Tools to support implementation of guidelines for primary and secondary prevention of stroke in primary care.

This section discusses the tools to support implementation of guidelines that were developed as part of this Programme. The tools developed were a treatment algorithm for use by GPs when managing hypertension, and a training session to support primary and secondary preventions. Each tool will be addressed in turn.

The Hypertension Management Algorithm

Authors: Clare Taylor; Jonathan Betts; Jonathan Mant; Richard McManus

We developed a decision support tool to help GPs decide what BP agents to use, and how to intensify therapy based on the NICE and BHS guidelines.[1] The decision support tool took the form of a web based treatment algorithm (see figure.1). The algorithm was piloted by the GPs who participated in the PAST-BP study and was used by GPs when implementing the intervention.

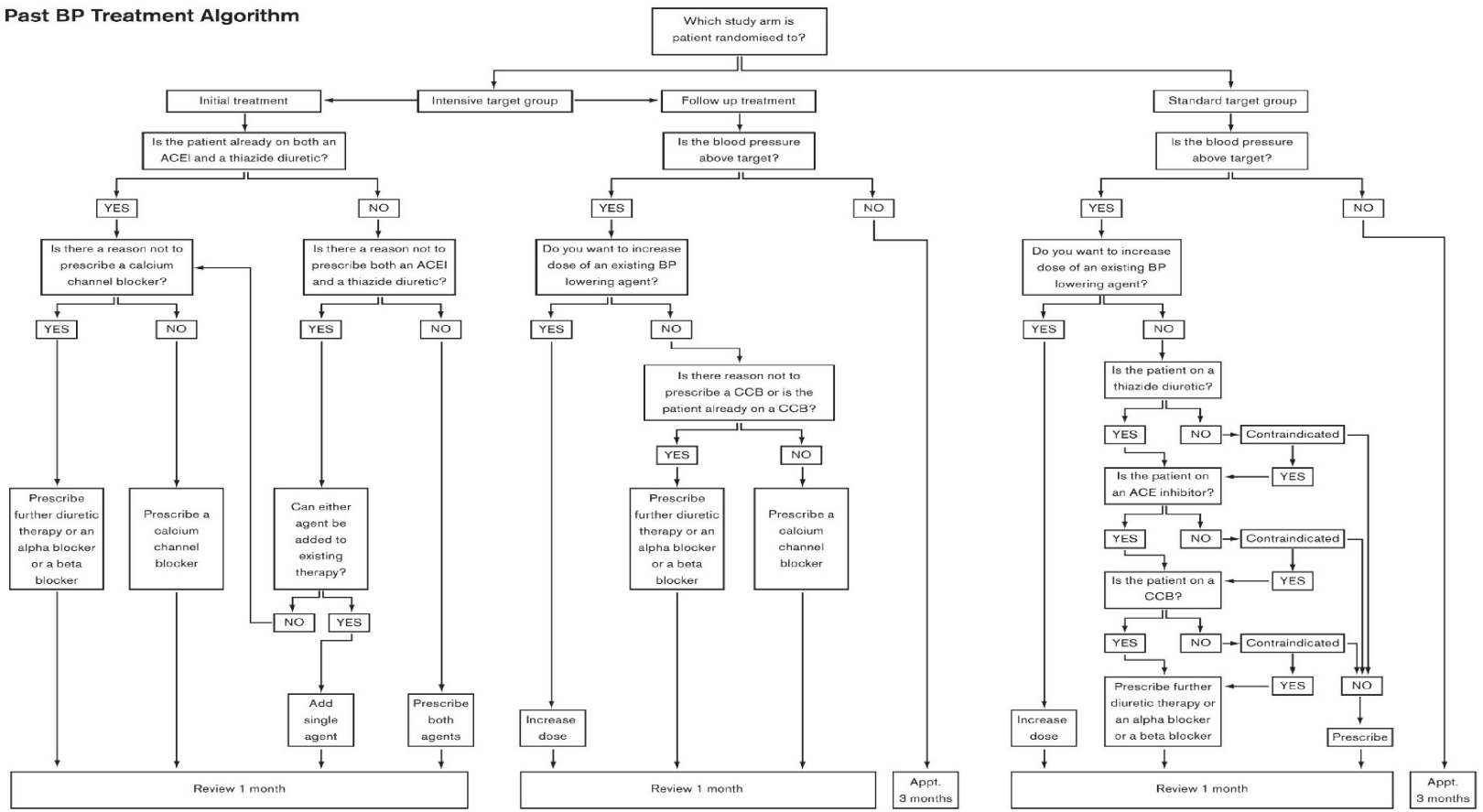


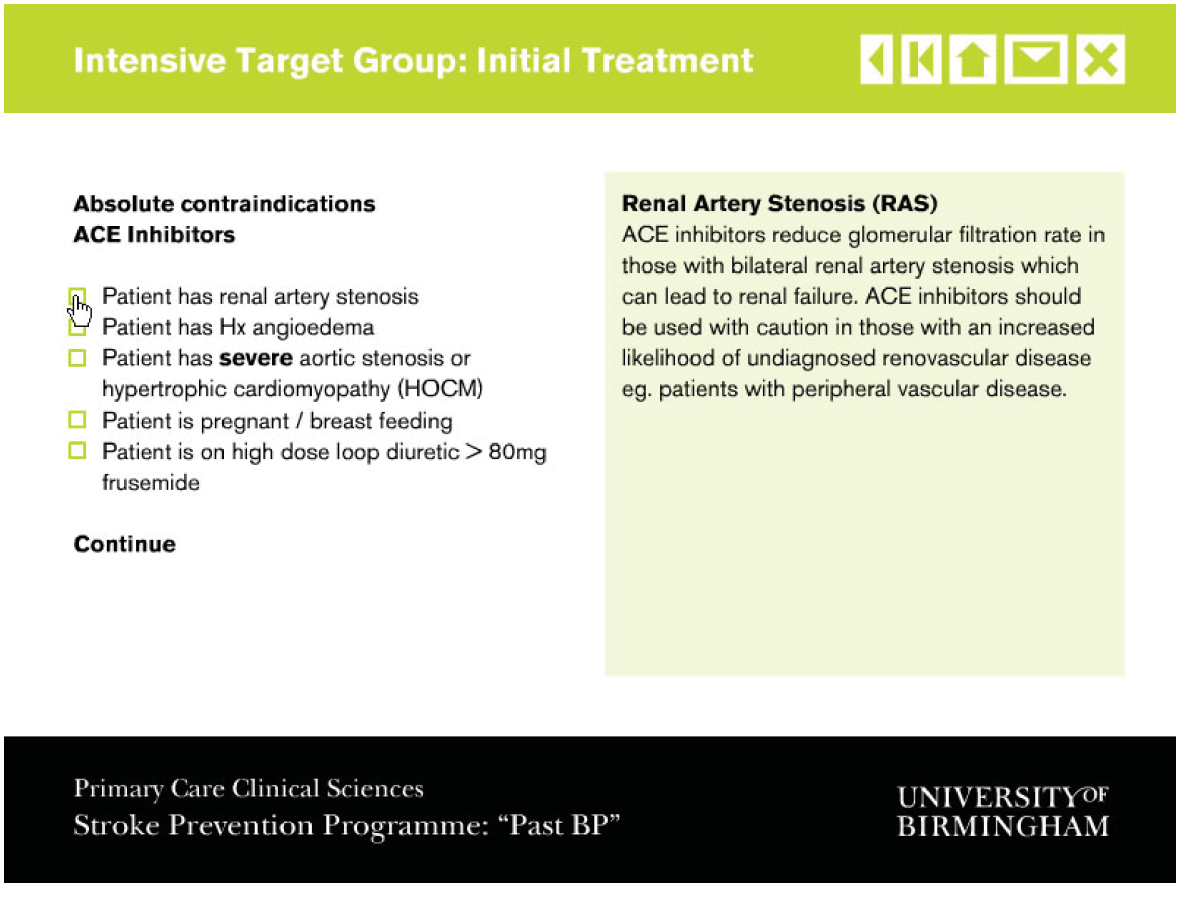
Figure 1: Past BP Treatment Algorithm

Algorithm Development

A GP with an interest in cardiovascular research and a software designer worked together on this project. The web-based tool needed to guide the user through the treatment algorithm using single steps. Relevant clinical information was presented at each step to allow the user to make a decision. The initial screen allowed the user to select if the patient was in the intensive target or standard target group, allowing all subsequent steps to be tailored to the correct part of the algorithm.

