






STUDY PROTOCOL

Social and Ethical Aspects of Remote and Hybrid Care in the Special Allocation Scheme in general practice (SEARCH): A mixed methods feasibility study protocol

[version 1; peer review: awaiting peer review]

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Abstract

Background

Despite the growing body of research on remote primary care and access for (digitally) excluded groups, very little is known about care for patients who have been *deliberately* excluded from mainstream services. The 'Special Allocation Scheme' (SAS) in England provides GP services to patients who have been excluded from their GP practice after being reported for violent behaviour. Patients registered on SAS are likely to be offered remote services, in part because patients are often placed in an 'out-of-area' SAS practice.

Our aim is to find out more about the needs of patients on the SAS, whether and when it is appropriate to offer remote options, and who these options might benefit or disadvantage. We also aim to develop safe, ethical, and meaningful ways to involve patients with experience on the scheme in research and service development.

Methods

Workstream 1 includes a national scoping survey of SAS provision

across England. Workstream 2 comprises of three ethnographic case studies of SAS services, including observation and interviews with patients, NHS staff and national/regional decision makers.

Workstream 3 involves two codesign workshops with patients, researchers, clinicians, support staff and third sector care providers to co-produce a set of reflections and best practices to inform future research and service redesign in this context. An iterative and participatory-informed PPIE approach is adopted throughout, involving patients and other stakeholders from early conceptualisation to study design, analysis and codesign of outputs.

Conclusions

Whilst remote solutions can improve access to primary care for some, they are not suitable for every patient population and can widen health inequalities. This is a novel study in a critically under-researched area of service delivery with clear practical and ethical implications for practice. Findings will develop understanding and transferable learning for SAS delivery and inform the design of a future study.

Plain Language Summary

The 'Special Allocation Scheme' (SAS) in England provides GP services to patients who have been excluded from their GP practice after being reported for violent behaviour. Patients registered on SAS are likely to be offered remote services, in part because patients are often placed in an 'out-of-area' SAS practice.

There is extremely limited evidence available on the needs of patients on SAS, whether and when it's appropriate to offer remote options, and how this service can best be organised for patients and staff involved. It is likely that many of these patients already experience multiple disadvantages, and it might be difficult for staff to know how best to support patients.

We will first find out how, where, and to whom SAS services are provided through a national survey. We will then take a closer look at care provided to patients on SAS through observations and interviews with patients and staff at three English SAS providers, alongside broader interviews with policy and decision makers.

We will prepare for this work by involving people with experience in working for and with patients on SAS, as well as patients with lived experience of SAS and/or other forms of exclusion in care. This will help us develop approaches for safe, ethical, and meaningful patient involvement in the current study, as well as possible future research.

We hope this project will help improve the way that research is done with and for patients who experience exclusion in care. Overall findings will provide insights into the accessibility, inclusivity, and

quality of GP services for patients on SAS. We will co-design resources for use by researchers and/or healthcare providers for further patient involvement, research and/or service redesign in this area.

Keywords

Primary care, access, digital inclusion, patient removal, special allocation scheme, remote consultations, telemedicine, empirical ethics

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Introduction

Background and rationale

The rapid acceleration of digital and remote primary care during the pandemic has been embraced by some policymakers and providers as a means to tackle ongoing issues around access and increasing demand for services. It has also raised multiple concerns around the exacerbation of existing inequalities and the creation of new patterns of exclusion. Whilst existing evidence suggests remote options can play an important role in overcoming geographical and practical access issues (Goodridge & Marciniuk, 2016; Huxley *et al.*, 2015), remote consultations are far from suitable for every population (Brunton *et al.*, 2015; O’Cathail *et al.*, 2020). Research into primary care during the pandemic showed how clinical relationships with homeless patients were affected by the rapid digitalisation of care (Howells *et al.*, 2021) and how remote consulting can present challenges to identifying and managing safeguarding concerns (Dixon *et al.*, 2022). When it comes to the increasing number of remote services provided via online platforms, it has become clear that digital disparities interact with multiple categories of disadvantage (Dakin *et al.*, 2024; Husain *et al.*, 2022), invoking the “inverse digital care law”: that people most in need of support are least likely to engage with digital platforms, exacerbating healthcare inequalities (Davies *et al.*, 2021).

