

# Effectiveness of visits from community pharmacists for patients with heart failure: HeartMed randomised controlled trial

Richard Holland,<sup>1</sup> Iain Brooksby,<sup>3</sup> Elizabeth Lenaghan,<sup>1</sup> Kate Ashton,<sup>1</sup> Laura Hay,<sup>4</sup> Richard Smith,<sup>1</sup> Lee Shepstone,<sup>1</sup> Alistair Lipp,<sup>5</sup> Clare Daly,<sup>2</sup> Amanda Howe,<sup>1</sup> Roger Hall,<sup>1</sup> Ian Harvey<sup>1</sup>

**EDITORIAL** by Ballantyne  
Research p1101

<sup>1</sup>Clinical Trials Unit, School of Medicine, Health Policy and Practice, University of East Anglia, Norwich NR4 7TJ

<sup>2</sup>Academic Pharmacy Practice Unit, University of East Anglia

<sup>3</sup>Norfolk and Norwich University Hospital NHS Trust, Norfolk NR4 7UY

<sup>4</sup>Lothian NHS Board

<sup>5</sup>Great Yarmouth and Waveney Teaching Primary Care Trust, Great Yarmouth, Norfolk, NR14 8AB

Correspondence to: R Holland  
r.holland@uea.ac.uk

BMJ 2007;334:1098-101  
doi: 10.1136/bmj.39164.568183.AE

## ABSTRACT

**Objective** To test whether a drug review and symptom self management and lifestyle advice intervention by community pharmacists could reduce hospital admissions or mortality in heart failure patients.

**Design** Randomised controlled trial.

**Setting** Home based intervention in heart failure patients.

**Participants** 293 patients diagnosed with heart failure were included (149 intervention, 144 control) after an emergency admission.

**Intervention** Two home visits by one of 17 community pharmacists within two and eight weeks of discharge. Pharmacists reviewed drugs and gave symptom self management and lifestyle advice. Controls received usual care.

**Main outcome measures** The primary outcome was total hospital readmissions at six months. Secondary outcomes included mortality and quality of life (Minnesota living with heart failure questionnaire and EQ-5D).

**Results** Primary outcome data were available for 291 participants (99%). 136 (91%) intervention patients received one or two visits. 134 admissions occurred in the intervention group compared with 112 in the control group (rate ratio=1.15, 95% confidence interval 0.89 to 1.48; P=0.28, Poisson model). 30 intervention patients died compared with 24 controls (hazard ratio=1.18, 0.69 to 2.03; P=0.54). Although EQ-5D scores favoured the intervention group, Minnesota living with heart failure questionnaire scores favoured controls; neither difference was statistically significant.

**Conclusion** This community pharmacist intervention did not lead to reductions in hospital admissions in contrast to those found in trials of specialist nurse led interventions in heart failure. Given that heart failure accounts for 5% of hospital admissions, these results present a problem for policy makers who are faced with a shortage of specialist provision and have hoped that skilled community pharmacists could produce the same benefits.

**Trial registration number** ISRCTN59427925.

## INTRODUCTION

Research on the treatment of heart failure focuses on drug treatment, yet evidence from trials of multidisciplinary interventions suggests that education and drug review interventions are effective at reducing hospital readmission and mortality.<sup>1</sup> Trials to date have generally used heart failure specialist nurses to deliver these interventions, almost all involved fewer than 200 patients, and most were done outside the United Kingdom. Unfortunately, few heart failure nurses exist throughout the UK.<sup>2</sup>

Community pharmacists, of whom there are more than 12 000 in the UK, provide a possible alternative. They are well placed geographically to provide a local service. They are highly trained in therapeutics, used to dealing with patients on a one to one basis, and skilled in drug problems and adherence. The only UK evidence to support their use is from two small studies that were limited by their size.<sup>3,4</sup> We have assessed a community pharmacist led intervention in a large randomised controlled trial.