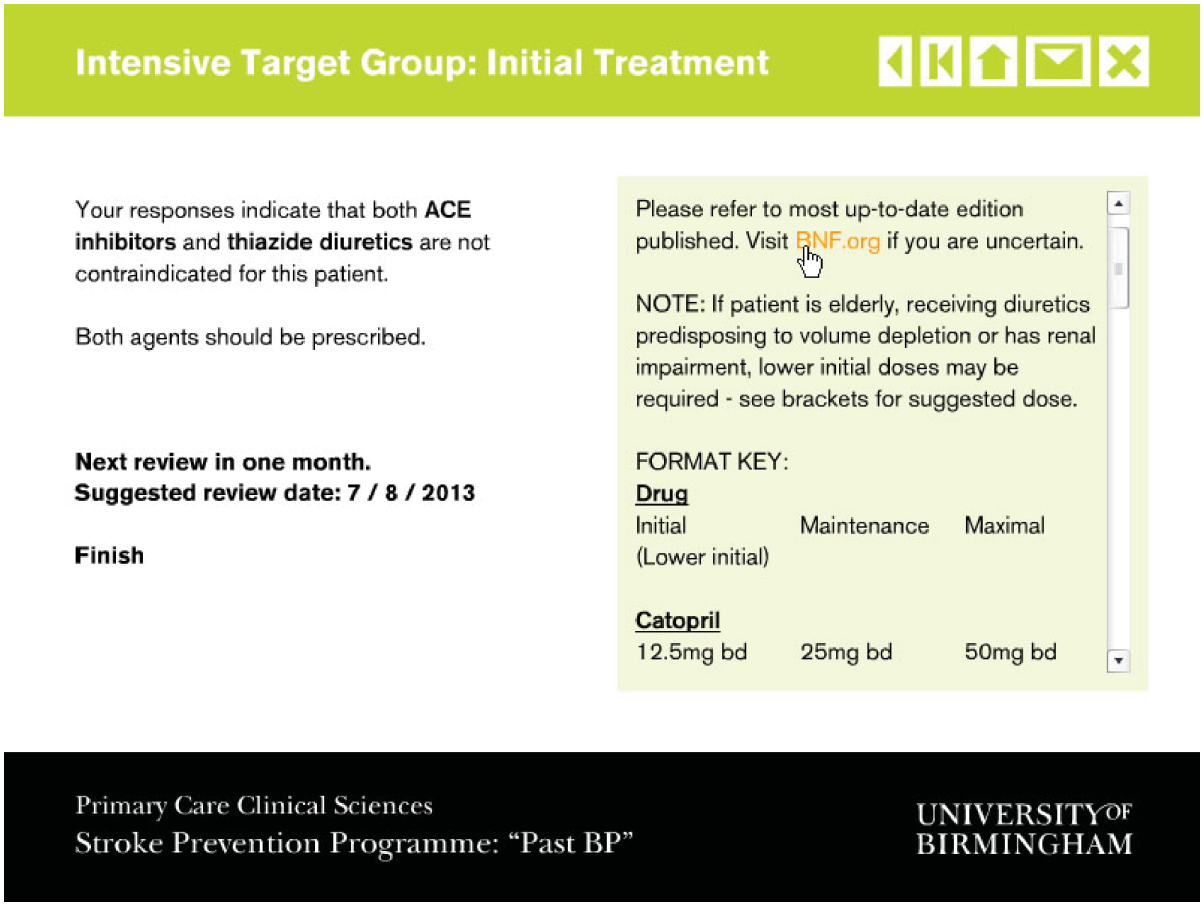
If the intensive target group was selected, and this was the initial visit, the next screen asked if the patient was already on an angiotensin converting enzyme (ACE) inhibitor or a thiazide. If the answer was 'No' the next screen advised an ACE inhibitor may be appropriate and gave a list of absolute contraindication from the British National Formulary (BNF) issue 55.[2] The user was asked to tick any contraindications on the list which applied to the patient. By hovering over the name of each contraindication, further information was shown on the right hand side of the screen as shown in Figure 2. If no absolute contraindications were ticked, the next screen showed a list of relative contraindications in a checklist with further information also available in the right hand box.

Figure 2 – Screenshot showing absolute contraindications list for ACE inhibitors in intensive arm of web-based algorithm



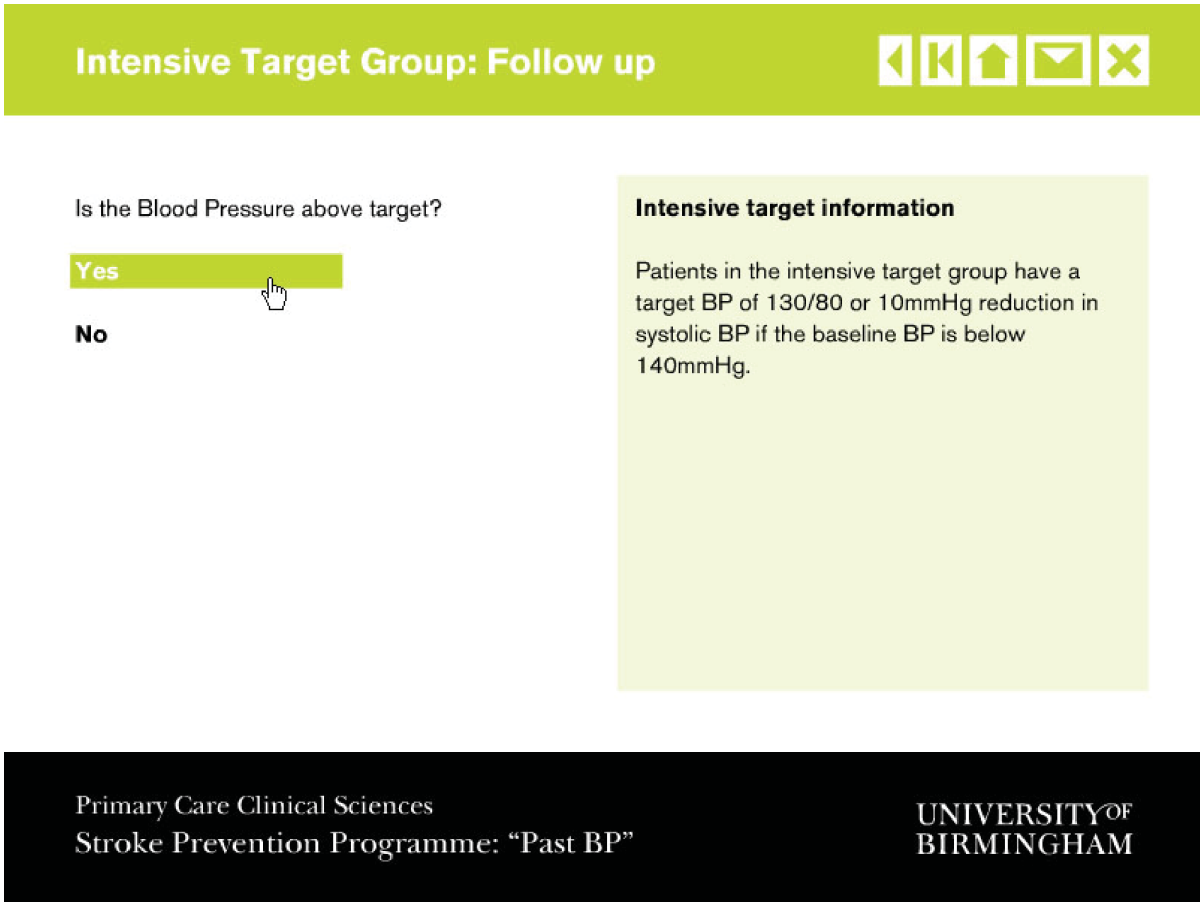
If no relative contraindications were ticked, the final screen explained 'your response indicated that ACE inhibitors are not contraindicated for this patient and could be prescribed'. The right hand box showed a range of ACE inhibitors and gave initial, maintenance and maximal doses as per BNF 55 to give the user all the information required for prescribing. The next date for review was also shown at the bottom of the screen as shown in Figure 3.