Despite the growing body of research focused on remote primary care and access for (digitally) excluded groups (Dakin *et al.*, 2024; Dixon-Woods *et al.*, 2005; Paddison & McGill, 2022), very little is known about the access needs and challenges in providing care to patients who have been *deliberately* excluded from their regular GP practice. Patients on the Special Allocation Scheme (SAS, previously known as “the violent patient service”) have been de-registered from their GP following a report of violent or aggressive behaviour where a GP or member of practice staff has feared for their safety or wellbeing. Patients on the scheme have diverse needs but we know that they are often extremely complex needs. A high proportion experience severe and multiple disadvantage, which is associated with significant barriers to accessing primary care, experiences of stigma and discrimination, and (for some) a low uptake of specialist (e.g. homeless) services due to feeling unsafe (Potter *et al.*, 2024). The SAS is, we argue, a neglected case of exclusion in the field of primary care, which raises important questions about the intersection between complex need, remote care, and (digital) exclusion.

Until the early 2000s, GPs in the UK could remove any patient from their list without giving the patient or the Health Authority a reason (O’Reilly *et al.*, 1998; Saeed, 2003; Steele & Gilliland, 1999), leaving the patient to navigate the challenges of re-registering with a new GP with their “struck-off status” (Saeed, 2003). The scheme in its current form was introduced as a Directed Enhanced Service in 2004 and aims to “provide a secure environment to patients who have been removed from their GP practice...so they can continue to receive primary medical services” (NHS England, 2024) Although the allocation is temporary, patients will usually be registered for a minimum of 12 months (NHS England, 2017), with some patients remaining

on the scheme for much longer¹. To our knowledge, there is no up-to-date data published about the patients currently served by the scheme and no centralised data sets or channels for information sharing across SAS service providers. The voices of patients who are registered on the SAS their GP remain absent, with the exception of one piece of grey literature and a few brief media reports, which suggest that care might be harder to access on SAS despite post-pandemic policies to offer remote and in-person options and a choice of access modalities (Eastern Daily Press, 2019; Fulfilling Lives South East Partnership, 2020).

There is an urgent need to conduct research that includes patients who have experience of the SAS and the stakeholders involved in delivering their care. This has become particularly pertinent since the pandemic and the rapid changes to primary care that have emerged over this period. A recent survey found “a near doubling of violent incidents in General Practice over the past five years” (Lacobucci, 2022) and GP leaders have reported that this worsened during the pandemic when primary care faced increased pressures with the lack of available in-person care, giving the impression (perpetuated by the media) that GPs were “closed” (Mroz *et al.*, 2021). This has been corroborated by national level stakeholders and local SAS providers, who highlight the rapid expansion of remote care patients have had to come to terms with. When patients are removed from GP lists, primary care commissioners have a responsibility to ensure they receive ongoing care in modalities that meet the “reasonable needs of patients” (British Medical Association, 2024). However, as we describe below, referral to the SAS is likely to renew the imperative to engage with remote services, raising important questions around continuity of care and equity amongst those with social care needs (Hughes *et al.*, 2022; Ladds *et al.*, 2023).

Scoping the literature on primary care for excluded patients

We carried out a scoping review of the literature seeking evidence on the removal of, and care for, patients from primary care in the UK. We identified a small set of published studies and commentaries (16 publications in total) from between 1979 and 2014 on this topic. Of these 16 publications, 11 included evidence from England, 3 from Scotland, 1 from Northern-Ireland and 1 from both England and Wales. Crucially, however, none of the included literature reported on the delivery or experience of care in a post removal context such as the Special Allocation Scheme. This also left an evidence gap when it came to remote primary care for excluded patients, particularly given that the most recent paper was over a decade old. Publications focussed on the rates and reasons for removal and 2 on policies and processes of removal. 4 of the publications were commentaries or letters, 5 reported on mixed methods studies, 2 were quantitative and 5 qualitative (4 of these came from one particularly engaged research group). 3 of these studies develop theorisation around removal, but again, it remains unclear how this relates to the post-removal context. The authors of

¹ Exceptions include successful appeals or use of the break clause of 6 months with a minimum of 3 reviews

the qualitative papers critique the use of postal surveys and other quantitative methods and argue that there is a need “detailed qualitative investigations... of this important primary care issue” (Stokes *et al.*, 2001).

