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Research Involvement and Engagement

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Patient and public involvement in randomised controlled trial design and implementation: a process evaluation of the linking you to support and advice (LYSA) trial

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Abstract

Background The implementation of Patient and Public Involvement (PPI) in randomised controlled clinical trials (RCT) is crucial for improving the relevance and quality of research. PPI entails active engagement of patients and the public in various stages of the research process. The processes for effectively implementing PPI in RCTs remain underexplored and heterogeneous.

Methods An explorative single case study of the Linking You to Support and Advice (LYSA) randomised controlled trial, NCT05035173, aims to evaluate the processes of implementation of PPI through different stages of the research cycle.

Results The development and review of the grant application resulted in a more patient focused study development. Furthermore, the review of surveys, questionnaires and patient facing study materials led to amendments mainly referring to the language used. PPI contributors helped to co-design the symptom management resources in partnership with the project team. Evaluation of the ePRO collection tool did not result in any further amendments. PPI contributors participated in the development of the study's acronym and focus group discussion. As a direct result of PPI input further work and research was done in the area of metastatic breast cancer. PPI contributors participated in social media work, review and co-authorship of this paper.

Conclusions Implementation of PPI through different stages of RCT's is effective. It highlighted the importance of PPI in improving the relevance and quality of research. While PPI offers numerous benefits, its implementation is not without challenges. Barriers such as resource and time constraints, and varying levels of stakeholder engagement pose a challenge to effective PPI integration.

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Key message

This manuscript demonstrates how meaningful PPI was intergated throughout the design and delivery of LYSA trial, from early protocol development to dissemination. PPI contributors were involved in reviewing study proposal, co-designing symptom management pathways, reviewing patient facing documents, and more. Their perspective ensured the study was aligned with patient needs. This case study illustrates the impact of involving PPI in all phases of a clinical trial, from trial design through dissemination.

Plain English summary

This paper looks at how patients and the public were involved in a cancer survivorship research study in Ireland. In the LYSA trial, PPI contributors played a crucial role in identifying research priorities and reviewing study documents. They collaborated with the principal investigator to ensure the study was patient focused. After securing funding, PPI contributors were recruited with the help of healthcare professionals, forming a panel of six patient advocates and 65 stakeholders. PPI members reviewed study materials, such as surveys and symptom management resources, contributing valuable insights based on their personal experiences with cancer. They also helped design the trial's acronym and suggested improvements, such as adding colour to materials. Their input influenced the development of a Menopause, Diet and Cancer book and resources for cancer survivors. Throughout the trial, PPI contributors participated in virtual meetings and emails, providing feedback and suggestions. They contributed to focus group discussions and advocated for further research, particularly in the area of metastatic breast cancer. Additionally, PPI members helped disseminate trial findings through media, social platforms, and a PPI contributor is a co-author on this publication. One PPI member received a national award for her involvement.

Introduction

Patient and Public Involvement (PPI) can be defined as research carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them [1]. The term 'public' includes patients, carers, people who use health and social care services and people from organisations that represent services users [1]. There has been an increased interest in the implementation of PPI in research and clinical trials.

Internationally, PPI is well established in the UK and Canada [2]. On the contrary, across Europe (countries in WHO European region, excluding UK), PPI is unevenly established and implemented. This is mainly due to the lack of available infrastructure, guidance, and support. According to the systematic review conducted by Biddle and colleagues, the Netherlands had the highest number of published studies reporting PPI, followed by the Scandinavian countries, Norway, Denmark, and Sweden. On the other hand, in Ireland, the review identified only one published study of PPI reporting [3]. This review reported overall positive attitude towards PPI, however studies reported that the role of PPI remains marginal or rather tokenistic. Often in research, PPI is implemented to meet the requirements of funding bodies [3].

Despite the development of several frameworks and guidelines, PPI cannot be approached as 'one size fits all' method. Often, a single 'one size fits all' approach can be less useful than the use of multiple adapted resources, frameworks, and guidelines [4, 5].

