HDR Oxford - Large-scale recruitment using routine data
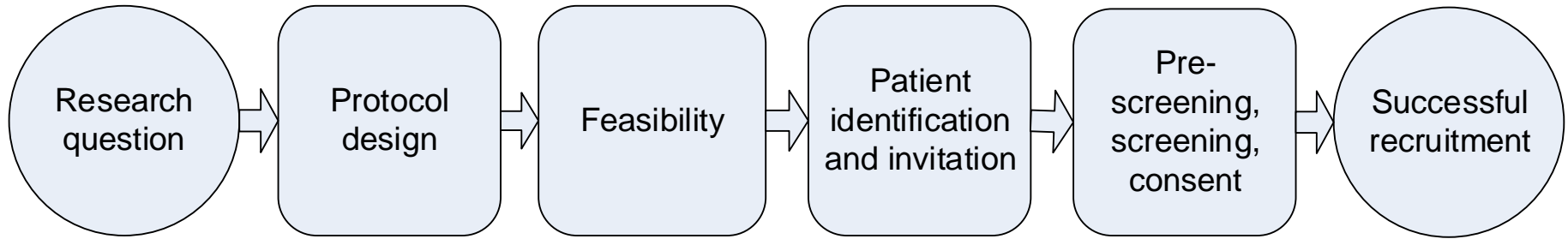
Dr Marion Mafham

Clinical Trial Service Unit

Nuffield Department of Population Health

University of Oxford

Large-scale recruitment using routine data

Research question → Protocol design → Feasibility → Patient identification and invitation → Pre-screening, screening, consent → Successful recruitment

Protocol design

- Simple inclusion and exclusion criteria
- Should identify a population which
  - Has a disease process or risk factor status likely to be amenable to the intervention
  - Has a sufficiently high risk of the primary outcome
  - Can be easily identified from the routine health record

A recent cardiovascular trial

Inclusion criteria

Coronary artery disease is defined as:

- Myocardial infarction within the last 20 years, or
- Multi-vessel coronary disease* with symptoms or with history of stable or unstable angina, or
- Multi-vessel percutaneous coronary intervention (PCI), or
- Multi-vessel CABG surgery

Peripheral arterial disease is defined as:

- Previous aorto-femoral bypass surgery, limb bypass surgery, or percutaneous transluminal angioplasty revascularization of the iliac, or infra-inguinal arteries, or
- Previous limb or foot amputation for arterial vascular disease, or
- History of intermittent claudication and one or more of the following: 1) An ankle/arm blood pressure (BP) ratio < 0.90, or 2) Significant peripheral artery stenosis (≥50%) documented by angiography, or by duplex ultrasound, or
- Previous carotid revascularization or asymptomatic carotid artery stenosis ≥50% as diagnosed by duplex ultrasound or angiography.

*Refers to stenosis of greater than or equal to 50% in 2 or more coronary arteries, confirmed by invasive coronary angiography, or non-invasive imaging or stress studies (e.g. exercise or pharmacologic) suggestive of significant ischemia in 2 or more coronary territories; or in 1 coronary territory if at least one other territory has been revascularized.

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ORION-4 study

Inclusion criteria

- Prior myocardial infarction; or
- Prior ischaemic stroke; or
- Peripheral artery disease (prior lower extremity artery revascularization or aortic aneurysm repair).

Feasibility

"natural human tendency is wishful thinking"

NHS Digital Feasibility electronic search

i) Diagnosis of **HEART ATTACK (MYOCARDIAL INFARCTION)**

- i.e. ICD9 code: 410*, 412* and/or

- ICD10 codes: I21*, I22*, I23*, I252 and/or

- READ codes: G30*

- **Or**

ii) Diagnosis of **STROKE**

- i.e. ICD9 codes: 433*, 434* and/or

- ICD10 codes: I63*, I64* and/or

- READ codes: G63*, G64*, G66* and/or

- **Or**

iii) Surgery or procedure for **PERIPHERAL VASCULAR DISEASE**

- i.e. OPCS-4 procedure codes: L16*-28* inclusive, L48*-65* inclusive, L71*

Identification and invitation

- Data protection laws

- Ethical issues

- Response rate

UK ORION-4 recruitment model

Electronic sear...

Details of po...
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Inv...

Oxford University Hospitals **NHS**

You are welcome to bring a relative or friend to your appointment. The study can pay back reasonable travel expenses.

What should I do next?

