Sean Kearns

Research Nurse

Recruitment and Retention in Clinical Trials

Outline

- Recruitment in Clinical Trials
- Literature
- Clinical Trials Transformation Initiative
- Recruitment Planning
- Initiatives to increase Recruitment
- Retention in Clinical Trials
- Literature
- Group Work

Recruitment

2015 Analysis of registered trials showed **19%** were closed or ended early because of not enough participants

86% of clinical trials do not reach recruitment targets in their time periods.

This has implications scientifically, financially, policy-wise and even ethically

Some of the literature …

BMC Medical Research Methodology

BioMed Central

Open Access

Research article

Increasing recruitment to randomised trials: a review of randomised controlled trials

Judith M Watson* and David J Torgerson

Address: York Trials Unit, Department of Health Sciences, University of York, York, YO10 5DD, UK

Email: Judith M Watson* - jmw19@york.ac.uk; David J Torgerson - djt6@york.ac.uk

* Corresponding author

Published: 19 July 2006

BMC Medical Research Methodology 2006, **6**:34 doi:10.1186/1471-2288-6-34

This article is available from: http://www.biomedcentral.com/1471-2288/6/34

Received: 31 March 2006

Accepted: 19 July 2006

Open Access Research

BMJ Open

Detailed systematic analysis of recruitment strategies in randomised controlled trials in patients with an unscheduled admission to hospital

Ceri Rowlands,[1] Leila Rooshenas,[1,2] Katherine Fairhurst,[1,2] Jonathan Rees,[2,3] Carrol Gamble,[4] Jane M Blazeby[1,2,3]

Open Access Resear

BMJ Open

Recruitment and retention of participants in randomised controlled trials: a review of trials funded and published by the United Kingdom Health Technology Assessment Programme

Stephen J Walters, Inês Bonacho dos Anjos Henriques-Cadby, Oscar Bortolami, Laura Flight, Daniel Hind, Richard M Jacques, Christopher Knox, Ben Nadin, Joanne Rothwell, Michael Surtees, Steven A Julious

Cochrane Library

Cochrane Database of Systematic Reviews

Strategies designed to help healthcare professionals to recruit participants to research studies (Review)

Preston NJ, Farquhar MC, Walshe CE, Stevinson C, Ewing G, Calman LA, Burden S, Brown Wilson C, Hopkinson JB, Todd C

Published in final edited form as:
Contemp Clin Trials. 2008 March ; 29(2): 241–251.

Effectiveness of Recruitment in Clinical Trials: An Analysis of Methods Used in a Trial for Irritable Bowel Syndrome Patients

Siu Ping Chin Feman[1], **Long T Nguyen**[1], **Mary T. Quilty**[1], **Catherine E. Kerr**[1], **Bong Hyu Nam**[2], **Lisa A Conboy**[1,3], **Joyce P. Singer**[1], **Min Park**[1], **Anthony Lembo**[4], **Ted J. Kaptchuk**[1,3], and **Roger B. Davis**[1,3]

Contemporary Clinical Trials 66 (2018) 74–79

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Clinical trials recruitment planning: A proposed framework from the Clinical Trials Transformation Initiative

Grant D. Huang[a,*], Jonca Bull[b], Kelly Johnston McKee[c], Elizabeth Mahon[d], Beth Harper[e], Jamie N. Roberts[f], for the CTTI Recruitment Project Team

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[c] *Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285, USA*
[d] *Janssen Research & Development, 700 US Highway 202, Raritan, NJ 08869, USA*
[e] *Association of Clinical Research Professionals, 99 Canal Center Plaza, Alexandria, VA 22314, USA*
[f] *Duke University, 300 W. Morgan St., Durham, NC 27701, USA*

Trials

BioMed Central

Research

Open Access

What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies

Alison M McDonald*[1], Rosemary C Knight[2], Marion K Campbell[1], Vikki A Entwistle[1], Adrian M Grant[1], Jonathan A Cook[1], Diana R Elbourne[2], David Francis[3], Jo Garcia[2], Ian Roberts[2] and Claire Snowdon[2]

Address: [1]Health Services Research Unit, University of Aberdeen, Polwarth Building, Foresterhill, Aberdeen, UK, [2]Medical Statistics Unit, London School of Hygiene and Tropical Medicine, Keppel Street, London, UK and [3]Centre for Research and Innovation Management, Brighton

Email: Alison M McDonald* - a.mcdonald@abdn.ac.uk; Rosemary C Knight - Rosemary.Knight@lshtm.ac.uk; Marion K Campbell - m.k.campbell@abdn.ac.uk; Vikki A Entwistle - V.A.Entwistle@dundee.ac.uk; Adrian M Grant - a.grant@abdn.ac.uk; Jonathan A Cook - j.a.cook@abdn.ac.uk; Diana R Elbourne - diana.elbourne@lshtm.ac.uk; David Francis - d.l.francis@brighton.ac.uk; Jo Garcia - j.garcia@ioe.ac.uk; Ian Roberts - Ian.Roberts@lshtm.ac.uk; Claire Snowdon - cms1000@cam.ac.uk

* Corresponding author

Richards *et al. Trials* 2014, **15**:398
http://www.trialsjournal.com/content/15/1/398

TRIALS

METHODOLOGY

Open Access

The DiReCT study - improving recruitment into clinical trials: a mixed methods study investigating the ethical acceptability, feasibility and recruitment yield of the cohort multiple randomised controlled trials design

David A Richards[1*], Sarah Ross[1], Sarah Robens[2] and Gunilla Borglin[3]

What do we know?

