

What do know improves recruitment to trials: and what might improve the situation?

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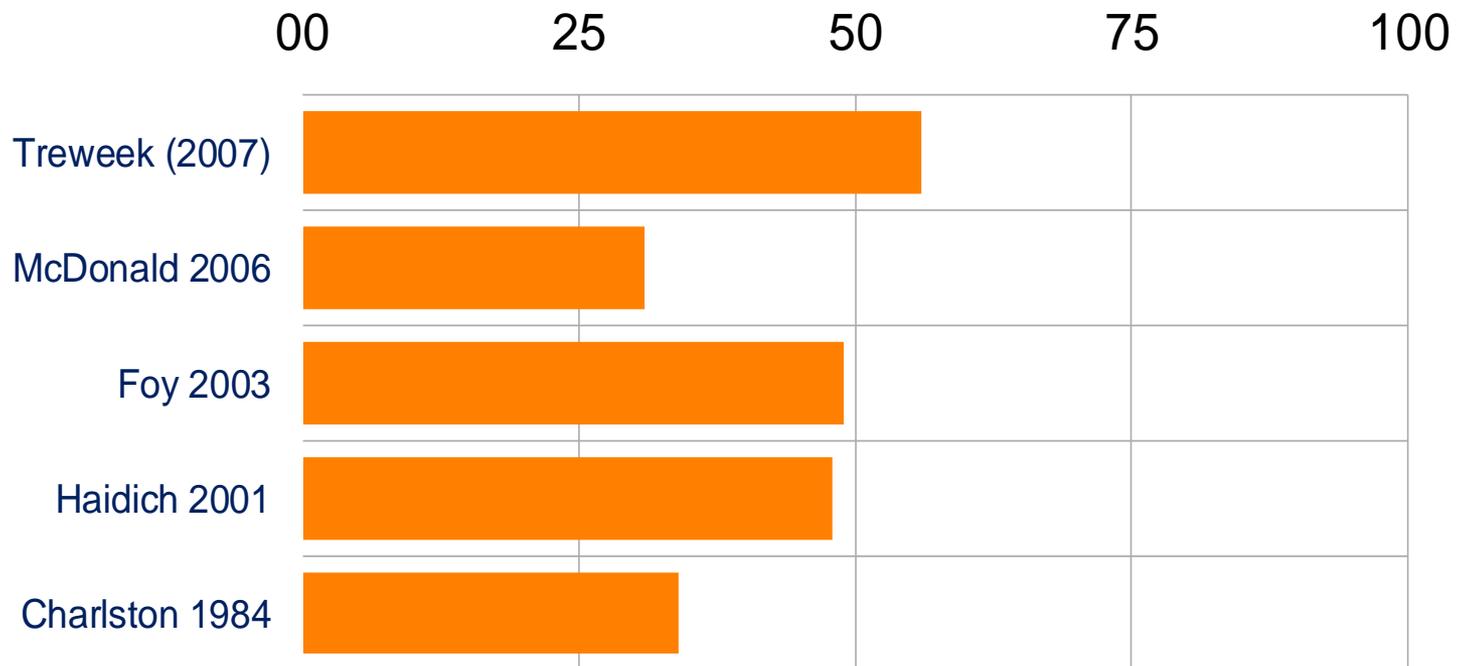
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What do you think we know?

1. How often do clinical trials fail to recruit to target?
2. Which of the following strategies have been shown to increase recruitment rates?
 - a) Open designs
 - b) Opt out V Opt in
 - c) Telephone reminders
 - d) Audiovisual aids
 - e) Trial Booklets
 - f) Study Questionnaires
 - g) Financial Incentives
3. What other strategies might be effective?
 - a) Intervention modelling
 - b) Via EMRs (Incident, Prevalent)
 - c) PBRNs

1. How often do clinical trials fail to recruit to target?



Seget S, Optimizing patient recruitment and retention in late stage clinical trials, 2010 Business Insights Ltd

- 45% failed to reach 80% of the pre-specified sample size.
- Sampling frame 60 studies funded by the MRC & HTA

Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study

MK Campbell, C Snowdon, D Francis, D Elbourne, AM McDonald, R Knight, V Entwistle, J Garcia, I Roberts and A Grant (the STEPS group)



2. What works? a-g

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Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis

Shaun Treweek,¹ Pauline Lockhart,¹ Marie Pitkethly,² Jonathan A Cook,³ Monica Kjeldström,⁴ Marit Johansen,⁵ Taina K Taskila,⁶ Frank M Sullivan,¹ Sue Wilson,⁶ Catherine Jackson,⁷ Ritu Jones,⁸ Elizabeth D Mitchell⁹

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This review is an abridged version of a Cochrane Review previously published in the Cochrane Database of Systematic Reviews 2010, Issue 4, Art. No.: MR000013 DOI: 10.1002/14651858.MR000013.pub5 (see www.thecochranelibrary.com for information). Cochrane Reviews are regularly updated as new evidence emerges and in response to feedback, and Cochrane Database of Systematic Reviews should be consulted for the most recent version of the review.

ABSTRACT

Objective: To identify interventions designed to improve recruitment to randomised controlled trials, and to quantify their effect on trial participation.

Design: Systematic review.

Data sources: The Cochrane Methodology Review Group Specialised Register in the Cochrane Library, MEDLINE, EMBASE, ERIC, Science Citation Index, Social Sciences Citation Index, C2-SPECTR, the National Research Register and PubMed. Most searches were undertaken up to 2010; no language restrictions were applied.

