Undertaking Studies Within A Trial to evaluate recruitment and retention strategies for randomised controlled trials: lessons learnt from the PROMETHEUS research programme

Adwoa Parker,[1] Catherine Arundel,[1] Laura Clark,[1] Elizabeth Coleman,[1] Laura Doherty,[1] Catherine Elizabeth Hewitt,[1] David Beard,[2] Peter Bower,[3] Cindy Cooper,[4] Lucy Culliford,[5] Declan Devane,[6,7] Richard Emsley,[8] Sandra Eldridge,[9] Sandra Galvin,[6,7] Katie Gillies,[10] Alan Montgomery,[11] Christopher J Sutton,[12] Shaun Treweek[10] and David J Torgerson[1*]

[1]York Trials Unit, Department of Health Sciences, University of York, York, UK
[2]Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Science, NIHR Biomedical Research Unit, University of Oxford, Oxford, UK
[3]National Institute for Health Research School for Primary Care Research, Centre for Primary Care and Health Services Research, University of Manchester, Manchester, UK
[4]School of Health and Related Research, University of Sheffield, Sheffield, UK
[5]Bristol Trials Centre, Clinical Trials and Evaluation Unit, University of Bristol, Bristol Royal Infirmary, Bristol, UK
[6]School of Nursing and Midwifery, University of Galway, Galway, Republic of Ireland
[7]Health Research Board-Trials Methodology Research Network, Galway, Republic of Ireland
[8]Department of Biostatistics and Health Informatics, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK
[9]Institute of Population Health Sciences, Queen Mary University of London, London, UK
[10]Health Services Research Unit, University of Aberdeen, Foresthill, Aberdeen, UK
[11]University of Nottingham, Nottingham Clinical Trials Unit, University Park Nottingham, Nottinghamshire, UK
[12]School of Health Sciences, University of Manchester, Manchester, UK

[*]Corresponding author david.torgerson@york.ac.uk

Disclosure of interests of authors

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/HTQW3107.

Primary conflicts of interest: Adwoa Parker holds a NIHR Advanced Fellowship (NIHR302256), received funding from the MRC and NIHR as part of being a co-applicant on this PROMETHEUS programme (MR/R013748/1), is a co-applicant on a NIHR HTA-funded trial (ACTIVE, Award ID: 15/130/84) that was funded by PROMETHEUS, received funding from the Wellcome Trust, through the Centre for Future Health (CFH) at the University of York to developing a training intervention for staff to improve participant recruitment into randomised controlled trials, received funding through an institutional award from a NIHR CTU Infrastructure award (NIHR132547), is Editor for the special SWAT edition for the Journal Research Methods in Medicine and Health Sciences and is a SWAT Collection Advisor for F1000Research, and is supervising a PhD Studentship (2021–4) titled 'The cost effectiveness of SWATs for improving recruitment and retention in RCTs'.

Catherine Arundel received funding from two NIHR HTA grants as a co-applicant (PROFHER-2, award ID 16/73/03; and SWHSI-2, award ID 17/42/94) – both of which received PROMETHEUS funding, received a salary through institutional funding from the MRC and NIHR for the PROMETHEUS programme (MR/R013748/1), received funding through an institutional award for the DISC trial (NIHR HTA award ID 15/102/04) – which received PROMETHEUS funding, and received funding through an institutional award from a NIHR CTU Infrastructure award (NIHR132547).

Laura Clark received a salary through institutional funding from the MRC and NIHR for the PROMETHEUS programme (MR/R013748/1) and received funding through an institutional award from a NIHR CTU Infrastructure award (NIHR132547).

Elizabeth Coleman received a salary through institutional funding from the MRC and NIHR for the PROMETHEUS programme (MR/R013748/1).

Laura Doherty received a salary through institutional funding from the MRC and NIHR for the PROMETHEUS programme (MR/R013748/1) and received funding through an institutional award from a NIHR CTU Infrastructure award (NIHR132547).

