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BMJ Open

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

Journal:	BMJ Open
Manuscript ID	bmjopen-2022-070200.R1
Article Type:	Communication
Date Submitted by the Author:	20-Dec-2022
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Primary Subject Heading :	Renal medicine
Secondary Subject Heading:	Research methods
Keywords:	Nephrology < INTERNAL MEDICINE, NEPHROLOGY, Dialysis < NEPHROLOGY, End stage renal failure < NEPHROLOGY, Quality of Life
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Reducing the carbon footprint of research: experience from the NightLife study Total number of words: 1850 with abstract, 1725 without abstract Niamh Quann¹, Steph Burns², Katherine L Hull^{3,4}, Victoria Cluley³, Carla Richardson¹, Kateryna MacConaill^{3,4}, Carmel Conefrey⁵, Leila Rooshenas⁵, Helen Eborall⁶, James O Burton^{3,4,7} on behalf of the NightLife Study Team ¹Leicester Clinical Trials Unit, College of Life Sciences, University of Leicester, Leicester, UK ²University Hospitals of Leicester NHS Trust, Leicester, UK ³Department of Cardiovascular Sciences, College of Life Sciences, University of Leicester, Leicester, UK ⁴John Walls Renal Unit, Leicester General Hospital, University Hospitals of Leicester NHS Trust, Leicester, UK ⁵Population Health Sciences, Bristol Medical School, University of Bristol, UK ⁶Usher Institute, College of Medicine and Veterinary Medicine, University of Edinburgh ⁷School of Sport, Exercise and Health Sciences, Loughborough University, Loughborough, UK Name, address, e-mail address and telephone number of the corresponding author: Niamh Quann, Leicester Clinical Trials Unit, College of Life Sciences, University of Leicester, University Road, Leicester, LE1 7RH, UK. Email: ng8@le.ac.uk. Key words: Carbon footprint, CO₂ 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 coordinated 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

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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 CO₂ 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 CO₂ 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
	Ò.	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
		0
orkstream 1		

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 CO₂ 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-toface 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 CO₂ 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

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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); CO₂ 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 CO₂ 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.

Page **9** of **12**

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

The NightLife study is funded by the National Institute for Health and Care Research (NIHR) Health m essarily thu Technology Assessment (HTA) programme (funder reference: NIHR127440). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

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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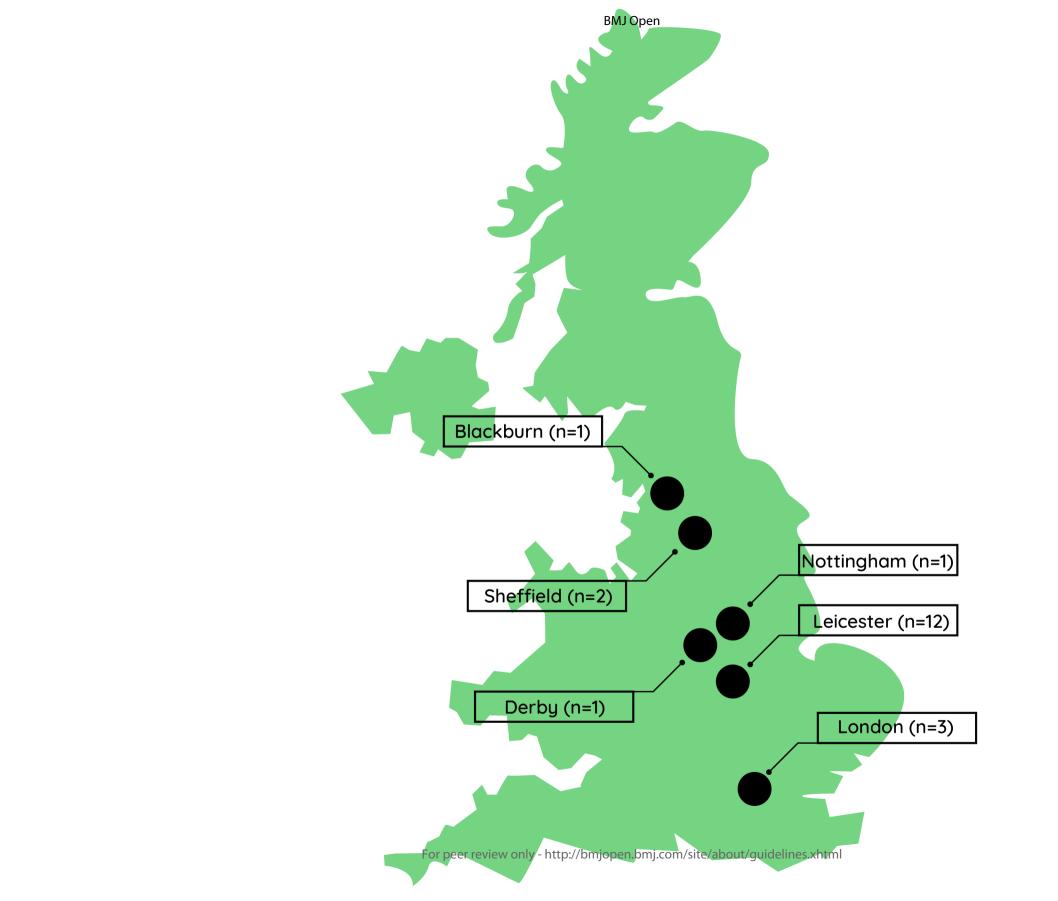
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2 3	
4	Figures
5 6	Figure 1: Map of UK showing geographical locations of PPIE group members
7 8	Tables
9 10 11	Table 1: Table summarising the net CO_2 emission reduction for each workstream and equivalent values
12 13	
14 15	
16 17 18	
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46 47	
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58 59	
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	Page 12 of 12