Study selection: Randomised and quasi-randomised controlled trials, including those recruiting to hypothetical studies. Studies on retention strategies, examining ways to increase questionnaire response or evaluating the use of incentives for clinicians were excluded. The study population included any potential trial participant (eg, patient, clinician and member of the public), or individual or group of individuals

ARTICLE SUMMARY

Article focus

- Despite representing the gold standard in evaluating the effectiveness and safety of health interventions, many randomised controlled trials do not meet their recruitment targets.
- Poor recruitment can lead to extended duration, greater resource usage and findings that are not as statistically precise as intended; in the worst case, a trial may be stopped.
- A systematic review was carried out to identify methods used to improve recruitment to randomised controlled trials, and to quantify their effects on participation.

Key messages

- There are promising strategies for improving recruitment to trials, most notably telephone reminders, open-trial designs, opt-out strategies and financial incentives.
- Many trials of recruitment methods involve hypothetical trials, and the applicability of the findings to the real world is still unknown.
- There is a clear knowledge gap with regard to recruitment strategies aimed at those recruiting to trials.

Strengths and limitations of this study

- This Cochrane review utilised a comprehensive search and appraisal strategy, thereby

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Methodology Review

Strategies to improve recruitment to randomised controlled trials

Shaun Treweek¹, Elizabeth Mitchell², Marie Pitkethly³, Jonathan Cook⁴, Monica Kjeldström⁵, Marit Johansen⁶, Taina K Taskila⁷, Frank Sullivan⁸, Sue Wilson⁹, Catherine Jackson¹⁰, Ritu Jones¹¹, Pauline Lockhart⁹

Editorial Group: Cochrane Methodology Review Group

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Am scores 0

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Abstract | Article | Figures | Tables | References | Other Versions | Cited By

View Full Article (HTML) | Summary (61K) | Standard (686K) | Full (889K)

Abstract

Background

Recruiting participants to trials can be extremely difficult. Identifying strategies that improve trial recruitment would benefit both trialists and health research.

Objectives

To quantify the effects of strategies to improve recruitment of participants to randomised controlled trials.

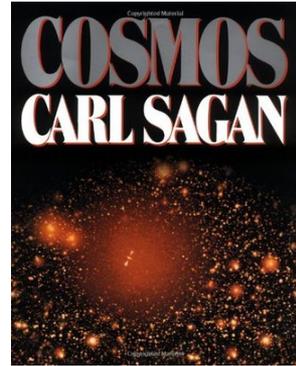
Search methods

We searched the Cochrane Methodology Review Group Specialised Register (CMR) 2010, Issue 2, part of *The Cochrane Library* (online)

6 comparisons

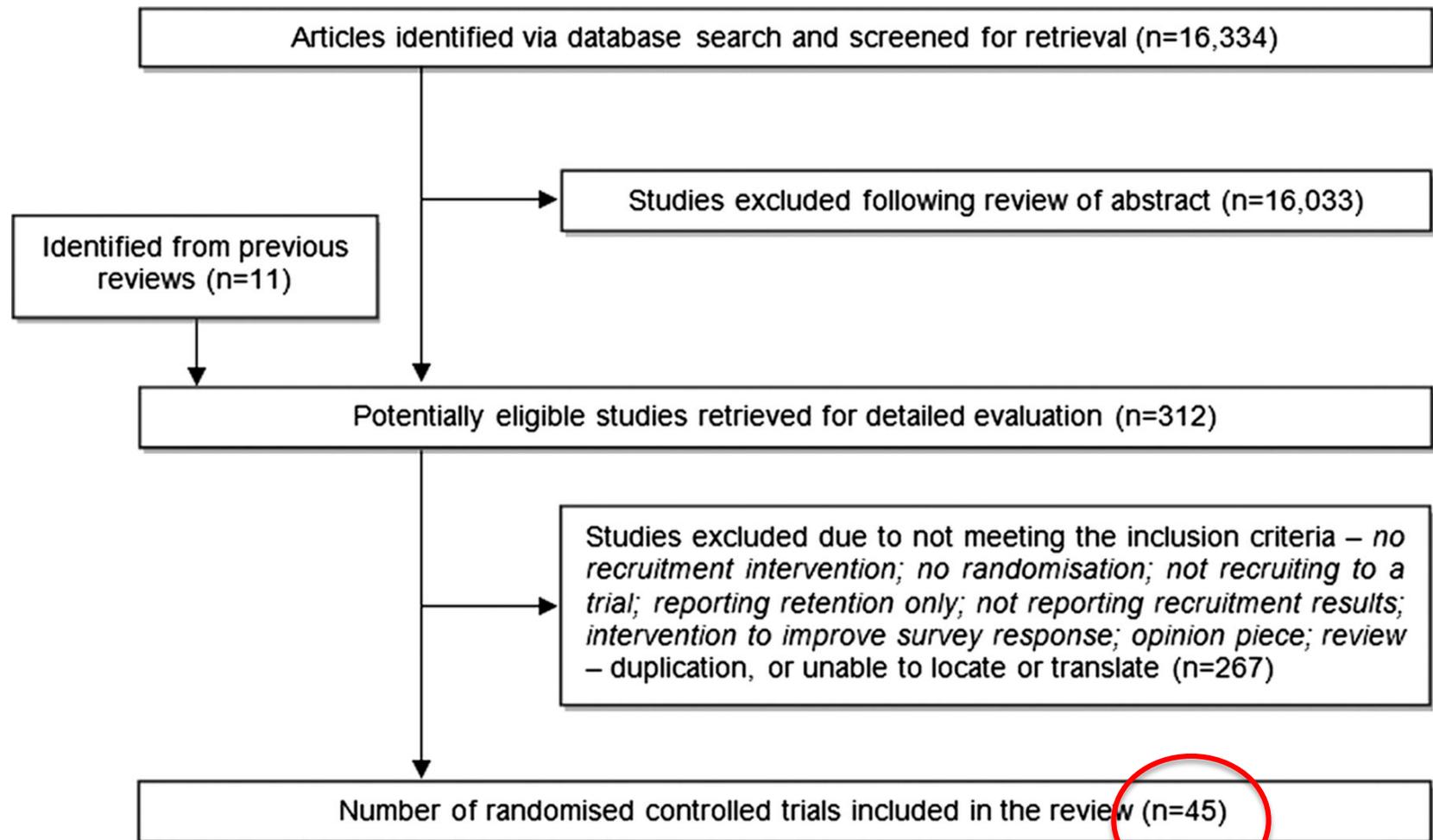
41 comparisons

The absence of evidence is not the evidence of absence.