Catherine Elizabeth Hewitt received funding from the MRC and NIHR as part of being a co-applicant on this PROMETHEUS programme (MR/R013748/1), and has also been the recipient of a range of NIHR funding, award IDs: HTA-133865, HTA – 16/111/91, HTA – 132718, HTA – 17/94/36, HTA – 17/76/06, RfPB – PB-PG-0317-20047, HTA – 131483, RfPD – 201176, RfPB – PB-PG-0418-20034, HTA – 15/154/07, HTA – 131784, HTA – 135304, PHR – 16/122/20, HTA – 15/102/04, PHR – 15/05/28, HSDR – 15/70/26, PGfAR – 201174, HTA – 15/130/84, HTA – 16/167/57, HTA – 16/73/03, HTA – 127739, HTA – 11/36/37, PHR – 14/186/11, HTA – 132808, HTA – 127467, HTA – 15/166/08, HTA – 128625, HTA – 133880, HTA – 17/42/94, HTA – 11/136/52, PGfAR – RP-PG– 1214-20017, HSDR – 129213, HTA – 133784, PGfAR – RP-PG-0216-20002, HTA – 14/49/149, PGfAR – RP-PG-1016-20003, PHR – 128341, HTA – 131805, PGfAR -200607, HTA – 133418, HTA – 127510, RIGHT – 200806, PGfAR – RP-PG-0217-20006, HTA – 13/26/01. She is a member of the NIHR HTA Commissioning Committee (2015 to present) and Deputy Chair (2019 to present). Prof Hewitt has also been a member of the HTA Commissioning Sub-Board (2016–17) and is a current member of the following committees: NIHR CTU Standing Advisory Committee (2020–4); HTA Post-Funding Committee (2020–3); HTA Funding Committee Policy Group (2020–3).

David Beard holds a NIHR Senior Investigator award, has received a range of NIHR funding, award IDs: HSDR – 131537, HTA – 14/140/63, HTA – 129830, HTA – 127807 RfPB – PB-PG-1215-20041 RfPB – PB-PG-0215-36084, HTA – 134398, HTA – 12/196/08, HTA – 131629, HTA – 15/80/40, HTA – 135260, HTA – 15/103/03, HTA – 15/39/06, HTA – 128043, PGfAR – RP-PG-0615-20002. Prof Beard also received funding from the MRC and NIHR as part of being a co-applicant on this PROMETHEUS programme (MR/R013748/1) and is a member of the NIHR HTA Commissioning Committee (2020 to present).

Peter Bower holds a NIHR Senior Investigator award, along with a range of other NIHR funding, award IDs: HSDR – 12/130/33, PRP – 201428, RfPB – PB-PG-0416-20033, RfPB – PB-PG-0816-20035, PGfAR – RP-PG-1016-20010, HSDR – 17/09/08, HSDR – 13/54/34, HSDR – 14/21/21 HTA – 16/84/01 PRP – 200933, HSDR – 151666, HSDR – 12/130/15, HSDR – 134436 HTA – 14/29/01 PDG – 202044, HSDR – 16/48/07, PGfAR – RP-PG-0216-20003, HSDR – 14/156/16, PGfAR – 202030, PGfAR – RP-PG-1210-12007, PGfAR – RP-PG-1214-20003, GHRG – 134638. Prof Bower also received funding from the MRC and NIHR as part of being a co-applicant on this PROMETHEUS programme (MR/R013748/1).

