BMJ

RESEARCH

Carbon cost of pragmatic randomised controlled trials: retrospective analysis of sample of trials

Katy Lyle, research fellow,[1] Louise Dent, acting principal research fellow,[1] Sally Bailey, senior programme manager,[1] Lynn Kerridge, chief executive officer,[1] Ian Roberts, professor of epidemiology and public health,[2] Ruairidh Milne, director of strategy and development[1]

[1]NIHR Evaluation, Trials and Studies Coordinating Centre, University of Southampton, Southampton SO16 7NS

[2]London School of Hygiene and Tropical Medicine, London WC1E 7HT

Correspondence to: K Lyle
k.lyle@southamtpon.ac.uk

Cite this as: *BMJ* 2009;339:b4187
doi:10.1136/bmj.b4187

ABSTRACT

Objective To calculate the global warming potential, in carbon dioxide (CO_2) equivalent emissions, from a sample of pragmatic randomised controlled trials.

Design Retrospective analysis.

Data source Internal data held by NIHR Evaluation, Trials and Studies Coordinating Centre.

Studies included All eligible pragmatic randomised controlled trials funded by the NIHR Health Technology Assessment programme during 2002 and 2003.

Main outcome measure CO_2 equivalents for trial activities calculated with standard conversion factors.

Results 12 pragmatic randomised controlled trials involving more than 4800 participants and a wide range of technologies were included. The average CO_2 emission generated by the trials was 78.4 (range 42.1-112.7) tonnes. This is equivalent to that produced in one year by approximately nine people in the United Kingdom. Commuting to work by the trial team generated the most emissions (average 21 (11.5-35.0) tonnes per trial), followed by study centres' fuel use (18 (9.3-32.2) tonnes per trial), trial team related travel (15 (2.0-29.0) tonnes per trial), and participant related travel (13 (0-46.7) tonnes per trial).

Conclusions CO_2 emissions from pragmatic randomised controlled trials are generated in areas where steps could be taken to reduce them. A large proportion of the CO_2 emissions come from travel related to various aspects of a trial. The results of this research are likely to underestimate the total CO_2 emissions associated with the trials studied, because of the sources of information available. Further research is needed to explore the additional CO_2 emissions generated by clinical trials, over and above those generated by routine care. The results from this project will feed into NIHR guidelines that will advise researchers on how to reduce CO_2 emissions.

INTRODUCTION

Global warming is heavily influenced by human activity, is considered to be the biggest global health threat of the 21st century, and is already having impacts on health.[1 2] The Climate Change Act,[3] which outlines the government's commitment to reduce the United Kingdom's carbon output by 80% by 2050, became law in 2008. The National Health Service is committed to reducing its carbon output,[4 5] to which clinical research contributes. This is manifest in the NHS carbon reduction strategy, which sets the NHS a target of reducing its 2007 carbon footprint by 15% by 2015.[5]

Total public funding for clinical research will be increased to £1.7 billion (€1.9bn; $2.8bn) by 2010.[6] With more funding than ever before available for clinical research, considering its environmental impacts is increasingly important. As far as we are aware, only one previous study has attempted to quantify the environmental impact of a clinical trial. That study calculated the carbon dioxide (CO_2) equivalent emissions of the CRASH trial.[7] Total CO_2 emissions for the CRASH trial were estimated at 629 tonnes, or 63 kg per participant. As the CRASH trial was international and recruited more than 10 000 participants, it is unlikely to be representative of pragmatic randomised controlled trials in the UK.

As a leading funder of research in the NHS, the Health Technology Assessment programme of the National Institute for Health Research (NIHR) is interested in the CO_2 emissions from the research it funds. On behalf of the Health Technology Assessment programme, the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) completed a feasibility study to quantify the CO_2 emissions of a randomised controlled trial in the Health Technology Assessment programme. The analysis was then extended to a sample of trials to determine which elements of the trials produce the most emissions. This paper presents the results of that research.

METHODS

All randomised controlled trials that were funded by the Health Technology Assessment programme during 2002 and 2003 were eligible for inclusion in the study. We stipulated that the final report of the project must have been submitted by September 2008 to ensure that the trials were complete before data collection began.

