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Reducing the carbon footprint of research: experience from the NightLife study

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Reducing the carbon footprint of research: experience from the NightLife study

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Key words: Carbon footprint, CO_2 emissions, climate change, environmental sustainability, carbon reduction, carbon impact, clinical trials, trial conduct, randomised controlled trial

Abstract

The National Health Service (NHS) has made a commitment to meet targets set by the UK Climate Change Act (2008). Research forms a core part of the NHS. Tackling environmental sustainability challenges is fundamental to reducing the carbon footprint of clinical trials. The National Institute for Health and Care Research (NIHR) provide guidelines and recommendations in their 'Carbon Reduction Strategy' (2019). While climate change and CO_2 emissions are significant issues, research sustainability and support from funding organisations is lacking. Policies and requirements from funding organisations do not mirror the global emphasis on carbon reduction. This communication reports the reduction in the carbon footprint of the NightLife study (ISRCTN87042063), an ongoing multi-centre randomised controlled trial assessing the impact of in-centre nocturnal haemodialysis on quality of life.

Following the declaration of the COVID-19 pandemic outbreak by the World Health Organization (WHO)(1) in March 2020, the UK Government implemented a series of restrictions limiting face-to-face contact and enforcing social distancing. This had a significant impact on the delivery and conduct of health research. Adaptation required resourceful approaches to ensure patient safety and data integrity. Driven by the pandemic, trial management teams, working closely with Principal Investigators (PI) and Trial Management Groups (TMG), played a key role in rapidly adjusting the way clinical trials were designed and undertaken (2). While reductions in the carbon footprint of research activities were not the driving force for the changes required during the pandemic, it was nevertheless a significant and positive outcome. It is important that, where possible, clinical trials use these approaches to ensure carbon reductions and demonstrate an ongoing, responsible commitment to sustainability.

Overview of the NightLife study

The NightLife study is an ongoing randomised controlled trial (RCT) using mixed methods to assess the effectiveness and cost effectiveness of thrice weekly, extended hours, in-centre nocturnal haemodialysis in comparison to standard care. The study is funded by the NIHR (funder reference NIHR127440; REC reference 20/WM/0275), sponsored by the University of Leicester and co-ordinated by the Leicester Clinical Trials Unit (LCTU). It includes three main workstreams: a RCT and internal pilot (workstream 1), an ongoing process evaluation (workstream 2) and a QuinteT Recruitment Intervention (QRI, workstream 3) (3).

Adjustments to the NightLife study delivery in response to the COVID-19 pandemic

All TMG, oversight committee and Patient Participation, Involvement and Engagement (PPIE) meetings were reconfigured and held online. Following UK Government instruction, staff worked from home wherever possible. Recruitment, feasibility assessments, site selection and initiation visits were completed remotely. Queries and outstanding actions resolved via email correspondence.

Qualitative data collection through ethnographic methods and interviews with the research team, dialysis unit staff and individuals with kidney disease were paused and additional data collection techniques were considered to reduce face-to-face contact. This included virtual interviews using common conference software programmes and 'photovoice'; a participatory research method that utilises participant-led photography of the phenomena being researched (in this case, the lived experience of haemodialysis) and allows remote access to experiences and phenomena outside of the immediate field of study (4, 5).

Calculation of carbon footprint

Using a web-based carbon footprint calculator (6, 7), the CO_2 emissions saved by converting to virtual approaches, home working and alternative qualitative data collection techniques were estimated. The calculator took into account: travel modality (including specific features such as vehicle and fuel type), number of people travelling and distance in miles. For air travel, airport codes and flight class were considered. Carbon savings were calculated over the first 18 months of the NightLife study.

What have we learnt?

Carbon reduction

To date, innovative changes to the management of the NightLife study have resulted in a net CO_2 reduction of 136 tonnes. The CO_2 reduction of each workstream is outlined below, with real-life equivalent values detailed in table 1 (6, 7).

Table 1: Table summarising the net CO_2 emission reduction for each workstream and equivalent values (6, 7)

Workstream	Net CO_2 emission reduction	Equivalent value
Workstream 1	12 tonnes	12 trees planted
		6,000 CO_2 fire extinguishers
Workstream 2	20 tonnes	20 trees planted
		20 x 500m^3 hot air balloons
Workstream 3	0.32 tonnes	Approximately half a tree planted
		38,926 smartphones charged
Other benefits	104 tonnes	104 trees planted
		Driving 624,000km in a diesel car
Total	136 tonnes	136 trees planted
		586 return flights from London to Rome

Workstream 1

The net saving for workstream 1 was 12 tonnes (emissions reduced 12 tonnes; emissions used 0). Key savings were related to travel due to online reconfiguration of study meetings, UK-wide site selection visits and SIVs.

Workstream 2

The net saving for workstream 2 was 20 tonnes (total emissions reduced 20 tonnes; emissions used 0.74 tonnes). 50% of participants opted for virtual interviews/'photovoice' in place of traditional ethnographic methods such as face-to-face semi-structured interviews. Subsequently, researcher travel to base hospitals and satellite haemodialysis units was also reduced by 50%. The purchase of a smartphone and two electronic tablets incurred a CO_2 emission of 0.74 tonnes.

Workstream 3

The net saving for workstream 3 was 0.32 tonnes (total emissions saved 0.32; emissions used 0). Researcher travel was reduced by 100% as semi-structured interviews, attendance and observations of, TMG meetings, investigator meetings and SIVs, and provision of feedback regarding recruitment to participating units were completed remotely.

Cost savings

All adaptations to the study organisation, management and design were made within the original study budget and resulted in significant cost savings. This included costs for travel, consumables and researcher time. The underspend was repurposed for researcher training, participant benefit and further opportunities for scientific communication (conference attendance and publication open access dissemination costs) following funder approval.

Other benefits

Additional carbon savings were incurred through virtual attendance at national and international conferences and reduced travel due to home-working, saving 71 tonnes and 33 tonnes respectively across all workstreams. Virtual PPIE activities resulted in geographical and ethnic diversity of group members as individuals joined from various locations across the UK (see figure 1).

