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Research Article

Public and patient involvement (PPI) in the design, execution and dissemination of a trial: the BISTRO trial

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Published January 2025
DOI: 10.3310/DOTR5903

Abstract

Background: For people receiving haemodialysis, a balance has to be struck between removing sufficient but not too much fluid during a treatment session and maintaining any remaining kidney function they might have. In the BISTRO trial, this study sought to establish if getting the balance right might be improved by the additional use of bioimpedance, a device that measures body fluid composition to help decide how much fluid to remove during dialysis. Designing and executing this trial, which incorporated complex and repeated trial procedures that would be dependent on participant engagement, presented challenges that demanded effective public and patient involvement.

Objectives: This study aimed to develop an effective public and patient involvement participation model, ensuring that the patient voice was heard by the Trial Management Group, with a Patient Advisory Group undertaking coproduction of all participant-facing documents and communications, including dissemination of the trial results, with the main purpose of maximising participant engagement in the study.

Design: An open-label randomised controlled trial in which 439 participants from 34 centres were allocated for regular assessments of their bodily fluid content with or without the use of bioimpedance measurements.

Interventions: Development of an effective public and patient involvement working model that was represented within the Trial Management Group, contributing to protocol design, selection of bioimpedance device, and coproduction of all participant-facing communications including dissemination of trial findings.

Main outcome measures: Public and patient involvement contribution prior to trial initiation, description of the participant-facing communications, adherence to trial materials, dropout and dissemination of trial findings. Post-trial evaluation by research teams, Patient Advisory Group and co-applicants.

Results: An effective working model was developed which relied on remuneration of the public and patient involvement patient lead and use of social media (e.g. WhatsApp) to maximise inclusivity. The Patient Advisory Group coproduced with the Trial Management Group a series of communication postcards and newsletters and a web page to support the participants and disseminate the trial results that were highly rated by research teams, but not always passed on to trial participants. Participant adherence to the main trial outcomes was excellent (113.6% urine collections obtained). Potentially avoidable dropout was 14.4%, with 3.6% being clearly attributable to inability or unwillingness to comply with the trial procedures. Reflections by the Patient Advisory Group indicated that they felt valued, involved and listened to but anticipated more direct involvement with the trial participants, recommending that barriers to this be addressed during the trial design and set-up.

Limitations: Evaluation of public and patient involvement was retrospective and there was a lack of real-time assessment of the impact of public and patient involvement that might have supported a causative link between public and patient involvement interventions and the successful delivery of the trial.

This article should be referenced as follows:
Coyle D, Ormandy P, Fernandes da Silva N, Davies S. Public and patient involvement (PPI) in the design, execution and dissemination of a trial: the BISTRO trial [published online ahead of print January 29 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/DOTR5903

Conclusions: Public and patient involvement played an important role in the design, delivery and dissemination of the BISTRO trial. Key to this success was the close relationship between the Patient Advisory Group and the Trial Management Group. Given the complexity of the intervention, dropout was reasonably low and did not compromise trial findings, but reasons were not always clear. Prospective gathering of data to capture the impact of public and patient involvement is recommended and direct support for participants facilitated.
Funding: This article presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number 14/216/01.
A plain language summary of this research article is available on the NIHR Journals Library Website https://doi.org/10.3310/DOTR5903.

Background

Public and patient involvement (PPI) in large-scale research study trials is complex and often poorly measured,[1] but available evidence suggests that involving patients from the design through to the execution of a trial improves the quality, uptake and relevance of the research.[2–4] Indeed, PPI is more effective when people with lived experience of the condition being studied are involved as research partners.[3–5] The Guidance for Reporting Involvement of Patients and the Public, Version 2 Short Form checklist was used to guide PPI reporting in this paper, in an attempt to link the outcomes with the PPI activity.[6]

BISTRO – *Bio*Impedance *S*pectroscopy *T*o preserve *R*enal *O*utput – is a UK-wide, multicentre randomised controlled trial designed to establish whether the addition of bioimpedance measurements to a clinical protocol for making fluid assessments in haemodialysis patients adds value to the preservation of native kidney function after the initiation of dialysis treatment.[7,8] Bioimpedance is a medical device that provides information about body composition, estimating the content of fluid in the body tissues, which has the potential to improve clinical decisions when deciding how much fluid should be removed during a dialysis session.[9]

Where possible, patients start dialysis before their own kidney function has completely gone with the expectation that this will continue to decline over time. Observational studies have found that the longer this native residual kidney function (RKF) is maintained, the better the survival and quality of life is for patients.[10–12] One of the reasons why RKF may decline more rapidly is the risk associated with removing fluid on dialysis, which may lead to *volume depletion* (i.e. reduced circulating blood volume and tissue fluid content), which can cause a reduction in kidney perfusion that in turn accelerates the existing kidney damage.[13] To prevent this from happening, a clinical protocol was developed designed to support the assessment of fluid status of people on haemodialysis at regular intervals so that volume depletion during a dialysis session was avoided.[7] The study then undertook a randomised controlled trial to see if using a bioimpedance to provide an 'objective' measure of fluid status in addition to the clinical protocol resulted in better preservation of RKF.[8] Clinicians set a *target weight* on the basis of this assessment and the actual weight of the patient at the end of the dialysis session should be the same.

For several reasons, the involvement of patients with lived experience of dialysis was critical in undertaking the BISTRO trial. Firstly, management of fluid status is an example of a complex intervention[14,15] that requires input from both clinicians (e.g. doctors, nurses and dieticians) and dialysis patients themselves, and indeed the agreed target weight may require some degree of negotiation in what should be a shared decision, not universally adopted by kidney doctors.[16,17] Secondly, the outcome of interest – RKF, despite its apparent importance – is not routinely measured in UK dialysis units,[18] and it requires commitment from patients to collect the volume of urine passed between two dialysis sessions. This was a source of genuine concern for the feasibility of the trial. Thirdly, this was a trial that would involve repeated assessments and interventions over a prolonged period of time – up to 2 years – requiring patients to remain committed to the trial if excessive dropouts were to be avoided. This follow-up included the completion every 3 months of extensive questionnaires to collect patient-reported outcomes. It was clear that patient involvement would be critical to the delivery of a successful trial.

