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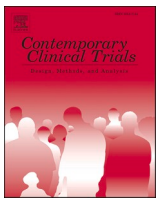

Central data monitoring of clinical trials: A survey of the UK clinical research collaboration (UKCRC) registered clinical trial units

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ABSTRACT

Background: Central data monitoring involves activities performed by trial staff to improve the quality, integrity, and reliability of trial processes and data collection whilst a trial is open. The aim of this research was to determine the variation in activities conducted and the factors, roles and documentation involved across UKCRC registered clinical trials units (CTUs).

Methods: A survey asking about the central data monitoring activities conducted by trials units was sent to all UKCRC registered CTUs on 25th April 2025. We listed 16 central monitoring activities and asked about whether or not they were conducted on any, some or all trials and which staff role was responsible.

Results: Responses were received from 63.5% (33/52) of CTUs) between until 5th June 2025. 8 of the 16 activities: protocol non-compliance, patient flow (e.g., CONSORT chart), recruitment versus predicted recruitment, eligibility issues, consent issues, data completeness for primary analysis, missing case report forms (CRFs), and data outliers, are conducted for all trials by at least 27/33 (81.8%) of the units and for some trials by all the trials units. 10/16 (62.5%) of the activities were done by a mixture of staff roles at the majority of units.

Conclusions: Our survey shows the variety in the central data monitoring activities conducted by UKCRC CTUs and the variation as to who is conducting these activities. We recommend actions to improve the consistency and quality of monitoring in trials run by UKCRC-registered CTUs. When setting up new trials, CTUs should consider implementing the central data monitoring activities described, with particular emphasis on the eight activities undertaken by all units surveyed.

1. Background

Clinical Trials Units (CTUs) are specialist units which have been set up with a specific remit to design, conduct, analyse and publish clinical trials and other well-designed studies.The UKCRC brings together the NHS, research funders, industry, regulatory bodies, Royal Colleges, patient groups and academia in a UK-wide environment that facilitates and promotes high quality clinical research for the benefit of patients. A UKCRC registration process has been established for academic CTUs responsible for coordinating multi-centre clinical studies. In order to become UKCRC-registered, CTUs must demonstrate a track record of experience in coordinating multi-centre trials, expert staff to develop studies, robust quality assurance systems and evidence of long term viability of capacity for trials coordination. Most of these CTUs are involved in a mix of therapeutic areas but all are part of a collaborative network that attempt to share best practice across all therapeutic areas. This is intended to help improve the quality and quantity of available expertise to carry out UK clinical trials.

Clinical trial monitoring is an integral part of good clinical practice aiming to ensure the participants' rights, safety and well-being. It also ensures the reliability of trial results as the trial progresses and is one of the principal quality control activities. [1,2] Centralised data

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monitoring is an evaluation of accumulated data, performed in a timely manner, by the sponsor's qualified and trained persons [2], and includes activities that aim to improve the quality, integrity, and reliability of trial processes and data collection whilst a trial is open. They typically involve computer programming to identify issues in accumulating centralised trial data. Therefore, in our experience within academic CTUs such as those registered with the UKCRC, statisticians are often responsible as they have programming skills, but other roles may also be responsible e.g. data managers, trial managers, programmers, trial monitors. These activities can complement and reduce the extent and/or frequency of on-site monitoring or be used instead of on-site monitoring and can help identify systemic or site-specific issues, including protocol non-compliance and potentially unreliable data. [1,2]

Though central monitoring has been shown to improve quality,

Table 1
Definitions of central monitoring activities assembled from consensus meetings.

