

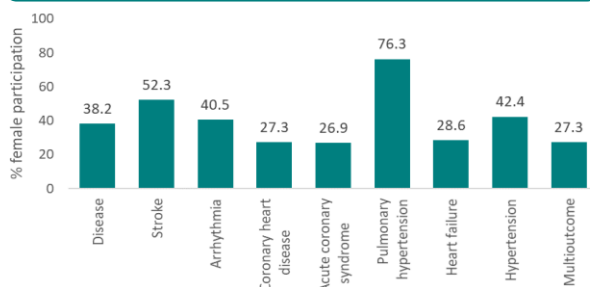
Are women and older patients represented equally in clinical trials?

By Kelly Roussi (Researcher/ Editor)

According to a recent article, women are **more reluctant** to participate in clinical trials related to cardiovascular research, even though they are **more likely to be affected** by cardiovascular conditions and die from heart disease ¹.

Cardiovascular disease is **the main cause of death among women** on a worldwide level², **BUT...**

Female participation in clinical trials according to type of cardiovascular condition ²



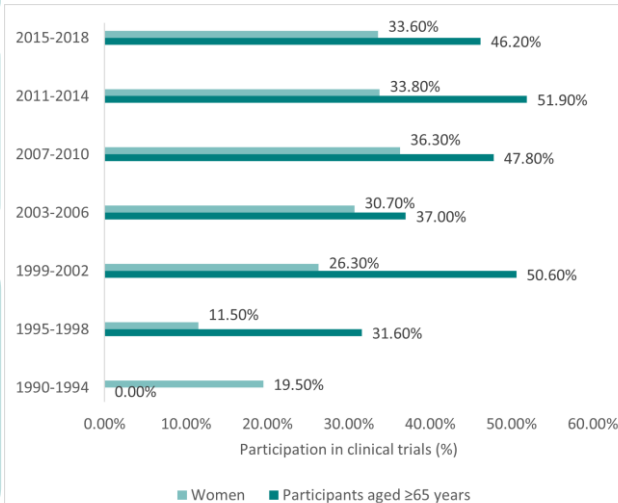
Dr Jeske van Diemen – Amsterdam University Medical Centre, Netherlands

“Women more often have **barriers** which make it difficult to attend follow-up appointments, such as **not holding a driving licence or caring for grandchildren**”

During the previous century, participation of women in clinical trials was limited due to the **detrimental effects on embryos and fetuses** after female exposure to different drugs and agents. In addition, **hormone fluctuations and differences in physiology** between the two sexes was a factor to be taken into consideration ¹.

Participation of women and older participants in randomized clinical trials of lipid-lowering therapies: a systematic review ³

Participation of women and patients aged over 65 years in clinical trials ³



Objective

❖ To determine the **rates and trends in female and older patients (≥65 years)** in RCTs of lipid-lowering therapies between 1990 and 2018.

Methods

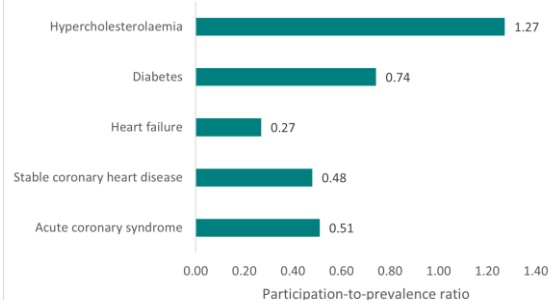
- Literature search on **MEDLINE/PubMed and ClinicalTrials.gov** by two independent investigators
- RCTs with **at least 1,000 patients** on lipid-lowering therapy and **follow-up of at least a year**
- Focus on **women and patients over the age of 65**

Results

- ✓ Overall representation of **women was 28.5%** and of **older participants was 46.7%**
- ✓ **Modest increase** in the enrolment of female participants between 1990-1994 and 2015-2018 and **increase in mean age** of participants and **in representation of older participants** from 1995-1998 to 2015-2018

Our thoughts:

- There is still a long way towards equal representation of women and older patients in clinical trials
- **Women are generally under-represented** in trials related to **diabetes and cardiovascular conditions**, given the **high rates** of women suffering from these diseases in the general population ³.
- Although there has been an increase in the rates at which these patient groups are represented over the last 30 years, these generally **still remain below 50%**.
- Variations relevant to differences in **physiology, endocrinology or due to the progression of age** should be considered for different patient groups included in clinical trials.



The participation-to-prevalence ratio indicates the percentage of women among trial participants to the percentage of women among the disease population. A ratio between 0.8 and 1.2 indicated a similar proportion within these two populations. Figure adapted from Khan 2020 ³

References

1. The Guardian, “Recruiting women for cardiovascular research is harder, study finds” <https://www.theguardian.com/science/2021/aug/06/recruiting-women-for-cardiovascular-research-is-harder-study-finds>
2. Jin X, Chandramouli C, Alloco B, Gong E, Lam CSP, Yan LL, Women’s Participation in Cardiovascular Clinical Trials From 2010 to 2017, Circulation. 2020;141:540–548, <https://doi.org/10.1161/CIRCULATIONAHA.119.043594>
3. Khan SU, Khan MZ, Raghu Subramanian C, Riaz H, Khan MU, Lone AN, Khan MS, Benson EM, Alkhoul M, Blaha MJ, Blumenthal RS, Gulati M, Michos ED. Participation of Women and Older Participants in Randomized Clinical Trials of Lipid-Lowering Therapies: A Systematic Review. JAMA Netw Open. 2020 May 1;3(5):e205202. doi: 10.1001/jamanetworkopen.2020.5202. PMID: 32437574; PMCID: PMC7243092.