Figure 3: Screenshot showing final screen in patient in intensive arm at initial visit with no contraindications to ACE inhibitors or thiazides



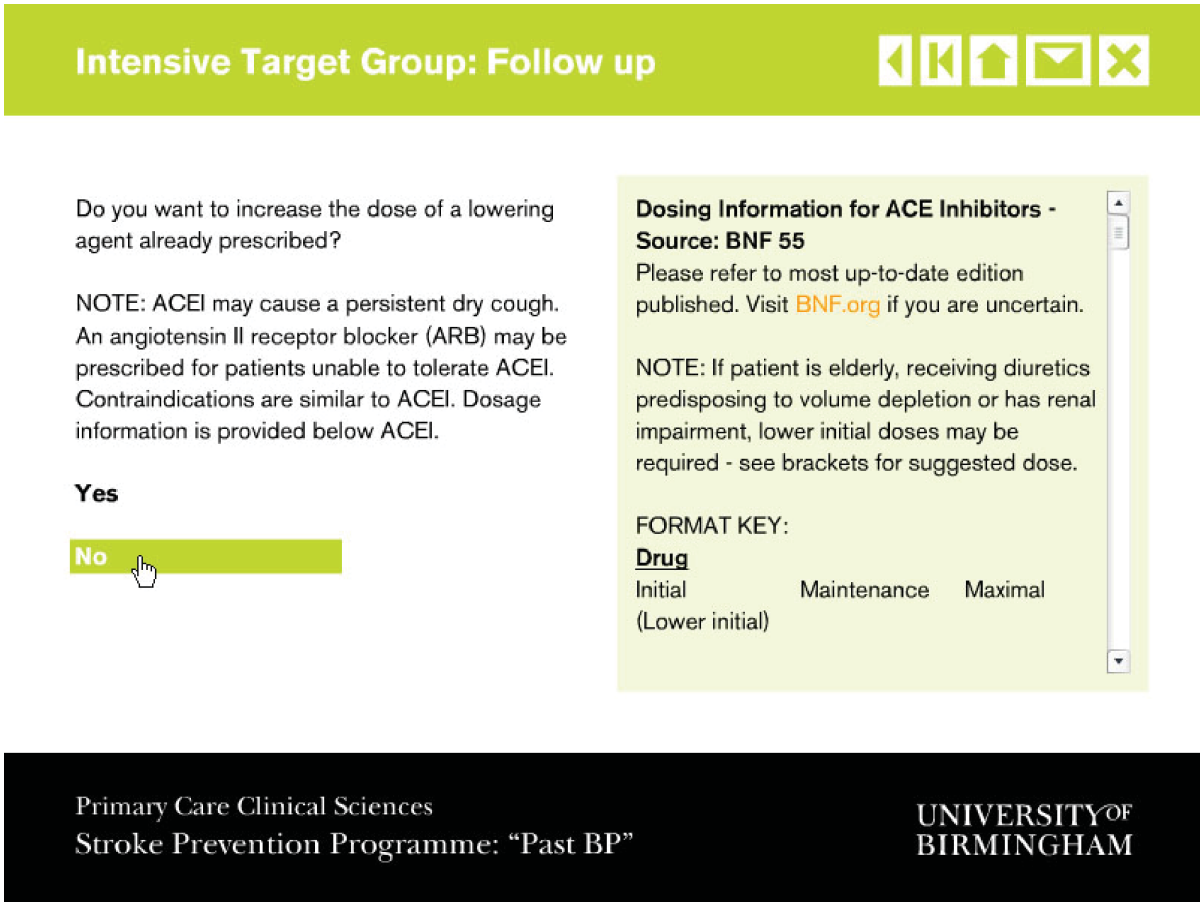
For both the intensive and standard target groups at follow-up, the first screen asked ‘Is the blood pressure above target?’ An information box on the right hand side reminded the user of the target blood pressure for patients in that arm of the study as shown in Figure 4. This avoided the user having to stop to recheck the study protocol.

Figure 4: Screenshot showing first screen in patient in intensive arm at follow-up



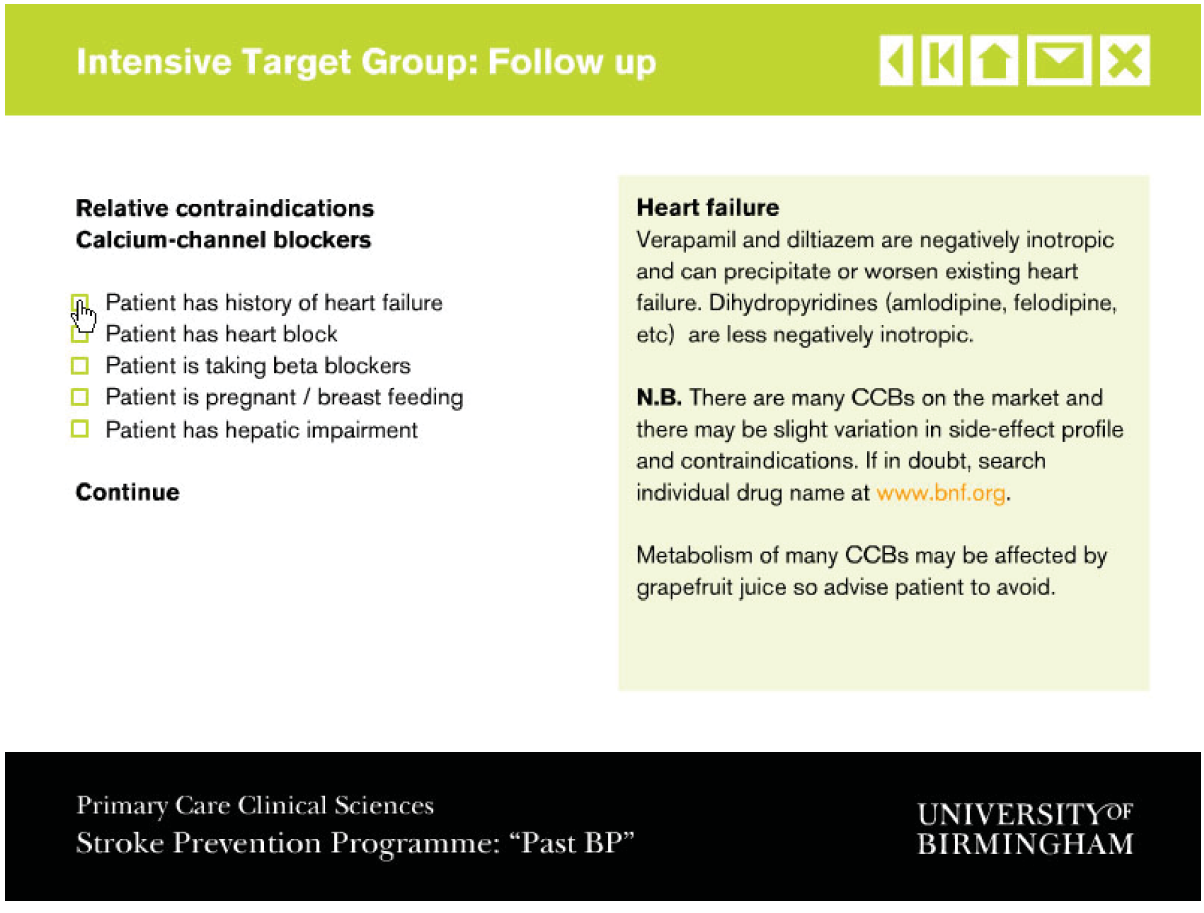
If the answer was ‘No’ a final screen appeared asking the user to continue current therapy and review in 3 months with the follow-up date given. If the answer was ‘Yes’ the user was shown the next question in the algorithm which related to treatment. For example, if the blood pressure was above target the user would be asked if they wanted to increase the dose of a blood pressure lowering agent which was already prescribed. Dosing information from the BNF was presented in the right hand box as shown in Figure 5.

Figure 5: Screenshot showing patient in intensive arm at follow-up with blood pressure above target