We used information that is routinely held by NETSCC. The main sources of data were the project files and the published monograph, or the final report

Trial elements and activities for which data were collected

Study centres
- Fuel use

Participant related travel
- Participants' travel
- Visitors' travel

Trial team commuting
- Staff commuting to work

Trial team related travel
- Travel for steering group meetings
- Travel for data monitoring committee meetings
- Trial coordinator's travel
- Travel for training
- Travel to conferences
- Travel for Health Technology Assessment monitoring visits
- Other trial meetings/travel

Information technology equipment
- Energy use in manufacture

Trial technologies
- Energy use in manufacture
- Distribution and deliveries

of the project if it had yet to be published. Project files are used for monitoring purposes and contain documents such as grant application forms, six monthly progress reports, extension requests, and minutes of steering group meetings.

Using the methods of the CRASH audit,[7] the NHS footprinting report,[5] and the greenhouse gas reporting protocol developed by the World Business Council,[8] we compiled a list of elements of trials that we believed would generate CO_2 emissions and a list of the activities within each element that would generate the emissions. We searched the data sources for information on these activities and any other activities not included in the list that we believed had a CO_2 value. The box shows the elements and activities of trials for which we collected data.

We used standard conversion factors to convert the data into CO_2 values. The information contained in the data sources was not always sufficient to allow us to do the calculations. In these instances, we made informed assumptions to supplement the information and allow it to be converted into CO_2. The conversion factors and assumptions used are detailed below.

Transport

National travel—We used a conversion factor of 0.25 to calculate the CO_2 emissions per kilometre travelled. This conversion factor comes from the NHS footprinting report and accounts for the direct and indirect emissions from all modes of transport.[5] We used Google maps UK to calculate all distances. We assumed that staff travelled to meetings from their workplace. In the absence of detailed information about travel, we calculated CO_2 from the amount of money spent on journeys. We used a conversion factor of 0.43 kg of CO_2 per pound spent, which we derived from the NHS footprinting report.[5]

International travel—We calculated the CO_2 value of any flights that were made during the trial by using a CO_2 calculator available at the climate care website (www.climatecare.org/roughguides/). The tool calculates the CO_2 emissions from a return flight between any two cities. We assumed that travellers departed from the nearest airport to their place of work and flew directly to the airport of the city to which they were travelling.

Distances

Primary care—We assumed the distance travelled for primary care visits to be 2.4 km. This is the average distance that patients live from their general practice, according to data from an Ipsos-MORI survey for the Department of Health (DH, personal communication, 2008).

Secondary care—We assumed the distance travelled to secondary care visits to be 17.4 km. We took this from a study using hospital episode statistics data, which found that 17.4 km was the median distance that patients travel for elective hospital visits.[9]

Staff commuting—We assumed the distance travelled by staff commuting to work on the trial to be 14 km, which was found to be the average distance commuted to work in the national travel survey 2006.[10] We assumed that trial employees would take 40 days' leave pro rata, including 30 days' annual leave and 10 days' sick leave.[11]

Energy consumption at study centres

We calculated energy consumption at the study centres by using conversion factors available from the Department for Food Environment and Rural Affairs.[12] The amount of energy used differs according to the type of accommodation. Table 1 shows the conversion factors we used for different types of accommodation, which represent the amount of energy used per square metre of office space in a year. We assumed that each employee would be allocated 10 m^2 of office space, which was recommended by the Carbon Trust (Carbon Trust, personal communication, 2008).

Manufacture and delivery of trial technologies

We calculated the energy used in the manufacture and delivery of the trial technologies from the amount of funding allocated for the purchase of the technologies. This method was used in the NHS report.[5] We

Table 1 | Conversion factors for energy use at study centres

Type of accommodation	Total CO_2 (kg/m2/year)
Hospital: teaching and specialist	17.49
General practice/health centre/outpatients	65.79
Primary school	47.52
Acute and maternity	18.64
Office: air conditioned	154.30

Table 2 | Conversion factors for manufacture and delivery of trial technology

Pharmaceuticals	0.24	0.51
Medical instruments/equipment	0.20	0.51

assumed that 95% of the money allocated to trial technologies in the full proposal was used to purchase the technology and that the remaining 5% was spent on delivering the technology. We did not find any evidence on which to base these figures. Table 2 shows the conversion factors used to calculate the emissions for different types of technology.

