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Randomised trials in general practice in West Yorkshire: a brief guide to design, delivery and dissemination for researchers

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Who is this guide for?

This guide is intended for relatively advanced researchers planning a randomised trial in general practice in West Yorkshire. Earlier career researchers may wish to check out existing Information for Researchers.

The guide summarises key considerations around enrolling and supporting general practices in trials. It is based on the experience and consensus of local research leads and managers, research network managers, trial methodologists and researchers.

You may be designing a trial or considering including general practices from West Yorkshire in a trial which has been funded or has started. Whilst many points in this guide should be self-evident to experienced trialists, it may help as an aide memoire or directory of useful contacts and sources of help.

Design

Issues to consider	*Resources and people to talk to*
General Familiarise yourself with existing advice and resources on designing and conducting trials.	Trial Forge NIHR Clinical Trials Toolkit NIHR Research Design Service
Priority setting It may to easier to leverage local support if you are addressing a recognised national AND local priority.	West Yorkshire R&D Strategy statements (e.g. Ten Big Ambitions)
Pragmatism Consider whether you are doing an explanatory (efficacy) or pragmatic (effectiveness) trial. Pragmatic trials are generally more likely to be directly applicable to 'real world' health care delivery than explanatory trials.	PRECIS-2
Intervention Consider whether you are evaluating a relatively 'simple' or complex intervention. Designing and conducting trials of relatively simple interventions may still entail negotiating hidden complexities. For example, a Clinical Trial of an Investigational Medicinal Product (CTIMP) evaluating the safety or efficacy of a drug typically has strict regulatory and monitoring demands. Consider readiness of intervention for evaluation, e.g. whether optimised for a definitive trial. Consider readiness of intervention for implementation, e.g. resource and training needs. Risk manage and validate any new software or modifications to ensure local compatibility.	MRC framework for the development and evaluation of complex interventions
Data sources and management	West Yorkshire R&D

If using routinely collected data, consider information governance and data sharing agreements. Scope potential sources of routine data, e.g. via NHS Digital. Review whether a study-specific Data Protection Impact Assessment (DPIA) is needed.	NHS Digital Secure Data Environment service
Data collection Minimise burden on ALL of patients and carers, primary care staff, and research staff. Consider using routinely collected data where feasible and appropriate. However, remember that the data are in a clinical reporting system and not a database. Consider how you will obtain such data, including costs. Pilot data collection to identify and address items that may cause difficulties during the trial.	NIHR Clinical Research Network (CRN) Yorkshire and Humber West Yorkshire R&D PPIE groups Primary care staff
Feasibility Ensure that primary care staff, independent of study teams, review trial protocols at early and late phases of development to identify feasibility and acceptability concerns. This should include practice staff who may have a substantive role in operationalising the protocol (e.g. administrators with a role in patient identification). Consider the feasibility of all aspects of site and patient identification and recruitment, intervention delivery and data collection. Review and revise trial procedures so that they centre more on the needs and abilities of general practice staff than the expectations and norms of trialists. Specify tasks for practice staff, where feasible (AACTT - action, actor, context, target, time). However, practices can be staffed and operated in very different ways and therefore trial protocols need to be sufficiently flexible to accommodate such variations.	NIHR CRN Yorkshire and Humber NIHR Research Design Service West Yorkshire R&D
Research staff Clarify who will be carrying out tasks within practices. Staff conducting any pre-consent activities need to have employment contracts with their general practices for access to patient identifiable data. Consider whether the trial will be delivered by a research nurse or practice staff, e.g. for consent or intervention procedures. Having a research nurse to deliver trial (or CRN) makes this feasible for practices that are less research active.	NIHR CRN Yorkshire and Humber
Costing NHS activities *Service Support Costs* are the additional patient care costs incurred by the project. These costs end once the R&D activity	NIHR CRN Yorkshire and Humber AcoRD