Cindy Cooper received funding from the MRC and NIHR as part of being a co-applicant on this PROMETHEUS programme (MR/R013748/1), and has also been the recipient of a range of NIHR funding, award IDs: CTU – 135424, CTU- 132546, CTU- 129761, CTU- 130354, CTU-34 (Infrastructure award), CTU- 129671, CTU- 129743, CTU- 129762, CTU- 135420, CTU- 135458, HTA – 12/21/01, RfPB – PB-PG-0817-20027, HTA – 09/06/01, EME – 133169, HTA – 13/14/01, HTA – 15/08/40, PDG – 202607, HTA – 14/140/80, HSDR – 14/140/80, Undefined stream – 127963, PDG – RP-DG-0615-10008, HTA – 16/81/01, PHR – 15/49/32, HTA – 15/38/04, HTA – 17/16/04, PGfAR – 201618, HTA – 15/35/03 PGfAR – RP-PG-1016-20006. She is a member of the NIHR CTU Standing Advisory Committee (2016–23).

Lucy Culliford received funding from the MRC and NIHR as part of being a co-applicant on this PROMETHEUS programme (MR/R013748/1), and has also been the recipient of a range of NIHR funding, award IDs: EME – 134140 PRP – 203243, RfPB – 201483, RfPB – PB-PG-0418-20029, HTA – 127849, EME – 15/180/55, HTA – 133554, EME – 13/94/15, HTA – 131850, HTA – 127457, HTA – 16/24/09, HTA – 15/101/16, HTA – 16/142/04, EME – 17/145/40, HTA – 16/140/07.

Declan Devane is the Scientific Director of the Health Research Board-Trials Methodology Research Network (HRB-TMRN). The HRB-TMRN is funded by the Health Research Board and its brief includes the funding of SWATs. He is a co-applicant on NIHR funded projects: HSDR – 150979, HTA – (17/148/07). He is a co-applicant on this PROMETHEUS programme (MR/R013748/1) and participates in a number of Data Safety Monitoring Boards and Advisory Boards.

Richard Emsley has received a range of NIHR funding, award IDs: NIHR300051 NIHR300051, PB-PG 1014-35011 NIHR127755, NIHR130971, 15/187/05, RP-PG-0216-20009, PB-PG-0613-31113, 17/80/09, 15/48/21, 16/111/51, 12/3000/40, NIHR128623, NIHR131175, 13/119/18, NIHR200605, NIHR129926, 16/101/02, NIHR131125, NIHR134702, 15/178/09, 14/29/01, RP-PG-0218-20006, RP-PG-1016-20010, 14/197/65, 15/31/04, NIHR132690, 14/68/08. Prof Emsley is a member of the NIHR HTA Clinical Evaluation and Trials Committee (2018–21), a member of the NIHR Clinical Trials Unit Standing Advisory Committee (2020–3), a member of the NIHR Strategy Board (2022) and is a NIHR Research Professor (2019–24).

Sandra Eldridge has received a range of NIHR funding, award IDs: CTU-32 (infrastructure award), CTU – 135421, CTU – 129741, PGfAR – RP-PG-0610-10097, HTA – 08/14/41, PGfAR – 202037, PGfAR – RP-PG-0611-20002, PGfAR – RP-PG-0615-20009, PGfAR – RP-PG-1212-20018, PHR – 16/139/01, RIGHT – 200824, PHR – 127793, PGfAR – RP-PG-0609-10181, PGfAR – RP-PG-0617-20004, PGfAR – RP-PG-1016-20008, PGfAR – RP-PG-0612-20001, PGfAR – RP-PG-1209-10038, PGfAR – RP-PG-0218-20001, GHR – 133850. Prof Eldridge is a member of the NIHR CTU Standing Advisory Committee, has been a member of the HTA Clinical Evaluation and Trials Committee (2014–8).

Sandra Galvin is the National Programme Manager of the Health Research Board – Trials Methodology Research Network Ireland, employed under funding grant HRB-TMRN-2021-001, which funds SWAT

research, is a co-applicant on this PROMETHEUS programme (MR/R013748/1), and is a SWAT Collection Advisor for F1000Research.

Katie Gillies has been the recipient of a range of NIHR funding, award IDs: HTA – 129248, RfPB – PB-PG-0416-20033, HTA – 132999, HTA – 14/192/71, HTA – 133561, HTA – 17/68/01, HTA – 130310, HTA – 127280, HSDR – 131537. Dr Gillies is a member of the NIHR HTA Clinical Evaluation and Trials Committee.

