Trials

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Working with underrepresented groups: lessons from the SCHEMA trial

Paula Foscarini-Craggs[1*], Arman Iranpour[2,3], Katie Aafjes-van Doorn[4], Matthew Franklin[5], Toni Leigh Harrison[2,3], Iain McKinnon[2,3], Rachel McNamara[1], Elizabeth Randell[1], Sophie Rose[1], Jennifer Condie[1], Ania Zubala[6], Muhammad Riaz[1] and Simon Hackett[2,3]

Abstract

There is a growing focus on ensuring research is accessible and inclusive to individuals traditionally not represented. To be truly inclusive, the broader context needs to be explored, as barriers might not only be linked to population characteristics but also to the complexity of their environment, and limited research opportunity within certain healthcare professions. The SCHEMA trial is a randomised controlled trial evaluating whether interpersonal art psychotherapy is effective at reducing aggressive behaviour in individuals with learning disability or borderline intellectual function in secure care. The trial illustrates the challenges and solutions to conducting research in secure care settings, a challenging environment, with an underrepresented patient population and healthcare professionals unfamiliar with conducting research. To better understand the challenges, a survey was circulated to understand site staff's general experience with research and their specific experiences of the SCHEMA trial. Difficulty of balancing research with other responsibilities and a fear of making a mistake were the most common barriers. The top two facilitators were working with collaborators and the presence of clear guidelines and protocols. Site setup was identified as the most challenging stage of the trial, while follow-up data collection was identified as the least challenging. In response to these challenges, the central trial team worked closely with site staff to provide tailored support to address the unique needs of the healthcare professionals and participant population.

Keywords Trial methodology, Underrepresented groups, Forensic research, Intellectual disability research

*Correspondence:
Paula Foscarini-Craggs
FoscariniCraggsP@Cardiff.ac.uk
[1] Centre for Trials Research, Cardiff University, Neuadd Meirionnydd, Heath Park, Cardiff, Wales CF14 4YS, UK
[2] Faculty of Medical Sciences, Newcastle University Population Health Sciences Institute, Baddiley-Clark Building, Richardson Road, Newcastle Upon Tyne, England NE2 4AX, UK
[3] Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust, Jubilee Rd, Newcastle Upon Tyne, England NE3 3X, UK
[4] New York University Shanghai, West Yangsi Rd, Pudong Xin Qu 567, Shanghai 200124, China
[5] Sheffield Centre for Health and Related Research (SCHARR), School of Medicine and Population Health, The University of Sheffield, Regent Court, 30 Regent Street, Sheffield S1 4DA, England, UK
[6] Centre for Brain Sciences, Royal Edinburgh Hospital, The University of Edinburgh, Kennedy Tower, Morningside Place, Edinburgh EH10 5HF, UK

Over the last few years, there has been growing recognition of the way that research, and clinical research in particular, has excluded certain groups of individuals. Underserved groups are context dependent but are generally understood to have a higher healthcare burden and lower representation in research compared to other groups [1]. Examples of underserved groups can include those with mental health conditions, learning disabilities, and prison populations. Work supported by the National Institute of Health Research and the National Health Service (NHS) along with other knowledge user groups has identified several barriers to inclusion in research. While the exact manifestation of the barrier will depend on the needs of the underrepresented group, they can generally be grouped into three categories: language, access,

and trust [2]. Language relates to the way that information regarding the research is presented, the level of health literacy, and the ability for an individual to engage with study material [2]. Access refers to the location of research sites, the burden of participation, and research inclusion and exclusion criteria [2]. Lack of engagement in research due to mistrust can stem from previous negative experiences, cultural experiences, and a misunderstanding of the role or importance of research [2]. Including underrepresented groups in research is only one piece of the wider inclusion puzzle that needs to be addressed to ensure that we are adequately addressing the health needs of the whole population and reducing health disparities [1, 2].