## METHODS

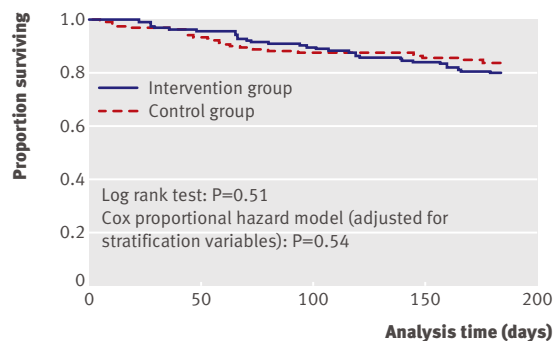
**Recruitment and assignment**—Researchers recruited patients from three large district general hospitals. Eligible patients were adults, admitted as an emergency in which heart failure was an important ongoing clinical condition, and prescribed two or more drugs on discharge. We randomised patients to receive the pharmacist intervention or usual care. Community pharmacists could participate if they held a postgraduate qualification in pharmacy practice or had recent continuing professional development in therapeutics. Pharmacists received training in heart failure, heart failure drugs, exercise, diet, smoking cessation advice, and communication skills.

**Intervention**—The pharmacist arranged the home visit within two weeks of discharge. Where appropriate, pharmacists educated the patient/carer about heart failure and their drugs and gave basic exercise, dietary, and smoking cessation advice. They also encouraged completion of simple sign and symptom monitoring diary cards, and fed back recommendations to the general practitioner and local pharmacist. We provided pharmacists with a detailed manual describing expected components of their visit and asked them to deliver education in line with the British Heart Foundation's heart failure booklet,<sup>5</sup> which they left with patients. One follow-up visit occurred at six to eight weeks after discharge to review progress and reinforce original advice.

**Masking and the control group**—The nature of the intervention meant that no clear "placebo" could be provided. Participants were told after randomisation which group they were in. Those in the control group received usual care.

**Outcome data and analysis**—The primary outcome was total emergency admissions to hospital over six months. Secondary outcomes included deaths and self assessed quality of life measured with the EQ-5D and the Minnesota living with heart failure questionnaire.<sup>6-8</sup> Participants completed a

This article is an abridged version of a paper that was published on [bmj.com](http://bmj.com) on 23 April 2007. Cite this version as: *BMJ* 23 April 2007, doi: 10.1136/bmj.39164.568183.AE (abridged text, in print: *BMJ* 2007;334:1098-101)



Kaplan-Meier graph showing time to death in intervention and control groups

questionnaire that measures drug adherence and the European heart failure self care behaviour scale.<sup>9</sup> We collected data on primary care activity, including numbers of home visits, practice attendances by patients, and numbers of drugs prescribed, for patients in practices with more than three patients in the trial. Emergency admission data came from Hospital Episode Statistics. The Office for National Statistics provided mortality data. We used Poisson regression to compare the number of readmissions between groups. We used survival analysis to analyse mortality and analysis of covariance to analyse questionnaire data. We adjusted all analyses for New York Heart Association class and recruitment site and also adjusted the analysis of questionnaire data for baseline scores. We analysed patient data according to the intention to treat principle.

## RESULTS

### Participant flow and follow-up

We approached a total of 555 patients between December 2003 and March 2005. We randomised the 339 (61%) patients who agreed and excluded 46 patients after randomisation. The two groups were similar at baseline. Primary outcome data were available for 291 (99%) patients.

### Study pharmacists and intervention visits

We recruited 17 study pharmacists. Of 149 patients in the intervention group, 136 (91%) received first visits. Second visits were carried out for 119 (80%) patients; most of the losses were because of death or readmission. Pharmacists spent an average of 5 hours 53 minutes delivering each patient's intervention. Pharmacists reported that they provided lifestyle advice to more than 95% of visited patients and advice on symptom self management to all but one patient. Alcohol and smoking cessation advice were delivered to a lower proportion of patients, as few smoked or drank alcohol. Visits

generated a total of 384 recommendations to general practitioners (2.8/visited patient). Approximately one third of recommendations related to heart failure drugs or monitoring; the remainder generally referred to other drug advice or monitoring.

### Number of hospital readmissions

A total of 112 emergency readmissions occurred in the control group and 134 in the intervention group (table). The Poisson model indicated a non-significant 15% increase in the intervention group's rate of readmission (rate ratio=1.15, 95% confidence interval 0.89 to 1.48; P=0.28).

### Secondary outcomes

**Mortality**—Mortality data were available for all patients. Fewer deaths occurred in the control group than in the intervention group (24 v 30). The figure shows the Kaplan-Meier survival graph. The hazard ratio comparing intervention and control groups was 1.18 (95% confidence interval 0.69 to 2.03; P=0.54).