Alan Montgomery received funding from the MRC and NIHR as part of being a co-applicant on this PROMETHEUS programme (MR/R013748/1). He has been the recipient of a range of NIHR and MRC funding, award IDs: CTU – 132545, CTU – 135422, CTU-26, RfPB – PB-PG-0613-31083, RfPB – PB-PG-1217-20026, HTA – 12/190/05 EME – 11/47/03 RfPB – PB-PG-0817-20005, HTA – 15/110/02, HTA – 132711, HTA – 10/57/24, HTA – 129210, HTA – 127393, HTA – 127292, HTA – 131159, HTA – 16/96/09, HTA – 132016 EME – 128240 PGfAR – 203279, HTA – 12/24/02, HTA – 129515, PRP – 015/0309, PDG – RP-DG-0615-10005, HTA – 129917, HTA – 12/127/10, HTA – 17/94/31, HTA – 131440, COVID-19 – 133443, MRC – MR/K025643/1, MRC – MR/V020803/1. Prof Montgomery is an independent member of Trial Steering/Data Monitoring Committees for various NIHR-funded studies. He was a member of the HTA Clinical Evaluation and Trials Committee (2015–21).

Christopher J Sutton has received institutional funding from the MRC and NIHR for the PROMETHEUS programme (MR/R013748/1). He has also been the recipient of a range of NIHR funding, award IDs: HSDR – 130581, RfPB – 201093, RfPB – 203475, HTA – 16/111/31, RfPB – PB-PG-0214-33010, RfPB – PB-PG-1216-20024, RfPB – 203468, RfPB – 203507, HTA – 131483, PDG – 202044, HSDR – 14/04/16, EME – 132622, HTA – 133418. He is a member of the NIHR HTA Commissioning Committee (2020 to present).

Shaun Treweek received funding from the MRC and NIHR as part of being a co-applicant on this PROMETHEUS programme (MR/R013748/1). He has also been the recipient of NIHR and MRC funding, award IDs: PHR – 129791, HTA – 12/127/12, HTA – 15/130/73, MRC – MR/K025643/1. He is Editor-in-Chief of the journal '*Trials*'.

David J Torgerson received funding from the MRC and NIHR as part of being the Chief Investigator on this PROMETHEUS programme (MR/R013748/1). He has also been the recipient of a range of NIHR funding, award IDs: HTA – 14/49/149, PHR – 15/05/28, CTU-40 (infrastructure award), HTA – 127510, PHR – 128341, CTU – 132547, RfPB – 203506, PGfAR – RP-PG-0609-10171, HTA – 13/26/01, HTA – 15/166/08, PGfAR – RP-PG-0615-20003, HTA – 15/130/84, HTA – 15/154/07, RfPB – PB-PG-0416-20035, HTA – 16/73/03, PHR – 16/122/20, HTA – 16/167/56, HTA – 16/167/57, HTA – 17/42/94, HTA – 17/94/36, RfPB – PB-PG-0418-20034, HTA – 127739, HTA – 128625, HTA – 132718, PHR – 131745, HTA – 131805, HTA – 132674, RfPB – 202203. Prof Torgerson is an Editorial board member for the Journal Research Methods in Medicine and Health Sciences and is a SWAT Collection Advisor at F1000Research.

Published January 2024
DOI: 10.3310/HTQW3107

Scientific summary

Undertaking Studies Within A Trial to evaluate recruitment and retention strategies for randomised controlled trials: lessons learnt from the PROMETHEUS research programme

Health Technology Assessment 2024; Vol. 28: No. 2
DOI: 10.3310/HTQW3107

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Many delivery aspects of randomised controlled trials (RCTs) have not been subjected to rigorous evaluation. Strategies to enhance recruitment and retention often tend to not be based on evidence. However, there is an increasing interest in embedding RCTs of such strategies. The Medical Research Council (MRC) funded systematic techniques for assisting recruitment to trials (START), which found it feasible to test two strategies for recruitment and retention across a number of trials by performing randomised 'Studies Within A Trial (SWATs)'.