There has been less work on exploring how the underrepresentation of certain health professions or the complexity of the environment can have a significant impact on the availability, accessibility, and success of research. Certain professions, particularly those who are classed as allied health professionals, such as art therapists, have lower levels of involvement in research training during their qualification period, as well as post-qualification [3]. This is despite a growing focus on more holistic and multidisciplinary care pathways that will include these professions. The underrepresentation of these professions in research could be due to them typically providing care in a wider variety of settings, and to patient groups that are also typically underrepresented in research. Significantly, this lack of exposure to research represents a barrier to both the underrepresented professions as well as the underrepresented patient populations [4, 5]. Complex settings can also act as a barrier as underrepresented professions may not engage in research while working in these settings due to perceived lack of support or knowledge [3].

The SCHEMA trial is an excellent case study on examining the challenges and solutions to conducting research with underserved populations in complex settings, due to the restrictions to access that are associated with a forensic setting, and with underrepresented professions. SCHEMA is a two-arm randomised controlled effectiveness trial comparing manualised interpersonal art psychotherapy and usual care (UC) to UC and delayed interpersonal art psychotherapy treatment control group. The trial involves people with an intellectual disability or borderline intellectual function who are in secure care. The trial aimed to recruit 150 participants across 8 secure care settings in the UK [6]. The trial recruited from both medium and high secure sites with a generally stable population. SCHEMA participants received 12–15 individual art therapy sessions delivered by health and care professions council accredited art therapist (for full trial details see published protocol paper [6]). Due to the setting and topic area, we worked with several site research teams that either had limited or no research experience at all. Support was provided through the site Research and Development (R&D) department, but the support provided varied across each site.

Recruitment challenges in forensic and prison-based studies

A systematic review of studies using art psychotherapy interventions for forensic and forensic psychiatric patients [7] reveals significant variability in recruitment success, reflecting the inherent difficulties in engaging these underserved groups. Sample sizes ranged widely from 7 to 159 participants (median = 39, mean = 47.6, SD = 42.2), with most studies ($n = 15$) recruiting fewer than 50 participants. Only two studies exceeded recruiting 100 participants, one of which combined male and female forensic psychiatric patients and another focused on a mixed-gender correctional institution ($n = 159$ and $n = 105$ respectively). The high standard deviation underscores the inconsistency in recruitment feasibility across settings, likely influenced by factors which result in additional complexities such as institutional restrictions (e.g. security protocols, limited researcher access), population characteristics (e.g. cognitive impairments, behavioural challenges), and staff capacity (e.g. competing clinical priorities).

A review of 28 studies in another meta-analysis [8] which looked at studies using psychological and psychosocial interventions for forensic mental health inpatients found similar trends. Recruitment numbers varied substantially, ranging from just 6 to 67 participants per study. The average sample size was modest (M = 26.4, SD = 17.1). Notably, the majority of studies (76%) included 34 or fewer participants, while only three studies managed to exceed 50 participants.

These findings align with the barriers identified in the SCHEMA trial, where small sample sizes and complexities due to the setting and staff with limited research experience are emblematic of research in secure care environments, even given multisite collaboration. These challenges can be seen in the median time from obtaining ethics to greenlight for recruitment, 202.5 days (range 82–389 days) within the SCHEMA study. This is approximately 10% longer than what has been reported in previous work looking at the site setup process in UK secondary care centres [9]. It then took sites a median of 74.75 days (range 12–133 days) to recruit their first participant. This can negatively impact a site's ability to achieve their recruitment target.

In an effort to better understand and support the site research teams and to contribute to the work being conducted in the wider research community around

underserved groups and underrepresented professions in research, we conducted a brief survey. The survey was developed by reviewing literature around research inclusivity and experience [10–13], as well as the challenges discussed with the SCHEMA research sites. The survey was divided into six sections: research training and experience (1 question), attitudes to research (16 questions), perceived facilitators to being involved (2 questions), perceived barriers to being involved (2 questions), research phases (1 question), and final thoughts around their experience (3 questions). Questions were a combination of five-point Likert scale, ranking statements, and free text. Data were analysed using descriptive statistics (quantitative data) and basic content analysis (qualitative data). The survey was circulated to 51 staff members who were involved in the trial across the eight SCHEMA sites. Staff were informed of the purpose of the survey, and consent was assumed if a staff member completed it.

