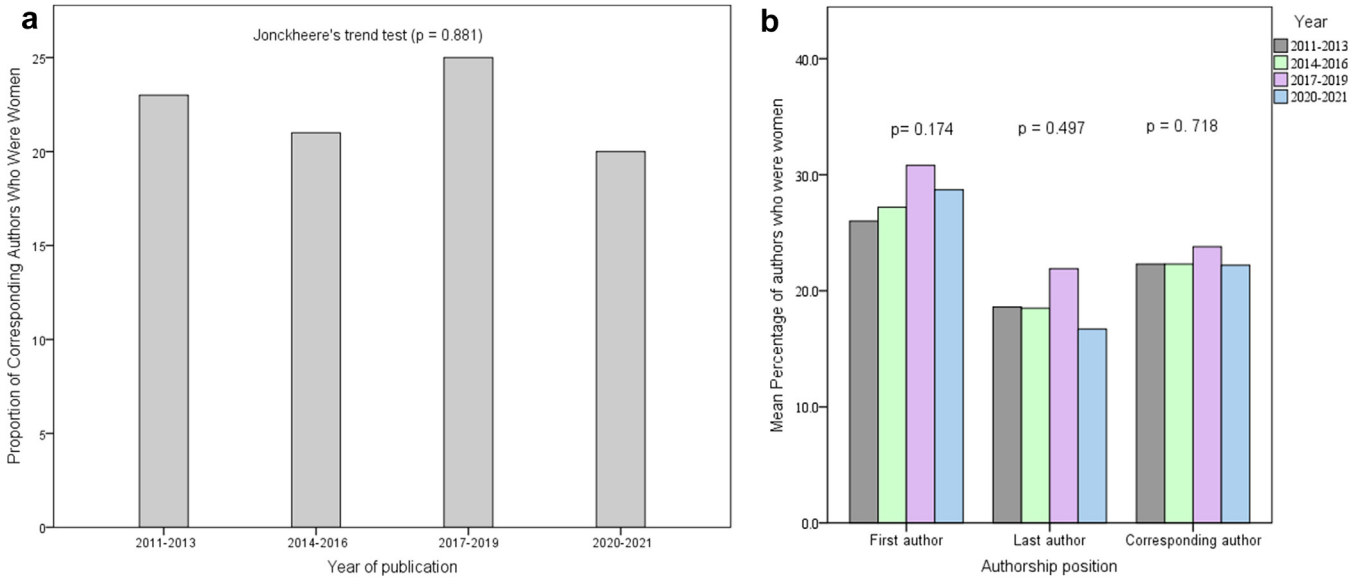


**Figure 1.** Temporal trends in proportion of women as lead authors (panel a) and temporal trends in gender of first, last, or lead authors of RCTs (panel b), $n = 395$.
RCT, randomized controlled trials.

This was particularly notable among the top medical journals and despite the fact that women comprised up to 40% of nephrology trainees in the United States and made up 40% of the nephrology workforce in Canada.[8–10] Overall, women were less likely to be enrolled in nephrology RCTs as participants but more likely to be enrolled when women were lead authors. Our findings demonstrate underrepresentation of women in trial leadership in nephrology and this was associated with lower enrollment of women as RCT participants.

Our findings show a higher proportion of women being first and last authors than another recent report, possibly related to the journal selection and definition of a "nephrology" RCT; however, both studies show that the trends are stable over time.[26] Moreover, our study examined corresponding authorship and female participation in RCTs and their association with author characteristics. However, these disparities are not as prominent as in specialties such as cardiology. For example, in heart failure trials, women accounted for only 11% of lead authorship but have more women enrolled as participants, more women as coauthors and steering committee members.[5,27,28] Several RCT characteristics were associated with lower odds of women

