Timeline cluster: a graphical tool to identify risk of bias in cluster randomised trials.

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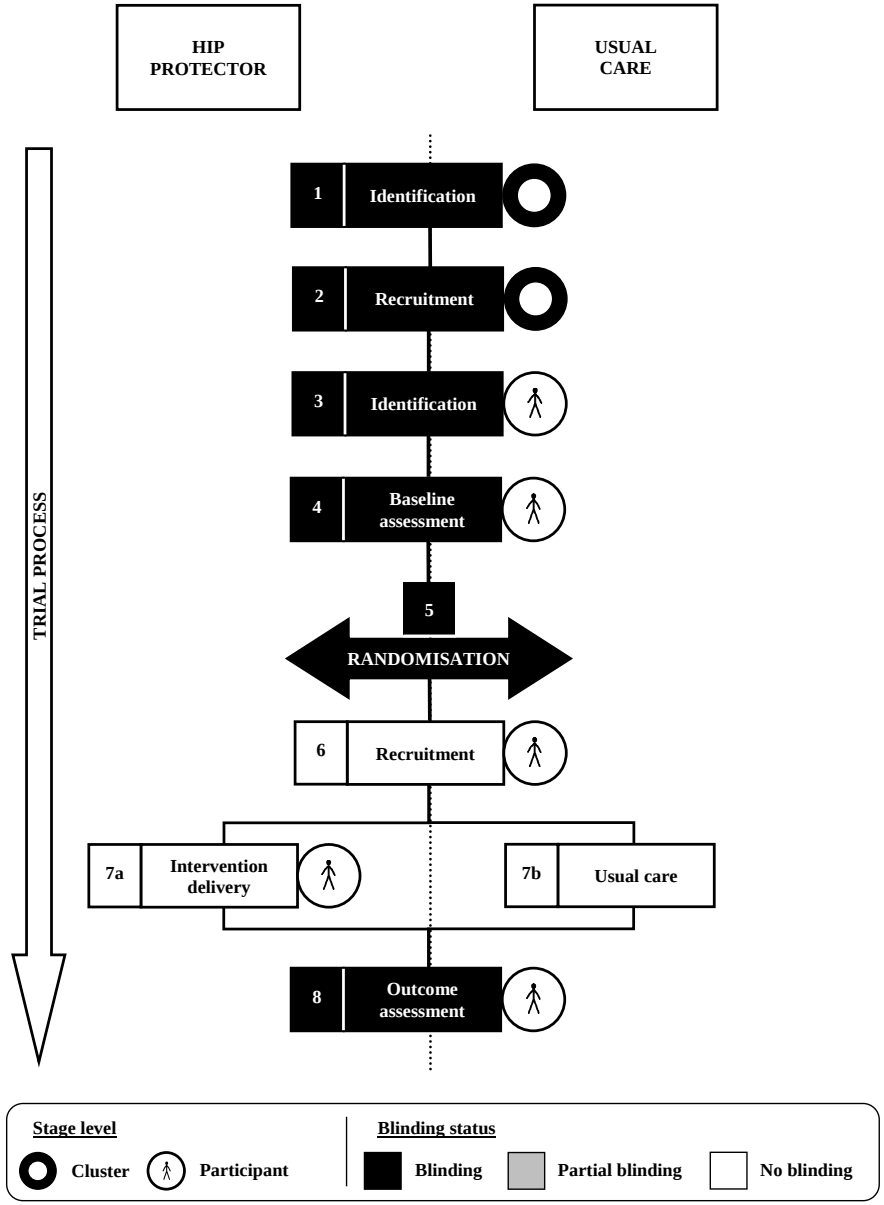

Figure 2: Example of a Timeline cluster diagram for a cluster trial with a risk of recruitment bias: a cluster trial evaluating a hip protector to reduce hip fractures in older adults[13]

1	**Cluster identification** Community-based healthcare centers in the southern and central parts of Finland are approached. In each center that agrees to participate in the trial, the local research coordinator identifies treatment units that care for older adults at high risk of hip fracture (geriatric long-stay facilities or outpatient care units for supported living at home).
2	**Cluster recruitment** Research coordinator takes consent from treatment unit.
3	**Participant identification** All eligible subjects in the treatment unit are identified by the research coordinator with the help of the other caregivers.
4	**Participant baseline assessment** Baseline data for eligible subjects are collected by the research coordinator with the help of the other caregivers from the treatment unit.
5	**Randomisation** Randomisation with a 1:2 ratio (allocating more clusters in the control group) is performed at treatment unit level by an independent physician, at the President Urho Kaleva Kekkonen Institute for Health Promotion Research, by using sealed envelopes. All clusters (treatment units) from a given healthcare center are randomised at once as soon as participant identification is completed within this center.
6	**Participant recruitment** Participants (or their family members) receive information and provide written consent. During the trial, participants who have consented but drop out because of death, new inability to walk, hip fracture or withdrawal of consent, are replaced, whenever possible, by new eligible subjects from a waiting list. No blinding for recruiters and participants.
7a	**Intervention delivery** Participants wear of a hip protector whenever they are on their feet. No blinding for care providers and participants.
7b	**Usual care** None of the participants use a hip protector. No blinding for care providers and participants.
8	**Participant outcome assessment** Fracture of the hip or the proximal femur prospectively recorded during the study and confirmed by radiographs.*

*We used the report of the trial to apply the Timeline cluster tool post hoc for illustrative purpose. We assumed that those who read the radiographs were blinded although this is not clearly specified in the report.