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Randomised controlled trial of intravenous antibiotic treatment for cellulitis at home compared with hospital

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Abstract

Objectives To compare the efficacy, safety, and acceptability of treatment with intravenous antibiotics for cellulitis at home and in hospital.
Design Prospective randomised controlled trial.
Setting Christchurch, New Zealand.
Participants 200 patients presenting or referred to the only emergency department in Christchurch who were thought to require intravenous antibiotic treatment for cellulitis and who did not have any contraindications to home care were randomly assigned to receive treatment either at home or in hospital.
Main outcome measures Days to no advancement of cellulitis was the primary outcome measure. Days on intravenous and oral antibiotics, days in hospital or in the home care programme, complications, degree of functioning and pain, and satisfaction with site of care were also recorded.
Results The two treatment groups did not differ significantly for the primary outcome of days to no advancement of cellulitis, with a mean of 1.50 days (SD 0.11) for the group receiving treatment at home and 1.49 days (SD 0.10) for the group receiving treatment in hospital (mean difference 0.01 days, 95% confidence interval −0.3 to 0.28). None of the other outcome measures differed significantly except for patients' satisfaction, which was greater in patients treated at home.
Conclusions Treatment of cellulitis requiring intravenous antibiotics can be safely delivered at home. Patients prefer home treatment, but in this study only about one third of patients presenting at hospital for intravenous treatment of cellulitis were considered suitable for home treatment.

Introduction

Cellulitis, an acute bacterial infection of the skin and subcutaneous tissues, is a common condition that often requires treatment with intravenously administered antibiotics. This treatment is delivered in hospital in most countries, but intravenous treatment at home is used increasingly, particularly in the United States where insurance companies are reluctant to fund more expensive hospital treatment.[1] Many retrospective reports exist on the outcomes of intravenous antibiotic treatment for cellulitis at home, which indicate that this is a safe alternative to inpatient treatment in hospital.[2–6] Only one small prospective randomised trial has been reported that compared treatment at home with treatment in hospital, which included 37 patients with cellulitis.[7] This study concluded that home treatment for conditions such as cellulitis and pneumonia was safe and associated with fewer adverse complications in elderly patients.

In the three years before this study, Christchurch Hospital admitted more than 500 patients each year for inpatient treatment of cellulitis. In the year before this study 1.7% of all adult medical admissions and 0.7% of surgical admissions were patients with the principal diagnosis of cellulitis. In 2001 Pegasus Health, an independent practitioners' association of 230 general practitioners in Christchurch, started a community care programme that delivered medical and nursing care to patients who would otherwise require hospital admission. The advent of this community care service initiated from general practice provided an ideal opportunity to mount a prospective, randomised trial with the objectives of comparing the safety, efficacy, and acceptability of home treatment with hospital treatment of cellulitis requiring intravenous antibiotics. Our hypothesis was that home treatment of cellulitis with intravenous antibiotics was as effective as hospital treatment and more acceptable to patients.

Methods

No clearcut guidelines exist for when cellulitis requires treatment with intravenous antibiotic other than in case oral antibiotics fail. In this study the decision whether intravenous antibiotics were required was left to the attending doctors in the emergency department who assessed the patient.

No validated objective measures seem to exist of when cellulitis is improving or when patients can be switched from intravenous to oral antibiotics. We chose as our primary outcome measure the time to when the cellulitis failed to advance. This outcome has been used in one previous study.[8] Other outcomes recorded included the total numbers of days when patients received intravenous antibiotics and oral antibiotics, and calendar days in hospital or looked after by the home care team. The decision when to switch patients from intravenous to oral antibiotics was left entirely to the attending doctor in the hospital or home. We recorded patients' transfers from home to hospital and the reasons for transfer. We kept a record of all serious complications experienced by patients. We used questionnaires to assess patients' level of functioning and pain as well as satisfaction with their care.

Christchurch Hospital serves the whole metropolitan area of Christchurch (population in 2001 was 318 000), and all acutely referred patients are treated there. We informed all general prac-



An appendix and table showing mean scores on the SF-36 with standard deviations for days 3 and 6 are on bmj.com

titioners in Christchurch and emergency department staff at Christchurch Hospital of this trial before it started.

