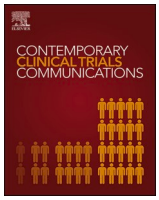
Contemporary Clinical Trials Communications 28 (2022) 100936

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc



Comparing the effects of a patient-designed-and-informed participant information leaflet in comparison with a standard, researcher-designed information leaflet on recruitment, retention and understanding: A study-within-a-trial

Christopher P. Dwyer [a], Robert A. Joyce [b], Fionnuala Rogers [c], Sinéad M. Hynes [b,*]

[a] Applied Psychology, School of Social Science, Technological University of the Shannon, Athlone, Ireland
[b] Discipline of Occupational Therapy, School of Health Sciences, National University of Ireland, Galway, Ireland
[c] Cardiff University, Cardiff, Wales, UK

ARTICLE INFO

Keywords:
Recruitment
Retention
SWAT
Study-within-a-trial
PPI
Patient involvement

ABSTRACT

Background and aim: The process of trial recruitment is vital, given its impact on resources, statistical power and the validity of findings. A participant information leaflet (PIL) is often the initial and primary source of information engaged by potential participants during recruitment. Research suggests that a variety of manipulations to a PIL can be made during its development to enhance understanding, readability and accessibility. In light of this, PIL-design led by *Public and Patient Involvement* (PPI) may also yield positive effects in this respect, as well as consent and retention. This study-within-a-trial (SWAT) compared the effects of a PPI-developed PIL with a standard, researcher-developed PIL on rates of consent, retention, decision certainty, understanding, readability, accessibility, likeability and decision to consent.

Method: This SWAT used a double-blind, two-armed randomised design. The SWAT was conducted within a host trial of cognitive rehabilitation in multiple sclerosis.

Results: A total of 234 people expressed interest in the trial, of which 94 were retained at 6-month follow up. Results revealed no effects on levels of consent and retention between the two PIL groups.

Conclusions: These null effects provide interesting points of discussion and important implications for not only future research on PILs, but also for future research that involves recruitment to health-related interventions.

1. Background

A research intervention's recruitment process is crucial for its success, given the impact on statistical power, validity of findings and investment of resources [1,2]. The participant information leaflet (PIL) is the primary source of information used by potential participants during the recruitment process. It is critical for ensuring that potential participants understand both the broader and more specific implications of what they are consenting to Ref. [3]. Though the informed consent process necessitates provision of some form of ethically reviewed and approved PIL, such consideration does not guarantee the *quality* of the PIL (e.g. with respect to readability or accessibility). Thus, it can be argued that just because the presentation of a PIL is not unethical, that does not ensure that it is appropriate [4].

Understanding of PILs is often poor amongst participants in health-related research [3,5]. Information leaflets are often complex [6]; for example, with respect to length and accessibility of language [7,8]. Though the information provided within the PIL must contain sufficient detail and certain characteristics in order to achieve the ethical requirements pertaining to informed consent [9], the detail and complexity must be balanced with the competing demand of comprehension [6]. On the other hand, though research does indicate that PILs can often be lengthy [10] and, as a result, less likely to be read [6,11], it also indicates that reducing length is ineffective and may negatively impact comprehension due to, for example, a lack of clarity [12].

A limited body of research, yielding mixed results, has evaluated the effects of various manipulations to PIL development on recruitment and comprehension, such as out-sourcing for professionally-designed PILs [e.g.7]; using iterative, user-tested formats [e.g. 7; 13]; and comparing font adjustments [e.g. 14]. However, in practical terms, some of these

* Corresponding author. Discipline of Occupational Therapy, School of Health Sciences, Áras Moyola, National University of Ireland, Galway, Ireland.
E-mail address: sinead.hynes@nuigalway.ie (S.M. Hynes).

https://doi.org/10.1016/j.conctc.2022.100936
Received 10 December 2021; Received in revised form 11 April 2022; Accepted 25 May 2022
Available online 2 June 2022

manipulations can be costly with respect to both finances and time, which may not be feasible for trials limited by funding restrictions. As a result, it is necessary to identify a practical, feasible means of enhancing PIL clarity and comprehension, as well as subsequent participant retention [4].

People express interest in participating in health-related research for a variety of reasons, for example to achieve some benefit to their own personal health [15], but may choose not to take part because of fear, worry, or lack of understanding of research requirements. PIL-design by an individual eligible to participate in the intervention (e.g. living with the chronic illness), but without any personal bias involved with actually participating, may yield positive effects on recruitment and comprehension; that is, PIL-development led by a *Public and Patient Involvement* (PPI) member. PPI is an effective means of enhancing the likelihood of a successful trial by involving people with lived experience of a particular condition as partners throughout the research process [16,17]. In light of extant theory and research, a PIL developed through PPI may enhance trial understanding and recruitment (with respect to consent), as well as participant retention.

The aim of the current study is to compare the effects of two PILs designed to facilitate informed consent of potential participants – a PPI-designed-and-informed PIL (PPI-PIL) and a standard, researcher-designed PIL (SR-PIL) on: recruitment (i.e. consent), decision certainty, retention, understanding, readability, accessibility, likeability and decision to consent.

2. Methodology

The protocol for this study-within-a-trial (SWAT) was previously published in HRB Open Research [see 4] and registered at the Northern Ireland Network for Trials Methodology Research SWAT Store (SWAT105; 30/JUL/2019). Ethical approval was awarded by Galway University Hospitals on August 13, 2019, Ref: C.A 2231 and was conducted at the National University of Ireland, Galway. SWAT Reporting Guidelines Template (PROMETHEUS group, 2021) was used in the reporting of this SWAT and can be viewed in Appendix 1.