Demographics

The survey collected a total of 23 (45%) responses from staff participants involved in the SCHEMA trial. The respondents ranged from 25 to 67 years old, and the gender distribution was predominantly women (see Table 1 for full breakdown). Additionally, two respondents reported having participated in the NIHR associate PI training scheme as part of the trial [14], suggesting interest in engaging with research leadership or coordination. At most sites, the research support staff were from the R&D department and therefore would not regularly work in the secure care setting.

Table 1 Participant demographics

	Research support	PI	Therapist	Total
Women	7	2	5	14
Men	3	3	1	7
Non-binary/third gender	0	0	1	1
Total*	10	5	7	22

*One individual did not report their gender

Demographic data also revealed insights into the respondents' prior involvement in research. Participants were asked to rank their experience on a 5-point Likert scale (no experience to regularly works in research). The most common level of research experience amongst respondents prior to joining the SCHEMA trial was none or little experience (41%). A detailed breakdown of roles and research experience can be found in Table 2.

Research experience and prior involvement

The survey highlighted a broad spectrum of prior research experience amongst staff. While some participants regularly worked in research, a significant proportion had little to no experience. This variation in familiarity with research processes may have influenced sites' engagement with SCHEMA and their ability to navigate recruitment challenges.

Perceived barriers to research participation

The most commonly reported barriers to research engagement were the difficulty of balancing research activities with other responsibilities and a fear of making mistakes. These concerns were particularly pronounced in staff who had limited prior research experience, suggesting that 'research-naïve' sites may require additional support and reassurance when engaging in studies. Additionally, qualitative responses indicated that structural and systemic factors—such as time constraints within the NHS and the dominance of medical research paradigms—were perceived as obstacles to broader participation in research. Time and logistical constraints had a particular significant impact due to the secure care setting:

> *"Research content required a different skill set than my normal clinical work. Consent for participants was more indepth. considerations around recording devices and clinical security needed to be facilitated" (SCHEMA Therapist)*

Due to access restraints limiting R&D support at some sites, and the needs of the patient population, therapists were tasked with more data collection responsibilities

Table 2 Survey respondents' roles and research experience

Role	Little or no experience	Moderate experience	Very familiar or regularly works in research	Total
Research support	1	3	4	8
Therapist	7	1	1	9
Principal investigator*	1	1	3	5
Total	9	5	8	22

*At some sites, the PI was also a therapist

than would be normally expected. This added extra burden to both therapists and R&D staff as they needed additional training, and data collection took longer as well.

Facilitators and motivators

Conversely, the key facilitators that encouraged participation were collaborative working relationships and the presence of clear guidelines and protocols:

> *"More teamwork and cohesion between research and clinical teams. Faster paced recruitment as easier to approach patients" (Research Support Officer)*

Staff members emphasized the importance of structured support from the central trial team, particularly in navigating the complexities of site setup and ethical approvals in secure care settings. The provision of tailored guidance such as quick start guides or regular meetings appeared to mitigate some of the anxieties associated with research involvement, particularly for sites with limited prior research experience.

Challenges across different phases of the trial

Site setup was identified as the most challenging stage of the trial. Delays in approvals, logistical difficulties, and unfamiliarity with research procedures contributed to significant hurdles in issuing permission to sites to start recruitment.

> *"I valued the enthusiasm and thoughtfulness of Simon and his team, and for the resource it's self, but I as i've gone through and finally got to the point of delivery, I realised I could have done with much longer training and maybe some role-playing of the filling out of forms." (Therapist)*

By contrast, follow-up data collection was considered the least challenging stage, likely due to increased familiarity with research processes over time and the structured nature of follow-up assessments. Follow-up data collection was typically carried out by the same individuals who performed the baseline data collection.

