IMJ Official Journal of the Irish Medical Organisation

Ir Med J; April 2024; Vol 117; No. 4; P945
25th April, 2024

Patient and Public Panel Involvement to Optimise a Patient Information Leaflet Format

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Abstract

Introduction

A patient information leaflet (PIL) is traditionally written by academics. Patient and Public Involvement (PPI) in research design can result in better quality and relevance of research. The aim of this project was to investigate a PPI Panel's opinion on the navigation and accessibility of a standard A4 PIL format compared to a newly redesigned A5 booklet format.

Methods

A new PIL format was developed, based on PIL recommendations published in 2021, and subsequently reviewed and compared against a standard template by a PPI Panel for ease of navigation and accessibility. The written information did not differ between versions. PPI panel members were approached via email to participate in a two-part qualitative and quantitative online survey. Qualitative data was analysed through thematic analysis.

Results

4 (58%) of the PPI Panel responded, with a 4 (100%) completion rate. 3 (75%) found the original format "somewhat difficult" to read, whilst 3 (75%) found the new booklet format

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"somewhat easy" or "extremely easy" to read. All responders found the new format easier to navigate. The qualitative data produced two themes: appearance and language.

By changing the PIL format, the accessibility of information increased. The qualitative feedback by the PPI Panel helped improve the PIL, ensuring it is patient-centred, facilitates patient understanding of the trial and aids the informed consent process.

Introduction

Patient and Public Involvement (PPI) in research design leads to better quality and improved relevance of clinical research, by focusing on areas that patients consider to be important and bringing a new perspective to the study design.[1] The National Cancer Control Programme (NCCP)'s National Cancer Strategy 2017-2026 highlighted the increased survival rates of cancer patients, with approximately 200,000 people living with and beyond cancer in Ireland. The NCCP proposes the enrolment of 6% of cancer patients to therapeutic clinical trials by 2026.[2] Barriers for clinical trial recruitment and retention include language, cultural factors, trial design, beliefs about medical research, and time constraints, amongst others.[3]

A Patient Information Leaflet (PIL) and informed consent are key components to trial recruitment and are traditionally written by academic researchers. PILs provide information to potential participants regarding the study, how it will be carried out, why they are being asked to take part, what the benefits and risks are. The European Union General Data Protection Regulations (GDPR) now require study sponsors to provide potential participants with information regarding their personal data, how it is stored and processed following their participation. Within Ireland, it is recommended that patient-facing documents are developed for a reading age level of 11 – 12 years old by the National Adult Literacy Agency.

In 2021, a set of guidelines, including 44 recommendations, were published from an expert consensus conference in relation to preparing accessible and understandable clinical research PILs.[4] The recommendations included the format of PILs: they should be in a booklet format, use columns and have headings to ensure an "easy-to-read and accessible layout".[4]

The University College Cork Cancer Trials Group (UCC CTG) have developed and piloted two survivorship trials with leveraged funding from the Irish Cancer Society; LIAM Mc [NCI: CTRIAL-IE 23-18; NCT05946993] & LYSA [NCT05035173] trials.[5,6,7] The LIAM Mc (Linking In with Supports and Advice for Men impacted by Metastatic cancer) trial is a 12-week interventional programme based in the Mardyke Arena, a UCC affiliated state–of-the-art sports and rehabilitation facility. The programme encompasses an intensive

multidisciplinary approach to provide men with personalised tools and coping mechanisms for life with cancer. An important aspect of this programme is to demonstrate how to improve the survivorship supports and services for underserved communities of men who have not traditionally been the focus of such initiatives, such as the Travelling community, LGBTQ+ community, ethnic minority and migrant communities and communities with social disadvantages. Therefore, ensuring that information regarding the trial is accessible was vital.

Given the numerous barriers to trial recruitment and the positive impact that collaboration with a PPI panel can have on study design and success, a project was facilitated through the LIAM Mc Trial, collaborating with the UCC CTG PPI Panel focusing on the PIL.

Thus, the aim of this project is to investigate the PPI Panel's opinion on the navigation and accessibility of a standard A4 patient information leaflet format (Appendix 1) compared to a newly redesigned A5 booklet format (Appendix 2). A key aspect to this project was that the written information in the PIL did not change across the different formats.

