Summary of the course
&
How to report a cohort study

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Biostat III – 2020-02-19

Outline

- **Summary of the course**
- Checklist of a cohort analysis
- How to report a cohort study

Summary of the course

Day 1 Topics

- Central concepts in survival analysis: survival time, time-to-event, censoring, truncation, survivor function, hazard function.

- Estimating survival non-parametrically.
  - Kaplan-Meier
  - Actuarial method
  - The methods are different in how the time intervals are chosen, and handle ties (i.e. if several study participants have the same survival time) in different ways because of the assumptions about how time is measured
  - K-M assumes time is measured continuously

- Non-parametric method for testing differences in survival between groups.
  - Log-rank test

Summary of the course

Day 2 Topics

- Timescales
  - Rates vary over different timescales, e.g. time-since-entry, attained age, calendar time
  - Difference between time-at-risk (persontime) and timescale
- Constant, overall rates (average rates) and rates that vary over time
- Estimating rates as events over persontime
- Estimating and modelling rates using Poisson regression
- Confounding and effect modification (interaction) when modelling rates
  - Linear predictors, interpretation of estimates
- Timesplitting
- Adjusting for the timescale as a covariate in the Poisson model
  - Yielding a stepwise hazard rate

Summary of the course

Day 3 Topics

- Modelling rates using Cox proportional hazards model.
- The proportional hazards assumption; i.e. no interaction with underlying timescale
- Assessing the proportional hazards assumption (for both Cox and Poisson regression).
  1. Plotting S(t), h(t)
  2. Plotting –log(-log(H(t))
  3. Schoenfeld residuals (Cox model)
  4. Test for interaction with time (timesplitting in both Cox and Poisson regression)
- Modelling non-proportional hazards (for both Cox and Poisson regression).
  - Modelling interaction with time
- Comparison of the Cox and Poisson regression models (illustration that they are very similar).
- Testing the effect of an exposure using Wald and LR tests

Summary of the course

Day 4 Topics

- Time-varying exposures
- Stratified Cox models
  - An alternative way to control for non-proportional hazards
- Flexible parametric survival models
  - An alternative to Cox and Poisson, and useful for other measures
- More on censoring and truncation, including informative censoring
- Competing risks analysis (limited coverage)
- Standardized mortality ratios (SMR), standardized incidence ratios (SIR)
- Some biases in survival analysis/cohort studies.

Summary of the course

Day 5 Topics

- How to critically evaluate a cohort study from a methodological perspective
- Risk set sampling (e.g., the nested case-control design) and the case-cohort design
  - Matching (NCC) or no matching (case-cohort) on timescale and yet get inference for the full cohort
- How to report a cohort study

Outline

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- **Checklist of a cohort analysis**
- How to report a cohort study

Checklist of a cohort analysis

1. Think in advance (before starting the analysis)

- Define the outcome
  - When is start/end of follow-up, define risktime (persontime)
  - What/when is the event
  - What/when are censoring events

- What timescales are important
  - Time-varying rates
  - Confounding by time
  - Effect modification by time
  - Is any timescale part of research question (do you want to estimate effects over time)

- What other confounders/mediators/effect modifiers should be included?
  - Are all covariates fixed, or are some time-varying?

Checklist of a cohort analysis

2. Data preparations

- Define and code the outcome (event) variable (include censoring)
  - Define and code start of follow-up
  - Define and code end of follow-up (include censoring)
  - Code event indicator and risktime (in Stata: **stset**)
- Define and code all covariates
- Define and code the timescales (need for timesplitting?)
- Any time-varying exposures (need to timesplit and allow the time-varying exposures)

Checklist of a cohort analysis

3. Descriptive analysis

- Estimate and plot survival curves (not for delayed entry data) (**sts graph**)

- Estimate and plot hazard rates (**sts graph, haz**)
  - How does the rate vary over time? By exposure groups? By confounders?
  - Is the proportional hazard assumption valid for all exposures/confounders?

