Using the QuinteT Recruitment Intervention (QRI) to support recruitment to Randomised Controlled Trials

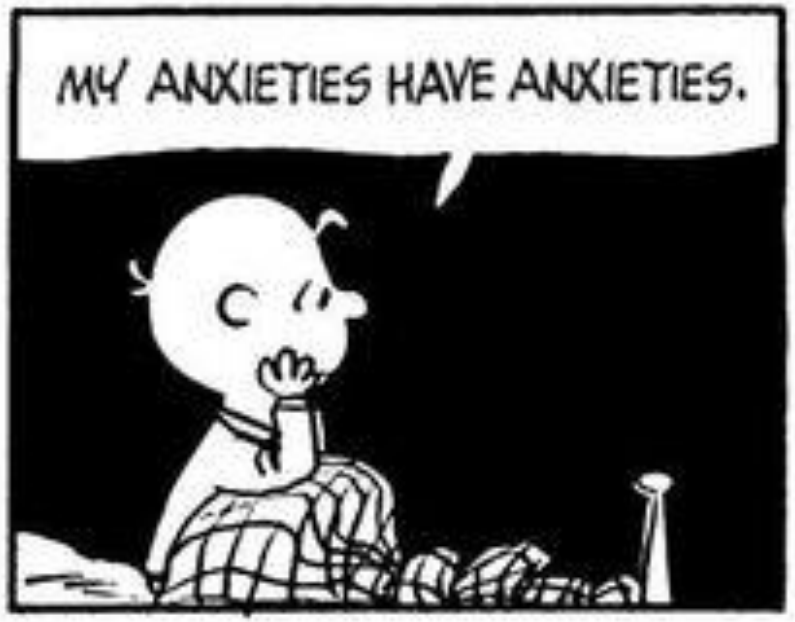
SITU/NDORMS
University of Oxford
30 January 2025

Nicola Mills, Leila Rooshenas, Julia Wade
Ava Lorenc

Recruitment

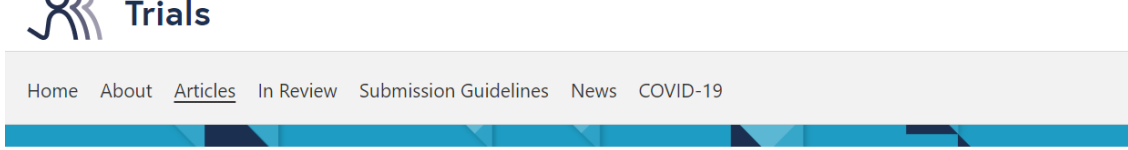
Recruitment is often harder than we anticipate

Recruitment: why worry?



Good news: there are strategies that can help

Research to improve trial recruitment and retention



Research | Open Access | Published: 25 November 2021

Exploring reasons for recruitment failure in clinical trials: a qualitative study with clinical trial stakeholders in Switzerland, Germany, and Canada

Matthias Briel, Bernice S. Elger, Stuart McLennan, Stefan Schandelmaier, Erik von Elm & Priya Satalkar

Trials **22**, Article number: 844 (2021) | Cite this article

MRC START
Developing the science of recruitment

Trials Methodology TMRP Research Partnership

TRIAL FORGE

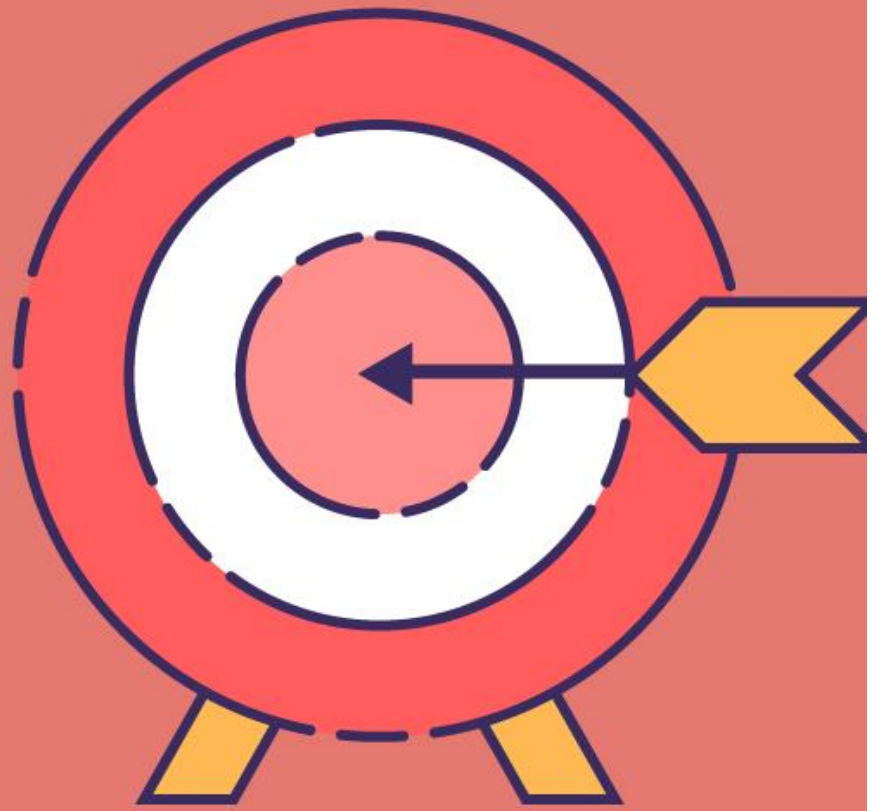
RRCA

PRioRiTy

QuinteT
Qualitative research Integrated within Trials

MRC | Hubs for Trials Methodology Research
ConDuCT-II Hub

NIHR | Bristol Biomedical Research Centre



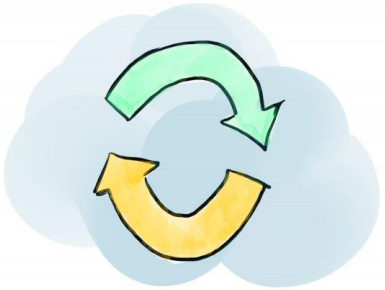
Goals of talk

- Introduce you to the QuinteT Recruitment Intervention
- QRI techniques for rapidly identifying recruitment issues
- Examples of trials with barriers identified

Please chip in throughout!

QRI Origin: the ProtecT study

- Started with a very challenging prostate cancer trial: ProtecT
  - Surgery *vs* radiotherapy vs 'watchful waiting'



ELSEVIER

Journal of Clinical Epidemiology 62 (2009) 29–36

Journal of Clinical Epidemiology

ORIGINAL ARTICLES

Development of a complex intervention improved randomization and informed consent in a randomized controlled trial

Jenny L. Donovan[a,*], J. Athene Lane[a], Tim J. Peters[b], Lucy Brindle[h], Elizabeth Salter[a], David Gillatt[c], Philip Powell[d], Prasad Bollina[e], David E. Neal[f], Freddie C. Hamdy[g] for the ProtecT Study Group

[a]*Department of Social Medicine, University of Bristol, Bristol BS8 2PR, UK*
[b]*Department of Community Based Medicine, University of Bristol, Bristol BS8 2AA, UK*

QRI Origin: the ProtecT study

Education And Debate

Quality improvement report **Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study Commentary: presenting unbiased information to patients can be difficult**

BMJ 2002 ; 325 doi: https://doi.org/10.1136/bmj.325.7367.766 (Published 05 October 2002)
Cite this as: *BMJ* 2002;325:766

Improving design and conduct of randomised trials by embedding them in qualitative research: ProtecT (prostate testing for cancer and treatment) study

Jenny Donovan, professor of social medicine (jenny.donovan@bris.ac.uk) [a], Nicola Mills, research associate [a], Monica Smith, research associate [b], Lucy Brindle, research associate [a], Ann Jacoby, professor of medical sociology [c], Tim Peters, professor of primary care health services research [d], Stephen Frankel, professor of epidemiology and public health [a], David Neal, professor of surgery [e], Freddie Hamdy, professor of urology, for the Protect Study Group [f]

- Recruitment rates improved following feedback – 30% to 60-70% for remainder of trial.

