**Title Page**

**Title**

Can a Public and Patient Involvement (PPI) informed Participant Information Leaflet (PIL) improve trial recruitment, retention, and quality of decision making? Results of a randomised controlled double-blind Study Within a Trial (SWAT)

**Short Running Trial**

PPI Participant Information Leaflet SWAT

**Authors**

Linda O’Neill1,2,3, Peter Knapp4, Suzanne L Doyle5, Sanela Begic1,2, Emily Smyth1,2, Neil Kearney3,8, Sophie Grehan1,2, Adwoa Parker4, Peter Browne2, Ricardo Segurado6, Deirdre Connolly2,7, Jacintha O’Sullivan2,8, John V. Reynolds2,8, Emer Guinan1,2, Juliette Hussey1,2

**Affiliations**

1 Discipline of Physiotherapy, School of Medicine, Trinity College Dublin, the University of Dublin, Dublin, Ireland

2 Trinity St James’s Cancer Institute, Dublin, Ireland

3 Clinical Research Centre, School of Medicine, University College Dublin, Dublin, Ireland.

4 Department of Health Sciences and the Hull York Medical School, University of York, York, United Kingdom

5 School of Biological and Health Sciences, Technological University Dublin, Dublin, Ireland

6 School of Public Health, Physiotherapy and Sport Sciences, University College Dublin, Dublin, Ireland.

7 Discipline of Occupational Therapy, School of Medicine, Trinity College Dublin, the University of Dublin, Dublin, Ireland

8 Department of Surgery, School of Medicine Trinity College Dublin and St James’s Hospital, Dublin, Ireland

**Correspondence to:**

Dr Linda O’Neill, linda.oneill1@ucd.ie

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**Abstract (250 words max)**

**Introduction**

Public and Patient Involvement (PPI) may be utilised to improve aspects of trial conduct. Specifically, this study within a trial (SWAT) aimed to examine if a PPI informed participant information leaflet (PIL) could improve recruitment, retention, and decision making of an exercise-based rehabilitation trial (RESTORE II) for upper gastrointestinal (UGI) cancer survivors.

**Methods**

Phase 1 applied qualitative methods to develop and refine a PPI informed PIL. Phase 2 embedded a randomised controlled double-blind SWAT within the RESTORE II trial, comparing a standard PIL (PIL A) to the PPI informed PIL (PIL B) in terms of recruitment, retention, and quality of decision making (Decision Making Questionnaire (DMQ)).

**Results**

Phase 1 recruited 16 PPI members (mean age 67.01 (9.28) years, mostly male (81.25%), and all UGI cancer survivors) who developed and refined PIL B. In Phase 2, 307 potential RESTORE II participants were randomised to receive either PIL A (n= 154) or PIL B (n=153). The overall recruitment rate was 28.66%. (PIL A 26.6% vs PIL B 30.7%, OR 1.22 (95% CI 0.74 to 2.01, p=0.43)), retention was 84.1% (PIL A 85.4% vs PIL B 83.0%, OR 0.84 (95% CI 0.26 to 2.65, p=0.760)). No significant difference in mean (SD) DMQ scores was observed PIL A: 29.09 (4.4) vs PIL B: 29.06 (5.1) (mean difference 0.03, 95% CI -1.64 to 1.69, p=0.49).

**Conclusions**

A PPI informed PIL did not improve recruitment, retention, or decision making for the RESTORE II trial.

**Patient or Public Contribution**

Patients with UGI cancer informed the development of the interventional PIL B. Author PB provided input from the patient’s perspective throughout the SWAT as a member of the Trial Steering Committee.