Aims

To address these issues and ensure that there was a strong PPI to support the trial, this study set out aims as follows:

(a) To deliver an effective PPI engagement model, including the use of online and social media platforms, to provide an accessible and effective PPI input.
(b) To use the patient voice to inform the trial managers about aspects of patient burden, for example, poor clinical health, coming to terms emotionally with kidney failure and the restrictions in lifestyle, ensuring these factors are taken into account in the protocol design.

(c) To adopt a collaborative approach to the design and implementation of the study protocol, including co-design of mechanisms to support research nurses in the field and coproduction of all participant-facing documents and communications.
(d) As part of the overall dissemination of results, produce lay versions for study participants and the wider patient population.

The purpose of this publication is to report the approaches that were taken to achieve these goals and examine how they influenced the design and conduct of the trial, including subject recruitment, and report how the trial was disseminated to the participants and the wider kidney failure population. As the trial was briefly interrupted by the COVID-19 pandemic, the impact of this on the trial is also evaluated.

Trial design

BISTRO is a multicentre, open-label randomised controlled trial in which clinicians and patients were blinded to the fluid assessments made by the bioimpedance device in the control arm. The full protocol of the study was published prior to enrolment of participants, and the main outcomes of the study have been published.[7,8] The objectives of the trial were first set out in a specific call by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme following consultation with clinicians and patients in 2014.[19] Patients were involved in the study design from its inception, and the PPI plan was described in the original grant application and protocol. The trial was approved by the UK Integrated Research Application System (Project number 20613) and NHS permissions were obtained from the UK Health Research Authority.

Setting and participants

Thirty-four in-centre main and satellite haemodialysis units across the UK recruited patients within 3 months of commencing in-centre haemodialysis who still had RKF. The only exclusions were planned kidney transplant within 6 months, expected survival < 6 months and an inability to undertake the trial procedures and give written, informed consent. Participants remained in the study for up to 2 years, including after they had stopped having any urine output (the primary study outcome), so that data on the quality of life and symptoms could still be collected.

Interventions to ensure effective public and patient involvement

The National Institute for Health and Care Research defined PPI in 2021 as an active partnership between patients, carers and members of the public with researchers that influences and shapes the research.[3] For this study, PPI influenced study design and execution in the form of recruitment, retention and dissemination strategies, a continuous relationship.[20]

Public and patient involvement input prior to grant funding

The study team worked closely with the NIHR Devices for Dignity (D4D) Healthcare Technology Co-operative Renal Theme to develop the PPI plan. D4D has a strong PPI focus on technology adoption and a patient partnership lead (David Coyle) with lived experience of kidney disease and an understanding of how research works. David Coyle joined the study team as a patient co-investigator and PPI lead. Members of the D4D patient network provided advice during the bid phase and were invited to become members of the BISTRO Patient Advisory Group (PAG) should the study bid be successful.

Development of an effective working model

On commencement of the trial (March 2017), a multitiered PPI structure and virtual PAG group was formed, and an induction meeting held. This included full briefing of the trial objectives and education and training in the use of social media platforms which went on to be the method of working together (i.e. established prior to COVID; see *Figure 1*). The PPI lead was the interface between the PAG and the Trial Management Group (TMG) of which he became a permanent member, remunerated from the grant via D4D. Regular meetings of the PAG were held throughout the study to discuss all aspects of the trial and coproduce communication materials. For example, early in the trial there was a concern that recruitment would be compromised because patients would find urine collections difficult (initially planned as a 48-hour collection between two dialysis treatments) and the PAG was able to advise on alternative collection periods which were subsequently adopted and validated. PAG members were remunerated for face-to-face meetings between £50 and £75 including travel expenses and £20 per hour for online WhatsApp meetings.

The collaborative approach

Throughout the trial there were regular 'open forum meetings', held with the research teams delivering the study, initially held monthly then every 2–3 months as the

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FIGURE 1 The BISTRO trial interfaces. The PAG was fully integrated with other groups involved in delivery the trial.

trial progressed, in which difficulties in delivering the trial were raised and where appropriate, advice from the PAG was sought to solve these.

Dissemination of results

Prior to presenting the results at UK Kidney Week (June 2022) and in particular the National Kidney Federation Patient and Carer Conference (October 2022), the main study findings were presented to the PAG who helped develop the materials for presentation to a patient audience and the final newsletter.

Main outcome measures for public and patient involvement

- Contributions to study design and selection of the bioimpedance device.
- Coproduction of participant support and communication tools: delivery of information to participants using postcards, coproduced newsletters and study website.
- Participant recruitment and adherence to trial procedures measured as the proportion of successful urine collections (as required for the primary and main secondary trial outcome) and completion of patient-reported outcomes.
- Participant dropout from the trial, reasons and time spent in the trial, and dissemination of trial results.
- Reflection by PPI participants.

Results

An overview of the activities of the BISTRO PPI activity and how these fit with the trial timeline is shown in *Figure 2*.