Aims

The aim of the PROMoting THE USE of Studies Within A Trial (PROMETHEUS) programme was to build on the START initiative and make embedding SWATs standard practice across Clinical Trials Units (CTUs). We intended to pump prime and facilitate the start of at least 25 SWATs across multiple CTUs within 30 months. The ultimate aim was to make the inclusion of SWATs routine when conducting a trial in a CTU. We share our experience of delivering the PROMETHEUS programme, along with the lessons learnt for undertaking randomised SWATs of recruitment and retention methods.

Methods

A network of 10 CTUs and one primary care research centre committed to conducting randomised controlled SWATs of recruitment and/or retention interventions was established by the PROMETHEUS team. We identified promising recruitment and retention interventions from a variety of sources including Cochrane systematic reviews, the Northern Ireland Network for Trial Methodology Research SWAT Repository Store, and existing prioritisation exercises. Promising strategies were reviewed by our patient and public (PPI) members to create an initial priority list of seven recruitment and eight retention interventions. The programme allowed host trial teams to apply for funding of up to £5000 and receive support from the PROMETHEUS team to design, implement and report SWATs. We also tested the feasibility of undertaking co-ordinated SWATs, across multiple host trials simultaneously.

Results

The PROMETHEUS programme funded 42 SWATs, embedded within 31 host trials, across 12 CTUs. The mean cost of a funded SWAT was £3535. Of the 42 SWATs, 12 tested the same SWAT across multiple host trials using a co-ordinated SWAT design and four tested more than one strategy in a factorial design. Two recruitment and five retention strategies were evaluated in more than one host trial. In the space of just 4 years, PROMETHEUS will add 18% more SWATs to the Cochrane review of global recruitment strategies, and 79% more SWATs to the Cochrane review of global retention strategies. The results from the SWATs reported to date found there was no evidence of a significant difference in recruitment for any of the strategies tested. For retention, pre-notifying participants by card prior to sending questionnaires was effective [risk difference 3.3%, 95% confidence interval (CI) −3.0% to 9.6%]; as was pre-notifying participants by letter or e-mail (risk difference 3.8%, 95% CI −6.1% to 13.6%). Sending personalised text messages was more effective for improving the return of postal questionnaires compared to non-personalised text messages (risk ratio 1.16, 95% CI 1.00 to 1.33); and resulted in fewer completions via telephone compared with a non-personalised text [adjusted odds ratio (OR) 0.44, 95% CI 0.22 to 0.87]. Including a pen with a questionnaire probably

increases retention and response rate (pooled OR 1.21, 95% CI 1.09 to 1.35). We highlight key lessons learnt below (see *Recommendations* section).

Conclusions

The PROMETHEUS programme significantly increased the international evidence base for both recruitment and retention strategies within RCTs. The funded SWATs evaluated a wide range of recruitment and retention strategies; however, the COVID-19 pandemic negatively impacted five funded SWATs, with two being delayed and three prematurely terminated. Through this project, we identified that when provided with both funding and practical support, host trial teams successfully implemented SWATs. PROMETHEUS led to an overall increase in the evidence base; however, ongoing 'routine' application of SWATs across RCTs employing the lessons learnt is required to ensure that efficient trial conduct strategies are identified.