**Keywords**

Public and Patient Involvement; Recruitment; Retention; Participation Information; Trial Understanding

# Introduction

Advancements in cancer detection and treatments have led to a growing number of cancer survivors globally [1]. Accordingly, there has been a surge in research which aims to investigate strategies aiming to optimise quality of life in cancer survivorship and mitigate any negative sequalae of cancer and its’ treatments [2]. Exercise based rehabilitation is an example of such a strategy which increasingly has demonstrated efficacy, with strong evidence that thrice weekly moderate intensity aerobic training and twice weekly resistance training may alleviate symptoms of anxiety, depression, fatigue and improve quality of life and physical functioning for cancer survivors [3]. Nevertheless, questions remain regarding its impact on other cancer related symptoms, optimum dosing, and its effects in cancers other than breast, prostate, and colorectal cancer [3, 4]. To this end, trialists in cancer survivorship are continuing to explore the impact of exercise-based rehabilitation in cancer survivorship [3, 5]. However, recruitment and retention in these types of trials may be problematic limiting the generalisability and impact of findings and ultimately delaying the integration of much needed rehabilitation services into survivorship care [6, 7]. Consequently, it is incumbent upon trialists in cancer survivorship to explore strategies which may ameliorate recruitment and retention rates.

Increasingly, there has a been a growth in trials methodology research, which is the study of how we conduct research and is critical to developing and enhancing the conduct of clinical trials [8]. Trial methodologists in the United Kingdom and Ireland have worked collaboratively over the past decade to establish key priorities for trials methodology research [9]. Consistently, strategies to improve recruitment, and retention have been identified by trialists as priorities for investigation [8], with public and patient involvement (PPI) being once such intervention meriting exploration [10]. PPI refers to the active involvement of the public and patients in research [11] and is now an integral part of the research process. Not only is PPI essential to ensuring the patient voice is to the fore of clinical research, but increasingly evidence supports that PPI may impact positively on the conduct of clinical trials [10, 12]. For example, a systematic review and meta-analysis by Crocker et al investigating the impact of PPI interventions on rates of clinical trial recruitment and retention found that PPI interventions modestly improved the odds of participant recruitment (odds ratio 1.16, 95% confidence interval 1.01 to 1.34). Consequently, given the need to enhance recruitment and retention to rehabilitative trials in cancer survivorship we sought to explore if a PPI intervention could impact positively on recruitment and retention in an exercise-based rehabilitation trial in cancer survivorship.

The RESTORE II trial was a two-armed, single blind, randomised controlled trial comparing a multidisciplinary programme of supervised and homebased aerobic and resistance exercise, one-to-one dietary counselling, and group based multidisciplinary education to standard care in Upper Gastrointestinal (UGI) cancer survivorship [13]. A pilot randomised controlled trial of this intervention achieved positive recruitment and retention rates of 40.37% and 93.02% respectively [14]. Given the potential positives of PPI informed participant information, investigators leading the RESTORE II trial developed a Study Within A Trial (SWAT) with a view of optimising trial recruitment and retention further. The overall aim of the SWAT was to explore the impact of the PPI informed PIL in the RESTORE II Trial. Specific objectives were to; i) convene a panel of PPI members (UGI cancer survivors and/or family members) to develop and refine a PPI informed PIL, and ii) examine the impact of the PPI informed PIL on recruitment rates, trial retention, and quality of decision making about the trial. This manuscript is presented in line with the SWAT reporting guidelines[15].

# Methods

2.1 Study design

The study design has been described in detail elsewhere [16]. In brief the study was conducted over two distinct phases: Phase 1 (development) and Phase 2 (evaluation) (**Figure 1**). In Phase 1, public and patient involvement (PPI) representatives informed the development of the interventional participant information leaflet (PIL). In Phase 2, a randomised controlled Study within a trial (SWAT) was hosted within the RESTORE II trial at St James’s Hospital Dublin (SJH), Ireland, a national centre for UGI cancer care, to compare the PPI informed PIL to the standard PIL.