Page 14 of 13

BMJ Open

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

Journal:	BMJ Open
Manuscript ID	bmjopen-2022-070200.R2
Article Type:	Communication
Date Submitted by the Author:	16-Feb-2023
Complete List of Authors:	Quann, Niamh; University of Leicester College of Life Sciences, Leicester Clinical Trials Unit Burns, Steph; University Hospitals of Leicester NHS Trust Hull, Katherine; University Hospitals of Leicester NHS Trust, John Walls Renal Unit; University of Leicester, Department of Cardiovascular Sciences Cluley, Victoria; University of Leicester Department of Cardiovascular Sciences Richardson, Carla; University of Leicester College of Life Sciences, Leicester Clinical Trials Unit MacConaill, Kateryna; University Hospitals of Leicester NHS Trust, John Walls Renal Unit, Leicester General Hospital Conefrey, Carmel; University of Bristol Medical School Rooshenas, Leila; University of Bristol, School of Social and Community Medicine Eborall, Helen; University of Edinburgh , Usher Institute Burton, James; University of Leicester Department of Cardiovascular Sciences; University Hospitals of Leicester NHS Trust, John Walls Renal Unit, Leicester General Hospital
Primary Subject Heading :	Renal medicine
Secondary Subject Heading:	Research methods
Keywords:	Nephrology < INTERNAL MEDICINE, NEPHROLOGY, Dialysis < NEPHROLOGY, End stage renal failure < NEPHROLOGY, Quality of Life
	<u> </u>

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3 4	1	Reducing the carbon footprint of research: experience from the NightLife study
5 6 7	2	Total number of words: 1982 with abstract, 1793 without abstract
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46 47	20	
48 49	21	Key words: Carbon footprint, CO ₂ emissions, climate change, environmental sustainability, carbon
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24	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.

38 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 CO₂e savings and demonstrate an ongoing, responsible commitment to sustainability.

47 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).

54 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

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and workstream 3 (which were due to run in parallel) were paused for nine months due to theimpact of COVID-19 on research delivery.

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'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).

74 Calculation of carbon footprint

75 The original grant application outlined the total number of planned face-to-face meetings and 76 related costings for the duration of the study. This was used to map the study activities which were 77 reconfigured to virtual methods. Using a web-based carbon footprint calculator (7), the CO₂e saved 78 by converting to virtual approaches, home working and alternative qualitative data collection 79 techniques were estimated. The calculator took into account: travel modality (rail, car, bicycle, air 80 travel), specific features such as vehicle and fuel type, number of people travelling and distance in 81 miles. For air travel, airport codes and flight class were considered. Estimated CO₂e savings were 82 calculated over the first 18 months of the NightLife study.

