



EXAMPLE III

Integrating a gender dimension into a fictitious research proposal by means of the Gender Awakening Tool.

Summary of the fictitious research proposal

Past research has shown that spatial perception enhances a safe driving style. Furthermore, it is known that the risk of a car accident increases when the driver is under the influence of alcohol. These findings have led to the idea that the consumption of alcohol might negatively influence spatial insight. The goal of this research is to find out whether the consumption of alcohol and spatial perception negatively correlate.

Two Dutch universities will work together to accomplish this research. Participants will be attracted by posters at both universities and small ads in free local papers. There is a website with information for interested persons. Participants can subscribe to this research by e-mail or telephone.

Inclusion criteria:

- 18-65 years old
- able to give informed consent
- average alcohol intake per week: 3 - 7 glasses
- in possession of a driving license

Exclusion criteria:

- pregnancy
- the use of medication that interacts with alcohol

The participants will be tested on three mornings. Every test morning the participants must come in sober. They are first asked to indicate their level of tiredness on a scale, after which they have to solve a spatial perception puzzle. They will then drink one unit of alcohol. After 15 minutes the level of tiredness has to be indicated again and a second puzzle (with the same degree of difficulty) has to be solved. The time needed to solve the puzzles will be measured.

On the second and third test morning the same procedure will be followed, with the difference that on the second morning the participants will be asked to consume two units of alcohol and will have to solve the puzzle after 25 minutes, and that three units of alcohol be consumed at the third test morning and that the participants must solve the puzzle after 35 minutes.

100 persons will be included as participants in this research, of which 50 participants will be given a placebo (non-alcoholic beer).

Three results per participant will be measured: the required time to solve the puzzle after one, two and three alcohol consumptions. These results will be compared to the time required to solve the puzzle when no alcohol is consumed, in order to assess if the consumption of (one, two or three units of) alcohol leads to significant deterioration in spatial perception compared to a non-alcohol situation.

Applying the Gender Awakening Tool

- what researchers should ask themselves with respect to gender and sex issues

Step 1. Relevance check

- *Are human (materials) object of research? Or animal material that serves as a model for human biology/physiology?*
- *Will humans be confronted with the effect of the research?*



Human beings are involved as subjects in the research and the results of the research will have an influence on women and men. In other words, there is a sex and gender relevance, i.e. gender and/or sex issues might be of influence on the research results and should be considered.

Step 2. Literature search

- *Are sex or gender differences documented in literature?*
- *Do I want to address gender and/or sex differences in my research?*

Males perform better in spatial perception tests than women, although the strength of those sex differences varies among the different aspects of visuospatial ability (Wizemann & Pardue, 2001). The literature study could now help us determine which category of spatial perception is relied upon when driving, and if differences in performance between men and women exist for this particular category. This should then be taken into account when analysing the results of our research.

Furthermore, we can find in the literature that men consume alcohol more frequently than women, which can lead to habituation, and that women's bodies absorb alcohol sooner than men's. Besides that, women's body composition and lean body mass differ from that of men. Taken together, the result is that for the same effect of alcohol, women will need to drink less. We therefore have to take into account that the blood alcohol level of men and women might not be the same after one, two and three alcoholic consumptions.

Step 3. Research questions and hypotheses

- *What research questions can I formulate with regard to gender and sex issues?*
- *What are my hypotheses with respect to sex and gender issues?*

The central question is whether alcohol intake negatively influences spatial perception. If we would like to adopt a gender dimension, we could add a question like: "Does the relation between alcohol intake and spatial perception differ between men and women?" Even more innovative would be to centre your research on *why* they differ.

On the basis of what we know we also have to formulate our research hypotheses with respect to gender. For example, we can hypothesise that when alcohol negatively correlates with spatial perception, we expect women to show a bigger effect than men, because their blood alcohol levels are expected to be higher.

Step 4. Research methods and design

- *Are both women and men included in the research population?*
- *Is it necessary/possible to collect sex disaggregated data?*
- *Is the research method validated for both sexes?*

The protocol states that 'participants' will be tested, but they don't elaborate on this. Are these participants women or men, or both? If we would want to include both sexes into our population, we will have to think of the effects that the recruitment ads have on the composition of the population. Which sex will they reach? For example, we intend to hang posters at university, but if we do so at a technical faculty we will have to count with attracting men primarily. We should also consider which sex and/or social class reads the free local newspaper we are advertising in. Can we reasonably expect our mode of advertising to reach an equal amount of men and women?