2.2 Recruitment

Phase 1 recruited PPI members, namely patients and/or their family members who had previously undergone treatment for cancer of the oesophagus, stomach, pancreas, or liver. Exclusion criteria included communication or cognitive difficulties which would inhibit ability to take part in the interview/ focus group process. A three-pronged approach to PPI member recruitment was implemented. First, participants of the RESTORE I trial or feasibility study [14, 17] were invited by letter to participate, second, PILs were provided to patients attending the UGI cancer clinic at SJH during October 2019, and finally individuals could self-refer by responding to adverts disseminated by the host trial charity partners, the Irish Cancer Society and the Oesophageal Cancer Fund. Phase 1 participants were required to give written informed consent. They received a small gratuity voucher (€20) for their participation, and parking costs were covered at SJH for those attending in person.

Phase 2 of the SWAT included all potential RESTORE II trial participants. The RESTORE II Trial [13] recruited participants with UGI cancer from SJH who had completed treatment with curative intent, were greater than 3 months post-surgery, and free from significant co-morbidity that would preclude maximal exercise testing.

2.3 Phase 1 – Development and Refinement of PPI Informed PIL

Phase 1 was conducted over two distinct sub-phases: Phase 1a (development of the PPI informed PIL) and Phase 1b (refinement of the PPI informed PIL).

2.3.1 Phase 1a – Development of the PPI informed PIL

In Phase 1a, patients or close family members were invited to take part in a one-to-one semi structured interview or a focus group discussion. All focus groups and face-to-face interviews were conducted in the Clinical Research Facility (CRF) at SJH. Participants who were unable to attend SJH at the time of the focus groups/interviews were given the opportunity to complete a 1:1 interview remotely via video or telephone call.

The focus groups and interviews were led by Dr Peter Knapp (PK), a male researcher experienced in PPI engagement and qualitative research, and who had no other involvement in the RESTORE II trial. The project manager, Dr Linda O’Neill (LON) a female researcher experienced in cancer rehabilitation was present for all interviews and focus groups to provide expertise on the host trial. Focus groups and interviews followed an agreed topic guide, which asked participants to comment on the standard RESTORE II Trial PIL. The standard PIL was developed prior to the first focus group according to the institutional template. Participants were invited to make suggestions to enhance the content, language, structure and visual appeal of the PIL. The Consensus-Orientated-Decision-Making model [18] was used to guide the focus group participants to consensus. Following completion of the Phase 1a focus groups/interviews recordings were transcribed verbatim and a simple thematic analysis was performed guided by the Braun and Clarke model [19] by LON and PK who then applied these key findings to develop an initial draft of the PPI informed PIL in consultation with a graphic design company (Making Sense Design Ltd).

2.3.2 Phase 1b – Refinement of the PPI Informed PIL

Two months after completion of Phase 1a, participants were asked to return for a second focus group/interview. Individuals who had expressed an interest in participation but were unable to attend for Phase 1a were also eligible to take part. Participants were provided with the draft PPI informed PIL via post a week before the Phase 1b focus group/ interview. In Phase 1b, participants critiqued the PPI informed PIL that had been drafted based on the Phase 1a findings and focused specifically on its structure, content, language and visual appeal. As per Phase 1a, focus groups/interviews were audio recorded, transcribed verbatim, and analysed using a basic thematic approach by LON and PK. The PIL was then refined by the graphic design team. The final draft of the PPI informed PIL was then circulated to Phase 1 participants for approval prior to submission for ethical approval for use in the RESTORE II trial. The finalised PIL was printed professionally, in colour and A4 booklet format.

2.4 Phase 2 – Evaluation

Following ethical approval, the resultant PPI informed PIL was tested in a prospective, randomised, double blind, parallel trial design. Potential RESTORE II trial participants were randomised to receive either the standard PIL (PIL A) or the PPI informed PIL (PIL B). Recruitment to RESTORE II was completed via the institutional database at SJH. Following medical team approval eligible trial participants received a letter from the lead clinical investigator (JVR) and the project manager (LON) inviting them to express an interest in participating in the RESTORE II trial along with PIL A or PIL B, the Decision-Making Questionnaire (DMQ), and a stamped addressed envelope.