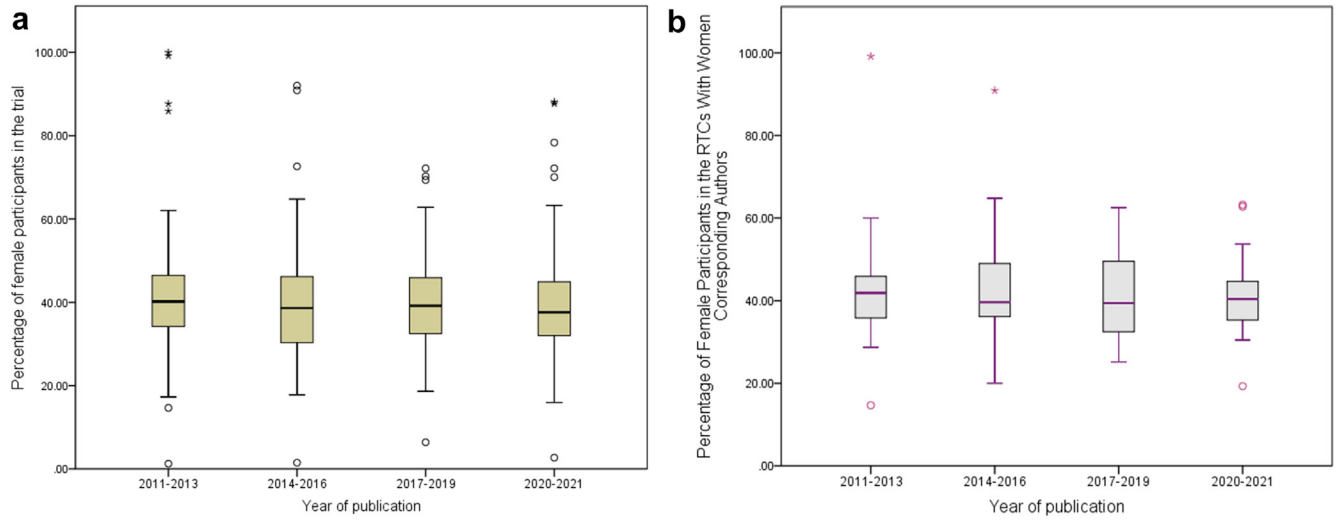


**Figure 2.** Proportion of women who participated in RCTs by era of publication (panel a) and percentage of women participants in RCTs with women as lead authors by era of publication (panel b), $n = 395$.
RCT, randomized controlled trials.

**Table 3.** Multiple regression analysis of RCT characteristics with women leaders (corresponding author)

| RCT characteristics | OR (95% CI) | *P*-value |
|---|---|---|
| Region | | |
| North America/Europe | 1 (Reference) | - |
| Asia/Australia/South America/New Zealand | 0.61 (0.29, 1.30) | 0.20 |
| Source of funding for RCTs | | |
| Public | 1 (Reference) | - |
| Industry | 0.30 (0.14, 0.63) | 0.002 |
| Public and Industry | 0.61 (0.28, 1.36) | 0.23 |
| Number of Centers | | |
| One | 1 (Reference) | - |
| More than one | 1.15 (0.61, 2.17) | 0.67 |
| Scope | | |
| National | 1 (Reference) | |
| International | 0.37 (0.13, 1.03) | 0.06 |
| Type of Intervention | | |
| Drug | 1 (Reference) | - |
| Procedure/Health service/Device/Program | 1.58 (0.84, 2.96) | 0.16 |
| Sex-specific eligibility criteria | | |
| Absence | 1 (Reference) | - |
| Presence | 1.78 (0.93, 3.39) | 0.08 |

CI, confidence interval; OR, odds ratio; RCT, randomized controlled trial.

being first authors, including multicenter trials, trials coordinated in North America or Europe, trials involving drug interventions, and trials with men as senior authors.[24] The lower rate of participation of women in nephrology and kidney transplantation RCTs in our study is in keeping with early work that suggests that the proportion of women enrolled in nephrology RCTs is among the lowest of all specialties.[29] This underenrollment was also illustrated in heart failure related RCTs, where 40% enrolled 20% or fewer women; trials with men-only leadership teams were associated with a greater odds of underenrollment of women relative to disease distribution.[24] RCTs among dialysis populations found that women made up 40% of participation, whereas women are understudied in kidney transplantation trials, and both studies revealed underreporting of sex or gender subgroup analyses.[20,25] Notably, there was no available data on how many women and men were approached and declined to be included in the trials, a possible future consideration to improve disparities.

RCTs are often considered the "gold standard" for evaluating the effectiveness and safety of health interventions.[30-33] However, women often perceive research institutes to be less supportive and less inclined to include them than men in research networks, which are required to galvanize support for multicenter RCTs.[32-34] Moreover, women encounter obstacles related to research funding because they are less likely to receive National Institute of Health awards, and this can impede the progress of their research careers.[35-38] Furthermore, women were underrepresented in journal editorial boards, which can impact the ability of women to obtain grants.[39,40] A gender disparity in industry-sponsored research funding for RCTs has also been found where women physicians receive significantly less industry funding for research, which is restricted to a small group of collaborations that rarely include women.[41] These findings of a gender disparity within industry-funded research were also noted in our study and warrant exploration around the application to industry-funding versus public-funding.

Nephrology has made strides in improving gender representation in leadership positions, with a growing number of women taking on presidency roles in lead organizations such as the International Society of Nephrology, the National Kidney Foundation, the American Society of Transplant, and the American Society of Nephrology.[42-44] However, gaps remain with women underrepresented in national conferences and academic grant rounds, receiving fewer achievement awards, and are less likely to be listed as first author.[20,25,36,45-48] These disparities can contribute to women being left out of leadership roles and can impact their growth and promotion. One possible barrier contributing to this underrepresentation is the presence of additional responsibilities for women, such as caregiving and parental leave, which may hinder their ability to fully engage in networking opportunities and research promotion.[42]