Recommendations

Recommendations for funders

- All trial funders should contribute to the effort to improve the efficiency of trials. Funders should encourage the teams that they fund to undertake SWATs.
- Funding streams specifically designed to support SWATs must be made available to trial teams to continue building the trial process evidence base, for recruitment and retention as well as for other stages of the trial design and delivery process. This includes funding streams for undertaking specific SWATs, as well as infrastructure funding to support CTUs and other centres to undertake co-ordination activities that will support the design, conduct, reporting, and implementation of SWATs and their findings to inform the work of the National Institute for Health and Care Research (NIHR), the MRC, and other funders.
- PROMETHEUS has demonstrated that co-ordination of activity remains crucial to the delivery of SWATs. A central, national co-ordination point that provides hands-on support needs to continue and funding should be allocated for this. Additionally, CTUs should identify a lead for SWATs, to support SWAT activities and evidence-based trial conduct within the CTU, as well as links with others undertaking SWATs elsewhere to share best practice. The funding for both central and CTU-based support should be ongoing.
- SWAT priorities need to be identified and communicated clearly to funders, and funders should use these priorities to inform their funding decisions.
- Funders should develop a mechanism to promote SWAT questions that have been identified as a priority during the funding application process.
- The mean cost of funding requested for a standalone SWAT within PROMETHEUS was £3535 (range £500–5000). The co-ordinated SWATs cost was £10,668 (training SWAT) and £1306.40 (Christmas cards); however, these did not include costs for central co-ordination, data preparation and sharing by the host trial teams, data cleaning, analysis and write-up. These costs suggest that the £10,000 being offered by the NIHR for trial teams to include a SWAT should be sufficient for most planned SWATs. However, there may be occasions where trial teams may wish to test strategies that may be more expensive.
- When applying for SWAT funding, trial teams should be asked to indicate whether the question they are addressing is a priority SWAT question, and to provide a clear rationale for selecting that particular question.
- If teams are unable to undertake a SWAT, funders should ask that recruitment and retention methods are clearly reported to support the evidence base.

Recommendations for Sponsors

- Our experience suggests that there is a need for clear, easily accessible information about the nature of SWATs, as well as the role of the funder in supporting SWATs.
- Any future changes proposed by the Health Research Authority (HRA) to the approvals process need to be communicated clearly and applied consistently to each SWAT.

Recommendations for involving patient and public involvement partners in Studies Within A Trial research

- PPI should be considered when undertaking a SWAT, in the same way PPI is expected to be undertaken in the main trial.
- PPI partners should be involved to develop novel and untested recruitment and retention strategies, as well as to adapt existing strategies to the context of their specific host trial and the population being enrolled.

Recommendations for oversight committees

- Our experience suggests that Trial Management Groups (TMGs) play a key role in decisions about whether a SWAT is undertaken and continued in the host trial or not. TMG members should encourage the uptake of SWATs in their trials. While the findings of SWATs may not always directly inform their host trial, the findings of SWATs undertaken during the early, or internal pilot, phase of the trial may inform the decisions about which strategies should be used at a later stage, such as in the main trial.
- Trial Steering Committees should review the SWAT activity and progress, in the same way that they review substudies in a trial.
- Data Monitoring Committee review is dependent on the specific host trial and SWAT strategy being evaluated.

Recommendations for journals and reviewers

- Journal peer reviewer profiles should be updated to include methodological interests and expertise, to support evidence of suitability to undertake a peer review for a SWAT.
- When selecting peer reviewers, the SWAT and methodology interests as registered by reviewers should be used where possible.
- SWATs are a niche area and so to increase the pool of reviewers, journals should consider being more flexible when assessing reviewer credentials to review a SWAT, such as allowing relevant experience in place of a PhD.
- Reviewers should be advised that in many instances informed consent from participants need not be obtained when undertaking a SWAT, due to the low risk associated with the intervention and in the case of retention SWATs due to existing consent for further research being in place. This may depend on the jurisdiction. In the UK, this approach is supported by HRA guidance in relation to grading for SWAT interventions and approvals.
- Robust and transparent reporting is necessary, that is compliant with CONsolidated Standards Of Reporting Trials (CONSORT).