Trial process and integrity checks
1. *Consent issues* Checks to look for lack of informed consent prior to any trial specific assessments or treatment. This might require programming to compare dates of consent with dates of non-routine, trial specific assessments.
2. *Eligibility issues* Where checks are run on screening data to look for consented patients that do not fit the eligibility criteria. These are specific protocol non-compliance checks that need to be addressed quickly and are often programmed into the database capture system as validations to alert the user at the time of data entry. However, some checks may be more complex and require programming outside the system e.g. blood samples collected at two time points within the last week.
3. *Recruitment vs predicted recruited* A regularly updated graph showing actual recruitment versus predicted recruitment since the trial opened. This allows timely remedial action to be taken e.g. opening more sites if the recruitment rate is slower than anticipated. It may also check for inclusivity of recruitment in underserved groups as per INCLUDE guidelines. [10]
4. *Checking randomisation algorithm* This is a check that ensures that the randomisation algorithm is running precisely as expected. Although a table of baseline characteristics is typically checked for randomisation imbalance by the IDMC, this specific monitoring activity checks to see if each patient was allocated as expected e.g. according to the pre-specified balanced blocks or according to accumulating strata where a minimisation algorithm was used (and random number generated where a random element is used). This may not be considered necessary if a commercial system is being used or if testing prior to the trial is considered adequate.
5. *Patient flow* Describing the passage of patients through from screening to primary endpoint assessment. The purpose of this is early identification of any differences between assumptions at the planning stage compared to reality e.g. the proportion of patients going into different randomisations in a platform trial or the proportion of patients dropping out before providing primary endpoint data. This might be done as a CONSORT diagram or table.
6. *Patient's early cessation of trial participation* A detailed description of when, why and at what level patients are withdrawing from a clinical trial prior to the final assessment timepoint. This is often conducted as part of patient flow (point 2 above) but provides more detail e.g. check of rates across sites (it may be that a site has misinterpreted the protocol and are stopping their patients earlier than required) or level of withdrawals across sites (some sites may be withdrawing patients from non-routine assessments).
7. *Checking assumptions used in sample size calculations* Sample size calculations often incorporate assumptions e.g. the event rate in the control arm.
8. *Protocol non-compliance* Checks to protect trial integrity by looking for evidence of protocol non-compliance e.g. treatment starting later than the maximum time allowed after randomisation, an assessment being conducted outside of a specified time window, drug dosages above maximum allowed. The purpose of this is to identify particular constraints in the protocol that sites struggle to follow and that might need amending or to identify particular sites that are having local issues.
Data collection checks
9. *Data completeness for primary analysis* This is a part of the patient flow description but looks in greater detail at the reasons for why patients can't be included in the primary analysis e.g. a quality of life form not fully completed, or conducted too late, or not entered into the database in error. Typically, this is produced for an Independent Data Monitoring Committee (IDMC) meeting but may also be assessed prior to a meeting to allow resolvable issues to be rectified.
10. *Critical data monitoring* During trial set up when defining the data to be collected, some data items e.g. the primary and key baseline and secondary endpoints may be highlighted as being critical to the reporting of the trial. Such data will have more resource spent on chasing any missing items during the running of the trial and the percentage of patients missing those items can be closely monitored.
11. *Missing CRFs* This check is sometimes built into database systems, but can require more complex programming to check for assessments that are due according to protocol-prescribed time windows (e.g. a 6 month follow up visit may be allowed between 5 and 7 months post randomisation date). These checks will also have to account for patients who have died or withdrawn (depending on level of withdrawal) prior to the end of the assessment windows. They identify assessments that may have been missed or deaths/withdrawals that have not been reported.
12. *Data outliers* A statistical check for data that lies outside of an expected range, e.g. greater than 3 standard deviations away from a mean. This identifies data that may have been incorrectly reported (e.g. using the wrong units) or specific sites that may have an instrument that needs recalibrating.
Site performance checks
13. *Metric specification and assessment* This involves identifying, calculating and comparing site-level metrics that can be used to assess each site's performance and potentially trigger on-site monitoring e.g. proportion of patients with adverse events, proportion of expected CRFs that are missing, number of protocol non-compliances per patient enrolled, proportion of open data queries 3 months after notification. Previous work has made recommendations as to which metrics to look at and how best to monitor them [11–13]
14. *Selecting patients for source data verification* During a trial, patients may be selected to have their trial data checked against source data by clinical trial monitors. Selecting patients may be done randomly or on the basis of issues of concern (e.g. data inconsistencies or outliers).
15. *Check for fraudulent data entry* This involves checking for data distributions that suggest the fabrication of data or systematic error in its collection e.g. looking for sites with data distributions that differ from those at other sites using bubble plots. [5]
16. *Complex range and consistency checks* Range (does a data item fall within an acceptable range of values e.g. adult height $>$ 0.5 m cm and $<$ 3 m) and some consistency checks (is one data value consistent with another e.g. is treatment start date greater than randomisation date) are often programmed into a clinical trial database to check data as it is entered and can be considered routine data management. However, more complex checks often need to be programmed outside of the database; either to reduce database testing and data entry time, or because they require updating over time and can be considered as central data monitoring. For example, in oncology trials, consistency of overall disease stage and T, N and M stage.

