	Component	Hypothetical open-label unblinded RCT
1.	Eligibility criteria	Inclusion criteria: • Aged 55 to 84 at recruitment • no previous statin use Exclusion criteria: • Prior history of CHD, stroke, peripheral vascular disease, heart failure, cancer, schizophrenia or dementia *(from clinical notes)* • Signs of subclinical CHD *(from clinical examination)*
2.	Recruitment period	From January 2002 to December 2002
3.	Follow-up duration	Start: • At recruitment End, whichever happens first of: • CHD, death, loss to follow-up or December 2006

Component		Hypothetical open-label unblinded RCT
4.	Treatments to be compared	Patients are randomly assigned to either: a. Initiate statin therapy at baseline b. Nothing
5.	Outcome	First of: • CHD diagnosis confirmed by a physician • Death
6.	Estimand	Cumulative survival curves by assigned treatment
7.	Analysis plan	• Kaplan-Meier estimation of cumulative survival curves • Log-rank test of whether they are different

Component		• Emulated non-randomised trial
1.	Eligibility criteria	**Inclusion criteria**: • Aged 55 to 84 in 2002 • With at least one medical record between 2000 and 2002 **Exclusion criteria** *(with information derived from EHRs)*: • Prior history of CHD, stroke, peripheral vascular disease, heart failure, cancer, schizophrenia or dementia • Record of subclinical CHD • Statin use between 2000 and 2002 • Missing data on potential confounders (baseline BMI, smoking, SBP, etc)
2.	Recruitment period	From January 2002 to December 2002
3.	Follow-up duration	**Start**: • 1st clinical record in 2002 **End,** whichever happens first of: • CHD diagnosis, or death • January 2007 • Last linked record if before January 2007

Component		Emulated non-randomised trial
4.	Treatments to be compared	a. Patients who initiated treatment in first record of 2002 b. Patients who did not initiate treatment in in first record of 2002
5.	Outcome	First of: • CHD diagnosis reported in clinical records • Death
6.	Estimand	Cumulativ… where confounding due to treatment …essed
7.	Analysis plan	*[Estimation of marginal cumulative survival curves by treatment group, obtained by fitting an appropriate survival model which includes all relevant confounders and then averaging over their distribution]*

This is beyond the content of this course!

Reference for the exercise

This practical was inspired by this paper (to be found in Moodle)

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Observational data for comparative effectiveness research: an emulation of randomised trials to estimate the effect of statins on primary prevention of coronary heart disease

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