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Sheridan, Rebecca [orcid.org/0000-0002-7715-1224](https://orcid.org/0000-0002-7715-1224), Knapp, Peter [orcid.org/0000-0001-5904-8699](https://orcid.org/0000-0001-5904-8699), Bower, Peter et al. (6 more authors) (Accepted: 2020) Patient recruitment to a diabetic retinopathy screening trial through optimised patient information materials : an embedded study within a trial (SWAT). F1000research. 779. ISSN 2046-1402 (In Press)

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## RESEARCH ARTICLE

# Patient recruitment to a diabetic retinopathy screening trial through optimised patient information materials: an embedded study within a trial (SWAT) [version 1; peer review: 1 approved, 1 approved with reservations]

Rebecca Sheridan<sup>1</sup>, Peter Knapp <sup>1,2</sup>, Peter Bower<sup>3</sup>, Vichithranie Madurasinghe<sup>4,5</sup>, Deborah M Broadbent<sup>6,7</sup>, Lola Awoyale<sup>8</sup>, Amu Wang<sup>6</sup>, Tracy Moitt <sup>8</sup>, on behalf of the ISDR Trial Group

<sup>1</sup>Department of Health Sciences, University of York, York, UK

<sup>2</sup>Hull York Medical School, York, UK

<sup>3</sup>Division of Population Health, Health Services Research & Primary Care, University of Manchester, Manchester, UK

<sup>4</sup>Nuffield Department of Population Health, University of Oxford, Oxford, UK

<sup>5</sup>Institute for Population Health Sciences, Queen Mary University of London, London, UK

<sup>6</sup>Department of Eye and Vision Science, University of Liverpool, Liverpool, UK

<sup>7</sup>St. Paul's Eye Unit, Royal Liverpool University Hospital, Liverpool, UK

<sup>8</sup>Liverpool Clinical Trials Centre, University of Liverpool, Liverpool, UK

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## Abstract

**Background:** Printed participant information about trials is often technical, long and difficult to navigate. Optimisation and user testing can improve information materials, and may improve participant understanding and rates of recruitment.

**Methods:** A study within a trial (SWAT) was undertaken within the ISDR trial. Potential participants in the ISDR trial were randomised to receive either the standard trial information or revised information that had been optimised through information design and user testing.

**Results:** A total of 3,169 patients were randomised in the SWAT. Recruitment rates to the ISDR trial were 25.3% in the optimised information group and 26.1% in the standard information group (odds ratio 0.951; 95% CI 0.752 to 1.201;  $p=0.672$ ). Clinic attendance rates were 71.6% in the optimised information group and 69.3% in the standard information group (OR 1.145; 95% CI 0.885 to 1.480;  $p=0.304$ ).

**Conclusions:** Optimisation of participant information through information design and user testing did not affect rate of recruitment to the host ISDR trial.


**Registration:** ISRCTN ID [ISRCTN87561257](https://www.isrctn.com/ISRCTN87561257); registered on 08 May 2014.

## Open Peer Review

Reviewer Status ? ✓

	Invited Reviewers	
	1	2
<b>version 1</b>	?	✓
28 Jul 2020	report	report

1. **Winfried M Amoaku**, University of Nottingham, Nottingham, UK

2. **Manavi D Sindal** , Aravind Eye Hospital and Postgraduate Institute of Ophthalmology, Pondicherry, India

Any reports and responses or comments on the article can be found at the end of the article.

**Keywords**

SWAT, trial, recruitment, patient information, user testing, diabetic retinopathy, screening



This article is included in the **Studies Within A Trial (SWAT)** collection.

**Corresponding author:** Peter Knapp ([peter.knapp@york.ac.uk](mailto:peter.knapp@york.ac.uk))

**Author roles:** **Sheridan R:** Writing – Original Draft Preparation, Writing – Review & Editing; **Knapp P:** Conceptualization, Data Curation, Investigation, Methodology, Writing – Original Draft Preparation, Writing – Review & Editing; **Bower P:** Conceptualization, Funding Acquisition, Investigation, Methodology, Writing – Review & Editing; **Madurasinghe V:** Formal Analysis, Methodology, Writing – Review & Editing; **Broadbent DM:** Conceptualization, Funding Acquisition, Methodology, Writing – Review & Editing; **Awoyale L:** Data Curation, Project Administration, Writing – Review & Editing; **Wang A:** Data Curation, Project Administration, Writing – Review & Editing; **Moitt T:** Data Curation, Methodology, Project Administration, Writing – Review & Editing;

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## Introduction

Information materials for potential randomised controlled trial participants are often long and complex<sup>1-3</sup>. This can result in a lack of understanding of key study details<sup>1,4,5</sup>, limiting the ability to provide informed consent.