- Estimate crude hazard rates (**strate**) - how many events are in each exposure category, this will limit the modelling power and subgrouping/interactions in analysis
  - How does the rate vary by exposure groups? By confounders?

- Check where the events occur over time (**hist _t if _d==1**)

Checklist of a cohort analysis

4. Modelling

- Choose a model (see slides on Poisson vs Cox);
  - Poisson: If interest in rates and HRs, multiple timescales, interactions with time (non-proportional hazards)
  - Cox: If interest in HRs, no interest in main timescale (but adjustment is important), one main timescale (no multiple timescales), proportional hazards/non-proportional hazards (different HRs over time in timebands)
  - FPM: If interest in rates and HRs, and other measures that can be obtained from the model, interactions with time (non-proportional hazards). Nice graphs which are easy to communicate.

- Run models addinging covariates and confounders according to your research questions
  - Test for significant effects using Wald or LR tests
  - Include interactions between fixed exposures
  - Test proportional hazards assumption; account for non-proportional hazards by including interactions with timescale

Outline

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- **How to report a cohort study**

How to report a cohort study

- Methods section should include:

- Description of the cohort, inclusion and exclusion criteria
  - Period of recruitment of participants: Ages, years, geographical region
  - Follow-up, start/end
  - Lost-to-followup, dropout (censoring events)
  - Truncation, e.g. register coverage over calendar time and ages

- Discussion of limitations (can be included in Discussion section)
  - Truncation problems, and potiental biases
  - Ascertainment problems for outcomes and exposures, e.g. only severe cases of disease are recorded in the In-Patient Registry, and how this may affect time-to-event

How to report a cohort study

- Statistical methods section should include:

  - Start and end of followup, definition of time-to-event, outcome of interest, censoring events, competing events (competing risks), unit of time
  - Survival proportions estimated using Kaplan-Meier or actuarial methods (but not if delayed entry); if any standardisation is used; tests for survival proportion (e.g. log-rank test)
  - Rates, estimated as events over persontime, unit for the rate (e.g. per 100,000 pyrs)
  - Model used for rates (e.g. Cox, Poisson, FPM)
  - Measure of association between exposure and outcome (e.g. hazard ratio with 95% CI)
  - Estimation of other quantities (e.g. SIR, cumulative incidence, rate differences)
  - Main timescale used in models, and other timescales of interest
  - If timesplitting used, describe which timescales and categories of timesplitting
  - Fixed and time-varying exposures
  - Main effects, interaction effects, adjustments
  - Which tests for associations (LR test, Wald test) and significance level
  - Assessment of the proportional hazard assumption, which methods/tests were used
  - If non-proportional hazards effects were included (i.e. interaction with timescale)
  - Which software (including version) and special commands (e.g. stpm2 for FPM)

Guidelines for reporting: STROBE – observational studies

STROBE Statement: Ava

strobe-statement.org/index.php?id=available-checklists

STROBE Statement

Strengthening the reporting of observational studies in epidemiology

UNIVERSITÄT BERN

- Home
- Aims
- News
- Available checklists
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- Publications
- Translations
- Commentaries
- Discussion forum
- STROBE group
- Endorsement

STROBE checklists

Version 4 as published in Oct / Nov 2007!