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer

F.C. Hamdy, J.L. Donovan, J.A. Lane, M. Mason, C. Metcalfe, P. Holding, M. Davis, T.J. Peters, E.L. Turner, R.M. Martin, J. Oxley, M. Robinson, J. Staffurth, E. Walsh, P. Bollina, J. Catto, A. Doble, A. Doherty, D. Gillatt, R. Kockelbergh, H. Kynaston, A. Paul, P. Powell, S. Prescott, D.J. Rosario, E. Rowe, and D.E. Neal, for the ProtecT Study Group*

Lessons from application to new wave of RCTs:

- Audio-recordings *are key* – but not easily collected.
  - Need CI support
  - Integration into protocol from outset.
- Need sufficient time to implement 'actions'… and time for actions to take effect.
- Generated new knowledge about recruitment…

Original research

Using qualitative research methods to improve recruitment to randomized controlled trials: the Quartet study

Isabel de Salis, Zelda Tomlin, Merran Toerien[1], Jenny Donovan
Department of Social Medicine, University of Bristol, Bristol; [1]Department of Sociology, University of York, York, UK

Objective: Randomized controlled trials (RCTs) are considered the optimum method for evaluating health care interventions, yet many fail to recruit sufficient participants in a timely manner. The ProtecT (Prostate testing for cancer and Treatment) study employed qualitative research methods as part of a complex intervention to improve recruitment to the RCT. The Quartet (Qualitative research to improve recruitment to trials) study was set up to evalute whether the ProtecT study's success in increasing randomization rates could be replicated in other trials experiencing recruitment difficulties. This paper reports on the issues that emerged from the attempts to apply qualitative research methods to improve recruitment rates in RCTs collaborating with the Quartet team.

Methods: The methods used were: investigation of RCT documents; semi-structured interviews and focus groups with RCT staff; audio-recording of recruitment appointments; and individual and group feedback sessions for RCT staff. Data were analysed using content and thematic analysis.

Results: Barriers arose when we attempted to establish collaborations with RCTs. Difficulties were encountered in securing the commitment of all relevant staff because of poor communication between lead investigators and other staff as well as RCT staff's concerns about having recruitment appointments audio-recorded. Recruitment processes were often more complex than anticipated. Governance procedures took considerable time and resources, limiting the time available for data collection and implementation of the intervention before recruitment closure.

Conclusion: Straightforward replication of the ProtecT complex intervention was more complicated than expected. However, the study has increased understanding of RCT recruitment and identified ways to overcome barriers to collaboration. Such research is more easily undertaken in the feasibility stage of an RCT, and greater success will be achieved if the research is integrated into the everyday conduct of RCTs.

Journal of Health Services Research & Policy Vol 13 Suppl 3, 2008: 92–96

The QuinteT Recruitment Intervention

Understand recruitment issues as the RCT is underway

Actions to optimise recruitment

Journal List › Trials › v.17; 2016 › PMC4898358

Trials

Trials. 2016; 17: 283.
Published online 2016 Jun 8. doi: 10.1186/s13063-016-1391-4

PMCID: PMC4898358
PMID: 27278130

Optimising recruitment and informed consent in randomised controlled trials: the development and implementation of the Quintet Recruitment Intervention (QRI)

Jenny L. Donovan, Leila Rooshenas, Marcus Jepson, Daisy Elliott, Julia Wade, Kerry Avery, Nicola Mills, Caroline Wilson, Sangeetha Paramasivan, and Jane M. Blazeby

Author information ▸ Article notes ▸ Copyright and License information Disclaimer

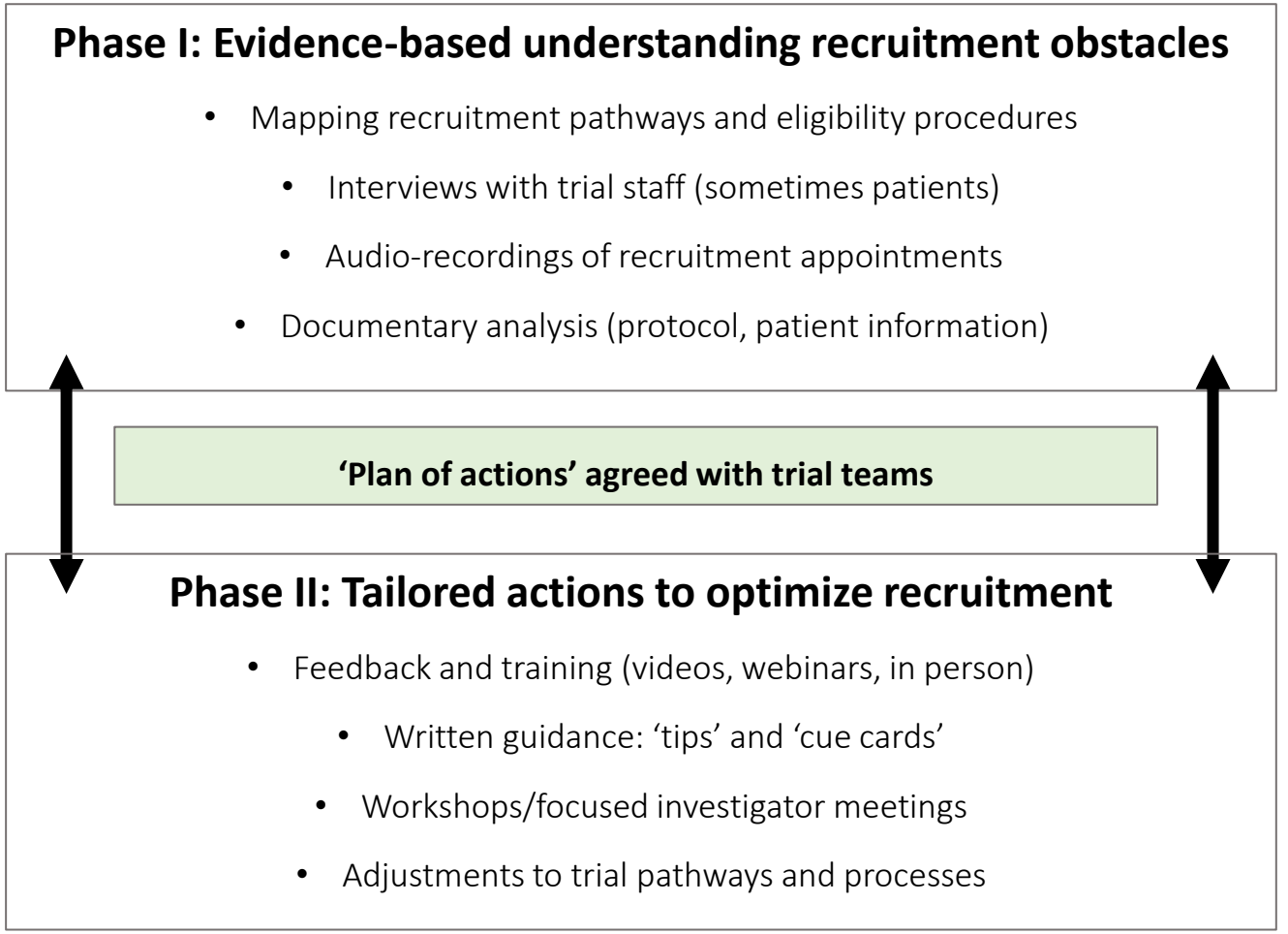
Donovan et al. Trials. 2016; 17: 283.
https://tinyurl.com/**yy5lnqdc**

***Aims to optimise* recruitment:**
All eligible patients have a fair opportunity to make an informed decision about trial participation

The QuinteT Recruitment Intervention

Understand recruitment issues as the RCT is underway

Actions to optimize recruitment



By-Band-Sleeve
BUILDING EVIDENCE TOGETHER

HAND-1 Study
MANY HANDS MAKE BETTER RESEARCH

Violet
STUDY

Prepare
for Kidney Care
Comparing preparation for responsive management with preparation for renal dialysis

CompARE
Trial

VALOR

PART
Partial prostate Ablation versus Radical prosTatectomy

NAIROS

Inspire

POUT

H4RT
The High-volume Haemodiafiltration vs High-flux Haemodialysis Registry Trial

Lots of collaborations!
Jointly building the evidence base for optimizing recruitment

TRombone

The ROMIO Study

TOPIC 2

The Sunflower Study

SPARE

MASTER
Male synthetic sling versus Artificial urinary Sphincter Trial

COMET
A Study for Low Risk DCIS
Expanding Knowledge and Options

ETTAA

optima
personalised treatment of breast cancer

BASIL-2

PulMiCC
International

TRIAL
MARS 2

CSAW
CAN SHOULDER ARTHROSCOPY WORK?