2.1. Study design

A SWAT design was used here. A SWAT is a self-contained research study embedded within a host trial for the purpose of investigating or evaluating trial processes and/or alternatives [18]. The SWAT was part of a larger, single-blind, cluster-randomised controlled feasibility and preliminary efficacy trial of the Cognitive Occupation-Based programme for people living with Multiple Sclerosis (COB-MS) [19], from here on referred to as 'the host trial'. This SWAT was a double-blind, randomised trial comparing the effects of a patient-designed-and-informed PIL with a standard, researcher-designed PIL. Both patients and those collecting outcome data were blinded to allocation.

2.2. Participants

No separate inclusion or exclusion criteria was necessary for the SWAT. The host trial included people with a diagnosis of multiple sclerosis (MS), 18 years of age or older, who were fluent in written and spoken English, had cognitive difficulties, and no neurologic history other than MS, no history of major depressive disorder, schizophrenia, or bipolar disorder I or II; no history of diagnosed substance use or dependence disorder.

People with MS were not eligible to participate if they had cognitive impairment that would affect reliable participation or capacity to give informed consent; were experiencing a current relapse; undergoing cognitive rehabilitation; and/or were incarcerated or institutionalised.

Participant recruitment took place between November 2019–August 2020 (allowing for rechecking consent with participants following COVID-19 impacts). Two-hundred and thirty-four individuals made contact to express interest in participating in the host trial, of whom 207 provided contact and postage details and were, subsequently, sent a randomly allocated PIL (104 PPI-PIL; 103 SR-PIL). Fig. 1 has SWAT flow diagram of participants through the SWAT.

2.3. Materials & measures

Both participant information leaflets, the PPI-PIL and the SR-PIL, as well as a GDPR addendum and consent form can be viewed online at Open Science Framework: https://osf.io/d52gx/,[20]. Outcome measures included:

- **Consent** was measured dichotomously by whether or not the individuals sent a signed informed consent form to participate in the host trial by post or provided in person to research assistant.
- **Retention** was measured dichotomously by whether or not the participants completed the trial. Notably, *level of retention* was also measured by (1–4) testing phases completed.
- The **Decisional Conflict Scale** [DCS; 21] is a 16-item questionnaire, answered via a five-point Likert scale, ranging from strongly agree (0) to strongly disagree (4), used to measure decision certainty, with respect to decision to provide consent to participate in this SWAT. The scale is established as valid and reliable with test–retest correlations and Cronbach's α of 0.78 [22]. Reliability in the current SWAT was $\alpha = 0.95$. The five sub-scales of the DCS were also analysed (informed: $\alpha = 0.91$; values clarity: $\alpha = 89$; support: $\alpha = 0.66$; uncertainty: $\alpha = 0.79$; and effective decision: $\alpha = 0.88$).
- **Understanding, readability, accessibility, likeability and decision to consent** were assessed via a six-item questionnaire (see Table 1), developed through discussion and agreement with a PPI advisory panel, to be answered via six-point Likert scale, ranging from strongly disagree (0) to strongly agree (5). Reliability for understanding and decision to consent were $\alpha = 0.89$ and $\alpha = 0.07$, respectively.

2.4. Procedure

Participants were recruited through advertisement in various media and relevant outlets, across the Republic of Ireland. Advertisements did not provide detailed trial information that would contaminate or influence assimilation via the PILs. Interested parties self-selected through contacting the researchers by email or phone. Verbal consent to receive a PIL through post was obtained through this contact, before making their decision to participate in the host trial. Participants were not aware that two versions of the PIL were available. Study information was only provided by post (and not electronically). Individuals interested in further information were randomly allocated to either the SR-PIL or PPI-PIL conditions, using 1:1 allocation, via randomised block permutation (i.e. two randomised blocks of four and six per block). Participants were also sent a consent form for the host trial and the outcome measures relevant to the SWAT. SWAT data and formal, written consent were either posted back to the research team (stamped-addressed envelope provided) or collected by a researcher upon visiting the participant on baseline assessment for the host trial. The researcher who created the randomisation schedule was not involved in posting out material or consenting participants.

The *standard, researcher-designed PIL* (SR-PIL) was purpose-written for the host trial by a post-doctoral researcher with over 10 years' research experience. The SR-PIL was written in light of templates from past trials for structure and included/addressed study background, procedure, eligibility, consent, funding/support and descriptions of both potential risks and benefits. Available here: Information Sheet Number 1 https://osf.io/d52gx.

The *PPI-designed-and-informed PIL*(PPI-PIL) was developed by a PPI member of the research team, who would otherwise be eligible to participate in the intervention. The PPI member had neither experience

