

Figure S1: Example of a Timeline cluster diagram for a cluster randomised trial with no recruitment of participants: The IRIS trial, assessing training of general practitioners in identification and referral of women victims of domestic violence^{1,2}

1	Cluster identification The research team identifies all general practices (GPs) belonging to either Bristol or Hackney primary care trust and having an electronic medical record system compatible with the use of clinician prompts. The study is then proposed to a random sample of GPs generated from random number tables, with stratification on the primary care trust area and on some practice characteristics: number of whole-time-equivalent female doctors, general practice postgraduate training status, number of patients registered with the practice and percentage of the practice population on low incomes defined by the low income scheme index.
2	Cluster recruitment Randomly selected practices are contacted sequentially within each strata in rank order. They receive a postal invitation to participate, including details of the study and a copy of an editorial from a general practice journal highlighting domestic violence as a central primary care issue. They have a telephone contact with one of the investigators to discuss a possible participation. For practices expressing initial interest to participate, further information sheet is sent by e-mail or postal mail (a practice visit to explain the study in more details is also offered). Individual clinicians within practices provide implicit consent, assumed from their subsequent attendance at training sessions and their completion of study questionnaires.
3	Randomisation Randomisation is performed by an independent statistician not involved in the identification of participants. A minimisation programme is used, including a random component to maximise balance between groups in the percentage of whole-time-equivalent female doctors, general practice postgraduate training status, number of patients registered with the practice and percentage of the practice population on low incomes. Randomisation is performed separately for each primary care trust area, practices are randomised one after the other once recruited.
4a	Intervention delivery General practitioners and other members of the practice clinical team receive multidisciplinary training sessions held within each practice. Posters are displayed and leaflets are available within the practice. Electronic prompts are integrated in the electronic medical record system. Periodic feedback of identification and referral data are provided to practice teams. No blinding for practice staff; patients are not aware they are part of a research study.
4b	Usual care Practices provide usual care. No blinding for practice staff; patients are not aware they are part of a research study.
5	Participant identification All women aged ≥ 16 years within each practice are eligible to participate in the study. There is no participant information and no participant consent. A research associate identifies eligible women from the electronic medical records in each practice. Research associates are not blinded to allocation status, but identification is standardised and all eligible women are included. Validity of participant identification is assessed by an independent researcher blinded to allocation status in a random selection of 8 practices.
6	Participant outcome assessment Referral of women to specialist domestic violence agencies for 1 year following the educational sessions in intervention practices, extracted from routinely collected data. Research associates collecting outcome data are not blinded to allocation status, but outcome extraction is based on a detailed flowchart. Research associates may refer to a panel for arbitration in difficult cases. Validity of referral data collection is assessed by an independent researcher blinded to allocation status in a random selection of 8 practices.