The value of this experience

To date, adaptations to the management of the NightLife study have resulted in a net reduction of 136 tonnes of CO_2. Key savings were related to travel due to reconfiguration of study meetings, UK-wide site selection visits and SIVs. Extrapolating these data forward will lead to further increases in savings over the five year study period based on a hybrid approach now that restrictions have been lifted.

The benefits of the NightLife study adaptations go beyond the positive environmental impact. Interestingly, 50% of participants opted for virtual interviews and/or 'photovoice' in place of face-to-face semi-structured interviews, which revealed a holistic insight into the lived experience of haemodialysis. Photovoice allowed the researcher to approach the observational element differently, allowing participants to lead data collection and extend it into their home life; the experience of haemodialysis is a constant life disruption, not limited to the time spent in the clinical environment. This added richness in findings that may not have been achieved with traditional ethnographic methods alone.

All adaptations to the study organisation, management and design were made within the original study budget and resulted in significant cost savings which were repurposed following funder approval. Additional carbon savings were incurred through virtual attendance at national and international conferences and reduced travel due to home-working.

Teleconferencing, video-conferencing and web-based training materials were proven to be effective, with positive working relationships built and maintained. The inaugural investigator meeting was held entirely remotely with more than 40 attendees from the research and nephrology community across the UK. The virtual nature of TMG, Data Safety Monitoring Committee (DSMC) and Trial Steering Committee (TSC) meetings allowed more flexibility for meeting attendance, particularly for committee members based abroad. Indeed, the frequency of these meetings was increased to support the ongoing oversight of the study at no additional cost. However, there is room and need for hybrid approaches to some clinical trial activities, with an acceptance of some CO_2 emissions.

Debates are ongoing about how to incorporate a diverse range of patient voices in the design and delivery of research, highlighting a lack of diversity and inclusion (8). The use of alternative meeting techniques as part of the NightLife study resulted in both geographical and ethnic diversity of the PPIE group, enriching the feedback of the lived experience of kidney disease and haemodialysis.

The findings of our work are supported by a retrospective analysis of 12 pragmatic randomised control trials (9); CO_2 emissions are often generated in areas where steps could be taken to reduce them, such as travel and trial conduct. Resistance to such changes, however, is common. Trial-related travel is often comprised of heavy carbon emissions (particularly where multi-centre studies are concerned). Traditionally this has included travel to SIVs across the UK (by rail and road), as well as investigator meetings which often include international travel (by air), oversight committee meetings, training, onsite monitoring and closedown visits, as well as conference attendance throughout the study's duration. These are travel related activities that most Clinical Trials Units (CTUs) cost for when considering the generation of a trial grant. This is generally done by aligning activities and associated costs with the risk of study. For example, clinical trials of investigational medicinal products (CTIMPs) are deemed higher risk, therefore onsite monitoring of participating sites and pharmacies and resulting travel is a necessity. However, where trials are not bound by such strict legislation, COVID-19 has presented an opportunity to change these practices in a way that reduces the trial's carbon footprint, as reflected by our changes in the NightLife study.

Typically, most CTUs continue to utilise paper Investigator Site Files (ISFs). However, this approach to trial organisation and data management is being challenged and there is widespread recognition from the research community for significant improvements in environmental sustainability within clinical trials (10) . There are many ways to reduce waste with increasing scope to switch from paper to electronic trial management systems (e.g. ISFs) in order to (i) minimise paper usage and storage requirements; (ii) increase document accessibility; (iii) streamline management, monitoring and archiving of multi-centre clinical trials and; (iv) reduce monetary costs. Adshead *et al* suggest that clinical trials with a lower carbon footprint should be prioritised by funders, and just as researchers have to justify to funders the budget for a trial, they should also have to justify the carbon footprint to their stakeholders and demonstrate that it as low as possible (10).

An aid for future trial design and further work

To the authors' knowledge, this is one of few articles to consider and evaluate the environmental improvements that can be made by remote working and virtual adaptations to study designs when establishing a multi-centre RCT in patients with end-stage kidney disease. This work has the potential to act as a guide for other clinical trials to reduce cost and their environmental impact. It also demonstrates how to enhance geographical diversity of research teams (including PPIE members) without excessive cost.

Take home messages

The COVID-19 pandemic presented a need to adapt clinical trials to protect patients, carers, clinical teams and researchers, and accelerated a pre-existing drive to reduce the carbon footprint of research. Study processes needed to evolve rapidly to ensure they were robust and financially lean in the COVID-19 era. The legacy of such changes has been wide ranging but of note, the impact on CO_2 emission reduction experienced in the NightLife study is a benefit that should inspire and drive the reduction of the carbon impact of all clinical trials from now and into the future. We have highlighted opportunities for investigators and trial management teams to implement alternative approaches to designing and conducting clinical trials in order to make them less carbon intensive, more environmentally sustainable and better value for money.

Contributors

The paper was conceived by NQ and JB. SB performed the carbon footprint calculations. NQ, JB, KH, VC, CR, KM, CC, LR and HE reviewed and approved the final draft submitted.

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Competing interests

None declared.

Patient consent

Not required.

Provenance and peer review

Not commissioned; externally peer reviewed.

Data sharing statement

All data relevant to the study are included in the article.