Recommendations for trial teams and methodologists undertaking SWAT research

- There remains a need for continually updated research priorities to allow researchers to address the questions relevant at that time.
- When SWAT priorities are set, methodologists need to provide enough information to enable teams to make informed decisions about evaluating the priorities set.
- Further work is needed to help teams identify suitable SWAT strategies for their host trials.
- SWAT priorities need to be communicated clearly and consistently to trial teams.

Recommendation for trial conduct and using SWAT evidence

- As the evidence base develops for effective and cost-effective recruitment and retention strategies, it will become increasingly important for trial teams to use this evidence base to inform their recruitment and retention activities. Trial teams need to actively engage with the evidence base to inform their practice. Funders will need to actively support the trials they fund to use evidence-informed recruitment and retention strategies.

Recommendations for future research

- There remains a substantial need for more high-quality SWAT evidence and so Chief Investigators should be encouraged to consider the embedding of a SWAT at the funding stage. Further work is therefore needed to increase the awareness of the methodological importance of SWAT research with research teams, and to develop engagement strategies to increase SWAT activity.
- Future research needs to focus on identifying whether further replications are needed for existing evidence. If so, the gaps in the evidence base should be targeted. More co-ordination and replication of SWAT evaluations are encouraged.
- A 'real-time' and dynamic communication strategy including a clear cost and resource breakdown for each suggested SWAT should be developed. This will alleviate the burden on trials teams to begin costing exercises and enable them to make an informed decision more quickly as to whether they can embed a given SWAT.
- There is a need to aid teams to identify and select a suitable SWAT for their host trial populations. Pragmatic decisions on which SWAT may be appropriate and feasible to include should be taken as required. A mechanism to communicate SWAT research priorities is needed, and this information needs to be readily accessible for all trialists to refer to.
- Our findings demonstrate that within an individual host trial, there is often a capacity to address more than one SWAT question, either separately, or simultaneously using a factorial design. This suggests that there is a capacity to significantly speed up and strengthen the evidence base through teams undertaking more than one SWAT in their trials where relevant.
- For certain strategies, co-ordinated SWATs should be encouraged. This method could be used to rapidly replicate SWAT evaluations to plug the evidence gap, as well as to evaluate more complex recruitment and retention strategies that may be more challenging to undertake using individual SWATs. Materials should be developed to advise teams on how to undertake co-ordinated SWATs, as well as a method of networking to enable teams to promote their co-ordinated SWAT and collaborate.
- As the evidence base develops, it will become increasingly important for trialists to utilise the evidence base in a systematic way to identify both effective and ineffective strategies to inform their practice. Future work should therefore consider issues around the dissemination and implementation of SWATs and develop guidance to enable the wider trials community to undertake, report and adopt the findings of SWATs. Implementation science, the study of methods to promote the uptake of evidence-based practice, could be used to inform any such future work. Funders can also help by questioning strategies proposed by trial teams that are known to be either ineffective or not cost-effective.
- Improving the knowledge of the potential 'harms' from implementing interventions that have no evidence of benefit is an important next step to help improve uptake.
- While establishing the effectiveness of recruitment or retention strategies is important, the high costs of research waste and limited public finance mean that cost considerations around SWATs are just as important. With only one retention strategy having high Grading of Recommendations, Assessment, Development and Evaluations (GRADE) certainty of cost effectiveness, we encourage trial teams to undertake streamlined economic evaluations alongside all their SWATs in the future, for strategies shown to be effective, as well as those that are ineffective. For cost effectiveness, trial teams should look to report the cost per additional participant recruited or retained (i.e. the incremental cost-effectiveness ratio). Value of information analyses can help determine the need for further SWAT evidence where several SWATs already exist.