83

84 What have we learnt?

85 Carbon reduction

To date, innovative changes to the management of the NightLife study have resulted in an estimated
net CO₂e 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 CO₂e saving for each workstream and real-life equivalent values



	Net CO ₂ e saving	Original method as	Adaptations	Real-life
Workstream		per grant	implemented	equivalent value
		application		equivalent value
		Face-to-face trial	Virtual trial	
		management,	management,	
		oversight	oversight	
		committee, patient	committee, patient	Driving 37,015 km
Workstream 1	12 tonnes	experience, site	experience, site	in a car
		feasibility and study	feasibility and study	
		launch meetings.	launch meetings.	
			Queries and actions	
			resolved via email.	
		In-person	'Photovoice'; virtual	
	20 tonnes	observations; real-	interviews; reduced	Driving 61,692 km in a car
		time field notes;	researcher travel to	
		face-to-face	base hospitals and	
Workstream 2		interviews; regular 🦉	satellite	
		researcher travel to	haemodialysis units.	
		base hospitals and	0	
		satellite		
		haemodialysis units.		
		Face-to-face	Virtual interviews;	
		interviews; in-person	remote attendance	
		attendance at, and	at, and observations	
		observations of, trial	of, trial	Driving 987 km in
Workstream 3	0.32 tonnes	management,	management,	a car
		investigator and site	investigator and site	
		initiation meetings;	initiation meetings;	
		face-to-face	virtual provision of	
		provision of	feedback to	

			feedback to	'recruiters' at		
			'recruiters' at	participating units.		
			participating units.			
			In-person	Virtual conference		
	Other benefits	104 tonnes	conference	attendance; home-	Driving 624,000	
			attendance; onsite	working.	km in a car	
			working.			
	Total	136 tonnes	-	_	Driving 419,503	
					km in a car	
92	2					
93	3 Workstream 1					
94	The net saving	for workstream 1 was	12 tonnes of CO ₂ e (emi	issions saved 12 tonnes;	emissions used	
95	5 0). Key savings	were related to trave	due to online reconfigu	uration of study meeting	s, UK-wide site	
96	5 visits.					
97	7					
98	3 Workstream 2					
90						
99	• The net saving f	The net saving for workstream 2 was 20 tonnes of CO_2e (total emissions saved 20 tonnes; emissions				
.00) used 0.74 tonne	used 0.74 tonnes). 50% of participants opted for virtual interviews/'photovoice' in place of				
.01	traditional ethn	traditional ethnographic methods such as face-to-face semi-structured interviews. Subsequently,				
<u>^</u>)					
02	2 researcher trav	researcher travel to base hospitals and satellite haemodialysis units was also reduced by 50%. The				
03	purchase of a smartphone and two electronic tablets incurred 0.74 tonnes of CO_2e .					
104	ł					
105	Workstream 3					
06	5 The net saving 1	for workstream 3 was	0.32 tonnes of CO_2e (to	otal emissions saved 0.32	2; emissions	
107	v used 0). Resear	cher travel was reduc	ed by 100% as semi-stru	uctured interviews, atter	ndance and	
08	3 observations of	, trial management m	neetings, investigator me	eetings and site visits, ar	nd provision of	
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109	reedback regard	aing recruitment to pa	articipating units were c	ompleted remotely.		
110)					

111	Cost savings
	cost satings

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 CO₂e 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 CO₂e 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 CO₂e. 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