In light of the context and emerging questions outlined above, we carried out a critical synthesis of the included literature focussing on issues of inequalities, access, and models of care for excluded patients – including remote care specifically. Several qualitative papers discuss the unequal power imbalance between doctors and excluded patients (Shaw, 2004; Stokes *et al.*, 2003; Stokes *et al.*, 2004), whilst others comment on or demonstrate an overrepresentation or misrepresentation of certain demographic groups in this context: 4 included papers focussed on the intersection between patient removals and psychiatric services (Robertson, 1979; Shaw, 2004; Williamson *et al.*, 2012; Williamson *et al.*, 2014), with papers published from the 2000s onwards using the term ‘revolving door patients’ to describe patients who are repeatedly referred to psychiatric services from primary care, highlighting high levels of deprivation, substance use disorder and complex health needs. However, the commentary by (Stokes *et al.*, 1999b) points to a potential misrepresentation of psychiatric patients as disproportionately affected by GP removal in the literature. Ethnic inequalities were another concern, with Stokes *et al.* (1999b) hypothesising that South Asian patients may be more likely to be removed from GP lists, though ultimately this was not supported by the data. Qualitative and anecdotal evidence highlights the exclusionary practices and negative construction of patients (at risk of being) removed from primary care more broadly (Saeed, 2003; Sampson *et al.*, 2004; Shaw, 2004).

Evidence on the accessibility of care for patients removed from their usual GP is hard to ascertain as very few papers look directly at the needs, perspectives and experiences of excluded patients and none cover the post-exclusion care setting (i.e. SAS, or as previously named, ‘violent patient’ services). Shaw (2004) and Sampson *et al.* (2004) both highlight how patient referral to psychiatric care is coupled with high access needs for healthcare more broadly and several of the commentaries raise concerns about access post exclusion. These predate the introduction of the SAS but the invocation of excluded patients as a potential “underclass” with restricted access to care (Yamey, 1999) highlights the social and ethical stakes of exclusion from primary care services. Whilst there were several mentions of access issues related to limited local options for re-registration post-removal, these papers predated the statutory obligation to provide at least one GP service within each Integrated Care System, and the mainstreaming of remote primary care options. There was no data or mention of different modalities of care (including remote or digital appointments or access routes) for patients removed from their usual GP care. However, we know from one piece of grey literature that patients on the SAS can find both the long-distance travel and remote services on SAS challenging (Fulfilling Lives South east Partnership, 2020).

In sum, there is a significant gap in the literature on the access needs and challenges for SAS patients who have been deliberately excluded from primary care. More research is needed to understand the social, ethical, and clinical complexities of remote care technology adoption in the specific SAS context. This will inevitably bring its own set of ethical and practical challenges. We discuss these challenges below, homing in on the need to manage higher levels of risk and vulnerability (for both participants and researchers) in the proposed study. We do not see these challenges as insurmountable, and – crucially – are all too aware of the danger of further excluding or disadvantaging seldom heard groups by avoiding research that meaningfully involves them (Cheraghi-Sohi *et al.*, 2020; Luchenski *et al.*, 2018). Drawing on the INVOLVE principles (INVOLVE, 2015) and the wealth of expertise and experiences in PPIE from our own team (Adeyemi *et al.*, 2022), this study aims to adopt an iterative, participatory approach towards building an evidence base on primary care in SAS to address the complexities and challenges we have described above.

Methods

Patient and public involvement

We adopt an iterative and participatory-informed PPIE approach throughout, involving patients and other stakeholders from early conceptualisation to study design, analysis and codesign of outputs. Two public collaborators, both with lived experience of exclusion in care, are involved the overall management and delivery of the study. Our third sector collaborator will further offer local knowledge and networks and share expertise in working with marginalised groups.

Initial ideas for this project emerged from real-world observations of ethical dilemmas about competing patient/staff needs and triage challenges in a linked study. We brought this case and SAS more generally to our PPIE group (existing of 9 diverse patients/carers), who voiced the urgent need to find out who patients on this scheme are and how to support stakeholders in delivering suitable care to them. As part of developing this project from an initial ‘research problem’ to a full project proposal, we further organised two patient and public workshops, involving a total of 6 participants with self-identified lived experiences of complex needs and/or exclusion in care, to evaluate possible research needs. These contributors highlighted the importance of finding out who people on SAS are, what needs they have, how they can best be helped (framing this as part of providers’ ‘duty of care’) and how NHS staff on SAS can be supported in doing so. Other practical recommendations have further informed our study design, such as the need for participant debriefs and signposting, trauma-informed research skills, and collaboration with a third sector organisation.