Protocol

We recruited participants from patients with cellulitis who were attending Christchurch Hospital's emergency department, whether self referred or referred by their general practitioner or a general practitioner after hours. Patients who were considered to require intravenous antibiotic treatment for cellulitis by the emergency doctor and who met the eligibility criteria received an invitation to take part in the trial.

Patients were eligible for the trial if they had clinical signs of cellulitis, were assessed as requiring intravenous antibiotic treatment because of severity of cellulitis or failure of oral antibiotic treatment, were 16 years or older and mentally competent to give informed consent, had a telephone at home and a caregiver nearby, and were currently resident in the Christchurch metropolitan area.

Exclusion criteria were pregnancy; treatment with intravenous antibiotics for cellulitis of the same site in the preceding month; two or more signs of systemic sepsis (temperature >38°C or <36°C, heart rate >90/min, respiratory rate >20/min); and a blood count showing a white cell count above 12×10^9/l or less than 4×10^9/l and more than 0.1×10^9/l immature neutrophils.[9]

Other possible exclusion criteria were signs of severe cellulitis or serious comorbidities such as cellulitis of the face, hands, or over joints; presence of tissue necrosis, severe lymphangitis, blistering, or a very large affected area; comorbidities such as immunosupression, peripheral vascular disease, obesity, alcoholism, or severe diabetes. The more of these relative exclusion criteria were present the more hospital admission was recommended.

Routine blood tests were not required, and the criteria for exclusion were deliberately kept flexible as ultimately the staff in the emergency department often had to make a subjective judgment about the suitability of a patient for entry into the trial. This decision was made independently from the investigators conducting the trial, and junior staff in the emergency department always conferred with consultant staff in making the decision to enrol patients in the trial. Between the hours of 8.00 and 22.00, a member of the study team visited the patient in the emergency department and, after the patient had read the trial information and consent sheets, obtained informed consent. Outside this time patients received an initial dose of intravenous cephazolin and were looked after in the emergency department's observation ward until the following morning when study staff obtained informed consent.

Assignment

Once a patient had given consent he or she was assigned a unique study number, and allocation to home or hospital treatment was determined by phoning an off-site coordinator who kept the randomisation list and assigned each study number to either home or hospital treatment. The randomisation list was produced by SAS code from the SAS statistical package (SAS Institute, Cary, NC 27513-2414, USA) using randomly allocated block sizes with a maximum of 20. In each block, equal allocations were made to the two arms of the trial.

The study team collected information on the participants in the emergency department, including demographic information (sex, date of birth, ethnicity, address, occupation, community card status); details of any current or recent use of antibiotics, the location of cellulitis; and the presence of any skin necrosis, lymphangitis, blistering, or ulceration.

The researcher drew an indelible line with a marker pen around the peripheral margin of the cellulitis and dated this for comparison on following days.

Before leaving the emergency department, every participant received his or her first intravenous dose of 2 g of cephazolin. If renal impairment was suspected or known, the creatinine concentration was measured and the dose adjusted. Those participants randomly allocated to hospital treatment were then admitted to a hospital ward under the care of the on-call medical team who managed the subsequent clinical treatment, including the choice of ongoing intravenous antibiotic. Participants allocated to hospital treatment were visited each day by the study team to record clinical progress.

Patients who were randomly allocated to community treatment continued with 2 g of intravenous cephazolin (modified in renal impairment) twice daily. Their own general practitioner or a general practitioner from the community care team visited them daily for medical review, and community care nursing staff attended twice daily to monitor the cellulitis and administer intravenous antibiotics. Research staff reviewed community and hospital participant clinical records in all cases. This review included duration of stay, details of antibiotic treatment, and complications.

At entry into the trial and at days 3 and 6, we administered a questionnaire modified from the short form 36 (SF-36) instrument, which focused on functional and physical aspects of health.[10] At trial entry we asked patients to respond about their health before the infection, whereas at days 3 and 6, we asked them to respond about their health in the previous 24 hours. We administered questionnaires face to face at trial entry and when participants remained in hospital or by telephone if the patients had left hospital. Patients completed a patient satisfaction questionnaire four weeks after entry into the trial.