Review of results from following paper …

Contemporary Clinical Trials 66 (2018) 74–79

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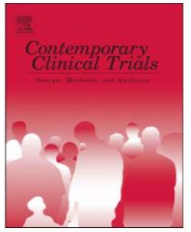

Clinical trials recruitment planning: A proposed framework from the Clinical Trials Transformation Initiative

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[e] Association of Clinical Research Professionals, 99 Canal Center Plaza, Alexandria, VA 22314, USA
[f] Duke University, 300 W. Morgan St., Durham, NC 27701, USA

Methodology

LITERATURE REVIEW

SURVEY

PLANNING
FRAMEWORK DESIGN

EXPERT MEETING

RECOMMENDATIONS

Phase 1: Literature Review

- 46 Articles were included exploring the barriers and solutions to overcome recruitment challenges
- Limited Data
- Findings showed

➢Open Label trials over Blinded

➢Clear opt out procedures and language

➢Telephone Reminders

➢Financial Incentives

Lit review Barriers to Trial Recruitment

- Trial Design
- Study Staff Resources
- Recruitment Strategies Employed
- Targets and Timelines
- Patient – Staff Communication
- Compensation/ Incentives
- Human Factor
- Processes, Policies and Resources

Phase 2: Survey Results regarding BARRIERS

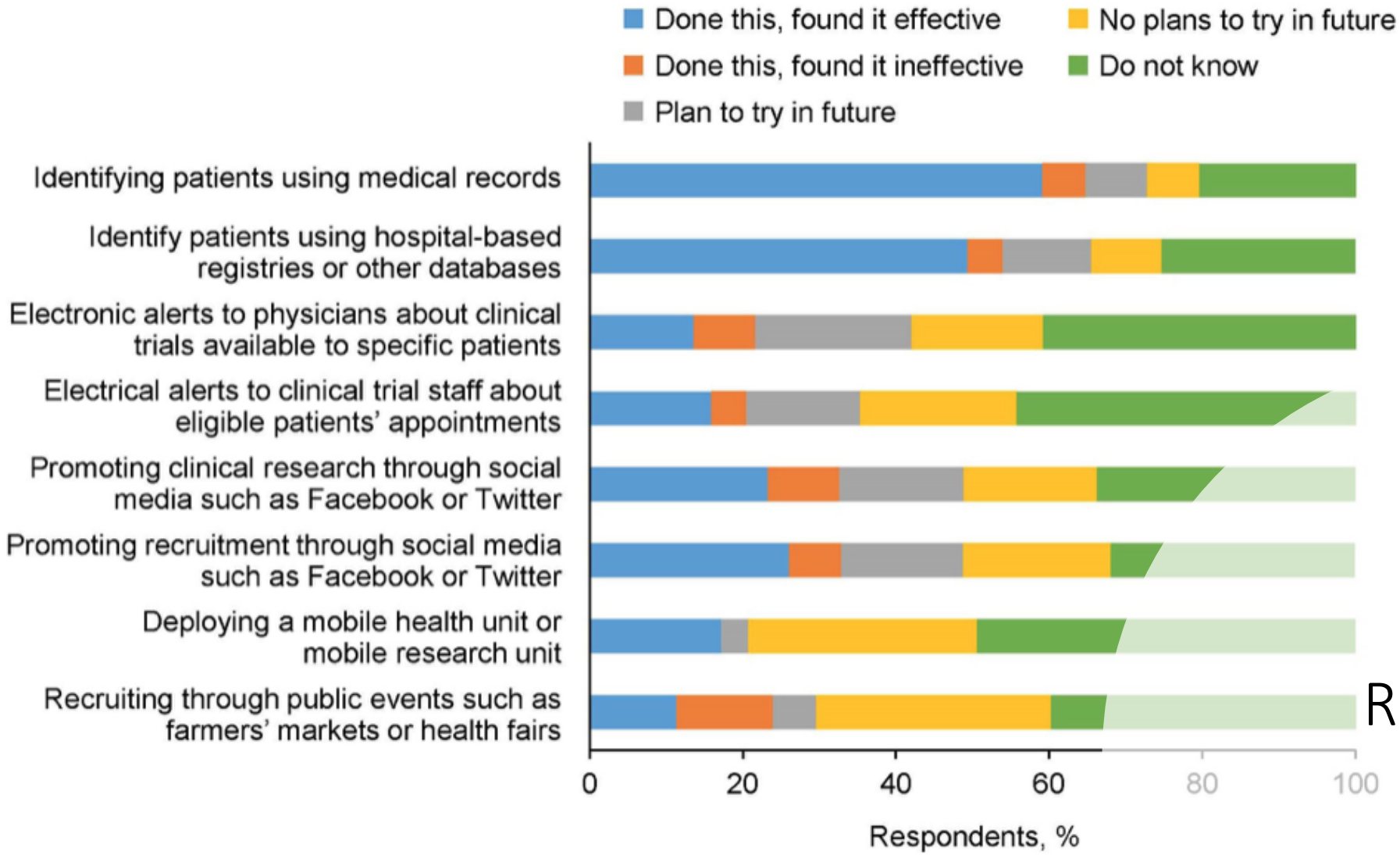
- Finding participants who meet eligibility criteria (81%)
- Insufficient Staff time (67%)
- Length or complexity of consent forms (66%)
- Protocol Requirements other that Inc/Exc (60%)
- Transport and out of pocket expenses for participants (56% and 67%)