2.4.1 Randomisation

Randomisation was overseen by the CRF at SJH. Participants were randomised in a 1:1 ratio, using block randomisation (blocks of 2,4,6,8), by an online randomisation system (www.sealedenvelope.com) and was shared with and accessed by members of the research team not directly involved in recruitment.

2.4.2 Blinding

Participants invited to participate in the RESTORE II trial were blinded to the SWAT. Trial members responsible for recruitment were also blinded to SWAT allocation.

2.4.3 Outcomes

The primary outcome for this SWAT was recruitment rate to the RESTORE II trial, defined as the proportion of eligible participants who agreed to take part in the RESTORE II trial. Secondary outcomes were retention and trial understanding. Retention was defined as ‘the proportion of randomised participants who participated in the RESTORE II host trial up to and including the first follow-up data collection time point (T1 – post-intervention assessment completed 12 weeks post enrolment).

Quality of decision making was measured using a modified version of the TRECA Decision-Making-Questionnaire (DMQ)[20], which evaluates the utility of information to help make informed decisions about trial participation. The DMQ consists of nine Likert scale questions which are scored from 0-4 and have a total possible score range of 0-36, with a higher score indicating better quality of decision making [21]. In the case were missing values occur, up to three missing responses are permitted and the total score is calculated by replacing the missing values with the mean value of the completed responses [21]. There are also three ‘open text’ questions which give respondents the opportunity to highlight parts of the PIL that were explained well, items they may require further information on, and make any other additional comments [20], responses to these items were categorised using content analysis. The DMQ was provided to potential RESTORE II trial participants along with the recruitment letter and allocated PIL. Potential RESTORE II trial participants received a follow-up phone call from the recruitment team to check their interest in participation one week after they received the trial information. During that call researchers asked potential RESTORE II trial participants to complete the DMQ and return in the stamped addressed envelope provided.

2.4.4 Sample Size

A sample size of approximately 300 patients was projected for this SWAT to give 80% power to detect an improvement in recruitment rates from 40 to 56% [1].

2.5 Statistical Analysis

Statistical analyses were performed using SPSS 29 (SPSS Inc., Chicago, IL, USA), following intention-to-treat principles. Baseline characteristics of Phase 1 SWAT and RESTORE II participants were analysed descriptively. Continuous data was presented as mean (standard deviation) and categorical data as counts and percentages. For analysis of recruitment and retention rates, logistic regression was used to determine odds ratios and their associated 95% confidence intervals and p-values. Independent t-tests were used to determine differences between groups (PIL A and PIL B) for total DMQ score.

# Results

3.1 Phase 1 PPI Member Characteristics

Phase 1 recruited 16 PPI members (**Table 1**). Twelve had previously completed the RESTORE Programme (RESTORE Feasibility Study or Pilot RCT) [3, 4], three were recruited from the UGI Cancer Clinic at SJH, and one responded to adverts on social media.

PPI members were mostly male (n=13, 81.25%), retired (n=11 (68.75%), all white with English as first language. Highest level of education completed was reported as follows: third level, n=7 (43.75%), upper secondary (n=4, 25%), lower secondary (n=2, 12.5%), and primary (n=3, 18.75%). All had a history of cancer diagnosis; oesophageal (n=14, 87.5%), stomach (n=1 (6.25%)), and pancreas (n=1 (6.25%)), and were a mean (standard deviation) 4.45 (2.28) years post diagnosis. Thirteen had previously participated in a rehabilitation trial (81.25%). Fourteen took part in Phase 1a, with 12 taking part in a focus group (85.71%), one completed a telephone interview (7.14%), and one took part in a face-to-face interview (7.14%). Fifteen took part in Phase 1b, with 14 taking part in a focus group (93.33%) and one took part in a telephone interview (6.67%).

3.2 Phase 1 Key Findings

Phase 1a focus group and interviews resulted in five key recommendations; i) revise how the PIL is presented, ii) revise how the trial title is presented, iii) provide all key information on the first page, iv) emphasise the potential benefits of trial participation, v) revise text and diagrams to improve readability. In Phase 1b, specific revisions on the visual appearance, text and layout were recommended. Specific details of all Phase 1 recommendations and supporting quotes are presented in **Table 2**.