2. Rapidly diagnosing recruitment issues

Core QRI methods for rapidly understanding recruitment

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QRI Phase 1: Understanding recruitment obstacles

- Set of core elements
  - Each element employs particular research strategies
    - Opportunity to examine recruitment from multiple vantage points
      - Flexible, driven by emerging findings
        - Rapid understanding

MAPPING RECRUITMENT PATHWAYS; SCRUTINISING SCREENING LOGS

INTERVIEWS WITH TRIAL STAFF (AND POSSIBLY PATIENTS)

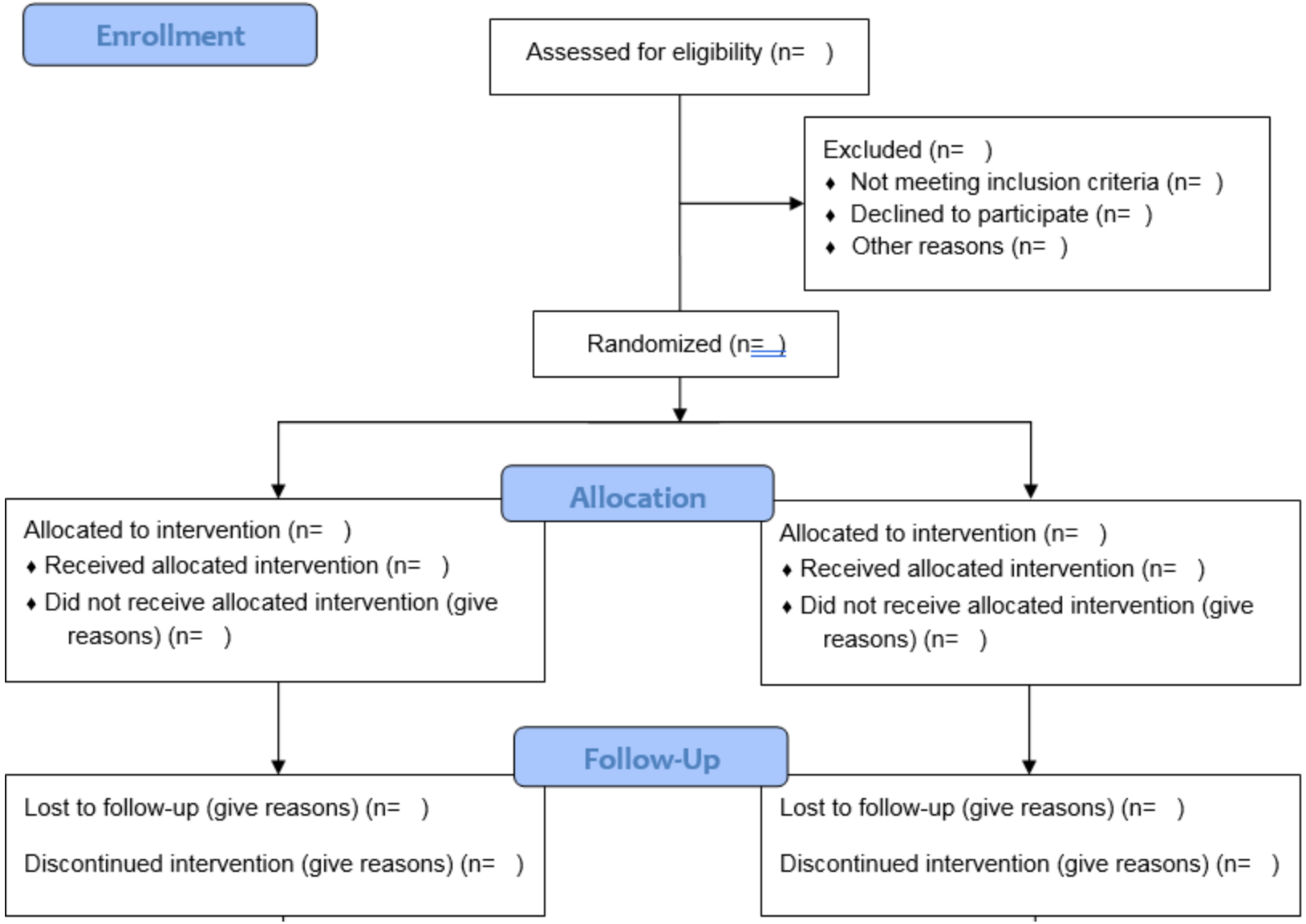
AUDIO-RECORDINGS OF 'RECRUITMENT CONSULTATIONS'