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3 4	137	differently, allowing participants to lead data collection and extend it into their home life; the
5 6	138	experience of haemodialysis is a constant life disruption, not limited to the time spent in the clinical
7 8 9	139	environment. This added richness in findings that may not have been achieved with traditional
9 10 11	140	ethnographic methods alone.
12 13	141	
14 15	142	All adaptations to the study organisation, management and design were made within the original
16 17	143	study budget and resulted in significant cost savings which were repurposed following funder
18 19 20	144	approval. Additional CO_2e savings were incurred through virtual attendance at national and
21 22	145	international conferences and reduced travel due to home-working.
23 24	146	
25 26	147	Teleconferencing, video-conferencing and web-based training materials were proven to be effective.
27 28 29	148	The inaugural investigator meeting was held entirely remotely with more than 40 attendees from
30 31	149	the research and nephrology community across the UK. The virtual nature of trial management and
32 33	150	oversight committee meetings allowed more flexibility for meeting attendance, particularly for
34 35	151	committee members based abroad. Indeed, the frequency of these meetings was increased to
36 37 38	152	support the ongoing oversight of the study at no additional cost. However, there is room and need
39 40	153	for hybrid approaches to some clinical trial activities, with an acceptance of some CO_2e .
41 42	154	
43 44	155	Debates are ongoing about how to incorporate a diverse range of patient voices in the design and
45 46 47	156	delivery of research, highlighting a lack of diversity and inclusion (8). The use of alternative meeting
48 49	157	techniques as part of the NightLife study resulted in both geographical and ethnic diversity of the
50 51	158	patient experience group, enriching the feedback of the lived experience of kidney disease and
52 53	159	haemodialysis.
54 55 56	160	
57 58	161	The findings of our work are supported by a retrospective analysis of 12 pragmatic randomised
59 60	162	control trials (9); emissions are often generated in areas where steps could be taken to reduce them,

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such as travel and trial conduct. Resistance to such changes, however, is common. Trial-related 163 164 travel is often comprised of heavy emissions (particularly where multi-centre studies are concerned). 165 Traditionally this has included travel to site visits across the UK (by rail and road), as well as 166 investigator meetings which often include international travel (by air), oversight committee 167 meetings, training, onsite monitoring and closedown visits, as well as conference attendance 168 throughout the study's duration. These are travel related activities that most Clinical Trials Units 169 (CTUs) cost for when considering the generation of a trial grant. This is generally done by aligning 170 activities and associated costs with the risk of study. For example, clinical trials of investigational 171 medicinal products (CTIMPs) are deemed higher risk, therefore onsite monitoring of participating 172 sites and pharmacies and resulting travel is a necessity. However, where trials are not bound by such 173 strict legislation, COVID-19 has presented an opportunity to change these practices in a way that 174 reduces the trial's carbon footprint, as reflected by our changes in the NightLife study. 175 176 Typically, most CTUs continue to utilise paper Investigator Site Files (ISFs). However, this approach to 177 trial organisation and data management is being challenged and there is widespread recognition 178 from the research community for significant improvements in environmental sustainability within 179 clinical trials (10). There are many ways to reduce waste with increasing scope to switch from paper 180 to electronic trial management systems (e.g. ISFs) in order to (i) minimise paper usage and storage 181 requirements; (ii) increase document accessibility; (iii) streamline management, monitoring and 182 archiving of multi-centre clinical trials and; (iv) reduce monetary costs. Adshead et al suggest that 183 clinical trials with a lower carbon footprint should be prioritised by funders, and just as researchers 184 have to justify to funders the budget for a trial, they should also have to justify the carbon footprint 185 to their stakeholders and demonstrate that it as low as possible (10). 186