National Institute for Health Research (NIHR) had established INVOLVE in 1996 to support and encourage active public involvement in research in the UK [1, 6, 7]. Today, the UK is one of the leaders in conduct, implementation, and reporting of PPI [2, 8].

Major funding bodies are increasingly making PPI a requirement to encourage Patient and Public Involvement and Engagement (PPIE) [9]. Studies have shown that PPI in research and clinical trials can improve the quality and relevance of research [1]. PPI should be implemented at all stages of the research process. However, research shows that it is mostly implemented in the early phases of the research cycle and dissemination of results [10, 11].

PPI in Ireland

In Ireland, there is a lack of evidence to determine to what extent PPI is established and implemented in research. There are several tools and resources available to help facilitate implementation of PPI. For instance, PPI Ignite Network was established in 2017 by the Health Research Board (HRB) and the Irish Research Council (IRC), with co-funding from each of the Lead Universities [12]. PPI Ignite provides resources and support to researchers to foster advancements in health and social research care in Ireland [12]. Furthermore, in 2018 the Department of Health created Framework for Public Involvement in Clinical Effectiveness [13]. The framework was designed to enhance and improve public participation in making decisions related to healthcare. According to the framework, the following three conditions are essential for successful public involvement (i) a clear purpose and objective from the outset of the process, (ii) a clear structure of how public involvement will be conducted, (iii) a commitment to the process [13].

LYSA trial

Linking You to Support and Advice (LYSA) trial is a feasibility study for a survivorship clinic in Irish Cancer centers for women following treatment for breast and gynaecological cancer [14]. The LYSA trial is a complex interventional randomised control trial. The study's primary objective is to evaluate the feasibility of introducing a women's malignancy survivorship clinic incorporating symptom management through electronic Patient Reported Outcome (ePRO) collection into routine follow up care in patients with early-stage HR-positive breast and gynaecologic cancer post-primary therapy. Patients were randomised to either an experimental or active comparator arm. Recruitment took place from March 2021 until August 2022 and the study recruited the target of 200 women across two sites, Cork University Hospital (CUH) and University Hospital Galway (UHG). For more trial information please refer to the study protocol https://doi.org/10.1186/s40814-022-01219-5 [14].

The rationale for incorporating PPI in the LYSA trial was based in the need to ensure that the research was relevant, acceptable, and responsive to the needs of individuals living as cancer survivors. These patient populations face unique physical, emotional, and psychosocial challenges that may not be fully understood or anticipated by researchers or clinicians alone. Involving people with lived experience of cancer from the earliest stages of study development allowed us to identify priorities that matter most to patients, improve the clarity and accessibility of study materials, and shape a trial design that is both feasible and sensitive to participants' needs. Rather than using a purely advisory panel, we aimed to create a more integrated form of engagement in which PPI contributors influenced key decisions and provided ongoing feedback throughout the trial lifecycle. This approach was essential to enhancing the study's overall quality, inclusivity, and potential for real-world impact.

Methods

This exploratory single case study is evaluating the processes used to implement PPI through different stages of the randomised clinical trial.

The planning for the implementation of PPI in the LYSA trial was initiated at the preliminary phase of the clinical trial design, ensuring its integration from the outset. The study team adhered to current frameworks and guidelines, aiming for a meaningful application of PPI. Following the INVOLVE guidelines closely [1], the team laid out a structured plan to incorporate PPI across the seven distinct stages of the research cycle, thereby embedding patient and public perspectives comprehensively throughout the project.