1.[20] E. Mahon, J. Roberts, P. Furlong, G. Uhlenbrauck, J. Bull, Barriers to trial recruit- ment and possible solutions, Appl. Clin. Trials 25 (2016).

How do we combat these Barriers?

- Education of Patients, Physicians and Research Staff
- Implementation of Technology for screening – erecords
- Community involvement and input in design, planning and dissemination – PPI
- Increase in Flexibility of Visits and consenting process
- Less Narrow Inc/Exc
- Decrease excess data needs

1.[20] E. Mahon, J. Roberts, P. Furlong, G. Uhlenbrauck, J. Bull, Barriers to trial recruit- ment and possible solutions, Appl. Clin. Trials 25 (2016).



Recruitment Methods

Figure 2. Respondents' organizations' experience with the named recruitment methods. N ranged from 86-88 for each method rated.

Phase 3: Planning a Framework

- The research team at the CTTI formed a framework for strategic recruitment planning
- Addressing that Prevention is superior than reactionary work
- Earlier Planning is paramount
- Three themes

1. **Trial Design and Protocol development**
2. **Trial Feasibility and Site Selection**
3. **Recruitment Communication and Planning**

Phase 4: Expert Panels

60 Stakeholders

Review and Provide Recommendations

Included:

Professional Service Organsiations

- Clinical Research Organisations
- Drug and Device Sponsors
- Patient Advocacy Groups
- Academics
- Research Staff
- Investigators

Fig. 1. CTTI Framework for Strategic Recruitment Planning.

1.) Trial Design and Protocol Development

Table 1
Recommendations for efficient and effective clinical trial recruitment planning.

Recommendation	Practical steps
Trial Design and Protocol Development	
Identify and engage all stakeholders as equal partners in the process	• Include as diverse a group of interested parties including patients, caregivers, patient groups, investigators, sponsors, funders, site staff, key opinion leaders, and providers. • Incorporate their input and include appropriate partner representation on committees (e.g., advisory, steering, protocol writing).
Ensure the relevance of the scientific question to stakeholders	• Determine the relevance of the scientific question and impact at trial conclusion (e.g., filling unmet need, relevance of outcomes to patients, generalizability).
Limit protocol complexity to reduce the burden of participation	• Reduce procedures to those directly related to the scientific question. • Consider invasiveness and risks. • Limit activities that create additional work for sites and patients.
Develop realistic eligibility criteria	• Identify and eliminate items that are not necessary for ensuring safety of participants. • Eliminate items that are not directly relevant to answering the primary research question.
Optimize data collection to only what's necessary to maintain patient safety and answer the scientific question	• Collect only the data necessary to maintain participant safety and/or address the primary and secondary objectives.

2.) Trial Feasibility and Selection

Trial Feasibility and Site Selection	
Conduct an evidence-based trial feasibility analysis	• Do an environmental scan or SWOT (strengths, weaknesses, opportunities, threats) analysis. Targets may include competition, policy, seasonal fluctuations, awareness, disease stage and rarity, satisfaction with current therapies, and economic concerns. • Incorporate site activation, screening, and enrollment factors. • Map out anticipated events to identify potential pitfalls and bottlenecks in setting expectations. • Use historic and benchmarked data to estimate realistic timelines.
Establish realistic metrics and milestones	
Develop an adequate budget and resources	• Develop an initial recruitment budget that accounts for appropriate factors and appropriate patient outreach. • Emphasize site activation timelines and realistic enrollment periods in resource determination.
Ensure appropriate site selection	• Develop an ideal site profile that includes investigator experience, site capabilities, site infrastructure, institutional resources, and target population access.
Engage in suitable site performance monitoring	• Develop a plan to regularly meet with sites. • Schedule timely teleconferences/meetings to discuss recruitment successes and challenges. • Create a short survey for persons offered enrollment but who decline to participate. • Ask sites what they need to support efficient and effective recruitment.