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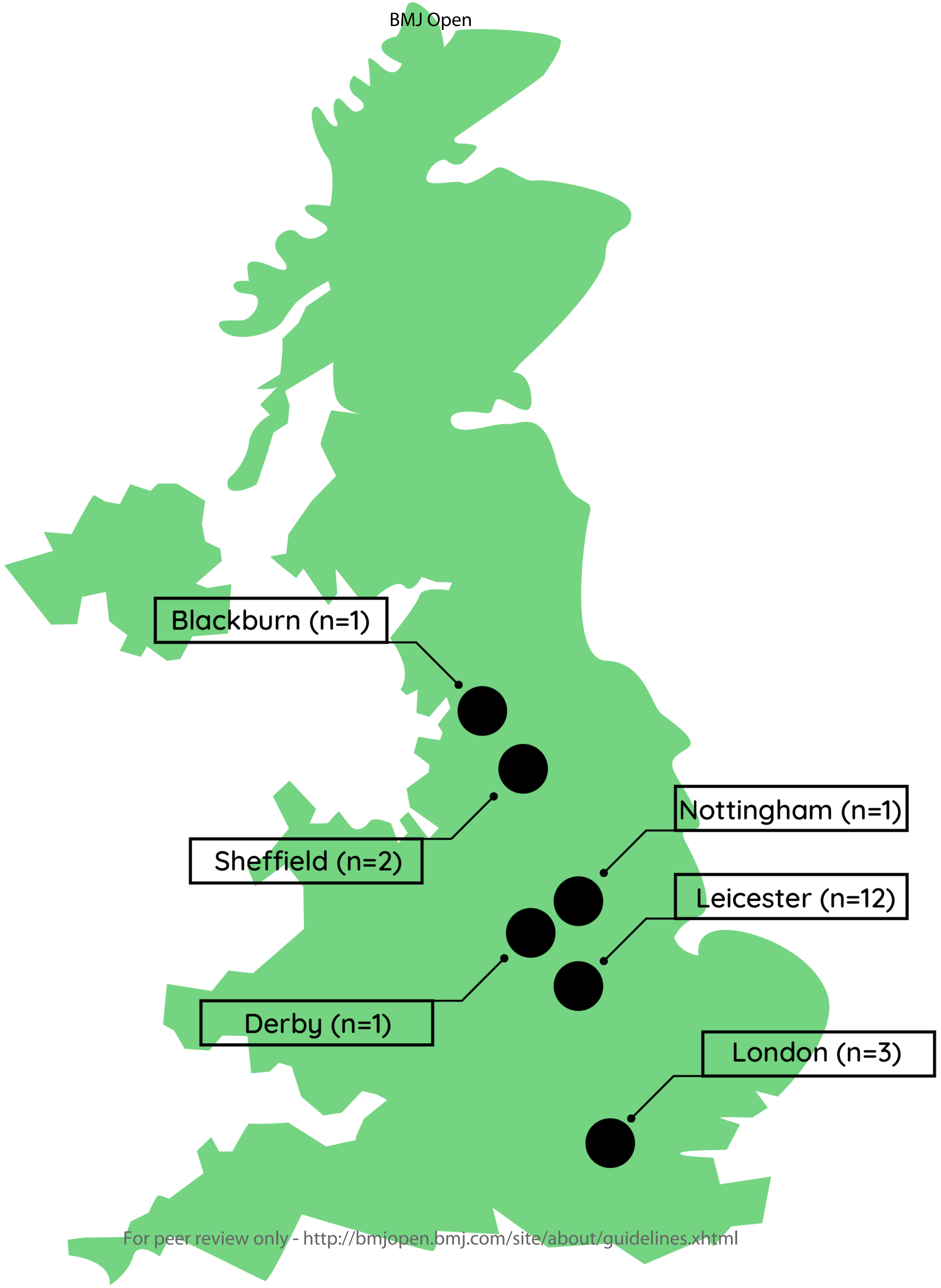
Figures

Figure 1: Map of UK showing geographical locations of PPIE group members

Tables

Table 1: Table summarising the net CO_2 emission reduction for each workstream and equivalent values


Blackburn (n=1)
Sheffield (n=2)
Nottingham (n=1)
Leicester (n=12)
Derby (n=1)
London (n=3)

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Key words: Carbon footprint, CO_2 emissions, climate change, environmental sustainability, carbon reduction, carbon impact, clinical trials, trial conduct, randomised controlled trial

Abstract

As set out in the Climate Change Act (2008), the UK National Health Service (NHS) has made a commitment to halve greenhouse gas emissions by 2025 and reach net-zero by 2050. Research forms a core part of NHS research activity; reducing the carbon footprint of clinical trials is a core element of the National Institute for Health and Care Research (NIHR) 'Carbon Reduction Strategy' (2019). However, support from funding organisations on how to achieve these targets is lacking. This brief communication reports the reduction in the carbon footprint of the NightLife study; an ongoing multi-centre randomised controlled trial assessing the impact of in-centre nocturnal haemodialysis on quality of life. By using remote conferencing software and innovative data collection methods, we demonstrated a total saving of 136 tonnes of carbon dioxide equivalent (CO_2e) over three workstreams during the first 18 months of the study, following grant activation on 1st January 2020. In addition to the environmental impact, there were additional benefits seen to cost as well as increased participant diversity and inclusion. This highlights ways to make trials less carbon intensive, more environmentally sustainable and better value for money.

Introduction

The social distancing restrictions implemented during the COVID-19 pandemic (1) had a significant impact on the delivery and conduct of health research in the UK. Trial management teams played a key role in rapidly adjusting the way clinical trials were designed and undertaken (1). Although reductions in the carbon footprint of research activities were not the driving force for the changes required during the pandemic, it was nevertheless a significant and positive outcome. It is important that, where possible, clinical trials use these approaches to ensure CO_2e savings and demonstrate an ongoing, responsible commitment to sustainability.

Overview of the NightLife study

The NightLife study is an ongoing randomised controlled trial (RCT) using mixed methods to assess the clinical and cost effectiveness of thrice weekly, extended hours, in-centre nocturnal haemodialysis in comparison to standard care (ISRCTN87042063(2); see study website(3)). The study includes three main workstreams: an RCT and internal pilot (workstream 1), an ongoing process evaluation (workstream 2) and a QuinteT Recruitment Intervention (QRI, workstream 3) (4).