One approach to improve materials is through optimisation and user testing, involving revisions to the text and design based on people's ability to find and understand informational content<sup>6</sup>. Whilst people tend to prefer the materials revised after user testing<sup>7,8</sup>, a recent review concluded there was no evidence that optimised information materials improve recruitment<sup>9</sup>. However, the relevant evidence base is small<sup>10-14</sup> and a recent 'review of reviews' found that information quality can facilitate research participation<sup>15</sup>.

## Study aims

This study within a trial (SWAT) aimed to assess whether optimisation through user testing of patient information materials could increase recruitment to the Individualised Screening for Diabetic Retinopathy (ISDR) trial<sup>16</sup>.

## Methods

### Ethical statement

ISDR was approved by the Health Research Authority (REC reference: 14/NW/0034). The SWAT was approved by Yorkshire and the Humber REC – South Yorkshire (11/YH/0271). The REC waived the requirement to obtain participant consent for the SWAT.

### Design

SWAT conducted within ISDR, which investigated the safety and acceptability of changing from annual screening to personalised (individualised) risk-based screening for diabetic patients<sup>16</sup>. This study is one of the SWATs run by the MRC-funded Systematic Techniques to Assist Recruitment to Trials (START) programme<sup>17</sup>.

### Participants

SWAT participants were eligible for ISDR<sup>18</sup> and aged 16 years or older.

### Intervention

All participants were posted a study invitation letter and participant information sheet (PIS) alongside their annual screening clinic appointment. The control group received the standard ISDR materials (see *Extended data*<sup>19</sup>) whilst the intervention group were sent optimised patient information materials (see *Extended data*<sup>20</sup>) developed through two rounds of user testing.

If the patient attended their scheduled screening appointment, they were approached by a researcher to determine whether they had received, read and understood the information and whether they wanted to participate in ISDR. Clinic attendance and trial participation were recorded. If a researcher was not available on the clinic date, patients were not invited to participate.

### User testing

User testing was undertaken face-to-face by Luto Research Limited at their premises in Leeds, UK, and involved 20 people,

to reflect the age and gender distribution of the ISDR target population. In the first testing round 10 participants were given printed copies of materials and read the standard invitation letter and PIS (see *Extended data*)<sup>19</sup>. They were then asked to locate and demonstrate their understanding of 16 key items of trial information within the materials<sup>6</sup>. Materials were then revised based on participants' responses. A second testing round was then completed using the same method, testing revised versions of the PIS and invitation letter.

Through testing, wording edits were made to the invitation letter to simplify content. Changes to the PIS included adding a title page, a summary of key points and a contents page, highlighting headings using coloured text and enlarged font, and simplifying wording. The final optimised PIS was presented as an A5 booklet (see *Extended data*)<sup>20</sup>.

## Outcomes

The primary outcome measure was the proportion of patients in each group who were randomised within ISDR. The secondary outcome was the proportion of patients attending their screening appointment.

### Sample size

A power estimate was generated using an estimated baseline recruitment rate of 20%, whereby running the trial for 16 weeks (clusters) would provide 84% power to detect a planned 10% difference (alpha 0.05).

### Randomisation

Cluster randomised allocation to receive the standard or optimised PIS by week of mail-out (1:1), by random number generator, determined by date of clinic appointment; the SWAT ran for sixteen weeks (January-May 2016). Patients attended clinic at one of seven sites across Liverpool, UK. Concealment of allocation was achieved because the appointment schedule was set before SWAT allocations were randomised. Recruiting researchers were not masked as they saw the ISDR booklet the patients brought with them; patients were not masked but were nevertheless unaware that a SWAT was ongoing.