3.) Recruitment Communication Planning

Recruitment Communication Planning	
Identify all stakeholders and partners	• Identify and include stakeholders who are critical to study communication.
Identify participant locations based on where participants may seek treatment and relevant information	• Identify potential participant pathways into the study so that barriers and bottlenecks may be addressed while the protocol is in development.
Develop and test tailored messages	• Develop messages on key points related to the study (e.g., reason for study, importance, value) for study participants, research staff and providers.
Develop creative material and select appropriate channels for delivery	• Develop creative material and identify channels for reaching audiences. • Conduct formative research such as focus groups, social listening exercises, and semi-structured interviews.
Develop a realistic communication budget	• Plan the budget early to ensure that recruitment costs are anticipated and covered. • Ensure a well-researched communication strategy is deployed in order to achieve efficient and effective communication and outreach efforts.
Monitor and evaluate both the recruitment process and performance with meaningful metrics	• Develop a method for successful recruitment performance monitoring and evaluation: 1. Securing stakeholder buy-in. 2. Define measurable recruitment goals. 3. Identify meaningful metrics for each goal. 4. Define success for each metric. 5. Identify the required data for each metric. 6. Collect process and performance data. 7. Analyze the data. • Consider embedding recruitment intervention studies into clinical trials and share the results (good and bad)

Recruitment Plan

- Who are my patient population?
- Who is going to be involved in recruitment?
- Where will I be recruiting?
- Who can I train that can help?
- Is recruitment competitive?
- Is anyone else working on this trial nationally?

Recruitment Methods

- Database trawl.
- Chart review.
- Specialist nurses.
- New Referrals.
- GP referral.
- Patient organisation.
- Charities.
- Self Referral.
- Specialist units.
- Social Media

Pre Screening – Database or Chart

- Disease status
- Compare patient data with Inc/ Exc
- Medical/Surgical History
- Trial History / Trial Status
- Medications
- Mental Health History
- Drug/Substance Abuse
- Compliance
- Logistics
- Social Situations

LOOKS GOOD :

GET IN TOUCH

Initial Contact

- Discuss patient with P.I and or CNS
- Provide General Trial Information
- Answer any follow up Q's
- Be Explicit that it is optional
- Provide PIL
- Allow time to discuss
- If possible do this in person

Pre – Screening log

- Keep track of all the patients that you pre-screen
- Accountability to sponsor
- Shows trends
- May guide protocol amendments
- May identify gaps

Screening and Enrollment Log

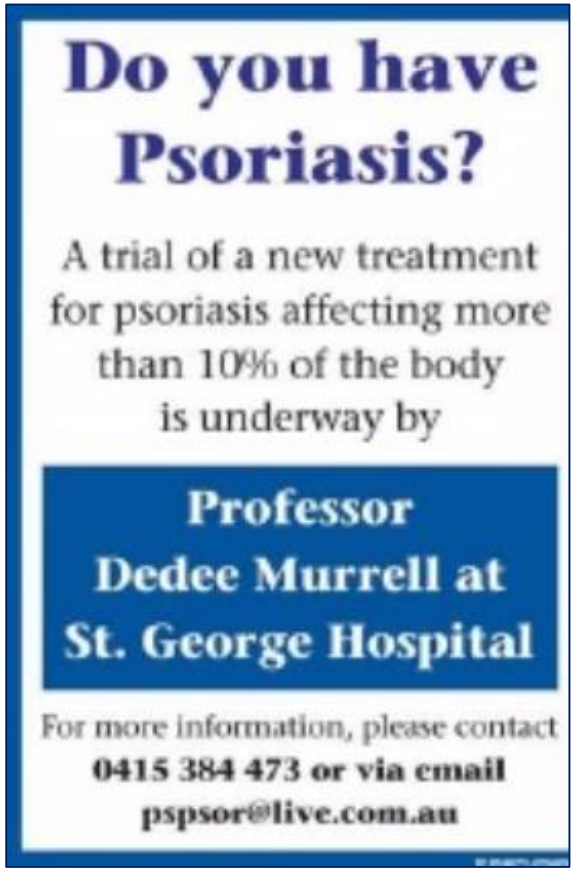
Patient Name	Telephone Pre-Screen Date	Potentially Eligible ?	Screening Visit Date	Study ID Number	Consented/Enrolled ?	Eligibility *	Staff Initials
		Yes No			Yes No	❒ Screen Failure, Reason:	
					Date:	❒ Eligible	
		Yes No			Yes No	❒ Screen Failure, Reason:	
					Date:	❒ Eligible	
		Yes No			Yes No	❒ Screen Failure, Reason:	
					Date:	❒ Eligible	
		Yes No			Yes No	❒ Screen Failure, Reason:	
					Date:	❒ Eligible	
		Yes No			Yes No	❒ Screen Failure, Reason:	
					Date:	❒ Eligible	

GDPR

Recruitment Places

- Newspaper
- Television
- Radio
- Poster
- Leaflets
- Internet
- Social media

Think about Design and Intention



The PAREXEL Clinical Pharmacology Unit, located at Harbor Hospital in Baltimore is currently seeking Volunteers to participate in a clinical research study to evaluate a new Investigational medication for Psoriasis, a disorder which affects the skin and joints.