TRIAL DOCUMENT ANALYSIS E.G PROTOCOL, PATIENT INFORMATION MATERIAL

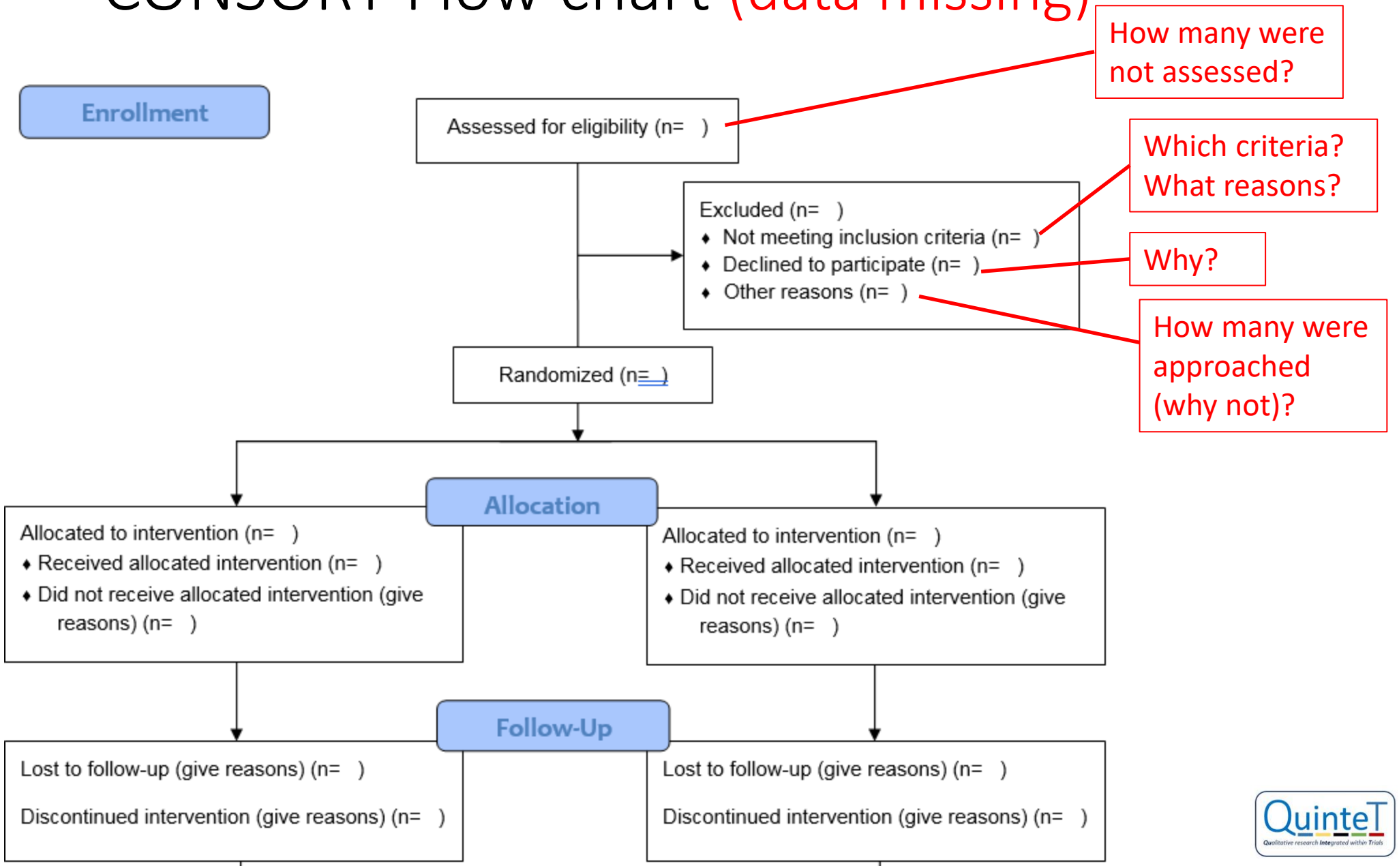
OBSERVATIONS OF INVESTIGATORS' MEETINGS

Recruitment screening logs

CONSORT Flow chart



CONSORT Flow chart (data missing)



Wilson et al. Trials (2018) 19:50
DOI 10.1186/s13063-017-2413-6

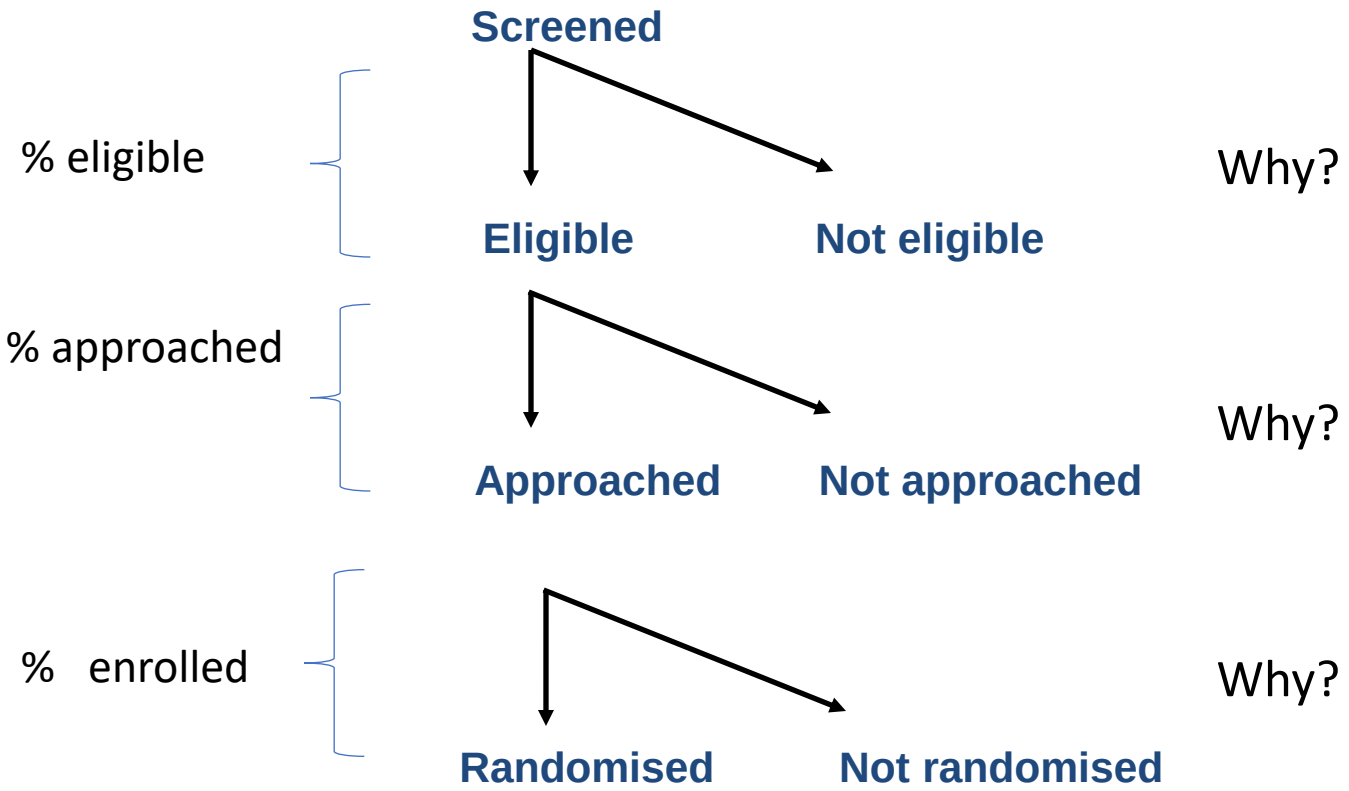
Trials

METHODOLOGY Open Access

Development of a framework to improve the process of recruitment to randomised controlled trials (RCTs): the SEAR (Screened, Eligible, Approached, Randomised) framework

Caroline Wilson[1*], Leila Rooshenas[1†], Sangeetha Paramasivan[1†], Daisy Elliott[1], Marcus Jepson[1], Sean Strong[1], Alison Birtle[2], David J. Beard[3], Alison Halliday[4], Freddie C. Hamdy[4], Rebecca Lewis[5], Chris Metcalfe[1,6], Chris A. Rogers[7], Robert C. Stein[8], Jane M. Blazeby[1] and Jenny L. Donovan[1,9]