Adjustments to the NightLife study delivery in response to the COVID-19 pandemic

Prior to the COVID-19 pandemic, it was planned to conduct all meetings and qualitative study elements in a face-to-face manner by ≥20 collaborators across the UK. This included in-person study launch and oversight committee meetings. Following UK Government instruction, staff worked from home wherever possible. All meetings, including trial management, oversight committee, patient experience and site feasibility were reconfigured and held online. Queries and outstanding actions were resolved via email correspondence. While study processes were conducted remotely, the patient population (adults receiving thrice weekly in-centre haemodialysis) enabled in-person recruitment for workstream 2, however all qualitative data was collected remotely. Workstream 1 and workstream 3 (which were due to run in parallel) were paused for nine months due to the impact of COVID-19 on research delivery.

Qualitative data collection through ethnographic methods (in-person observations and real-time field notes) and interviews with the research team, dialysis unit staff and individuals with kidney disease were paused and additional data collection techniques were considered to reduce face-to-face contact. This included virtual interviews using common conference software programmes and 'photovoice'; a participatory research method that utilises participant-led photography of the phenomena being researched (in this case, the lived experience of haemodialysis) and allows remote access to experiences and phenomena outside of the immediate field of study (5, 6).

Calculation of carbon footprint

The original grant application outlined the total number of planned face-to-face meetings and related costings for the duration of the study. This was used to map the study activities which were reconfigured to virtual methods. Using a web-based carbon footprint calculator (7), the CO_2e saved by converting to virtual approaches, home working and alternative qualitative data collection techniques were estimated. The calculator took into account: travel modality (rail, car, bicycle, air travel), specific features such as vehicle and fuel type, number of people travelling and distance in miles. For air travel, airport codes and flight class were considered. Estimated CO_2e savings were calculated over the first 18 months of the NightLife study.

What have we learnt?

Carbon reduction

To date, innovative changes to the management of the NightLife study have resulted in an estimated net CO_2e saving of 136 tonnes. The saving of each workstream is outlined below, with real-life equivalent values detailed in table 1 (7).

Table 1: Table summarising the net CO_2e saving for each workstream and real-life equivalent values (7)

Workstream	Net CO_2e saving	Original method as per grant application	Adaptations implemented	Real-life equivalent value
Workstream 1	12 tonnes	Face-to-face trial management, oversight committee, patient experience, site feasibility and study launch meetings.	Virtual trial management, oversight committee, patient experience, site feasibility and study launch meetings. Queries and actions resolved via email.	Driving 37,015 km in a car
Workstream 2	20 tonnes	In-person observations; real-time field notes; face-to-face interviews; regular researcher travel to base hospitals and satellite haemodialysis units.	'Photovoice'; virtual interviews; reduced researcher travel to base hospitals and satellite haemodialysis units.	Driving 61,692 km in a car
Workstream 3	0.32 tonnes	Face-to-face interviews; in-person attendance at, and observations of, trial management, investigator and site initiation meetings; face-to-face provision of	Virtual interviews; remote attendance at, and observations of, trial management, investigator and site initiation meetings; virtual provision of feedback to	Driving 987 km in a car

		feedback to 'recruiters' at participating units.	'recruiters' at participating units.	
Other benefits	104 tonnes	In-person conference attendance; onsite working.	Virtual conference attendance; home-working.	Driving 624,000 km in a car
Total	136 tonnes	-	-	Driving 419,503 km in a car

Workstream 1

The net saving for workstream 1 was 12 tonnes of CO_2e (emissions saved 12 tonnes; emissions used 0). Key savings were related to travel due to online reconfiguration of study meetings, UK-wide site visits.

Workstream 2

The net saving for workstream 2 was 20 tonnes of CO_2e (total emissions saved 20 tonnes; emissions used 0.74 tonnes). 50% of participants opted for virtual interviews/'photovoice' in place of traditional ethnographic methods such as face-to-face semi-structured interviews. Subsequently, researcher travel to base hospitals and satellite haemodialysis units was also reduced by 50%. The purchase of a smartphone and two electronic tablets incurred 0.74 tonnes of CO_2e.

Workstream 3

The net saving for workstream 3 was 0.32 tonnes of CO_2e (total emissions saved 0.32; emissions used 0). Researcher travel was reduced by 100% as semi-structured interviews, attendance and observations of, trial management meetings, investigator meetings and site visits, and provision of feedback regarding recruitment to participating units were completed remotely.

Cost savings

All adaptations to the study organisation, management and design were made within the original study budget and resulted in significant cost savings. This included costs for travel, consumables and researcher time. In the first 18 months, the estimated total travel saving was £9,659 across all workstreams, meaning 93% of the travel budget (£10,391) and 24% of the entire non-staff costs (£40,603) were saved. The underspend was repurposed for researcher training, participant benefit and further opportunities for scientific communication (conference attendance and publication open access dissemination costs) following funder approval.

Other benefits

Additional CO_2e savings were incurred through virtual attendance at national and international conferences and reduced travel due to home-working, saving 71 tonnes and 33 tonnes of CO_2e respectively across all workstreams. Virtual patient experience activities resulted in geographical and ethnic diversity of group members as individuals joined from various locations across the UK (see figure 1).

The value of this experience

To date, adaptations to the management of the NightLife study have resulted in a net saving of 136 tonnes of CO_2e. Key savings were related to travel due to reconfiguration of study meetings, UK-wide site visits. Extrapolating these data forward will lead to further increases in savings over the five year study period based on a hybrid approach now that restrictions have been lifted.

The benefits of the NightLife study adaptations go beyond the positive environmental impact. Interestingly, 50% of participants opted for virtual interviews and/or 'photovoice' in place of face-to-face semi-structured interviews, which revealed a holistic insight into the lived experience of haemodialysis. Photovoice allowed the researcher to approach the observational element differently, allowing participants to lead data collection and extend it into their home life; the experience of haemodialysis is a constant life disruption, not limited to the time spent in the clinical environment. This added richness in findings that may not have been achieved with traditional ethnographic methods alone.

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Debates are ongoing about how to incorporate a diverse range of patient voices in the design and delivery of research, highlighting a lack of diversity and inclusion (8). The use of alternative meeting techniques as part of the NightLife study resulted in both geographical and ethnic diversity of the patient experience group, enriching the feedback of the lived experience of kidney disease and haemodialysis.