187 An aid for future trial design and further work

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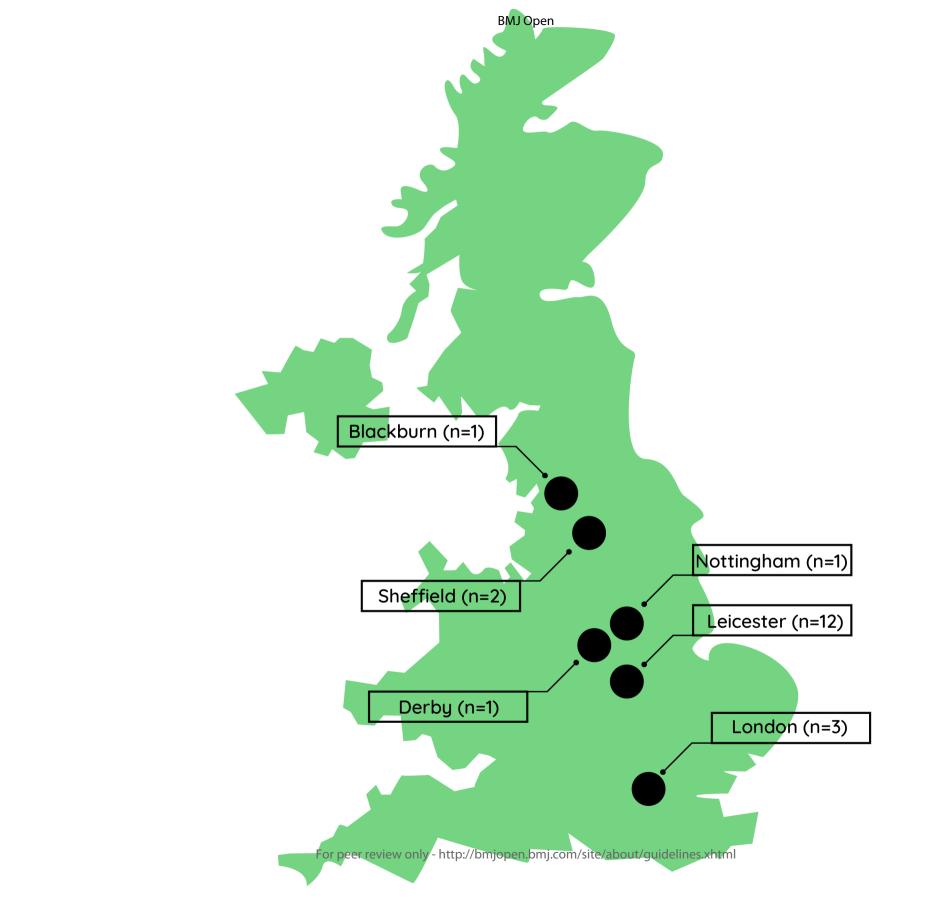
3 4	188	To the authors' knowledge, this is one of few articles to consider and evaluate the environmental
5 6	189	improvements that can be made by remote working and virtual adaptations to study designs when
7 8	190	establishing multi-centre RCTs. This work has the potential to act as a guide for other clinical trials to
9 10 11	191	reduce cost and their environmental impact. It also demonstrates how to enhance geographical
11 12 13	192	diversity of research teams without excessive cost.
14 15	193	
16 17	194	Take home messages
18 19	195	The COVID-19 pandemic presented a need to adapt clinical trials to protect patients, carers, clinical
20 21 22	196	teams and researchers, and accelerated a pre-existing drive to reduce the carbon footprint of
23 24	197	research. Study processes needed to evolve rapidly to ensure they were robust and financially lean
25 26	198	in the COVID-19 era. The legacy of such changes has been wide ranging but of note, the impact on
27 28	199	CO _{2e} saving experienced in the NightLife study is a benefit that should inspire and drive the
29 30 31	200	reduction of the carbon impact of all clinical trials from now and into the future. We have
32 33	201	highlighted opportunities for investigators and trial management teams to implement alternative
34 35	202	approaches to designing and conducting clinical trials in order to make them less carbon intensive,
36 37	203	more environmentally sustainable and better value for money.
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2 3 4	205 206	Contributors
5 6	207	The paper was conceived by NQ and JB. SB performed the carbon footprint calculations. NQ, JB, KH,
7 8 9	208	VC, CR, KM, CC, LR and HE reviewed and approved the final draft submitted.
9 10 11	209	
12 13	210	Funding
14 15	211	The NightLife study is funded by the National Institute for Health and Care Research (NIHR) Health
16 17	212	Technology Assessment (HTA) programme (funder reference: NIHR127440). The views expressed are
18 19 20	213	those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social
21 22	214	Care.
23 24	215	
25 26 27	216	Competing interests
27 28 29	217	None declared.
30 31	218	Care. Competing interests None declared. Patient consent Not required.
32 33	219	Patient consent
34 35	220	Not required.
36 37 38	221	
39 40	222	Provenance and peer review
41 42	223	Not commissioned; externally peer reviewed.
43 44 45	224	
45 46 47	225	Data availability statement
48 49	226	No additional data available.
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3 4	251	Figures
5 6 7	252 253	Figure 1: Map of UK showing geographical locations of patient experience group members
8	254	Tables
7	253 254 255 256	Tables Table 1: Table summarising the net CO2e saving for each workstream and real-life equivalent values