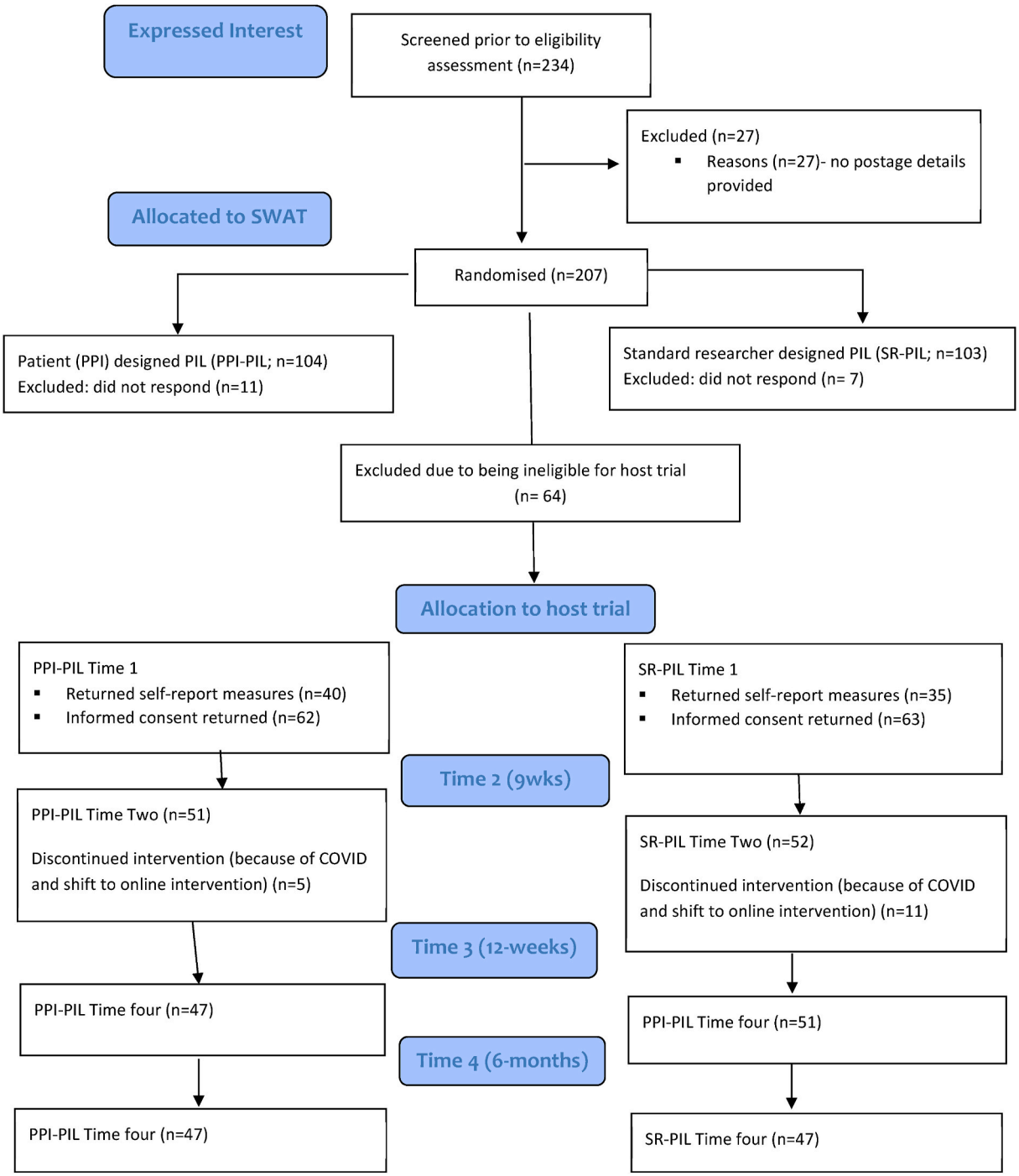


Fig. 1. CONSORT diagram [20]- flow of participants through SWAT.

nor a background in research or healthcare; and developed the PIL within his first week of taking up a PPI role, which further diminished potential bias from working in a research environment. Thus, the PPI-PIL was written from a patient perspective, in light of what was deemed both necessary for potential participants to know and useful to know about the host trial. The only restriction on PPI-PIL development was that the PPI member was required to include/address information consistent with the SR-PIL, such as study background, procedure, eligibility, consent, funding/support and descriptions of both potential risks and benefits. The PPI member was given broad headings of these items but no other information or templates were provided, unless required. Available here: Information Sheet Number 2 https://osf.io/d52gx.

The PIL developers were blinded to each other's PIL and did not liaise or discuss the PILs during their development, both of which were submitted separately to the principal investigator for subsequent submission for ethical approval. No changes were made by the principal investigator. Both PILs were accompanied by a principal investigator-developed addendum regarding GDPR guidelines in order to ensure consistency in this context, for ethical purposes. Both PILs passed ethical approval stage with no changes required.

2.5. Data analysis

SPSS (version 26) was used to analyse the data. A series of chi-square tests of independence was performed to examine the relationship

Table 1
Questionnaire regarding understanding, readability, accessibility, likeability and decision to consent.

1. The *Study Information Leaflet* played a large role in my decision to participate in the study. (Decision to consent)
2. I was able to read the information presented in the *Study Information Leaflet.* (Readability/Understanding)
3. I was able to understand the information presented in the *Study Information Leaflet.* (Understanding)
4. The language used in the *Study Information Leaflet* was accessible to me. (Accessibility/Understanding)
5. I knew I was going to consent participate before I was even presented the *Study Information Leaflet.* (Decision to consent)
6. Overall, I liked *Study Information Leaflet* that was presented to me. (Likeability)

between these two source perspectives (i.e. PPI-PIL and SR-PIL) on both consent and retention. A series of analyses of variance was also conducted to examine the effects of source perspective on level of retention, understanding, readability, accessibility, likeability, decision certainty and decision to consent regarding the two different PILs.

3. Results

Two-hundred and seven participants (N = 207) were sent either a SR-PIL or a PPI-PIL to review before providing informed consent, along with the questionnaire pack. Of those, 64 were ineligible to take part; 18 either explicitly declined participation or did not respond (11 PPI-PIL; 7 SR-PIL); 75 returned the self-report measures (40 PPI-PIL; 35 SR-PI)l; and125[1] sent back informed consent. From the time of baseline assessment (N = 113), 103 completed T2 (9-weeks from baseline) assessment, 98 completed T3 (3-month follow-up) assessment and 94 completed the final, T4 (6-month follow-up) assessment. See Fig. 1 for flow diagram of participants through SWAT [23].

3.1. Self-report measures

Descriptive statistics are presented in Table 2. Results from a series of independent samples t-tests revealed a significant difference between groups on two DCS sub-scales, with those receiving the SR-PIL scoring higher on both 'informed' ($t = 2.16$, $df = 71$, $p = .034$, two tailed, $d = 0.51$) and 'values clarity' ($t = 2.11$, $df = 71$, $p = .039$, two tailed, $d = 0.49$). There were no other significant differences between groups. Table 3 presents correlations among outcome measures.