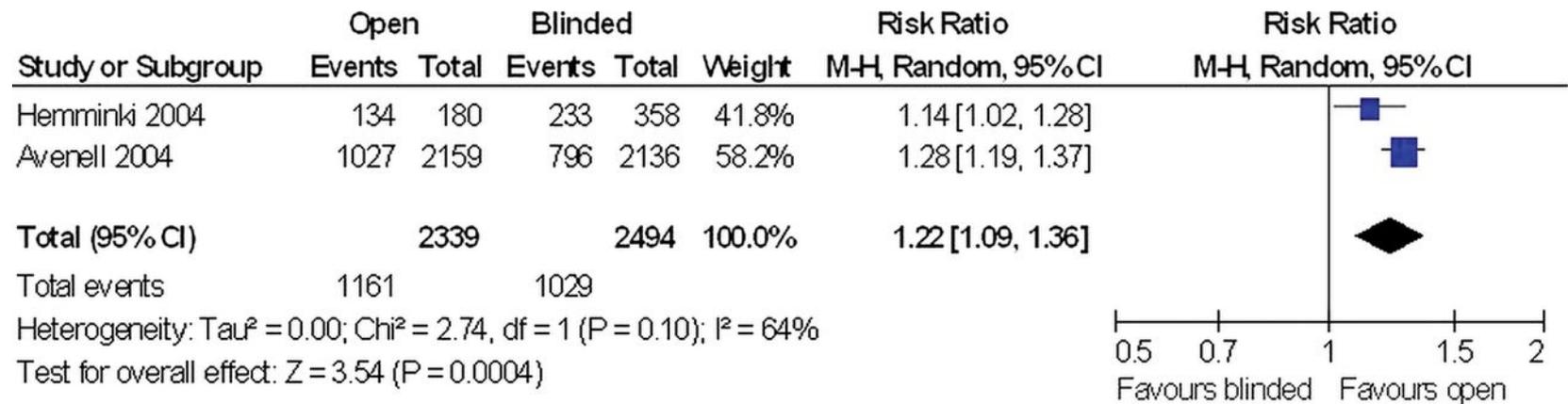
- a) Open designs
- b) Reducing the burden of consent
- c) Telephone reminders
- d) Audiovisual aids
- e) Trial Booklets
- f) Study Questionnaires
- g) Financial incentives

Flow of studies into the review.



Treweek S et al. BMJ Open 2013;3:e002360

a Recruitment with open and blinded trial design.



Treweek S et al. BMJ Open 2013;3:e002360



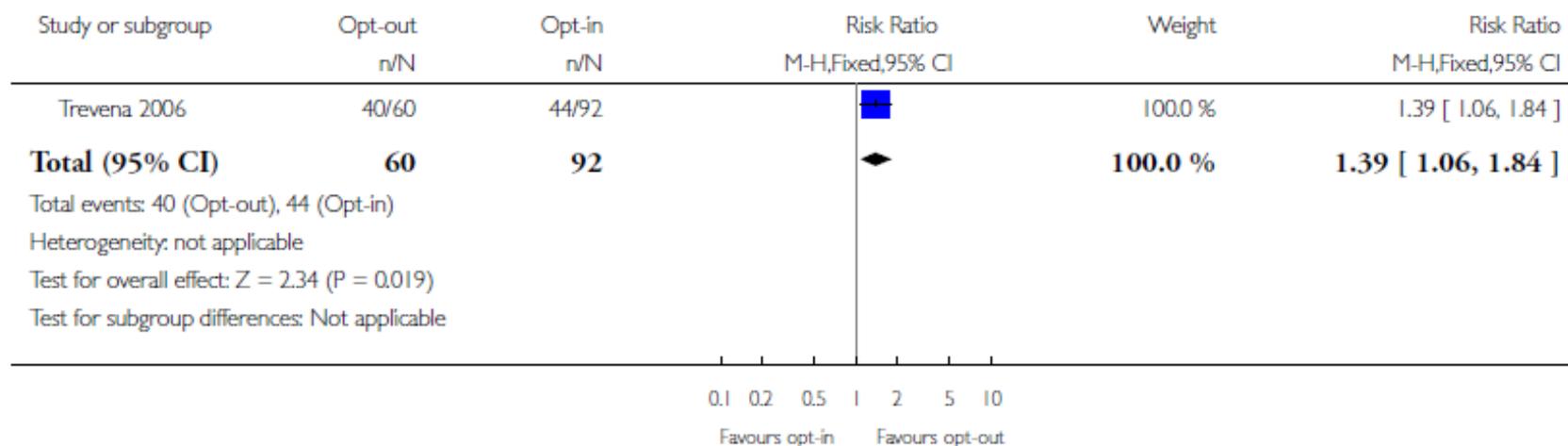
b Opt out V Opt in

Analysis 4.1. Comparison 4 Opt-out consent vs opt-in consent, Outcome 1 Participant recruited.