The research proposal furthermore states that future participants can obtain information from a website. What does this mean in practice? Although women nowadays have as much access to computers as men, men use the internet more



frequently than women, resulting in a lower knowledge level about the web in women (Wasserman & Richmond-Abbott, 2005). We could consider this when we are constructing the website on which to obtain information, for instance.

Third, the research takes place in the morning. What effect could this have on the composition of the research population? In the Netherlands, for example, there are lots of families in which the man works full-time, the woman part-time. In such a case it would seem more likely that women will have time to participate. We could also think of which of the sexes it could affect more that, after three units of alcohol, they cannot drive anymore for some hours (e.g. driving to work, taking the children to school).

In this research it is certainly possible to collect sex disaggregated data, simply by noting the sex of the participants. Given the information of male/female differences above, it also proves necessary. The research proposal, however, does not specify if such a plan exists.

Furthermore, it seems that the research method is not validated for both sexes, after all, the fact that women have to drink less than men to reach the same blood alcohol level is not taken into account. We at least have to take note of that in our reporting and integrate this knowledge into our analysis. Even better is to correct for this, for example by determining the blood alcohol level by means of breath analyzers or taking blood samples and asking participants to perform the spatial perception test at blood alcohol levels of e.g. 0,1; 0,2; and 0,4. This way we can truly compare the differential effects in men and women.

Step 5. Data-analysis and interpretation

- *Is decided and substantiated as what kind of variable gender and/or sex is included?*
- *Are the data analysed per sex and if so, is the statistical power big enough?*

If the literature study indicates so or if the researchers suspect that the factor sex could be an effect modifier, the research results must be either analysed per sex or corrected for it, so that no confounding arises. We should also distinguish between sex as an effect modifier and as a prognostic factor. Sex as an effect modifier is associated with differences in treatment effect, prognostic or risk factor effects or with differences in accuracy of a diagnostic test. If sex is associated with the clinical course or the natural history of a disease, sex is a prognostic factor (Prins et al., 2007). In all cases we must argue our choice (not) to include sex as a certain variable in our analytical model.

If we plan to do subgroup analysis and analyse the results per sex, we should calculate if our research has enough power with the current sample size. It might be that we have to enlarge the trial with sufficient members from each subgroup, so that a subgroup analysis can be performed. Next to biological factors (sex), we should also be aware of cultural factors (gender) that might modify the intervention effect, for example gender differences in compliance and completeness of follow-up (Van Wely et al., 2005).

In this case, we suspect that the division into sex-based subgroups of 100 participants, which are already split in 50 experimental and 50 controls, will statistically not be able to tell us much about the male/female subgroups. We should then either recruit more participants, or we could opt for a second trial, and investigate one sex per time.

Step 6. Reporting the results

- *Has it been avoided that the results of one sex are generalised to the other sex?*
- *Are gender or sex differences visualised in tables and graphics?*
- *Are the results and conclusions regarding sex and gender issues reported?*
- *Has it been considered if the results affect women and men in a different way?*



We have already mentioned before that in the protocol the sexually undefined 'participants' are mentioned. It is unfortunately quite likely that during the reporting of the results, the same undefined terms will be used. This is dangerous, because when we have only studied men, we cannot simply generalize the results to women. And that's what we would be doing when we talk about the effect of a treatment on 'participants' or 'patients', because who could guess we are talking about men only? We should also mind that our title rightly reflects the subjects under investigation.

If we study sex and gender differences, the results must be reported - even if no subgroup differences are found. That sex is no effect modifier is as important information as if it would have been.

Step 7. Conclusion & recommendations

- *What can be recommended with respect to gender issues for future research?*
- *How can information on sex and/or gender differences be translated into preventive, diagnostic and therapeutic practices?*

If (even a small) effect of sex was found, researchers can formulate recommendations with respect to future research concerning gender and/or sex issues. Also, if there was no possibility to explore sex and gender issues in this research although they seem relevant to the research topic, a recommendation should mention the need to explore these issues further in future research.

Lastly we have to look at the implications our research might have on the preventive, diagnostic and therapeutic practices. Do the results have different meaning for men and women? In our example, let's say we do find that alcohol negatively influences driving through affecting the spatial perception. Given the fact that women need to drink less alcohol consumptions to reach the same alcohol blood level as men, what could this for example mean for prevention campaigns 'translating' the legally allowed blood alcohol level into a 'safe' number of alcohol units? Would there be a need to differentiate between preventive recommendations for men and women, on the basis of our research?

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