**Quality of life**—EQ-5D scores at six months could be compared for 108 intervention patients and 104 controls (91% of surviving intervention patients and 87% of surviving controls). Whereas intervention patients' scores were unchanged, controls' scores decreased by 10% (worsened), although the difference between groups was not significant (adjusted mean difference=0.07, 95% confidence interval -0.01 to 0.14; P=0.08). Minnesota living with heart failure questionnaires were completed by 78 intervention patients and 80 control patients at six months (66% of surviving intervention patients and 67% of surviving controls). Whereas intervention patients' scores increased (worsened) slightly, those for control patients decreased (improved) slightly. This difference was not significant (adjusted mean difference=3.73, -3.67 to 11.13; P=0.32).

**Drug adherence and behaviour change**—Patients in both groups reported very high levels of adherence at all times of follow-up; no between group differences were evident. Heart failure behaviour scores improved in both groups, although final scores were non-significantly lower (better) in the intervention group.

**Appropriateness of visit and patient satisfaction**—Pharmacists considered that the first visit was definitely useful for 68 (50%) patients and probably useful for 51 (38%) patients; they considered second visits to be definitely useful for 37 (31%) patients and probably useful for 58 (49%). One hundred and two (82% of those surviving) intervention patients responded to the satisfaction questionnaire at three months, of whom 75 (74%) considered the visits to have been extremely or very useful.

**Primary care data**—We included 135 patients from 25 practices in this analysis (70 intervention patients, 65 controls). We did one unplanned (post hoc) analysis, which summed all primary care activity (home visits, attendances at general practices, and telephone calls). This analysis suggested that the intervention led to a 17% increase in primary care activity (rate ratio=1.17,

Number of emergency hospital readmissions by group during six months' trial follow-up

Group	No of readmissions over 6 months							Total admissions	Person years of follow-up
	0	1	2	3	4	5	6		
Control	70	49	13	9	1	0	1	112	64.58
Intervention	72	42	18	12	1	2	1	134	67.18

**WHAT IS ALREADY KNOWN ON THIS TOPIC**

Educational and symptom self management interventions can decrease mortality and readmissions in heart failure patients when delivered by specialist personnel  
Specialist staff to deliver such interventions are in short supply

**WHAT THIS STUDY ADDS**

Patients were very satisfied with an educational and symptom self management intervention delivered by community pharmacists  
This intervention did not lead to reductions in admissions or mortality of the magnitude seen with specialist interventions  
Community pharmacists may not with current training be sufficiently expert to deliver the type of intervention needed to reduce heart failure admissions and mortality

95% confidence interval 1.06 to 1.29;  $P=0.002$ ). In addition, all individual primary care activities were increased in the intervention group but, with the exception of general practitioners' telephone calls and prescription items, differences between the groups were not statistically significant.

**DISCUSSION****Principal findings of the study**

The results suggest that this community pharmacist intervention does not lead to reductions in hospital admissions, in contrast to those found in trials of specialist nurse led interventions in heart failure.<sup>1</sup> The intervention seemed to lead to an increase in primary care activity. The intervention had no clear effect on mortality, although deaths were greater in number in the intervention group. The intervention led to no clear improvement in quality of life or drug adherence; we saw some indication of improved self care, but changes were not statistically significant.

**Strengths and weaknesses**

We believe that the internal validity of this study was high. However, patients could not be blinded to treatment group, which may have biased their responses to questionnaires. The trial used a large number of pharmacists and broad inclusion criteria to ensure its generalisability.

Most non-pharmacological trials in heart failure have tended to be small (median 180 patients).<sup>1</sup> By comparison, this study was larger ( $n=293$ ). Recent meta-analyses have suggested that such interventions yield reductions in admissions of approximately 10-20%.<sup>1</sup> This trial had a sample size based on a 40% effect.<sup>4 10</sup> Our confidence limit around the main outcome, however, suggests that at best our intervention could lead to either a small decrease (10%) or a potentially substantial increase (50%) in admissions.

Despite these problems related to sample size, the finding that the intervention at best had no clear positive effect did seem to be consistent. Instead, it would seem to have increased health service activity in both secondary and primary care with no comparable health improvement. The intervention, although appreciated by patients, affected their heart failure "self care" only modestly, and the two quality of life measures seemed to move in different directions.

**Meaning of the study**

One possible explanation of our findings is that the intervention was not delivered as intended. This seems unlikely, as pharmacists reported delivering all components of the intervention. Furthermore, the visits seemed to be well received by patients. The intervention was reasonably brief, and further research is needed to examine whether more focused interviewing skills of motivating behavioural change or promoting shared decision making would improve outcomes for patients.<sup>11 12</sup>

Our intervention may have been too late in the disease course to evoke behaviour change. This study included a broad mix of heart failure patients, and many patients may have already made changes to their behaviour (such as stopping smoking) or adapted their lifestyle.