stops even if the same patient care service continues to be provided. *Treatment Costs* are the care costs that would continue to be incurred if the patient care service in question continued to be provided following the end of the research study. *Excess Treatment Costs* occur when treatment costs (the patient care costs) in a research study are greater than in routine care. They also include the cost of any additional training required to deliver a new intervention. Agree the attribution of research costs with an AcoRD specialist from the CRN using the SoECAT tool (for non-commercial studies). Do this at the time of applying for research funding to ensure that site-level Research Costs are met via that funding. Fully cost all practice activities related to patient identification and consent. Failures to do so and under-estimating true costs will undermine motivation and ability of practices to participate. Consider costing in time of West Yorks R&D staff to sit on trial management or steering committees; the payback from this in terms of access to advice and negotiating obstacles is typically worthwhile.	Guidance from DHSC Online SoECAT guidance
Regulatory approvals General practices recruited as research sites will need to confirm capability and capacity to participate if they are actively involved in recruiting patients. This includes practices acting as Patient Identification Centres. However, there may be circumstances when confirming capability and capacity are not necessary (e.g. certain types of cluster trial). Identify other regulatory approvals needed, e.g. Medicines and Healthcare products Regulatory Agency (MHRA) for trials of medicines and devices.	Health Research Authority
Trial management and oversight Ensure that trial management and oversight groups include people with relevant experience of general practice organisation and delivery (e.g. general practitioners, practice managers, practice nurses).	

Delivery

Issues to consider	*Resources or people to talk to*
Key people and organisations Identify key people and organisations who can support your trial and are happy to be named as supporters in your recruitment of practices.	West Yorkshire R&D NIHR CRN Yorkshire and Humber Local GP federations Research colleagues

Portfolio adoption Seek portfolio adoption from the CRN, ensuring wherever possible that any study accruals are attributed to primary care.	NIHR CRN Yorkshire and Humber
Timing Be aware of additional demands on general practices at certain times of year. These include preparing for Quality Outcome Framework submissions (end of March), peak periods of staff leave (school holidays), vaccination campaigns (Autumn), and Winter pressures. Although there is seldom a perfect time, timing of research activities should be sensitive to high demand periods.	
Publicity Start and maintain a campaign of repeated communications (e.g. email notices, social media and newsletters) to practices promoting your trial via different channels, e.g. WY Integrated Care Board email updates, local medical committee newsletters. Look for and use events (e.g. educational meetings) to promote participation in your trial.	West Yorkshire R&D NIHR CRN Yorkshire and Humber
Highlight benefits and costs Highlight likely benefits to services and patients, without creating unrealistic expectations or under-estimating effort and costs involved for practices.	
Peer influence Identify socially influential, credible individuals within localities who can encourage participation, either generally or for specific studies.	
Feedback Deliver comparative feedback to practices on patient recruitment, e.g. via regular newsletters.	
Incentives and rewards Consider any monetary or broader incentives for practices to participate, e.g. access to trial interventions, education.	
Protocol refinement Seek rapid feedback from early recruiting practices to identify and fix procedural problems and to promote participation to other practices. This may mean mandating what is absolutely necessary to ensure scientific integrity whilst being flexible on other trial processes.	
The evidence base for recruitment methods	Trial Forge

The above suggestions for trial delivery are largely based upon experience and limited evidence. Review and revise your trial methods as the evidence base evolves.	Cochrane review of strategies to improve recruitment to randomised trials
Patient identification centres Consider use of patient identification centres (PICs) to achieve economies of scale. Patient searches need to be sufficiently sensitive and specific to make best use of limited time for screening.	
Workforce development Explore ways to support and mentor general practice staff developing as principal investigators (PIs). This may include the NIHR Associate PI scheme and the joint NIHR and Academy of Medical Royal Colleges (AoMRC) Clinician Researcher Credentials Framework.	NIHR Associate PI Scheme NIHR and AoMRC Clinician Researcher Credentials Framework

Dissemination

Issues to consider	*Resources or people to talk to*
Push, Pull, and Linkage & Exchange Consider a structured and active approach to dissemination, e.g. *Push* - Identify potential channels for disseminating trial findings beyond academic papers and meetings. *Pull* - Create an appetite for your eventual trial findings by highlighting the need for your trial and reporting progress, e.g. via social media. *Linkage and exchange* - Identify and develop or maintain relationships with key regional and national bodies which may be important in supporting dissemination and implementation.	West Yorkshire R&D Maximising the benefits of research: Guidance for integrated care systems
Contextualising findings Clarify what your trial findings add to evidence from existing systematic reviews.	
Tailoring dissemination Don't forget to include practices in your dissemination strategy! Consider how to tailor the content and format of trial findings to general practices.	
Indicators Consider whether any important trial process and outcome endpoints can be adopted as quality indicators, especially if using routinely collected data, to monitor subsequent uptake in routine practice.	

Contributors

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