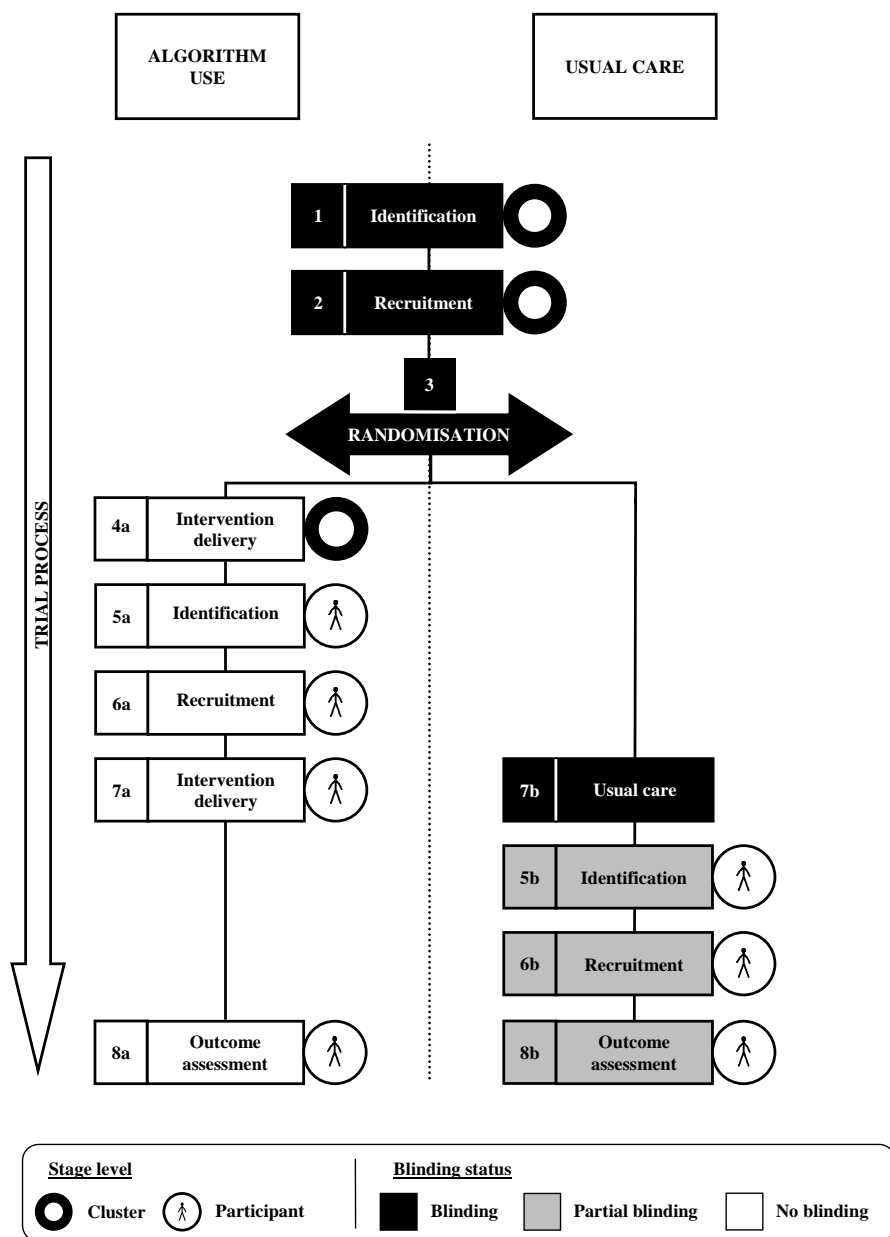


Figure S2: Example of a Timeline cluster diagram for a cluster randomised trial with a differential recruitment process: a cluster trial assessing an algorithm for diagnosis of active labour³
 NB: The trial is described as initially planned, without taking into account what is described in the Results section. Timeline cluster diagram is depicted as it would have been depicted in the trial protocol.

1	Cluster identification The research team identifies maternity units in Scotland with at least 800 annual births
2	Cluster recruitment Research team approaches all eligible maternity units and discusses about the study with head of midwifery and other stakeholders at each units. Clinical directors provide consent.
3	Randomisation A statistician not involved in participant recruitment performs randomisation. A minimisation program is used to maximise balance between groups on the presence of an on-site midwife managed birth unit
4a	Intervention delivery at cluster level Midwives are invited to participate in the study, they attend workshops, have individual contacts and receive a training manual on the use of the algorithm. Thereafter, midwives consent to study participation.
5a	Participant identification in the algorithm group The admitting midwife identifies eligible women on admission to the labour suite. No blinding for admitting midwife.
5b	Participant identification in the usual care group Midwives retrospectively identify women who would have been eligible for the trial when they first presented for labour admission, regardless of subsequent labour outcome. Midwives receive minimal information about the study, they do not have access to the algorithm.
6a	Participant recruitment in the algorithm group The admitting midwife provides oral and written information about the study and seeks consent prospectively from women on admission to the labour suite. Women provide consent for the use of the algorithm and collection of identifying data. No blinding for admitting midwives and women.
6b	Participant recruitment in the usual care group Midwives provide oral and written information about the study to women in the postnatal ward. Women consent for collection of identifying data only. Midwives receive minimal information about the study, they do not have access to the algorithm.
7a	Intervention delivery at participant level Midwives use the algorithm for diagnosis of active labour during the admission assessment of women. No blinding for midwives and women.
7b	Usual care Women receive usual care. Admission assessment is performed by midwives using clinical judgement alone. Midwives receive minimal information about the study; they don't have access to the algorithm. Women have no information about the study.
8a	Participant outcome assessment in the algorithm group Use of oxytocin (any dose) for augmentation of labour collected from case records after delivery by midwives.* No blinding for midwives. In the meantime, use of oxytocin is retrospectively collected from the case records of 200 women who gave birth in each maternity unit before implementation of the study to allow for adjustment on baseline value in outcome analysis.
8b	Participant outcome assessment in the usual care group Use of oxytocin (any dose) for augmentation of labour collected from case records after delivery by midwives.* Midwives receive minimal information about the study, they do not have access to the algorithm. In the meantime, use of oxytocin is retrospectively collected from the case records of 200 women who gave birth in each maternity unit before implementation of the study to allow for adjustment on baseline value in outcome analysis.