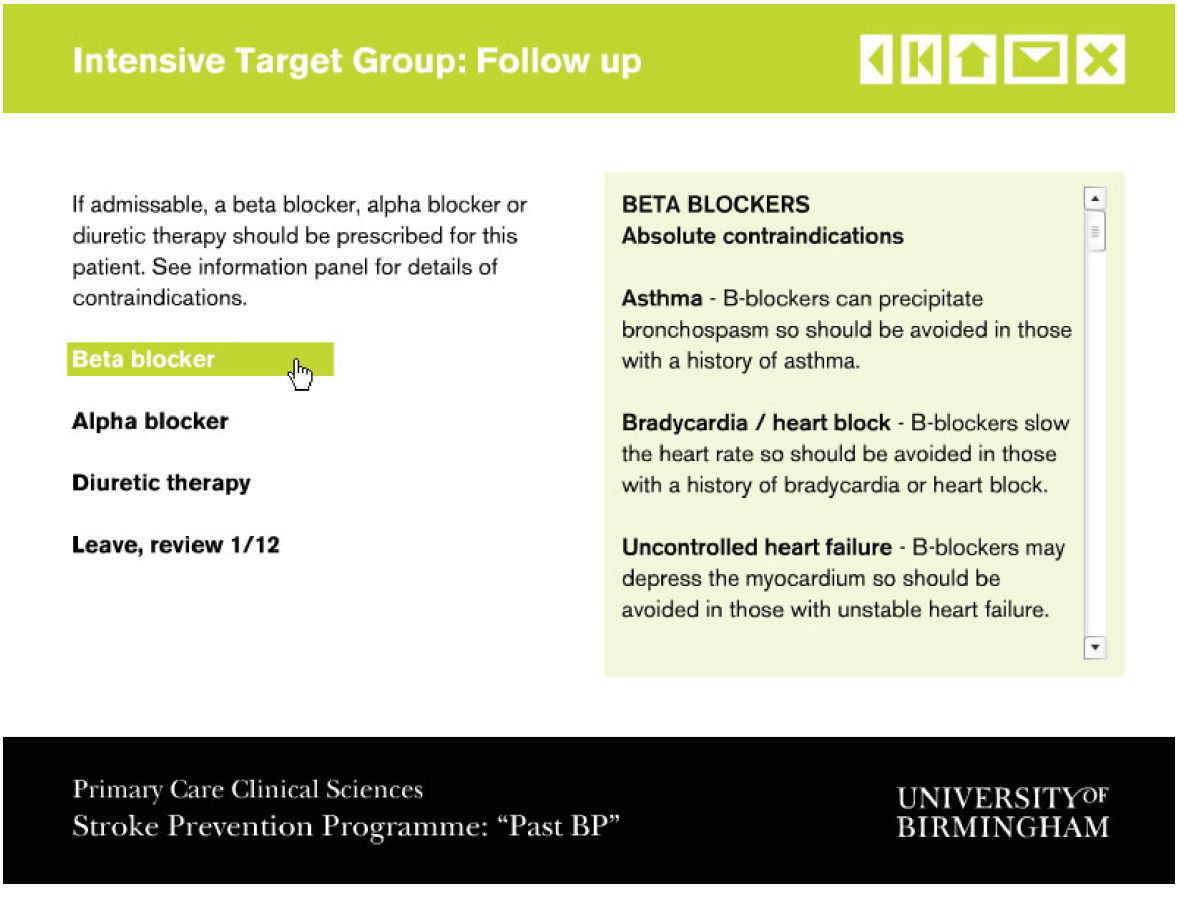
If the maximal tolerated dose of ACE inhibitor was already prescribed the next screen asked 'Is the patient prescribed a calcium channel blocker?' If the answer was 'No', a contraindications checklist for calcium channel blockers (CCB) was presented as shown in Figure 6. If none were ticked, a screen with CCB dosages and date for next review was shown.

Figure 6: Screenshot showing contraindications list for calcium channel blockers in patient with blood pressure above target where treatment is being intensified



If the answer was 'Yes' a further screen with a choice of other antihypertensives was offered as shown in Figure 7.

Figure 7: Screenshot of intensive target group follow up with further antihypertensive choices



The standard target group part of the algorithm had the same series of screens but blood pressure targets were higher.

User Training Sessions

Before recruiting patients, all GPs attended a half-day session which covered the background to the study, key areas of the protocol and training on how to use the algorithm. The tool was demonstrated using examples to illustrate the scenarios users were likely to come across during the study. The four scenarios and correct outcome are shown below. Many GPs commented that the standard arm of the algorithm would be useful to use in all patients with hypertension in their practices, not just those in the PAST-BP study, and this may be an area of further research which is required.

Scenario 1

Patient AB is a 60 year old man with a previous history of stroke. He has just arrived at your practice and is currently not taking any medications. He is otherwise fit and well and his last blood tests, including U+E, are completely normal. His blood pressure today is 150/95.

He has kindly agreed to be involved in the study and has been randomly allocated to be in the standard treatment arm.

Please use the algorithm to decide what blood pressure medication this man should receive.

Answer – Start an ACE inhibitor or thiazide.

Scenario 2

Patient CD is a 40 year old female who had a transient ischaemic attack 6 months ago. Her cholesterol was found to be high. She has no other medical history of note.

Her current medications are Simvastatin 40mg nocte, Dipyridamole M/R 200mg bd, Aspirin 75mg od, Perindopril 2mg od.

Her blood pressure today is 160/88.

Her last U+E were normal.

She has kindly agreed to be involved in the study and has been randomly allocated to be in the standard treatment arm.

Please use the algorithm to decide what changes should be made to this lady's blood pressure medication.

Answer – Increase dose of Perindopril.

Scenario 3

Patient EF is a 58 year old man discharged from hospital 3 months ago following a middle cerebral artery infarct. He has recovering well and manages at home with the help of his wife. He has diabetes and hypertension. He had an episode last year when his right great toe had swollen up and this was thought to be due to gout.

His medications are Perindopril 8mg od, Simvastatin 40mg nocte, Aspirin 75mg od, Dipyridamole M/R 200mg bd.

His blood pressure today is 146/86.

Last blood results including U+E were all normal.

He has kindly agreed to be involved in the study and has been randomly allocated to be in the intensive treatment arm.

Please use the algorithm to decide what changes should be made to this mans blood pressure medication.

Answer – On maximum dose of Perindopril and blood pressure above target so add a calcium channel blocker. A thiazide is contraindicated due to history of gout and diabetes.

Scenario 4

Patient GH is a 62 year old female who had a stroke 1 year ago. She has kindly agreed to be involved with the study and has already been allocated to the intensive group and was seen 1 month ago for her initial assessment. She does not have any other significant past medical history. She developed a cough some months ago on Ramipril so this drug was stopped.

Her medications are Aspirin 75mg od, Simvastatin 40mg od, Bendrofluazide 2.5mg od, Losartan 100mg od.

Her blood pressure today is 140/90.

Her last blood tests were all normal.

She has returned for review as part of the study.

Please use the algorithm to decide what changes should be made to this lady's blood pressure medication.

Answer – Blood pressure is above target and on maximal dose of losartan so add calcium channel blocker.

Algorithm Software

The computerised algorithm was created using Adobe Flash software; a multimedia and vector graphics authoring platform that can be viewed using Adobe Flash Player - a browser plug-in - or as a self contained 'Projector' executable program.

A major benefit of using the Flash platform was the established proliferation of the web plug-in and in most cases no special set-up was required by the target users; the application was simply accessed by navigating to a web page on which the tool was embedded.

Where intended users were unable to access the internet an exact copy of the tool was distributed as a standalone executable version.

Flash's integrated development environment leant itself well to the direct interpretation of the original flow diagrams of the algorithms due to its layered frames timeline. 'Actionscript' code placed in these frames interpreted user input variables to direct the flow of each respective algorithm. The authoring platform also allowed the algorithms to be created in a modular manner, which enabled the re-use of sequences that dealt with individual classes of antihypertensive across different pathways. This meant the information presented to the user for any given antihypertensive (such as contraindications or dosages) was the same for both arms of the study, and only the blood pressure targets differed.

The graphical user interface was designed to be clear and simple, offering straight forward navigation options and providing information relevant to each step of the algorithms' sub- routines. Following the half day training sessions, nearly all users were able to use the algorithm without any further guidance and most found it very intuitive and easy to operate.

Discussion

This decision support tool was developed as part of the PAST BP trial, and was designed to allow the intensive blood pressure target arm of the trial to be implemented systematically and in line with current guidelines. Training sessions (as discussed above) were carried out to ensure that GPs were familiar with the study protocol and as part of the piloting of the algorithm. During these training sessions, informal discussion with GPs revealed that they were all very positive about the algorithm and they would welcome the availability of a non-study specific algorithm that was generally available to them. This was discussed more formally during the HCP interviews, where it was thought

that although the algorithm was straightforward to use, it required more time than was possible during the consultation period with their patient.

Primary and Secondary Prevention Training

A training course was developed to support secondary and primary prevention of stroke which was aimed at GPs and practice nurses. The course is organised and run by Dr Ellen Murray at the Continuing Professional Development Unit at the University of Birmingham.

Course Content

The course is a one day course that aims to improve HCP understanding of primary and secondary stroke prevention. The programme encompasses: the prevention of stroke; the diagnosis and management of acute stroke and TIA; and rehabilitation post stroke. Table 1 shows an example of the study day programme.

Table 1: Stroke Prevention in Primary Care course programme

09.30	Coffee and Registration	
09.45	**Welcome and Introduction**	Professor Jonathan Mant
10.00	**Diagnosis and management of acute stoke**	Dr Christine Roffe
10.45	*Coffee*	
11.00	**Stroke management in primary care, national guidelines and QOF**	Professor Richard McManus
11.30	**Primary prevention of stroke and stroke related disease**	Professor Jonathan Mant
12.00	**Secondary prevention - Optimal blood pressure management, cholesterol lowering, lifestyle interventions**	Professor Jonathan Mant
12.30	**Lunch**	
13.00	**Role of carotid endarterectomy**	Mr Malcolm Simms
13.30	**Anti platelet therapy and anticoagulation following stroke/TIA**	**Dr David Sandler**
14.15	**Early recognition and acute management of TIA**	Dr Don Sims
15.00	**Rehabilitation, shared care, self management**	**Professor Cath Sackley**
16.00	**Plenary and close**	**Professor Jonathan Mant**

Experts in each specific area were engaged to present to the delegates.

