The OMACS-PIL study - a randomised controlled study within the OMACS observational study

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Methodology

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Abstract

Background There has been little research to investigate whether the appearance of paper Patient Information Leaflets (PILs) used to describe research studies to potential participants influences their decision to take part. Embedding a Study Within a Study (SWAS) is an efficient way of answering this type of methodological question. We included a randomised SWAS within a large cohort study, Outcome monitoring After Cardiac Surgery (OMACS), to address this question. Methods Potential participants for the OMACS study were randomised to receive one of three PILs, identical in content but with varying formatting and use of colour: PIL A (enhanced format), PIL B (hybrid format) and PIL C (standard format). Consent to OMACS was the primary outcome. Consent rates using the three different PIL formats were collected and compared. Results For the SWAS, 1517 PILs were sent to potential participants and 640 (42%) consented to take part in OMACS. PIL B had the highest recruitment rate, with 45% of patients consenting to participation; 40% and 41% of patients consented to participation with PIL A and C respectively. Compared to PIL C, the consent rate was 4% higher with PIL B (45% versus 41%, 95% Confidence Interval (CI) -2% to +10%, p=0.16) and 1% lower with PIL A (40% versus 41%, 95% CI -7% to +5%, p=0.72). Conclusions PIL B, a hybrid format, led to the highest consent rate, and this format is being used for the remainder of the host study and will be used to inform the design of PILs for other research studies.

Background

Much research has been conducted on how to improve Patient Information Leaflets (PILs), the consent process and recruitment in Randomised Controlled Trials (RCTs) and to improve response rates to postal questionnaires and this is summarised in several reviews [1-6]. The main focus of this research with respect to PILs has been on the readability or length of PILs [7-15], use of different media such as audio-visual materials [5], or interactive electronic materials [16] rather than how the appearance of paper PILs can be improved. The outcomes have been patients' understanding of the study, or satisfaction with the informed consent procedure. There has been less focus on whether recruitment rates can be improved, leading to a lack of evidence in this area. The conclusion of a Cochrane review [4] was that there is currently no clear evidence as to whether modifications to the information presented to participants improves recruitment to RCTs. This conclusion is consistent with that of previous reviews that reported that more research is required[1, 2].

With respect to the format of the PIL, Reinert and colleagues [11] performed a quantitative and qualitative analysis of study PILs and concluded that information presented to potential participants *"needs to be well structured and designed in an appealing manner"* . This study focused on how the appearance of the paper PIL might affect the decision to take part in a study, rather than the content. However, efforts were still made to make sure the content was readable and the length of the PIL kept to a minimum. This research was conducted as a Study Within a Study (SWAS) by nesting it within a large cohort study, Outcome Monitoring After Cardiac Surgery (OMACS). The objective of the SWAS, OMACS-PIL, was to compare rates of consent using different formats of the host study PIL.

Methods

The Main Study (OMACS)

The OMACS study is an ongoing cohort study aiming to gain consent from cardiac surgery patients at our institution (University Hospitals Bristol NHS Foundation Trust) to collect and use quality of life data, plus routinely collected data on their operation and subsequent recovery to be used in a range of research studies. Patients are approached for consent by post 3 months after their operation. The inclusion criteria for OMACS are adult participants over the age of 18 years who have undergone cardiac surgery at our institution, and around 1000 patients per year are approached to take part. The only patients not eligible to participate are prisoners, patients without the mental capacity to give consent and patients whose main residence is outside the United Kingdom. OMACS is ongoing and the results of the SWAS will be applied to future recruitment to OMACS. This study was chosen as it uses postal consent, where the appearance of the PIL may have more impact than face-to-face consent, plus the large target population meant that the SWAS could be completed quickly.

The SWAS (OMACS-PIL)

OMACS –PIL was an RCT to investigate whether recruitment to the main OMACS study was affected by the format of the information provided to the potential participant. Three different information leaflets were prepared, each with the same content but using different styles and formatting. PIL A (enhanced format) and PIL B (hybrid format) were produced with a specialised graphics package called InDesign (Adobe Systems Incorporated) and PIL C (standard format) was produced using Microsoft Word (Microsoft Corporation). PIL A was a full colour tri-fold leaflet, PIL B was a double-sided A4 sheet using columns to break the text up and some colour on headings, and PIL C was a black and white A4 double-sided sheet with “standard” formatting. Examples of each format can be seen in Figure 1. Potential participants were randomly assigned to receive either PIL A, B or C in the ratio of 1:1:1.