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

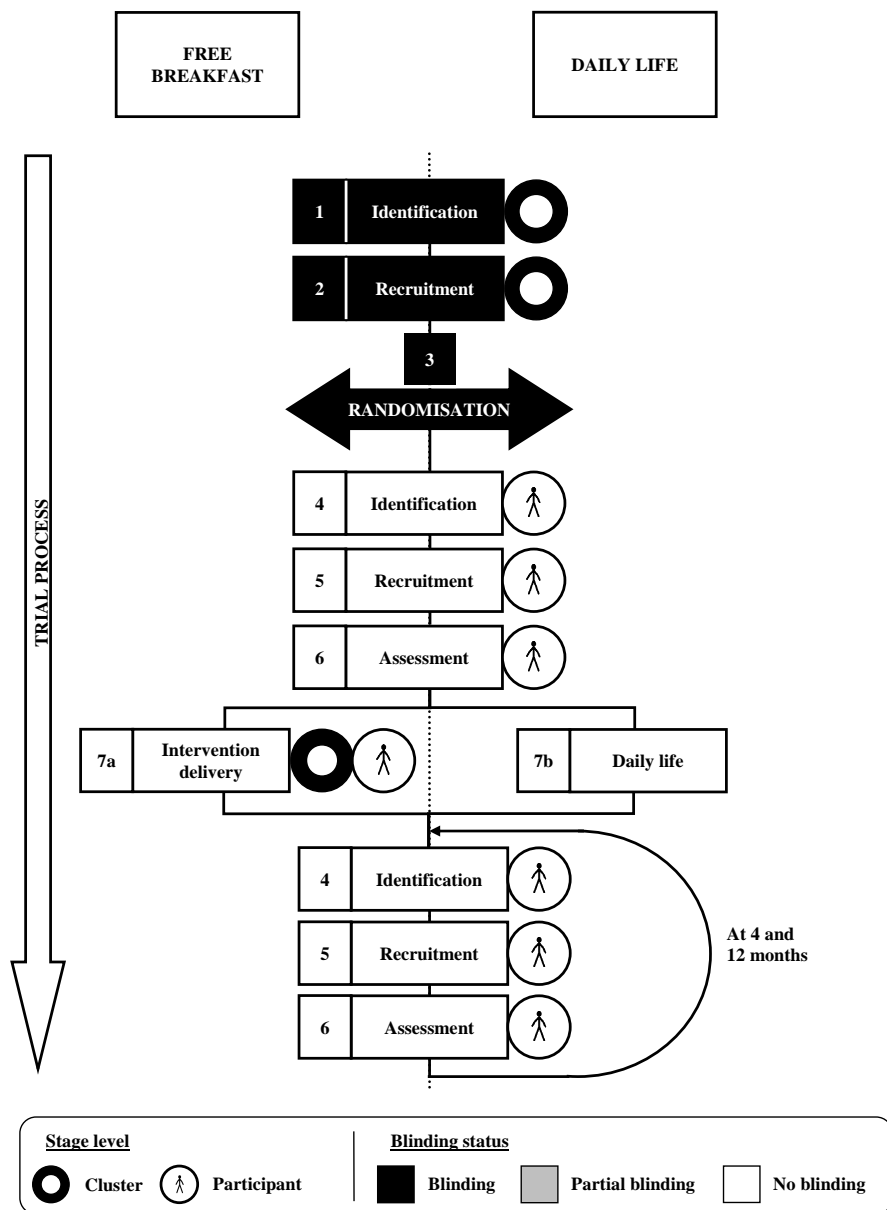


Figure S3: Example of a Timeline cluster diagram for a repeated cross-sectional cluster randomised trial: a cluster trial assessing breakfast provision in primary schools ^{4,5}