3.2. Consent & retention

A series of chi-square tests were conducted to assess potential differences between groups on consent and retention. Results revealed no difference between groups on level of consent (SR-PIL: 63 consented, 7 did not; PPI-PIL: 62 consented, 11 did not). The odds ratio for consent is 0.9373 between PPI-PIL and SR-PIL, with 95% confidence interval (−0.622, 0.4924).

Following consent, 55 SR-PIL and 58 PPI-PIL completed baseline. Notably, three individuals who had completed baseline dropped out in light of COVID-19 and were subsequently dropped from this analysis as a result of reasoning unrelated to the PILs (consistent with footnote 1). Upon restart, there were 54 SR-PIL and 56 PPI-PIL. At T2, 52 SR-PIL were retained in comparison with 51 PPI-PIL. At T3, 51 SR-PIL were retained in comparison with 47 PPI-PIL. Finally, at T4, 47 SR-PIL were retained in comparison with 47 PPI-PIL. There were no significant differences regarding retention at any time point. The T3 the odds ratio for retention between PPI-PIL and SR-PIL is 1.0667, with 95% confidence interval (0.25449, 1.87891).

Table 2
Descriptive statistics for self-report measures.

Measure	Group	N	M	SD
Decision to consent (Q1)	SR-PIL	35	3.97	1.10
	PPI-PIL	40	3.93	1.02
Readability/Understanding (Q2)	SR-PIL	35	4.60	.69
	PPI-PIL	40	4.70	.61
Understanding (Q3)	SR-PIL	35	4.63	.55
	PPI-PIL	40	4.55	.81
Accessibility/Understanding (Q4)	SR-PIL	35	4.69	.47
	PPI-PIL	40	4.60	.67
Decision to consent (Q5)	SR-PIL	35	4.23	1.11
	PPI-PIL	40	3.83	1.50
Likeability (Q6)	SR-PIL	34	4.24	.92
	PPI-PIL	40	4.50	.64
Decision to consent Total	SR-PIL	35	4.74	1.60
	PPI-PIL	40	5.10	1.85
Understanding Tot	SR-PIL	35	13.91	1.44
	PPI-PIL	40	13.85	2.01
DCS Total	SR-PIL	35	8.17	7.67
	PPI-PIL	38	5.42	6.40
Uncertainty (DCS sub-scale)	SR-PIL	35	1.46	1.62
	PPI-PIL	38	1.05	1.33
Informed (DCS sub-scale)	SR-PIL	35	1.86	1.73
	PPI-PIL	38	1.03	1.55
Values Clarity (DCS sub-scale)	SR-PIL	35	1.97	1.89
	PPI-PIL	38	1.13	1.51
Support (DCS sub-scale)	SR-PIL	35	1.26	1.52
	PPI-PIL	38	1.00	1.38
Effective Decision (DCS sub-scale)	SR-PIL	35	1.63	1.93
	PPI-PIL	38	1.21	1.61

3.3. Post Hoc analysis

Subsequent to participant consent, the researchers were contacted by an independent researcher, conducting a study on the 'readability and understandability' of PILs in Ireland and the UK [24], in which the two PILs from this SWAT were included within the analysis. Results revealed that, relative to 176 PILs analysed, the SR-PIL was rated 'difficult' with respect to reading ease (among 51.3% of the sample); and found to have a reading age of 18.4 years ($M = 16.1$, where 11–12 is recommended); a mean sentence length of 24 words (among 35.3%, in which 15–20 words was recommended); a clear communication score of 46.7 (M = 68.5, in which >90 is recommended); and a suitability assessment score of 69 (i.e. layout and presentation), which was deemed 'adequate' – one point shy of 'superior' (M = 66). On the other hand, the PPI-PIL was rated as using 'plain English', (among 7.1% of the sample), with a reading age of 14.5, (which was closer to the recommended level), a mean sentence length of 18.7, a clear communication score of 71.4 and a suitability assessment score of 80, which was deemed as 'superior'. The results suggest that the PPI-PIL achieved recommended thresholds on reading ease, mean sentence length and suitability, whereas the SR-PIL only achieved recommended levels on suitability. In a broader context, the PPI-PIL was deemed more 'readable and understandable' than the SR-PIL in all categories assessed.

4. Discussion

4.1. Interpretation of results

Though the current research produced a number of non-significant findings, these null effects are both interesting and important to consider for a number of reasons. First, there was no important effect of PIL on rate of consent or on retention at any time point. There are a number of possible explanations for these null effects. With respect to retention, it could be the case that a PIL it not likely to have an effect on retention or attrition rates, which is a perspective consistent with recent

[1] The study was delayed in light of COVID-19, by approximately six months, in the time between consent and baseline assessment. During this time, 12 participants dropped out for reasons outside the remit of this SWAT.

Table 3
Correlations among relevant outcome measures.[3].

	1	2	3	4	5	6	7	8	9	10	11	12
1. DCS	–											
2. Uncertainty	.91[3]	–										
3. Informed	.86[3]	.67[3]	–									
4. Values Clarity	.88[3]	.75[3]	.83[3]	–								
5. Support	.84[3]	.77[3]	.61[3]	.58[3]	–							
6. Effective Decision	.90[3]	.83[3]	.64[3]	.69[3]		–						
7. Understanding	.35[2]	.26[1]	.36[2]	.32[2]	.27[1]	.48[3]	–					
8. Readability	.30[1]	.27[2]	.28[1]	.35[2]	.21	.21	.88[3]	–				
9. Accessibility	.35[2]	.23[1]	.37[2]	.32[2]	.28[1]	.33[2]	.92[3]	.70[3]	–			
10. Likeability	.58[3]	.47[3]	.60[3]	.57[3]	.39[2]	.48[3]	.37[2]	.40[3]	.33[2]	–		
11. Decision to Consent	.09	.03	.14	.15	.11	.02	-.13	-.02	-.22	.24[1]	–	
12. Level of Retention												–

research that reviewed retention strategies and found that it is still not clear what might help to encourage people to stay involved in trials [25].