Public and patient involvement input prior to grant funding and protocol development

Co-ordinated by patient co-applicant of the study, this was provided by the D4D Patient Network and a PAG from Leeds Kidney Unit (combined numbers 8), who had specific experience of the use of bioimpedance in clinical care over several years. Their contributions to the final funding submission included: design of the fluid-assessment proforma, in particular ensuring that the process of setting the target weight was shared with patients and capturing this information on the protocol proforma; extending the recruitment period to up to 3 months after dialysis initiation (in recognition that this is a traumatic time for patients, and facing them with the decision to join a trial immediately on starting dialysis would affect the recruitment); advice on study procedures, specifically

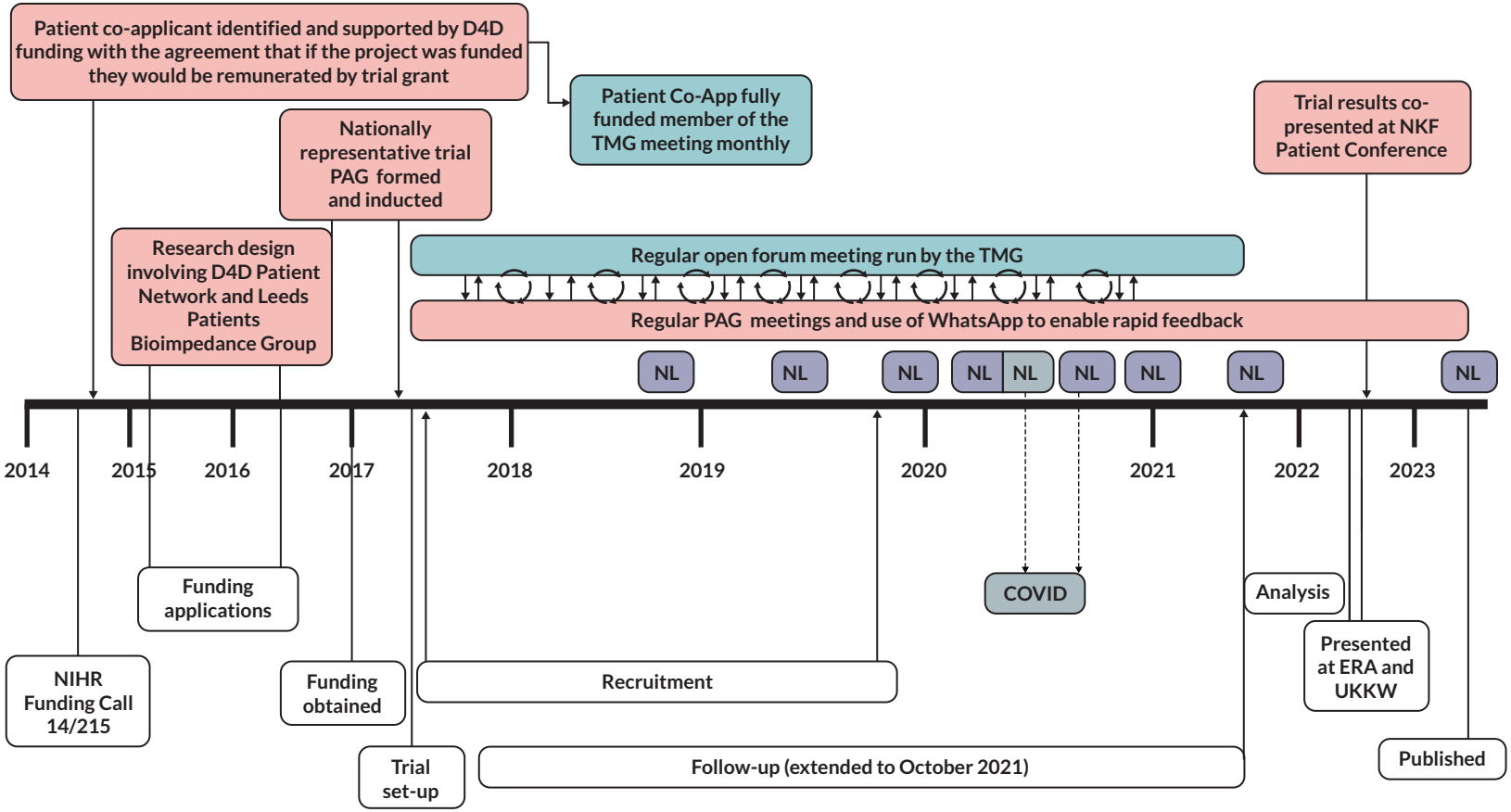

FIGURE 2 An overview of the trial timeline (in black), timing of the PPI activities (in pink) and how these were co-ordinated with those of the TMG (in blue). ERA, European Renal Association; NL, newsletter; UKKW, UK Kidney Week.

urine collections (including the development of three different sets of urine collection instructions designed to capture the needs of different patients under differing circumstances, see *Report Supplementary Material 1*). The group recognised that the burden of participation by patients was high and did consider less frequent collection of patient-reported outcome measures (PROMs). The decision was made not to decrease the frequency but to ask the site research teams at the site initiation visits not to put undue pressure on the participants when asking them to complete these. The funder specified that there must be an open, independent approach to selecting the bioimpedance device. This was undertaken by a panel under the oversight Kidney Research UK, a process that included the patient perspective which was given equal emphasis alongside assessments of accuracy, ease of use, ability to make the desired measurements, cost and underpinning evidence (see protocol and main outcomes for more details[7,8]).

Formation of the Patient Advisory Group and production of participant support and communication tools

Once the trial was funded, the BISTRO PAG was formed and through the use of social media a core group of five members remained active throughout the study, with an additional three members joining more briefly. PAG members were drawn from around the UK, included representation of ethnic minorities and connected through WhatsApp social media, which became the preferred communication vehicle for the group. Social media training was offered to each PAG member to enhance confidence and skills. The PAG and the TMG coproduced all patient-facing materials, facilitated by the fact that one of the patients is a professional designer. This included specification of layout, colour scheme, type font, use of graphics and images, tone of voice and use of plain English narrative, creating a distinctive 'BISTRO House Style'. This required approval by the ethics committee and a modification of the study protocol (December 2017). Templates submitted to the ethics committee are shown in the *Report Supplementary Material 1*.

Patient leaflets

To show appreciation and maintain study participation, a series of A5 postcard-style leaflets were created for dissemination by the research nurses (*Figure 3*). These included:

- *Welcome to the* BISTRO *trial!* A personal thank you from the Chief Investigator for joining the study and a pull-out card with name and contact details of the local research nurse.
- *Let's keep the* BISTRO *trial going!* Reassuring participants when urine production ceased and encouraging them to remain in the study.
- *Thank you for your involvement:* issued when participants completed the trial, thanking them for their involvement and signposting where more information can be found on the trial results.
- *Thank you for your involvement (2):* issued when participants leave the study early for example, transplanted or moved to hospital, thanking them for their involvement and explaining what will happen with their data.