Statistical methods

The study was designed to have 200 participants, 100 in each arm. With power of 80% and $\alpha_2=0.05$, a moderate difference of 0.40 standard deviations was detectable between the two arms for the primary outcome of no advancement of cellulitis. The clinician researchers thought that a difference of up to two days would be acceptable. The standard deviation in each group was not known, but as long as it was less than five days the study had adequate power. We used survival analysis for the main clinical outcomes and, to compare the groups, χ^2 tests for contingency tables and t tests for continuous variables. We carried out our analyses in SAS, version 8.02 (SAS Institute, Cary, NC 27513-2414, USA).

Results

The trial ran from July 2002 until June 2003. We randomised 200 patients meeting the inclusion criteria to receive treatment either at home or in hospital. At the end of the trial we excluded six patients, three from each trial arm (owing to the randomisation process 101 patients were randomised initially to home treatment and 99 to hospital treatment) from the final analysis. Three of these patients had their diagnosis changed after trial entry to dermatitis, erythema nodosum, and a ruptured Baker's cyst. One patient was lost to follow up, one withdrew consent, and one home patient was allergic to cephazolin and had to be withdrawn from the trial as we did not have available an alternative intravenous antibiotic for home treatment at that time. Figure 1 shows the flow of participants through the trial.

Table 1 shows the distribution of key variables between the two care groups. The two groups were similar except that the

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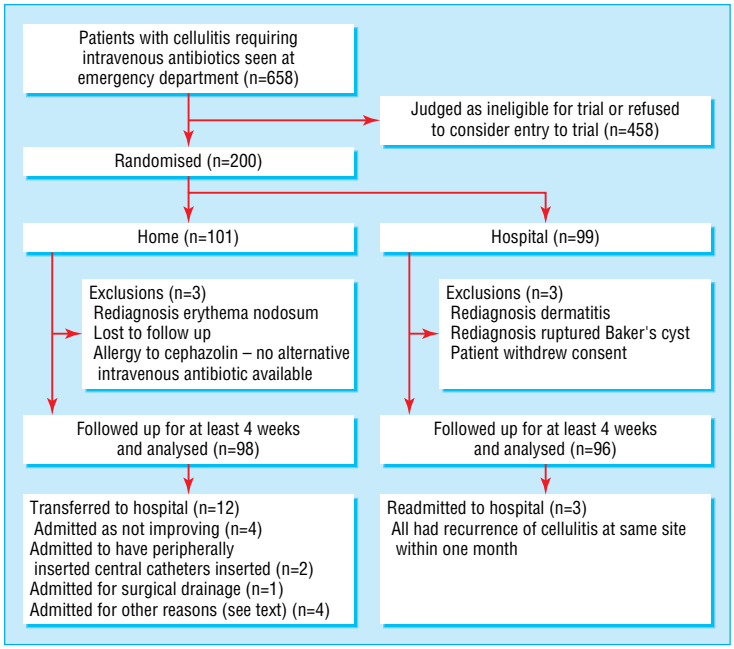


Fig 1 Flow of participants through the trial

hospital care group were younger than the home care group (48 years *v* 55 years, respectively) and had a lower proportion of users of community service cards (37% *v* 53%). (Community service cards entitle holders to subsidised general practice, and they are issued on the basis of low income.) All patients treated at home received intravenous cephazolin. Fifty five per cent (53) of the hospital patients received cephazolin as well, but 29% (28) of the hospital patients received flucloxacillin and the remaining hospital patients various other antibiotics.

Table 1 Characteristics of patients at baseline. Values are percentages (numbers) of patients unless otherwise indicated

Variable	Home care (n=98)	Hospital care (n=96)
Age in years (SD)	54.6 (20.6)	48.4 (19.0)
Age range in years	16-94	19-92
Male sex	61 (62)	70 (73)
Ethnicity:		
European	77 (79)	78 (81)
Maori	10 (10)	5 (5)
Pacific	2 (2)	1 (1)
Other	9 (9)	13 (12)
High use health card*	12 (12.6)	6 (6.4)
Community service card	52 (53)	35 (37)†
Highest educational level:		
Primary	9 (9.4)	5 (5.2)
Secondary	52 (53.1)†	61 (63.5)
Post-secondary	36 (37.5)†	30 (31.3)
Previous oral antibiotic for this episode	71 (72)	74 (77)
Site of infection:		
Lower limb	80 (82)	72 (75)
Upper limb	16 (16)	22 (23)
Other	2 (2)	2 (2)
Intravenous antibiotic used:		
Cephazolin	98 (100)	53 (55)
Flucloxacillin	—	[28 (29)
Other	—	15 (16)

*These patients attract a subsidy for general practitioners' visits as they have been to their general practitioner at least 12 times in the past year.
†One patient missing.