In preparing for study set-up and delivery, we organised two workshops to collaboratively develop our approach to recruitment, consent, data collection and PPIE procedures. In the first workshop, we brought together our two public collaborators, NHS staff from our primary care site, and our third sector collaborator to develop safe and ethical approaches to

recruitment, consent, and data collection, drawing on tacit knowledge and expertise from stakeholders experienced in working with and for deliberately excluded patients. This led to the codesign of a working protocol for safe and ethical fieldwork at our primary site, to be revised and tailored to our secondary case sites. The second workshop was cofacilitated by our third sector collaborator and involved 8 public contributors (diverse in age, gender, ethnicity) with lived experiences of exclusion in care (e.g. due to homelessness). These contributors reviewed our Plain English Summary, offered practical recommendations on ensuring a sensitive and trauma-informed interview process (e.g. room layout, how to prepare research participants for the interviews, allowing participants to bring a support person, etc), and inputted into our ongoing PPIE strategy.

Throughout data collection, analysis and synthesis, we will further organise ad-hoc one-to-one PPIE sessions (up to 10) to discuss 'live' practical or ethical issues, which will inform ongoing revisions to data collection methods (where possible) and/or feed into the codesign work. As discussed below, the study will end with a codesign workstream where we will bring together researchers, healthcare practitioners, third sector stakeholders, and (former) SAS patients to discuss findings and develop resources based on our research to inform future research and service redesign in this context.

Ethical approvals

Ethical approvals have been granted from the London - Camden and Kings Cross Research Ethics Committee and UK Health Research Authority (July 2025, 25/LO/0411).

Aims and research questions

In the SEARCH study, we seek to start building an evidence base on the delivery of primary care in the Special Allocation Scheme, with a focus on a) generating insights on the accessibility, inclusivity, and quality of hybrid models of care and b) developing and piloting approaches for the safe, ethical, and meaningful involvement of this seldom heard group in broader research and service development. To address these aims, we adopt the following research questions:

1. Where, how, by whom, and at what scale are SAS services delivered in England? What are common needs of patients on the SAS with regards to accessing and participating in GP care (including in digital or remote contexts)?
2. How can we work with service providers, lived experience contributors, and other actors in the wider system of care to develop a robust, safe and ethical methodology for a) conducting qualitative research in SAS contexts, and b) involving SAS patients in PPIE work?
3. How do patients and providers navigate and experience in-person and/or remote care in the SAS context,

and what implications does this have for the accessibility and quality of care for this group of patients?

4. How can SAS providers be adequately supported to deliver high-quality, ethical and trauma-informed services to patients on SAS?

Study design

This is a mixed methods study using a combination of PPIE and codesign, national scoping (stakeholder mapping and national survey) and ethnographic research methods with service providers and patients in three sites involved in providing SAS services in England.

A. Scoping the provision of SAS in England: A national survey (WS1)

We plan to conduct a national scoping survey with SAS providers in England (up to 50 respondents) to examine the scale and nature of current SAS provision. We will ask relevant staff (e.g. GP partner, practice manager) at these SAS practices to complete the survey (only one respondent per organisation). The survey will include questions about a) the scope and nature of SAS consultations (e.g. estimated number of registered SAS patients, estimated frequency of SAS appointments, use of consulting modalities, use of triage systems), b) types and availability of existing local data (if any) on SAS services (to inform future quantitative research) and c) staff perspectives on challenges and improvement opportunities in delivering SAS (e.g. perceived needs amongst SAS patients, local challenges and enablers in successful delivery).

Possible respondents will be identified through an initial SAS provider mapping exercise, supported through publicly available information on sites receiving NHS funding to deliver SAS (NHS England, 2025) dissemination via Clinical Research Networks, ICBs, and our existing SAS contact at NHS England. We will further leverage our research group's established interdisciplinary network of research, policy, practice, and community stakeholders in the primary care domain.

The survey was developed based on early scoping of literature and stakeholder engagement (described above), and extends earlier survey instruments used in previous research on hybrid and remote care provision across the UK (Papoutsi *et al.*, 2024; Shaw *et al.*, 2021). An initial version of the survey has been piloted with staff at our primary case study site, with relevant changes made. The survey will be administered online (through the Oxford JiscMail account/Qualtrics), in paper copies, or over the telephone (depending on respondent preferences).