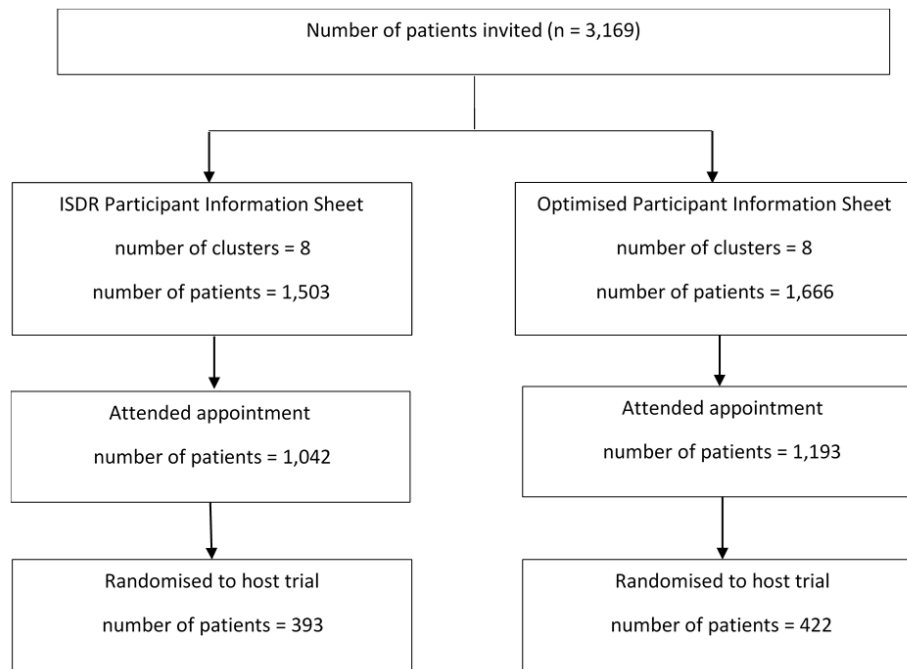
### Statistical analysis

Odds ratios (ORs) and corresponding 95% confidence intervals (CIs) were calculated to compare the proportion of patients from each randomised group (standard or optimised information) and the proportion of patients attending their appointment. Intention-to-treat analysis was used, with patients randomised to the SWAT irrelevant of whether a researcher was available for recruitment. Analyses were adjusted for cluster design and conducted in Stata version 14.2<sup>21</sup>.

## Results

3,169 participants were invited, 1,503 (47.4%) were randomised to the control group and 1,666 (52.6%) to the intervention group (*Figure 1*)<sup>22</sup>.

A total of 2,235 (70.5%) patients attended a screening appointment and 815 (25.7%) patients were randomised to host trial (*Table 1*). There was no difference between the control group and the intervention group in randomisation (26.1% vs 25.3%; OR=0.951, 95% CI 0.752 to 1.201, p=0.672) or



**Figure 1.** Flow diagram of recruitment to the host trial.

**Table 1.** Attendance at screening appointment and randomisation to the host trial by intervention group.

Outcome	Intervention				Odds ratio (95% confidence interval)	p - value
	ISDR participant information sheet		Optimised participant information sheet			
	number of patients	%	number of patients	%		
<sup>1</sup> Attended screening appointment	1,042/1,503	69.3%	1,193/1,666	71.6%	1.145 [0.885 to 1.480]	0.304
<sup>2</sup> Randomised to host trial	393/1,503	26.1%	422/1,666	25.3%	0.951 [0.752 to 1.201]	0.672

<sup>1</sup> Intra-cluster correlation coefficient is 0.008.

<sup>2</sup> Intra-cluster correlation coefficient is 0.004.

attendance (69.3% vs 71.6%; OR=1.145, 95% CI 0.885 to 1.480, p=0.304).

An additional 620 patients attended an appointment when no researcher was present and therefore were not asked to participate in ISDR. Sensitivity analysis including those patients did not substantially alter results.

**Discussion**

There was no statistically significant difference in randomisation to ISDR or attendance rates between those receiving standard or optimised materials. This is consistent with previous research<sup>9</sup>, including other embedded trials within

MRC START which have observed only small effects on recruitment<sup>11-13</sup>.

There was no prior reason to expect recruitment rates to be affected by date of posting because choice of mail-out date was determined by clinic appointment and there were no systematic trends in appointments by time.

Whilst there was no impact on recruitment, the optimised materials may have improved understanding of the trial thus enabling patients to make a more informed decision. Improved comprehension could also increase retention, due to greater understanding of the trial prior to recruitment. These outcomes

were not assessed and further research examining this is warranted.

The study sample size was large, and results are likely to be generalisable to adult diabetic patients.

## Conclusion

Optimised patient information materials did not affect appointment attendance rates or randomisation to the host trial.

## Data availability

### Underlying data

Figshare: ISDR trial SWAT dataset. <https://doi.org/10.6084/m9.figshare.12388136><sup>22</sup>.

### Extended data

Figshare: ISDR trial SWAT original participation materials. <https://doi.org/10.6084/m9.figshare.12388190>.v1<sup>19</sup>.

This project contains the following extended data:

- Appendix 1 – Original ISDR trial invitation letter.docx
- Appendix 2 – Original ISDR trial PIS.docx

Figshare: ISDR trial SWAT optimised participant materials. <https://doi.org/10.6084/m9.figshare.12388220>.v1<sup>20</sup>.