The SEAR FRAMEWORK



Potential to assess where biggest leaks are in recruitment pathway

Employ other methods to explore why

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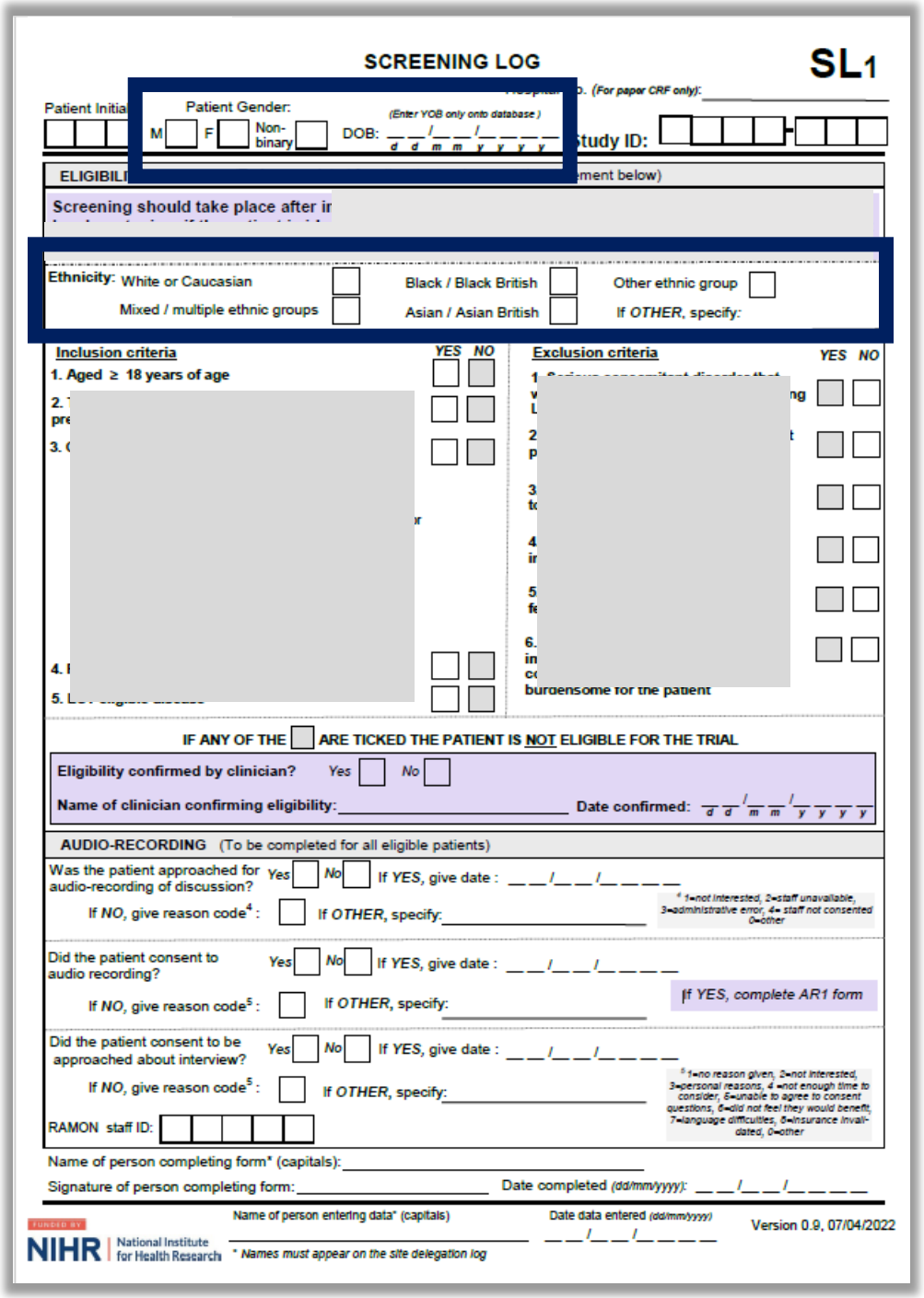
Collect data to monitor how inclusive recruitment is



SCREENING LOG

SL1

Patient Initials:

Patient Gender: M ☐ F ☐ Non-binary ☐

DOB: __ __/__ __/__ __ __ __ (Enter YOB only onto database) (d d m m y y y y)

Study ID:

ELIGIBILITY (see statement below)

Screening should take place after ir

Ethnicity: White or Caucasian ☐ Black / Black British ☐ Other ethnic group ☐

Mixed / multiple ethnic groups ☐ Asian / Asian British ☐ If OTHER, specify:

Inclusion criteria	YES	NO
1. Aged ≥ 18 years of age	☐	☐
2.	☐	☐
3.	☐	☐
4.	☐	☐
5.	☐	☐

Exclusion criteria	YES	NO
1.	☐	☐
2.	☐	☐
3. to	☐	☐
4.	☐	☐
5.	☐	☐
6. burdensome for the patient	☐	☐

IF ANY OF THE ☐ ARE TICKED THE PATIENT IS NOT ELIGIBLE FOR THE TRIAL

Eligibility confirmed by clinician? Yes ☐ No ☐

Name of clinician confirming eligibility: _____ Date confirmed: __ __/__ __/__ __ __ __ (d d m m y y y y)

AUDIO-RECORDING (To be completed for all eligible patients)

Was the patient approached for audio-recording of discussion? Yes ☐ No ☐ If YES, give date: __ __/__ __/__ __ __ __

If NO, give reason code[4]: ☐ If OTHER, specify: _____

[4] 1=not interested, 2=staff unavailable, 3=administrative error, 4= staff not consented 0=other

Did the patient consent to audio recording? Yes ☐ No ☐ If YES, give date: __ __/__ __/__ __ __ __

If NO, give reason code[5]: ☐ If OTHER, specify: _____ If YES, complete AR1 form

Did the patient consent to be approached about interview? Yes ☐ No ☐ If YES, give date: __ __/__ __/__ __ __ __

If NO, give reason code[5]: ☐ If OTHER, specify: _____

[5] 1=no reason given, 2=not interested, 3=personal reasons, 4 =not enough time to consider, 5=unable to agree to consent questions, 6=did not feel they would benefit, 7=language difficulties, 8=insurance invalidated, 0=other

RAMON staff ID: ☐☐☐☐☐

Name of person completing form* (capitals): _____

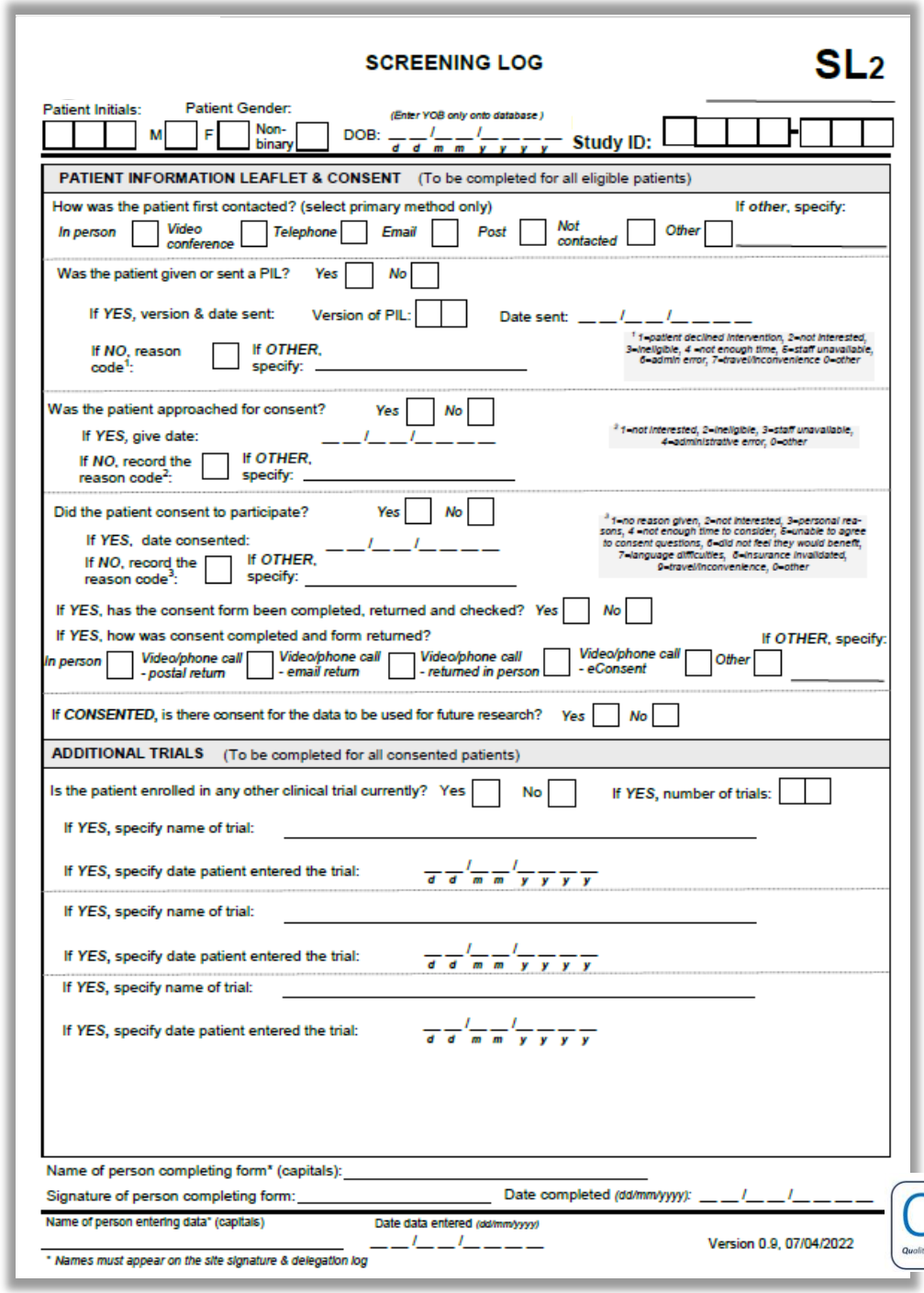
Signature of person completing form: _____ Date completed (dd/mm/yyyy): __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered (dd/mm/yyyy) __ __/__ __/__ __ __ __