The findings of our work are supported by a retrospective analysis of 12 pragmatic randomised control trials (9); emissions are often generated in areas where steps could be taken to reduce them, such as travel and trial conduct. Resistance to such changes, however, is common. Trial-related travel is often comprised of heavy emissions (particularly where multi-centre studies are concerned). Traditionally this has included travel to site visits across the UK (by rail and road), as well as investigator meetings which often include international travel (by air), oversight committee meetings, training, onsite monitoring and closedown visits, as well as conference attendance throughout the study's duration. These are travel related activities that most Clinical Trials Units (CTUs) cost for when considering the generation of a trial grant. This is generally done by aligning activities and associated costs with the risk of study. For example, clinical trials of investigational medicinal products (CTIMPs) are deemed higher risk, therefore onsite monitoring of participating sites and pharmacies and resulting travel is a necessity. However, where trials are not bound by such strict legislation, COVID-19 has presented an opportunity to change these practices in a way that reduces the trial's carbon footprint, as reflected by our changes in the NightLife study.

Typically, most CTUs continue to utilise paper Investigator Site Files (ISFs). However, this approach to trial organisation and data management is being challenged and there is widespread recognition from the research community for significant improvements in environmental sustainability within clinical trials (10) . There are many ways to reduce waste with increasing scope to switch from paper to electronic trial management systems (e.g. ISFs) in order to (i) minimise paper usage and storage requirements; (ii) increase document accessibility; (iii) streamline management, monitoring and archiving of multi-centre clinical trials and; (iv) reduce monetary costs. Adshead *et al* suggest that clinical trials with a lower carbon footprint should be prioritised by funders, and just as researchers have to justify to funders the budget for a trial, they should also have to justify the carbon footprint to their stakeholders and demonstrate that it as low as possible (10).

An aid for future trial design and further work

To the authors' knowledge, this is one of few articles to consider and evaluate the environmental improvements that can be made by remote working and virtual adaptations to study designs when establishing multi-centre RCTs. This work has the potential to act as a guide for other clinical trials to reduce cost and their environmental impact. It also demonstrates how to enhance geographical diversity of research teams without excessive cost.

Take home messages

The COVID-19 pandemic presented a need to adapt clinical trials to protect patients, carers, clinical teams and researchers, and accelerated a pre-existing drive to reduce the carbon footprint of research. Study processes needed to evolve rapidly to ensure they were robust and financially lean in the COVID-19 era. The legacy of such changes has been wide ranging but of note, the impact on CO_{2e} saving experienced in the NightLife study is a benefit that should inspire and drive the reduction of the carbon impact of all clinical trials from now and into the future. We have highlighted opportunities for investigators and trial management teams to implement alternative approaches to designing and conducting clinical trials in order to make them less carbon intensive, more environmentally sustainable and better value for money.

Contributors

The paper was conceived by NQ and JB. SB performed the carbon footprint calculations. NQ, JB, KH, VC, CR, KM, CC, LR and HE reviewed and approved the final draft submitted.

Funding

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Competing interests

None declared.

Patient consent

Not required.

Provenance and peer review

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Data availability statement

No additional data available.

References

1. Mitchell EJ, Ahmed K, Breeman S, Cotton S, Constable L, Ferry G, et al. It is unprecedented: trial management during the COVID-19 pandemic and beyond. Trials. 2020;21(1):784.
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Figure 1: Map of UK showing geographical locations of patient experience group members

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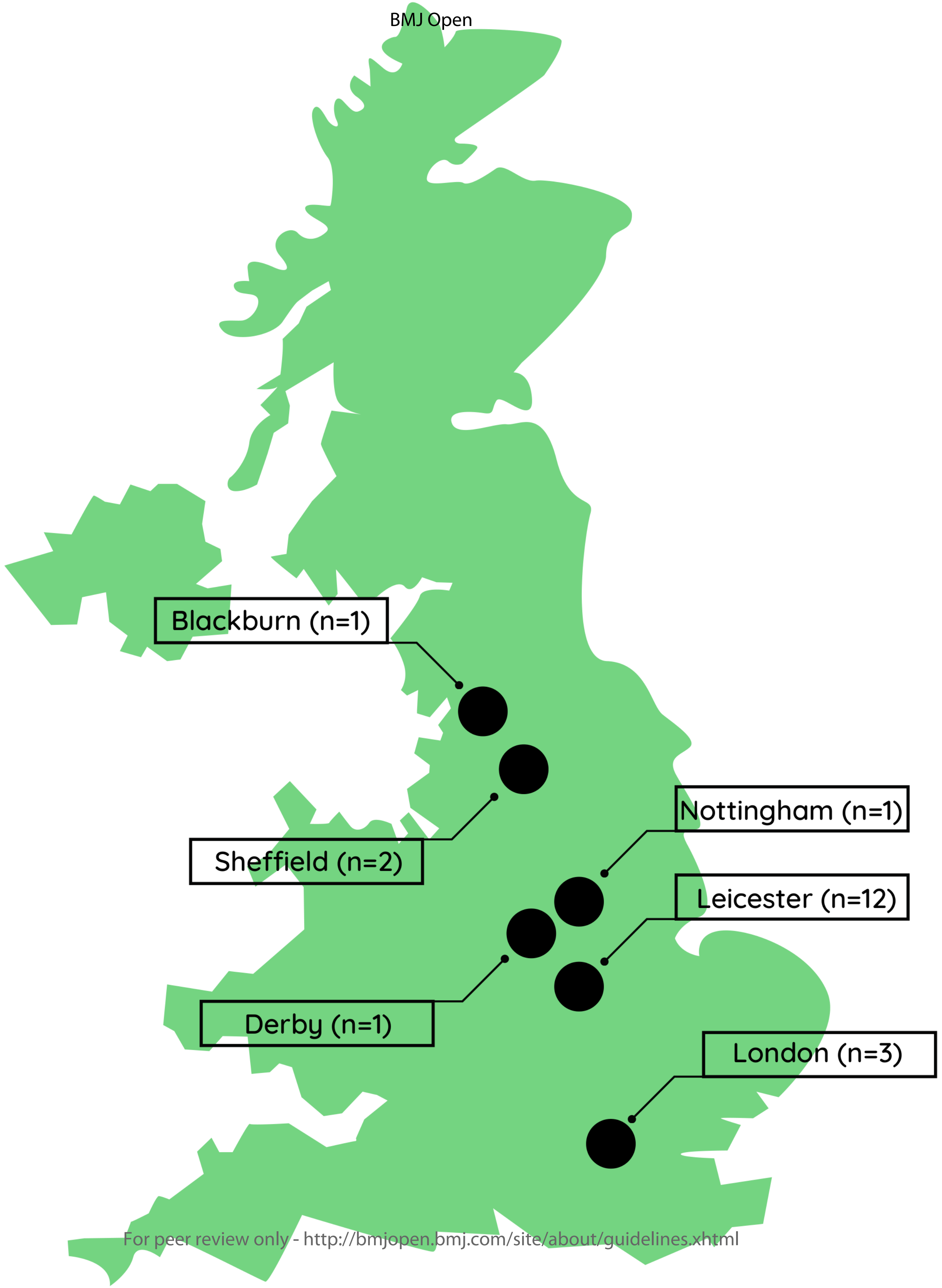
Table 1: Table summarising the net CO_2e saving for each workstream and real-life equivalent values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Reducing the carbon footprint of research: experience from the NightLife study