Information technology equipment

We calculated the CO_2 emissions relating to the production of information technology equipment for the trials from the amount of money spent on the purchase of such equipment during the trial. We used a conversion factor of 0.21, which came from the NHS footprinting report.[5]

Sensitivity analysis

In our analysis, we calculated the total CO_2 emissions of the trials, including those that would have occurred as part of routine practice as well as those solely attributable to the trial, as we could not separate these emissions in our data. One could argue that staff commuting to work should not be included in the analysis, as the researchers would still need to commute to work even if they were working in another field. To account for this, we did a sensitivity analysis to calculate the CO_2 emissions of the trials excluding those generated by staff's commuting.

RESULTS

Twelve randomised controlled trials met the inclusion criteria (fig 1), involving more than 4800 participants and a wide range of technologies, including medical devices, pharmaceuticals, and psychological therapies. The average number of participants was 402, the average cost per participant was approximately £2500, and the average number of study centres was 16.

We calculated the total CO_2 emissions generated by the 12 trials as 941.2 tonnes, which is equivalent to that produced in one year by about 103 people in the UK.[13] Table 3 shows the CO_2 emissions for each trial, which ranged from 42.1 tonnes to 112.7 tonnes.

Our analysis shows that the average amount of CO_2 produced by the trials was 78.4 tonnes, equivalent to that produced in one year by about nine people in the UK.[13] The average amount of CO_2 produced in one year of a trial was 18.1 (range 8.9-30.1) tonnes. On average, the trials produced 306.2 (80.0-883.7) kg of CO_2 per participant, 0.1 (0.07-0.15) kg of CO_2 per pound spent, and 5.6 (3.8-9.5) tonnes of CO_2 per whole time staff member.

Across all of the trials, commuting to work by trial teams accounted for the most CO_2 emissions (26%), followed by use of fuel at study centres (23%) and trial team related travel (19%). Participants' travel accounted for 16% of emissions, trial technologies accounted for 14% of emissions, and information technology equipment accounted for 2% of emissions. The amount of CO_2 that was generated from different trial elements varied between the randomised controlled trials (fig 2).

The CO_2 emissions generated by participant related travel ranged from 0 to 46.7 tonnes (average 12.6 tonnes per trial). This variation can in part be explained by the difference in the number of visits that were required in the different trials, which ranged from none to 36. Additionally, participants' visits took place in a variety of locations in secondary care, primary care, and the community, which corresponds to the use of different distances in our calculations.

The amount of CO_2 produced by trial team related travel ranged from 2.0 to 29.0 tonnes (average 14.7 tonnes per trial), owing to the different activities in the trials and the organisation of the trials. For example, the number of steering group meetings needed for the trials ranged from three to 10, and the number of people attending ranged from four to 13. The number of site visits the trial coordinators made during the trials also varied greatly. The average number of conferences that the trial teams attended ranged from one to 21 (total 78, of which 16 were international).

The CO_2 generated from use of fuel at the study centres ranged from 9.3 to 32.2 tonnes (average 18.1 tonnes per trial), and that generated from the trial team commuting to work ranged from 11.5 to 35.0 tonnes (average 20.9 tonnes per trial). These calculations were based on the number of staff working on the trial, the length of time they were employed on the trial, and the type of accommodation they occupied.

The CO_2 emissions related to the trial technology ranged from 0 to 35.9 tonnes (average 10.7 tonnes per trial), and emissions related to information technology equipment ranged from 0.4 to 2.9 tonnes (average 1.5 tonnes per trial). The CO_2 emissions from these elements are directly proportional to the cost of the technologies.