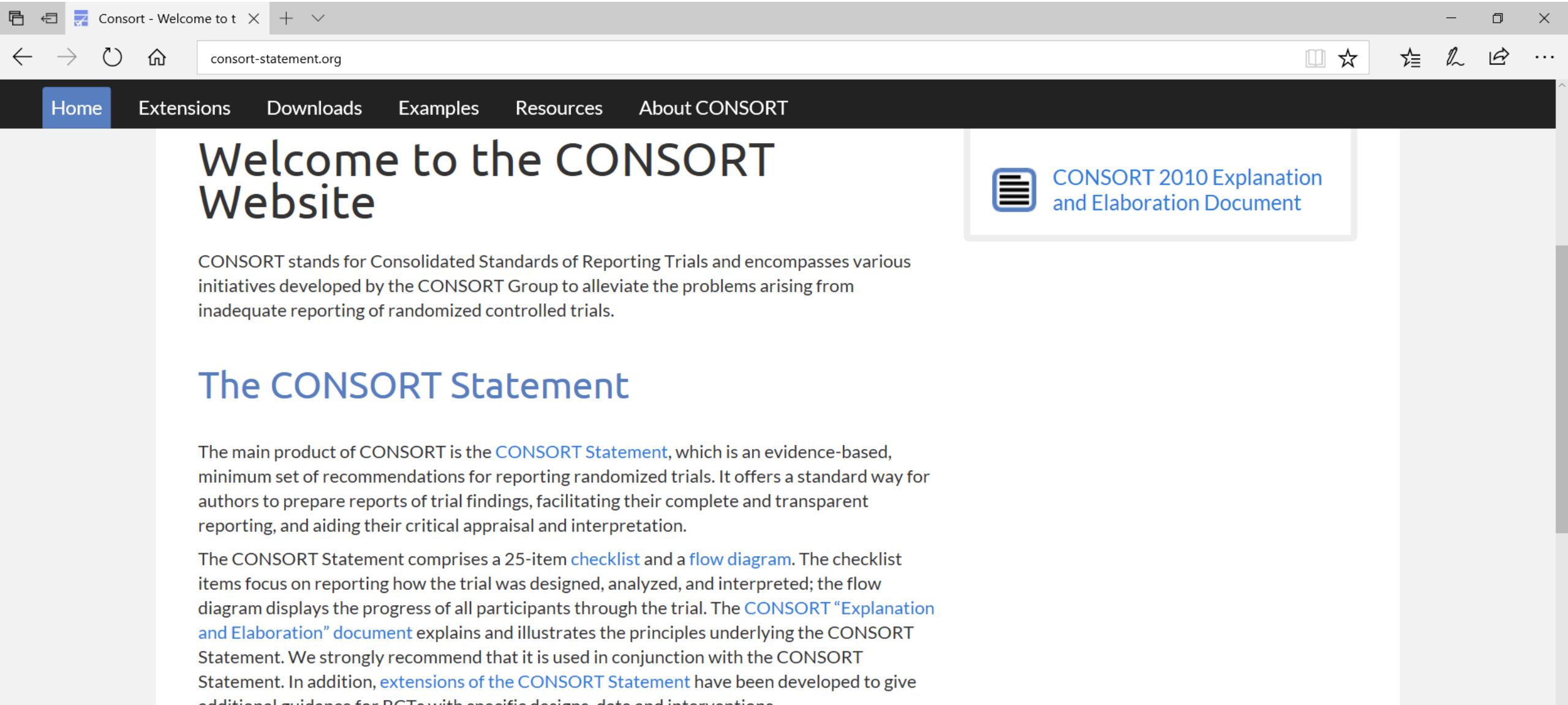
- STROBE checklist for **cohort, case-control, and cross-sectional studies** (combined)
  download PDF / Word
- STROBE checklist for **cohort, case-control, and cross-sectional studies**
  download PDF / Word
- Checklist for **cohort studies**
  download PDF / Word
- Checklist for **case-control studies**
  download PDF / Word
- Checklist for **cross-sectionalstudies**
  download PDF / Word
- Draft STROBE checklist for **conference abstracts**
  download PDF