Quantitative data will be analysed using descriptive statistics (using SPSS). Qualitative data in free-text questions will be thematically analysed. All respondents will have the opportunity to register their contact details to be invited to participate in research and PPIE activities (e.g. codesign workshops), where

relevant. This may inform further elements of the study (e.g. site selection).

B) Ethnographic case studies of three SAS services (WS2)

The ethnographic workstream will involve observations and interviews at three case sites delivering SAS services in England. This will follow a dual methodology approach (Leonard-Barton 1990), which involves the “synergistic use of a longitudinal single site with replicated multiple sites”. Put simply, means that we will focus on a single site over time but compliment this with some more rapid pilot work in the two other sites.

Study settings

Following our methodological approach and sampling strategy in the ModCons and Remote by Default studies, the selection of study sites are oriented to generating high levels of transferability (rather than statistical generalisability). As is usual in case study research we seek variation in relation to key features to capture case studies that are of empirical interest for this study, including practice size, levels of deprivation and ethnic diversity, digital maturity, specific delivery model of SAS care, and use of remote care. The two included sites are varied in geographical location, rurality, local demographics, and model of SAS provision (Table 1). The third site will further be selected through theoretical sampling based on emerging ethnographic data (e.g. using contacts developed through our scoping work).

(See Table 1 for characteristics of case study sites)

Data collection methods

Data collection methods will be tried and tested ethnographic methods from general practice settings, based on linked

NIHR funded studies, Remote by Default 2, the ModCons sub-study and Together-2, in which we have been ethnographically investigating hybrid models of in person and remote care in GP practices in England. These methods will be iteratively tested and adapted to establish the feasibility of their application in SAS settings.

Informed consent: informed consent will be obtained for all participants using verbal or written methods as appropriate before any of the below activities are carried out. Verbal consent may be taken in instances where, for example, the person being consented cannot fully read and understand the written study documents due to literacy issues. In cases where verbal consent is required, this will be done verbally, and a Record of verbal consent form will be completed by the person taking consent. A copy of all verbal and written consent forms will be given or sent to the participants for their records. Approaching informed consent as a dynamic and ongoing process, this study is designed to include multiple built-in moments for participant to (re)confirm consent at various stages in the study (as described in the Ethical and Trauma informed approaches below).

Ethnographic observations

Ethnographic observations will be conducted at our primary site over a total of six months by experienced ethnographic researchers in our team (NB, JvD, SS, FD). We will follow a ‘team ethnography’ approach (Bikker *et al.*, 2017), adapted from our ModCons study. This approach facilitates the involvement of interdisciplinary perspectives, enables the research team to simultaneously observe different elements of practice processes, and helps maintain safety and wellbeing in a high security setting.

Table 1. Characteristics of included case study sites.

Site pseudonym	Geographical location	Site characteristics	Approach to SAS provision	Modality and broader infrastructure of delivery
Harmond Park Medical Group	Southeast England	Urban/Suburban GP practice, typically serving between 15-30 patients on SAS alongside mainstream primary care	Run by a team of care coordinators, and the practice manager, clinical care delivered primarily by one GPs and nurse practitioner.	Appointment booking via text, email or voicemail; telephone triage for a mix of in-person visits and telephone calls for consultations.
Bracken Hill Surgery	South Central England	Rural GP practice, typically serving between 20-40 patients on SAS alongside mainstream primary care	Predominantly led by one GP, with support from other senior GPs and the practice manager	Appointment booking via the same system as mainstream services using flags to identify SAS patients. Telephone triage for a mix of in-person visits and telephone calls for consultations.
<i>To be identified based on theoretical sampling, informed by emerging findings.</i>	-	-	-	-

In addition to a practice familiarisation day at each case site, we will carry out approximately 8 half days of ethnographic observation at the primary site and 5 half days at the two secondary sites. This will include direct observations of telephone, video, and in-person consultations with SAS patients (with consent); triage and administrative practices around the organisation of SAS; And multi disciplinary team meetings. In line with the dual methodology approach, observations at the two secondary sites involve more focused observations informed by initial findings from the primary case study site. We will write extensive fieldnotes to record observations of the day-to-day practices and reflexive notes about methodology, which we will use to inform the later stages of the project (co-design workshop and development of future bid). We will not record the personal details (full names, date of birth, address or any other personally identifying information) in fieldnotes. In order to protect the privacy of patients who have not consented to participate in the study, we will avoid observing particular documents or tasks that identify them (e.g. looking at screens with patient names and medical records open).