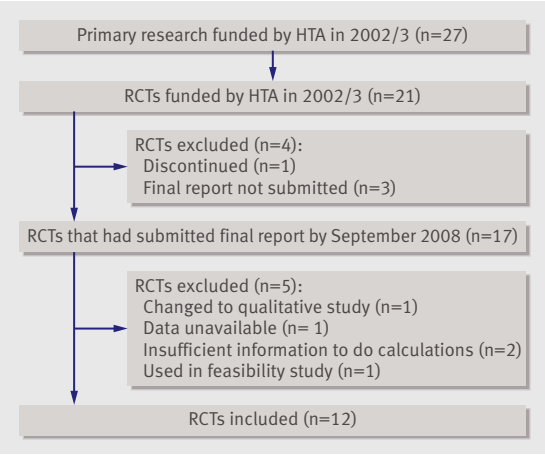

Fig 1 | Flow diagram of included and excluded randomised controlled trial (RCTs). HTA= Health Technology Assessment

Table 3 | CO_2 emissions for each trial included in study

Trial No	No of participants	Cost per participant (to nearest £100)	Total CO_2 (t)	CO_2 per year (t)	CO_2 per participant (kg)	CO_2 per £ spent (kg)	CO_2 per WTE staff (t)
1	201-300	£1900	42.1 (27.9)	8.9 (5.9)	175.5 (116.2)	0.09 (0.06)	4.1 (2.7)
2	>500	£670	46.7 (31.1)	13.4 (8.9)	80.0 (53.2)	0.12 (0.08)	4.2 (2.8)
3	>500	£1200	52.6 (41.1)	12.6 (9.9)	89.9 (70.3)	0.07 (0.06)	6.4 (5.0)
4	>500	£1200	72.0 (52.1)	19.6 (14.2)	130.6 (94.5)	0.11 (0.08)	5.1 (3.7)
5	301-500	£2400	72.9 (52.1)	13.9 (9.9)	211.9 (151.5)	0.09 (0.06)	4.9 (3.5)
6	0-200	£7300	76.0 (48.3)	14.2 (9.1)	883.7 (561.9)	0.12 (0.08)	3.8 (2.4)
7	201-300	£3700	85.3 (56.1)	19.3 (12.7)	387.7 (255.2)	0.11 (0.07)	4.1 (2.7)
8	201-300	£2800	86.2 (73.4)	19.2 (16.3)	397.3 (338.4)	0.14 (0.12)	9.5 (8.1)
9	301-500	£1400	91.2 (77.1)	20.3 (17.1)	201.3 (170.2)	0.15 (0.12)	9.2 (7.8)
10	>500	£1000	101.5 (73.5)	20.7 (14.9)	95.0 (68.7)	0.09 (0.07)	5.1 (3.7)
11	301-500	£2100	102.0 (80.3)	25.0 (19.7)	321.6 (253.2)	0.15 (0.12)	6.6 (5.2)
12	0-200	£4800	112.7 (77.7)	30.1 (20.7)	700.2 (482.7)	0.15 (0.10)	4.5 (3.1)

Values in parentheses relate to sensitivity analysis excluding CO_2 from staff commuting to work.
WTE=whole time equivalent.

Sensitivity analysis

A sensitivity analysis excluding the emissions generated by staff commuting to work found that the average amount of CO_2 produced by the trials was 57.6 (27.9-80.3) tonnes, which is equivalent to that produced in one year by about six people in the UK.[13] On average, the trials produced 13.3 (5.9-20.7) tonnes of CO_2 a year, 218.0 (53.2-561.9) kg of CO_2 per participant, 0.08 (0.06-0.12) kg of CO_2 per pound spent, and 4.2 (2.4-8.1) tonnes of CO_2 per whole time staff member. Table 3 shows the individual results of the sensitivity analysis for each trial.

DISCUSSION

We found that most of the CO_2 emissions produced by pragmatic randomised controlled trials come from trial related travel (including commuting by the trial team and participant and trial team related travel) and use of fuel at the study centres. The trials varied in the proportion of CO_2 generated by different elements of the trial.

Strengths and weaknesses

This is the first study we are aware of that has attempted to calculate the CO_2 emissions from a sample of randomised controlled trials involving a range of technologies and groups of participants. The trials took place in various settings and were based in multiple centres throughout the UK. Perhaps a more accurate way to calculate the CO_2 emissions of a trial would be to prospectively collect information on activities with a CO_2 value for the duration of the trial. Although this might provide a more accurate estimate, it would be very burdensome on time and resources. We therefore believe that, although our analysis may not represent the exact CO_2 emissions produced by these trials, it does provide a good guide as to the level of CO_2 emitted and the trial related activities that generate the most emissions.

