

Does the format of the participant information sheet affect the recruitment rate into an interventional trial? A Study Within a Trial (SWAT)

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Background

- Clinical trials are a key component of evidence based medicine, however many fail to recruit to time and target...
- ...this poses ethical issues over research waste¹.
- Finding ways to improve recruitment is a priority for methodology research²
- Information given to patients can be lengthy and difficult to understand^{3,4}.
- Simplifying patient information might improve the consent process, without compromising understanding^{5,6}

What did we do?

An "optimised" PIL (PIL A) was designed and patients were randomised (1:1) to receive this or the "conventional" style (PIL B)
Staff were provided envelopes in randomisation order and were not aware of the PIL until they opened the envelope with the patient

Columnar layout

Fewer pages

Reduced word count

Shorter paragraphs

Improved readability score

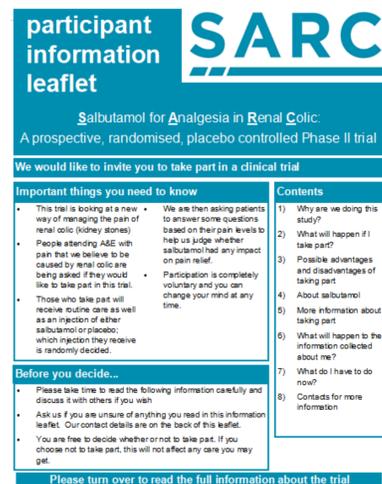


Fig.1: The front page of PIL A, with information on how it was designed to be improved on standard templates

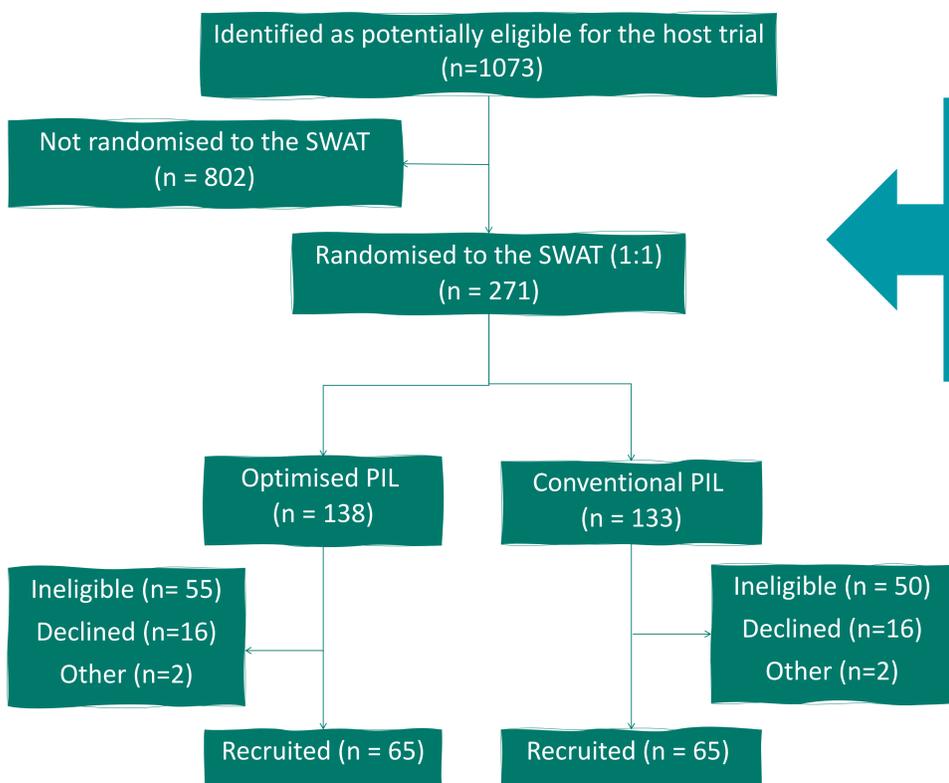
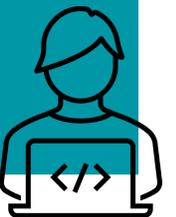


Fig.2: Flowchart of participant recruitment

Screening data were collected for patients, including reasons they were not recruited to the host trial (Fig. 2)

Analysis

- Analysis included all randomised participants based on which group they were assigned, irrespective of the reason they were not recruited.
- Recruitment rate was compared between the two PIL groups using a Chi-squared test for association at a 5% significance level.
- Responses to the decision making questionnaire were compared between the two groups using Kruskal Wallis or Fisher's Exact test



Decision making questionnaire

- All participants recruited to the host trial were asked to complete a Likert questionnaire designed to gather more information on the impact the PIL they were given had on their understanding and decision making⁷.
- Responses to the questions were compared between the two PIL groups but there were **no statistically significant differences** identified.
- The **biggest difference** of around 20% for "Yes, Completely" answers was observed for "I knew what taking part would look like" and "Information helped me make my decision" in favour of the optimised PIL, but these were not significant (p=0.069 and p=0.156 respectively).

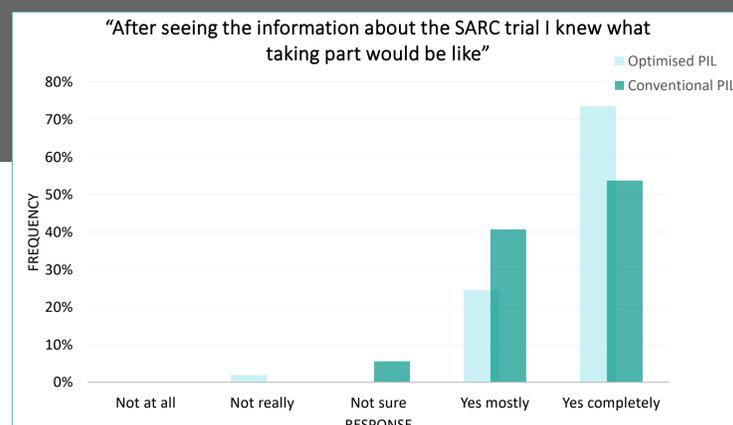


Fig.4: Observed percentages of responses to Q2 of the decision-making questionnaire

Comparison of recruitment rate

- Recruitment was compared between the two PIL groups.
- There was **no statistically significant difference** in recruitment between the two groups (p=0.771)

	Recruited	Optimised PIL	Conventional PIL	Total
Yes n (%)	65 (47)	65 (49)	130 (48)	
No n (%)	73 (53)	68 (51)	141 (52)	
Total n (%)	138 (51)	133 (49)	271 (100)	

Fig.3: Observed frequencies of recruitment for each group

Conclusions

- Recruitment was similar in the two PIL groups.
- On the whole, the answers given in the decision-making questionnaire were slightly more positive for the optimised PIL than the conventional PIL, but this was **not** statistically significant.
- Although the Improvements made to the PIL did not impact on recruitment, researchers could still consider ways to improve the information given to patients.

Strengths/Limitations

- It was straight forward and inexpensive to implement in a single site study.
- Implementation at multiple sites would entail site staff randomising, which may not be appropriate

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