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

Journal:	BMJ Open
Manuscript ID	bmjopen-2022-070200.R3
Article Type:	Communication
Date Submitted by the Author:	03-Mar-2023
Complete List of Authors:	Quann, Niamh; University of Leicester, Leicester Clinical Trials Unit, College of Life Sciences Burns, Steph; University Hospitals of Leicester NHS Trust Hull, Katherine; University of Leicester, Department of Cardiovascular Sciences, College of Life Sciences; University Hospitals of Leicester NHS Trust, John Walls Renal Unit, Leicester General Hospital Cluley, Victoria; University of Nottingham, School of Sociology and Social Policy Richardson, Carla; University of Leicester, Leicester Clinical Trials Unit, College of Life Sciences MacConaill, Kateryna; University Hospitals of Leicester NHS Trust, John Walls Renal Unit, Leicester General Hospital Conefrey, Carmel; University of Bristol Medical School, Bristol Population Health Science Institute Rooshenas, Leila; University of Bristol, Bristol Population Health Science Institute, Bristol Medical School Eborall, Helen; University of Edinburgh , Usher Institute, College of Medicine and Veterinary Medicine Burton, James; University of Leicester, Department of Cardiovascular Sciences, College of Life Sciences; University Hospitals of Leicester NHS Trust, John Walls Renal Unit, Leicester General Hospital
Primary Subject Heading :	Renal medicine
Secondary Subject Heading:	Research methods
Keywords:	Nephrology < INTERNAL MEDICINE, NEPHROLOGY, Dialysis < NEPHROLOGY, End stage renal failure < NEPHROLOGY, Quality of Life

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3 4	1	Reducing the carbon footprint of research: experience from the NightLife study
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48 49	21	
50 51	22	Keywords: Carbon footprint, CO ₂ e emissions, climate change, environmental sustainability, carbon
52 53 54	23	reduction, carbon impact, clinical trials, trial conduct, randomised controlled trial
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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.

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39 Introduction

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> 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 (CO₂e) savings and demonstrate an ongoing, responsible commitment to sustainability.

48 **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).

54

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55 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 56 57 elements in a face-to-face manner by ≥20 collaborators across the UK. This included in-person study 58 launch and oversight committee meetings. Following UK Government instruction, staff worked from 59 home wherever possible. All meetings, including trial management, oversight committee, patient 60 experience and site feasibility were reconfigured and held online. Queries and outstanding actions 61 were resolved via email correspondence. While study processes were conducted remotely, the 62 patient population (adults receiving thrice weekly in-centre haemodialysis) enabled in-person 63 recruitment for workstream 2, however all qualitative data was collected remotely. Workstream 1

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and workstream 3 (which were due to run in parallel) were paused for nine months due to theimpact of COVID-19 on research delivery.

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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-toface 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).

75 Calculation of carbon footprint

76 The original grant application outlined the total number of planned face-to-face meetings and 77 related costings for the duration of the study. This was used to map the study activities which were 78 reconfigured to virtual methods. Using a web-based carbon footprint calculator (7), the CO₂e saved 79 by converting to virtual approaches, home working and alternative qualitative data collection 80 techniques were estimated. The calculator took into account: travel modality (rail, car, bicycle, air 81 travel), specific features such as vehicle and fuel type, number of people travelling and distance in 82 miles. For air travel, airport codes and flight class were considered. Estimated CO₂e savings were 83 calculated over the first 18 months of the NightLife study.