Newsletters

These were designed to inform participants of the trial progress and explain how research studies are conducted in an interesting and involving way to aid participant retention. A three-section format was adopted:

- Opening remarks from the study CI highlighting key messages, achievements and milestones, thanking participants for their continued support.
- A series of articles featuring people who worked on the study, what they did and their role in the study, such as the role of the research nurse and the patient contribution.
- A participant section, raising awareness of the support and information available to participants.

These newsletters are shown in full in the *Report Supplementary Material 1*. Two special editions of the newsletter were produced during the COVID pandemic, including during lockdown, at a time when having in-centre dialysis was especially frightening for haemodialysis patients.

Study website

A study website was developed that had content specifically designed by the PAG and TMG for participants (*Figure 4*). This included:

- Introduction to the BISTRO PAG group, with short profile of PAG members, a description of PAG's remit and a contact e-mail address.
- A Frequently Asked Questions section coproduced by TMG project manager and patient co-investigator and validated by PAG.
- Jargon Buster button with links to charity sites with plain English explanations of terms used by clinicians, the NHS and BISTRO study.
- Patient information containing copies of previous newsletters, clinical and NHS information written in plain English.

FIGURE 3 Examples of the BISTRO participant postcards issued on an individual basis at key milestones in the trial.

Evaluation of materials and support

After the trial was complete, a survey was sent to the centres to get their views on the participant and researcher support materials. Only 50% of the centres responded despite several reminders. All reported finding these materials useful, 93% found the website useful, and 75% of them passed on details of the website to patients, and disappointingly 25% of the sites reported not passing on the newsletters to trial participants. This is a useful reminder to other PAGs to check the use of materials during the study, not just at the end. Patients did not offer much spontaneous feedback and processes were not put in place to capture this, but what limited feedback the patients offered was positive. Of those who attended the open forum sessions (and this varied over the course of the trial considerably, but usually 15–20 sites), all found them helpful. The forums provided the TMG with opportunities to modify and provide specific advice with the help of the PAG, and they informed the content of the newsletters and protocol change to urine collections (See *Interdialytic urine collections*). Based on the feedback, the PAG set up a system by which patients could be supported directly by PAG members if they wanted to discuss any concerns they might have with trial participation, and that was General Data Protection Regulation compliant (GDPR) and approved by the sponsors research governance office. However, in reality, this service was not used by local research nurses who were unable to resolve local GDPR issues.

Participant adherence to trial procedures

Interdialytic urine collections

Participants were asked to collect their urine between two of the dialysis sessions (48-hour gap) every 2 months during the study. Prior to trial initiation, this was considered to represent a significant risk. In fact, as it turned out, the collection of urine by patients was less of a problem than failure of procedures in the dialysis unit, for example, missing or losing blood samples that were required to accompany these collections so that clearance of solutes by the kidney could be calculated. Following concerns raised by the PAG and investigator sites at the open forum meetings that some patients could not complete a full 48-hour collection, the kidney function calculator, software developed for the study,