[3–5] regulatory bodies provide very little guidance as to what central data monitoring activities should be conducted. In 2013, the Food and Drug Administration (FDA) in the USA encouraged greater use of centralised monitoring practices as part of risk-based monitoring. [6] The UK clinical trial regulatory agency (the Medicines and Healthcare products Regulatory Agency (MHRA)) provides some guidance about central data monitoring. [7] It says: "It is recommended that where the sponsor is undertaking many trials, some generic central monitoring processes are contained in standard operating procedures (SOPs), rather than trial specific documents". However, it also says "there does not appear to be a list of accepted or validated metrics for sponsors to use". Consequently, individual CTUs have had to generate their own ways of identifying which central data monitoring activities to conduct on which trials. The more recent concept of risk to critical to quality factors as being discussed in ICH E6 R3 may also be used to help select metrics at some CTUs [2].

A previous survey of UKCRC registered CTUs has shown variation in central monitoring practice across units. [8] It found that more than half of CTUs (19/36, 53%) do not use an automated monitoring report when centrally monitoring trials. For the remainder, 5 (14%) use the same monitoring programming code for all of their trials, 4 (11%) choose pre-written modules with some bespoke programming and 8 (22%) write bespoke software programming for each trial. However, it was not clear as to what checks were being included in these processes. The UKCRC monitoring, statistics, and data/information system operation groups saw an opportunity to inform best practice by:

i) identifying all potential central monitoring checks currently conducted at UKCRC registered CTUs that trial staff should be aware of when setting up a trial
ii) identifying the variation in checks conducted across UKCRC registered CTUs and the factors, roles and documentation involved
iii) providing recommendations as to how to improve the consistency of central monitoring across UKCRC registered CTUs.

In order to address these objectives, we set up a focus group to develop a survey, the results of which are presented here. We followed the CROSS checklist for reporting survey studies when writing this article. [9]

2. Methods

A group of 8 statisticians and data management staff from 7 UKCRC registered CTUs (from England, Wales and Scotland) convened to design the survey. This group was assembled by the Chairs/Deputy Chairs of the Monitoring, Statistics, and Data/Information Systems Operations Groups of the UKCRC CTU Network as a group of experienced trialists representing expertise in statistics, monitoring, data and trial management. Through a series of three consensus meetings between them, 16 types of check activities that could be defined as central data monitoring were identified (Table 1).The group then developed a survey (see supplementary document) that asked for information about:

- the trials unit
- whether each of the 16 activities in Table 1 were ever conducted at the unit, who conducted the activity, and whether they were conducted on some or all trials
- what other central monitoring activities the unit conducted
- any additional comments the respondent would like to make related to these points (free text)
- how planned activities are documented
- and what factors influence the level of central monitoring for a trial.

The survey was accessible online in Google Forms and a link to the survey was emailed via the UKCRC CTU network on 25th April 2025 to all 52 registered CTU Statistics Leads. They were encouraged to involve others from within their CTU in completing the survey, including from other teams within the CTU (Data Management, Trial Management, Quality Assurance). One joint response per trials unit was requested with a deadline for responses of 30th May 2025. Generic reminders were sent out on the 14th May 2025 and 25th May 2025 to encourage a response, and the survey deadline was extended until the 7th June 2025. Additionally, where a response had not been received from a unit, targeted emails were also sent to individuals within the unit.

Descriptive statistics were produced using STATA SE version 19 tabulating the survey results as frequencies and percentages. Linear graphs, together with Spearman's rho, were constructed to show the relationship between the number of statisticians at a trials unit and the number of central activities a) done just by statisticians and b) done for all trials.

The survey did not require ethical review as it was considered a service evaluation.

3. Results

Responses were received from 63.5% (33/52) of CTUs between 29th April 2025 and 5th June 2025. Table 2 shows the characteristics of the responding CTUs all of whom conduct Clinical Trials of Investigational Medicinal Products (CTIMPs). A minority (14/33 (42.4%)) conduct Phase I trials and nearly all (32/33 (97.0%)) conduct Phase III/IV trials involving less than 1000 patients. There was a median of 11 statisticians at each unit (IQR: 5–15, range: 2–40).

Table 3 shows the results of the survey as to which units perform which activities. It can be seen that the top 8 activities: protocol non-compliance; patient flow (e.g., CONSORT chart); recruitment versus predicted recruitment; eligibility issues; consent issues; data completeness for primary analysis; missing CRFs; and data outliers; are conducted for all trials by at least 27/33 (81.8%) of the units and for some trials by all the CTUs. Seven of the activities were not done at all by at least one trials unit. One activity, checks for fraudulent activity, was only conducted for any trials at 18/33 (54.5%) of CTUs.

