

Making the most of your research cohort

Lucy Culliford
Research Fellow, CTEU Bristol

Funded & supported by

NIHR

Challenges

- Constant pressure to be efficient
- Finite population of potential research participants
- Lack of evidence base for good practice in clinical trials

Answer

- SWATs!
 - Studies within a trial
- Offers:
 - Efficiency
 - Answer more than just the primary research question
 - Generates evidence for good practice

How have we used SWATs?

- Embedding several SWATs into a large cohort study
- Able to get answers quickly – annual target population is 1000 patients per year
- Long term project – at least 5 years
 - Implement findings of SWATs
 - Run multiple SWATs

OMACS

- Outcome Monitoring After Cardiac Surgery
- Aim to recruit every cardiac surgery patient
- Research cohort utilising:
 - In-hospital data
 - Quality of Life questionnaires
 - Routine data collected at a national level (Office of National Statistics, NHS Digital Hospital Episode Statistics)
- Approach by post 3 months post-op
- 12 month follow-up questionnaire
- 3 SWATs planned, more to come!

SWAT 1

- Does the appearance of information given to potential research participants influence their decision to take part?

PIL A - tri-fold coloured leaflet produced using a graphic design package, InDesign, professional printers (= TEST PIL)

PIL B - coloured A4 sheet produced in InDesign, professional printers (= HYBRID PIL)

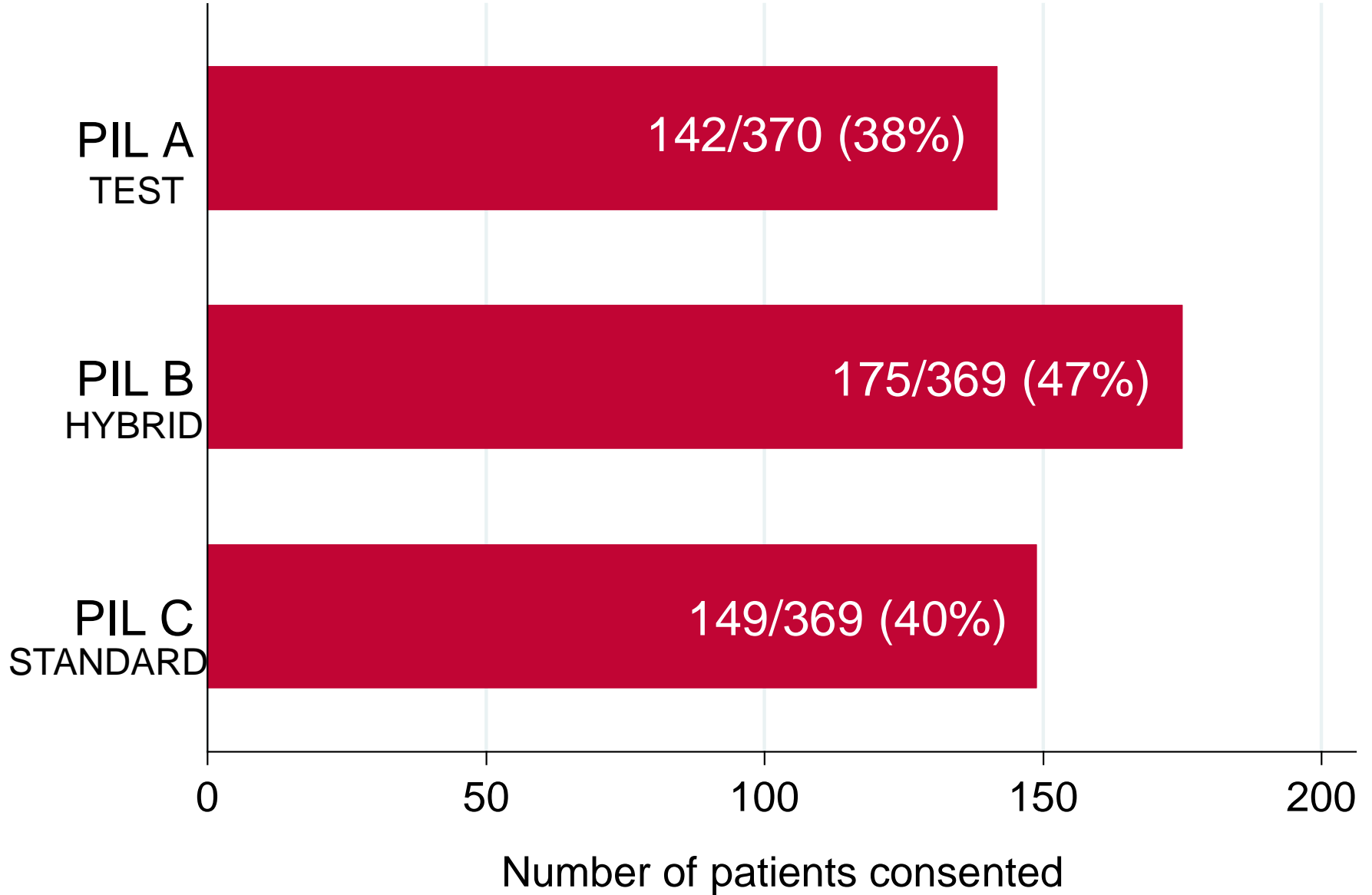
PIL C - black and white A4 sheet produced in Microsoft Word (= STANDARD PIL)