84

85 What have we learnt?

86 Carbon reduction

To date, innovative changes to the management of the NightLife study have resulted in an estimated
net CO₂e 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 CO₂e saving for each workstream and equivalent kilometres

92 driven in a car (7)

	Net CO ₂ e saving	Original method as	Adaptations	Equivalent
Montrature		per grant	implemented	kilometres driven
Workstream		application		in a standard
				(non-electric) car
		Face-to-face trial	Virtual trial	
		management,	management,	
		oversight	oversight	
		committee, patient	committee, patient	
Workstream 1	12 tonnes	experience, site	experience, site	37,015 km
		feasibility and study	feasibility and study	
		launch meetings.	launch meetings.	
			Queries and actions	
			resolved via email.	
		In-person	'Photovoice'; virtual	
	20 tonnes	observations; real-	interviews; reduced	
		time field notes;	researcher travel to	61,692 km
		face-to-face	base hospitals and	
Workstream 2		interviews; regular	satellite	
		researcher travel to	haemodialysis units.	
		base hospitals and	2/	
		satellite		
		haemodialysis units.		
		Face-to-face	Virtual interviews;	
		interviews; in-person	remote attendance	
		attendance at, and	at, and observations	
Workstream 3	0.32 tonnes	observations of, trial	of, trial	987 km
Workstream 5		management,	management,	567 Km
		investigator and site	investigator and site	
		initiation meetings;	initiation meetings;	
		face-to-face	virtual provision of	

Page **5** of **13**

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			provision of	feedback to			
			feedback to	'recruiters' at			
			'recruiters' at	participating units.			
			participating units.				
			In-person	Virtual conference			
	Other benefits	104 tonnes	conference	attendance; home-	624,000 km		
			attendance; onsite	working.			
	-		working.				
	Total	136 tonnes	-	-	419,503 km		
93							
94	Workstream 1						
95	The net saving f	for workstream 1 was	12 tonnes of CO₂e (emis	ssions saved 12 tonnes;	emissions used		
96	0). Key savings	were related to travel	due to online reconfigu	ration of study meeting	s, 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 trave	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	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	observations of, trial management meetings, investigator meetings and site visits, and provision of					
110	feedback regard	ding recruitment to pa	articipating units were co	ompleted 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

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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 CO₂e. 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

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3 4	138	differently, allowing participants to lead data collection and extend it into their home life; the
5 6	139	experience of haemodialysis is a constant life disruption, not limited to the time spent in the clinical
7 8	140	environment. This added richness in findings that may not have been achieved with traditional
9 10 11	141	ethnographic methods alone.
12 13	142	
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16 17	144	study budget and resulted in significant cost savings which were repurposed following funder
18 19 20	145	approval. Additional CO $_2$ e savings were incurred through virtual attendance at national and
20 21 22	146	international conferences and reduced travel due to home-working.
23 24	147	
25 26	148	Teleconferencing, video-conferencing and web-based training materials were found to be effective.
27 28	149	The inaugural investigator meeting was held entirely remotely with more than 40 attendees from
29 30 31	150	the research and nephrology community across the UK. The virtual nature of trial management and
32 33	151	oversight committee meetings allowed more flexibility for meeting attendance, particularly for
34 35	152	committee members based abroad. Indeed, the frequency of these meetings was increased to
36 37	153	support the ongoing oversight of the study at no additional cost. However, an objective assessment
38 39 40	154	of the impact of remote working and study activities is beyond the scope of this work. As we move
41 42	155	away from the COVID-19 lockdown era, there is room and need for hybrid approaches to various
43 44	156	clinical trial activities, with an acceptance of some CO_2e emissions.
45 46	157	
47 48 49	158	Debates are ongoing about how to incorporate a diverse range of patient voices in the design and
50 51	159	delivery of research, highlighting a lack of diversity and inclusion (8). The use of alternative meeting
52 53	160	techniques as part of the NightLife study resulted in both geographical and ethnic diversity of the
54 55	161	patient experience group, enriching the feedback of the lived experience of kidney disease and
56 57 58	162	haemodialysis.
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164	The findings of our work are supported by a retrospective analysis of 12 pragmatic randomised
165	control trials (9); emissions are often generated in areas where steps could be taken to reduce them,
166	such as travel and trial conduct. Resistance to such changes, however, is common. Trial-related
167	travel is often comprised of heavy emissions (particularly where multicentre studies are concerned).
168	Traditionally this has included travel to site visits across the UK (by rail and road), as well as
169	investigator meetings which often include international travel (by air), oversight committee
170	meetings, training, onsite monitoring and closedown visits, as well as conference attendance
171	throughout the study's duration. These are travel related activities that most Clinical Trials Units
172	(CTUs) cost for when considering the generation of a trial grant. This is generally done by aligning
173	activities and associated costs with the risk of study. For example, clinical trials of investigational
174	medicinal products (CTIMPs) are deemed higher risk, therefore onsite monitoring of participating
175	sites and pharmacies and resulting travel is a necessity. However, where trials are not bound by such
176	strict legislation, COVID-19 has presented an opportunity to change these practices in a way that
177	reduces the trial's carbon footprint, as reflected by our changes in the NightLife study.
178	
179	Typically, most CTUs continue to utilise paper Investigator Site Files (ISFs). However, this approach to
180	trial organisation and data management is being challenged and there is widespread recognition
181	from the research community for significant improvements in environmental sustainability within
182	clinical trials (10) . There are many ways to reduce waste with increasing scope to switch from paper
183	to electronic trial management systems (e.g. ISFs) in order to (i) minimise paper usage and storage
184	requirements; (ii) increase document accessibility; (iii) streamline management, monitoring and
185	archiving of multicentre clinical trials and; (iv) reduce monetary costs. Adshead et al suggest that
186	clinical trials with a lower carbon footprint should be prioritised by funders, and just as researchers
187	have to justify to funders the budget for a trial, they should also have to justify the carbon footprint
188	to their stakeholders and demonstrate that it as low as possible (10).

