

1) Title of Project

Supporting the implementation of recruitment and retention Studies Within a Trial (SWATs)

2) Abstract

Introduction: Adequate recruitment and retention is essential for the successful completion of a randomised controlled trial (RCT). Recruitment and retention strategies used frequently have no evidence of their effectiveness. Studies within a Trial (SWATs) enable rigorous evaluation of these strategies. The MRC funded PROMETHEUS programme originally successfully embedded 42 SWATs in host trials. The overall aim of this NIHR CTU Infrastructure grant is to continue the PROMETHEUS programme, and to build on the successes of the earlier work to increase SWAT research activity by identifying and supporting teams to do so.

Methods: Research activities were undertaken to increase SWAT activity, SWAT publications and dissemination. A range of strategies were developed on the basis of emergent discussions with different trial teams.

Results and conclusions: We emailed all UKCRC registered Clinical Trials Unit (CTUs) in the UK to encourage them to implement at least one recruitment and one retention SWAT in the next 12 months. As a consequence, we met with teams to discuss embedding SWATs within their host trials. We also held two well attended webinars, with two more planned for 2021. We have collaborated with Trial Forge and set up a SWAT network that currently has 19 member CTUs with over 50 individual members. We continued to work with teams to support SWAT research and collaborated with the HTA to promote the support PROMETHEUS could offer, this resulted in changes to their feedback given to teams to promote the support the PROMETHEUS group could provide. We have successfully collaborated with the Health Research Authority (HRA) to pilot a streamlined approval process which will speed up the implementation and dissemination of SWATs. To aid the publication and dissemination of SWAT publications we have developed the 'SWAT collection' with the reporting platform F1000 and have created a network of SWAT peer reviewers. We are leading on creating a special issue on SWATs in the SAGE journal Research Methods in Medicine and Health Sciences. We are also in the process of producing a HTA monograph in the Spring of 2022 summarising our SWAT research. We have increased our networking and are now collaborating with the Trial Methodology Research Partnership working groups and undertaking SWAT related research activity. We have created new reporting guidelines for SWATs which are currently being piloted.

Conclusion: There is a great need for SWAT research and teams are keen to engage with research activities promoting and supporting this. The infrastructure support we received has made a significant difference to the wider use of SWATs.

3) Introduction

Adequate recruitment and retention are essential for the successful completion of randomised controlled trial (RCTs). However, strategies undertaken are often not evidence based. A consequence of this is that trials could be using ineffective strategies or strategies that have a negative impact on recruitment or retention. To remedy this, rigorous evaluations of these strategies are necessary; and studies within a trial (SWAT) enable this evaluation.

The PROMETHEUS programme was an MRC funded initiative that aimed to fund 25 SWATs of up to £5k testing recruitment and/or retention interventions. This programme funded 42 SWATs within 32 host trials. During the running of the programme the PROMETHEUS team worked with 14 trials units and a large number of trial personnel and gained insight into the support and infrastructure required to enable teams to undertake SWATs.

SWATs need to be reported and disseminated quickly to support the evidence base. There are several barriers to this rapid reporting, including financial and time. The F1000 reporting platform enables SWATs to be published quickly due to following a post publication peer reviewing process, and is also less costly than some other open access reporting options. Consequently, it is gaining popularity amongst researchers publishing SWATs.

Feedback from the PROMETHEUS programme was positive. It was noted that having a central coordination point that focused on SWAT activity increased the evidence base around recruitment and retention strategies. From experience gained throughout the PROMETHEUS programme several areas that could be developed to support SWAT activity were identified.

Therefore, the overall aim of this NIHR CTU Infrastructure grant is to continue to increase SWAT research activity by identifying and supporting teams to do so.

4) Methods

To increase SWAT research activity, we undertook a range of complementary activities:

1. We contacted all UK CTU directors in the UK to ascertain whether they had the capacity to embed at least one of two SWATs within the next 12 months. We invited teams to discuss this further and to contact the PROMETHEUS team for resources, such as protocols.
2. As part of the original PROMETHEUS programme, we held a dissemination webinar. We identified that webinars were an effective method to engage with researchers. Following this we surveyed attendees to identify further webinar and training opportunities. We analysed this feedback and developed a targeted and bespoke training and webinar series.
3. We initiated the development and established a SWAT Network in collaboration with Trial Forge (<https://www.trialforge.org/>).