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Abstract

As set out in the Climate Change Act (2008), the UK National Health Service (NHS) has made a commitment to halve greenhouse gas emissions by 2025 and reach net-zero by 2050. Research forms a core part of NHS activity and reducing the carbon footprint of clinical trials is a core element of the National Institute for Health and Care Research (NIHR) Carbon Reduction Strategy (2019). However, support from funding organisations on how to achieve these targets is lacking. This brief Communication article reports the reduction in the carbon footprint of the NightLife study, an ongoing multicentre randomised controlled trial assessing the impact of in-centre nocturnal haemodialysis on quality of life. By using remote conferencing software and innovative data collection methods, we demonstrated a total saving of 136 tonnes of carbon dioxide equivalent over three workstreams during the first 18 months of the study, following grant activation on Jan 1st, 2020. In addition to the environmental impact, there were additional benefits seen to cost as well as increased participant diversity and inclusion. This work highlights ways in which trials could be made less carbon intensive, more environmentally sustainable and better value for money.

Introduction

The social distancing restrictions implemented during the COVID-19 pandemic had a significant impact on the delivery and conduct of health research in the UK. Trial management teams played a key role in rapidly adjusting the way clinical trials were designed and undertaken (1). Although reductions in the carbon footprint of research activities were not the driving force for the changes required during the pandemic, it was nevertheless a significant and positive outcome. It is important that, where possible, clinical trials use these approaches to ensure carbon dioxide equivalent (CO_2e) savings and demonstrate an ongoing, responsible commitment to sustainability.

Overview of the NightLife study

The NightLife study is an ongoing randomised controlled trial (RCT) using mixed methods to assess the clinical and cost effectiveness of thrice weekly, extended hours, in-centre nocturnal haemodialysis in comparison to standard care (ISRCTN87042063(2); see study website(3)),. The study includes three main workstreams: an RCT and internal pilot (workstream 1), an ongoing process evaluation (workstream 2) and a QuinteT Recruitment Intervention (QRI, workstream 3) (4).

Adjustments to the NightLife study delivery in response to the COVID-19 pandemic

Prior to the COVID-19 pandemic, it was planned to conduct all meetings and qualitative study elements in a face-to-face manner by ≥20 collaborators across the UK. This included in-person study launch and oversight committee meetings. Following UK Government instruction, staff worked from home wherever possible. All meetings, including trial management, oversight committee, patient experience and site feasibility were reconfigured and held online. Queries and outstanding actions were resolved via email correspondence. While study processes were conducted remotely, the patient population (adults receiving thrice weekly in-centre haemodialysis) enabled in-person recruitment for workstream 2, however all qualitative data was collected remotely. Workstream 1 and workstream 3 (which were due to run in parallel) were paused for nine months due to the impact of COVID-19 on research delivery.

Qualitative data collection through ethnographic methods (in-person observations and real-time field notes) and interviews with the research team, dialysis unit staff and individuals with kidney disease were paused and additional data collection techniques were considered to reduce face-to-face contact. This included virtual interviews using common conference software programmes and 'photovoice'; a participatory research method that utilises participant-led photography of the phenomena being researched (in this case, the lived experience of haemodialysis) and allows remote access to experiences and phenomena outside of the immediate field of study (5, 6).

Calculation of carbon footprint

The original grant application outlined the total number of planned face-to-face meetings and related costings for the duration of the study. This was used to map the study activities which were reconfigured to virtual methods. Using a web-based carbon footprint calculator (7), the CO_2e saved by converting to virtual approaches, home working and alternative qualitative data collection techniques were estimated. The calculator took into account: travel modality (rail, car, bicycle, air travel), specific features such as vehicle and fuel type, number of people travelling and distance in miles. For air travel, airport codes and flight class were considered. Estimated CO_2e savings were calculated over the first 18 months of the NightLife study.

What have we learnt?

Carbon reduction

To date, innovative changes to the management of the NightLife study have resulted in an estimated net CO_2e saving of 136 tonnes. The saving of each workstream is outlined below, with real-life equivalent values detailed in table 1 (7).