All PPI activities and engagement were recorded using the adapted approach by Tomlinson et al. Tomlinson's approach offers a structured framework for documenting and categorising PPI as engagement activities. It enables systematic recording of who was involved, the context and nature of their contributions, and how these inputs informed specific aspects of the research. This method facilitates transparency and supports subsequent evaluation of the scope, timing, and impact of PPI throughout the study. Record of interaction sheet was initially created by the research assistant and Clinical Nurse Manager (CNM). The worksheet was then completed by the study's CNM or research assistant, when there was contact made with the members of the PPI panel. The worksheet was used to record the following information (i) Date (DD/MM/YY), (ii) Format of contact (in-person, online via Teams, by email and phone call), (iii) PPI panel, (iv) Stage of study (Project design, Project development, Project analysis and Project dissertation), (v) Task, (vi) Interaction Feedback and (vii) Direct changes made based on the interaction [15]. (Table 1 shows an example from this worksheet). The PPI group comprised patient advocates (individuals with lived experience of cancer) and professional stakeholders (e.g., clinicians, oncologists, and nurses). In addition to the full group, subgroups were formed to allow for more specific input when needed. These consisted either only of patient advocates or of professional stakeholders, depending on the need for review or discussion. Study materials review and communications were sometimes directed to the full PPI group, particularly when broader perspectives were needed, and at other times specifically to patient advocates when input from lived experience was most relevant to the task at hand (e.g., reviewing participant-facing documents).

Guidance for Reporting Involvement of Patients and the Public - Long Form (GRIPP2-LF) reporting checklist was used as a reporting tool for this paper.

The LYSA trial received full ethical approval, granted by Clinical Research Ethics Committee of the University Teaching's Hospital [ECM 4 (y) 20/10/2020 & ECM 3 (ddd) 08/12/2020], (ClinicalTrials.gov identifier: NCT05035173) [16]. As this publication is a direct output from the LYSA trial specific ethical approval was not deemed necessary. Members of the PPI panel have voluntarily agreed to work with the study team and have agreed to data being published.

Results

Stage 1 'identifying and prioritising' & stage 2 'commissioning'

At the inception stage of the trial design, one PPI contributor with lived experience of cancer collaborated with the Principal Investigator (PI), a medical oncologist, to support early-stage study input. This involved study review and amendments to the initial study proposal. The

Table 1 Sample table used to record PPI activities and engagement - adapted approach by Tomlinson et al

Date (DD/MM/YY)	Format	PPI Panel/ Patient Advocates	Stage of study	Task	Feedback interaction	Direct changes made	Notes about positive and negative effect of the interaction
18/12/2020	Video call	PPI Panel	Project development	2–3 Month meeting	**Attendance**: 25 **Highlights**: Randomisation-Keeping the control group involved & content was discussed PPI input - Encouraged to use a slow approach with diet and exercise as the patient may not be emotionally in a place to take on this advice too strong initially.	consider a Survivorship Day for the control group at the end of the study. • Symptom clusters and their impact in QOL. Pathway prioritisation will be made by patient and nurse discussion. (More collaboration with the patient priorities)	- Agreements made about regular interactions: 1 monthly email + every 2–3 month meeting. - The interaction brought up further proactive interactions.
01/01/2021	Emails	Patient Advocates	Project Development	Review appropriate care plan and opportunity to review relevant pathways	5 pathways reviewed and positive feedback received, minor amendments made	• Excited by resources supports available for ladies. • Would have loved this on completing treatment. • May be ready for different information at different stages. • Go slowly to begin with, if early days after completion of treatment. • Alot of guilt around getting cancer so to be careful with prevention and advice. • Encourage self-care	Positive patient feedback, patient friendly. Needs medical support to complete.

review culminated in the joint development of the grant application. The PPI contributor wrote a letter of support for the ethics application, in which she highlighted, based on her personal experience of cancer, the clear need for the study and the importance of addressing the specific challenges faced by cancer survivors. The collaboration led to more patient focused outputs of the study. The patient involvement was crucial to align patient requirements with the grant call.