3.3 Phase 2 Participants

The RESTORE II SWAT commenced in February 2022. A total of 307 participants met the RESTORE II eligibility criteria from February 2022 to May 2024. 154 were randomised to receive PIL A and 153 were randomised to receive PIL B (**Figure 1**). Baseline characteristics are only available for participants who consented to the RESTORE II trial due to data protection legislation (**Table 3**). The mean (standard deviation) age was 67.01 (9.28), participants were mostly male (n=60, 68.18%), all were ethnically white, and for all but one participant English was their first language (98.86%).

3.4 Phase 2 Results

**3.4.1 Primary Analysis**

*Recruitment*

Of the 307 participants approached to take part in the RESTORE II trial, 88 consented to participation representing a recruitment rate of 28.66%. For those receiving PIL A the recruitment rate was 26.6% (n=41/154). For those receiving PIL B the recruitment rate was higher 30.7% (n=47/153). Logistic regression gave an OR of 1.22 (95% CI 0.74 to 2.01, p=0.43) meaning whilst participants receiving PIL B were 22% more likely to be recruited, there was no statistically significant effect of PIL type on recruitment.

**3.4.2 Secondary Analysis**

*Retention*

Of the 88 participants randomised into the RESTORE II trial, 74 (84.1%) were still participating at the T1 (post-intervention) timepoint (35/41 (85.4%) PIL A and 39/47 (83.0%) PIL B). The logistic regression gave an OR of 0.84 (95% CI 0.26 to 2.65, p=0.76), meaning whilst participants who received PIL B were 16% less likely to be retained at T1, there was no statistically significant effect of PIL type on retention.

*Decision-Making Questionnaire*

A total of 144 (46.9%) DMQ questionnaires were returned (73/154 (47.4%) who received PIL A, and 71/153 (46.4%) PIL B). Of the 144 returned DMQs 130 were fully completed (90.28%). Of those who received PIL A 65/73 returned were fully completed (89.04%), and those receiving PIL B, 65/71 (91.54%) of the DMQs returned were fully completed. Amongst RESTORE trial consenters the DMQ return rate was 70.5% (n=62/88), whereas amongst non-consenters it was 37.4% (n=82/219). The overall DMQ total mean score was 29.07 (SD 4.74). No significant difference in total mean DMQ score was observed between the groups (PIL A 29.09 (SD 4.4) vs PIL B 29.06 (SD 5.1), mean difference 0.03, 95% CI -1.64 to 1.69, p= 0.49,). **Table 4** summarises the responses to each question on the DMQ scale.

There were 21 responses (PIL A n=10, PIL B n=11) to question 10 ‘*Is there any additional information that you would have wanted?*’ Key responses included; i)seeking information on timing/dates of intervention and assessments (n=12, PIL A n=6, PIL B n=6), ii)reported no further information needed (n=4, PIL A n=3, PIL B n=1), iii) seeking clarity on definitions e.g. usual care, current treatment, home based exercise (n=2, PIL A n=0, PIL B n=2). Seventy-five participants responded to Question 11 ‘*Identify aspects of information that were explained well*’ (PIL A n=37, PIL B n=38). Frequent responses included; i) all of the information (n=30, PIL A n=13, PIL B n =17), ii) the assessments (n=7, PIL A n=6, PIL B n=1), iii) the RESTORE II Rehabilitation Programme (Exercise, Diet and Education) (n=17, PIL A n=7, PIL B n=10), iv) the possible benefits and risks of participation (n=5, PIL A n=3, PIL B n=2) and v)the individual commitment required for participation (n=8, PIL A n=7 control, PIL B n =1). There were 38 responses to Question 12 ‘*Do you have any other comments?*’ (PIL A n=23, PIL B n=15). Responses included; i) travel burden prohibited participation(n=13, PIL A n=6, PIL B n=7), ii) family commitments prohibited participation (n=3, PIL A n=0, PIL B n=3), and iii) work commitments prevented participation (n=2, PIL A n=1, PIL B n=1), iv) altruism motivated participation (n=2, PIL A n=1, PIL B n=1), and v) declined participation as too far into recovery (n=2, PIL A n=2, PIL B n=0).