Clinical outcomes

The primary clinical outcome was days to no advancement of cellulitis. The mean was 1.50 (SD 0.11) days for the home treatment group and 1.49 (0.10) days for the hospital group (mean difference 0.01 days, 95% confidence interval −0.3 to 0.28). Because of the marked skew in all clinical outcomes we also compared the treatment arms by survival analysis, as shown in figure 2 and table 2. We found no significant differences on any of these outcomes, neither for simple comparisons of the two types of care nor when controlling for age, sex, location of cellulitis, and prior use of antibiotics.

Patients' functional outcomes

We used independent *t* tests to analyse modified SF-36 questionnaires administered at baseline and at days 3 and 6 and found no significant differences in levels of physical functioning or pain between the two treatment arms (see appendix and table A on bmj.com))

Patients' satisfaction with site of treatment

Table 3 summarises the patients' level of satisfaction after one week of oral antibiotic treatment with the care they received as well as their theoretical preference for location of care. Most patients in both treatment arms were satisfied with the care they received. However, only one in 20 of the community arm would prefer hospital treatment, whereas one in three of those receiving hospital care felt that home care was preferable. These results strongly imply that home care is the preferred treatment choice of cellulitis patients, particularly those who have experienced community care.

Complications

Eleven patients (12%) randomised to home treatment required transfer to hospital. Four did not show satisfactory clinical improvement; one required surgical drainage under general anaesthetic; and two needed insertion of peripherally inserted central catheters. One patient was admitted because of an ischaemic toe, one because of a severe rash, one because of nausea and vomiting after starting oral antibiotics, and one because she was not coping at home.

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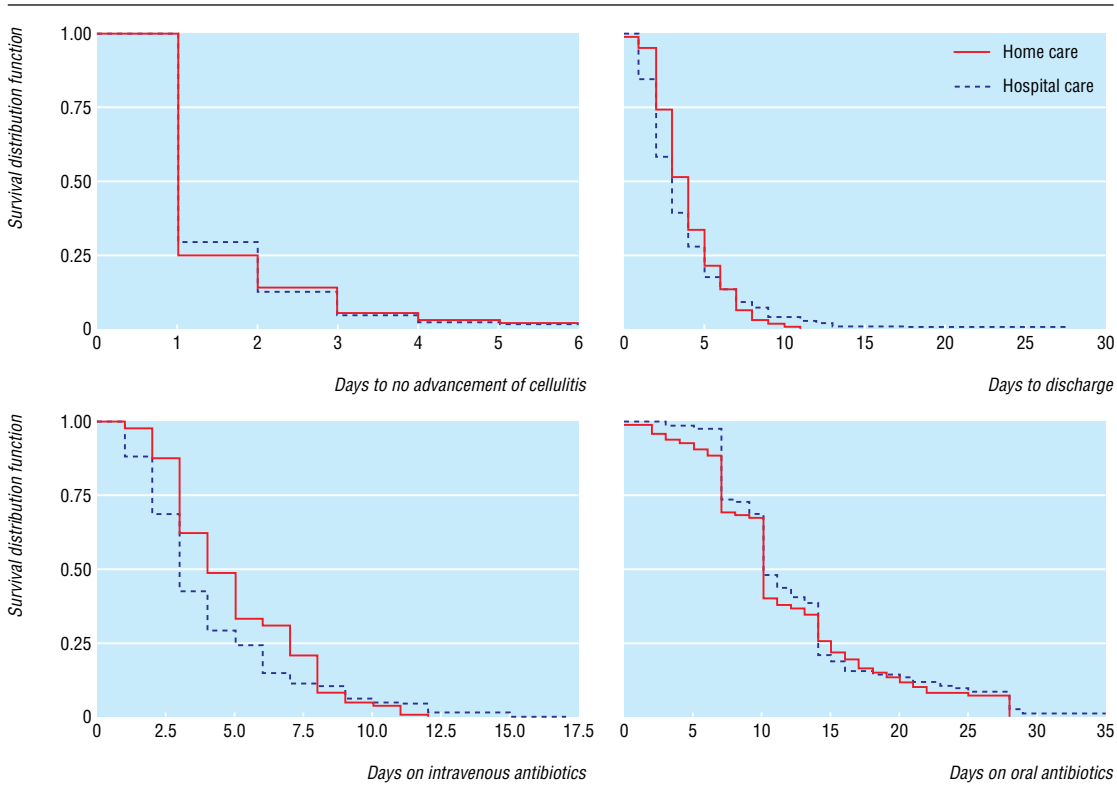