PPI and stakeholders panel recruitment

Following the successful funding application further study development including PPI recruitment commenced by the trial's Clinical Nurse Manager (CNM) and a research assistant. The LYSA trial PPI Panel included patient advocates and multidisciplinary stakeholders. PPI contributors' recruitment started in November 2020, by the CNM. The recruitment process was completed in line with the INVOLVE Guide to Patient and Public Involvement [1]. To facilitate recruitment of PPI contributors, the CNM reached out via email to the disease-specific consultants, clinical nurse specialists, funding bodies and various cancer support centres in the Health Service Executive (HSE) South region. An extensive network of healthcare professional colleagues was a valuable resource for recruitment of patients who might be interested in being involved in research. All interested patient advocates formed part of our PPI panel. These advocates took part in an 'informal interview' to ensure they fully understood the level of commitment and involvement. These discussions were conversational in nature and designed to explore contributors lived experience, and willingness to engage with trial activities. Example questions included:

- *"Have you previously participated in any research, advocacy, or support activities?"*
- *"Would you feel comfortable reviewing study materials or taking part in group discussions?"*
- *"What reimbursement was suitable for their time and expertise?"*

Responses to these questions helped ensure that contributors had relevant lived experience with cancer, interest in contributing meaningfully to the research, and the capacity to engage with the study team and other PPI members. This informal, discussion-based approach supported the identification and recruitment of contributors whose perspectives would be most relevant and valuable to the development, design and delivery of the trial.

An additional five patient advocates were recruited by the CNM. The recruitment was finalised in December 2020, with a total of 6 patient advocates and 65 multidisciplinary stakeholders making up the LYSA PPI panel.

Stakeholders were professionals who have expressed interest in joining the panel or have previously worked on design and implementation of the trial design. Many of the stakeholders were involved in the management of the trial specific cohort of patients in their clinical practice.

Upon the establishment of the PPI panel, the first PPI team meeting took place via Microsoft Teams to confirm the structure of future interactions. It was agreed by the study team and the PPI panel that meetings would take place virtually every 3 months and a monthly update email would be sent at the end of each month. All meetings took place virtually as the trial took place at the peak of the COVID-19 pandemic and lockdown restrictions were in place. Seven virtual PPI meetings took place between December 2020 and September 2023. Meetings were planned and were focused on the following agenda: updates on the team structure, recruitment and study status update, followed by a general discussion. Meetings were an opportunity to provide regular study updates to the PPI panel and gain insights for future work, studies and complimentary pieces to the study such as the Metastatic Breast Cancer (MBC) Day of "Hope, Tools and Solidarity" organised in a local cancer support centre and the development of a Dietary Book focusing on Menopause and Cancer Survivorship.

PPI characteristics

Six female PPI contributors had a history of cancer: breast, gynae and lymphoma cancer. PPI contributors mean age at project initiation was 48. All PPI contributors had somewhat similar reasons for joining the PPI panel. One of the common motives for joining the PPI panel is 'to give something back' to the health system that has helped them through their cancer journey. They believed that more can be done in the medical space of cancer survivorship and that they can be 'the voice' for those who are unable to voice their concerns. Four out of these six PPI contributors had previous experience in patient advocacy.

The first PPI interaction/engagement with the PPI panel took place on 18th December 2020 via Microsoft Teams videocall. Throughout the study there was a total of 46 interactions recorded, including seven virtual meetings and seventeen monthly update emails. Additional PPI interactions occurred outside of scheduled virtual meetings and monthly email updates. This interaction was mainly due to additional PPI activities such as review of study documentation, input of study related resources, invitation to study related events and reimbursement details.

73% of interactions took place via email, followed by 19% videocalls via Teams. The remaining 8% of interactions were categorised as "Other" and included both in-person meetings and additional phone calls. This category also captured unscheduled or ad hoc phone conversations that were not part of the planned video or email communications but still contributed meaningfully to the overall PPI process. Meeting attendance varied throughout the study and there was a linear decline in attendance over time.