Methods

The LIAM Mc Trial received full ethical approval, granted by Clinical Research Ethics Committee of the University Teaching's Hospital [ECM 4 (v) 01/11/2022 & ECM 5 (11) 31/01/2023]. This project was also working in partnership with the UCC CTG's established PPI Panel who have signed a voluntary agreement to work with researchers to develop and improve clinical trials, and therefore specific ethical approval was not deemed necessary. The project was conducted in line with the Declaration of Helsinki and using Good Clinical Practice guidelines. [8,9]

Standard PILs for Non-Regulated Trials are based on an A4 template.[10] The original PIL used in the LIAM Mc Trial followed this standard A4 template. The newly formatted PIL was produced in line with the 2021 recommendations as an A5 booklet, with a cover page and a contents section. The pages of the booklet were divided into two columns per page, with specific headings, following from left to right. An additional two pages were added with clear contact information for the potential participants at the front and back of the booklet.

A mixed methods approach was used to capture data using the Qualtrics Survey Tool.[11] The survey consisted of 8 questions, using a combination of free text input, multiple choice answers and slider scale questions to provide a comprehensive overview of the PPI Panel's perspective. [12]

The slider scale questions were divided to 5 scale points, ranging from "*extremely difficult"* to "*extremely easy".* The following 4 slider scale questions were included: "*How easy did you find the original PIL to read?*", "*How easy did you find the new PIL to read?", "How easy was it to navigate the original PIL?*" and "*How easy was it to navigate the new PIL?*". A simple multiple-choice question was included at the end of the quantitative section: "*Which PIL did you prefer?*". The PPI-P had two options: the original PIL or the new PIL.

Free text input questions were used to collect open-ended responses. An essay text box allowed PPI-P to give their opinion and provide more detailed information on comparison between the two PILs. Three questions were included: "*What did you like or dislike about the original PIL?*", "*What did you like or dislike about the new PIL?*" and "*Would you give any suggestions or comments as to how we can improve the PIL further?"*.

Members (n=7) of the UCC CTG PPI-P had previously consented to be contacted for involvement in potential projects. These members were approached via email. The "PIL Project" was advertised in a UCC CTG monthly newsletter in Spring 2023. An invitation email was sent outlining the purpose of the "PIL Project". If the PPI member agreed to take part, a copy of both PILs were posted to their home address for review and a link to the survey was sent to their email address. The team was notified by Qualtrics once the PPI-P completed the survey. Following the completion, PPI-P involved consented to the use and publication of the results.

All data used in the analysis was anonymised. The qualitative and quantitative data was collected and exported from Qualtrics into a .csv file. Qualitative data was analysed using a simple thematic analysis approach.[13] This data was analysed by two researchers (KJ & KM) in the team to ensure themes were coherent and clear. The raw quantitative data was reviewed and cleaned to ensure any anomalies or duplications were accounted for (n=1). Clean data was then analysed in two categories: ease of reading and ease of navigation, presented as bar charts.

Results

58% (n=4) of the UCC CTG and LIAM Mc PPI Panel members participated in this project, with a 100% completion rate among participants. The quantitative data is presented in Figure 1 and Figure 2. Overall, 75% (n=3) of the PPI-P preferred the A5 booklet format compared to the original A4 format. As seen in Figure 2, 75% (n=3) of the PPI-P found the original format "somewhat difficult" to read, whilst 50% (n=2) found the new format "somewhat easy" to read and 25% (n=1) found it "extremely easy" to read.