RESEARCH STUDY
PSORIASIS VOLUNTEERS NEEDED

Please reference study # 96042

We are recruiting the following populations:

- Males
- Females not able to bear children.
- Have chronic Plaque Psoriasis over 3% of your body.
- Ages 18 – 65.
- Weigh between 88 lbs and 308 lbs.

The study involves one screening visit, one in-house stay of 1 night and 14 outpatient visits. If you qualify and complete that study you may receive up to $3760.00 in compensation.

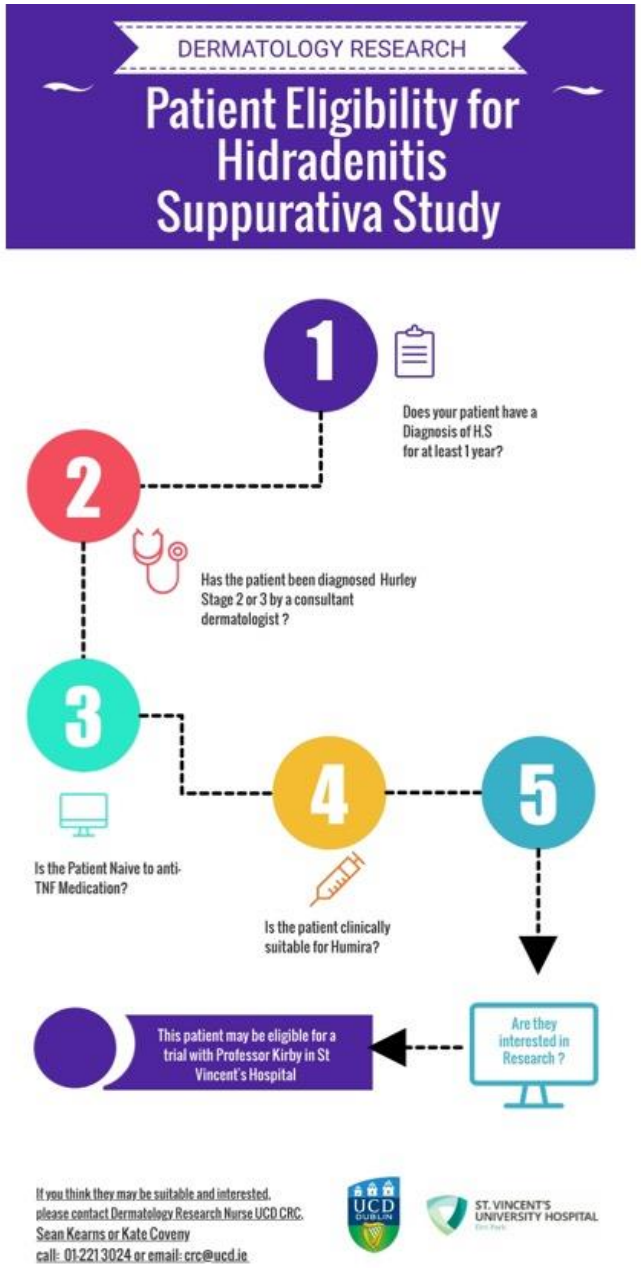
For more information, please visit our website www.baltimoretrials.com, or contact us toll free at **1-800-797-2448** (Monday to Friday between 9AM and 5PM).

Good tools for design

- VISME
- 99 DESIGNS
- IN HOUSE HOSPITAL DESIGNER
- PATIENTS THEMSELVES
- PATIENT GROUPS
- CONTACT ME

Business Cards

Eligibility for Physicians



Recruitment Reflection

HOW ARE MY DROP OUT RATES?

WHY ARE PEOPLE DROPPING OUT?

WHAT CAN I DO TO COMBAT THIS?

METHODS TO IMPROVE RECRUITMENT

SVUH Registry for Trials

Clinical Trials

Take Part in Advancing Healthcare

Do you want to contribute to on-going medical research? Are you interested in helping to evaluate new treatments or tests to improve patient outcomes?

St. Vincent's University Hospital is at the forefront of cutting edge clinical research in Ireland and internationally. As a large academic teaching hospital, we strive to advance medical care for all of our patients by supporting high-quality clinical research opportunities – in conjunction with our partners in UCD – which will ultimately

Research

- Clinical Trials
  - Clinical Trials Search
- Our Research Centres
- Our Research Groups
- Research and Laboratory Facilities

BUR02

This study aims to establish the long-term safety and tolerability profile of Burosumab in the treatment of adults with XLH and to provide continued treatment for subjects previously enrolled in UX023-CL303 and UX023-CL304 clinical trials.

Status: **Open Recruiting**

Omics Study of Psoriasis and Atopic Dermatitis

Psoriasis and atopic Dermatitis are inflammatory skin diseases. With this research study we hope that we will be able to understand the mechanism of these skin diseases in patients and determine the key factors in the body which may cause the progression of the disease by comparing healthy subjects against subjects with either psoriasis or atopic dermatitis

Status: **Open Recruiting**

The TOPaz Study

This study aims to investigate if a two year spell of treatment with a drug call Teriparatide, followed by one dose of treatment called Zoledronic Acid can reduce the risk of broken bones (fractures) in Osteogenesis Imperfecta (brittle bone disease). We are comparing this treatment with the usual treatment that patients with OI normally receive.