Stage 3 'designing and managing' - PPI in planning and design of LYSA trial

PPI contributors were involved in several reviews of study material in the design phase of the trial. They reviewed all materials that study participants would receive during the trial. This included reviewing all surveys that would be sent out to participants in the intervention and control groups. (Table 2) Study surveys were reviewed physically in paper-format and this review resulted in minor amendments mostly referring to the language used. PPI members then reviewed the surveys online. The study's CNM sent surveys to the patient advocates via email as if they were the study participants. This online review did not result in any further amendments. All PPI contributors found the online use of surveys very user friendly.

In addition to study surveys, PPI contributors reviewed all study symptom pathways. PPI contributors helped to co-design the symptom management resources in partnership with the project team. (Table 2) They were enthusiastic by resources and supports developed for study participants. They believed that this information and resources would have been helpful if they had them available when they were finishing their treatment. PPI contributors used their personal experience with cancer, in particular breast and gynaecological to inform amendments to study material.

PPI contributors assessed and evaluated the ease of use of the electronic Patient Reported Outcome (ePRO) collection tool. (Table 2) There was positive feedback on the ease of use and the only amendments recommended were the use of visual graphics and colour. All PPI contributors felt that the study logo and study material should be more colourful. Following the review, the study material and online platforms were amended by applying agreed pink/purple colour palette.

The final PPI activity ahead of the start of the intervention was the development and review of the study's acronym. (Table 2) Extensive review resulted in the LYSA (Linking You to Support and Advice) acronym.

Stage 4 - 'undertaking'

As part of the process evaluation, four PPI contributors participated in Focus Group Discussion (FGD) that took place virtually over Microsoft Teams on 9th June 2022.

Although the LYSA trial involved early-stage breast cancer only, during the 'undertaking' stage, as a direct result of PPI input and recommendations, further work

Table 2 PPI activities by study stages and their impact on the trial

Stage of study	PPI activity	Description of activity	Impact on study
Study Development	Early consultation	Based on personal experience of cancer wrote a letter of support for grant application	Provided justification of study relevance Trial design addressed patient needs
Study Design - Participant Materials	Review of patient facing written material	Reviewed and edited language and formatting for clarity and tone	Improved readability and accessibility of study materials
Study Design	Engaged in the virtual consults	Provided the feedback on accessing and performing the virtual consults	Improved accessibility and acceptability of using virtual consults
Study Design	co-design the symptom management resources	Partnered with the study team to create resources and information for patients	symptom management resources were more patient friendly, and addressed symptoms important to patients
Study Design	Review the electronic Patient Reported Outcome (ePRO) collection tool	assessed and evaluated the ease of use of the ePRO tool	Amended the visual graphics and colours
Study design	Study acronym development	Worked with the study team to create a study acronym	Extensive review resulted in the LYSA (Linking You to Support and Advice) acronym.
Trial Implementation	Ongoing email feedback	Provided input on participant experience and communication during trial roll-out	Allowed responsive adjustments to processes in real time
Dissemination	Manuscript review	Reviewed and named co-author of the manuscript	Ensured all information in the manuscript is relevant and accurate

and research was done around improving the quality of life and symptoms experience in patients with MBC. Following discussions at our 3 monthly online meetings, concerns about the lack of resources around MBC came up on different occasions as women needed further support for them and their families. This led to the successful application for further grant funds to do a systematic review and needs assessment around metastatic breast cancer [17].

PPI advocates shared their concerns about the lack of information and resources about diet and use of supplements. These discussions have led to the LYSA research dietitians successfully securing funding from the Irish Cancer Society to develop Ireland's first ever resource specifically targeted at menopausal female cancer survivors on nutrition during survivorship. This work has encompassed national focus groups [18] a national supplement survey, and the creation of a national review panel, encompassing patient advocates.