Delegates and Course Evaluation

Two courses have so far been held, and a total of 41 delegates attended both days. Of these 17 were GPs, 17 were practice nurses and 7 were researchers with an interest in stroke. Detailed evaluation and feedback was collected from the delegates to ensure the course fulfils the learning needs of its target audience, and to enable development and improvement of the course for future sessions.

Delegate Feedback

Overall the feedback from all delegates was very positive. It was described as 'highly relevant', 'very useful' and 'very enjoyable and informative'. Sessions on 'Stroke Prevention and Screening for AF' and 'Early Recognition and Acute management of TIA' were considered particularly helpful and relevant to those working in primary care. The session on the role of carotid endarterectomy was described by some nurses as being too technical and focussed on the doctors in the audience, 'was interesting but was very high pitched educationally i.e. meant for medical students or qualified doctors. (not nurses). A bit hard to follow.' However, overall it was felt interesting and useful to know what happens to patients who have a stroke once they arrive in hospital.

The overall satisfaction with the course was very high. Delegates were asked to rate the day on: value of experience; standard of presentations; level the presentations were pitched at; benefit to clinical practice; time allowed to ask questions; interest in attending similar courses. All delegates agreed or agreed strongly with all statements, with only one delegate saying that they would not be interested in further courses. Overall evaluation can be seen in figures 8 and 9

Figure 8: Evaluation results of first training session

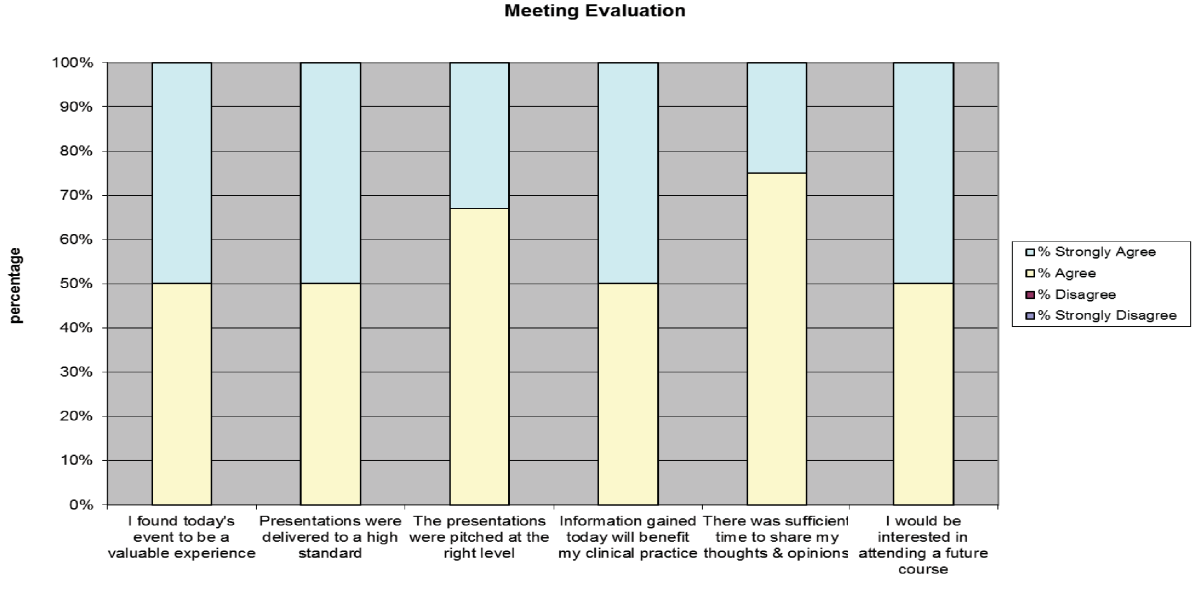
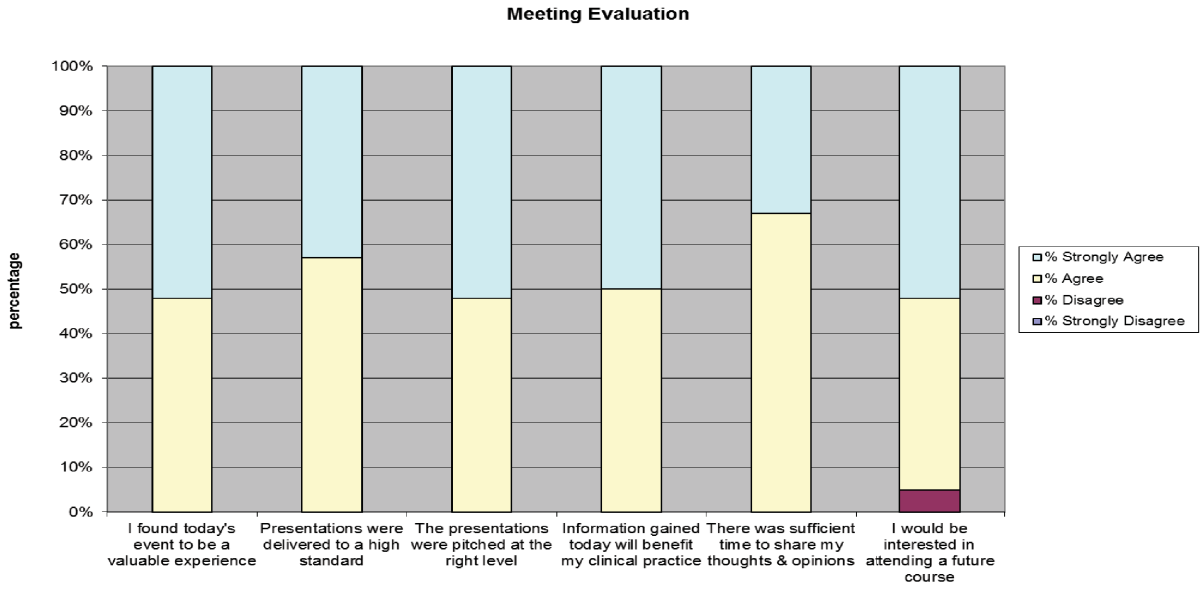


Figure 9: Evaluation results of second training session



Future Courses

Given the positive feedback received about the training course, and the overwhelming agreement that it will benefit the clinical practice of all delegates, further courses will be carried out. The courses will continue to be organised by the Continuing Professional Development Unit at the University of Birmingham; the number and timing of the courses will be led by the demand for places.

Before and After Study: the impact of screening on risk factor control and drug management - comparing screening practices and control (non-screening) practices.

Authors: R Mullis; J Mant; K Fletcher

The aim of this project is to determine the potential effect of a screening programme similar to the 'Vascular health checks' initiative that was introduced into England in 2009. In this analysis, we use the screening of patients that we carried out to inform the potential role of a polypill (see section 2) as an intervention in its own right. The outcome data that we use to explore the impact of this screening was collected from General Practice information systems before the screening was carried out to examine the prevalence of 'high cardiovascular risk' and use of cardiovascular risk lowering treatments, but repeated again after the screening was completed. This section will present this 'before and after' study. Identification and treatment of cardiovascular risk factors is compared in the intervention practices, in whom systematic screening for cardiovascular risk took place as part of this programme of research, with control practices, in which no such systematic screening took place.

Background

In April 2009 in England, a programme of 'vascular health checks' for all patients aged 40-74 years with no previous history of cardiovascular disease was introduced. Full implementation was planned for 2012-13. The aim of these health checks is to identify previously unrecognised cardiovascular disease risk. The impact of any health check/screening program is dependent on uptake by those invited to attend, and the rigour with which preventive treatments are used in people identified as being at risk. The Department of Health cost effectiveness modelling assumes a 75%.[3] uptake. however recent pilot work shows this estimation to be highly optimistic.[4] We have previously reported on adherence to national guidelines for primary and secondary prevention of cardiovascular disease in patients aged 40-74 years attending general practice in the UK in an earlier study in the programme. This analysis aims to determine any effect of the cardiovascular screening programme that we carried out.

Methods

Anonymised data were obtained from the electronic health records of all patients aged over 40 years registered at general practices across the West Midlands area of the UK. Data were collected using MIQUEST software. Pre-screening data queries were run in 19 practices between 17/10/08 and 06/10/09. The systematic screening conducted as part of this programme of research (see section 2.2) took place at 9 of these practices between 20/01/2009 and 28/05/2010, and is described in full in section 2.2. In the remaining ten control practices, no screening was conducted by the research team, but some screening may have occurred as a result of implementation of the national 'vascular health checks'. Post-screening data collection was carried out between 10/11/09 and 04/02/13 at 15 of the original 19 general practices (6 screening practices and 9 control practices). Post-screening data collection was not possible at four general practices because of the implementation of new clinical computer systems between data collection points that prevented use of the original MIQUEST search algorithm.