Status: **Open Recruiting**

Usage of Omics Technology for Identification of Critical Mediators and Pathways in Patients with Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa is an inflammatory skin disease affecting approximately 1% of the population and Adalimumab (Humira) is a medication that has been licenced for the treatment of patients with HS. We are trying to further understand how Humira works in HS. We hope to determine the factors in the body which may cause improvements for the disease with Humirea treatments

Status: **Open Recruiting**

Usage of Omics Technology for Identification of Critical Mediators and Pathways in Patients with Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa is an inflammatory skin disease affecting approximately 1% of the population and Adalimumab (Humira) is a medication that has been licenced for the treatment of patients with HS. We are trying to further understand how Humira works in HS. We hope to determine the factors in the body which may cause improvements for the disease with Humirea treatments

ELIGIBILITY CRITERIA

If you are over 18 years old and have a diagnosis of H.S. You will be seen by a dermatologist and if clinically suitable for Humira then a member of the research team will work with you on the remaining inclusion criteria.

Therapeutic Area	Dermatology
Type of Study	Clinical Trial
Study Status	Open Recruiting
Sponsor	U.C.D. and via a strategic partnership with Science Foundation Ireland and Abbvie
Principal Investigator	Professor Brian Kirby
Contact	Sean.kearns@ucd.ie

Research

› Clinical Trials
› **Clinical Trials Search**
› Our Research Centres
› Our Research Groups
› Research and Laboratory Facilities

View more Clinical Trials

Reaffirmation

in the team at James Cook Hospital

Recruitment of 1st patient to TOPaZ

Thank you so much for [illegible] help!

Newsletters

TOPaZ Newsletter
May 2019

Wishbone Day May 6th

Raising Awareness Osteogenesis Imperfecta

Update

Thank you all very much for your continuing support of the TOPaZ clinical trial

Amazing month for TOPaZ recruiting 11 participants!

May 6th was Wishbone Day – an international awareness-raising day for Osteogenesis Imperfecta and we wish the OI community all the very best in all the activities that took place this week. If you would like to find out more please visit http://www.wishboneday.com/

Substantial Amendment 6 implementation date has been postponed as the majority of sites requested additional time to review. We will be in touch with sites when the amendment is due to go live with all the information required.

Please also note the safety announcement from Ranbaxy (UK) Ltd attached to the newsletter email regarding an incorrect PIL sent in a batch of Zoledronic acid.

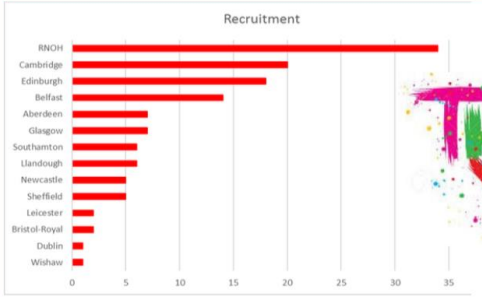
Recruitment

Recruitment to date: 130

34%

- Well done to Dr Rachel Crowley and Laura Feeney at St Vincent's University Hospital, Dublin for recruiting your first participant last month!
- Once again thank you to Judith, Richard, Deirdre and the team at RNOH for continuing to rapidly recruit and have now recruited way over 30!
- Also congratulations to Ken, Tracey and the team at Cambridge for surpassing Edinburgh and reached 20 recruits last month!

Thank you all for your hard work!



Contact Information
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Phone: 00 44 (0) 131 651 9915
Twitter: @TOPaZ_Trial
Address: Edinburgh Clinical Trials Unit, Usher Institute, University of Edinburgh, Level 2, Nine Edinburgh BioQuarter, Edinburgh, EH16 4UX

accord
Academic and Clinical Central Office for Research and Development

NHS Lothian

NHS National Institute for Health Research

Lanyards

Lanyards with Inc/Exc

What do subjects want ?

Group Discussion and feedback

Group Work

- What are some novel or unique things you've done or seen in Clinical Research?
- Was it effective ?
- Why?
- Could you apply it to your area?

Sean Kearns

Research Nurse

Retention in Clinical Trials

Retention

Retention of participants is a major challenge and a key methodological priority

Poor reporting persists as a challenge. On average 6-11% of participants will withdraw or be lost to follow up

Statistical analysis is employed to account for these challenges

Review of results from following paper …

Kearney *et al. Trials* (2017) 18:406
DOI 10.1186/s13063-017-2132-z

Trials

RESEARCH Open Access

Identifying research priorities for effective retention strategies in clinical trials

Anna Kearney[1*], Anne Daykin[2], Alison R. G. Shaw[2], Athene J. Lane[2], Jane M. Blazeby[2], Mike Clarke[3], Paula Williamson[4] and Carrol Gamble[1]

Missing Data

Table 1 Current causes of missing data within the cohort of Health Technology Assessment Programme (HTA)-funded trials