Interviews

Patients

Across the 3 case study sites, we will interview patients who are currently registered on SAS (up to 18 in total) to examine experiences of accessing and receiving primary care through SAS. Using narrative interview methodology (Green & Thorogood, 2018), these interviews will seek to elicit narrative accounts from initial registration on SAS to most recent encounters with the service. We will add probes about experiences of care *before* being registered on SAS, where and *only if* this is considered relevant for our study by patients. Where the case study site adopts particular digital or remote tools for accessing care (e.g. online forms, mobile apps or telephone services), we will further incorporate complementary ‘think aloud’ questions to encourage participants to talk us through the process of accessing care (or attempting to) in the context of their day-to-day lives (Koro-Ljungberg *et al.*, 2013). As part of this, we will seek to identify specific needs and/or sociomaterial circumstances in which remote modalities may be more or less suitable for patients.

Depending on the preferences of participants and their access to technology, we will conduct interviews in-person (if deemed acceptable and safe by the practice team), over telephone (using a project-based mobile telephone), or over video (MS Teams). This gives patients an opportunity to meet outside of the GP practice to provide maximum privacy and/or distance from the clinical setting if that is desired. When interviews are conducted in-person, we will conduct them at the GP practice in a room in their standalone SAS unit with the GP providing care to the patient on site (but not in the room) and on-site security in accordance with the risk assessment of the SAS team.

Patients will be sampled opportunistically as they engage with the service, by requesting an appointment or being invited to the surgery (e.g. for a long-term condition review).

They may also be identified to take part in an interview by their local clinical team at participating sites who have routine access to data to identify patients receiving SAS services. Potential participants will be screened for capacity to consent and safety considerations by their clinical team² before being invited to the study. Given that most SAS providers tend to have a small list of patients, we aim for up to 8 patients at our main site and up to 5 patients at each of our two secondary sites. Where possible, we will seek to recruit participants from a diverse range of characteristics including age (excl. below 18), gender, ethnicity, literacy, disability, primary language, and access to/skills in using digital services.

NHS staff

Across the 3 case study sites, we will interview NHS staff (up to 15) involved in organising or delivering aspects of SAS, seeking variation in role (e.g. triage personnel, clinical staff, management). These interviews will be conducted during our ethnographic observations, using the ‘go-along’ interview method (Carpiano, 2009). This is a practice-based interview method that takes place as people go about daily routines in familiar spaces or journeys between spaces. Beyond benefits for minimising staff workload, this interview method encourages those we are shadowing to describe what they do as they are doing it, allowing us to capture experiences of, and reflections on, decision-making as it unfolds. This may involve, for example, accompanying the GP before a SAS consultation (e.g. explaining the clinical reasoning for conducting it in person or remotely), a short debrief after the consultation about how the consultation unfolded and any follow ups needed, or sitting with a care coordinator to observe how decisions about care for patients on SAS are made during the booking process.

In addition to go along interviews, core staff members involved in the organisation and delivery of SAS services may also be asked to participate in a semi-structured (follow-up) interview to capture more high-level insights about their views on, and experiences of, the service. Semi-structured staff interviews will be done in person at the practice or remotely via teleconferencing software (MS Teams) depending on participant preference.

National and regional decision makers

We will also conduct broader semi-structured interviews with national and regional decision makers (up to 5) involved in planning for or overseeing NHS SAS provision (e.g. NHS England, commissioners, British Medical Association or similar). These interviews will seek to establish if national strategy and guidance has been developed, how this has been done, and the underlying logics, values, and visions for the future that

² It must be noted that the role of ‘gatekeepers’ in facilitating access to participants is ethically complex and has clear potential downsides in compromising inclusion in research, especially when it concerns research on socially excluded people (Emmel *et al.*, 2007). However, following an in-depth discussion in the stakeholder workshop, it was felt that this procedure was a necessary trade-off to mitigate acute risks for researchers and participants.

have shaped this. These interviews will be done remotely via teleconferencing software (MS Teams) or by telephone (depending on participant preferences).