Stage 5 'disseminating'

PPI contributors were involved in dissemination by taking part in print and social media work. Patient advocates have given informal interviews to the media and a local magazine that featured the LYSA trial and cancer survivorship research.

One PPI contributor received a national award for their Patient and Public Involvement work. This award was a result of her tireless patient advocacy work and significant involvement in the LYSA trial. The LYSA team nominated this advocate for the award as she was a catalyst from the grant application stage and work for the trial.

Further, PPI participation in dissemination of results was done following the end of the study. PPI contributors will be involved in developing the lay summary of the study.

Furthermore, the manuscript was sent to all patient advocates for review. 3 patient advocates expressed an interest in reviewing the manuscript. One patient advocate completed a more in-depth review and expressed an interest in being a co-author of this paper. The other two patient advocates had no previous experience or training in reviewing scientific publication.

Stage 6 & 7 'implementing' and 'evaluating impact'

The PPI panel have shown interest in participating in future LYSA research and LYSA 2. Additionally, there is now a Cancer Trials Group (CTG) PPI Panel that they may want to join for future opportunities and projects. This panel was established after the LYSA PPI panel, with significant input from the LYSA team, who contributed their learnings to its development [19].

This paper evaluated the impact of PPI activities on design and conduct of a randomised controlled clinical trial.

Discussion

This case study on the implementation of PPI in the LYSA trial, underpinned by the INVOLVE guidelines, sheds light on the nuanced process of embedding PPI across the various stages of a randomised controlled clinical trial. Our findings underscore the importance of initiating PPI at the earliest phases of trial design to ensure its meaningful integration and to mitigate the risk of tokenistic involvement. The structured approach to PPI facilitated the engagement of patient advocates and stakeholders throughout the trial, from the initial planning stages through to dissemination and evaluation of results.

The application of the GRIPP2-LF reporting checklist enhanced the transparency and quality of reporting on PPI activities, although challenges such as the perceived complexity of the checklist and the need for more reflexive collaboration with service users were identified. Despite these challenges, the active involvement of PPI contributors led to tangible improvements in trial materials, participant engagement strategies, and the overall relevance of the research to patient communities.

Although there is a significant increase in implementation of PPI, the research area of public involvement is still underreported. Reporting of implementation of PPI across different research disciplines is essential to understand and optimise variables and processes of PPI. [20, 21] Gilfoyle and colleagues stated that research in Ireland should move from the tokenistic and "checklist approach" and move towards more meaningful PPI that would improve quality of PPI [22].

The case of the LYSA trial illustrates the value of PPI in enhancing the design, conduct, and dissemination of clinical research. The outputs that resulted from the PPI activities has made the study more patient focused and relevant to the public. Although the study team has had a positive experience of working with the PPI contributors, we believe that more could have been done to implement PPI across different stages of clinical trial. Several important outputs, such as identifying research priorities, reviewing study materials, and ensuring the research is patient-centered from the beginning, were achieved during the initial stages of the study. Decline in PPI activities at later stages of the trial was impacted by the research team's clinical responsibilities and not having dedicated allocated time for planning PPI activities. The priority at this point was to complete the trial, carry out the intervention, and follow the protocol in a timely manner.

Critique from our PPI contributors suggest they want feedback and follow-up on their involvement in the research project. They gained significant insight into the overall research process, including the time and costs involved, and believe that when PPI is properly integrated, it has the potential to enhance the valuable contributions PPI members bring to the entire research field.

Challenges and limitations

Maintaining the engagement and power dynamics within the PPI panel was a challenge and limitation to successful and more meaningful implementation of PPI. Meeting attendance, email replies and willingness to participate in additional activities was declining as the trial progressed. Based on the feedback received, the declining engagement was attributed to the time commitment and the busy daily schedules of the PPI contributors. Three contributors were still working full-time, some were receiving treatment, and all six had children. Often, the timing and schedule of meetings were not suitable.