This project contains the following extended data:

- Appendix 3 – Optimised ISDR trial invitation letter.docx
- Appendix 4 – Optimised ISDR PIS.pdf

## Reporting guidelines

Figshare: CONSORT checklist for ‘Patient recruitment to a diabetic retinopathy screening trial through optimised patient information materials: an embedded study within a trial (SWAT)’. <https://doi.org/10.6084/m9.figshare.12388175>.v1<sup>23</sup>.

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](https://creativecommons.org/licenses/by/4.0/) (CC-BY 4.0).

## Acknowledgements

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The ISDR Trial Group is: Simon P Harding (Chair), Deborah M Broadbent (ISDR Trial Principal Investigator), Paula Byrne, Anthony C Fisher, Mark Gabbay, Marta García-Fiñana, Marilyn James, Tracy Moitt, John R Roberts, Daniel Seddon, Irene M Stratton, Paula Williamson, Duncan Appelbe, Lola Howard, Ayesh Alshukri, Abigail Bennett, Christopher P Cheyne, Paula Byrne, Antonio Eleuteri, Christopher Grierson, Bryar Kadir, Mehrdad Mobayen-Rahni, Andrew Ovens, Christopher J Sampson, David Szmyt, Clare Thetford, Amu Wang, Helen Cooper, John Collins, Sue Howlin, John Kelly, Nathalie Massat, Gideon Smith, Vineeth Kumar, Chris Rogers, Julia West, Naveed Younis.

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# Open Peer Review

Current Peer Review Status: ? ✓

Version 1

Reviewer Report 26 November 2021

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**Manavi D Sindal** 

Aravind Eye Hospital and Postgraduate Institute of Ophthalmology, Pondicherry, Tamil Nadu, India

The Authors present interesting information on optimised patient information material and its impact on patient recruitment to the trial.

They randomised patients into two arms- one arm received standard PIS, while the other received an optimised PIS with more details on the trial as well as simpler language. The optimised material was developed after mock rounds with age matched controls.

The SWAT revealed that the attendance to screening as well as recruitment to ISDR trial was comparable in both arms. Use of optimised material did not alter the attendance rates.

The authors utilise robust methodology and sound statistics.

A few minor alterations can make the manuscript better:

1. In the abstract- ISDR needs expansion.
2. In sample size calculation- the derived sample size has to be mentioned.
3. Discussion can be more elaborate, and mention results of previous reports.

**Is the work clearly and accurately presented and does it cite the current literature?**

Yes

**Is the study design appropriate and is the work technically sound?**

Yes

**Are sufficient details of methods and analysis provided to allow replication by others?**



Yes

**If applicable, is the statistical analysis and its interpretation appropriate?**

Yes

**Are all the source data underlying the results available to ensure full reproducibility?**

Yes

**Are the conclusions drawn adequately supported by the results?**

Yes

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Vitreoretinal surgery

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

Reviewer Report 22 April 2021

<https://doi.org/10.5256/f1000research.27513.r83385>

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**Winfried M Amoaku**

Academic Ophthalmology, University of Nottingham, Nottingham, England, UK

This manuscript reports on a study within a trial (SWAT) undertaken within the 'Individualised Screening for Diabetic Retinopathy' (ISDR) trial to assess optimisation through user testing of patient information materials, and effects on recruitment. This was to test a hypothesis that there was no evidence that optimised information materials improve recruitment into studies.

Potential participants in the ISDR trial were randomised to receive either the standard trial information or revised information optimised through information design and user testing. Amongst the 3,169 randomised into this study recruitment rates were 25.3% in the optimised information group and 26.1% in the standard information group. Clinic attendance rates were similar in the study groups.

The study concluded that optimisation of participant information through information design and user testing did not affect rate of recruitment.  
The study findings are useful, and worth indexing.

However, the manuscript can be improved with revisions as follows:

**'Introduction'**

Para 1 line 3: to read 'the ability of potential participants to...'

Para 2 line 2: to read: 'which involves..' (instead of 'involving')

Para 2 line 6: change 'improve' to 'improved'

### **'Intervention'**

Revise to read: 'All participants were sent study information.....alongside their annual screening clinic appointment by post.'

### **'Results'**

Avoid commencing sentences with digitised numbers.

Insert 'A total of' preceding '3,169 participants'.

User Testing, Line 9: insert and suggestions after "participants' responses" to read "participant responses and suggestions".

**Is the work clearly and accurately presented and does it cite the current literature?**

Yes

**Is the study design appropriate and is the work technically sound?**

Yes

**Are sufficient details of methods and analysis provided to allow replication by others?**

Yes

**If applicable, is the statistical analysis and its interpretation appropriate?**

Yes

**Are all the source data underlying the results available to ensure full reproducibility?**

Yes

**Are the conclusions drawn adequately supported by the results?**

Yes

**Competing Interests:** No competing interests were disclosed.

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.**

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