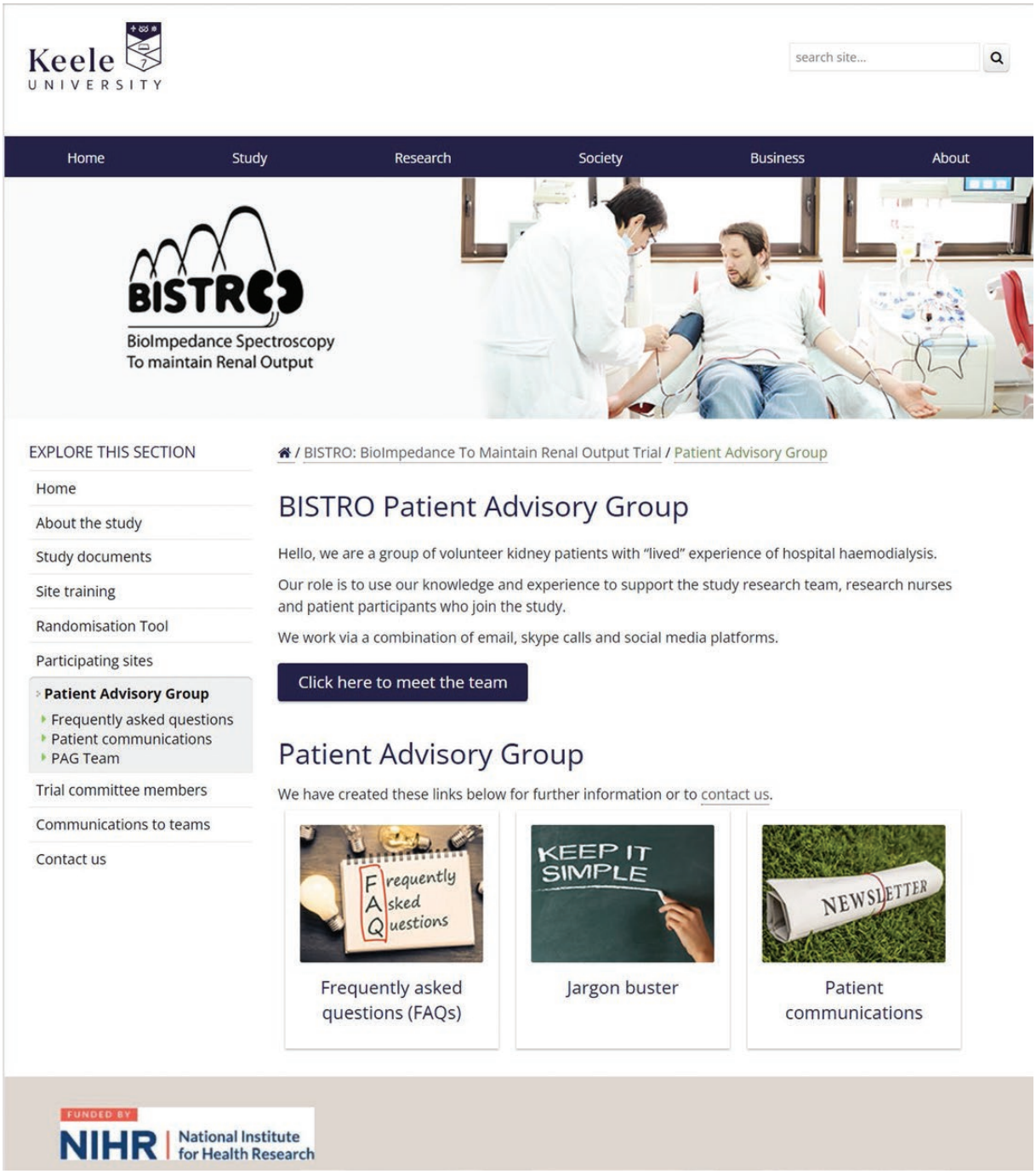

FIGURE 4 The participant page on the BISTRO trial website.

was modified to accommodate shorter, timed collections and subsequently the underlying model assumptions were validated. Of the total number of urine collections that were required (3407), 276 (8.1%) were not feasible because of the moratorium on non-COVID-19-related research during the pandemic. This left 3313 'expected' collections of which 3765 were documented (113.6%), the excess reflecting that sometimes more than one collection was completed by the participants because of problems at the sites, for example, in obtaining adequate contemporary blood samples. Of the completed collections, 708 could not be used to calculate the RKF, the shortfall being due to errors at the site, such as failure to record length of collection and/or administrative problems (i.e. system errors rather than mistakes made by trial participants).

Patient-reported outcomes were the other major trial procedure that required study participants to give their time. These were collected every 3 months, although the length of the questionnaire was greater at months 12 and

24. They were to be filled out even after the participant had reached the primary outcome (anuria). Adherence to this trial procedure was less good, with 88% completing the questionnaires at baseline and 50% at 12 months and 38% at 24 months. Of the 72 participants who reached the primary outcome, 40% continued to report outcomes as requested.

Participant recruitment and dropout

When planning the study, the anticipated proportion of eligible patients who would agree to participate in the study was estimated at 25%. In reality, of 990 patients eligible prior to screening, only 443 declined to consent for the study and the remaining were screening failures. At no stage was patient willingness to be recruited considered to be a limiting factor for trial progression.

However, the trial did see a higher proportion of dropouts than was anticipated when designing the study, 122 (27.7%) in total, as compared with the predicted 52 withdrawals. This included a number of reasons that this study had failed to consider, which were largely beyond the control of participants or research staff. They include recovery of kidney function (10), change of dialysis unit (12), change of dialysis modality (10) and change in dialysis shift which precluded bioimpedance measurements (2) (*Table 1*). Of the remaining 88, a specific reason was not recorded in 29, and in further 18 cases, it was the choice of the patients to withdraw, but their reason for doing so was withheld – as it was their right as stated on the patient information sheet. Sixteen withdrew because they were unwilling or unable to comply with the trial procedures, and the detailed reasons for this are summarised in *Table 1*. Likewise, there were several patients who had to withdraw because of worsening health, loss of capacity or dialysis withdrawal (25 in all). Of patients who withdrew, the median time in the study did not differ when comparing those specifically citing inability to comply with trial procedures with those leaving the study due to health reasons. When a specific reason was not given, then time in the study was about half as long, suggesting that for whatever reason this group is different (see *Table 1*).

On 26 March 2020, COVID-19 pandemic lockdown measures came into force in the UK, including a 3-month moratorium on non-COVID-related research. Two special COVID newsletters (see numbers 4 and 5, *Report Supplementary Material 1*) were developed with the PAG (which remained committed to the trial throughout) so as to keep participants informed of how this would affect the trial, emphasising that it would not be stopped, with the hope of maintaining interest. As can be seen in *Figure 5*, this resulted in a cessation in trial delivery and as a result no dropouts occurred during this period. There was no evidence of an acceleration in trial dropout after trial activity was resumed.

Dissemination of results

Once the trial results became available, these were discussed with the PAG prior to any form of dissemination. Given that the primary intervention of the trial was negative, that is, incorporation of bioimpedance into target weight setting was not associated with better preservation of RKF, the PAG felt strongly that it remained important to present the data highlighting the very clear positive messages that came from the trial as follows: that BISTRO has provided evidence that RKF can be maintained for much longer than previously reported, that clinicians using the proforma were on average very good at estimating the right fluid status, and that there was a strong agreement between clinicians and patients on target weight setting when reported, which was so in the majority of cases. At a dedicated meeting, they approved the slides used at the presentation of the primary analysis to the NKF Annual Patient Conference in the autumn of 2022. Subsequently, the health economic analysis (submitted for publication) demonstrated that there were quality of life and cost-saving benefits of the use of bioimpedance, and these findings are included in the final newsletter, developed with the PAG and disseminated to participating sites (see *Report Supplementary Material 1*).

Feedback from Patient Advisory Group members and trial co-applicants on the BISTRO public and patient involvement processes

Following completion of the trial, a structured discussion was held between the PAG members to obtain their reflections on the process. A number of themes were explored in the recorded conversation and a comprehensive list of comments can be found in the *Report Supplementary Material 1*. A number of themes were explored including prior experience of research, expectations, support, use of social media (of which the PAG had varied experience), whether they felt involved and listened to, what went well, lessons learnt, would they volunteer again and did they derive additional benefits from being involved (see *Table*, supplementary information).

Overall, the PAG members reported a positive experience of being involved. Their expectation was that they would have had more direct involvement with individual study participants and the barriers to enabling this to happen were a source of frustration. They pointed out this should have been anticipated and systems put in place prior to commencing the trial. They were proud of their contribution, felt listened to and that they made a difference to the trial conduct.