The Study Population

The study population for OMACS-PIL comprised patients eligible for the OMACS study during the period of the SWAS. With the approval of an NHS REC (ref 14/EM/1222), patients were not informed of the SWAS as knowledge of the SWAS may have influenced how they viewed the PIL.

Outcome

The outcome measure was consent to OMACS in each of the groups receiving PIL A, B or C.

Sample size

Assuming a consent rate of 70% with PIL C (based on historic data from a similar system which ran over several years[17]), a sample size of 1590 (530 per group) would give 90% power to detect a 10% difference in consent rate between any pair of PIL formats, with an overall significance level of 5% (with a

Bonferroni correction for the three comparisons). This was the number of patients to be sent a PIL, rather than the number of patients required to consent.

Statistical Analysis

The consent rates from the three different PIL formats were described and the differences in consent rate between pairs of PILs were calculated with 95% confidence intervals using Stata version 15.1 (StataCorp LP, College Station, Tex). Analysis took place at the end of the recruitment period for the SWAS.

Public and patient involvement (PPI)

In order to get some qualitative information about the PILs, the PILs were presented to the Bristol Biomedical Research Unit Cardiovascular PPI group which is made up of representatives who have had cardiac surgery, to elicit their preferences for the format and appearance of the PILs and the reasons for their preferences.

Results

For the duration of the SWAS, 1517 invitation letters and PILs were sent to eligible cardiac surgery patients. The numbers of each format of PIL sent were: Format A 505, Format B 506 and Format C 506. The age and sex of the target population is described in Table 1. The mean age was 64.9 years (standard deviation 13.4), and 1079/1517, 71.1% were male. The average age and proportion of male patients was very similar across the 3 groups (see Table 1).

In total, 640 patients (42%) consented to take part in OMACS. Consent rates across the three PIL formats are shown in Fig 2. PIL B had the highest recruitment rate, with 45% of patients consenting to participation and PIL A had the lowest recruitment rate, with 40% of patients consenting to participation. Compared to PIL C ('standard' format) the consent rate was 4% higher with PIL B (95% confidence interval (CI) -2% to +10%, p=0.16) and 1% lower with PIL A (95% CI -7% to +5%, p=0.72).

When the different PIL formats were presented to our Bristol Biomedical Research Unit Cardiovascular PPI group, their general preference was for PIL B, and their least favourite was PIL A. The PPI group felt very strongly that PIL A (Enhanced format) looked too professional, and looked like advertising material, similar to leaflets that are posted through letterboxes 'advertising takeaways'. They also did not like the fact that the study logo took up most of the front page of PIL A, when on receipt of the PIL they would not know what OMACS was. By contrast, with PIL B and PIL C, they could quickly understand that OMACS was a research study. Although the group did not dislike PIL C (standard), on balance they felt that the columnar presentation of PIL B made it more 'attractive' and easier to read.

Discussion

OMACS-PIL has provided some evidence that the formatting of a PIL can influence the perception of the study by potential participants, although the differences in consent rates were not statistically significant. The research team had hypothesised that PIL A would be most popular, as it looked the 'most professional', but it was exactly this aspect that the PPI group did not like. The consistency between the quantitative finding and the PPI feedback reinforces the benefit of PPI being an integral part of research.

The sample size achieved was just short of the 1590 target. This is because, due to the lower than expected rates of consent across all PILs, the timing and mode of consent was changed to seeking face-to-face consent at the time of the admission for the cardiac operation. The decision to change to face-to-face consent coincided with the sample size for the SWAS almost being met, and the decision was made to halt OMACS-PIL at this point.

The modest increase in recruitment with PIL B is consistent with other research on the design of consent materials, however much of this previous research has included other interventions alongside changes to the PIL. For instance, in a RCT within the Avon Longitudinal Study of Parents and Children Study, potential participants were randomised to receive one of eight combinations of three interventions: a prior-notification postcard or no contact, a standard or professionally designed consent pack, and a phone or postal reminder[18]. Of these interventions, the most effective was the reminder phone call with a 6.4% higher response rate (95% CI +2.3 to +10.6%; P = 0.002). The professionally designed consent pack had some impact, increasing response rates by 2.7% (95% CI: −0.06% to 5.5%; P = 0.06), but the prior notification postcard had no effect. Phone call reminders can have significant resource implications, hence our decision not to include this as an intervention.

