Quantitative research – Sampling – Blinding	Set-up & Conduct- Methods & Data Collection	
	VERSION	4.0

Aim
To prevent information bias or bias in effect size estimates, resulting from errors in measuring the variables in the study.

Requirements
In case of blinding, documentation about the type of blinding, how the blinding was carried out to participants and/or treatment providers and/or outcome assessors, description of the interventions and/or placebo, and the monitoring process.

Documentation
Documentation as described under 'Requirements'.

Responsibilities
Executing researcher:
- To be able to explain why this blinding procedure is selected;
- To carry out the blinding procedure as selected;
- To monitor the blinding process.

Project leaders:
- To advice the executing researcher about the type of blinding procedure that should be carried out and to make sure this blinding procedure is applied correctly.

Research assistant:
- To make sure participants, treatment providers and interviewers (if applicable) do not get to know their intervention in case of blinding.

How To
The aim of blinding is to prevent information bias or bias in effect size estimates resulting from errors in measuring the variables in the study (determinants and outcomes). For each study in which groups of participants are being compared, such as clinical trials (randomized or not), it is essential that groups are comparable, and remain comparable.

Information bias may occur through knowledge of the nature of the allocated intervention. For example:
- A participant may be more inclined to report no effect, if he/she is aware they are receiving a placebo treatment. The result is an underestimation of the placebo contribution in the intervention, and therefore an overestimation of the treatment effect size.
- A treatment provider may have a strong preference for one of the treatments, which may lead to not objectively reporting the condition of the participants treated.
- The researcher analyzing the results may have a strong preference for a given outcome, which may lead him to interpret the results of the intervention group more favorably.

Masking which participant will receive which treatment, i.e. blinding is a well-known solution. Blinding can be undertaken at the level of the participant, the treatment provider, the outcome measure (blinding of the individual undertaking the measurements) or the analysis (blinding of the person analyzing the data). A study is referred to as "single-blind" when the participant and/or

treatment provider are unaware which intervention the participant is receiving, or when the participant and treatment provider are aware of this, but the outcome measure is blinded, i.e. when the individual undertaking the measurements is unaware which intervention the participant is receiving. A study is usually referred to as "double-blind" when the participant and/or the treatment provider, as well as the outcome measure have been blinded. To avoid confusion, be explicit about which parties are blinded. *N.b.: Randomisation will not prevent information bias. Randomisation is intended to reduce confounding and prevent selection bias.*

The type of blinding depends on the research question and/or possibilities for blinding. In trials with randomisation at participants' level, it is difficult to keep the participant blinded to the treatment, particularly in the type of study in which different interventions are being compared. In this case, only outcome measures can be blinded. If it is not possible to do this, analyses should be carried out blindly. When blinding is not possible, or can only be implemented partially, the expected direction of bias can usually be discerned. This should be taken into consideration in the conclusions. Van der Feltz and Adèr [1] provide examples of the disastrous effect of single blinding on participant recruitment in a cluster-randomized study.
When blinding is carried out, it is important to equalize the look and feel of the interventions. In drug trials, blinding is often realized by administering drugs that look the same in terms of shape, color and taste. In intervention studies, participants can be told that there are two interventions and that the effects of these will be compared, without telling them too much about the content and differences, for instance that the 'control' intervention is a shorter version of the other. In other studies, attempts can be made to make the blinding procedure look the same throughout, for example the intervention and placebo. The analyses can be blinded by having the grouping variables entered by a different person and by not adding a value label.

Monitoring of the blinding process is important. Consider the option to ask each participant and/or treatment provider which group they suspect they were allocated to. A cross-tabulation can then be produced of the reported against the actual group allocation; the chi-square test should not be significant. However, this method is not recommended for the following reason: if the recovery of participants is such that the participants and/or treatment providers are able to see who received the experimental and evidently superior therapy (and therefore often recognize it), then this is not a case of failed blinding, but **convincing evidence for the superiority of the therapy. Finally, Fergusson et al (2010) highlights the importance of reporting the methods of blinding and the subsequent success of this blinding.** They state that *"trialists need to report a minimum set of information. This includes the counts of all patients allocated to each treatment; the counts of patients who guess treatment assignment by the group to which they were allocated; the counts of correct guesses and those who are undecided; the analytical methods and results used to assess success of blinding; and the author's interpretation of the efficacy of blinding and the effect on study results."*

References

- van der Feltz-Cornelis CM, Adèr HJ. Randomization in psychiatric intervention research in the general practice setting. International Journal of Methods in Psychiatric Research: 2000. 9(3):134-142.
- Fergusson D, Cranley Grass K, Waring D, & Shapiro S. (2004) Turning a blind eye: the success of blinding reported in a random sample of randomised, placebo controlled trials. BMJ doi: 10.1136/bmj.37952.631667.EE.

Audit questions

1. Has the blinding procedure been applied to your study?
    a. If not, then why not?
    b. If so:
        i. Were the participants and/or treatment providers blinded?
        ii. Were the outcome measurements blinded for the participants and/or treatment providers?
        iii. Were the data analyses blinded?

LINKS

Link		

DOCUMENT HISTORY

Version	Status	Date	Name
4.0	Revision	05NOV2020	Anouk Gathier, Prof. dr. Hans van der Wouden
3.0	Revision guideline	17MAY2017	EMGO
2.0	Revision format	12MAY2015	EMGO
1.1	-	01JAN2010	EMGO

DOCUMENT APPROVAL

Role	Name	Date
Project Leader	Dr. Seta Jahfari	16MAY2021