Guidelines for reporting: STROBE – observational studies

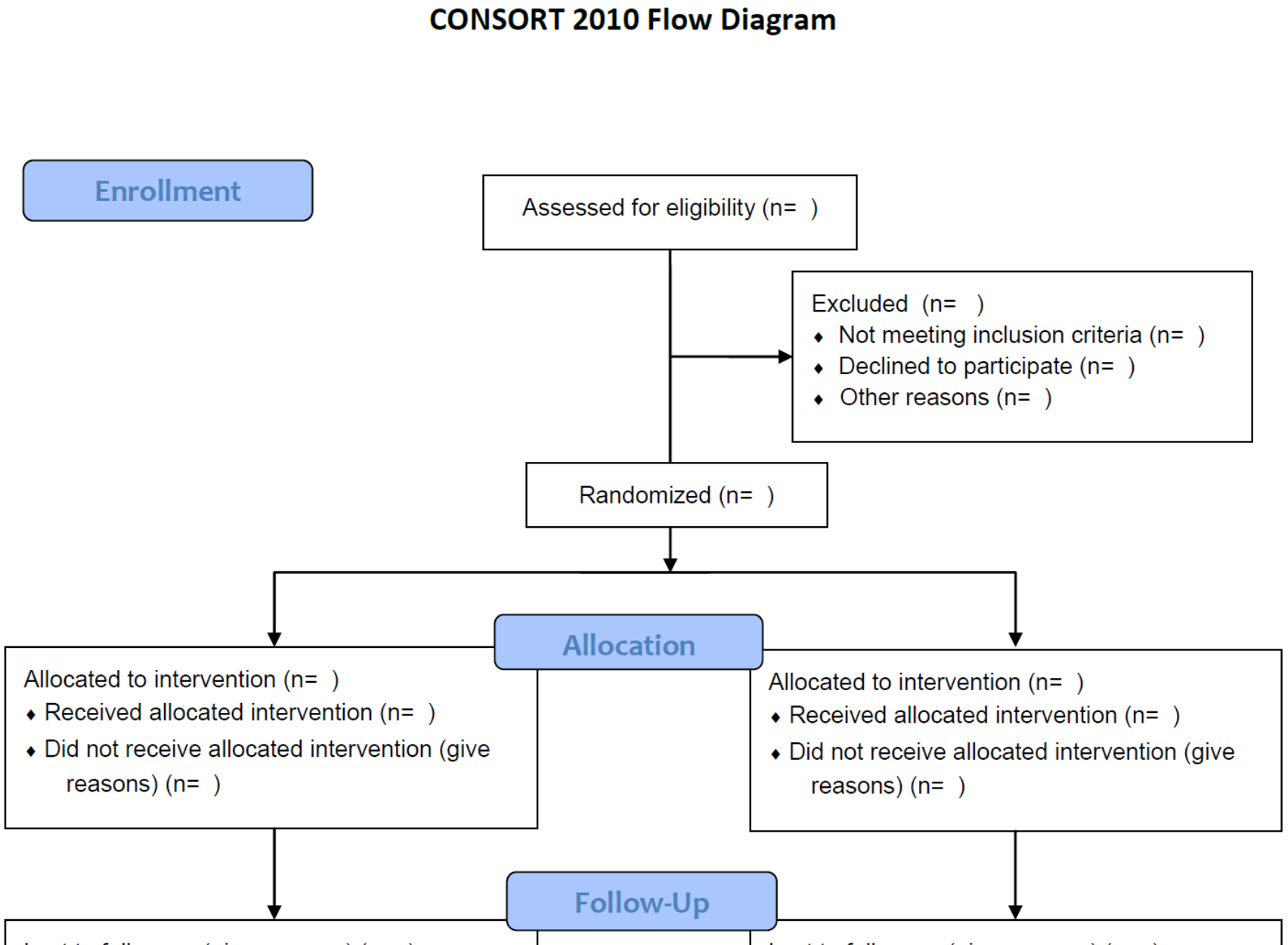
STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at