The MRC START programme has also looked at the format of the paper PIL, but this was part of an 'enhanced' PIL where the wording was refined after several rounds of user testing [12, 13]. This approach has resource implications and of the work published so far there have been only marginal improvements in recruitment [12, 15]. The Healthlines studies showed modest increases in a positive response to an invitation to participate in the study when using the enhanced PIL that, like OMACS-PIL, were not statistically significant (19% versus 16%, difference of 2.9%, 95% CI = -1.1% to 6.9% in the Healthlines Depression study, n = 1364, and 24.0% versus 21.9%, difference of 2.0%, 95% CI -4.3% to 8.4% in the Healthlines CVD study, n = 671) [12]. In Early CDT Lung Cancer Scotland (ECLS), the proportion of patients who positively responded to the invitation was 224/1136 (19.7%) in the intervention group (optimised PIL) and 205/1126 (18.2%) in the control group (difference of 1.5%, 95% CI = -1.7% to 4.7%) [15]. In addition to these MRC Start studies, the REFORM study concluded that there was limited evidence as to the benefit of using optimised information materials on recruitment and retention rates [14] and the recently updated Cochrane review of methods to enhance recruitment to RCTs, concluded that 'Using a tailored, user-testing approach to develop participant information leaflets makes little or no difference to recruitment.'[19]. There has been a Cochrane review of methods to increase response rates to postal questionnaires [6] but this focused on the design of the questionnaire or the method of postage (e.g. first class post) and not on the PIL provided to participants.

Resource implications for developing electronic media and the limited existing evidence that it can improve recruitment [5] were the reasons a multi-media approach was not explored in OMACS-PIL.

One area for concern in OMACS is that the overall response rate was much lower than expected. The expected response rate was based on similar work involving postal consent of cardiac surgery patients (Long Term Monitoring, LTM), which had been as high as 80% [17]. There are a few differences between the studies: the timing of approach for consent was at 3 months versus 12 months after cardiac surgery, and the 'packs' sent to OMACS patients had more documents and offered more choices in how to participate. LTM was conducted purely by post, whereas OMACS allowed participants to register, consent and complete questionnaires online if they preferred. This extra complexity may have contributed to the lower consent rate. The options were offered to allow participants to complete the study in the way most convenient to them, but it may be that the extra 'thinking' involved meant that they did not take part at all. Again, this shows that researchers need to not assume they know what patients want.

A limitation of this study is that all 3 PIL formats would not necessarily be suitable for all studies. The information required to convey this study was limited as OMACS is an observational study and not an RCT, and therefore was easily incorporated into the different formats. The format of PIL A may not be suitable for interventional trials where more information needs to be included. Even in OMACS, the volume of information included in the PIL has increased since the SWAS was conducted due to the requirements of NHS Digital, to obtain Hospital Episode Statistics which is a feature of the main study. The extra information was easily incorporated into PILs B and C but would have been more challenging to incorporate into PIL A due to the way that the information was presented and formatted. To make PIL B easier to use in OMACS and other studies without the need for specialist software, we have now recreated the format in Microsoft Word (Microsoft Corporation), and this format is now being used for the host study.

The PPI work included was informal and the PPI group was relatively small. However, their opinions were consistent with the quantitative finding of the SWAS.

A strength of OMACS-PIL is that the intervention could be implemented in any study and does not require rounds of user acceptability testing to see a positive improvement in recruitment rates as required by other projects (e.g. MRC START) or extra resources as required with telephone contact or using a multimedia approach. This means that it can be implemented with minimal or no impact on the study budget. OMACS-PIL was also randomised, and the participants were unaware of the SWAS and so were effectively 'blinded' to the interventions. However, based on the results of OMACS-PIL and the other similar studies, any improvement in consent rates are likely to be small.

Conclusions

The 'hybrid' PIL (PIL B) was preferred by the PPI group and resulted in a slightly higher consent rate to the host study than PIL A (enhanced format) or PIL C (standard format). PIL A, which was the most expensive to produce, was the least preferred option for the PPI group and did not improve consent rates.

PIL B is now being used as the PIL for the remainder of the OMACS study, and the findings from this study are being used to inform the design of PILs for interventional trials.

Abbreviations

HES Hospital episode statistics

LTM Long term monitoring

OMACS Outcome monitoring after cardiac surgery

PIL Patient information leaflet

PPI Public and patient involvement

RCT Randomised controlled trial

REC Research ethics committee

SWAS Study within a study

Declarations

Ethics approval and consent to participate

The study was approved by NRES Committee East Midlands - Nottingham 2 (14/EM/1222).

Consent for publication

Not applicable.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

LC designed the study with RB, RM and CR, and drafted the manuscript; JL created the enhanced and hybrid PILs; RE conducted the statistical analyses; DP, HT and MC reviewed and contributed to the writing of the manuscript. All authors read and approved the final manuscript

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Susan Plummer and Frances Gill sent out the PILs and collated the responses. Jenny Lamb designed PIL A and B.