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2 3 4	190	An aid for future trial design and further work
5 6	191	To the authors' knowledge, this is one of few articles to consider and evaluate the environmental
7 8	192	improvements that can be made by remote working and virtual adaptations to study designs when
9 10 11	193	establishing multicentre RCTs. This work has the potential to act as a guide for other clinical trials to
12 13	194	reduce cost and their environmental impact. It also demonstrates how to enhance geographical
14 15	195	diversity of research teams without excessive cost.
16 17	196	
18 19 20	197	Take-home messages
21 22	198	The COVID-19 pandemic presented a need to adapt clinical trials to protect patients, carers, clinical
23 24	199	teams and researchers, and accelerated a pre-existing drive to reduce the carbon footprint of
25 26 27	200	research. Study processes needed to evolve rapidly to ensure they were robust and financially lean
27 28 29	201	in the COVID-19 era. The legacy of such changes has been wide ranging but of note, the impact on
30 31	202	$\rm CO_2e$ saving experienced in the NightLife study is a benefit that should inspire and drive the
32 33	203	reduction of the carbon impact of all clinical trials from now and into the future. We have
34 35	204	highlighted opportunities for investigators and trial management teams to implement alternative
36 37 38	205	approaches to designing and conducting clinical trials in order to make them less carbon intensive,
39 40	206	more environmentally sustainable and better value for money.
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2 3 4	208 209	Contributors
5 6	210	The paper was conceived by NQ and JB. SB performed the carbon footprint calculations. NQ, JB, KH,
7 8	211	VC, CR, KM, CC, LR and HE reviewed and approved the final submitted manuscript.
9 10 11	212	
12 13	213	Funding
14 15	214	The NightLife study is funded by the National Institute for Health and Care Research (NIHR) Health
16 17 18	215	Technology Assessment (HTA) programme (funder reference: NIHR127440). The views expressed are
19 20	216	those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social
21 22	217	Care.
23 24	218	
25 26 27	219	Competing interests
27 28 29	220	None declared.
30 31	221	
32 33	222	Care. Competing interests None declared. Patient consent Not required. Provenance and peer review
34 35 36	223	Not required.
37 38	224	
39 40	225	
41 42	226	Not commissioned; externally peer reviewed.
43 44 45	227	
46 47	228	Data availability statement
48 49	229	No additional data available.
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5 6	255	Figure 1. Map of the UK showing geographical locations of patient experience group members
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