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TABLE 1 Reasons given for patients withdrawing from the trial

Category of reason	*N* (%)[a]	Number of days[b] in the study	Comments/examples of detailed reasons
Unable/unwilling to comply with trial procedures	16 (3.6)	352 (2–677)	'Patient finding being part of study too much as well as generally feeling unwell' 'Patient withdrew after MOCA 7 quest. experience' 'Patient non-compliant with dialysis and study procedures' 'Patient finding urine collections and questionnaires too challenging' 'Patient declined to continue'; 'patient non-compliant' 'Patient is unable to complete urine collections due to work commitments so has withdrawn consent' 'Patient has many comorbidities and he "can't be bothered" to complete the questionnaires' 'Patient stated that what is needed for the study is too much for her and she wants to focus on getting better' 'Patient non-compliant with dialysis and study procedures' 'Two urine collections were not tested and therefore no results were available. Patient has withdrawn consent on this basis'; 'recurrent DNA from dialysis'; 'patient very uncompliant'; 'she said had "had enough"' 'Unable to collect urine for CRF as patient is now incontinent' 'Found urine collections too much' 'Patient was too tired to comply with urine collections and was unhappy in general'
Worsening health, loss of capacity or dialysis withdrawal	25 (5.7)	359 (35–768)	'Unexplained loss of muscle mass' 'Withdrawn from dialysis'; 'non-dialysis-related terminal illness' 'Patient choice – ill health'; 'haemodialysis-related complication' 'Bed-bound, unable to mobilise with multiple issues' 'Decline in physical and mental health – dialysis reduced to 2 × week and transferred to nursing home' 'Patient increasingly frail; multiple hospital admissions'
Participant choice, no specific reason given or not reported	47 (10.7)	155 (3–655)	'Patient refusal to continue'; 'patients' decision' 'Patient has withdrawn for "personal reasons" and didn't want to explain further' 'Did not wish to continue – (when the study was extended)'
Change in dialysis unit	12 (2.7)	129 (20–525)	'Patient relocated to India'; 'transfer HD Unit' 'Patient transferring to another dialysis unit'
Switched dialysis modality	10 (2.3)	200 (47–585)	'The patient moved to home dialysis' 'Patient switched to PD'
Change in dialysis shift	2 (0.01)	At 174 and 677	'Patient has moved to twilight dialysis starting at 7 p.m.; unable to support'
Recovery of kidney function	10 (2.3)	63 (4–350)	

a Percentage expressed as the total number of participants.
b Median (range). MOCA = Montreal Cognitive Assessment (Version 7); DNA = Did not attend; CRF = Clinical Research Form; HD = Haemodialysis; PD = Peritoneal Dialysis
CRF = clinical research form; DNA = did not attend; HD = haemodialysis; MOCA = Montreal cognitive assessment (version 7); PD = peritoneal dialysis.

> *It's obvious to me that BISTRO is the one study where patient involvement has been really utilised and worked well in my opinion. Probably the only study I've seen from end-to-end process where I feel informed and consulted as a PAG.*
>
> *PAG member*

> *I was happy to see this one lived up to expectations. So, my view of what PAG groups were, when I first started my renal journey and getting involved in research my experience was quite warped by the fact that when I joined these groups it became a bit of a tick box exercise so they could say they had one.*
>
> *PAG member*

> *A strong history and background of collaborative working and co-production in the partner organisations meant an environment already existed that was conducive to progressive thinking about how patient involvement and engagement could be implemented.*
>
> *PAG lead*

The TMG members who worked closely with the PAG were asked to give their feedback; they acknowledged the commitment shown by the PPI team and suggested that PPI success was a result of

> *providing appropriate resource to cost in an experienced patient co-applicant into the study as an equal*

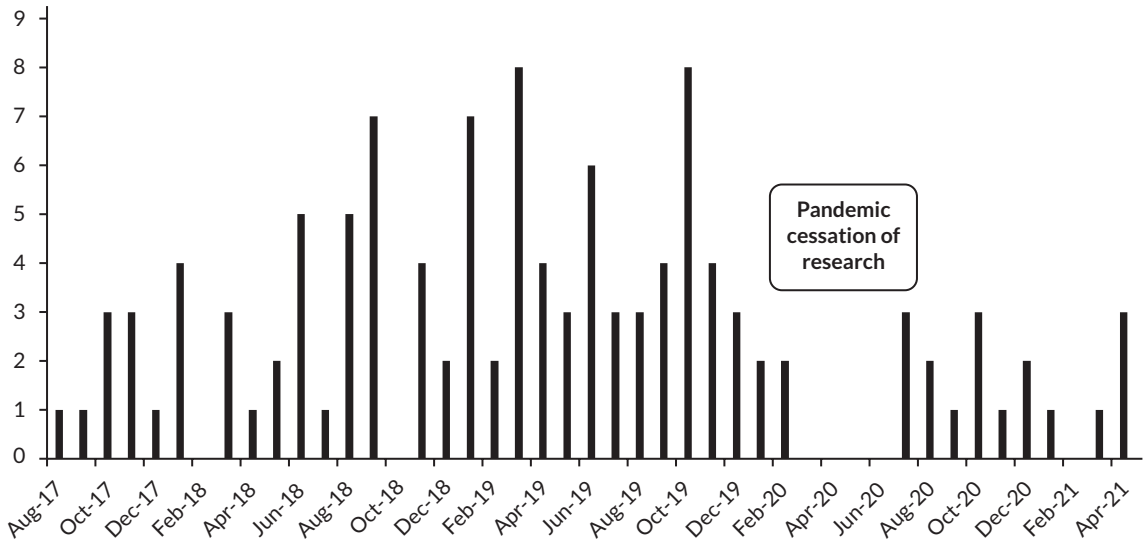

FIGURE 5 Frequency of dropouts (from any cause) during the course of the trial by month.

professional contributor to the project and engaging this person right from the grant writing stage was a Key success factor in the PPI approach.

TMG member

A well-structured and effective recruitment plan that publicised the trial in the right places, using material that contained accurate and accessible information, therefore supporting the CTU to recruit the maximum possible number of participants.

TMG member

Regular communication with participants and support groups about the progress of the trial and challenges, which helped study participant retention.