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4. We collaborated with the HTA to adapt their feedback to teams to promote the support the PROMETHEUS group can offer. We supported teams contacting the PROMETHEUS group from a variety of avenues to embed SWATs in their host trials.
5. In collaboration with Trial Forge and the Health Research Authority (HRA), we are piloting and developing an application procedure for a new coordinated SWAT approvals process.
6. We identified a mechanism to improve the dissemination of SWATs with the reporting platform F1000, and an expanded pool of peer reviewers to speed up the SWAT peer review process.
7. We developed a collaboration with the Trial Methodology Research Partnership (TMRP) working groups to increase PROMETHEUS activity and input on methodological research, in particular, around the promotion of SWATs.
8. We developed an effective template for the rapid and methodologically robust publication of SWATs.
9. We identified SWAT research priorities where gaps were found in the evidence base and investigated strategies to address this.

5) Results and Conclusion

Contacting CTUs

CTUs based in the UK (n=45) were emailed, 19 responses were received, to date, meetings have been held with three teams. The email correspondence and meetings have resulted in networking opportunities and enabled further strategies to be identified to aid SWAT research. When working with individual teams we were able to understand their research expertise and make specific recommendations as to which SWATs may suit their host trials.

Although teams were very interested in undertaking SWATs, most could not implement the nominated SWATs within the timescale of the SWAT NIHR CTU Infrastructure grant. This experience has been important and resulted in the PROMETHEUS group collaborating with Trial Forge to create a SWAT Network to engage with teams and identify methods to support SWAT activity.

Webinar series

The following webinars, information and training sessions have been organised as part of the PROMETHEUS host webinar series, these will be archived and be made publicly available for future use and reference. The webinars and training sessions have been developed iteratively following feedback from webinar attendees and discussions with research teams:

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Webinar one: 'The Implementation and management of studies within a trial'. September 2020

Specific examples of SWAT research were requested following the PROMETHEUS dissemination webinar along with providing the opportunity for attendees to discuss these and to network with teams undertaking similar research. This webinar had nine speakers presenting their SWAT research activity, how they implemented and managed their SWAT. This led to teams contacting the PROMETHEUS group for further information regarding SWAT interventions that were presented. Survey feedback resulted in webinars 2-4.

Webinar two: 'Recruitment and Retention Research priorities webinar'. April 2021

In collaboration with the Trial Methodology Research Partnership and Trial Forge, we presented SWAT research priorities, including the mapping work undertaken to identify gaps in the evidence base around recruitment and retention. Two SWATs that we identified as a priority were presented in detail (Pens for recruitment, personalised SMS for retention). We listed the support available from the PROMETHEUS team and circulated the protocols for each SWAT. This has led to some teams contacting the PROMETHEUS group for further information and with some actively working towards embedding one of the prioritised SWATs.

Since setting up the SWAT network we have met with teams. Many were aware of the two SWAT interventions that we had suggested teams embedded. Some fed back that the interventions were not something they could embed currently – one reason was that they were not in a position to carry out a recruitment SWAT as their current trials were in follow-up and the other was they didn't have the infrastructure to embed an SMS SWAT.

Webinar three: 'Researcher experience webinar'. October 2021

Through the development and set up of the Trial Forge SWAT Network, we have met with a diverse group of researchers. We have invited two of these teams to present at the next webinar as their work is of great interest and value to the methodological research community. One presenter will discuss their research experiences in conducting SWATs in low and middle-income countries, which is the first undertaken within this setting. The second speaker will present their work around the use of digital tools in the recruitment and retention of participants. This work is relevant in the increasing digital research environment that the COVID-19 pandemic has facilitated in creating.

Webinar four: 'The methodology of SWATs'. December 2021

A future webinar has been requested that provides information and examples of alternative, non-randomised SWAT designs, presented by researchers that have expertise within this

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area. One focus will be qualitative designs. Additionally, there will be presentations on: the importance of effective recruitment, recruitment and Prices Law, and the role of economic evaluations in existing and future SWATs.

Trial Forge SWAT network

Leading on from our work directly contacting CTU directors and meeting with teams, we identified the need for a SWAT network. We collaborated with Trial Forge to build on their 'SWAT centres' initiative¹. The Trial Forge SWAT network² was set up in June 2021 and currently has members from 19 CTUs both within the UK and internationally (Ireland and Australia) which comprises of approximately 50 individual members.

We will be promoting this Network again in October 2021 at the PROMETHEUS hosted webinar and there will be a Network meeting in Autumn 2021.

The PROMETHEUS group has also worked with students embedding SWATs and identified the need for support for students undertaking methodological research. Due to this we are creating student memberships to support students within the MSc and PhD work who are undertaking a SWAT.