We investigated the relationship (Supplementary Fig. S1) between the number of statisticians at a CTU and the number of central activities a) done just by statisticians (Spearman's rho = 0.212) and b) done for all trials (Spearman's rho = −0.003) but found no association.

Table 4 shows the other additional activities classed as central monitoring by the CTUs that responded to our survey. These include reconciliation of data (AEs with SAEs and clinical trial data with external data) and checking the distribution of screened with recruited patients for key demographics, and progress versus any stop/go criteria.

Table 5 suggests a wide variety in which documentation is used to describe planned central monitoring across trials units. The majority of trials units use monitoring SOPs and/or a data management plan and/or a trial monitoring plan and/or a risk assessment. One trials unit included central monitoring in all the documents in Table 5.

Table 2
Characteristics of the 33 responding CTUs.

	n	%
Types of trial conducted (at least 1)		
CTIMPs	33	100.0
Phase I	14	42.4
Phase II	22	66.7
Phase III/IV: <1000 patients	32	97.0
Phase III/IV: >1000–10,000 patients	26	78.8
Phase III/IV: >10,000 patients	7	21.2
Number of statisticians		0.0
1–5	10	30.3
6–10	5	15.2
11–15	10	30.3
16–20	6	18.2
>20	2	6.1

Table 3
Central monitoring activities at 33 UKCRC registered CTUs.

Central monitoring activity*	Done?		If done, who does these?						If done, all trials or some trials?			
			Statistician only		Other role only		Both statistician and other role		All		Some	
	n	%**	n	%**	n	%**	n	%**	n	%**	n	%**
Protocol non-compliance	33	100.0	2	6.1	11	33.3	20	60.6	31	93.9	2	6.1
Patient flow (CONSORT chart)	33	100.0	16	48.5	1	3.0	16	48.5	31	93.9	2	6.1
Recruitment vs predicted recruited	33	100.0	5	15.2	11	33.3	17	51.5	29	87.9	4	12.1
Eligibility issues	33	100.0	2	6.1	17	51.5	14	42.4	29	87.9	4	12.1
Consent issues	33	100.0	1	3.0	25	75.8	7	21.2	29	87.9	4	12.1
Data completeness for primary analysis	33	100.0	9	27.3	2	6.1	22	66.7	28	84.8	5	15.2
Missing CRFs	33	100.0	1	3.0	14	42.4	18	54.5	27	81.8	6	18.2
Data outliers	33	100.0	13	39.4	2	6.1	18	54.5	27	81.8	6	18.2
Patient's early cessation of trial participation	32	97.0	4	12.1	9	27.3	19	57.6	25	75.8	7	21.2
Critical data specification	31	93.9	7	21.2	1	3.0	23	69.7	24	72.7	7	21.2
Metric specification and assessment	29	87.9	4	12.1	5	15.2	20	60.6	21	63.6	8	24.2
Checking randomisation algorithm	28	84.8	24	72.7	4	12.1	0	0.0	21	63.6	7	21.2
Complex consistency checks	31	93.9	21	63.6	0	0.0	10	30.3	19	57.6	12	36.4
Selecting patients for source data verification	31	93.9	5	15.2	18	54.5	8	24.2	15	45.5	16	48.5
Checking assumptions used in sample size calculations	33	100.0	28	84.8	1	3.0	4	12.1	14	42.4	19	57.6
Check for fraudulent data entry	18	54.5	6	18.2	6	18.2	6	18.2	8	24.2	10	30.3

* Ordered by number of trials units conducting the activity on all their trials.
** % of total number of units in survey ($N = 33$).

Table 4
Other central monitoring activities that units reported.

Central monitoring activity	Performed by who?	Performed for all or some trials?
Reconciliation of AEs with SAEs	Stats + other	All
Progress vs stop/go criteria	Other	Some
Data reconciliation with external sources e.g. death data from NHS Digital	Stats + other	Some
Checking distribution of screened vs recruited by key demographics	Other	Some

Table 6 shows what factors dictate the level of central monitoring conducted on a trial. The most common factor is the risk level of the trial (30/32 (93.8%)). The next most common factor was the level of staff funding available for the trial (22/32 (68.8%)).