Causes of missing data	Number of trials (%) $n = 49$[a]
Patients withdrawing	41 (84%)
Losing contact with patients	30 (61%)
Patients not returning questionnaire	24 (49%)
Patient deaths	23 (47%)
Clinicians withdrawing patients	17 (35%)
Patients not attending a visit/clinic	14 (29%)
Missed measurement by clinical staff	12 (25%)
Patient outcomes other than death preventing measurement, e.g. coma, too ill to complete measures	10 (20%)
Data not provided by clinical staff	10 (20%)
Other	6 (12%)
Technology problems	4 (8%)
Laboratory problems	2 (4%)

Survey respondents chose all causes of missing data observed in their trial.[a]One person did not complete the question

TOP 5 TIPS

Table 2 Top five recommended practices to mitigate missing data recommended by chief investigators

Retention strategy	Number of respondents (%) $n = 50$
Monitoring (procedures, methods and systems for monitoring data return and following up outstanding data)	25 (50%)
Good site relationship/regular contact with sites to ensure buy in	15 (30%)
Site training (initiation training and triggered training)	11 (22%)
Multiple methods of data collection	10 (20%)
Well-chosen measures and outcomes	6 (12%)

See Additional file 3: Table S7 for complete list of recommend practices

Patient Information leaflets: a comparison

PLOS ONE

RESEARCH ARTICLE

Reducing attrition within clinical trials: The communication of retention and withdrawal within patient information leaflets

Anna Kearney[1]*, Anna Rosala- Hallas[2], Naomi Bacon[2], Anne Daykin[3], Alison R. G. Shaw[3], Athene J. Lane[3], Jane M. Blazeby[3], Mike Clarke[4], Paula R. Williamson[1], Carrol Gamble[1]

1 North West Hub for Trials Methodology Research/ Clinical Trial Research Centre, Biostatistics, University of Liverpool, Liverpool, United Kingdom, **2** Clinical Trial Research Centre, Biostatistics, University of Liverpool, Liverpool, United Kingdom, **3** ConDuCT-II Hub for Trials Methodology Research, University of Bristol, Bristol, United Kingdom, **4** Centre for Public Health, Queen's University of Belfast, Belfast, United Kingdom

* a.kearney@liv.ac.uk.

Findings:

98% of PIL state that you can withdraw from the trial

90% say that you can withdraw at any time, with no penalty and don’t have to give a reason