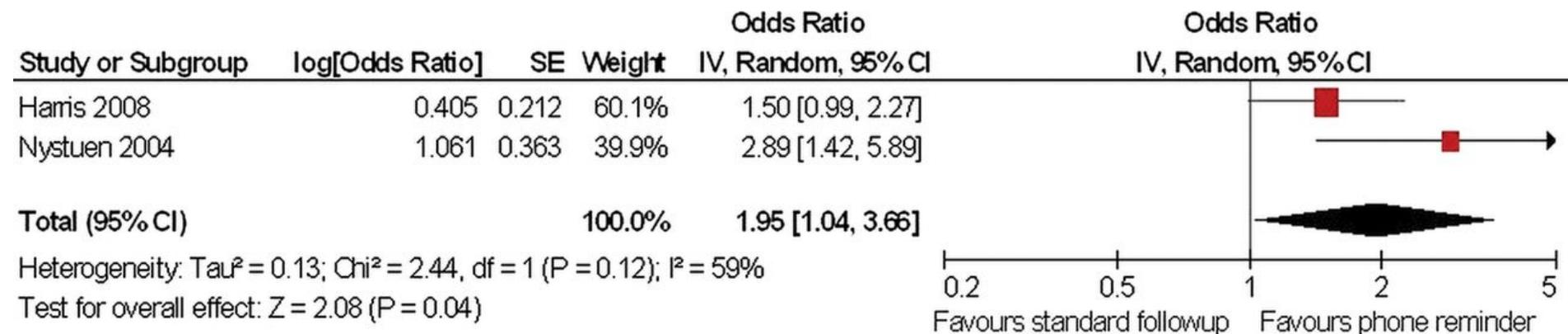
Review: Strategies to improve recruitment to randomised controlled trials

Comparison: 4 Opt-out consent vs opt-in consent

Outcome: 1 Participant recruited

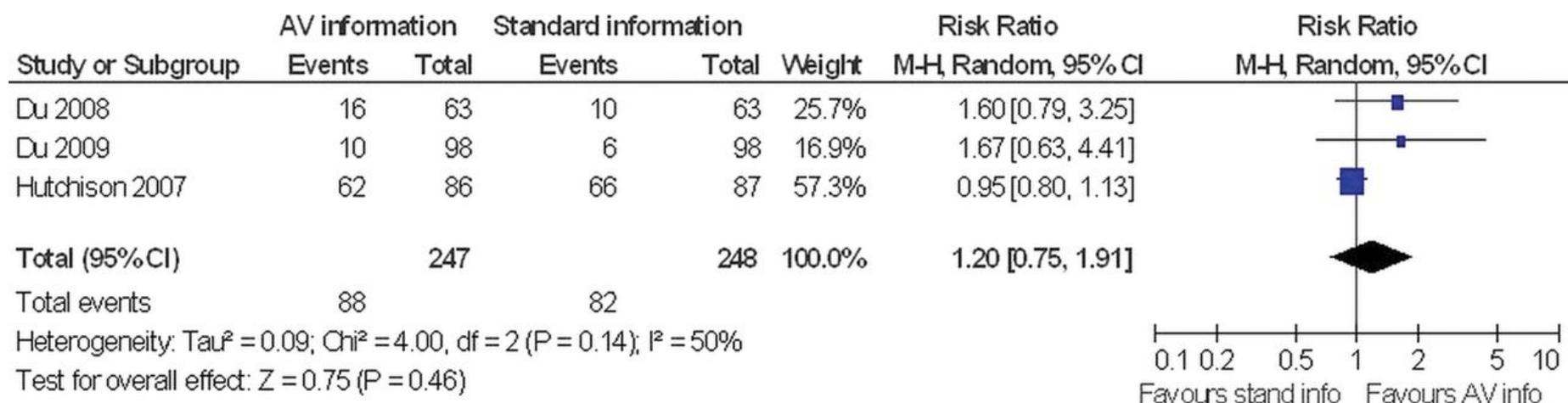


c Recruitment with telephone reminder V standard follow-up.



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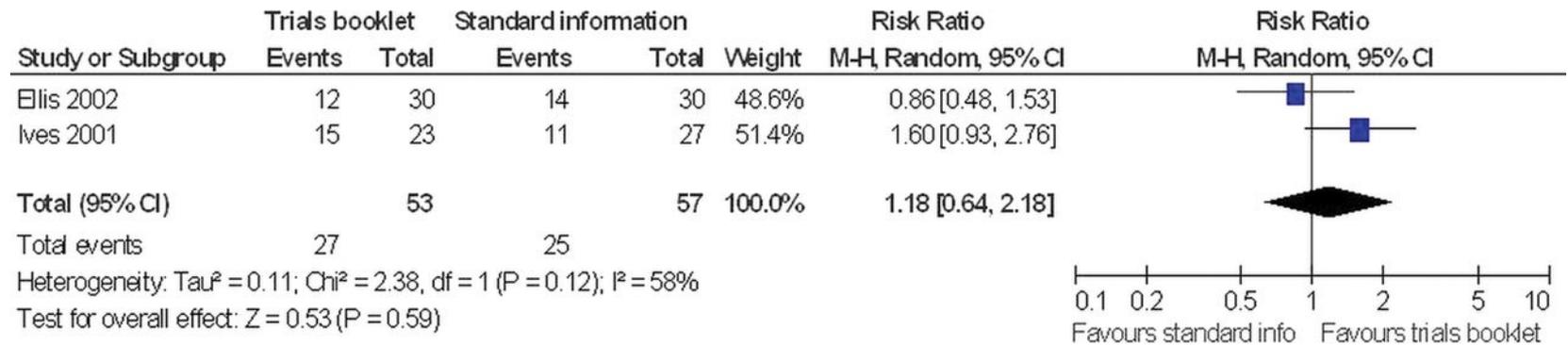
d Recruitment with audiovisual V standard trial information.



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e Recruitment with clinical trials booklet V standard trial information.