Table 1. Table summarising the net CO_2e saving for each workstream and equivalent kilometres driven in a car (7)

Workstream	Net CO_2e saving	Original method as per grant application	Adaptations implemented	Equivalent kilometres driven in a standard (non-electric) car
Workstream 1	12 tonnes	Face-to-face trial management, oversight committee, patient experience, site feasibility and study launch meetings.	Virtual trial management, oversight committee, patient experience, site feasibility and study launch meetings. Queries and actions resolved via email.	37,015 km
Workstream 2	20 tonnes	In-person observations; real-time field notes; face-to-face interviews; regular researcher travel to base hospitals and satellite haemodialysis units.	'Photovoice'; virtual interviews; reduced researcher travel to base hospitals and satellite haemodialysis units.	61,692 km
Workstream 3	0.32 tonnes	Face-to-face interviews; in-person attendance at, and observations of, trial management, investigator and site initiation meetings; face-to-face	Virtual interviews; remote attendance at, and observations of, trial management, investigator and site initiation meetings; virtual provision of	987 km

		provision of feedback to 'recruiters' at participating units.	feedback to 'recruiters' at participating units.	
Other benefits	104 tonnes	In-person conference attendance; onsite working.	Virtual conference attendance; home-working.	624,000 km
Total	136 tonnes	-	-	419,503 km

93

94 ***Workstream 1***

95 The net saving for workstream 1 was 12 tonnes of CO_2e (emissions saved 12 tonnes; emissions used
96 0). Key savings were related to travel due to online reconfiguration of study meetings, UK-wide site
97 visits.

98

99 ***Workstream 2***

100 The net saving for workstream 2 was 20 tonnes of CO_2e (total emissions saved 20 tonnes; emissions
101 used 0.74 tonnes). 50% of participants opted for virtual interviews/'photovoice' in place of
102 traditional ethnographic methods such as face-to-face semi-structured interviews. Subsequently,
103 researcher travel to base hospitals and satellite haemodialysis units was also reduced by 50%. The
104 purchase of a smartphone and two electronic tablets incurred 0.74 tonnes of CO_2e.

105

106 ***Workstream 3***

107 The net saving for workstream 3 was 0.32 tonnes of CO_2e (total emissions saved 0.32; emissions
108 used 0). Researcher travel was reduced by 100% as semi-structured interviews, attendance and
109 observations of, trial management meetings, investigator meetings and site visits, and provision of
110 feedback regarding recruitment to participating units were completed remotely.

111

Cost savings

All adaptations to the study organisation, management and design were made within the original study budget and resulted in significant cost savings. This included costs for travel, consumables and researcher time. In the first 18 months, the estimated total travel saving was £9,659 across all workstreams, meaning 93% of the travel budget (£10,391) and 24% of the entire non-staff costs (£40,603) were saved. The underspend was repurposed for researcher training, participant benefit and further opportunities for scientific communication (conference attendance and publication open access dissemination costs) following funder approval.

Other benefits

Additional CO_2e savings were incurred through virtual attendance at national and international conferences and reduced travel due to home-working, saving 71 tonnes and 33 tonnes of CO_2e respectively across all workstreams. Virtual patient experience activities resulted in geographical and ethnic diversity of group members as individuals joined from various locations across the UK (see figure 1).

The value of this experience

To date, adaptations to the management of the NightLife study have resulted in a net saving of 136 tonnes of CO_2e. Key savings were related to travel due to reconfiguration of study meetings, UK-wide site visits. Extrapolating these data forward will lead to further increases in savings over the five-year study period based on a hybrid approach now that restrictions have been lifted.

The benefits of the NightLife study adaptations go beyond the positive environmental impact. Interestingly, 50% of participants opted for virtual interviews and/or 'photovoice' in place of face-to-face semi-structured interviews, which revealed a holistic insight into the lived experience of haemodialysis. Photovoice allowed the researcher to approach the observational element differently, allowing participants to lead data collection and extend it into their home life; the experience of haemodialysis is a constant life disruption, not limited to the time spent in the clinical environment. This added richness in findings that may not have been achieved with traditional ethnographic methods alone.

All adaptations to the study organisation, management and design were made within the original study budget and resulted in significant cost savings which were repurposed following funder approval. Additional CO_2e savings were incurred through virtual attendance at national and international conferences and reduced travel due to home-working.

Teleconferencing, video-conferencing and web-based training materials were found to be effective. The inaugural investigator meeting was held entirely remotely with more than 40 attendees from the research and nephrology community across the UK. The virtual nature of trial management and oversight committee meetings allowed more flexibility for meeting attendance, particularly for committee members based abroad. Indeed, the frequency of these meetings was increased to support the ongoing oversight of the study at no additional cost. However, an objective assessment of the impact of remote working and study activities is beyond the scope of this work. As we move away from the COVID-19 lockdown era, there is room and need for hybrid approaches to various clinical trial activities, with an acceptance of some CO_2e emissions.

Debates are ongoing about how to incorporate a diverse range of patient voices in the design and delivery of research, highlighting a lack of diversity and inclusion (8). The use of alternative meeting techniques as part of the NightLife study resulted in both geographical and ethnic diversity of the patient experience group, enriching the feedback of the lived experience of kidney disease and haemodialysis.

The findings of our work are supported by a retrospective analysis of 12 pragmatic randomised control trials (9); emissions are often generated in areas where steps could be taken to reduce them, such as travel and trial conduct. Resistance to such changes, however, is common. Trial-related travel is often comprised of heavy emissions (particularly where multicentre studies are concerned). Traditionally this has included travel to site visits across the UK (by rail and road), as well as investigator meetings which often include international travel (by air), oversight committee meetings, training, onsite monitoring and closedown visits, as well as conference attendance throughout the study's duration. These are travel related activities that most Clinical Trials Units (CTUs) cost for when considering the generation of a trial grant. This is generally done by aligning activities and associated costs with the risk of study. For example, clinical trials of investigational medicinal products (CTIMPs) are deemed higher risk, therefore onsite monitoring of participating sites and pharmacies and resulting travel is a necessity. However, where trials are not bound by such strict legislation, COVID-19 has presented an opportunity to change these practices in a way that reduces the trial's carbon footprint, as reflected by our changes in the NightLife study.