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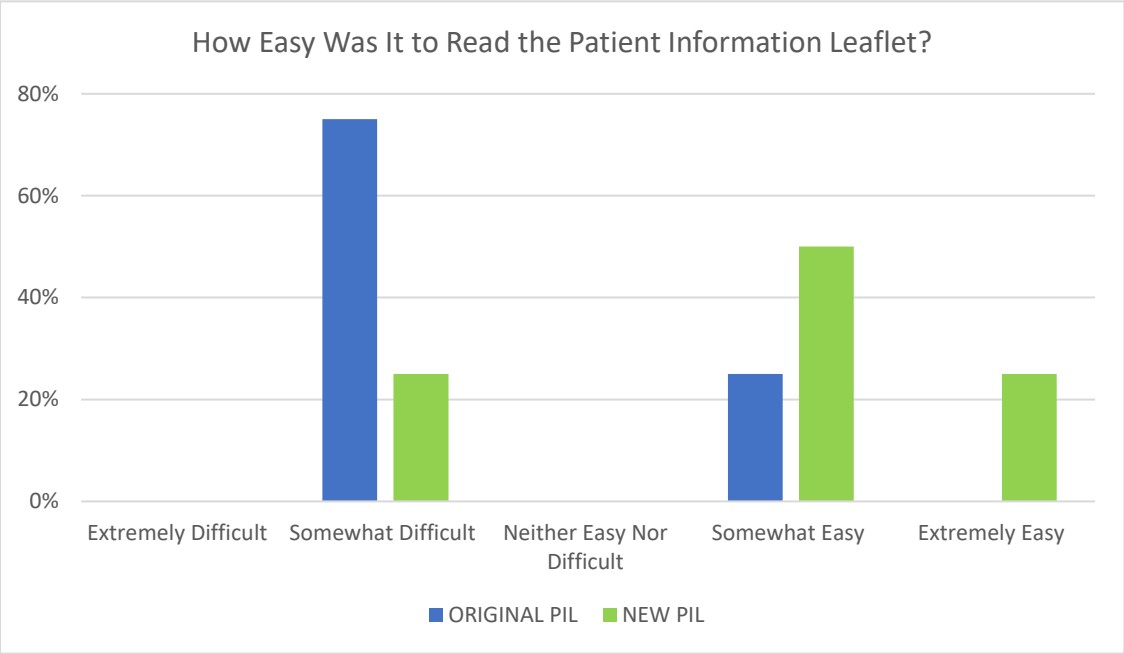

Figure 1: The Reading Accessibility of the PILs.

As presented in Figure 2, the entire PPI-P found the new format "somewhat easy" to "extremely easy" to navigate, and 50% of the PPI-P found the original A4 format "somewhat difficult" to navigate.

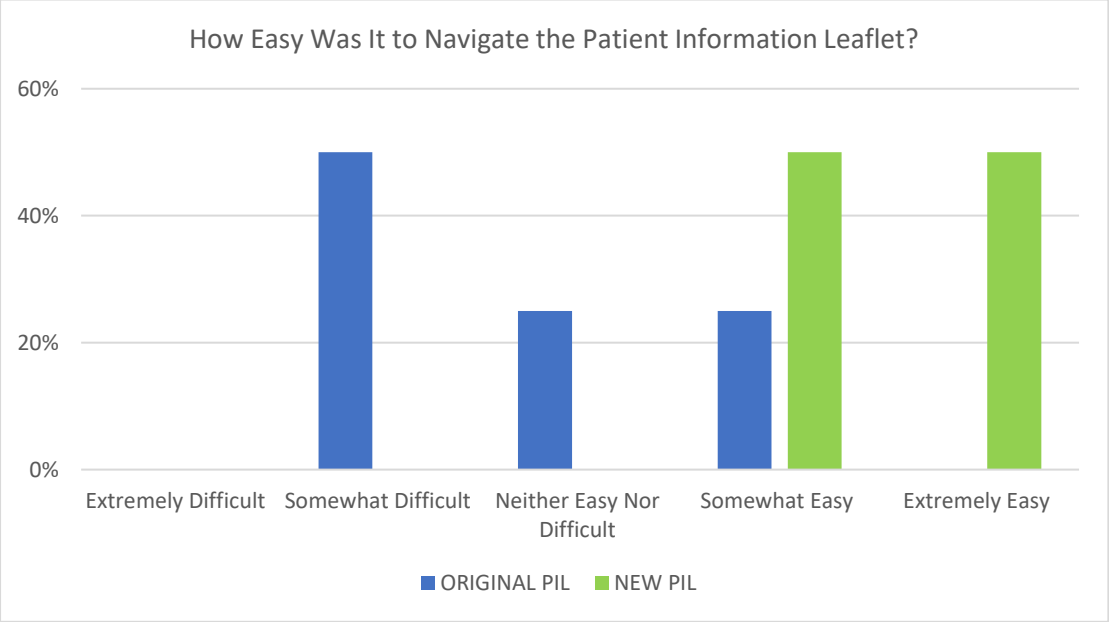

Figure 2: The Navigation Accessibility of the PILs.