Version 0.9, 07/04/2022

FUNDED BY NIHR | National Institute for Health Research

* Names must appear on the site delegation log



SCREENING LOG

SL2

Patient Initials:

Patient Gender: M ☐ F ☐ Non-binary ☐

DOB: __ __/__ __/__ __ __ __ (Enter YOB only onto database) (d d m m y y y y)

Study ID:

PATIENT INFORMATION LEAFLET & CONSENT (To be completed for all eligible patients)

How was the patient first contacted? (select primary method only) If other, specify:

In person ☐ Video conference ☐ Telephone ☐ Email ☐ Post ☐ Not contacted ☐ Other ☐ _____

Was the patient given or sent a PIL? Yes ☐ No ☐

If YES, version & date sent: Version of PIL: ☐☐ Date sent: __ __/__ __/__ __ __ __

If NO, reason code[1]: ☐ If OTHER, specify: _____

[1] 1=patient declined intervention, 2=not interested, 3=ineligible, 4 =not enough time, 5=staff unavailable, 6=admin error, 7=travel/inconvenience 0=other

Was the patient approached for consent? Yes ☐ No ☐

If YES, give date: __ __/__ __/__ __ __ __

If NO, record the reason code[2]: ☐ If OTHER, specify: _____

[2] 1=not interested, 2=ineligible, 3=staff unavailable, 4=administrative error, 0=other

Did the patient consent to participate? Yes ☐ No ☐

If YES, date consented: __ __/__ __/__ __ __ __

If NO, record the reason code[3]: ☐ If OTHER, specify: _____

[3] 1=no reason given, 2=not interested, 3=personal reasons, 4 =not enough time to consider, 5=unable to agree to consent questions, 6=did not feel they would benefit, 7=language difficulties, 8=insurance invalidated, 9=travel/inconvenience, 0=other

If YES, has the consent form been completed, returned and checked? Yes ☐ No ☐

If YES, how was consent completed and form returned? If OTHER, specify:

In person ☐ Video/phone call - postal return ☐ Video/phone call - email return ☐ Video/phone call - returned in person ☐ Video/phone call - eConsent ☐ Other ☐ _____

If CONSENTED, is there consent for the data to be used for future research? Yes ☐ No ☐

ADDITIONAL TRIALS (To be completed for all consented patients)

Is the patient enrolled in any other clinical trial currently? Yes ☐ No ☐ If YES, number of trials: ☐☐

If YES, specify name of trial: _____

If YES, specify date patient entered the trial: __ __/__ __/__ __ __ __ (d d m m y y y y)

If YES, specify name of trial: _____

If YES, specify date patient entered the trial: __ __/__ __/__ __ __ __ (d d m m y y y y)

If YES, specify name of trial: _____

If YES, specify date patient entered the trial: __ __/__ __/__ __ __ __ (d d m m y y y y)

Name of person completing form* (capitals): _____

Signature of person completing form: _____ Date completed (dd/mm/yyyy): __ __/__ __/__ __ __ __

Name of person entering data* (capitals) _____ Date data entered (dd/mm/yyyy) __ __/__ __/__ __ __ __

Version 0.9, 07/04/2022

* Names must appear on the site signature & delegation log

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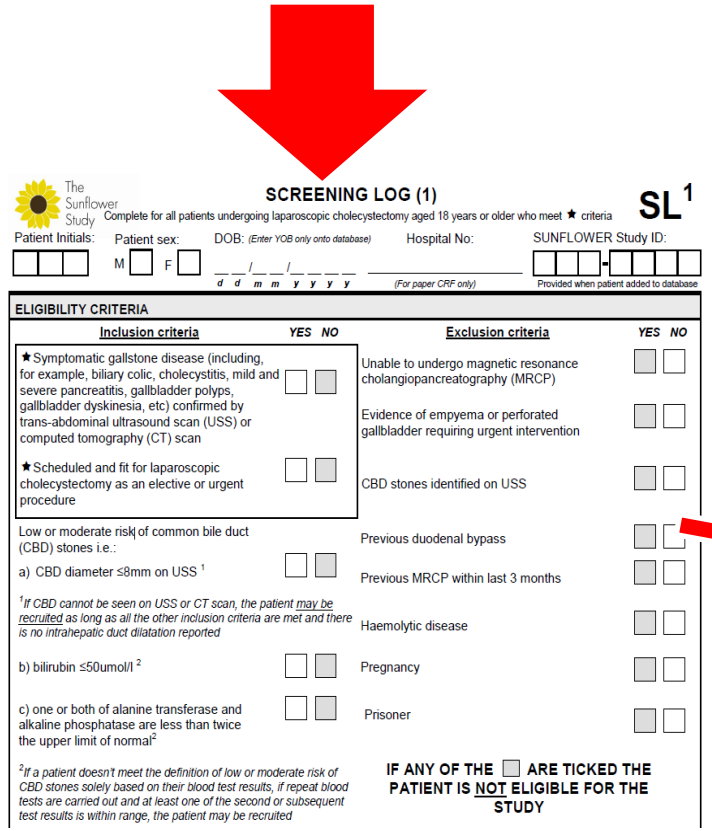
Monitor recruitment progress

Monitoring screening / recruitment data



The Sunflower Study

SCREENING LOG (1) SL[1]

Complete for all patients undergoing laparoscopic cholecystectomy aged 18 years or older who meet ★ criteria

Patient Initials: | Patient sex: M ☐ F ☐ | DOB: (Enter YOB only onto database) d d m m y y y y | Hospital No: (For paper CRF only) | SUNFLOWER Study ID: Provided when patient added to database

ELIGIBILITY CRITERIA

Inclusion criteria	YES	NO
★Symptomatic gallstone disease (including, for example, biliary colic, cholecystitis, mild and severe pancreatitis, gallbladder polyps, gallbladder dyskinesia, etc) confirmed by trans-abdominal ultrasound scan (USS) or computed tomography (CT) scan	☐	☐
★Scheduled and fit for laparoscopic cholecystectomy as an elective or urgent procedure	☐	☐
Low or moderate risk of common bile duct (CBD) stones i.e.:		
a) CBD diameter ≤8mm on USS [1]	☐	☐
b) bilirubin ≤50umol/l [2]	☐	☐
c) one or both of alanine transferase and alkaline phosphatase are less than twice the upper limit of normal[2]	☐	☐

[1] *If CBD cannot be seen on USS or CT scan, the patient may be recruited as long as all the other inclusion criteria are met and there is no intrahepatic duct dilatation reported*

[2] *If a patient doesn't meet the definition of low or moderate risk of CBD stones solely based on their blood test results, if repeat blood tests are carried out and at least one of the second or subsequent test results is within range, the patient may be recruited*

Exclusion criteria	YES	NO
Unable to undergo magnetic resonance cholangiopancreatography (MRCP)	☐	☐
Evidence of empyema or perforated gallbladder requiring urgent intervention	☐	☐
CBD stones identified on USS	☐	☐
Previous duodenal bypass	☐	☐
Previous MRCP within last 3 months	☐	☐
Haemolytic disease	☐	☐
Pregnancy	☐	☐
Prisoner	☐	☐

IF ANY OF THE ☐ ARE TICKED THE PATIENT IS NOT ELIGIBLE FOR THE STUDY

Centre	Open	Screened		Confirmed eligible (of all screened)		Randomised (of confirmed eligible)	
	(months)	N	Per open month	N	%	N	%
Your centre	11	44	4.0	22	50%	10	41%

Regular centre-by-centre recruitment reports and recruitment 'league tables' *(NB Missing 'approached' data in this eg)*

Centre	Patients consented (N)	Eligible patients who consented	Average consents/ mth
Southern Trust	22	66%	8.9
Local rival	31	47%	7.6
Your centre	10	41%	4.0
Small DGH	7	44%	0.3
Etc…			

QuinteT Qualitative research Integrated within Trials

Interviews with trial staff (and possibly patients)

Interviews with trial staff

WHO?