Intervention

For the purposes of this study, the 'intervention' was that patients identified as being of unknown cardiovascular risk who were aged 50 or over were invited to attend their practice for a screen of their cardiovascular risk. Where patients were identified to be at high cardiovascular risk (i.e. over 20% 10 year risk using the Framingham equation), the practice was informed. Further treatment was at the discretion of the practice.

Data collection

Extracted data included demographic information, cardiovascular risk factor details and records of prescribed medication (blood pressure or cholesterol lowering therapy). The analysis focuses on the population aged over 50 years at baseline (2008) since this was the population that we invited for screening to better understand the potential role of a polypill. However, it should be noted that the 'health checks' programme is open to people aged 40-74. Data from the 15 practices where both pre and post screening data collection was carried out were included in this analysis.

Outcome data

Existing cardiovascular disease was defined as presence of diagnosis of myocardial infarction, peripheral vascular disease, heart failure, ischemic heart disease [IHD], stroke or transient ischemic attack [TIA]).

Where patients had available risk factor information, cardiovascular disease risk was estimated using the Framingham equation[5] which uses age, gender, blood pressure, total/HDL cholesterol ratio, smoking status, and existence of diabetes and/or left ventricular hypertrophy to estimate a patients' risk of developing a future cardiovascular event. In accordance with NICE guidelines of the time, cardiovascular disease risk scores were adjusted by a factor of 1.4 and 1.5 respectively for patients of South Asian origin or with a family history of premature cardiovascular events.[6]

Where cardiovascular risk could not be calculated from existing risk factor information, individuals were classified as having unknown cardiovascular disease risk unless they were already receiving some form of prevention therapy, in which case they were assumed to have been identified as being at high risk previously. Patients with diabetes were classified as high risk provided they had at least one other recorded CVD risk factor (blood pressure recorded >140/90mmHg, cholesterol recorded >4mmol/l, current smoking status, and/or family history of premature CVD) in accordance with current NICE guidelines.[7]

Optimal treatment was defined in accordance with NICE guidelines, that recommend patients with existing cardiovascular disease and all patients at high risk are prescribed statin therapy and have blood pressure controlled to a target of 140/90 mmHg.

Analysis

Descriptive statistics were used to compare demographic characteristics of patients between screening practices and control practices as baseline and at follow-up (2012), and to define the proportion of patients within each risk group who were being treated in accordance with NICE guidelines. All data are presented as means ± standard deviation and proportions of the respective populations (unless otherwise stated).

Chi-squared tests were used to compare between groups the proportions of people within CVD risk categories, within target blood pressure categories, and those treated to guidelines.

For those practices involved in the screening programme, paired sample analyses were conducted on patients invited for screening, and for whom data were available at both time points (2008 [pre-screening] and 2012 [post-screening]).

All analyses were carried out using SPSS software (version 21, SPSS Inc., Chicago, USA).

Results

Population characteristics prior to screening (2008)

At the 15 included practices, 22,903 patients were aged 50 years or over. Prior to screening, cardiovascular disease risk was known in 46.2% of patients registered in the six practices where screening was to take place, and in 44.8% of patients in control practices. Existing cardiovascular disease was present in 18.3% and 15.3% of patients from screening and control practices respectively. Fifty-five percent of patients had an unknown risk of cardiovascular disease and therefore would be eligible for CVD screening. The recorded smoking status of patients varied significantly between screening and control practices (Chi-square test, $p<0.001$), with more "current smokers" and less "ex-smokers" in the screening practices (Table 86).

Table 86: Baseline characteristics for all patients aged ≥ 50

	Screening practices (n=6)	Control practices (n=9)
Population size	8541	14452
Mean (SD) Age (years)	66 (11.5)	65.1 (10.9)
Sex (%M)	47.6	49.0
Mean (SD) SBP (mmHg)	138 (17.3)	137 (16.2)
Mean (SD) DBP (mmHg)	79 (10.3)	78 (10.0)
Mean (SD) total cholesterol (mmol/L)	4.8 (1.1)	4.9 (1.1)
Mean (SD) HDL cholesterol (mmol/L)	1.5 (0.2)	1.5 (0.4)
Smoking status (%)		
- Current	20.0	15.5
- Ex	33.3	36.9
- Never	43.6	45.3
- Unknown	3.2	2.4
PMHx Diabetes (%)	11.9	11.1
PMHx CKD (%)	11.8	11.5
Framingham 10yr CVD Risk Score* (%)		
- Known CVD	18.3	15.3
- High ≥ 20%	13.6	14.5
- Low < 20%	14.4	15.0
- Unknown risk	53.8	55.2

*Adjusted for ethnicity & family history

Between screening and control practices, similar proportions of people (64%) had their BP measured within the previous 12 months, and equal proportions of people (42%) were being treated with at least one antihypertensive medication. Screening practices had a higher percentage of patients with a cholesterol measurement, and more being treated with a statin than control practices (Chi-square test, $p<0.001$) (Table 2).

Table 2: Percentage of people aged ≥ 50 with blood pressure or cholesterol readings and/or prescribed an antihypertensive or statin at baseline (2008)

	Screening practices	Control practices
% BP recorded in past 1yr	66.2	65.2
% cholesterol recorded in past 1yr	44.6	44.7
% Rx antihypertensive	40.4	41.4
% Rx statin	27.2	27.1

Mean BP (systolic and diastolic) was similar between screening and control practices, but there was a significant difference in the distribution of people within the BP categories (Table 3).

Table 3: Percentage of people aged ≥ 50 on and above target BP at baseline (2008)

	Screening	Control	P
BP above target [¥]	32.7	30.5	
BP on target[#]	33.1	34.4	0.002*
BP unknown	34.3	35.1	

[¥] SBP ≥140 and/or DBP ≥90 mmHg
[#] SBP <140 and DBP <90 mmHg
*Chi-square test

Within blood pressure categories, a greater proportion of people at control practices were being treated for hypertension (Table 89) although this difference was only statistically significant for those without a BP recording within 12 months (Chi-square test, $p<0.01$).

Table 4: Percentage of patients being treated with antihypertensive agents at baseline (2008)

	% patients treated with antihypertensive agents	
Blood pressure mmHg	Screening Practices	Control Practices
≥140/90	61.0	62.0
<140/90	55.2	56.1
No recorded BP	6.5	8.9

***Population characteristics post-screening (2012)*: Table 5**

Follow-up data were available at the 15 practices (six from practices involved in the screening programme, nine control practices) on a total of 22,643 patients aged 50 years or over. Cardiovascular disease risk was known in 66.5% of patients in the six practices where screening took place and in 66.4% of patients in the nine control practices. Approximately 34% of patients had an unknown risk of cardiovascular disease, significantly less than in 2008.

Existing cardiovascular disease was present in 24.6% and 17.8% of patients from screening and control practices respectively. Overall, the distribution of patients within the respective CVD risk categories (including those with known CVD) differed significantly between screening and control practices (Chi-square test, $p<0.001$).

The recorded smoking status of patients varied significantly between screening and control practices (Chi-square test, p<0.001), with more "current smokers" and less "ex-smokers" in the screened practices.

Table 5: 2012 characteristics for all patients aged ≥ 50

	Screening practices	Control practices
Population size	8239	14404
Mean (SD) Age (years)	64.6 (10.8)	64.7 (10.6)
Sex (%M)	47.4	49.1
Mean (SD) SBP (mmHg)	135 (16.5)	136 (15.8)
Mean (SD) DBP (mmHg)	78 (11.4)	78 (10.5)
Mean (SD) total cholesterol (mmol/L)	5.0 (1.2)	5.1 (1.1)
Mean (SD) HDL cholesterol (mmol/L)	1.4 (0.5)	1.5 (0.5)
Smoking status (%)		
- Current	31.1	16.3
- Ex	21.2	32.3
- Never	44.4	46.8
- Unknown	1.6	2.6
PMHx Diabetes (%)	12.0	12.9
PMHx CKD (%)	13.8	12.8
Framingham 10yr CVD Risk Score* (%)		
- Known CVD	24.6	17.8
- High ≥ 20%	19.2	21.7
- Low < 20%	22.6	26.7
- Unknown risk	33.5	33.6

*Adjusted for ethnicity & family history

Between screening and control practices, similar proportions of people (64%) had their BP measured within the previous 12 months, and equal proportions of people (42%) were being treated with at least one antihypertensive medication. Screening practices had a higher percentage of patients with a cholesterol measurement, and more being treated with a statin than control practices (Chi-square test, p<0.001) (Table 91).