Given the likelihood of additional correspondence between researchers and participants following consent, there are a wide array of variables that could potentially influence retention or attrition above and beyond the reading of a PIL at some time in the past. Moreover, in the context of the host trial, the likelihood of the PIL being remembered for an extended period of time was low (especially following a six-month delay in light of COVID-19), given the cognitive difficulties associated with the cohort being studied as part of the host trial. This perspective is also consistent with research indicating that study participants (who do not necessarily have cognitive difficulties) often forget or fail to recognise important aspects of the consent process when agreeing to participate in research [e.g. 26]. Thus, for these reasons, the null effects on retention should not be considered surprising.

It could also be the case, with respect to both retention and consent, that both PILs were adequately informative with respect to relaying the key information necessary to make a decision as to whether or not to commit to a study's protocol and/or provide consent, as reflected in the similar levels of consent and, perhaps to a lesser extent, retention. The evidence-base for SWATs focused on recruitment to randomised trials is ever-increasing [27] and there is high-certainty evidence that having an open trial and using telephone reminders (in postal intervention) improves recruitment. Interestingly there is also high-certainty evidence to suggest that a specialised way of developing PILs has little or effect on recruitment [27], which may reflect some of the findings seen here.

Though subsequent research by O'Sullivan and colleagues [24] suggests that the PPI-PIL in this SWAT was more 'readable' and 'understandable' (with respect to reading ease, reading level, sentence length, clarity and presentation), this speculation remains a distinct possibility given that both versions of the PIL were required to include information on study background, procedure, eligibility, consent, funding/support and descriptions of both potential risks and benefits. This perspective then suggests that even though the PPI-PIL was more readable and understandable, it does not mean that the SR-PIL could not be read or understood – perhaps the SR-PIL just requires more focus and time to assimilate. Thus, it could be argued that the manner in which the information is presented does not matter with respect to decision-making; rather, just as long as it is presented.

Of course, research indicates that presentation *can* affect understanding [3,12,13]; however, that does not necessarily mean that potential participants will not consent to participate despite not understanding. For example, because participation in health-related interventions is generally done to achieve some personal health benefit [15], prospective participants living with a chronic illness may not care about all of a study's details, rather the likelihood of its efficacy to provide such health benefit(s). That is, if a treatment being researched could possibly help living with a particular condition, people living with the condition will want to take part, regardless of whether or not they understand all the steps in the process. Thus, in addition to the possibility that both PILs were adequately informative, it may also be the case that much of the information was not important in participants' decision-making. This perspective also explains the difference found by O'Sullivan and colleagues [24] between the two PILs, despite the null effects in this SWAT. This perspective is also somewhat consistent with results from the self-report measures. Results revealed that those who received the SR-PIL scored higher on the DCS sub-scales of being 'informed' and 'values clarity', suggesting that those who received the SR-PIL felt both more informed and clearer on the issues that mattered most to them. While it may very well be the case that the SR-PIL was more successful in these two contexts with respect to potential participants' perceptions, it must also be acknowledged that participants, overall, may have answered the self-report measures in a socially desirable manner, as a means to ensure that they were accepted to the trial and not deemed ineligible for a lack of understanding or some other reason which can have a negative impact on potential participants [28]. This possibility is supported by two examples. First, 57.5% of participants scored less than 5 on the DCS (out of 64) and 31.5% scored 0, the latter which indicates a score of perfect agreement. Thus, in light of what might be considered a ceiling effect, it may be the case that the strength of responses on the DCS were inflated with a more positive bias – which may, in turn, have led to significant effects for 'informed' and 'values clarity' resulting from a statistical anomaly. The second example relates to the two 'decision to consent' questions on the purpose-developed questionnaire, in which case 90.7% of participants agreed that *'The Study Information Leaflet played a large role in my decision to participate in the study'*, yet – at the same time – 89.3% reported that *'I knew I was going to consent participate before I was even presented the Study Information Leaflet'*. Moreover, it was observed that there was a pattern of significance amongst correlational pairings, except in the case of 'decision to consent', which was the only measure with reverse scoring, suggesting that participants may simply have agreed out of social desirability, as suggested above. This issue should be considered a potential limitation of this SWAT, as it may be the case that genuine differences between groups could have been masked by 'socially desirable' responding. This perspective is further consistent with the finding that there was no difference between groups on 'understanding' from the purpose-built questionnaire, which was akin to the 'informed' and 'values clarity' DCS subs-scales. However, due to the fact that the purpose-built questionnaire is not an established scale, caution should be taken with respect to interpreting such data. Nevertheless, there were no other differences on the self-report measures.

Finally, it must also be acknowledged that many participants may have been taking part in research for the first time and so they would have little with which to compare their PIL. It may, for example, be difficult to determine what a 'likeable' PIL is if one has not previously encountered a PIL. That is, participants may not be aware of the information that is or should be pertinent to the decision-making process; or how the information could be (ideally) worded or presented.

4.2. Limitations

Though the results of this SWAT provide a number of interesting findings and points for discussion, in addition to the potential for influence of social desirability on self-report responding, there are some limitations that require consideration. For example, only 75 participants of the 207 who were sent a PIL completed at least one of the self-report measures. Thus, in response to both of these related limitations, it is recommended that future research using the DCS in similar contexts (and measures like it), is accompanied by explicit instructions indicating that: answers to the questions will not affect eligibility to participate or placement in the trial; items should be answered with complete honesty, so as to ensure the integrity of the study; and if further clarity or understanding is necessary, a researcher can make contact and provide such information.

