

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

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

<sup>1</sup>York Trials Unit, Department of Health Sciences, University of York, York, UK

<sup>2</sup>Nuffield Department of Orthopaedics, Rheumatology, and Musculoskeletal Science, NIHR Biomedical Research Unit, University of Oxford, Oxford, UK

<sup>3</sup>National Institute for Health Research School for Primary Care Research, Centre for Primary Care and Health Services Research, University of Manchester, Manchester, UK

<sup>4</sup>School of Health and Related Research, University of Sheffield, Sheffield, UK

<sup>5</sup>Bristol Trials Centre, Clinical Trials and Evaluation Unit, University of Bristol, Bristol Royal Infirmary, Bristol, UK

<sup>6</sup>School of Nursing and Midwifery, University of Galway, Galway, Republic of Ireland

<sup>7</sup>Health Research Board-Trials Methodology Research Network, Galway, Republic of Ireland

<sup>8</sup>Department of Biostatistics and Health Informatics, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK

<sup>9</sup>Institute of Population Health Sciences, Queen Mary University of London, London, UK

<sup>10</sup>Health Services Research Unit, University of Aberdeen, Foresthill, Aberdeen, UK

<sup>11</sup>University of Nottingham, Nottingham Clinical Trials Unit, University Park Nottingham, Nottinghamshire, UK

<sup>12</sup>School of Health Sciences, University of Manchester, Manchester, UK

\*Corresponding author [david.torgerson@york.ac.uk](mailto: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

## Plain language 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](http://www.journalslibrary.nihr.ac.uk)

# Plain language summary

## Aims of the research

A Study Within A Trial is a research study nested inside a larger 'host trial', promoting the use of Studies Within A Trial aimed to do Study Within A Trial routine practice in clinical trial units by funding and supporting at least 25 Studies Within A Trial.

## Background

The best way to test health and social care treatments is to do a randomised controlled trial ('trial'), where some patients get the treatment being tested and some do not. The results of different groups are compared to see if the treatment improves care. Recruiting patients and keeping them involved in trials is often very difficult. Research teams often do not know how best to recruit and keep patients engaged as the methods have not been tested to see if they work. The best way to test these methods is by doing a Study Within A Trial. We test a programme of Studies Within A Trial for recruiting and keeping patients engaged in trials.

## Methods

Trial teams were able to apply for funding of up to £5000 and receive support from Promoting the use of Study Within A Trial team to do Studies Within A Trial. We used our experience of doing Studies Within A Trial to outline lessons learnt for doing Studies Within A Trial.

## Results

We funded 42 Studies Within A Trial and gave teams necessary advice to do them. We significantly increased the knowledge for both recruitment and retention strategies, and found 'pre-notifying' before sending questionnaires, sending pens and personalised text messages were all effective for increasing responses by participants. We tested Studies Within A Trial across several different trials at the same time to find out more quickly whether their methods worked. We highlight key lessons learnt to guide others doing Studies Within A Trial, including involving patient partners; picking the right strategy to test; getting ethical approvals; how to do and report Studies Within A Trial.

## Conclusions

Promoting the use of studies within a trial was successful and supported more Studies Within A Trial than planned. We hope our experience will support those doing Studies Within A Trial in the future.

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/](http://www.publicationethics.org/)).

Editorial contact: [journals.library@nihr.ac.uk](mailto:journals.library@nihr.ac.uk)

The full HTA archive is freely available to view online at [www.journalslibrary.nihr.ac.uk/hta](http://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.

Copyright © 2024 Parker *et al.* This work was produced by Parker *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This is an Open Access publication distributed under the terms of the Creative Commons Attribution CC BY 4.0 licence, which permits unrestricted use, distribution, reproduction and adaptation in any medium and for any purpose provided that it is properly attributed. See: <https://creativecommons.org/licenses/by/4.0/>. For attribution the title, original author(s), the publication source – NIHR Journals Library, and the DOI of the publication must be cited.

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

## NIHR Journals Library Editor-in-Chief

---

**Dr Cat Chatfield** Director of Health Services Research UK

## NIHR Journals Library Editors

---

**Professor Andrée Le May** Chair of NIHR Journals Library Editorial Group (HSDR, PGfAR, PHR journals) and Editor-in-Chief of HSDR, PGfAR, PHR journals

**Dr Peter Davidson** Interim Chair of HTA and EME Editorial Board, Consultant Advisor, School of Healthcare Enterprise and Innovation, University of Southampton, UK

**Professor Matthias Beck** Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

**Dr Tessa Crilly** Director, Crystal Blue Consulting Ltd, UK

**Dr Eugenia Cronin** Consultant in Public Health, Delta Public Health Consulting Ltd, UK

**Ms Tara Lamont** Senior Adviser, School of Healthcare Enterprise and Innovation, University of Southampton, UK

**Dr Catriona McDaid** Reader in Trials, Department of Health Sciences, University of York, UK

**Professor William McGuire** Professor of Child Health, Hull York Medical School, University of York, UK

**Professor Geoffrey Meads** Emeritus Professor of Wellbeing Research, University of Winchester, UK

**Professor James Raftery** Professor of Health Technology Assessment, School of Healthcare Enterprise and Innovation, University of Southampton, UK

**Dr Rob Riemsma** Consultant Advisor, School of Healthcare Enterprise and Innovation, University of Southampton, UK

**Professor Helen Roberts** Professor of Child Health Research, Child and Adolescent Mental Health, Palliative Care and Paediatrics Unit, Population Policy and Practice Programme, UCL Great Ormond Street Institute of Child Health, London, UK

**Professor Jonathan Ross** Professor of Sexual Health and HIV, University Hospital Birmingham, UK

**Professor Helen Snooks** Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Please visit the website for a list of editors: [www.journalslibrary.nihr.ac.uk/about/editors](http://www.journalslibrary.nihr.ac.uk/about/editors)

**Editorial contact:** [journals.library@nihr.ac.uk](mailto:journals.library@nihr.ac.uk)