The following additional comments were made by the respondents to our survey (numbers in brackets show where multiple respondents made the same point):

- "Where data managers have access to reporting tools they perform some central monitoring e.g. missing data, eligibility issues. These may be built by the DM or a programmer/statistician at the start of the study."
- "Statisticians could align central monitoring reports with scheduled data monitoring committee reporting to minimise additional work required."
- "There is variation in practice in our unit according to the statistician's preferences/workload and how necessary monitoring is determined to be (via risk assessment)"
- "As a unit, we are keen to more formally incorporate central reporting to support monitoring but conscious of the additional funding that would be required." [x3]
- "We are working towards adding clarity to our trial monitoring plans as to roles and responsibilities for study monitoring as this is an area we have found challenging in the past. Any national guidance on this issue that can be developed from this survey will be very helpful and welcomed by our CTU" [x4]

Table 5
Where central monitoring processes are documented.

Location	Number of trials units (%)*
CTU monitoring SOPs/guidance	24 (75.0)
Data management plan	24 (75.0)
Trial monitoring plan	20 (62.5)
Risk assessment	19 (59.4)
Protocol	13 (40.6)
Data monitoring plan	8 (25.0)
Statistical analysis plan	7 (21.9)
Other**	4 (12.5)

* N = 32 due to missing data for one trials unit.
** Quality Management and Monitoring Plan; adhoc lists of reports and responsibilities; Trial-specific SOPs; Project Management Group Report template.

4. Discussion

The survey showed variation in both the central monitoring activities conducted by UKCRC CTUs and the roles conducting them. It showed that the top 8 activities in Table 1 are done on all trials by 80% of units and at least some trials at 100% of trials units. These activities seem to be considered the highest priority by UK CTUs and we recommend they should be considered for every trial and non-inclusion should be justified.

Seven activities were not done at all at some trials units. We provided a free text comments field in the survey and these suggested that some of this might have been due to misunderstanding about what early cessation, critical data and metric specification meant, thus indicating a lack of consensus about central monitoring definitions. Some units use commercially provided randomisation systems and may not feel that further validation of the algorithm is required. Not all units conduct

Table 6
What factors dictate the level of central monitoring conducted on a trial.

	Number or trials units (%)*
The risk of the trial	30 (93.8)
The level of staff funding available for the trial	22 (68.8)
Phase of trial	20 (62.5)
Complexity of trial design	20 (62.5)
Source of data e.g. HES (or other health systems data), paper CRFs, electronic data entry	20 (62.5)
Functionality of the database	19 (59.4)
Sample size of trial	15 (46.9)
Number/location of hospital sites	13 (40.6)
Some monitoring is done externally to the trials unit	11 (34.4)

* $N = 32$ due to missing data for one trials unit.

Box 1 Recommendations.

We suggest that those responsible for conducting clinical trials should:

1. consider the level of central monitoring that a trial might require at the grant application stage to ensure that sufficient resource is available
2. have a central monitoring SOP that gives an overview of the central monitoring processes at a unit and the variety of places that plans are documented in e.g. the trial monitoring plan
3. train new staff (even those who may have worked at other units) in this SOP and any relevant trial specific monitoring plans
4. consider at least the top 8 activities in Table 2 (or preferably all the activities in Table 2 and Table 3) during risk assessment in trial set up. Adverse event rates should also be considered for checking as a site metric especially in IMP trials.
5. use a trial specific monitoring plan to indicate which activities will be conducted and who is responsible in a per trial specific monitoring plan. This should include how each activity is to be documented and acted on e.g. which minuted trial meeting will consider which generated reports so that the evidence of conduct and consideration of each activity is clear.
6. decide central monitoring frequency based on risk assessment but where possible align with other trial processes to increase efficiency e.g. in order to improve the quality of data in time for interim analyses or as part of other routine analyses such data monitoring committee reports

trials where the risk level makes source data verification necessary and it is only conducted in all trials in 45.5% of units. Checks for fraudulent activity were only conducted for some trials at 54.5% of units (and in all trials only in 24.2% of units) perhaps reflecting the academic nature of their work and perception of a low risk of motivation for fraud amongst those providing data. Also it is possible for other types of checks, e.g. site metrics, to identify possible fraud without specifically checking for it, Although it is conducted at all trials units, checking assumptions used in sample size calculations is only conducted for all trials in 42.4% of units probably because not all trials have assumptions that can be checked e.g. some single arm Phase II trials.