One final limitation that must be considered was the arrival of COVID-19. The global pandemic halted the host trial and, as a result, it can be argued that further 'noise' was added with respect to variables that may have impacted interpretation of retention rate. As addressed in footnote 1, this was of particular concern at baseline assessment, which was delayed by approximately six months.

5. Summary & conclusion

Despite the null effects of PIL perspective on consent and retention rates, as well as a majority of the self-report measures, these findings are important as they suggest that it may not matter whether a PIL is developed by a researcher or PPI. This position is qualified in the context that, consistent with the host trial, prospective participants living with a chronic illness may not care about all of a study's details, rather the likelihood of efficacy for yielding health benefits. This recommendation is consistent with the cautionary suggestion that high levels of agreement on the DCS may result from misinterpreting the questionnaire as a means of assessing informed consent, eligibility or some other form of social desirability that could impact being 'accepted' to take part in the research. Though it was not an issue in the host trial, such misinterpretation or misunderstanding could potentially impact retention levels in the early stages of other trials. Moreover, this is not to say that participants did not understand the PILs; rather, it may be the case that they perceived being 'good candidate' or 'accepted' to the host trial as being a more important factor.

Overall, the only occasions of statistical significance observed in this SWAT were in relation those who received the SR-PIL scoring higher on the DCS sub-scales of being 'informed' and 'values clarity'; however, concurrent research by O'Sullivan et al. [24] suggests that the PPI-PIL was more readable and understandable. In light of interpretations above, the perceived benefits of *both* a PPI-PIL and SR-PIL remain. That is, as well as future research being conducted on the advantages and disadvantages of researcher-developed and PPI-developed PILs (which is also recommended), it is further recommended that future research utilise both researchers and PPI in the PIL development process. With that, it is also advised that researchers developing PILs consult O'Sullivan et al. [24], as it provides an up-to-date, integrated framework of recommendations for enhancing ease and understandability of PILs, with which researchers not in the field of PIL design may be otherwise unfamiliar. It is also recommended that PPI, as a result of better understanding the cohort targeted for recruitment (having lived experience of the specific condition [16]), may have better understanding of how that information can be best presented to potential participants. Thus, this research recommends that researchers and PPI work collaboratively, alongside evidence-based advice for PIL development, and plain language guidance, in order to ensure that PILs presented are as informative and accurate as possible. This will also help ensure that the information is suitably presented in a manner that is clear, concise and accessible to communities lay to research terminology and processes; so that such potential participants can be confident that they understand the information presented to them in a PIL.

Funding

This study was conducted within a trial funded by a Health Research Board Definitive Intervention and Feasibility Awards (DIFA-FA-2018-027).

Ethics approval

Ethical approval was awarded by Galway University Hospitals on August 13, 2019, Ref: C.A 2231 and was conducted at the National University of Ireland, Galway.

Declaration of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

Acknowledgements

The authors would like to acknowledge Lydia O'Sullivan for her feedback and analysis of the study materials developed for this study-within-a-trial, as included in: O'Sullivan, L., Sukumar, P., Crowley, R., McAuliffe, E., & Doran, P. (2020). Readability and understandability of clinical research patient information leaflets and consent forms in Ireland and the UK: a retrospective quantitative analysis. *BMJ open*, *10* (9), e037994. The authors would also like to thank the COB-MS Trial Steering Committee on their guidance in relation to the SWAT.

Appendix 1. Trial Forge Guidance [3 or 4]: A template for reporting the results of randomised Studies Within A Trial (SWATs)

CONSORT item to be included in publication		Additional information
Title and Abstract		
1a	Term 'SWAT' should be used in the title	SWAT is in the study title. Registry number SWAT105; 30/JUL/2019: title "Comparing the effects of a patient-designed-and-informed participant information sheet in comparison with a standard, researcher-designed information sheet on recruitment, retention and understanding: a study with a trial."
1b	Structured summary	Structured for the SWAT is provided.
Introduction: Background and objectives		
2a	Scientific background and explanation of rationale for the SWAT	Justification and background to the SWAT has been provided at the beginning of the manuscript.

(*continued on next page*)

(*continued*)