1	Cluster identification Infant, junior and primary schools located in both “Communities First” (deprived) areas and “Non-communities first” areas in 9 local education authorities are identified.
2	Cluster recruitment Head teachers are approached and schools in which head teachers express an interest in taking part in the study are visited by the research team. Head teachers agree to participate and provide a written consent to be randomised to either the control or intervention condition and to participate in data collection.
3	Randomisation Block randomisation is performed, stratified on local education authority, school size, free school meal entitlement and Welsh language medium. Two phases of randomisation are performed, the first for the participating schools in “Communities First” (deprived) areas and the second for the participating schools in “Non-Communities First” areas.
4	Participant identification In each school, at each time point (baseline and 4 and 12 months’ follow-up), one Year-5 (9-10 years) and one Year-6 (10-11 years) class is randomly selected. All eligible children’s names are provided by schools to the research team before data collection. Because of the random selection of classes at each time of the trial, some children could be assessed more than once. No blinding for participant identification.*
5	Participant recruitment Parents of eligible children are informed of the research by a letter and information sheet posted to them or sent home with children. They are asked to complete a consent return slip or to contact the school if they do not wish their child to participate in the study. At each time point of data collection, children are informed that they are under no obligation to participate. No blinding for teachers, parents and children.
6	Participant assessment Outcomes are breakfast skipping, breakfast diet and episodic memory assessed with individual self-reported questionnaires, administered simultaneously to the whole class. No blinding for teachers, children and research-team data-collection staff.
7a	Intervention delivery Schools set up a breakfast scheme. Guidelines regarding how the scheme should be run are provided to the schools, and a healthy breakfast is provided to children. No blinding for teachers and children.
7b	Daily life Schools are refrain to set up a breakfast scheme. No blinding for teachers and children.

*We used the protocol and report of the trial to apply the Timeline cluster tool post hoc for illustrative purpose. We assumed that those who performed participant identification at each time were not blinded to allocation, although this is neither clearly specified in the protocol or in the report.