Fig 2 Kaplan-Meier plots for primary and secondary outcomes

Three hospital patients (3%) required readmission within one month of discharge for further treatment of their cellulitis. Two hospital patients received peripherally inserted central catheters while in hospital, and two patients required surgical drainage under general or spinal anaesthetic.

Discussion

Many patients with cellulitis thought to require intravenous antibiotics can safely be treated at home under a primary care home treatment programme. The two treatment groups did not differ significantly for the primary outcome of days to no advancement of cellulitis, with a mean of 1.50 days (SD 0.11) for the group receiving treatment at home and 1.49 days (SD 0.10) for the group receiving treatment in hospital (mean difference 0.01 days, 95% confidence interval −0.3 to 0.28). None of the other outcome measures differed significantly except for patients' satisfaction, which was greater in patients treated at home.

Table 2 Home care versus hospital care: hazard ratios with 95% confidence intervals

	Days to no advancement of cellulitis (n=180)	Days on intravenous antibiotics (n=193)	Days to discharge (n=193)	Days on oral antibiotics (n)=194
Simple comparison				
Home care *v* hospital care	0.98 (0.73 to 1.32); P=0.90	0.84 (0.63 to 1.12); P=0.23	0.93 (0.70 to 1.23); P=0.60	1.09 (0.82 to 1.45); P=0.56
Comparison with covariates				
Home care *v* hospital care controlling for age, sex, location of cellulitis (upper *v* lower limb), and prior antibiotic treatment	(0.74 to 1.34); P=0.97	0.85 (0.64 to 1.14); P=0.29	0.95 (0.71 to 1.26); P=0.71	1.18 (0.88 to 1.59); P=0.27

Hazard ratio >1 implies home care treatment was faster; hazard ratio <1 implies home care treatment took longer.

Table 3 Patients' satisfaction with care after one week on oral antibiotics

Question	Satisfaction rating	Home care (n=91)	Hospital care (n=88)*	P value (Fisher's exact test)
Overall how satisfied are you with the care you received?	Very satisfied or quite satisfied	87 (96)	87 (96)	0.12
	Neither	3 (3)	2 (2)	
	Very satisfied or quite dissatisfied	1 (1)	2 (2)	
Overall how satisfied are you with the location of care you received?	Very satisfied or quite satisfied	85 (93)	59 (66)	<0.0001
	Neither	3 (3)	25 (28)	
	Very satisfied or quite dissatisfied	3 (3)	6 (7)	
Do you think it is preferable to provide the kind of care you received	In the hospital	5 (5)	27 (31)	<0.0001
	In the community	78 (86)	31 (35)	
	No preference	8 (9)	30 (340)	

*Numbers varied from 88 to 91 in hospital group owing to missing data for some questions.

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Strengths and weaknesses of this study

We conducted a large randomised controlled trial of home treatment compared with hospital treatment for cellulitis requiring intravenous antibiotics. The clinical outcomes we have reported of failure of cellulitis margin to advance, time on intravenous antibiotics, and time spent in hospital or in home care are practical clinical outcomes that could be used in further reports of cellulitis treatment. General practitioners could not obtain home intravenous antibiotic treatment for their patients in any other way during this trial, which ensured that we had good "capture" of patients suitable for home intravenous treatment. We were not able to keep a record of cellulitis patients who declined to be randomised into this trial as emergency doctors notified trial staff only of cellulitis patients thought to be suitable and willing to enter this study. Only one trial patient withdrew consent, ensuring a high participation rate among randomised patients.