12% stated that we may ask you to give a reason to help us understand

16% included information around the value of retention

6% included information around equipoise

Variance from Protocol to PIL

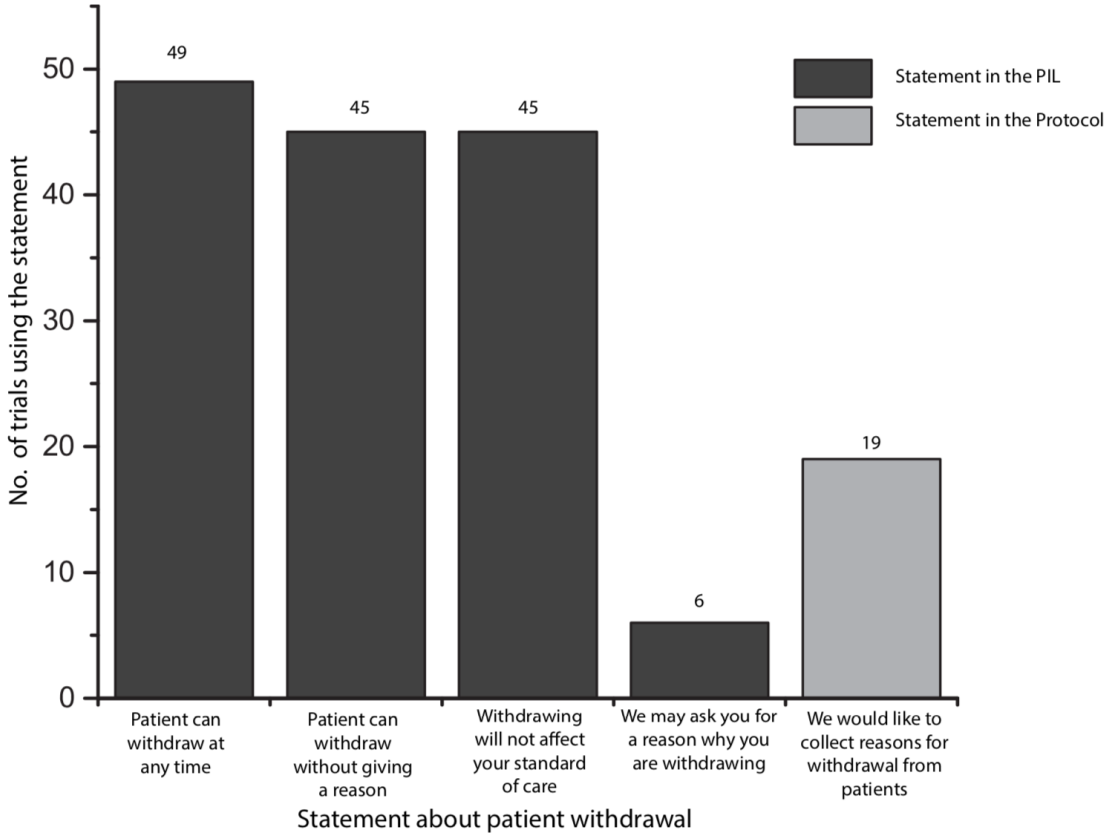
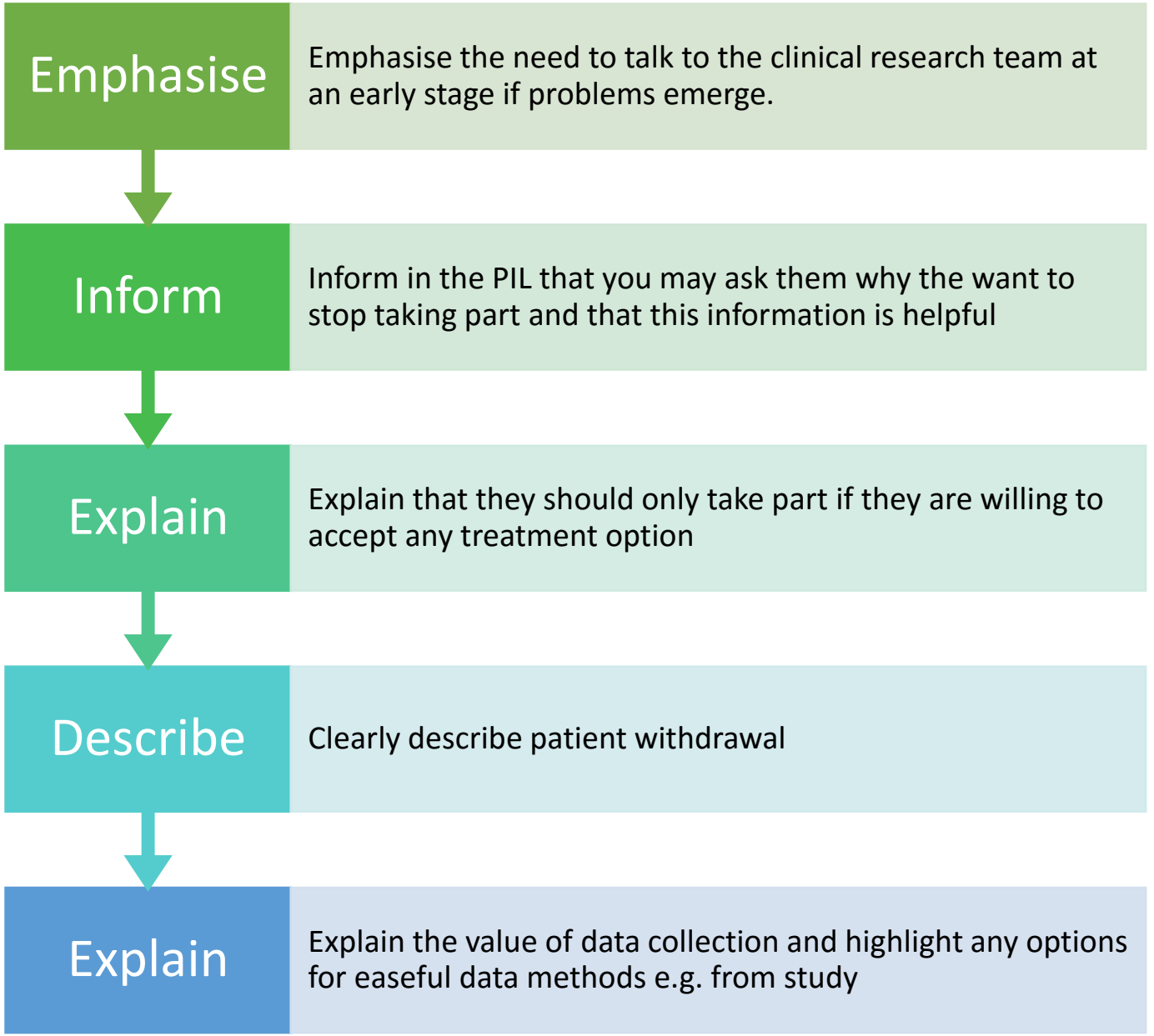


Fig 3. Frequency of communication about patient withdrawal within PIL and protocols (n = 50).

https://doi.org/10.1371/journal.pone.0204886.g003

Evaluation of PIL's (Recommendations)



Group Work - Retention

- What are some novel or unique things you've done or seen in Clinical Research?
- Was it effective ?
- Why?
- Could you apply it to your area?

Conclusions

Recruitment and Retention are priority issues in clinical research

Massive deficits still exist with only marginal improvements in last decade

Literature is scarce

Planning is paramount in both

We need to utilize our teams and each other

Be create, be innovative, be evidence based and where possible – access your own methods

Challenge

- As active recruiters in this area:

- Look to how we can document recruitment in our fields
- How can we test improvements
- How can we evaluate these
- Can we publish our findings and improve peer reviewed knowledge?