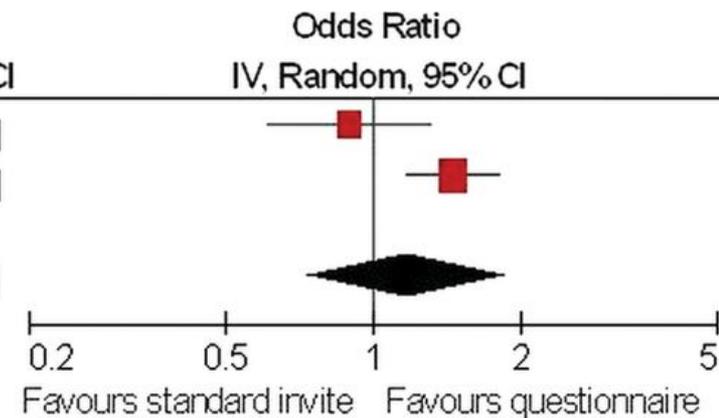


Treweek S et al. *BMJ Open* 2013;3:e002360



f Recruitment with invitation including study questionnaire V standard invitation.

Study or Subgroup	log[Odds Ratio]	SE	Weight	Odds Ratio IV, Random, 95% CI
Harris 2008	-0.105	0.197	44.3%	0.90 [0.61, 1.32]
*Kendrick 2001	0.372	0.113	55.7%	1.45 [1.16, 1.81]
Total (95% CI)			100.0%	1.17 [0.74, 1.87]
Heterogeneity: $\tau^2 = 0.09$; $\text{Chi}^2 = 4.41$, $\text{df} = 1$ ($P = 0.04$); $I^2 = 77\%$				
Test for overall effect: $Z = 0.68$ ($P = 0.50$)				



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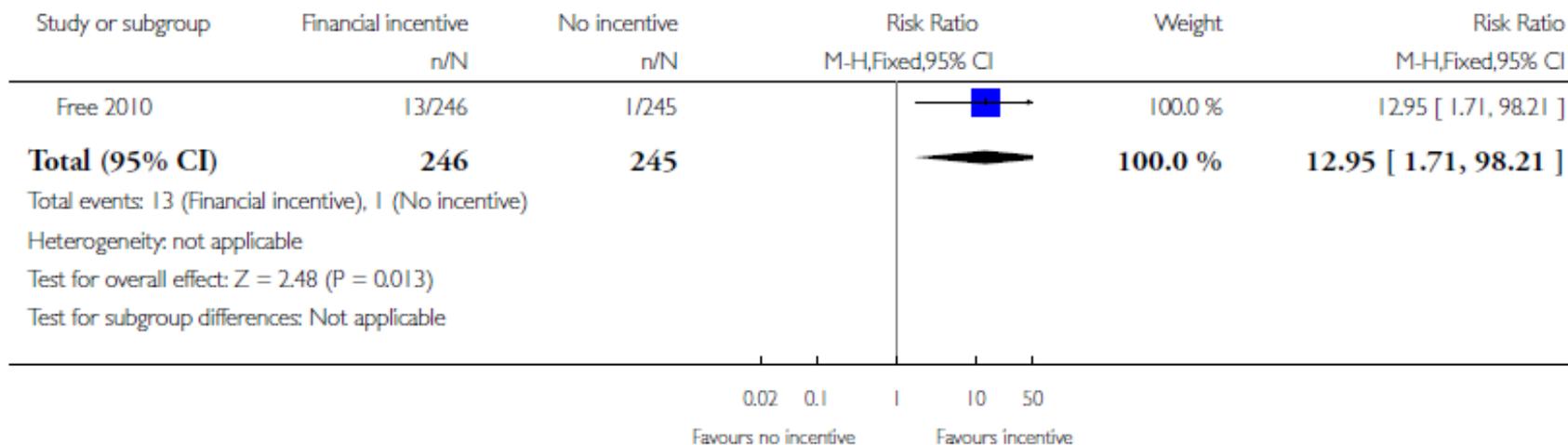
g Financial Incentives

Analysis 40.1. Comparison 40 Financial incentive vs no incentive, Outcome 1 Participant recruited.

Review: Strategies to improve recruitment to randomised controlled trials

Comparison: 40 Financial incentive vs no incentive

Outcome: 1 Participant recruited



What other strategies might be effective?

- a) Intervention modelling
- b) Via EMRs (Prevalent, Incident)
 - i. TrialTorrent
 - ii. Searches
 - Local
 - Integrated with EMR
 - Central
 - iii. SHARE
- c) Practice Based Research Networks

Web- Based Intervention Modelling (WIME) uses the LifeGuide system

The screenshot displays the LifeGuide Community Website interface. At the top, the title "Show Intervention" is visible. The main header features the "LIFEGUIDE COMMUNITY WEBSITE" logo on the left and the "UNIVERSITY OF Southampton" logo on the right. Below the header, a welcome message reads "Welcome to the LifeGuide community, Shaun Treweek." with a "Logout" button. A vertical navigation menu on the left includes links for Home, About, Contact, Workshops, Publications, Forum, Newsletters, LifeGuide Software, Help, and Intervention Manager. The Intervention Manager section lists "My Folders", "Demo Interventions", "Tutorial Interventions", and "My Account". The main content area is titled "Intervention Details" and contains an "Intervention Demo" section with a "Welcome!" message and a "Continue" button. Below this is an "Intervention information" table:

Full Name:	Demonstration
Short Name:	Demo
Description:	Demo
Deployed Date:	08/03/2010 02:47 GMT
Expiry Date:	08/03/2010 03:30
Owner:	Matt Ellis

To the right of the intervention details is a "Comments Per Page" section with a "Make Comments Per Page" button and a "Message Board" section with a "Write a Message" form and a "Post" button. A comment from "heindevries" is visible, dated "at 2:47PM on September 08 2010" with the text "Hello".