Typically, most CTUs continue to utilise paper Investigator Site Files (ISFs). However, this approach to trial organisation and data management is being challenged and there is widespread recognition from the research community for significant improvements in environmental sustainability within clinical trials (10) . There are many ways to reduce waste with increasing scope to switch from paper to electronic trial management systems (e.g. ISFs) in order to (i) minimise paper usage and storage requirements; (ii) increase document accessibility; (iii) streamline management, monitoring and archiving of multicentre clinical trials and; (iv) reduce monetary costs. Adshead *et al* suggest that clinical trials with a lower carbon footprint should be prioritised by funders, and just as researchers have to justify to funders the budget for a trial, they should also have to justify the carbon footprint to their stakeholders and demonstrate that it as low as possible (10).

An aid for future trial design and further work

To the authors' knowledge, this is one of few articles to consider and evaluate the environmental improvements that can be made by remote working and virtual adaptations to study designs when establishing multicentre RCTs. This work has the potential to act as a guide for other clinical trials to reduce cost and their environmental impact. It also demonstrates how to enhance geographical diversity of research teams without excessive cost.

Take-home messages

The COVID-19 pandemic presented a need to adapt clinical trials to protect patients, carers, clinical teams and researchers, and accelerated a pre-existing drive to reduce the carbon footprint of research. Study processes needed to evolve rapidly to ensure they were robust and financially lean in the COVID-19 era. The legacy of such changes has been wide ranging but of note, the impact on CO_2e saving experienced in the NightLife study is a benefit that should inspire and drive the reduction of the carbon impact of all clinical trials from now and into the future. We have highlighted opportunities for investigators and trial management teams to implement alternative approaches to designing and conducting clinical trials in order to make them less carbon intensive, more environmentally sustainable and better value for money.

Contributors

The paper was conceived by NQ and JB. SB performed the carbon footprint calculations. NQ, JB, KH, VC, CR, KM, CC, LR and HE reviewed and approved the final submitted manuscript.

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Competing interests

None declared.

Patient consent

Not required.

Provenance and peer review

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Data availability statement

No additional data available.

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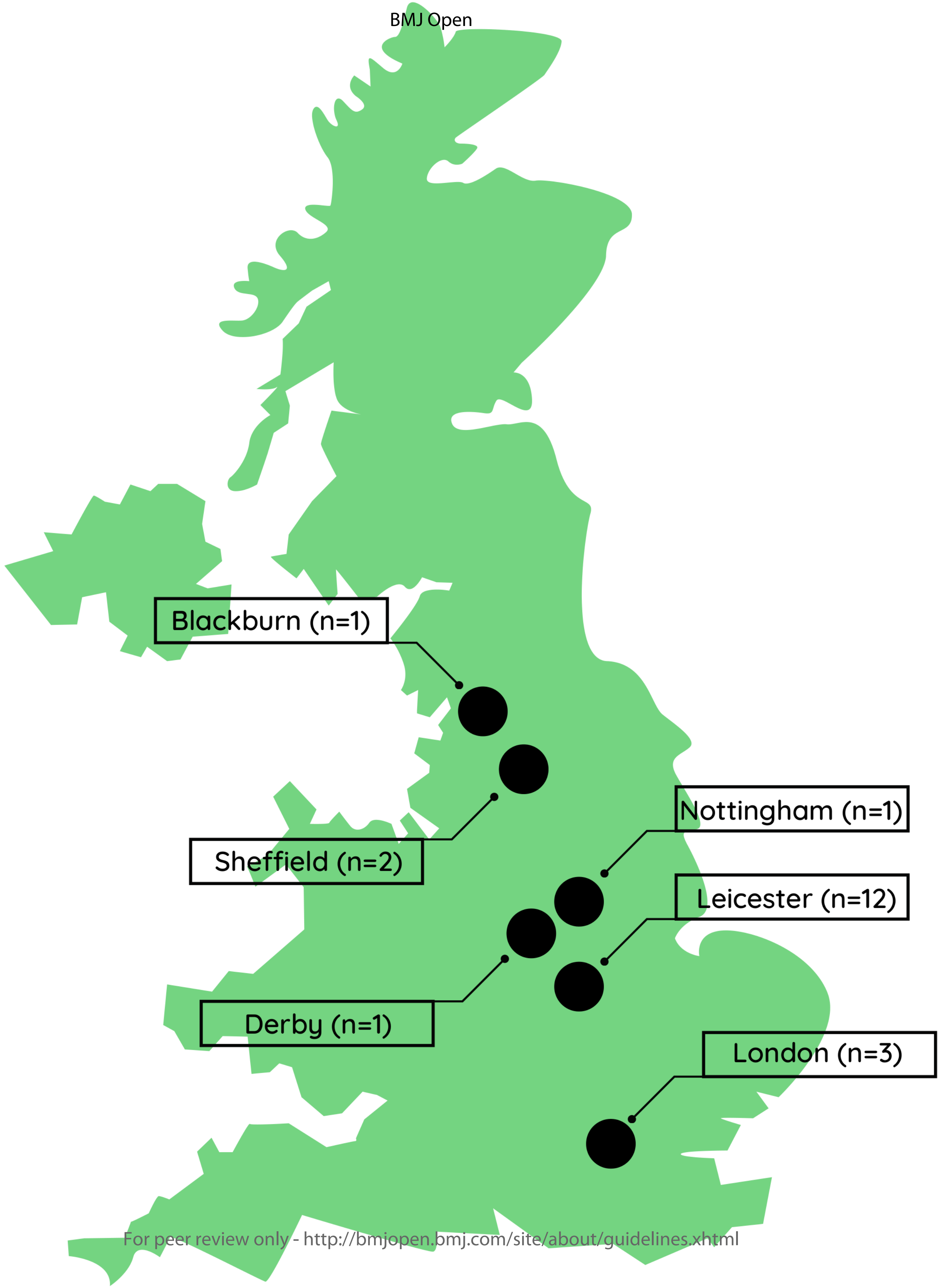
Figure title

Figure 1. Map of the UK showing geographical locations of patient experience group members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