Comparison with other studies

Our study can be compared with other reports of intravenous treatment for cellulitis at home. A study from Australia of 100 patients being treated for a variety of conditions generally requiring hospital treatment (cellulitis, pneumonia, pyelonephritis, etc) randomised half to home treatment.[7] This study included 37 patients with cellulitis, but the outcomes for this group of patients was not described separately. This study found that patients treated in hospital had higher rates of confusion and urinary and bowel complications. Overall, the patients treated at home spent 10.1 days in the programme, whereas the hospital patients stayed in hospital 7.4 days. Three other studies from Australia have described the results of intravenous treatment of cellulitis at home.[3 4 11] Patients in these studies all needed 5.5-6.5 days of intravenous treatment at home. In these studies, 5.8-7.8% of patients treated at home required transfer to hospital. These figures are broadly in keeping with our results, but patients in both of our treatment arms were kept on intravenous treatment for a shorter duration than in the above studies. Other reports of outpatient treatment with parenteral antibiotics exist, but they do not give sufficient detail on the outcomes of cellulitis treatment to compare usefully with this study. A US based registry for outcomes of outpatient treatment with parenteral antibiotics collects information from 24 participating sites. This registry has recorded a 12.6% rate of transfer to hospital for more than 5000 patients treated outside hospital with intravenous antibiotics.[12]

Other studies may have had a different threshold of severity of cellulitis in assessing the need for intravenous treatment and for when hospital admission should be considered mandatory. Almost 75% of our patients started receiving intravenous antibiotics after oral antibiotics had failed. This is a much higher proportion than reported in other studies and indicates that our threshold for giving intravenous antibiotics was appropriate.[2 4 7]

The high degree of satisfaction with home treatment we found has been reported from other studies of "hospital at home" programmes.[13 14]

Two studies from Australia and one from the United States have compared the costs of treatment for cellulitis and other acute medical conditions at home and in hospital.[2 6 15] These studies found that home treatment was about half as costly as hospital treatment.

Other reports of home intravenous treatment have been hospital outreach programmes, and this study shows that a programme initiated and delivered from general practice can achieve satisfactory clinical outcomes. The successful operation of this programme was dependent on a small group of trained nurses and general practitioners who were able to offer support to their colleagues in delivering treatment with intravenous antibiotics.

What is already known on this subject

Intravenous antibiotic treatment of cellulitis can be delivered in the home

The safety, efficacy, and costs of home treatment compared with hospital treatment have not been studied extensively

What this study adds

Intravenous antibiotic treatment can be delivered safely and effectively in patients' homes

Patients prefer home treatment

This home based treatment programme was initiated and delivered from primary care rather than a hospital outreach programme

Meaning of this study

Patients in the two treatment arms were comparable. These findings should be generalisable to other settings with comparable systems of healthcare delivery. It must be noted that only about a third of patients requiring intravenous antibiotics for cellulitis were considered suitable for home treatment during the study period. In total 558 adult patients with a primary diagnosis of cellulitis (including those in this study who were randomised to hospital treatment) were admitted to Christchurch Hospital during the study period. Many patients with cellulitis will require admission to hospital because of their frailty, comorbidities, home situations, or the severity of their cellulitis. Patients with cellulitis require careful and daily monitoring as some will require transfer to hospital. It is possible that more patients with cellulitis could have been considered for home treatment. Patients clearly much prefer home treatment for cellulitis.

Unanswered questions and future research

Having twice daily visits from the nurse increased the costs of home treatment in this study. A report of home treatment using once daily intravenous antibiotics and nurse visits has shown that this is a safe option.[11] We considered that only about one third of patients requiring intravenous antibiotics for cellulitis were suitable for home treatment, and it is possible that a higher proportion of cellulitis patients could have been safely treated at home. This study was too small to study predictors of failure of home intravenous antibiotic treatment.

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Contributors: PC, LT, SC, AP, and GM conceived the study. PC wrote the protocol and supervised the trial and interpretation and drafted the paper with contributions from the other authors and is guarantor. EW worked on the design of the study and supervised the data analysis and LF provided statistical advice and performed the data analysis.

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