Acute Recruitment Tools

Ben SMITH 52Y - 04/06/1956 (M) Gascoigne Farm Cottages, 16 Main Street, Barwick in Elmet, Leeds, LS15 4JQ - Complex Data View

Consultation Summary Guidelines Add List View Window Help

Complex Data View

Initial Filter

- 1 Problems
- 49 Consultation
- 1 Drug Allergies & Adverse
- 5 Recalls and Reviews
- Patient Preference
- 15 Medical History
- 6 Therapy
- 4 Lifestyle
- 8 Examination Findings
- Immunisations
- Miscellaneous
- 27 All Test Results
- New Registration Exam
- Child Health Surveillance
- Maternity
- Well Person Clinic
- 9 HP Interventions
- Elderly
- Disease Registers
- Asthma
- Diabetes

Allergy Status not rec...
Add Allergy
Add No Allergy

Health promotion
Health Promotion out of date
Health Promotion data incon...

Current Recalls

Immunisations Due in ...
Polio myelitis 1st 04/08/1956...
Tetanus 1st 04/08/1956 o/d

Cardiovascular Risk
CHD Risk: 22%
CVD Risk: 33%
Warning: Last BP Record > ...
Warning: Last Smoking Stat...
No HDL Cholesterol value a

Appointments Patient Select Patient Details Problems Consultations Journal

Filtered Summary/Grid Tests Therapy Guidelines Prison Guidelines

Date	Description	Clinician
28/12/08	Hb. A1C - diabetic control = 8.2%	DB
25/03/04	Corrected serum calcium level = 2.29 mmol/L	
	Serum albumin = 42 g/L	
	Red blood cell (RBC) count = 4.87 10 ⁹ /L	
	Mean corpuscular volume (MCV) = 92	
	Lymphocyte count = 2.63 10 ⁹ /L	
	Blood urea/renal function Equal to 5.6	
	Mean corpusc. Hb. conc. (MCHC) = 3	
	Serum creatinine = 78 umol/L	
	Mean corpusc. haemoglobin(MCH) = 3	
	Haematocrit - PCV = 0.45	
	Serum random glucose level = 4.8 mmol/L	
	Serum sodium = 137 mmol/L	
	Serum cholesterol = 6.5 mmol/L	
	Serum alkaline phosphatase = 96 iu/L	
	Basophil count = 0.03 10 ⁹ /L Authoris REPORTED 25/09/2000 16:17	
	Neutrophil count = 5.31 10 ⁹ /L	
	Haemoglobin estimation = 15.3 g/dL	
	Platelet count = 230 10 ⁹ /L	
	Serum potassium = 4.1 mmol/L	
	ALT/SGPT serum level = 43 iu/L Duty 25/09/2000 13:00 REPORTED 26/09/2000 09:52	
	Total white cell count = 8.74 10 ⁹ /L	
	Eosinophil count = 0.22 10 ⁹ /L	
	Monocyte count = 0.55 10 ⁹ /L	
	AST - aspartate transam (SGOT) = 27 iu/L	
	Serum bilirubin level = 15 umol/L	

SARMA for ROADv2.1.112 DB logged in

Current Patient : SMITH BEN 04/06/1956

ROAD - Response to Oral Agents in Diabetes
(First Line Treatment with Metformin)

The patient's HbA1c is above 7% and additional treatment might be appropriate. He/she fulfils the initial entry criteria for the ROAD study. If you feel the patient is suitable, please answer the following questions:

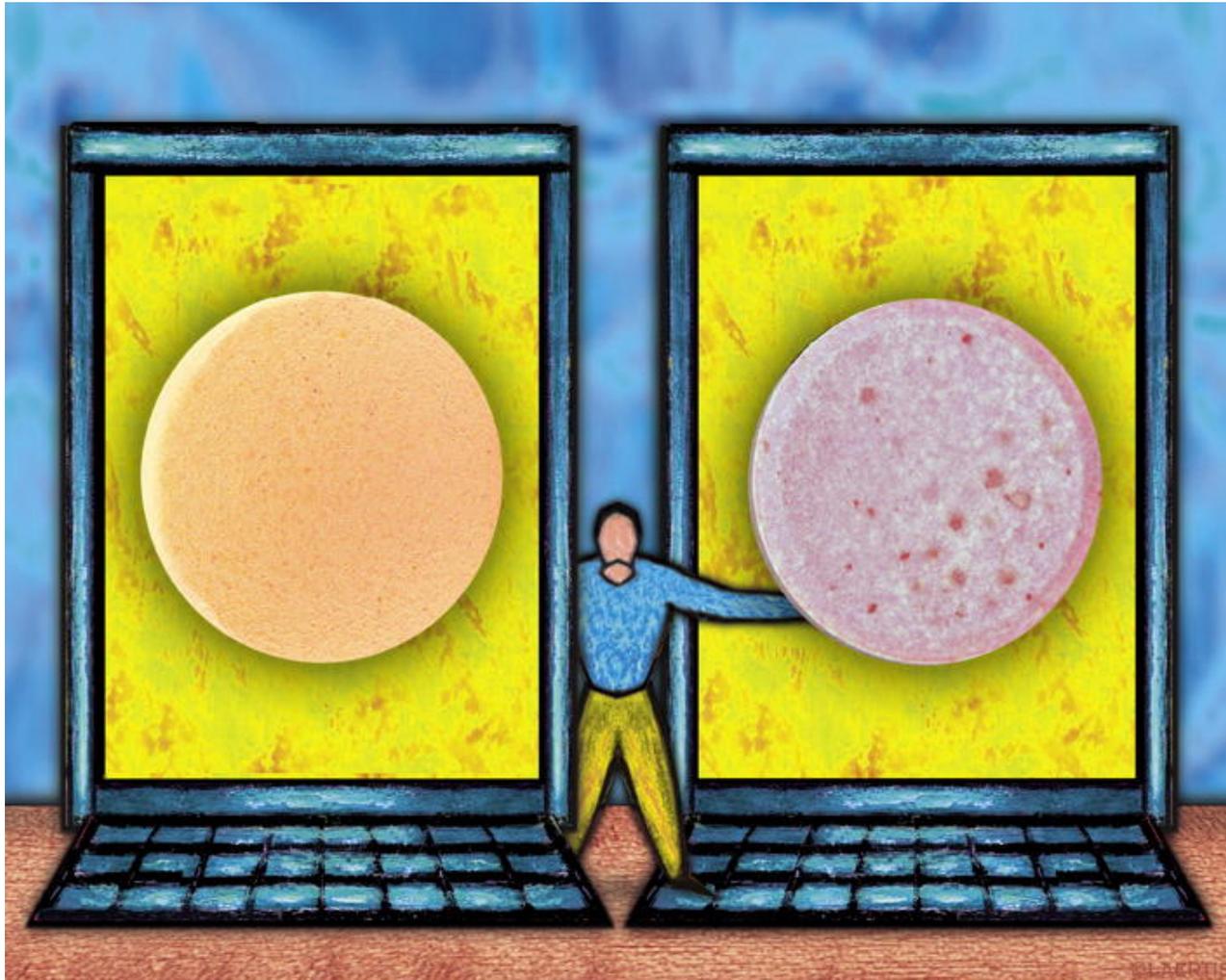
Thank you. The patient will be contacted within the next few days.