Guidelines for reporting: CONSORT – clinical trials



Guidelines for reporting: CONSORT – clinical trials



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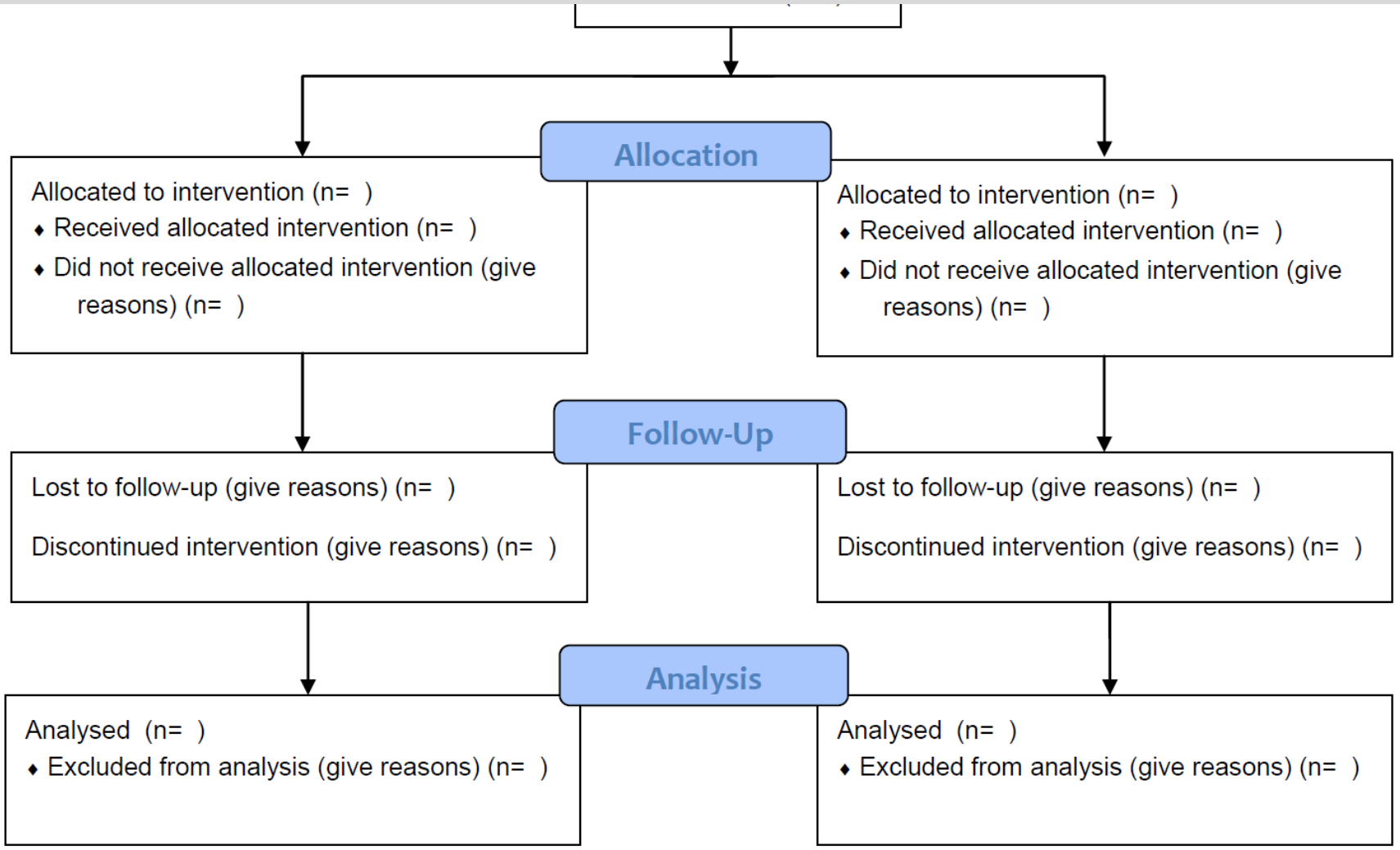

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Course evaluation

- Will be sent out to all participants via email
- Please give us constructive feedback
- We constantly develop the course and make improvements