The study has some limitations. We did the study retrospectively using data that was not designed for this purpose, which had several implications. Use of project files and reports meant that we attributed CO_2 values to the trial related activities reported, rather than all of the activities executed. Therefore, the results of this research are likely to be an underestimate of the total CO_2 emissions associated with the trials studied. The information we needed to calculate the CO_2 value was not always available, which meant that data had to be supplemented with assumptions. The amount of information contained within the files varied between projects, resulting in a variable number of assumptions being used for each trial.

We excluded two eligible trials from the study, as the information available was insufficient to allow us to do the calculations. We know that these studies involved a lot of travel, and they may have had a larger CO_2 value than the other studies that were included.

Comparisons with other studies

The only previous work in this area was a carbon audit of the CRASH trial,[7] which was estimated to have produced 629 tonnes of CO_2. Our estimate of the average

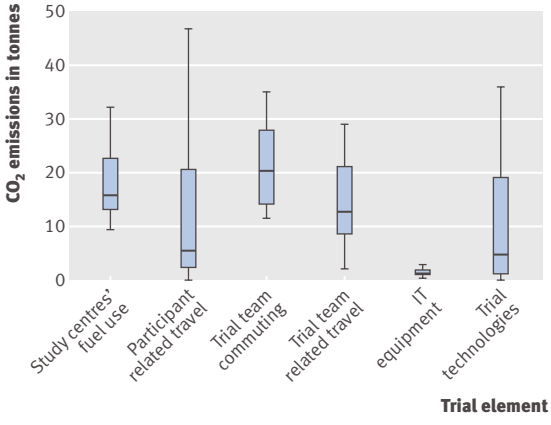

Fig 2 | CO_2 emissions generated by different elements of randomised controlled trials studied. Each box shows the median, with 25th and 75th centiles; vertical lines extend to minimum and maximum values

WHAT IS ALREADY KNOWN ON THIS TOPIC

One previous study examined the CO_2 emissions of a large, international randomised controlled trial

This was not representative of pragmatic trials carried out in the NHS

WHAT THIS STUDY ADDS

CO_2 emissions in randomised controlled trials were mainly generated from areas such as trial related travel, for which steps can be taken to reduce them

The results from this research will feed into NIHR guidelines, which will advise researchers on how to reduce CO_2 emissions from their trials and other research

CO_2 emission per trial was lower at 78 tonnes. However, the CRASH trial included 10 000 participants, whereas the average number of participants per trial in our sample was 402. The average CO_2 emission per participant in our study was 306 kg, whereas the corresponding figure in the CRASH trial was 63 kg, suggesting that per participant the CRASH trial was much less carbon intensive. The CRASH trial was a large simple trial of an acute care intervention. It involved no extra tests, and data collection was minimal and based entirely on the patients' clinical notes. Statistical data monitoring reduced the need for multiple site visits, which would have involved considerable amounts of extra travel. The CRASH trial did not involve any extra travel by participants, whereas most of the trials in our study involved several visits. These factors may account for the difference in CO_2 emissions per participant between our study and the CRASH trial. Nevertheless, the proportions of CO_2 emissions from different trial elements were similar between the two studies. Two of the most CO_2 intensive elements of the CRASH study were use of fuel at the coordinating centre and trial related travel, which is consistent with our findings.

Meaning of study

The government is committed to drastically reducing CO_2 emissions,[3] and all sectors must contribute to this reduction. Clinical research contributes to the NHS's carbon footprint, and the research community should be aware of the CO_2 emissions generated by their trials. This research shows that most CO_2 emissions from randomised controlled trials are generated in areas in which steps could be taken to reduce them. When aiming to minimise CO_2 emissions, trialists and funders should focus particular attention on the emissions generated by participants' travel and travel by the trial team, which can be reduced with simple changes. The number of visits by participants that are required for a trial should be kept to a minimum. Careful consideration of each visit and its purpose may show that the trial could be completed with fewer visits or that several visits could be combined. Alternative methods that do not require face to face encounters, such as telephone interviews, may be available for some assessments of participants. Some of the trials in our study have shown that simple steps can reduce the amount of travelling staff do during the trial and therefore lower CO_2 emissions. For example, some trials held meetings by teleconference to reduce travel; in one study, meetings were held in a location that was within walking distance for people attending. Technologies such as teleconferencing or videoconferencing could be used more and have the potential to reduce the carbon output from trials. This research will feed into NIHR guidelines that will expand on these recommendations and advise researchers on how to reduce CO_2 emissions from their trials and other research.