TMG member

The communication plan (e.g., social media) that links participants in the trial has been designed in a way that minimises any potential sources of bias.

TMG member

The patient perspective on the significance of the study results added to an effective dissemination plan.

TMG member

One TMG member summarised that

[T]he PPI BISTRO model, which embedded the patient voice in the TMG and the close working relationship between the PAG and TMG teams meant patient voice reached all elements of the study. The Dissemination plan and platform for the PAG group to communicate with patients via newsletters and study website was well planned and executed.

TMG member

The PPI trial lead (David Coyle) reflected on the support he had received in undertaking his role:

Key to the successful delivery of the PPI strategy was support framework consisting of: Professor Martin Wilkie (Nephrologist Sheffield Teaching hospital) who advised and educated the PPI group about bio-impedance and research methodology with his clear, plain English explanations, Prof Paula Ormandy and her team from Salford University who shared their PPI design knowledge & experience and delivering advice, training and support to PAG on the use of online and social media platforms. To Professor Simon Davies (CI) and Dr Nancey de Silva (study manager) from Keele University for their endorsement of PPI and constant support for all the PPI initiatives we undertook. Finally, to the wonderful PAG group members who grounded the content and plain English wording of all patient facing communications and for the personal and emotional support we gave to each other during COVID.

Discussion

Setting the target weight for intradialytic fluid removal is one of the most common decisions that affect the lives of people on dialysis. It is a complex intervention that has been addressed by very few clinical trials and a strong PPI was crucial in delivering a successful study. Working closely with the TMG, the PAG successfully produced a range of bespoke communications to support patient recruitment and their continued participation in the study, a process that was undoubtedly facilitated by having the PPI lead who had lived experience of dialysis and

expertise in research embedded within the TMG as a paid co-applicant.[3]

The trial design was not a significant barrier to recruitment of participants. The need for an extension of the recruitment period was down to the logistics of setting up the trial in more than 30 centres across the UK, especially challenging as all the sites had to be trained in the trial procedures which were complex. Of the centres involved, only two were routinely assessing RKF before the trial commenced and there was significant concern that participants may have difficulty with adhering to this intervention. In fact, this was not realised, and the collection of urine samples by patients was a major success in the trial delivery, with problems mostly being those related to dialysis unit or local laboratory procedures for whom this procedure was new. Detailed analysis of the reasons for study withdrawal does cite urine collections on several occasions, but these were relatively small in number. Overall, BISTRO showed that routine measurement of RKF is a realistic proposition and acceptable to most patients, particularly when tailored to fit better with people's lives. PPI feedback from study participants captured and championed by the PAG contributed to this success, challenging the TMG to develop methods that facilitated shorter urine collection periods that were more achievable and fit better alongside participant commitments. The BISTRO TMG validated methods that demonstrated it was not essential to collect so many blood samples to accompany the urine collection as usually specified, reducing the number of procedures for study participants and facilitating the future adoption of routine measurement of RKF.[21] These developments were routinely reported by the PPI lead to the Trial Steering Committee who in turn provided valuable advice, supporting the development of an 'app' to assist patients and clinicians in measuring RKF (currently in development).

An important goal of the PPI was to minimise dropout from the trial. Many of the ways in which PPI informed design and conduct of the trial were focused on this, including optimisation of the protocol, reflecting the state of mind of potential participants, the production of personalised postcards, and maintaining interest though frequent newsletters that were aimed at patients (not just the staff). Comparisons between BISTRO and other trials involving complex interventions are difficult to make as people on centre-based haemodialysis are to some extent a captive group of participants which might influence sustained participation. Studies that share some similarities with BISTRO, such as the HED-SMART trial[22] – which tested a self-management intervention on adherence in 235 haemodialysis patients over 9 months – found that 82.1% completed the protocol; the reasons for dropout are not reported. The LUST trial,[23] which tested the use of lung ultrasound to support fluid management in 367 in-centre haemodialysis patients (mean follow-up 1½ years), had 15.4% patient withdrawal. However, this was a very different population with a much higher number of deaths (> 30%), an event that will compete with trial withdrawal; it also required much less in the way of participation of patients in the trial procedures. In this context, the total dropout in BISTRO of 27.7% of participants might seem high, but of these, some of the reasons were positive (e.g. recovery of kidney function) or reflective of decisions and circumstances beyond the study teams' control (e.g. changing treatment modality or dialysis unit). Furthermore, BISTRO was intentionally a pragmatic trial with very few exclusions to participate. Overall, about half of the dropouts were potentially preventable (14.4% of trial population) and in only 16 participants (3.6% of the trial population) were they directly attributable to the trial procedures, although they were able to reserve their right not to give a reason for withdrawing, so this could well be an underestimate. Future trials may benefit from more prescribed PPI interventions to support patients remaining in trials such as BISTRO, although it was made clear to participating sites that participants not certain about the trial could be put in touch with a PAG member to discuss taking part or remaining in the study, but this did not actually happen. BISTRO was disrupted by the COVID-19 pandemic and in line with the suspension of all non-COVID-related research there was no trial activity for 3 months (longer in some sites). No dropouts during COVID were reported precisely because no data were collected. In response to COVID, the PAG felt that there should be extra support given via the newsletters and trial website, and in fact, an extra newsletter was produced (see *Figure 2* and *Report Supplementary Material 1*, Newsletter Issue number 5). No primary outcomes were missed but there is no detailed knowledge of how well the newsletters were delivered to participants during this time, but given the high mortality affecting dialysis units, it seems very likely that this was difficult to achieve.

Completion of PROMs proved more challenging. At the start of the trial, the proportion of questionnaires returned was good but it tailed off over time, something that has been reported recently[24] for longitudinal measures, with one study reporting completion rates as low as 27% at 1 year.[25] The strategy at the start of the trial was to ask research teams not to put undue pressure on trial participants, but what this study failed to do was to capture in real time the rates of PROM completion. This might have led the PAG and TMG to focus on this aspect

of the trial and develop methods to improve completion rates (e.g. giving participants multiple opportunities to complete the form).