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The qualitative data is represented in Figure 3. Two main themes emerged: the appearance of the PIL and the language used in the PIL. The latter theme is reported as a consequential finding as it was not the primary objective of this project.

The first theme in the data was regarding the appearance of the PILs. Overall, the new format was reported to be "*softer*" and "*friendlier*" than the original format, which was described as "*clunky*" and "*too official*". The use of two-column formatting was preferred as the sections were "*not as imposing*" as the original version, reading "*like a book*". Conversely, in the subtheme of text size, the original format was suggested as preferable due its "*large text*", making the document "*easy to read*".

The second theme, a consequential finding of the project, was around the language used in the PIL. The qualitative data was largely negative and to improve recruitment rates, the PPI-P reported language should be "*encouraging*" and appeal to all readers, "*not just those with an academic background*". It was reported that there was "*too much emphasis*" on "*risks, being harmed, negligence and legal action*".

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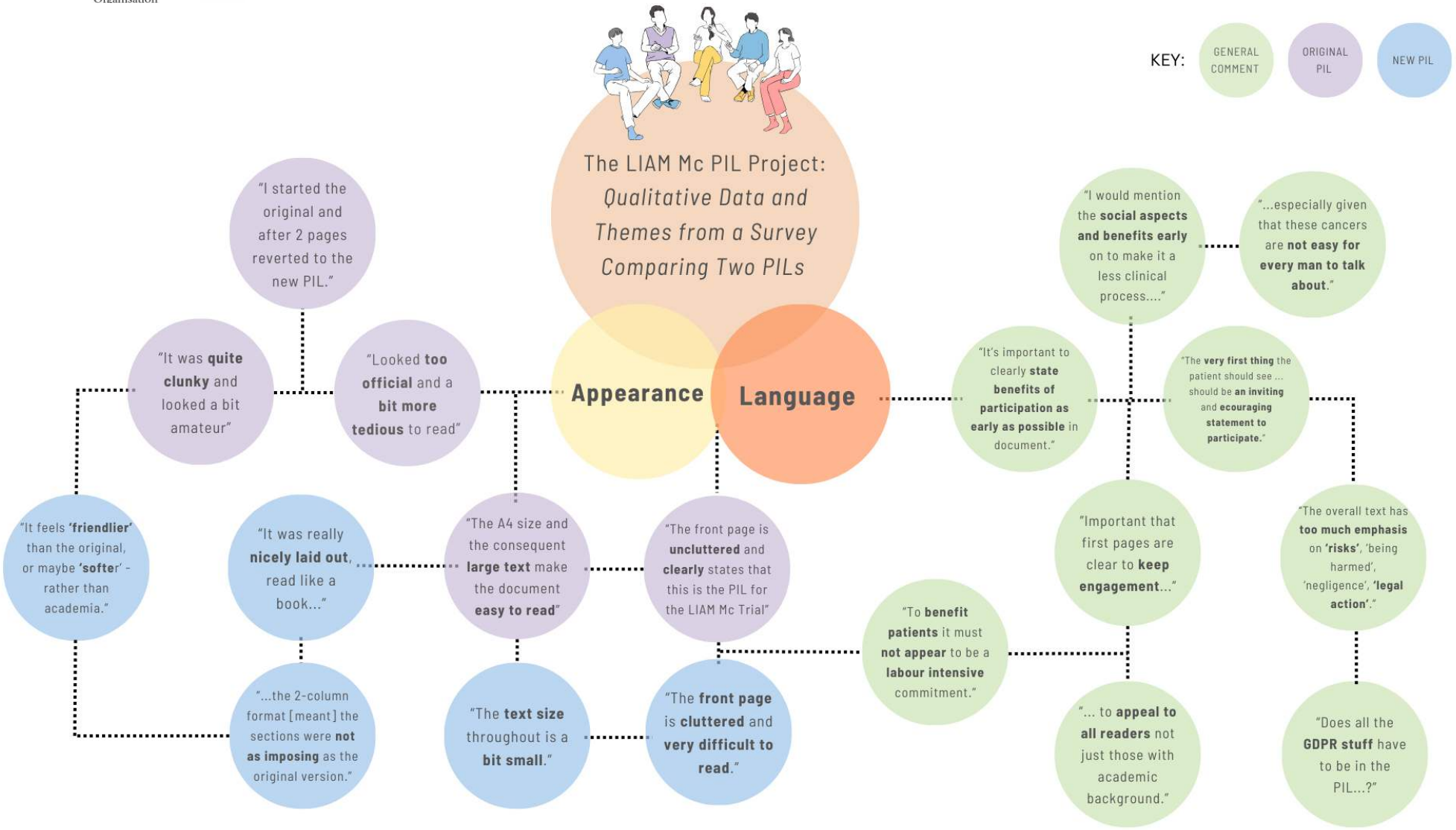