CONSORT item to be included in publication		Additional information
2b	Specific objectives or hypotheses for the SWAT	Does a patient (PPI)-designed PIL improve recruitment, decision certainty, retention, understanding, readability, accessibility, likeability and decision to consent compared to a standard, researcher-designed PIL in participants with MS?
Methods: Trial Design		
3a	Description of the SWAT (such as parallel, factorial, cluster) including allocation ratio	A two-arm double-blind, randomised trial SWAT was undertaken with an allocation ratio of 1:1. The SWAT protocol can be found at Northern Ireland Network for Trials Methodology Research SWAT Store (SWAT105; 30/JUL/2019) and full protocol published: https://doi.org/10.12688/hrbopenres.12981.2 Host trial: The host trial protocol is available at https://doi.org/10.1186/s13063-020-4179-5 and registered ISRCTN: ISRCTN11462710. Registered on 9 September 2019
3b	State changes (with reasons) to methods of SWAT following commencement	No changes occurred to the methods of the SWAT. The study was delayed in light of COVID-19, by approximately six months, in the time between consent and baseline assessment.
Participants		
4a	State eligibility criteria in SWAT, including differences to those from the host trial	See section "Method → Participants". SWAT did not have separate eligibility criteria.
4b	Include setting(s) and location(s) where SWAT data was collected	Host and SWAT trial data were collected in person (pre-COVID) and online (following trial restart). Data was returned either by post or collected in person (pre-COVID).
Interventions		
5	Describe SWAT intervention to enable replication, include how and when interventions were administered and recruitment dates.	SWAT describes what was included in the two PIL and circumstances of their development. Full protocol describes this in further detail. The PIL are available on Open Science Framework, along with recruitment material- see: https://osf.io/d52gx/
Outcomes		
6a	State primary and secondary outcome measure for SWAT. Include how and when they are assessed	Outcomes for SWAT- Consent (T1); Retention (T1-4); The Decisional Conflict Scale (T1); Understanding, readability, accessibility, likeability and decision to consent six-item questionnaire (T1).
6b	Include changes (and reasons) to SWAT outcomes after commencement	SWAT and host data were collected online following trial restart.
Sample Size		
7a	How sample size was determined for the SWAT.	As the host trial is a feasibility study, a formal sample size calculation was not required. A pragmatic approach is adopted where the aim is to examine the rate of retention of participants during the intervention and follow up periods. The sample size was felt that it would be large enough to inform them about the practicalities of a definitive randomised trial, allowing for attrition rate of 9%. The SWAT sample size was dependent on the host trial (COB-MS), therefore no formal sample size calculation was performed, which is in line with SWAT methodology [19, 29]. SWAT sample size was the same as that for the host trial- n = 100.
7b	When applicable, explanation of any interim analyses and stopping guidelines for the SWAT	There was no interim analysis of host trial or SWAT. The stopping rule specific unto the SWAT is recruitment of less than 70% during the recruitment phase set; protocol, including data collection period not tolerated by over 25% of participants.
Randomisation: Sequence generation		
8a	Method used to generate the random allocation sequence for the SWAT	Potential participants were randomly allocated to either the SR-PIL or PPI-PIL conditions, using 1:1 allocation.
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Randomised block permutation (i.e. two randomised blocks of four and six per block).
Allocation concealment mechanism		
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned for the SWAT	Allocation concealment was achieved by having a separate research staff member create the allocation sequence. Participant numbers were generated that had no link to the allocation and only this researcher had access to the "key" for this.
Implementation		
10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions for the SWAT	Randomisation was performed by postdoctoral researcher, one research assistants enrolled participants and one research assistant assigned the participant to the SWAT intervention or comparator
Blinding		
11a	If done, who was blinded to the SWAT after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Explain who was blinded. Blinding was achieved by blinding the research assistants collecting the data to the SWAT arm, and the participants themselves were blinded the SWAT arm they were allocated to.
11b	If relevant, description of the similarity of the SWAT interventions	Each of the PIL had a page that covered essential GDPR information included (created by PI). Available to view: https://osf.io/d52gx/
Statistical methods		
12a	Statistical methods used to compare groups for primary and secondary outcomes for the SWAT	All analyses for the SWAT was pre-planned in SWAT Statistical Analysis Plan, and is detailed in the published SWAT protocol.
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/A
Results		
Participant flow		
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome for the SWAT	A participant flow diagram has been provided in Fig. 1, as recommended in Ref. [23].
13b	For each group participating in the SWAT, losses and exclusions after randomisation, together with reasons	This is presented in the flow diagram, where available- Fig. 1.
Recruitment		
14a	Dates defining the periods of recruitment and follow-up of the SWAT	Participant recruitment took place between November 2019–August 2020 (allowing for rechecking consent with participants following COVID-19 impacts).
14b	Why the SWAT ended or was stopped	SWAT has finished as it has achieved objectives
Baseline data		
15	A table showing baseline demographic and clinical characteristics for each group	This has not been provided for the SWAT as this detail is not relevant to the outcome of the SWAT and will be reported in host trial publication.

(*continued on next page*)

(*continued*)

CONSORT item to be included in publication		Additional information
Numbers analysed		
16	For each group of the SWAT, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	All analysis was by original assigned groups.
Outcomes and estimation		
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results are presented in tables in the manuscript above with all relevant results presented.
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	See Results section.
Ancillary analyses		
18	Results of any other analyses performed on the SWAT data, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Post-hoc analysis completed [24] on the PIL has also been included here.
Harms		
19	All important harms or unintended effects in each group that took part in the SWAT (for specific guidance see CONSORT for harms)	No harms associated with the SWAT.
Discussion		
Limitations		
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses for the SWAT	Limitations section has been included above.
Generalisability		
21	Generalisability (external validity, applicability) of the SWAT findings	This has been included in the discussion.
Interpretation		
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation and recommendations for future research related to the SWAT have been included, balancing related research in the area.
Other Information		
23	Registration Registration number and name of trial registry	Host trial: ISRCTN: ISRCTN11462710. Registered on 9 September 2019 SWAT: Northern Ireland Network for Trials Methodology Research SWAT Store (SWAT105; 30/JUL/2019)
24	Protocol Where the full trial protocol can be accessed, if available	Host trial: available at https://doi.org/10.1186/s13063-020-4179-5 SWAT: full protocol available https://doi.org/10.12688/hrbopenres.12981.2
25	Funding Sources of funding and other support (such as supply of drugs), role of funders	This study was conducted within a trial funded by a Health Research Board Definitive Intervention and Feasibility Awards (DIFA-FA-2018-027). No separate funding for SWAT. Funders did not have any role in the research.
Additional		
	Data sharing	Data will be shared at the Irish Social Science Data Archive (ISSDA)http://www.ucd.ie/issda/data/following full analysis and write-up of the host trial.

References

[1] A. Britton, M. McKee, N. Black, et al., Choosing between randomised and nonrandomised studies: a systematic review, Health Technol. Assess. 2 (13) (1998) i–iv.

[2] J. Wade, J.L. Donovan, J.A. Lane, et al., It's not just what you say it's also how you say, it: opening the 'black box' of informed consent appointments in randomised controlled trials, Soc. Sci. Med. 68 (11) (2009) 2018–2028.

[3] T. McCaughey, C.Y. Chen, E. De Smit, et al., Participant understanding and recall of informed consent for induced pluripotent stem cell biobanking, Cell Tissue Bank. 17 (2016) 449.