To address the gender disparity and promote gender equity in nephrology, recruitment, retention, and promotion policies, tailored specifically to the field of nephrology that reduce barriers to women's advancement, can be implemented.[36,44,49] Sponsors can directly assist in career advancement for women nephrologists by utilizing their expertise and connections to help build diverse research teams. Sponsors can also advocate and provide roles such as manuscript collaboration, delivering keynote speeches, grant application assistance, and collaborative networks.[42,50] Organizations such as Women in Nephrology and Women in Transplant help provide opportunities and support for education, career guidance, and research opportunities across all aspects of women's careers; and therefore, should serve as a model for future opportunities on a global level. Efforts should be made to increase participation of women in RCTs because benefits are observed in women's health versus nonparticipation.[51] The inadequate representation of women in RCTs impeded the investigation of disease presentation and treatment response by sex and gender. Consequently, this may limit the generalizability of medical evidence.[15,17,18] This can be achieved by having sex-specific enrollment targets, increasing participant's

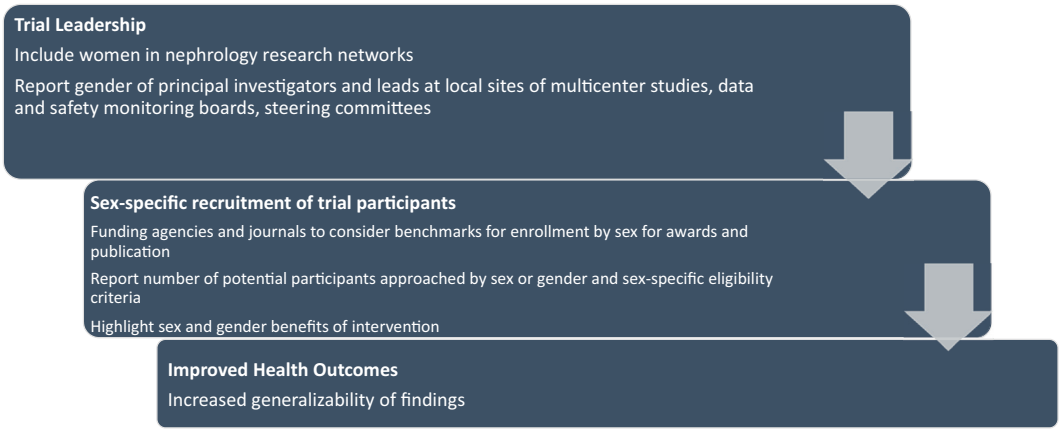


**Figure 3.** Strategies to improve sex and gender equity in nephrology RCTs.
RCT, randomized controlled trials.

awareness and learning of the health problem, and highlighting sex and gender benefits of the intervention.[52] For multicenter trials, publication of the sex and gender of the principal investigator, lead investigator at local sites, as well as steering and data and safety monitoring committees may also influence recruitment. The importance of reporting sex-specific eligibility criteria and analyses requires ongoing attention in RCT design (Figure 3).

Our study has limitations. We examined publications from high impact journals only and excluded studies of pediatric populations. Given the number of prespecified pairwise comparisons, it is difficult to draw firm conclusions about associations between trial characteristics and sex of authorship. It is important to note that data on the nephrology workforce by practice setting (i.e., community, hospital, and/or academic practice) was not available in Canada, the United States, or the United Kingdom (personal communications and web searches). We did not examine the weighted participation-to-prevalence ratio but instead used thresholds for enrollment of women participants for the vast types of subpopulations covered in this study. However, this was unlikely to alter our conclusions with the wide breadth of this study. Gender was inferred based on published gender pronouns, photos, and genderize.io.[23] This may not necessarily reflect the authors' self-identified gender, acknowledging that gender can be fluid. Further, targeted investigation is required to examine specific kidney diseases to ascertain whether there continues to be an underrepresentation of women in leadership roles and trial participation. Moreover, future research should investigate the relationship between the international scope of trials and the disparity in women nephrologists in lead authorship positions, such as limited networking opportunities, inadequate funding resources, or time constraints stemming from the challenges of balancing family responsibilities with extensive involvement in larger, international RCTs. These approaches can pave the way for international sponsorship and global connection opportunity for women researchers in nephrology.

## Conclusion

Women are less likely to lead RCTs and this is associated with underenrollment of women in RCTs. Increasing the presence of women in leadership positions and lead author roles in nephrology may result in greater inclusivity of women in nephrology and kidney transplantation research and consequently, as participants in clinical trials. Participation is crucial given the sex disparities in kidney disease pathogenesis and progression and can lead to better health outcomes for women with kidney disease.

## DISCLOSURE

MMS has received consulting fees from Bayer, GlaxoSmithKline, and Otsuka and has received honoraria from AstraZeneca. All the authors have declared no competing interests.

## ACKNOWLEDGMENTS

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## DATA AVAILABILITY STATEMENT

The data sets generated during this study are available from the corresponding author upon reasonable request.

## SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

**Item S1.** Search strategy.

**Item S2.** Data extraction.

**Figure S1.** Preferred reporting items for systematic reviews and meta-analyses flow diagram.

**Table S1.** Multiple regression analysis of clinical trial characteristics associated with women leaders who are nephrologists.

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