Figure 3: Interlinking themes and quotes from the qualitative section of the LIAM Mc PIL

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Discussion

PILs are a key component of clinical trials and act as a facilitator to trial recruitment. This project, facilitated through the LIAM Mc Trial, aimed to optimise the format of PILs by collaborating with a PPI Panel. The project followed recommendations published in 2021 to redesign a standard A4 PIL template to a new A5 booklet format. [4,10]

Whilst there are layers of complexity that influence recruitment to and participation in a clinical trial, this project is the first step in optimising PILs in the UCC CTG with the long-term aim to help facilitate trial recruitment through easily accessible information for patients.[1]

It has been reported that the top inefficiency in conduct of a clinical trial is failure to meet the recruitment targets.[15] Furthermore, research found that only 5% of American cancer patients actually participated in clinical trials, in contrast to the 70% who reported that they were willing to participate.[16] Some decisions regarding patient participation in clinical trials are not based on a full understanding of the trial, possibly because the information may be too complex or not designed to support an informed decision.[15] This project has further reiterated the barriers that complex language and poor design may have on clinical trial participation.

Involving PPI is vital to bridge a gap between academic/clinical researchers and patients. The partnership between the PPI advocate and the research team enables mutual learning and understanding of the patient perspective and the clinician perspective, working towards a scientific yet patient-centred clinical trial.[17] The PPI advocate's input to the clinical trial design ensures the understanding of what is important to the patients and works to broaden the researcher's perspective.[17]

By changing the format of a standard A4 PIL template to an A5 booklet, without changing its content, the majority of the PPI-P found it easier to read and all participants found it easier to navigate. In contrast, half of the PPI-P found the original standard PIL template "*somewhat difficult*" to navigate, and with the majority again finding it "*somewhat difficult*" to read.

As a result of this project, the A5 booklet format has been submitted and approved by the local research ethics committee for use in the LIAM Mc Trial.

While this project involved a relatively small number of PPI-P participants, the benefit of involving a PPI-P in PIL design is clear. Additionally, while there may have been some bias in

reporting based on labelling the PILs as “original” and “new”, the fact that the wording in both formats did not differ is a strength of this analysis. Future projects could utilise a larger sample size to gain a more in-depth perspective of a PPI-P opinion, in order to optimise PILs further.

A consequential finding of this project highlighted that the language used in the standard PILs may create a potential barrier for accessing information about a clinical trial (Figure 3). It is evident that working with PPI-P can play a role in breaking down barriers between academics, clinical researchers and patients. Furthermore, it is clear that more work needs to be done to make the language of a standard PIL more accessible to patients and their families.

The UCC Cancer Trials Group (Cancer Research @UCC) are working to progress this project to create a standard PIL template and collaborate with the Patient-Focussed Quality Working Group in University College Cork to concentrate on the language used in PILs to ensure future trials are accessible and patient-centric.

The aim of the LIAM Mc PIL Project was to work with a PPI panel to compare a standard A4 PIL format and a novel A5 booklet format PIL. A key aspect was that the written information in the patient information leaflets did not differ. By changing only the PIL format, both navigation and the accessibility of information improved. The qualitative feedback by the PPI panel has been vital to continuing our work to improve the PIL, working to ensure it is patient-centred, facilitates patient understanding of the trial and aids the informed consent process. A consequential finding was the impact of the language used in PILs as a barrier for patient understanding, and particular attention should be paid to the language used when PILs are being developed, with direct input from a PPI panel essential.