[4] C.P. Dwyer, R.A. Joyce, E.M. Bane, et al., An examination of the effects of a patient-designed-and-informed participant information sheet in comparison with a standard, researcher-designed information sheet on recruitment, retention and understanding: protocol for a study-within-a-trial [version 2; peer review: 2 approved, 1 not approved], HRB Open Res. 3 (2020) 4, https://doi.org/10.12688/hrbopenres.12981.2.

[5] A. Khan, B.J. Capps, M.Y. Sum, et al., Informed consent for human genetic and genomic studies: a systematic review, Clin. Genet. 86 (2014) 199–206.

[6] L. Ennis, T. Wykes, Sense and readability: participant information sheets for research studies, Br. J. Psychiatry 208 (2) (2016) 189–194.

[7] S. Cockayne, C. Fairhurst, J. Adamson, et al., An optimised patient information sheet did not significantly increase recruitment or retention in a falls prevention study: an embedded randomised recruitment trial, Trials 18 (2017) 144.

[8] M. Terblanche, L. Burgess, Examining the readability of patient-informed consent forms, Clin. Trials J. 2 (2010) 157–162.

[9] J.P. Ordovás Baines, E. López Briz, E. Urbieta Sanz, et al., An analysis of patient information sheets for obtaining informed consent in clinical trials, Med. Clin. (Barc) 112 (3) (1999) 90–94.

[10] K. Gillies, W. Huang, Z. Skea, et al., Patient information leaflets (PILs) for UK randomised controlled trials: a feasibility study exploring whether they contain information to support decision making about trial participation, Trials 15 (1) (2014) 62.

[11] S.M. Sharp, Consent documents for oncology trials: does anybody read these things? Am. J. Clin. Oncol. 27 (6) (2004) 570–575.

[12] G. Brierley, R. Richardson, D.J. Torgerson, Using short information leaflets as recruitment tools did not improve recruitment: a randomized controlled trial, J. Clin. Epidemiol. 65 (2) (2012) 147–154.

[13] P. Knapp, D.K. Raynor, J. Silcock, et al., Can user testing of a clinical trial patient information sheet make it fit-for-purpose? A randomized controlled trial, BMC Med. 9 (1) (2011) 89.

[14] A.J. Manley, T. Lavender, D.M. Smith, Processing fluency effects: can the content and presentation of participant information sheets influence recruitment and participation for an antenatal intervention? Patient Educ. Counsel. 98 (3) (2015) 391–394.

[15] S.K. McCann, M.K. Campbell, V.A. Entwistle, Reasons for participating in randomised controlled trials: conditional altruism and considerations for self, Trials 11 (1) (2010) 31.

[16] J.C. Crocker, I. Ricci-Cabello, A. Parker, et al., Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis, BMJ 363 (2018) k4738.

[17] A. Price, L. Albarqouni, J. Kirkpatrick, et al., Patient and public involvement in the design of clinical trials: an overview of systematic reviews, J. Eval. Clin. Pract. 24 (1) (2018) 240–253.

[18] S. Treweek, S. Bevan, P. Bower, M. Campbell, J. Christie, M. Clarke, et al., Trial forge guidance 1: what is a study within a trial (SWAT)? Trials 19 (1) (2018) 139.

[19] C.P. Dwyer, A. Alvarez-Iglesias, R. Joyce, T.J. Counihan, D. Casey, S.M. Hynes, Evaluating the feasibility and preliminary efficacy of a Cognitive Occupation-Based programme for people with Multiple Sclerosis (COB-MS): protocol for a feasibility cluster-randomised controlled trial, Trials 21 (1) (2020 Dec) 1–2.

[20] C. Dwyer, An examination of the effects of a patient-designed-and-informed participant information sheet in comparison with a standard, researcher-designed information sheet on recruitment, retention and understanding: protocol for a study-within-a-trial. http://doi.org/10.17605/OSF.IO/DGZBQ, 2020.

[21] A.M. O'Connor, Validation of a decisional conflict scale, Med. Decis. Making 15 (1) (1995) 25–30.

[22] A.M. O'Connor, User Manual-Decision Conflict Scale, Ottawa Hospital Research Institute, Ottawa, 2012.

[23] S.M. Eldridge, C.L. Chan, M.J. Campbell, C.M. Bond, S. Hopewell, L. Thabane, et al., CONSORT 2010 statement: extension to randomised pilot and feasibility trials, BMJ (2016) 355.

[24] L. O'Sullivan, P. Sukumar, R. Crowley, E. McAuliffe, P. Doran, Readability and understandability of clinical research patient information leaflets and consent forms in Ireland and the UK: a retrospective quantitative analysis, BMJ Open 10 (9) (2020 Sep 1), e037994.

[25] K. Gillies, A. Kearney, C. Keenan, et al., Strategies to improve retention in randomised trials, Cochrane Database Syst. Rev. (3) (2021), MR000032.

[26] E.R. Pedersen, C. Neighbors, J. Tidwell, T.W. Lostutter, Do undergraduate student research participants read psychological research consent forms? Examining memory effects, condition effects, and individual differences, Ethics Behav. 21 (4) (2011 Jul 1) 332–350.
[27] S. Treweek, M. Pitkethly, J. Cook, et al., Strategies to improve recruitment to randomised trials, Cochrane Database Syst. Rev. (2) (2018), MR000013.
[28] C.P. Dwyer, H. McAneney, F.M. Rogers, R. Joyce, S.M. Hynes, Exploring the impact of ineligibility on individuals expressing interest in a trial aimed at improving daily functioning regarding perceptions of self, research and likelihood of future participation, BMC Med. Res. Methodol. 21 (2021) 264, https://doi.org/10.1186/s12874-021-01464-x.
[29] J. Adamson, C.E. Hewitt, D.J. Torgerson, Producing better evidence on how to improve randomised controlled trials, BMJ 351 (2015) h4923.