Research and clinical staff responsible for overseeing or undertaking elements of the trial and/or recruitment process

AIM?

(a) Explore views about trial's importance, relevance and its interventions from practitioner's/ researcher's view;

(b) Understand how recruitment operates 'in practice' in each clinical centre, and how recruitment processes are overseen and co-ordinated

WHY?

a) Perception of equipoise & views about RCT rationale can impact who to approach and how study/treatments are explained;

(b) Can reveal unanticipated organisation/ logistical issues at site level

HOW?

Semi-structured using flexible topic guide covering clinical context/trial specific issues and generic trial areas

When? Early (or pre) recruitment (pragmatic) and possibly later to explore specific findings

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Qualitative research Integrated within Trials

Interviews with patients

Enables understanding of study and recruitment process from different perspective

NB Views on the study, treatments and participation are likely to have been influenced by what they've been told

Useful supplement if difficult to get data from other sources such as consultation recordings

Useful to do paired analysis with consultation recordings to understand how info is communicated by recruiters and understood by patients

A qualitative exploration of recruiters' and patients' perspectives and experiences of the recruitment encounter in randomised controlled trials

Nicola L Farrar

Bristol Medical School (PHS), Bristol Medical School, Bristol Doctoral College

Student thesis: Doctoral Thesis › Doctor of Philosophy (PhD)

QuinteT
Qualitative research Integrated within Trials

Interviews provide broad overview of perspectives on the trial and how recruitment is operationalised from recruiter's perspective BUT.....

The extent to which these views affect their behaviour or influence recruitment during appointments cannot be understood from these accounts alone SO.....

There is a need to gather data from other sources.....

Audio-recording recruitment consultations

Value of recording consultations

Enables direct observation of how the trial is actually presented by recruiters and received by patients

Provides insights into more subtle and often unanticipated practices that can facilitate or undermine recruitment

Opportunity to identify issues that are interpreted differently by patients than intended by recruiters, i.e likely remain “hidden” were it not for these data

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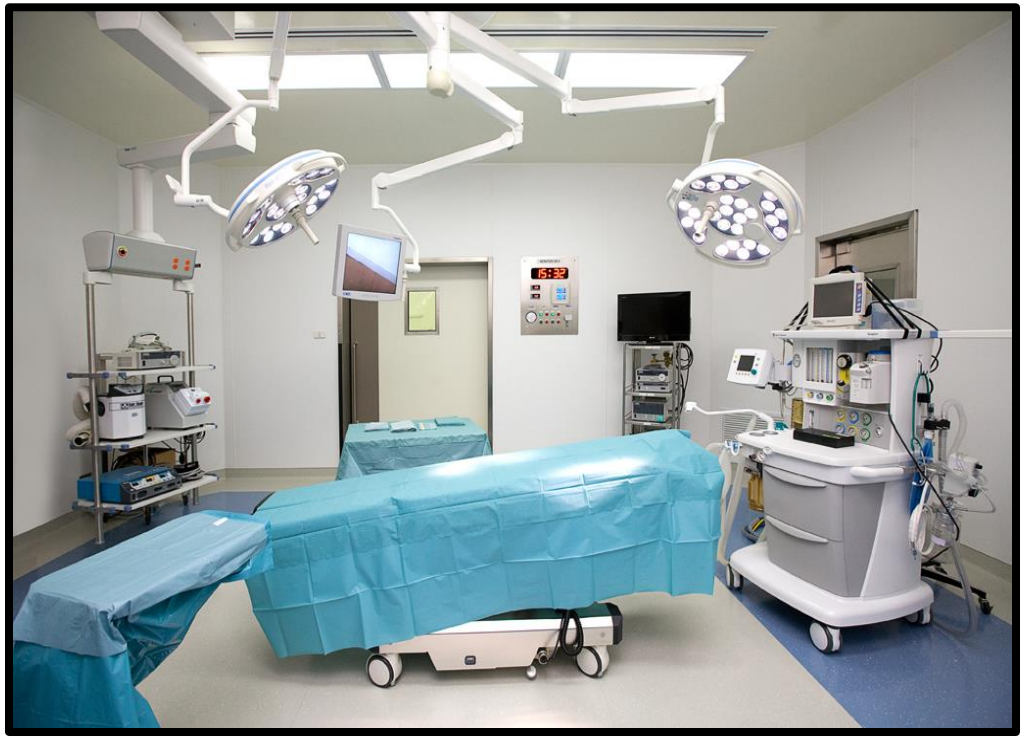
Qualitative research Integrated within Trials

Conveying uncertainty and equipoise



Chemotherapy + Surgery

Chemotherapy + Radiotherapy

Upcoming speakers:

R= Recruiter (surgeon); **Pt**= Patient; **Pt R**= Patient's relative

R: Essentially, what we all agreed was that there are two types of treatment that we could give you. The first is what we've always described as the standard treatment, which would be chemotherapy first to shrink this down and then an operation to remove it and give us the chance of cure.

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R: The other type of treatment that we have used over the years is treatment which doesn't involve an operation, which is, chemotherapy first to shrink this down, followed by radiotherapy to the area that is involved. We don't know which is best.

R: Essentially, what we all agreed was that there are two types of treatment that we could give you. The first is what we've always described as the standard treatment, which would be chemotherapy first to shrink this down and then an operation to remove it and give us the chance of cure.

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R: The other type of treatment that we have used over the years is treatment which doesn't involve an operation, which is, chemotherapy first to shrink this down, followed by radiotherapy to the area that is involved. We don't know which is best.

Pt R: The thing that's worrying me is, if she has the chemo and the radiotherapy…if that doesn't take it away, she might not be able to have the operation… but if she has the operation, then it's gone.

R: Essentially, what we all agreed was that there are two types of treatment that we could give you. The first is what we've always described as the standard treatment, which would be chemotherapy first to shrink this down and then an operation **to remove it** and give us the **chance of cure**.

R: The other type of treatment that we have used over the years is treatment which doesn't involve an operation, which is, chemotherapy first to shrink this down, followed by radiotherapy to the area that is involved. We don't know which is best.

PR: The thing that's worrying me is, if she has the chemo and the radiotherapy…if that doesn't take it away, she might not be able to have the operation… but if she has the operation, and then it's gone.