Limitations

The main limitation of this account and analysis of PPI in the BISTRO trial is the failure to collect real-time data during the course of the study from participants and dialysis units that might directly link the impact of PPI with its main objectives. This is not an aspect of the trial design that this study fully considered, but in the future embedded evaluation of PPI is essential within trials to clearly link what works for whom, and this should be a priority of researchers, reviewers and funders alike.[4] This study attempted to correct this deficit with a retrospective survey to the participating units, but this was far from ideal. Only 50% responded and given the rapid turnover in research nurses it is hard to be sure how representative the responses are. However, it was disappointing to discover that the newsletters, although well appreciated by the research teams, may not always have reached the trial participants. This shows that the study should have undertaken prospective audit of this activity – or asked the participating site's Research and Development departments to do so. As a result, it cannot be said with certainty to what extent the PPI influenced the experience of participants or how closely they engaged with the various communications and whether this might have influenced the dropout rate. The challenge is how to obtain this information without further adding to the burden of conducting and, more importantly, being in the trial, which could become self-defeating. Ideally, it would be collected automatically, and if recruitment or dropout from the trial had become seriously problematic, then implementation of parallel qualitative research may have become necessary.[20,26] This study largely followed the guidance available on assessing the impact of PPI that was available at the time (e.g. The Public Involvement Impact Assessment Framework Guidance),[27] in that it involved people with lived experience of dialysis at all stages of the process and were clear about the objectives. Indeed, the continuous dialogue between the PAG and TMG was certainly a strength of the study.[1,20] More recent guidance for evaluating PPI in research has been published since the funding for BISTRO was obtained and after publication of the research protocol.[28] Guidance available now would have led this study to collect data prospectively: for example, when participants were given the various communication materials, their feedback could have been captured and documented, rather than relying on informal confirmation at the regular clinics that was held for the investigator teams, albeit that this was generally very positive.[29]

Equality, diversity and inclusion

The diversity of participant in the trial has been reported elsewhere, including the synopsis. Briefly, non-white participation was 21%, which compares with 25% of the incident haemodialysis population. The PAG did include non-white participants and gender representation that was reflective of the dialysis population, but more importantly, the study sought to ensure geographical diversity given that this was a national trial.

Conclusions

This study has reported the approach to PPI in delivering the BISTRO trial. In considering whether the study met the UK Standards for Public Involvement,[30] there were a number of key aspects of the trial in which PPI played an important role. These included the trial design (including the original call from the NIHR), the choice of bioimpedance device, the design of the fluid-assessment proforma – which explicitly included views of the patient, and coproduction of materials designed to support trial participants and of patient-facing dissemination materials. Inclusion of the PPI lead with lived experience of dialysis within the TMG ensured that the team constantly reflected on public involvement.[1] Concerns expressed regarding the participation of patients in the trial procedures were not realised but there was significant dropout and it is not clear as to what impact PPI had on this. Prospective collection of data would have helped in this interpretation of the PPI impact[4,29] and would have helped with the need to better understand the interplay of the context and mechanisms within the trial itself.[1] Within the BISTRO study, the simple continuous dialogue between the TMG and an effective PAG provided clear advantages to the delivery of the complex trial.

Additional information

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This article should be referenced as follows:
Coyle D, Ormandy P, Fernandes da Silva N, Davies S. Public and patient involvement (PPI) in the design, execution and dissemination of a trial: the BISTRO trial [published online ahead of print January 29 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/DOTR5903

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Acknowledgements

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Data-sharing statement

The trial data are available to investigators under the conditions of a data-sharing agreement. This will include group- and individual-level fully anonymised data. Applications should be made to the corresponding author.

Ethics statement

Research ethics approval has been obtained through the UK Integrated Research Application System (Project number 20613, Approved: 12 September 2016) and NHS permissions obtained from the UK Health Research Authority (Approved 4 October 2016).

Information Governance statement

Keele University is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under

This article should be referenced as follows:
Coyle D, Ormandy P, Fernandes da Silva N, Davies S. Public and patient involvement (PPI) in the design, execution and dissemination of a trial: the BISTRO trial [published online ahead of print January 29 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/DOTR5903

the Data Protection legislation, Keele University is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: https://www.keele.ac.uk/legalgovernancecompliance/legalandinformationcompliance/informationgovernance/ or by email dpo@keele.ac.uk.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/DOTR5903.

Primary conflicts of interest: All the authors declared no competing interests.

Department of Health and Social Care disclaimer

This publication presents independent research commissioned by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, MRC, NIHR Coordinating Centre, the Health Technology Assessment programme or the Department of Health and Social Care.

This article was published based on current knowledge at the time and date of publication. NIHR is committed to being inclusive and will continually monitor best practice and guidance in relation to terminology and language to ensure that we remain relevant to our stakeholders.

Study registration

Current Controlled Trials ISCCTN11342007, completed 26 April 2016; NIHR Portfolio number: CPMS31766; Sponsor: Keele University.

Funding

This article presents independent research funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme as award number 14/216/01.

This article reports on one component of the research award BioImpedance Spectroscopy to maintain Renal Output: The BISTRO Trial. Other articles published as part of this thread are: **[LINKS to other articles]**. For more information about this research please view the award page https://www.fundingawards.nihr.ac.uk/award/14/216/01.

About this article

The contractual start date for this research was in June 2016. This article began editorial review in October 2023 and was accepted for publication in September 2024. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The Health Technology Assessment editors and publisher have tried to ensure the accuracy of the authors' article and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

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List of abbreviations

BISTRO	*Bio*Impedance *S*pectroscopy *T*o preserve *R*enal *O*utput
D4D	Devices for Dignity
NIHR	National Institute for Health and Care Research
PAG	Patient Advisory Group
PPI	public and patient involvement
PROMS	patient-reported outcome measures
RKF	residual kidney function
TMG	Trial Management Group

List of supplementary material

Report Supplementary Material 1
BISTRO Trial Newsletters (numbers 1–7)

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/DOTR5903).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by

peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

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