Table 6: Percentage of people aged ≥ 50 with blood pressure or cholesterol readings and/or prescribed an antihypertensive or statin at follow-up (2012)

	Screening practices	Control practices
% BP recorded in past 1yr	64.0	64.1
% cholesterol recorded in past 1yr	47.7	42.3
% Rx antihypertensive	42.2	42.3
% Rx statin	31.8	29.2

Mean BP (systolic and diastolic) was similar between screening and control practices, and there was no difference in the proportion of people on or above target BP values (Table 92). Compared with 2008, less people were above target for BP at follow-up.

Table 7: Percentage of people aged ≥ 50 on and above target BP at follow-up (2012)

Characteristic	Screening	Control	P
BP above target ¥	27.6	28.7	

BP on target[#]	36.3	35.4	0.196
BP unknown	36.0	35.9	

[¥] SBP >=140 and/or DBP >=90 mmHg
[#] SBP <140 and DBP <90 mmHg
*Chi-square test

In contrast to 2008, a greater proportion of people at screening practices were being treated for hypertension than at control practices (Table 93). This difference was statistically significant for both blood pressure categories (Chi-square test, $p<0.05$). However, control practices still had more patients that were being treated with antihypertensive agents who did not have a recent BP recorded.

Table 8: Percentage of patients being treated with antihypertensive agents at follow-up (2012)

	% patients treated with antihypertensive agents	
Blood pressure mmHg	**Screening Practices**	**Control Practices**
≥140/90	63.4	61.5
<140/90	59.6	57.3
No recorded BP	8.3	12.0

Table 94 describes the sub-population who were invited for screening and for whom follow-up data was available in 2012. Of people who were invited for screening but failed to attend, 62.0% were still classified as being at unknown cardiovascular risk in 2012 compared with 15.7% of those who attended screening. Seventeen percent of those who attended screening were known to have cardiovascular disease in 2012 compared with less than seven percent of eligible non-attenders. Treatment with antihypertensive agents was similar between attenders and non-attenders, although significantly more attenders were being treated with statins by 2012.

Table 9: 2012 Comparison of patients eligible for screening - attenders versus non-attenders

	Attended Screening	**Eligible non-attenders**
Population size	1415	2030
Framingham 10yr CVD Risk Category*	2012 (%)	
- Known CVD	17.2	6.8
- High ≥ 20%	18.1	11.4
- Low < 20%	49.0	19.8
- Unknown risk[§]	15.7	62.0
- Rx with antihypertensives	17.2	17.9
- Rx with statins	13.9	10.0

*Adjusted for ethnicity & family history
[§]Risk incalculable due to missing clinical data

Discussion

This section examined the data collected from General Practice information systems at two time points (pre- and post-screening). The prevalence of 'high cardiovascular risk' and use of cardiovascular risk lowering treatments between practices who took part in the CVD screening programme and control practices was compared. Overall, between the two time points there was a significant drop in the number of people at unknown risk of developing cardiovascular disease within 10-years. This was observed in both screening and control practices. This was to be expected, given that the screening programme coincided with introduction of the NHS programme of 'vascular

health checks' for all patients aged 40-74. However, when looking at just those patients who were invited for screening, the findings are very different, with many less people who attended the screening clinic being classified in 2012 as unknown CVD risk (approximately half the rate observed in the population aged over 50 years). Those people who attended screening would not subsequently have been invited for the NHS 'vascular health checks' but will have contributed to the observed decrease in the number at unknown risk at those practices.

In 2012, the prevalence of known CVD was higher in screening practices than controls, despite the universal introduction of the NHS health checks. One possible explanation could be that the screening clinics were more effective at identifying unrecognised cardiovascular disease than the health checks although this is not possible to verify with the data available.

Between 2008 and 2012 there was a significant drop in the number of people above target blood pressure (>140/90 mmHg). However, the proportion of people without a blood pressure measurement recorded within the previous 12 months remained the same at just over one third of the population. One possible reason for this might be that people found to be normotensive at screening or NHS health check would not routinely be invited back on a yearly basis, and therefore might not have a recent BP recorded in their notes.

At baseline, screening practices had higher rates of "current smokers" and less people categorised as "ex-smokers" than control practices. This discrepancy increased in 2012. This finding goes against the long-term trend of decreased smoking within the general population. This could be as a result of the nature of the questioning at screening clinic, with some "ex-smokers" being systematically re-categorised as "current smokers", although again this is not possible to verify with the data available.

Of people invited for screening but not attending, less than 7% had recognised cardiovascular disease in 2012 compared with 17.2% of those who attended screening. 62.0% of those who did not attend screening were still classified as being at unknown cardiovascular risk in 2012.. It is not clear from these data whether the higher proportion of people with cardiovascular disease in the group that attended screening reflects better recording of existing disease at the screening clinic, or better detection of subsequent disease post-screening.

Strengths and weaknesses of this study

The strengths of this study lay in the size of the dataset available. Capturing clinical data at two different time points on over 22,000 people aged 50 years or over provides a wealth of information with which to assess temporal changes to clinical practice in primary care. The main limitation is that information was not available on people who were no longer registered at the same general practice as they were in 2008. People can leave a particular general practice for several reasons. They may simply move away from the area and register elsewhere, they could have experienced a significant clinical event or severe deterioration in health causing them to move and register elsewhere, or they could have died. Across all practices, it would be expected that the reasons why people no longer remain registered at the same general practice would be broadly comparable, but we have no way of knowing whether this was the case here. Not having this information leaves a degree of uncertainty when trying to establish the effectiveness of the screening programme on primary prevention of cardiovascular events.

Having follow-up data from only six of the nine practices involved in the screening programme reduces the power of any inferential analyses undertaken here. This was unavoidable within the timeframe of the project as post-screening data collection was not possible because of system changes made to the clinical computers between data collection points that prevented use of the original MIQUEST search algorithm.

Conclusions

While this was a methodologically weak study that exploited collection of data that had been primarily collected for other purposes, it is possible to draw relevant conclusions for identification of cardiovascular risk in general practice. In essence, the screening programme had had minimal overall impact on the ability of practices to classify people on the basis of cardiovascular risk as compared to control practices, but the screening was associated with a higher identification of established cardiovascular disease and a marginally higher rate of use of cardiovascular preventive medications. This suggests that against the backdrop of the health checks programme, practice initiatives to screen are unlikely to have significant impact.

Further Development of Implementation Tools (The Hypertension Management Algorithm)

Following on from the positive feedback given by GPs who participated in the PAST BP trial, it would be possible to develop this algorithm to support the management of hypertension outside trial conditions. However, in order for this to be developed appropriately, the tool would need to be amended to reflect current guidelines (some changes to guidelines have been introduced since the closure of PAST BP) and to ensure that any study specific instructions are removed. Methods for ensuring that the algorithm continued to reflect further changes in guidelines would also need to be developed. Finally, formal evaluation of such a tool would need to be undertaken. This represents a significant undertaking, which is outside the scope of this project. Therefore, the intention is to seek further funding to formally develop and test the impact of the treatment decision algorithm.

Involving patients in Self-management of their Stroke Risk: Performance and persistence of a blood pressure self-management intervention

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Paper in preparation.

A training package to support patients in self-managing their stroke risk was developed as part of the Telemonitoring and Self-management in Hypertension (TASMINH2) trial. Implementation and impact of this process was evaluated in detail; the results of this evaluation is presented in this section. If successful, this training package could potentially be offered more generally to patients outside trial conditions.

Background

The diagnosis of hypertension and monitoring of blood pressure has been, until recently, the preserve of health professionals using blood pressure readings taken in a medical environment (so called "office" or "clinic" readings). Simple, accurate and widely available monitoring equipment has led to self (or home) monitoring of blood pressure becoming more popular, with at least 30% of people with hypertension reported to be self-monitoring their blood pressure in some surveys.[8 9]

Self-monitoring has been shown to be associated with small but significant reductions in blood pressure, to be cost effective and well-liked by patients.[10] Self-monitoring of blood pressure is commonly undertaken by patients on their own initiative using machines bought without medical advice and without undergoing any formal training or education.[8] National and international guidelines for self-monitoring have been proposed and have reached consensus on a number of issues. Measurements should be taken using a validated, automatic, upper arm BP machine, preferably with a memory and/or function to print or transmit readings, and using an appropriately sized cuff.[11] A wide variety of measurement schedules have been proposed, but a systematic review has found little evidence to determine what schedule is most appropriate other than suggesting a minimum of four days of monitoring.[12]

Self-management of hypertension, where patients adjust their own medication, takes the concept of self-monitoring a step further, but until recently had received little evaluation.[13] The TASMINH2 trial (telemonitoring and self-management in the control of hypertension) was a randomised controlled trial comparing usual hypertensive care to self-management of hypertension which comprised home monitoring of blood pressure with self-titration of medication. After one year, the primary outcome of change in systolic blood pressure, was 5.4mmHg lower in the self-management arm compared to usual care.[13]

Effective implementation of self-monitoring and especially self-management requires appropriate

patient education, an area which has received little attention to date. This analysis reports the development, evaluation and outcomes of the TASMINH2 training programme which aimed to ensure patients were educated, effective, confident and accurate in their self-management of blood pressure.