Loaded terminology: What we put out there about treatments can undermine equipoise

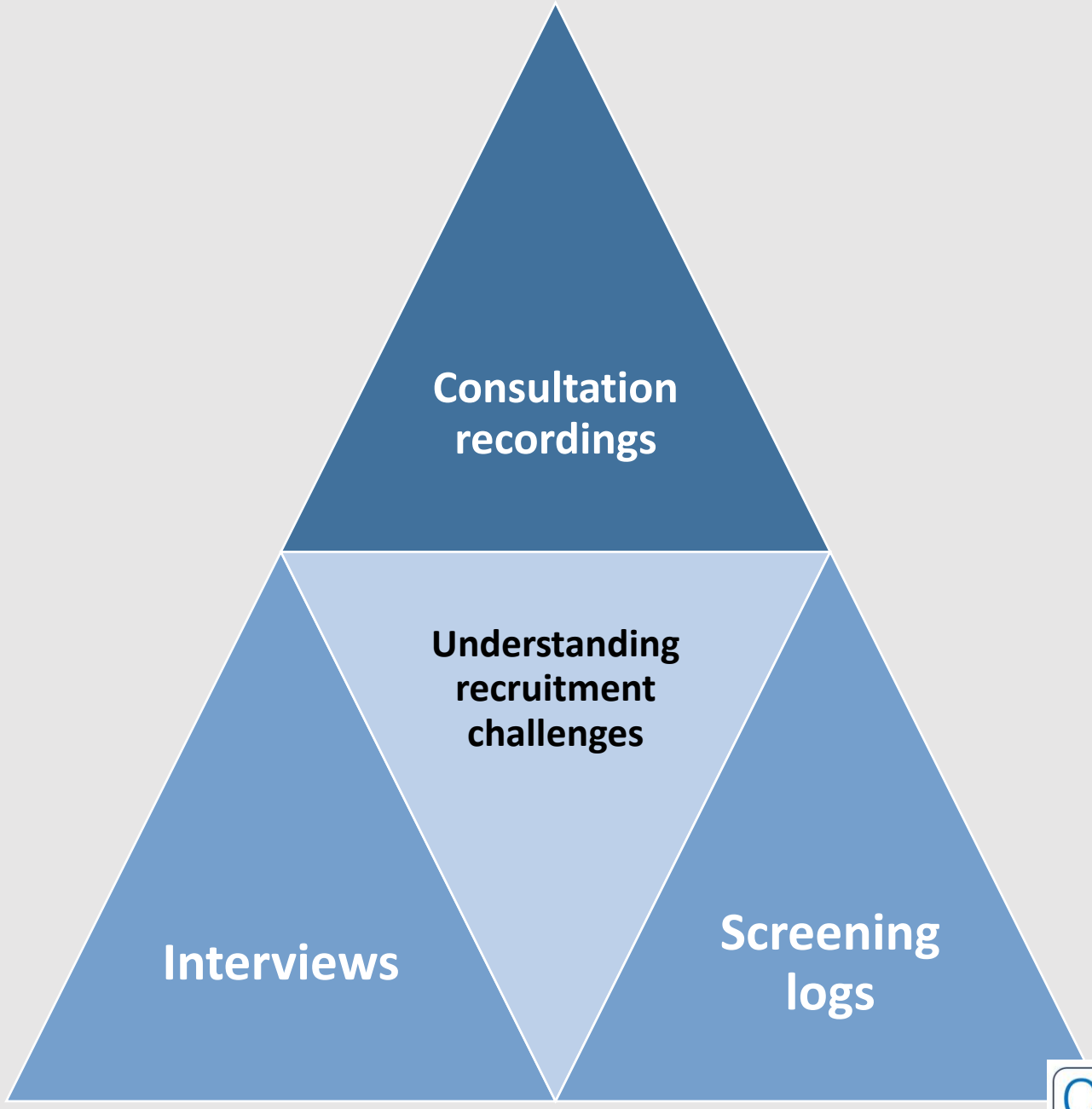
QuinteT
Qualitative research Integrated within Trials

Data collection and analysis occur in tandem

Findings are triangulated:

- Confirm or contradict findings
- Identify areas for further exploration
- Enable comprehensive understanding of the obstacles

Triangulation provides confidence in findings and proposed actions required to optimise recruitment in Phase 2

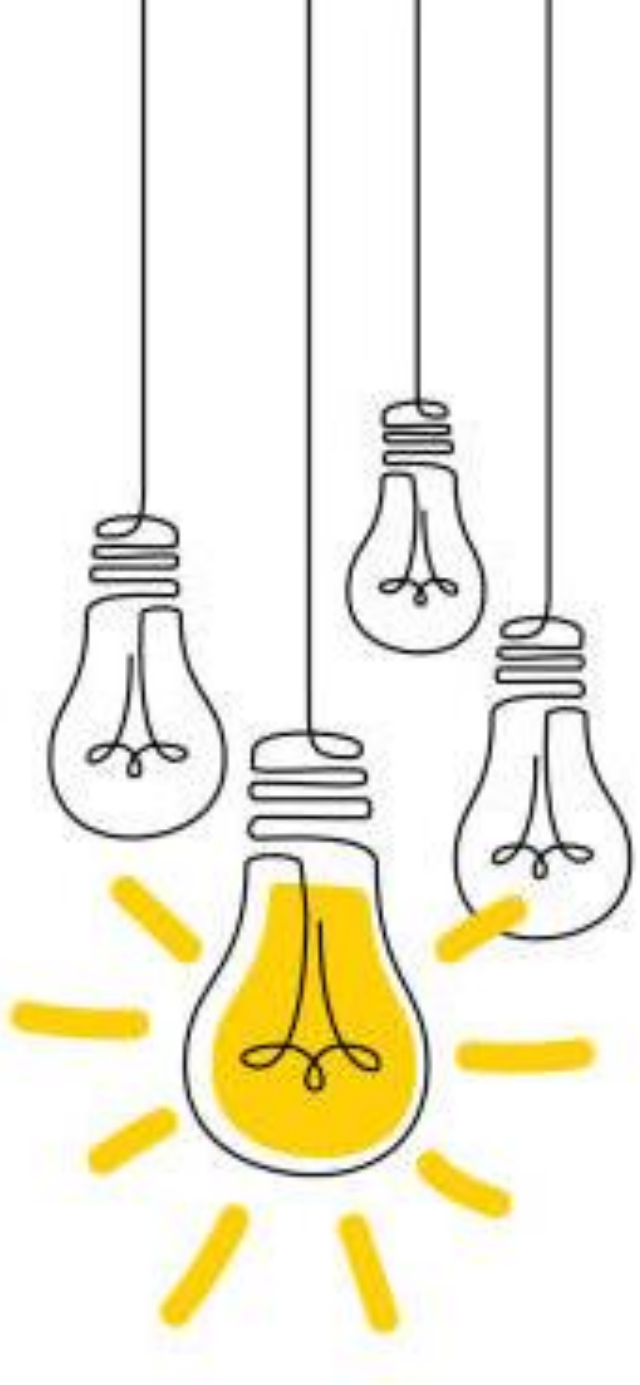


Our understanding of recruitment, and ways to optimise it, **are still developing**…

An active area of research

Interested in collaborating? Get in touch…

Julia.Wade@bristol.ac.uk
Carmel.Conefrey@bristol.ac.uk
Ava.Lorenc@bristol.ac.uk
QuinteT team
@QuinteTBristol



Pat: Right. Well my first response to that is, if this study wasn't here and the cost to the NHS was irrelevant, which would you as my doctor advise me to have?

Surg: I would give you the choice as it is now but the needle probably will work much… in your case you've got nice cords so you could do any of the two and it's involving mainly this joint, so the prognosis or improvement following this for any of the two procedures is very good. When it comes to this, the needle… the PIP joint is involved and if you've got nodules then the needle doesn't work very well-

Pat: Probably deliberate here but you haven't… you've ducked my question in fact. I think it's a fair question as your patient. I know this is… surgery's a lot more expensive to the NHS and the NHS is rightly therefore assessing how effective needles are, I'm just saying as my-

Surg: Needles have been done for years-

Pat: And I'm told… my reading of all this, the gold-plated procedure is the surgery and I think-

Surg: Yes.

Pat: and I assume that's because its more likely to be effective for a longer period.

Surg: So surgery, when you say surgery it involves both.

Pat: Well I mean the cutting, whatever, option two.

Surg: Personally, if you ask me, I would go with needle.

Pat: [Further discussion] I will follow your advice then. If your advice is that I should have the needle, that's fine, yes, you know more about this than I do.

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Creates a preference

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