# Discussion

PPI is essential to ensuring patients are at the heart of clinical research, and increasingly the efficacy of PPI in trials is being explored by trial methodologists [11]. This SWAT applied PPI purposefully with a view to improve the content, structure, and visual appeal of the PIL for the RESTORE II trial. However, the resultant PPI informed PIL did not lead to significant improvements in recruitment, retention, or quality of decision making for the RESTORE II trial.

An overall recruitment rate of 28.66% was achieved to the RESTORE II trial. Whilst the rate was slightly higher for the SWAT intervention group (PIL B) the difference was not statistically significant. Moreover, the recruitment rate to this definitive trial is much lower than the 40.37% achieved by the RESTORE I Pilot RCT conducted between 2016 and 2017 [14]. This lower than anticipated accrual rate may be attributed to a myriad of factors. First, the RESTORE II trial was due to commence in Spring of 2020 but due to restrictions associated with the COVID-19 pandemic, the trial was delayed and did not commence until Spring of 2022. The pandemic saw an unprecedented increase in the uptake of video calling and a rise in the acceptance of the remote delivery of healthcare via telehealth, including the provision of rehabilitation programmes [22, 23]. Resultantly attitudes towards face-to-face changed, and patients were much less open to hospital-based rehabilitation than they were previously [24-26]. Due to the nature of the SWAT, the investigators were restricted in their approach to recruitment. To maintain blinding to the SWAT intervention, recruitment was limited to letter-based invitation only. It was unforeseen that this lack of face-to-face recruitment may have detrimentally impacted the accrual rate. Prior work by this group has highlighted how direct recruitment by health care professionals can improve recruitment rates to exercise-based cancer rehabilitation trials [7]. Furthermore, the post pandemic changes in attitude to hospital-based rehabilitation may also have contributed to the lower retention rate achieved by the RESTORE II trial in comparison to its’ pilot (93% vs 83%)[27].

The inclusion of the DMQ in this SWAT provides better understanding into motivators and barriers to rehabilitation trial participation in cancer survivorship. In the context of cancer survivorship key motivators for trial participation include wanting access to the best or newest treatments and wanting closer supervision by one’s medical team [28, 29]. In addition, high levels of altruism are reported amongst cancer survivors with a resounding sense of needing to give back, and making things better for those in the future, and this was reported in our DMQ responses [30], and corresponds with findings from the pilot RCT of this intervention [31, 32]. Reasons for non-participation are often poorly understood but the DMQ highlighted some key reasons for non-participation in the RESTORE II trial. The three most frequently reported barriers to participation were travel, family, and work commitments, which align strongly with findings from systematic reviews of exercise oncology trials[6, 33]. As aforementioned given the emergence of telehealth as an acceptable mode of rehabilitation delivery, trialists should endeavour in designing future trials of interventions with greater flexibility to overcome these personal barriers to participation [26] to maximise trial accrual and retention.

Despite the lack of positive findings emanating from this SWAT it is important to highlight the immense value PPI brings to clinical trials[34]. In the past few decades there’s has been a switch from PPI being an act of tokenism in clinical trials to becoming a meaningful part of the trial design and implementation process [12], and increasingly the inclusion of PPI is expected if not mandated by higher education institutions and funders of research [35]. The rationale to include PPI in clinical trials is clear, for research to be truly meaningful it needs to consider the voice of the patients at the core of the research project [36]. However, we have moved beyond this tokenistic approach and increasingly trial methodologists are quantifying how PPI can enhance the conduct of clinical trials [37]. Whilst this SWAT did not show a significant of PPI on trial enrolment, others have, and PPI has also been reported to be effective in assisting researchers to secure funding, developing trial protocols and selecting appropriate trial endpoints [10, 38]. To this end, trials methodologists need to continue to investigate how PPI can be best incorporated to enhance aspects of trial conduct.