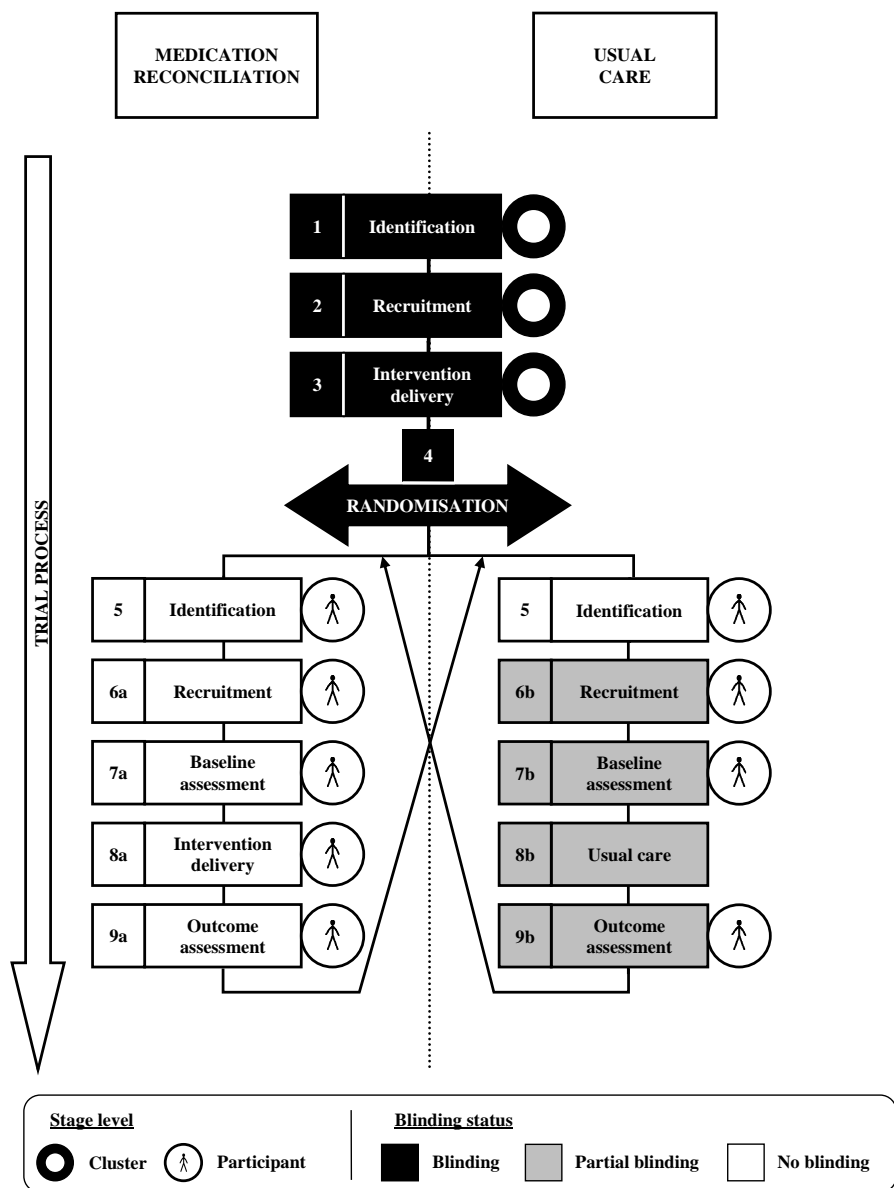


Figure S4: Example of a Timeline cluster diagram for a cluster cross-over trial: The REPHVIM trial, assessing medication reconciliation at patient's discharge on drug-related problems⁶

1	Cluster identification French hospital pharmacists are approached by the study team. Each hospital pharmacist who agrees to participate in the trial identifies 2 units from their hospital, one surgical and one medical unit.
2	Cluster recruitment Medical heads from hospital units receive information and provide written consent to take part to the study.
3	Intervention delivery at cluster level Hospital pharmacists are trained in medication reconciliation. Community pharmacists working in nearby participating hospital units are informed of the study in 3 ways: an article in a professional journal supported by the pharmacist unions, in a professional journal supported by the national council of the order of pharmacists, and a letter from the study scientific committee distributed by wholesale drug distributors.
4	Randomisation: cross-over design Randomisation is performed in a 1:1 ratio by an independent statistician with stratification on the hospital. Each hospital unit is randomised to perform medication reconciliation or usual care for a first 14-day period and is crossed over to the other group for a second 14-day period.
5	Participant identification In each hospital unit, unblinded hospital pharmacists identify eligible patients.
6a	Participant recruitment in the medication reconciliation group Participants are recruited by unblinded hospital pharmacists. They receive complete information and provide oral consent for intervention and for data collection.
6b	Participant recruitment in the usual care group Participants are recruited by unblinded hospital pharmacists. They receive a partial information because they are not aware of the existence of the medication reconciliation group -and provide oral consent for data collection.
7a	Participant baseline data collection in the medication reconciliation group Baseline data are collected by the unblinded hospital pharmacists. There is no blinding for patients. Contact details from the patient's community pharmacist are collected.
7b	Participant baseline data collection in the usual care group Baseline data are collected by the unblinded hospital pharmacists. Patients are not aware of the existence of the medication reconciliation group. Contact details from the patient's community pharmacist are collected.
8a	Intervention delivery Medication reconciliation at patient discharge is performed by a hospital pharmacist, followed by phone transmission of treatment modification to the patient's community pharmacist. No blinding for hospital pharmacists, community pharmacists and patients.
8b	Usual care No blinding for community pharmacists, but they are not aware that the patient is involved in a trial. No blinding for patients, but they are not aware of the existence of the medication reconciliation group.
9a	Participant outcome assessment in the medication reconciliation group Drug-related problem within 7 days following discharge assessed by a research pharmacist recruited for the study, using a standardized evaluation form. Assessment is centralised and performed by a phone call to both the participant and the community pharmacist. No blinding for the research pharmacist, community pharmacists and patients.
9b	Participant outcome assessment in the usual care group Drug-related problem within 7 days following discharge assessed by a research pharmacist recruited for the study, using a standardized evaluation form. Assessment is centralised and performed by a phone call to both the participant and the community pharmacist. No blinding for the research pharmacist, community pharmacists are not aware that the patient is involved in a trial and patients are not aware of the existence of the medication reconciliation group.

References

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