Read Term - Add

OK Cancel

Ben SMITH 52Y - 04/06/1956 (M)
1. Give Alcohol Advice to this patient

Pragmatic randomised trials using routine electronic health records eLung (Antibiotics in COPD) RetroPro (Statins in 1y prevention)



BMJ

Staa T v et al. BMJ 2012;344:bmj.e55

Embedding recruitment in software

- At appointment booking
- Before appointment
- In waiting room
- In consultation

www.cognisantmd.com/wp-content/uploads/2014/05/OceanWave-Brochure-web.pdf

ted Sites Web Slice Gallery Imported From IE



The Revolutionary Patient-Facing Solution for Registration, Self-Interviewing & Research.

Let new patients register and share their history online before their first appointment

Give your patients a tablet when they check in to capture patient email and clinic policy consent, changes to contact information, smoking status and more.



Let your patients take their time completing screens like the PHQ-9 at home or on a waiting room tablet.

Review patient history and red flags in your EMR before you see the patient.

BETTER ADMINISTRATION

OceanWave lets patients register and change contact information online at home, or on a tablet in the waiting room. Your patient data stays accurate and up-to-date, you eliminate paper, and save time and hassle for front-desk staff.

BETTER PATIENT CARE

OceanWave generates accurate, focused patient histories with concise clinical notes in your EMR, allowing you to easily identify "red flags" before you even see the patient. You stay on schedule, spend less time typing, and more on patient

BETTER RESEARCH & QIPs

OceanWave makes it easy to recruit or follow up on patient surveys using specific inclusion criteria at check-in. Securely collect, aggregate and store anonymous patient data across multiple sites with PHIPA compliance.

Remote Query on Central database of EMR data

Polypharmacy - Patient Search

Import Criteria
Export Criteria
Edit Criteria

Ages: 65 to 110

Gender: Both Male Female

Include Script Count
 Use BNF Chapters

Drug Count > 5

Prescribed After: 01/09/2009

Find Patients
Print List
Update Records

	CHINumber	Surname	Forename	Sex	Age	Count
Remove	1938146772	Snikeris	Tamsin	F	91	17
Remove	2001937440	Paton-Mackenzie	Marta	F	66	17
Remove	3300363563	Karson	Katy	F	80	21
Remove	1448118530	Loates	Goncalo	M	77	12
Remove	9324804441	Van Craenenbroeck	Janet	F	71	11
Remove	9139337837	Sharkey	Julianna	F	72	11
Remove	7396342238	Mcnee	Rozila	F	68	12
Remove	8030296243	Mcintyre	Lavinia	F	76	10
Remove	3218809676	Fitter	Oscar	M	89	14
Remove	2384782016	Smyth	Murdoch	M	74	10
Remove	5569686940	Jessiman	Mairietta	F	70	20
Remove	8223057516	Ferbrache	Uldis	M	76	6
Remove	2104559120	Wilson	Melvin	M	77	9
Remove	4720017457	Rohde	Gyorgy	M	73	8
Remove	2888342753	Hamilton	Ann-Marie	F	75	12
Remove	8596675720	Mclennan	Marlene	F	81	11
Remove	2950500320	Ford	Ian Abrach	M	80	16
Remove	3109553365	Galbraith	Kadie	F	82	7