This SWAT had some strengths and limitations. Key strengths of this SWAT include the use of PPI to inform the development of the interventional PIL, and the randomised double-blind approach to assessing its efficacy. SWAT embedment does however increase trial costs. Additional costs accrued due to the SWAT included the provision of gratuity vouchers, refreshments and parking costs for PPI members, international travel costs of facilitator, graphic design and printing costs. The lack of diversity in the Phase 1 PPI group is also a limitation. Whilst the PPI group were reflective of the UGI cancer population in the Republic of Ireland (mostly older white males) it was not reflective of other ethnic groups. In line with best practice, future work should aim to be more inclusive. A significant limitation of Phase 2 was the lack of demographic data for non-consenters to the RESTORE II trial. Due to the General Data Protection Regulations and Health Research Regulations such data could not be processed without informed consent. Finally, the low return rate of DMQs limited the ability to assess the impact of the interventional PIL on the quality of decision making around the trial. Accordingly, future work in this area should investigate strategies to optimise the return rate of DMQs.

# Conclusions

A PPI informed PIL did not lead to significant improvements in recruitment, retention and quality of decision making for the RESTORE II Trial. Notwithstanding this finding, trial methodologists should continue to investigate how PPI engagement may best enhance the conduct of trials.

**Author Contributions**

**Linda O’Neill:** conceptualisation, methodology, investigation, visualisation, formal analysis, project administration, writing - original draft preparation, writing - review and editing. **Peter Knapp:** conceptualisation, methodology, supervision, investigation, writing - review and editing. **Suzanne L Doyle**: conceptualisation, methodology, funding acquisition, writing - review and editing. **Sanela Begic:** investigation, project administration, writing – review and editing. **Emily Smyth:** investigation, project administration, writing – review and editing. **Neil Kearney:** investigation, project administration, writing – review and editing. **Sophie Grehan:** investigation, project administration, writing – review and editing. **Adwoa Parker:** methodology, writing – review and editing. **Peter Browne:** funding acquisition, writing – review and editing. **Ricardo Segurado**: methodology, formal analysis, writing - review and editing**. Deirdre Connolly:** funding acquisition, writing – review and editing. **Jacintha O’Sullivan:** funding acquisition, writing – review and editing. **John V Reynolds:** funding acquisition, writing – review and editing. **Emer Guinan:** conceptualisation, methodology, supervision, funding acquisition, writing - review and editing. **Juliette Hussey:** conceptualisation, methodology, supervision, funding acquisition, writing - review and editing.

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**Data Availability Statement**

The data that support the findings of this study are available on request from the corresponding author

**Ethics Statement**

Ethical Approval was obtained from the Tallaght University Hospital/ St James’s Hospital Research Ethics Committee.

**Conflict of Interest Statement**

The authors do not have any conflict of interest to declare.

**ORCID**

Linda O’Neill: <https://orcid.org/0000-0002-0109-9650>

Peter Knapp: <https://orcid.org/0000-0001-5904-8699>

Suzanne L. Doyle: <https://orcid.org/0000-0002-6887-0446>

Sanela Begic: <https://orcid.org/0009-0006-1828-156>X

Emily Smyth:

Neil Kearney:

Sophie Grehan:

Peter Browne: N/A

Adwoa Parker: <https://orcid.org/0000-0002-2880-3935>

Ricardo Segurado: <https://orcid.org/0000-0002-3547-6733>

Deirdre Connoly: <https://orcid.org/0000-0001-8539-8123>

Jacintha O’Sullivan: <https://orcid.org/0000-0001-8622-9858>

John V. Reynolds: <https://orcid.org/0000-0002-5501-9521>

Emer Guinan: <https://orcid.org/0000-0001-9715-146X>

Juliette Hussey: <https://orcid.org/0000-0002-8846-0639>

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