C) Data synthesis and codesign of a ‘best practice’ toolkit (WS3)

We will synthesise our data and learning throughout the study to develop resources (e.g. best practices, policy brief, codesigned resources) to inform the commissioning and high-quality delivery of SAS services, tailored to the respective needs of SAS patients. As part of this, we plan to organise two codesign workshops (approx. 5-8 stakeholders each) that bring together researchers, practitioners (clinicians, support staff and third sector care providers), and (if feasible and safe) (former) SAS patients to co-produce a set of reflections and best practices based on our research to inform future research and service redesign in this context. Options for one-to-one input from SAS patients will be provided where more appropriate or preferred. The toolkit will include a set of resources for helping other researchers and/or healthcare providers engaged in research, health service redesign or quality improvement for excluded and seldom heard groups in care and will be designed with support from designers from Design Science (an external design agency).

Analysis and engagement with theory

Initial study design and analysis was informed theoretically and methodologically by empirical ethics (Pols, 2015). Developed in the context of telecare research, this approach utilises ethnographic methods to examine social practices and ethical issues as they arise in practice, focusing on relationships between people and between people and technologies. Although related to care ethics, it is distinct from traditional care ethics because “*what care is and if it is good is not defined beforehand*” (ibid.). This is particularly important for the proposed study because the creation and maintenance of ‘good’ (remote) care depends on the context and particular relationships in question. Reflecting this, we plan to use a combination of remote and in person research methods and iteratively reflect on what ‘good’ research looks like in this context. The study is also informed theoretically by the Planning and Evaluating Remote Consultation Services (PERCS) framework, developed by our team in Oxford, to guide the planning, delivery and evaluation of remote consultation services from a theoretical and a practical perspective (Greenhalgh *et al.*, 2021). PERCS refines and extends the team’s work on the NASSS framework—focused on Non-adoption, Abandonment and challenges to Scale-up, Spread and Sustainability of technology-supported services (James *et al.*, 2021) – by examining the dynamic interaction between a number of domains, underpinned by ethics of care, clinical ethics and healthcare quality.

We will take an iterative approach to qualitative analysis and theorisation, using emerging data to identify further theories of relevance, drawing on fields including science and technology studies, medical sociology, medical anthropology, and organisational theory. PPI contributors will provide comments

on the themes developed from the data and to consider the veracity, sensitivity, and credibility of interpretations. Cross-case analysis will be conducted to generate transferable findings.

Ethics and governance

Ethical and trauma-informed approach to research

This project involves a range of ethical and safety risks that require careful consideration above and beyond standard conventions for ethics and governance in research. One of the main purposes of this feasibility study is to enable dedicated time and resources for the careful development of sensitive approaches for engaging patients registered on SAS in research and service redesign.

Respective ethical risks in conducting this study may broadly be classified into three domains. First, given the nature of the study (e.g. relating to past conflict in healthcare interactions), it is possible that sensitive topics will come up during the research, such as accounts of conflict, violence, or past trauma. Second, without stringent privacy and security measures, there may be acute risks to the safety of participants (e.g. failures to protect confidentiality may have severe consequences) or the researchers involved. Third, our study includes patients who may be members of marginalised groups, and there is a risk that study outputs could perpetuate stereotypes or stigma if not handled sensitively and reflexively.

To mitigate these risks, we will be extremely careful in taking a safe and ethical approach to research procedures, informed by our ongoing PPIE as outlined above. This includes:

- *The collaborative development, and continuous revision, of best practices for maintaining safety, ethics and safeguarding in research.* As above, we have conducted a workshop with NHS staff, patient contributors (with lived experience of exclusion in care), and third sector partners to develop a set of guidelines for safe and ethical fieldwork, partly informed by ethical principles for researching sensitive topics and working with vulnerable groups (Hilário & Rafael, 2020), as well as NHS and university-based safeguarding policies. This will function as a working draft, to be tailored to each specific case study setting in advance of research activities, and further revised based on ongoing feedback from patient and staff participants.
- *A reflexive and ‘trauma-informed’ approach to research practice* (Edelman, 2023). All researchers involved in fieldwork have undergone formal training in trauma-informed qualitative research methods. This includes being able to recognise the signs of trauma or emotional distress and techniques for distress management (e.g. being careful with probing, incorporating breaks where needed, developing hand-out resources on support services). We will consider potential impact of procedures on research participants, and explore preferences on, for example, research environment (e.g. remote, private

room) or researcher-participant concordance (e.g. sexuality, gender, ethnicity) while also maintaining safety. If desired, patients will be able to bring a trusted individual (e.g. carer, social worker) to the interview. Participant feedback regarding the research process will be routinely asked, with ongoing plans adjusted accordingly. We will also adopt trauma informed principles to protect the psychological wellbeing of researchers, such as practicing ‘safe empathy’ and maintaining professional boundaries under pressure, and through routine debriefs.