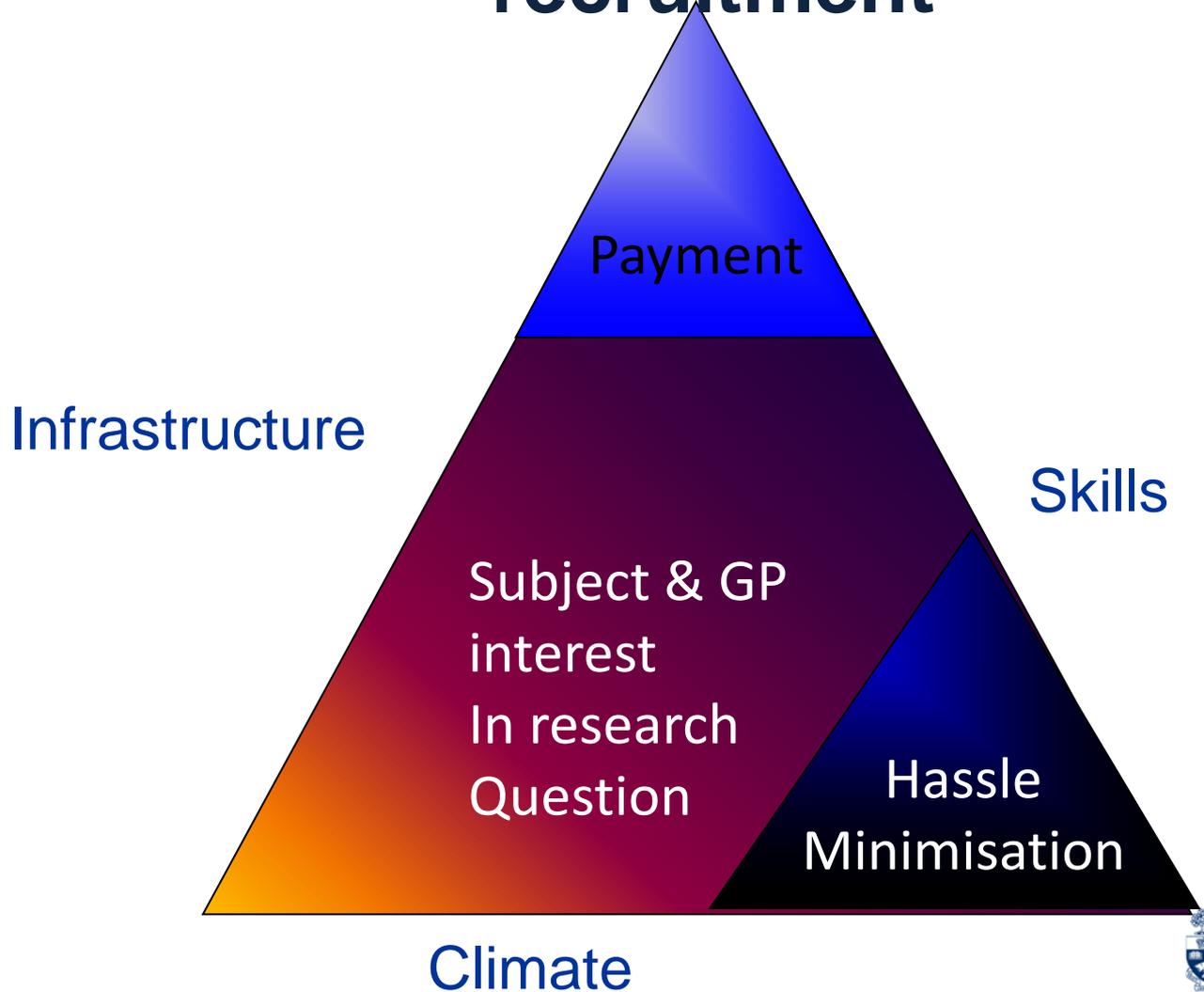
17/09/2010 - DIGOXIN tabs 125micrograms
17/09/2010 - ASPIRIN ec tab 75mg
17/09/2010 - QUININE SULPHATE tabs 300mg
17/09/2010 - FERROUS SULPHATE tabs 200mg
17/09/2010 - OMEPRAZOLE gastro-res cap 20mg
17/09/2010 - FUROSEMIDE tabs 40mg
17/09/2010 - AMLODIPINE tabs 5mg
17/09/2010 - HYDROXYZINE tabs 10mg
17/09/2010 - Fortisip Bottle liq [NUTRICIA]
16/09/2010 - SALMETEROL cfc free inh 25micrograms/actuation
16/09/2010 - CLENIL MODULITE cfc free inh 100micrograms/actuation
16/09/2010 - SALBUTAMOL cfc free inh 100micrograms/inhalation
03/09/2010 - PARACETAMOL tabs 500mg
06/08/2010 - COLCHICINE tabs 500micrograms
22/06/2010 - SIMVASTATIN tabs 40mg
28/04/2010 - BENDROFLUMETHIAZIDE tabs 2.5mg
26/02/2010 - CO-CODAMOL tabs 30mg + 500mg

Number of patients who matched the inclusion parameters: **2209**
Number of patients excluded: **963**
Total number of patients identified: **1246**

Number of male patients: **508** Number of female patients: **738**

Aged 15 or under: **0** Aged 15 or under: **0**
Aged 16 to 24: **0** Aged 16 to 24: **0**
Aged 25 to 34: **0** Aged 25 to 34: **0**
Aged 35 to 44: **0** Aged 35 to 44: **0**
Aged 45 to 54: **0** Aged 45 to 54: **0**
Aged 55 to 64: **0** Aged 55 to 64: **0**
Aged 65 or over: **508** Aged 65 or over: **738**
Average age: **76.22** Average age: **77.67**

Key PBRN Concepts when engaging with practices and potential subjects for trial recruitment



What do you think we know now?

1. How often do clinical trials fail to recruit to target?
2. Which of the following strategies have been shown to increase recruitment rates?
 - a) Open designs
 - b) Opt out V Opt in
 - c) Telephone reminders
 - d) Audiovisual aids
 - e) Trial Booklets
 - f) Study Questionnaires
 - g) Financial Incentives
3. What other strategies might be effective?
 - a) Intervention modelling
 - b) Via EMRs (Incident, Prevalent)
 - c) PBRNs

Research Implications

1. Few effective strategies identified
2. Insufficient/Inadequate research
 - 45 papers included
3. Low contribution from primary care
 - 7
 - 4 UK, 1USA, 1Can,1 Aus
4. Novel ideas promising
5. PBRNs offer a valuable laboratory to test new approaches