We are meeting with each team joining the Network to identify their SWAT interests and barriers and facilitators to conducting SWATs. To date we have identified the following action points required to further support SWAT research activity:

- Teams have requested online resources via the network for Chief Investigators (CIs) to be made available. Specifically, to explain the importance of SWATs and supply case studies from Chief Investigators who have successfully embedded a SWAT within their trials
- There is a need to identify a strategy to display and disseminate the SWAT research priorities
- The need and opportunity to collaborate with the Northern Ireland Network for Trial Methodology Research 'SWAT store'³ to add further information to this resource regarding SWAT research that is being/has been undertaken and recording the results.
- The development of a tool that research teams can use to identify a SWAT that is suitable for their host trial

This network will be crucial in increasing the evidence base around recruitment and retention strategies.

Supporting teams and acting as a coordination centre

The PROMETHEUS group have been contacted by several teams for advice on support to embed a SWAT. Advice given has been bespoke and has included the sharing of resources and linking an experienced team with a more inexperienced team to act as a mentor and point of contact regarding a specific SWAT intervention.

We collaborated with the HTA to increase the promotion of the services that PROMETHEUS can offer research teams in embedding a SWAT and applying for the funding available to do so. There is now a sentence included in feedback on stage one applications to research teams regarding the support that PROMETHEUS can offer.

SWAT approvals process

In collaboration with Trial Forge, we are working with the HRA to formalise a coordinated SWAT approval process. This will enable one team to hold overall approval for the SWAT and further teams to then embed the SWAT in their host trials following host trial sponsor approval and amendment approval (if applicable depending on the SWAT). This will speed up the implementation and dissemination of SWATs.

SWAT publication and peer review of SWATs

We worked with the reporting platform F1000 to discuss their publication policies around SWATs. We have now developed a 'SWAT Collection'⁴ and are working with them to create strategies to speed up the peer reviewing process of SWAT publications including the use of a reviewer checklist.

We identified that peer review was challenging, which was leading to delay in publication and dissemination of SWATs. To help mitigate this, we have been developing an international SWAT reviewer database to aid with this process which is continuously monitored and updated. Additionally, we are collaborating with the TMRP Retention group to identify further SWAT reviewers.

We have worked with the SAGE journal *Research Methods in Medicine and Health Sciences*⁵ for special issue of the journal in the autumn devoted entirely to SWATs. We also have an agreement with NIHR HTA to publish an HTA monograph summarising all of our work on SWATs to date.

Collaboration with TMRP working group

The PROMETHEUS team are now part of the Retention, Recruitment and Inclusivity TMRP Trial conduct working groups, with one member of the PROMETHEUS team (CA) co-leading the retention group. This has led to collaborative working and the development of strategies to increase SWAT activity. We are currently leading SWAT protocol development on SWATs

which have been identified as research priorities in the Cochrane systematic review of participant retention strategies and mapping work the TMRP retention group undertook. The development of these protocols will result in high quality identical replications that can be accumulated to determine the effectiveness of the intervention(s) and will facilitate teams to undertake the SWATs more rapidly as they will not have to write a protocol.

Reporting of SWATs

We have been drafting reporting guidelines for SWATs in collaboration with the Trial Forge teams both in the UK and internationally. Following rigorous stakeholder review and feedback, these guidelines have been developed into a reporting template. The template enables methodologically rigorous, rapid reporting and dissemination of a SWAT.

Identify SWAT research priorities

We have collaborated with the TMRP and the team that undertook the Cochrane Review of Participant Retention Strategies to identify gaps in the evidence base. We are working to identify and remedy areas of uncertainty and to promote additional undertaking of these SWATs to enable definitive evidence to be generated.

6) Dissemination

Key learning points will be disseminated:

- Webinars will be utilised to disseminate key findings and promote SWAT research priorities.
- Publications of key activities.
- Working with F1000 and *Research methods in medicine and health sciences* to publicise SWAT papers.
- The Trial Forge SWAT network website will be developed alongside webinars for network members to enable networking and collaboration opportunities.
- The PROMETHEUS group will maintain an active and visible role within methodology initiatives, such as the TMRP to allow collaboration and increase SWAT research activity.
- Presentation of findings at conferences.

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7) Acknowledgements

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8) References

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5. Research Methods in Medicine and Health Sciences Journal [Available from: <https://journals.sagepub.com/home/rmm> [Accessed 31st August 2021]

9) Appendices

N/A

10) Conflict of interest declaration

The authors have no conflict of interests to declare.