Three activities were only performed by statisticians at the majority of trials units: checking randomisation algorithm, complex consistency checks, and checking assumptions used in sample size calculations. Three activities were done by non-statisticians at the majority of units: identifying eligibility issues, identifying consent issues, and selecting patients for source data verification. All other 10/16 (62.5%) activities were done by a mixture of statisticians and another role (typically a trial or data manager) at the majority of units. This emphasises the need for clear allocation of activities to the most appropriate role in the trial monitoring plan and good communication amongst trial teams to perform central monitoring reliably and efficiently. The survey also showed the wide variety of documents in which the requirements and processes for central monitoring are described and also highlighted how they differ across trials units. Both the risk of the trial and staff funding available were cited as the main factors dictating the number of central monitoring activities undertaken. These two issues are probably being conflated as higher risk trials attract more staff funding. Central data monitoring can improve overall financial efficiency by reducing the amount of source data verification required whilst still maintaining trial safety and integrity, but appropriate staff need to be costed in to any grant applications. [14]

To the best of our knowledge, this is the first survey of trials units to ask about all aspects of central data monitoring. However previous work has looked at which metrics to use to assess site performance (activity 11 in our list in the methods section). One study concluded prioritising site level metrics that cover all the top 8 check activities that we suggest. [11] Another study highlighted just 4 checks that cover some of our top 8 activities. [12] Both studies also additionally suggested checking adverse event rates which we did not include in the list of activities that we presented in our survey as we considered this to be the annual safety report mandated by regulatory authorities for IMP studies and a pharmacovigilance activity and/or included in an IDMC report.

The additional comments provided by survey respondents suggest an appetite in the community for guidance on the topic of central data monitoring, which may increase its use. [15] Furthermore, we presented the results of this survey to both the UKCRC CTU monitoring and statistics operation groups at their annual meetings in June 2025 and there was unanimous appetite for further guidance. We make the following recommendations based upon the results of this survey:

We intend this to be the starting point for the development of more refined guidance as to when to use which central data monitoring activities. This could be done using expert groups under the auspices of the UKCRC CTU network.

This study has limitations. The response rate of the survey was 63.5% but is in line with another recent survey conducted of UKCRC trials units which had a response rate of 67% [16] Additionally, the data suggest that responses were provided from a wide variety of trials unit sizes covering a range of trial phases. However, it was clear that a lack of consensus about definitions hampered the responses to some of our questions. The survey was conducted solely in the UKCRC registered CTU network. Whilst this is UK based, we hope that the results and recommendations could be relevant to academic trials in all countries. Our survey did not ask how CTUs implement central monitoring activities e.g. frequency (recurrently or just once) of each activity and which is a manual or automated process.

5. Conclusion

Our survey shows the variety in the central monitoring activities conducted by UKCRC trials units and the variation as to who is conducting these activities, whether they are done for some or all trials, and how they are documented. We make a number of recommendations that we hope will improve the consistency and quality of central monitoring in academic trials. Further work on providing more detailed guidance is planned.

CRediT authorship contribution statement

Chris Hurt: Writing – review & editing, Writing – original draft, Visualization, Supervision, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Angela Casbard:** Writing – review & editing, Visualization, Project administration, Methodology, Investigation. **Lucy Kilburn:** Writing – review & editing, Visualization, Project administration, Methodology, Investigation. **Michelle Jasmine Lazaroo:** Writing – review & editing, Visualization, Project administration, Methodology, Investigation. **Lindsey Masters:** Writing – review & editing, Visualization, Project administration, Methodology, Investigation. **Jo Haviland:** Writing – review & editing, Visualization, Project administration, Methodology, Investigation. **Sharon B. Love:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Project administration, Methodology, Investigation, Conceptualization.

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Declaration of competing interest

All authors have no competing interests.

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Exeter Clinical Trials Unit.
Glasgow Clinical Trials Unit.
Hull Health Trial Unit.
Institute for Cancer Research - Clinical Trials and Statistics Unit.
Imperial Clinical Trials Unit.
Keele Clinical Trials Unit.
King's Clinical Trials Unit.
Leeds Institute of Clinical Trials Research.
Leicester Clinical Trials Unit.
London School of Hygiene & Tropical Medicine Clinical Trials Unit.
MRC Clinical Trials Unit at UCL.
NHS Blood and Transplant Clinical Trials Unit.
Northern Ireland Clinical Trials Unit (NICTU).
North Wales Organisation for Randomised Trials in Health and Social Care (NWORTH).
Nottingham Clinical Trials Unit.
National Perinatal Epidemiology Unit CTU.
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Papworth Trial Unit Collaboration, Cambridge.
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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cct.2026.108282.

Data availability

The survey and the data are available at DOI: https://doi.org/10.5522/04/30464870.

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