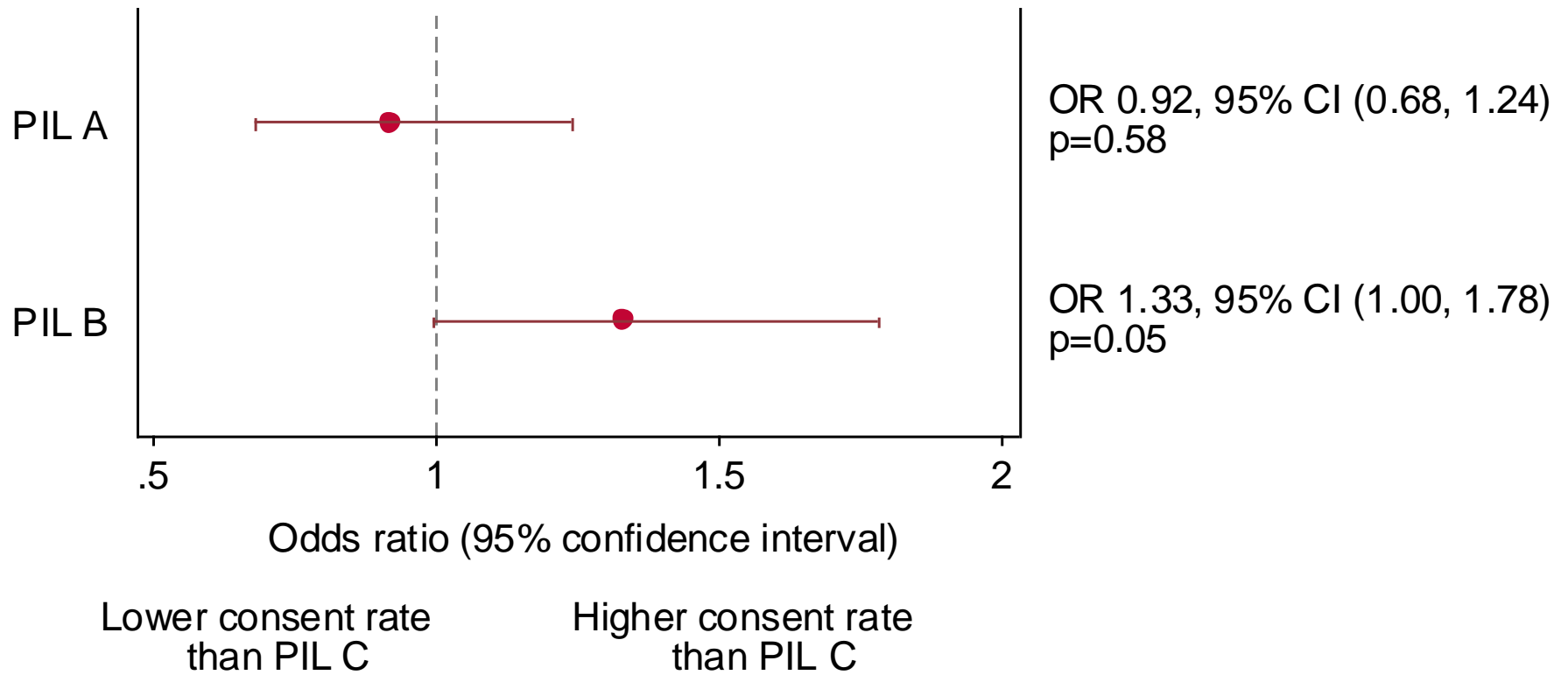
Methods

- Potential recruits randomised 1:1:1 to each format
- Content is identical in all formats
- Participants are not informed about the RCT
- Planned sample size = 1590 participants

Results

- Up to and including April 2017, 1108 letters have been sent to cardiac surgery patients.
 - Approximately 370 PILs of each version have been sent out.
 - 466 (42%) have consented to take part in OMACS.





PPI feedback

PIL B 'easier to read' than PIL C

PIL A 'looks like something you'd get through your door from a takeaway'

PIL A 'looks too professional'

Consensus: PIL B (HYBRID) was preferred

Conclusions

- PIL B (HYBRID) is more effective
- Transferred into Microsoft Word
- Being used as a template for other study PILs

Other SWATs planned

- What is the best way to collect high quality data about in-hospital complications?
 - Daily face-to-face collection on wards vs. review of medical notes after discharge
 - Time taken versus data completeness
 - Not started / likely to be redesigned as the move to ‘paper light’ has changed the way research nurses collect data

Other SWATs planned

- How can 12 month follow-up questionnaire return rates be maximised?
 - Part of a national SWAT looking at retention
 - ‘SWAT 24’ on the SWAT repository: Using a theoretically informed cover letter to improve response rates to annual postal questionnaires.
 - <https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/>
 - Aim to get results from different settings

Example text from the intervention:

“Such long-term studies require a **strong commitment** from doctors, patients and researchers to complete the study until the end. This means your surgeon and the OMACS team has **placed considerable trust in the** patients they asked to join this research. The study will **not be successful without the continued co-operation** and participation of their patients.”

Example text from the intervention:

“We recognise that completing a questionnaire is not something people usually do. Other study participants have found it helpful to plan ahead. For example, leaving the questionnaire out in the kitchen can serve as a reminder to complete it. Putting the envelope where it can’t be missed before leaving the house is a good reminder to take it with you to post.”

Example text from the intervention:

“You may feel that one person’s questionnaire is not that important in such a large study, but that is very far from the truth. **Every individual’s contribution is needed to maintain the integrity of the end results.**”

Thank you to the OMACS team

Any questions?