Finally, the pharmacists were not specialists in heart failure care. Their experience and training in heart failure were thus necessarily more limited than those of specialist heart failure nurses. In particular, they were not trained to titrate drugs such as low dose  $\beta$  blockers, which has been a feature of the most recent multidisciplinary interventions.<sup>2</sup>

**Unanswered questions and future research**

Pharmacists gave advice and recommendations on patients' complete drug regimen. This trial adds further evidence to suggest that drug review type interventions may not necessarily yield positive health service gains, even when they are focused on one disease area.<sup>13</sup> Whether a more intense version of our intervention could have yielded more positive effects is unknown.

Given that heart failure accounts for 5% of hospital admissions, these results present a problem for policy makers who are faced with a shortage of specialist provision yet desire services that are widely available and can reduce admissions. The next research steps should be to rigorously evaluate whether initiatives to deliver specialist care across larger geographical areas have been successful,<sup>14</sup> but also to determine how intense such services need to be.

We thank Annie Blyth, Vivienne Maskrey, Bett Barrett, Julia Hill, Jane Trippett-Jones, Jeanette Blacklock, and Lisa Regan for their hard work recruiting patients collecting data. We thank Catherine Heywood, clinical pharmacist, Norfolk and Norwich University Hospital (NNUH); Janis Riches, Norwich PCT smoking cessation adviser; Esmarie Van Tonder, senior community dietitian, NNUH; Janice Nash, physiotherapist, NNUH; Phillip Ralphs (patient representative); and Toni Hardiman, cardiology specialist nurse, NNUH, for delivering the heart failure training for the participating community pharmacists and Richard Youngs, Chris Abell, and Alexia Papageorgiou, UEA, for providing communication skills training for the community pharmacists. We also thank all the participating pharmacists, Norfolk Local Pharmaceutical Committee, and the study participants.

**Contributors:** See [bmj.com](http://bmj.com).

**Funding:** Research costs were funded by a project grant from the British Heart Foundation. Excess treatment costs were funded by Great Yarmouth and Southern Norfolk Primary Care Trusts. This trial received support for the educational training events from Pfizer UK.

**Competing interests:** None declared.

**Ethical approval:** Norwich District, King's Lynn, and Great Yarmouth and Waveney local research ethics committees.

- Holland R, Battersby J, Harvey I, Lenaghan E, Smith J, Hay L. Systematic review of multidisciplinary interventions in heart failure. *Heart* 2005;91:899-906.
- Blue L, Lang E, McMurray JJ, Davie AP, McDonagh TA, Murdoch DR, et al. Randomised controlled trial of specialist nurse intervention in heart failure. *BMJ* 2001;323:715-8.
- Goodyer I, Miskelly F, Milligan P. Does encouraging good compliance improve patients' clinical condition in heart failure? *Br J Clin Pract* 1995;49:173-6.
- Varma S, McElnay JC, Hughes CM, Passmore AP, Varma M. Pharmaceutical care of patients with congestive heart failure: interventions and outcomes. *Pharmacotherapy* 1999;19:860-9.
- British Heart Foundation. *Living with heart failure*. London: British Heart Foundation, 2004. (Heart Information Series No 8.)
- Rabin R, de Charro F. EQ-5D: a measure of health status from the EuroQol Group. *Ann Med* 2001;33:337-43.
- Holland R, Smith RD, Harvey I, Swift L, Lenaghan E. Assessing quality of life in the elderly: a direct comparison of the EQ-5D and AQL. *Health Econ* 2004;13:793-805.
- Rector TS, Cohn JN. Assessment of patient outcome with the Minnesota living with heart failure questionnaire: reliability and validity during a randomized, double-blind, placebo-controlled trial of pimobendan. *Am Heart J* 1992;124:1017-25.
- Jaarsma T, Stromberg A, Martensson J, Dracup K. Development and testing of the European heart failure self-care behaviour scale. *Eur J Heart Fail* 2003;5:363-70.
- Stewart S, Pearson S, Horowitz JD. Effects of a home-based intervention among patients with congestive heart failure discharged from acute hospital care. *Arch Intern Med* 1998;158:1067-72.
- Botelho R. *Motivational practice: a resource guidebook for skills development*. Rochester, NY: MHH Publications, 2004.
- Elwyn G, Edwards A, Kinnersley P, Grol R. Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices. *Br J Gen Pract* 2000;50:892-7.
- Community Pharmacy Medicine Management Project Evaluation Team. The MEDMAN study: a randomized controlled trial of community pharmacy-led medicines management for patients with coronary heart disease. *Family Practice* 2007 (advance access doi:10.1093/fampra/cm1075).
- British Heart Foundation. Heart failure nurses. [www.bhf.org.uk/living\\_with\\_heart\\_conditions/patient\\_support\\_resources/heart\\_nurses/heart\\_failure\\_nurses.aspx](http://www.bhf.org.uk/living_with_heart_conditions/patient_support_resources/heart_nurses/heart_failure_nurses.aspx).