The study team was often challenged to maintain active involvement and engagement, as well as their study roles and responsibilities, which were primarily patient focused. The study did not have a study project manager who would have dedicated PPI time to organise more focused resources, meetings, and events for PPI.

Recommendations

Our recommendations are to allow sufficient time for adequate PPI planning at the initiation stage of the study. Developing a strategic plan of PPI activities throughout the study will allow for adequate allocation of time, funding, and staffing. It is necessary to have a dedicated member of staff who would coordinate and plan for PPI activities during various stages of the research cycle.

Ahead of the start of the study, the study team should communicate with PPI contributors about their previous experiences, training, expectations, and reimbursement. Organising training and providing additional resources during the study can be time consuming, but worthwhile and needed in some instances.

PPI planning should be done using multiple resources and allow for modification. The LYSA trial, followed INVOLVE and GRIPP2 guidelines, as well as the Public Involvement Impact Assessment Framework (PiiAF) and relevant Irish PPI guidelines [1, 16, 23].

Economic assessment

To determine the sufficient budget for PPI we used the NIHR Budgeting for Involvement guide. This budget was only used for PPI contributors' reimbursement and organisation of PPI events. The LYSA trial was funded by an Irish Cancer Society grant and a grant from Breakthrough Cancer Research. The Irish Cancer Society had a dedicated budget for PPI. PPI contributors were paid for their work input and participation. Agreed method

of payment was through gift vouchers as per University College Cork (UCC) guidelines for PPI payment [24]. PPI contributors were paid at the end of each year depending on their participation and involvement with the trial. This method of reimbursement was agreed with the panel at the offset of their involvement.

At the initial planning stages, we underestimated the time required for successful engagement with the PPI panel. Therefore, we did not have allocated funding for a staff member in charge of coordination of PPI activities.

Conclusion

The findings from this study advocate for the ongoing development and refinement of PPI guidelines and frameworks to support the effective implementation of PPI in clinical trials and other research setting. With the ultimate aim, to improve the quality and impact of health research on patient and public communities. PPI in the LYSA trial had an invaluable impact. Active patient and public involvement and engagement from inception, led to impactful patient-focused research outputs. Amendments made, as a result of direct PPI input, ensured the study is more patient orientated and relevant to the general public. Time constraints on the part of the research team may have negatively affected further involvement and participation, particular when the team were performing the intervention. Dissemination also takes place often when the team have moved on to other projects/employment which can hinder a continued relationship with the PPI Panel.

Abbreviations

PPI	Patient and public involvement
RCT	Randomised controlled trials
NIHR	National institute for health research
PPIE	Public involvement and engagement
HRB	Health research board
IRC	Irish research council
LYSA	Linking you to support and advice
ePRO	Electronic patient reported outcome
CUH	Cork university hospital
UHG	University hospital galway
CNM	Clinical nurse manager
GRIPP2-LF	Guidance for reporting involvement of patients and the public - long form
PI	Principal investigator
HSE	Health service executive
MBC	Metastatic breast cancer
FGD	Focus group discussion
CTG	Cancer trials group
PiiAF	Public involvement impact assessment framework
UCC	University college cork

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40900-025-00746-8.

Supplementary Material 1

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Author contributions

K. M. developed the initial concept and layout for the manuscript. K. M., K. O'C., L. R. and G. C wrote the main manuscript text. K. M. prepared table and supplemental file for submission. All authors reviewed the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

The ethical approval was not required for this PPI project. The patients and members of the public were actively involved in the research project but were not participating as research participants. They were acting as collaborators by providing valuable knowledge and expertise based on their lived experience. The LYSA trial was granted ethical approval by the Clinical Research Ethics Committee of Cork Teaching Hospitals in December 2020 (ECM 4 (y) 20/10/2020).

Consent for publication

All authors and PPI contributors revised the manuscript and approved its final version for publication in Research Involvement and Engagement.

Competing interests

The authors declare no competing interests.

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