Recommendations for working with underserved groups and in complex environments

Based on the experiences during the SCHEMA trial, as well as the results from the survey, we have developed a set of recommendations to support the inclusion of underrepresented professions who may be working in challenging contexts. While these recommendations are a critical starting point for developing more inclusion research, these recommendations can be grouped into three categories: effective and diverse communication, building flexibility into trial processes, and providing sufficient training.

Communication

Regular contact with sites through fortnightly catch-ups and over email provided the necessary structured support and allowed the central trial team to respond to queries quickly and efficiently. It also gave sites the opportunity to anticipate and develop site-specific solutions to any upcoming problems and to reassure and empower site staff who had limited research experience, especially if there were concerns around making a mistake with trial procedures, especially during the early more challenging phases. As there were only 8 sites and it was feasible to hold these at an individual site level, this may not be practical with a large number of sites, but regular drop-in sessions could be scheduled that would fulfil the same role. The trial team also developed a summary sheet which outlined the key trial activities and the documents to be completed at each time point. Sites reported that they regularly brought the document to follow-up assessments or reviewed it immediately prior to conducting any trial activity.

Flexibility in trial processes

From a trial management perspective, it is important to develop flexibility within the protocol, where appropriate, to account for institutional restrictions, such as varying security levels in forensic settings or any other restriction that may be in place. The trial built in flexibility at the start to not make audio recordings mandatory. This was to address trust issues with participants and access limitations of what can be brought into secure care. The trial still ended up making several amendments to its protocol as well as internal procedures to allow, for example, a more flexible approach to providing vouchers or cash to participants as a way of thanking them (recognition payments) for their participation in the study.

Training

It is also important to consider what training is required, as site staff who have not previously been involved in research may not have completed Good Clinical Practice or other standard research training courses. While these courses are worthwhile, they can take up a substantial amount of time which may not be suitable for staff whose substantive post does not involve research. Identifying which training will be the most beneficial and providing condensed versions of other training during site initiation visits or other set-up activities will ensure that staff members feel that they have the knowledge to be involved in the research but are not overburdened. Signposting staff at study

sites to access training schemes, such as the NIHR Associate PI scheme, can support those who have the capacity and interest to further develop their research skills.

While most sites had R&D support, this was contingent on there being capacity within the R&D team and due to limits within some teams, R&D support was not available post setup phase. It would be beneficial to see more formal guidance to R&D departments to provide support throughout the life of the trial in underrepresented populations and especially if there are underrepresented professions involved in the delivery of the research.

While the SCHEMA trial is an excellent case study on the challenges of conducting research with underrepresented profession and in challenging environments, there are some limitations. We only had 45% of staff members respond to the survey. There may be bias in those who responded compared to those who did not respond. In addition, most sites were medium secure settings. This means that there may be some setting-specific challenges in high or low secure sites that were not adequately captured. The survey developed by looking at previous research exploring research inclusivity, but as there is limited work specifically exploring research delivery and environment, it may not adequately reflect the challenges and experiences of the research staff.

Conclusions

The SCHEMA trial is a unique opportunity to explore how a trial unit, NHS R&D team, and NHS staff can work together to deliver high-quality research to an underserved population but also offers valuable lessons on how to involve and support underrepresented professions in research. Both the context where research studies are taking place, the population, and the prior research experience of members of staff at study sites have a collective impact upon research delivery. There is evidence from research reported in systematic reviews that non-pharmacological psychosocial intervention studies in secure care struggle to achieve recruitment targets due to the complexity of the setting. We hope that the lessons learned can be valuable for anyone thinking of conducting research in such a context.

Abbreviations

NHS	National Health Service
R&D	Research and Development
UC	Usual care

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Authors' contributions

PFC and AI wrote the initial draft and designed the survey, SR, SH, and LR designed the survey, and all authors reviewed and inputted into the final draft.

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Data availability

Due to the limited number of participants, data from the research experience survey is not available.

Declarations

Ethics approval and consent to participate

The SCHEMA trial was approved by London-City & East REC and received full approval on 13/01/2023 (REC ID: 23/LO/0026; IRAS project ID: 319325). All staff agreed to complete the research experience survey.

Competing interests

The authors do not have any competing interests to declare.

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