Abbreviations

LIAM Mc	**L**inking **I**n with **A**dvice and supports for **M**en impacted by **M**etastatic **C**ancer
LYSA	**L**inking **Y**ou with **S**upports and **A**dvice
NCCP	National Cancer Control Programme
PIL	Patient Information Leaflet
PPI	Patient and Public Involvement
PPI-P	Patient and Public Involvement Panel
UCC CTG	University College Cork Cancer Trials Group

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Declarations of Conflicts of Interest:
None declared.

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References:

1. Hoddinott P, Pollock A, O'Cathain A, Boyer I, Taylor J, MacDonald C, Oliver S, Donovan JL. How to incorporate patient and public perspectives into the design and conduct of research. F1000Research. 2018;7:752. doi:10.12688/f1000research.15162.1
2. Government of Ireland. National Cancer Strategy 2017-2026. Dublin: Government of Ireland; 2017. Available from: http://health.gov.ie/wp-content/uploads/2017/07/National-Cancer-Strategy-2017-2026.pdf
3. Kadam RA, Borde SU, Madas SA, Salvi SS, Limaye SS. Challenges in recruitment and retention of clinical trial subjects. Perspect Clin Res. 2016;7(3):137-143. doi:10.4103/2229-3485.184820
4. Coleman E, O'Sullivan L, Crowley R, et al. Preparing accessible and understandable clinical research participant information leaflets and consent forms: a set of guidelines from an expert consensus conference. Res Involv Engagem. 2021;7(1):31. doi:10.1186/s40900-021-00265-2
5. Kearns N, Raigal-Aran L, O'Connell K, et al. The Women's Health Initiative cancer survivorship clinic incorporating electronic patient-reported outcomes: a study protocol for the Linking You to Support and Advice (LYSA) randomized controlled trial. Pilot Feasibility Stud. 2022;8(1):238. doi:10.1186/s40814-022-01186-x
6. Saab MM, McCarthy M, Murphy M, et al. Supportive care interventions for men with urological cancers: a scoping review. Support Care Cancer. 2023;31(9):530. doi:10.1007/s00520-023-07984-0
7. Linking in with Advice and Supports for Men Impacted by Metastatic Cancer (LIAM Mc). ClinicalTrials.gov identifier: NCT05946993. Updated 2023 Jul 19. Accessed 2023 Nov 1. Available from: https://clinicaltrials.gov/ct2/show/NCT05946993

8. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. JAMA. 2013;310(20):2191-2194. doi:10.1001/jama.2013.281053
9. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated addendum to ICH E6(R1): guideline for good clinical practice E6(R2). Step 4 version dated 2016 Nov 9. Available from: https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf
10. Beaumont Hospital Ethics (Medical Research Committee). Template Patient Information Leaflet. Available from: https://www.beaumontethics.ie/application/templates.htm
11. Qualtrics. Provo, Utah, USA: Qualtrics; 2005. Version: July 2023. Available from: https://www.qualtrics.com/uk/
12. Regnault A, Willgoss T, Barbic S; International Society for Quality of Life Research (ISOQOL) Mixed Methods Special Interest Group (SIG). Towards the use of mixed methods inquiry as best practice in health outcomes research. J Patient Rep Outcomes. 2017;2(1):19. doi:10.1186/s41687-018-0043-8
13. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77-101. doi:10.1191/1478088706qp063oa
14. You KH, Lwin Z, Ahern E, Wyld D, Roberts N. Factors that influence clinical trial participation by patients with cancer in Australia: a scoping review protocol. BMJ Open. 2022;12(4):e057675. doi:10.1136/bmjopen-2021-057675
15. Crocker JC, Ricci-Cabello I, Parker A, et al. Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis. BMJ. 2018;363:k4738. doi:10.1136/bmj.k4738
16. Gillies K, Huang W, Skea Z, Brehaut J, Cotton S. 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. 2014;15:62. doi:10.1186/1745-6215-15-62
17. Porter LD, Goodman KA, Mailman J, Garrett WS. Patient advocates and researchers as partners in cancer research: a winning combination. Am Soc Clin Oncol Educ Book. 2023;43:e100035. doi:10.1200/EDBK_100035