If you would like to attend, please telephone free of charge on 0800 585323 (Monday to Friday, 9am-5pm) to confirm your appointment (or to change it to a different day or time). Staff will also be available to tell you more about the study when you call. You can also e-mail on orion4@ndph.ox.ac.uk or write to the study co-ordinating centre at ORION-4, Clinical Trial Service Unit (CTSU), Richard Doll Building, Old Road Campus, Roosevelt Drive, Oxford, OX3 7LF.

If you do not want to attend, we would be very grateful if you could cancel your appointment as soon as possible so that it can be made available to someone else.

Thank you for taking time to read this letter. We do hope you will be able to join us in this important health project.
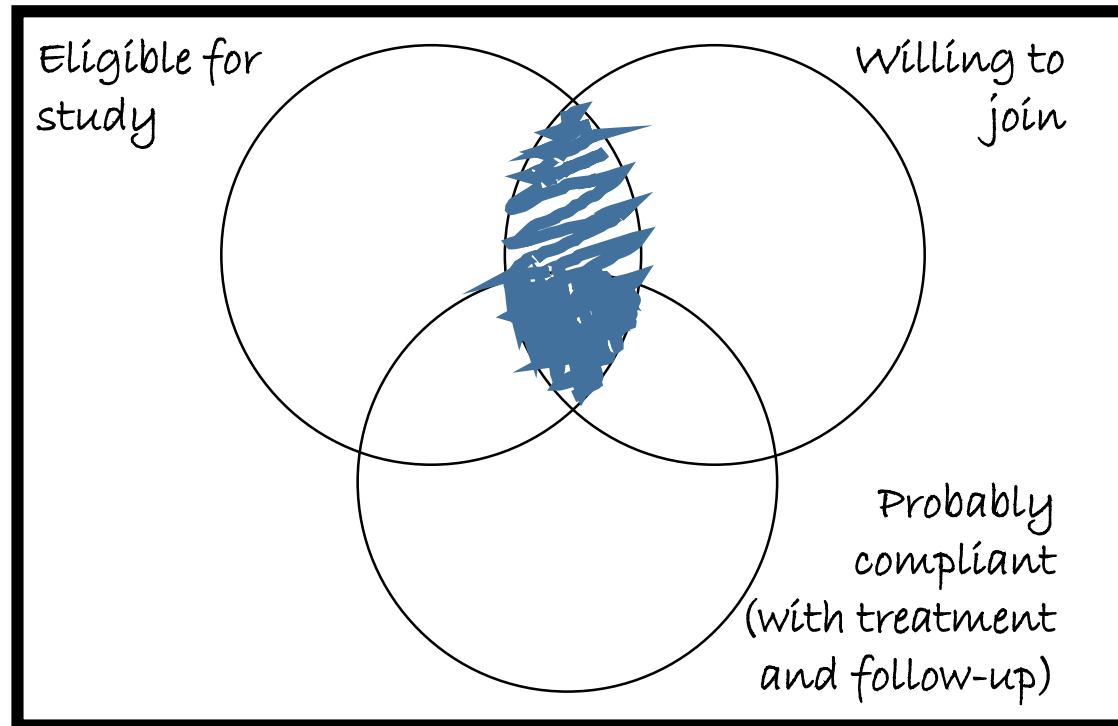
Yours sincerely,

Professor Jane Armitage
Honorary Consultant in Public Health Medicine
Oxford University Hospitals
NHS Foundation trust

Enc: Participant Information Leaflet [Version number]
       Location map

Richard Doll Building, Roosevelt Drive, Old Road Campus,
Headington, Oxford OX3 7LF (map enclosed)

Recruiting the right participants

Eligible for study

Willing to join

Probably compliant (with treatment and follow-up)

Recruitment without retention is pointless

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ASCEND study recruitment

	Central registers	GP registers	Other*	Total
Invited	300,188	120,875	2340	423,403
Returned Screening form	100,563	19,478	1213	121,254
Entered Run-in	16,091	9739	632	26,462
Randomized (% of those invited)	9013 (3%)	6037 (5%)	430 (18%)	15,480 (4%)

* HPS survivor, self-referral, friends and family, consultant clinic referral

Summary

- Simple inclusion and exclusion criteria

- Use the EHR to inform feasibility assessments

- Example of how the HES data-set can be used to recruit to a large trial

- Other populations might require different data-sets/approaches

- Effective patient engagement and retention is essential