Accepted: 8 March 2007

## "I haven't even phoned my doctor yet." The advice giving role of the pharmacist during consultations for medication review with patients aged 80 or more: qualitative discourse analysis

Charlotte Salter,<sup>1</sup> Richard Holland,<sup>1</sup> Ian Harvey,<sup>1</sup> Karen Henwood<sup>2</sup>

### EDITORIAL by Ballantyne Research p1098

<sup>1</sup>School of Medicine, Health Policy and Practice, University of East Anglia, Norwich NR4 7TJ

<sup>2</sup>School of Social Sciences, Cardiff University, Cardiff

Correspondence to: C Salter  
[c.salter@uea.ac.uk](mailto:c.salter@uea.ac.uk)

BMJ 2007;334:1101-4  
doi: 10.1136/bmj.39171.577106.55

### ABSTRACT

**Objective** To explore the advice giving role of pharmacists during consultation for medication review with patients aged 80 or more.

**Design** Discourse analysis.

**Setting** Participants' homes.

**Participants** Subsample of consultations within a large randomised trial of home medication review among patients aged 80 or more who had been admitted to hospital.

**Main outcome measures** Extent to which advice given by pharmacists was accepted and acknowledged by patients.

**Results** Pharmacists found many opportunities to offer advice, information, and instruction. These advice giving modes were rarely initiated by the patients and were given despite a no problem response and deliberate displays of competence and knowledge by patients. Advice was often resisted or rejected and created interactional difficulties and awkward moments during the consultations.

**Conclusions** The advice giving role of pharmacists during consultations with patients aged 80 or more has the potential to undermine and threaten the patients' assumed competence, integrity, and self governance. Caution is needed in assuming that common sense interventions necessarily lead to health gain.

### INTRODUCTION

Community pharmacists have been seen as ideally placed to deliver many of the preventive healthcare initiatives proposed by the UK government white paper "Choosing health." Medication review is one service offered in the new community pharmacy contract.<sup>1</sup>

In practice the changing role of community pharmacists in the United Kingdom is under-researched<sup>2-5</sup> and their role as advice giver or drug counsellor is ill

defined and diverse.<sup>6</sup> Little training exists for these new roles and even less in-depth research has been done into the implications of this approach to the work of pharmacists and its effect on relationships between healthcare professionals and patients.<sup>3,7</sup>

We previously evaluated whether domiciliary medication review affects hospital admission rates and quality of life among people aged 80 or more.<sup>8</sup> We report on a qualitative element of the trial that focuses on the ways in which pharmacists and older patients engage in the medication review consultation.

### PARTICIPANTS AND METHODS

We invited patients recruited to the HOMER trial between October and December 2002 to take part in the additional study. Twenty nine of 758 eligible participants with an abbreviated mental test score of eight or more (88.7% of the trial sample) were recruited.

Eleven of the 22 review pharmacists from the parent trial expressed an interest in the substudy. Seven (six were women) took part in the 29 observed and taped consultations. The pharmacists did not know the patients. They were working as community pharmacists and had a minimum of 15 years' experience (range 15-40) and at least one postgraduate qualification each (see [bmj.com](http://bmj.com)).

One researcher (CS) observed, taped, and transcribed the consultations. She noted any non-verbal cues, facial expressions, and body language. Participants were revisited by CS within a month to collect data on their perceptions of the encounter. Interviews were carried out with the pharmacists before and after the consultation.

CS transcribed and examined the transcriptions and notes by hand using transcription conventions adopted by Jefferson (box 1).<sup>9</sup>

This article is an abridged version of a paper that was published on [bmj.com](http://bmj.com) on 20 April 2007. Cite this version as: *BMJ* 20 April 2007, doi: 10.1136/bmj.39093.464190.55 (abridged text, in print: *BMJ* 2007;334:1101-4).