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Tables

Table 1 - Patient demography, by PIL type

		PIL A (n=505)	PIL B (n=506)	PIL C (n=506)	Overall (n=1517)
Age (years)	Mean (SD)	64.6 (13.5)	64.7 (14.2)	65.4 (12.5)	64.9 (13.4)
Sex (male)	n (%)	356/505 (70.5%)	368/506 (72.7%)	355/506 (70.2%)	1079/1517 (71.1%)

Figures

Figure 1

Appearance of the PILs PIL A - tri-fold coloured leaflet produced using a graphic design package, InDesign, professional printers (= ENHANCED PIL); PIL B - coloured A4 sheet produced using a graphic design package, InDesign, professional printers (= HYBRID PIL); PIL C - black and white A4 sheet produced in Microsoft Word (= STANDARD PIL)

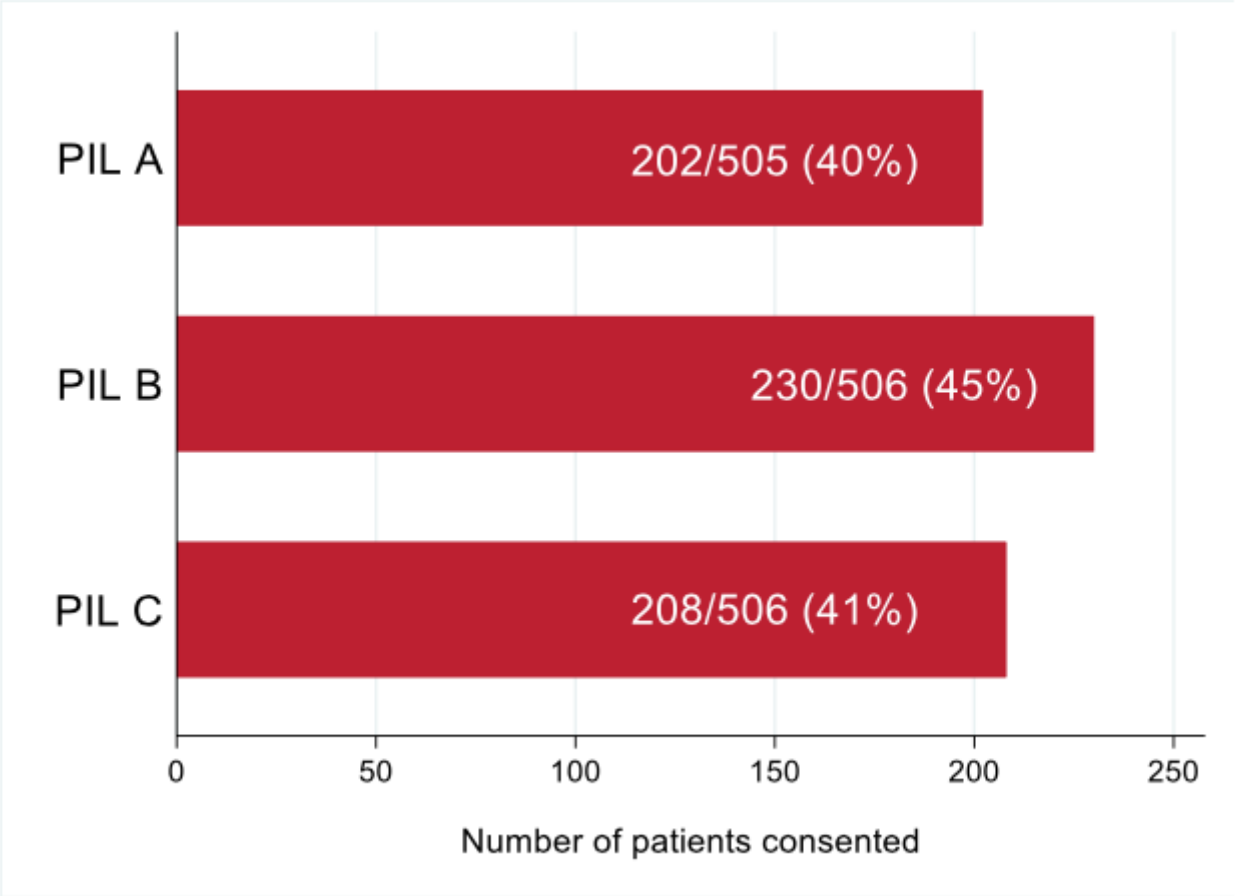

Figure 2

Consent rates by PIL type