

SWAT 261: Evaluation of participants' perspectives and preferences on dissemination of the results of a clinical trial

Objective of this SWAT

1. To address the lack of consensus on the most appropriate methods of sharing research findings with participants.
2. To evaluate the acceptability of a patient and public involvement and engagement (PPIE) based method of disseminating end of trial results.

Additional SWAT Details

Primary Study Area: Dissemination

Secondary Study Area: PPI; Qualitative

Who does the SWAT intervention target: Carer/Parent; Participants; Patients

Estimated resources needed to conduct the SWAT: Medium

Estimated cost of the SWAT (£): £10,000

Findings from Implementation of this SWAT

Reference(s) to publications of these findings: N/A

Primary Outcome Findings: N/A

Cost: N/A

Background

Dissemination of findings from randomised trials has traditionally relied on three main routes: (a) scientific meetings and peer-reviewed journals; (b) lay media; and (c) communication with groups holding a specific health interest.[1] However, as part of other research funded by the National Institute for Health and Care Research (NIHR) within the dialysis population, our Patient and Public Involvement and Engagement (PPIE) work identified clear consensus that a broader range of dissemination approaches is required. This reflects the wide age range and diverse preferences of people receiving haemodialysis. Moreover, improving how information is delivered to members of the public was identified as a top 10 research priority in trial methodology by the PRioRiTy study.[2]

In line with our commitment to ensuring that trial results are communicated effectively to participants and the wider public, we plan to evaluate participants' perspectives and preferences for the dissemination of the results of clinical trials. This Study Within a Trial (SWAT) adapts the design originally developed by Patricia Kearney in 2016 (SWAT 46).[3]

The SWAT will be embedded in the NightLife study (IRAS 280452; ISRCTN87042063), a randomised trial of the clinical and cost-effectiveness of thrice-weekly, extended, in-centre nocturnal haemodialysis compared with standard care, using a mixed-methods approach. Consistent with best practice, results from the NightLife study will be disseminated to all participants. The SWAT aims to address the current lack of consensus regarding optimal methods for sharing research findings with patients by evaluating a PPIE-informed dissemination strategy.

The SWAT will use a mixed-methods, two-stage design. Stage 1 will involve semi-structured focus groups with up to 10 participants purposively sampled from NightLife study participants, current haemodialysis patients, and members of the NightLife PPIE group. Guided by the Consensus Orientated Decision-Making (CODM) model,[4] participants will collaborate with researchers to design a patient-centred dissemination approach addressing format, content, language, visual presentation and level of detail. Discussions will inform refinement of health literacy and patient satisfaction measures for stage two. Stage 2 will comprise a randomised comparison involving 100 previous NightLife study participants who will be allocated 1:1 to receive either the standard report of the results or the patient-designed dissemination method. After reviewing their allocated version, participants will complete validated questionnaires assessing acceptability, comprehension and satisfaction via JISC online surveys. At the conclusion of the SWAT, all participants will receive access to both dissemination formats to support transparency.

This SWAT will contribute to the evidence base on effective patient involvement in research and on optimising end-of-trial dissemination strategies to enhance understanding, accessibility, and participant satisfaction.

Host Trial Population: Adults
Host Trial Condition Area: Renal

Interventions and Comparators

Intervention 1: Standard report of results
Intervention 2: PPIE-based method of results dissemination

Method for Allocating to Intervention or Comparator: Randomisation

Outcome Measures

Primary Outcomes: The primary outcome will focus on acceptability of the disseminated results, assessed using validated health literacy and patient satisfaction questionnaires.

Secondary Outcomes: N/A

Analysis Plans

Stage 1 (focus groups): The CODM model will be used to guide the focus groups and analyse the findings. The CODM model provides flexibility in exploring a topic of interest and reaching decisions with patient participants on how best to proceed.

Stage 2 (randomised trial): The questionnaire data be analysed using Microsoft Excel, SPSS, and R as necessary. Data will be presented descriptively using appropriate summary statistics: number and percentage; mean and standard deviation; median and interquartile range. Data will be assessed for normality using histogram plots and statistical tests, such as the Shapiro-Wilk test. Data will be presented separately for the two SWAT interventions.

Possible Problems in Implementing This SWAT

1. Dependence on the main NightLife study timeline: The SWAT is linked to the completion of the host study, because dissemination of the results to participants can only occur after finalisation of the main findings. Therefore, any delays in preparing the NightLife results could extend the SWAT timeline.
2. Turnaround time between the two stages: Findings from the Stage 1 focus groups need to be incorporated promptly into the PPIE-developed results materials before Stage 2 dissemination begins. If Stage 1 activities take longer than anticipated, this may reduce the time available for refinement of the PPIE-based materials.
3. Use of JISC online surveys for consent and data collection: The SWAT uses JISC online surveys to obtain electronic consent and to collect questionnaire responses. While this is efficient and secure, a small number of participants with limited digital access or lower confidence using technology may find online completion more challenging.

References Cited in This Outline

1. Fernandez CV, Kodish E, Weijer C. Informing study participants of Research Results: An Ethical Imperative. *IRB: Ethics and Human Research*. 2003;25(3):12-9.
2. Health Research Board – Trials Methodology Research Network. The PRioRiTty (Prioritising Recruitment in Randomised Trials) Study: Setting priorities for trial recruitment research [Internet]. [accessed 30 September 2025]. Available from: <https://priorityresearch.ie/wp-content/uploads/2017/04/192791-hrb-report-online-final.pdf>
3. Northern Ireland Network for Trials Methodology Research. SWATStore [Internet]; [accessed on 30 September 2025]. Available from: <https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/>

4. Racine E, Hurley C, Cheung A, Sinnott C, Matvienko-Sikar K, Baumgartner C, et al. Participants' perspectives and preferences on clinical trial result dissemination: the TRUST Thyroid Trial experience. HRB Open Research 2019;1:14.

References to This SWAT

N/A

Source of This SWAT

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