- *The provision of detailed, transparent, and easy-to-understand information about implications of the research and participation.* To make sure our consent processes are inclusive, we will develop an easy access patient-facing study information sheet (adapted to alternative formats, e.g. written version with visual aids/illustrations and/or an audio file, based on piloting with PPI collaborators and as we gain experience as the study progresses), and follow verbal consent procedures where needed (e.g. in cases of low literacy). As part of this, we will be transparent about any possible limitations to confidentiality may any significant safety concerns arise. Following trauma-informed practice, we will also provide clear instructions about what to expect (e.g. offering sample interview questions, describing the location). We will also make sure that participants understand that whilst we hope that the research will improve care for patients on the SAS in future, it will not directly change their care or influence any reviews that might result in them being de-registered from the scheme/re-registered with their usual GP (as recommended by a PPI contributor). Given the sensitive nature of the study, we will reconfirm consent twice after initial formal consent, including at the end of each observation or interview, and during an optional debrief (described below). Should the participant wish to withdraw, we will give the option for all relevant data collected up to that point to be destroyed.
- *The opportunity for debriefs and aftercare for participants where needed.* Signposting and debriefing options will be shared at the end of an observation and/or interview, and participants are given the opportunity to give feedback about the process (either directly or over e-mail after) with ongoing research procedures adjusted accordingly. As suggested by a PPI contributor, we will also have a resource sheet to hand with the contact details of local support and advocacy services that SAS patients involved in our research can turn to for help with their case (e.g. POHWER leaflet), more general support (e.g. leaflets of local mental health support charities), or other tools to help with future interactions (such as the ‘I am autistic card’ or similar resources provided by national or local charities – another PPI suggestion). The

participating site will have staff members available known to the participant (e.g. care coordinator) who can support debriefing. There will also be an opportunity to liaise with their GP if any further clinical support or signposting to local services is required.

- *Ensuring respectful, accurate, and non-stigmatising representation of SAS patients in research outputs and dissemination.* Through adopting a reflexive approach and extensive PPI throughout the project, including the involvement of lived experience contributors and third sector stakeholders to review our data interpretations and representations, academic outputs, and policy and practice recommendations.

Governance

Quarterly project team meetings as well as regular meetings with our senior mentor will take place with dedicated time to reflect on (potential or live) ethical issues and dilemmas, working iteratively to develop a set of ethical guidelines and principles that will be used in the research going forward. Our multidisciplinary team includes two patient collaborators with lived experience of exclusion in healthcare contexts, as well as a practicing GP, and a participatory methods expert. The project will also benefit from consultancy services provided by one of our third sector partners, Common Ambition, who have extensive experience in coproduction with people who have experience of multiple compound disadvantage, trauma informed practice, and peer research models.

Dissemination, outputs and anticipated impact

We plan to adopt a continuous approach to developing and spreading impact, building on early learning from our survey, PPIE and case studies to ensure different stakeholder perspectives shape the direction of the work. In addition to academic outputs, we will feedback key findings to policymakers and commissioners (e.g. via our established NHS England contact, invited talk at ICB leadership meetings) to help inform the design and delivery of the SAS in general practice. This will take place alongside work with case study and other SAS sites to build and share learning, making sure to feedback findings that identify ‘best practices’ or areas for improvement. We will also aim to support and promote future research and service redesign, including by coproducing resources aimed at helping other researchers and/or healthcare providers engaged in research, health service redesign or quality improvement for excluded and seldom heard groups in care (as described above). Reflections on our approaches to research and engagement, challenges we encountered, and how we overcame these will be disseminated (e.g. via a conference panel, blog) and inform the design of future projects in this area.

Conclusion

Whilst remote solutions can improve access to primary care for some, they are not suitable for every patient population and can widen health inequalities. This is a novel study in a critically

under-researched area of service delivery with clear practical and ethical implications for practice. Findings will develop understanding and transferable learning for SAS delivery and inform the design of a future study.

Data availability statement

Due to the sensitive nature of the data collected in this study, including personal narratives and potentially identifiable information (due to the small number and scale of SAS

services), the underlying data will not be made publicly available. This decision aligns with ethical obligations to protect participant confidentiality and is consistent with NIHR Open Research's data sharing policies regarding sensitive human data.

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