- Many trial teams wish to contribute to developing the evidence base by undertaking non-randomised SWATs. Future work that informs the development of guidance for undertaking non-randomised SWATs would be helpful.
- Working with trial teams to develop engagement strategies and training to undertake SWATs would be beneficial. Audience specific guidance should be developed to support SWAT research.
- Trial teams have expressed they want to undertake SWATs that are important and necessary to increase the evidence base. Collaboration with funders, working groups involved in priority setting, and trial teams is needed to develop a mechanism to communicate this dynamic and evolving information once priority SWATs have been identified.
- Work is needed to identify the barriers that teams have when undertaking a SWAT, and strategies and solutions for addressing these barriers should be identified and implemented.
- Continued and proactive collaboration is needed with working groups to enable networking, and collaboration with teams undertaking SWAT research.
- Reporting guidance is needed to support teams when writing publications to ensure sufficient information is included to GRADE evaluation can be undertaken.

Study registration

All SWATs in the PROMETHEUS programme had to be registered with the Northern Ireland Network for Trials Methodology Research SWAT Repository.

Funding details

This award was funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (NIHR award ref: 13/55/80) and is published in full in *Health Technology Assessment*; Vol. 28, No. 2. See the NIHR Funding and Awards website for further award information.

Health Technology Assessment

HTA MRC-NIHR BMBR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.6

Launched in 1997, *Health Technology Assessment* (HTA) has an impact factor of 3.6 and is ranked 32nd (out of 105 titles) in the 'Health Care Sciences & Services' category of the Clarivate 2021 Journal Citation Reports (Science Edition). It is also indexed by MEDLINE, CINAHL (EBSCO Information Services, Ipswich, MA, USA), Embase (Elsevier, Amsterdam, the Netherlands), NCBI Bookshelf, DOAJ, Europe PMC, the Cochrane Library (John Wiley & Sons, Inc., Hoboken, NJ, USA), INAHTA, the British Nursing Index (ProQuest LLC, Ann Arbor, MI, USA), Ulrichsweb™ (ProQuest LLC, Ann Arbor, MI, USA) and the Science Citation Index Expanded™ (Clarivate™, Philadelphia, PA, USA).

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta.

Criteria for inclusion in the *Health Technology Assessment* journal
Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme or, commissioned/managed through Better Methods, Better Research (BMBR), and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

Health Technology Assessment (HTA) research is undertaken where some evidence already exists to show that a technology can be effective and this needs to be compared to the current standard intervention to see which works best. Research can evaluate any intervention used in the treatment, prevention or diagnosis of disease, provided the study outcomes lead to findings that have the potential to be of direct benefit to NHS patients. Technologies in this context mean any method used to promote health; prevent and treat disease; and improve rehabilitation or long-term care. They are not confined to new drugs and include any intervention used in the treatment, prevention or diagnosis of disease.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

This report

This issue of the Health Technology Assessment journal series contains a project commissioned/managed by Better Methods, Better Research (BMBR). The Medical Research Council (MRC) is working with NIHR to deliver the single joint health strategy, which includes BMBR as part of the delivery model. This was launched as the Methodology Research Programme (MRP) in 2008. MRC is lead funding partner for MRP and part of this programme is the joint MRC–NIHR funding panel 'The Methodology Research Programme Panel'.

To strengthen the evidence base for health research, BMBR aims to ensure optimal research methods are being used to advance biomedical, health and care focused research, policy and delivery. In addition to the MRC and NIHR funding partners, the BMBR takes into account the needs of other stakeholders including the devolved administrations, industry R&D, and regulatory/ advisory agencies and other public bodies. The BMBR funds investigator-led and needs-led research proposals from across the UK that develops and delivers ways to improve the research methods being used by others. In addition to the standard MRC terms and conditions on governance of good research practice, projects commissions/ managed by BMBR are expected to provide a detailed report on the research findings and may publish the findings in the Health Technology Assessment, if supported by NIHR funds.

The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded under a MRC–NIHR partnership. The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the MRC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the MRC, NETSCC, the HTA programme or the Department of Health and Social Care.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Newgen Digitalworks Pvt Ltd, Chennai, India (www.newgen.co).