Unanswered questions and further research

In our analysis, we were unable to separate excess CO_2 emissions from those that occur during routine care. Further work is needed to explore the additional CO_2 emissions generated by randomised controlled trials over and above those generated by routine care. Our analysis included a range of randomised controlled trials, but we did not explore the effect of different research designs on CO_2 output, so further research is needed to explore the CO_2 emissions from other study designs. This study has developed methods to calculate the CO_2 emissions associated with trials. These methods could be expanded on and developed into a tool for use by researchers and funders to allow the carbon cost of a trial to be considered at the planning stage.

We thank the following people for their hard work in collecting data for the project: Syd Anstee, Lisa Douet, Marina Malaffo, Claire Rosten, and Tannaze Tinnati. We also thank David Pencheon for his advice and support.

Contributors: KL and LD were involved in all stages of the study. SB assisted with data collection and was a member of the steering group. LK and IR contributed to the design of the project through their involvement in the steering group. RM was a member of the steering group and was involved in revising the article critically and approving it for publication. All authors critically reviewed and agreed the final draft. KL and LD are the guarantors.

Funding statement: This study was carried out by NIHR Evaluations Trials and Studies Coordinating Centre (NETSCC), which manages the Health Technology Assessment programme. KL, LD, SB, LK, and RM are employed by NETSCC. No additional funding was sought for this research

Competing interests: None declared.

Ethical approval: Not needed.

Data sharing: No additional data available.

1 Costello A, Abbas M, Allen A, Ball S, Bell S, Bellamy R, et al. Managing the health effects of climate change: Lancet and University College London Institute for Global Health Commission. *Lancet* 2009;373:1693-733.

2 Richardson K, Steffen W, Schellnhuber HJ, Alcamo J, Barker T, Kammen DM, et al. Climate change: global risks, challenges and decisions. Copenhagen 2009, 10-12 March. University of Copenhagen, 2009. (Synthesis report.)

3 Department for Food Environment and Rural Affairs. Implementing the Climate Change Act 2008. www.defra.gov.uk/environment/climatechange/uk/legislation/.

4 NHS Sustainable Development Unit. Saving carbon, improving health: NHS carbon reduction strategy for England. NHS Sustainable Development Unit, 2009.

5 Sustainable Development Commission. NHS England carbon emissions: carbon footprinting report. Sustainable Development Commission, 2008.

6 HM Treasury. 2007 pre-budget report and comprehensive spending review: meeting the aspirations of the British people. Stationery Office, 2007. (Available at http://hm-treasury.gov.uk/pbr_csr07_index.htm.)

7 Burnett J, Clarke M, Darbyshire J, Haines A, Roberts I, Shakur H, et al. Towards sustainable clinical trials. *BMJ* 2007;334:671-3.

8 The greenhouse gas protocol: a corporate accounting and reporting standard. World Business Council for Sustainable Development, World Resources Institute, 2004.
9 Proppper C, Damiani M, Leckie G, Dixon J. Distance travelled in the NHS in England for inpatient treatment. Centre for Market and Public Organisation, 2006.
10 Department for Transport. National travel survey: 2006. National Statistics, 2007. (Transport statistics bulletin.) (Available at www.dft.gov.uk/pgr/statistics/datatablespublications/personal/mainresults/nts2006/.)
11 Chartered Institute of Personnel and Development. Absence management: a survey of policy and practice. CIPD, 2008. (Annual survey report 2008.)
12 Department for Food Environment and Rural Affairs. Guidelines to Defra's GHG conversion factors. DEFRA, 2008 (available at www.defra.gov.uk/environment/business/reporting/pdf/ghg-cf-guidelines-annexes2008.pdf).
13 Department of Trade and Industry. Energy—its impact on the environment and society. DTI, 2006.

Accepted: 1 September 2009