Methods

Participants

The trial methods are reported in detail elsewhere.[13] In brief, patients with uncontrolled hypertension were recruited from 24 primary care practices in the UK. Eligibility criteria included age 35-84yrs, baseline blood pressure >140/90 mmHg, no diagnosis of dementia, and treated hypertension with participants taking no more than two medications. The data presented here refer to those in the self-management group.

Monitoring and Self-Management Algorithm

The TASMINH2 self-management algorithm was developed from that used in the only previous study of self-titration of antihypertensives.[14] Key differences were the longer follow up period (12 months vs 8 weeks), choice of medication (free vs fixed regime) and individual monitoring periods (7 days vs 14 days monitoring at a time).

Participants were asked to measure their blood pressure daily for the first week of each month taking two readings each morning with a 5 minute rest in between. If the second reading was very high or low (>200/100 mmHg or systolic < 100 mmHg), a third reading was required. Measurements were coded as green (normal), amber (raised) or red (very high or low). Readings that remained very high or very low triggered the recommendation that the participant contacted their GP. Evening measurements were not required so as to reduce the complexity of the intervention and because of evidence that morning hypertension on home measurement is better correlated with stroke risk than evening hypertension.[15] At the end of each week of monitoring, participants transmitted their blood pressure readings to the research team by means of an automated modem device (i-modem; Netmedicial, De Meern, Netherlands), which was connected to the blood pressure machine and plugged into a normal telephone socket like an answerphone. Summary results for each participant were sent monthly to the relevant general practitioner and input from the study team was limited to checking that participants had followed the safety advice in the case of high or low readings by means of a telephone call.

The home blood pressure targets were <130/85 mmHg for uncomplicated hypertension and 130/75 mmHg for those with diabetes and/or chronic kidney disease. Home BP readings were grouped for a week's data and categorised as above target when four or more daily readings were above target; two consecutive weeks above target triggered a medication change. Very high or very low readings triggered a review by their GP. Over the eleven months of the intervention, an adherent participant should have obtained a total of 154 readings (two readings daily for one week per month over 11 months).

Self-Medication changes

Potential medication changes in response to a persistently elevated self-monitored home blood pressure were agreed by each patient and their GP at a consultation at the start of the trial, following completion of training. Patients subsequently needing to implement a medication change simply requested the new medication or increased dose using a sticker attached to their standard

repeat medication request form. The form was handed in to the GP-practice and a prescription was generated without the need to see a health professional. After two medication changes had been implemented, patients were asked to attend a further consultation with their GP to agree further potential medication changes if required.

Training Development and Review

The training programme was specifically designed for the TASMINH2 trial as no previously designed programme could be identified. Development of the training included consideration of published guidelines, consultation and piloting with a group of patients who had participated in an earlier trial and matched the criteria of the patients who would participate in the new study[16 17] Once implemented in the trial, a review was made of the first 50 patients undergoing training to check for any unforeseen problems.

Training

Participants randomised to the intervention group were invited to attend two training sessions, one week apart, conducted at the patients' GP office. Training sessions (the first a group session, the second individual) lasted 45-60 minutes and were led by the research team who followed a manual to ensure that training was conducted in a standardised manner. An individual training record was kept for each participant. Figure 10 includes the learning objectives undertaken in the training sessions and Figure 11 the assessments used to ensure these had been achieved.

Figure 10: **Training Programme Learning Objectives**

Training session 1 [small group or individual session] • Understand requirements of the study • Know who to contact and when • Competent demonstration of correct assembly of the blood pressure monitor and telemonitoring equipment • When and how to take blood pressure readings • Understand the readings and be able to interpret them • Understand and implement the daily colour coding system
Training session 2 [individual session] • Understand and implement the colour coding system for the overall week • Understand and implement the appropriate weekly actions • Understand how and when to implement self-titration of medication

Figure 11: Assessments

Assessment 1

Part A (home BP readings during practice week)

- Compare home readings recorded in manual with readings received by research team via modem
- Check categorisation of home readings (at least 5/7 should be correctly coded)
- Check categorisation of measurements in homework exercise

Part B (use of BP monitor)

- Correct position of cuff on arm
- Correct placement of arm and feet
- 2 readings taken 5 minutes apart while resting quietly
- 2nd reading recorded
- BP readings recorded correctly with date and time

Assessment 2

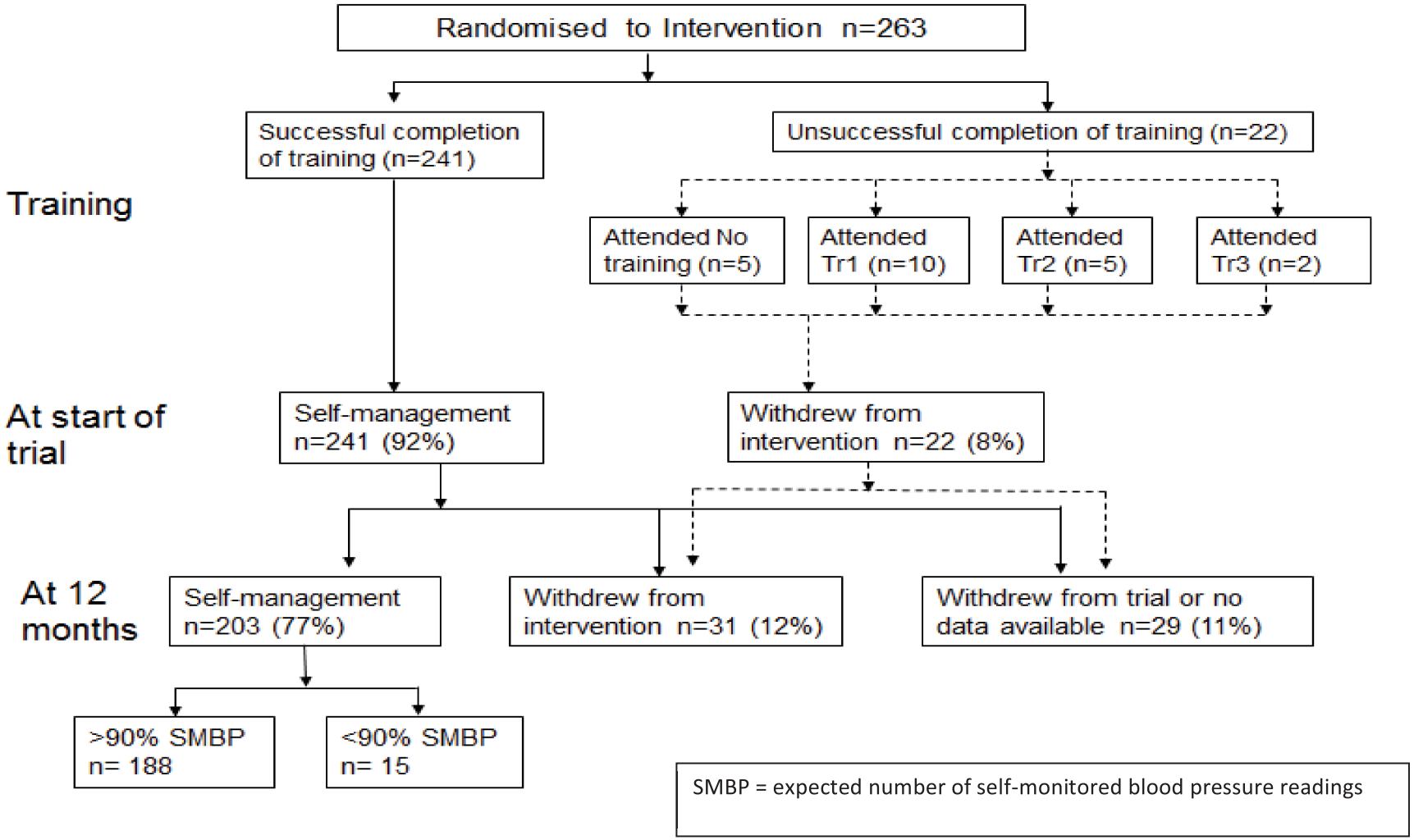
- Show understanding of categorisation of overall week
- Show understanding of appropriate action for month's categorisation
- Show understanding of how to implement a medication change
- Show understanding of when and where to seek advice

Results

Initial training

527 patients were recruited into the TASMINH2 trial, with 263 randomised to the self-management group and asked to attend training. 241 (92%) patients successfully completed the training package including the assessments and began self-managing their blood pressure (Figure 12). Patient choice (n=20), rather than failure of assessments (n=2), was the main reason that 22 patients (8%) did not complete the training programme:

Figure 12: Flow chart showing numbers of patients undertaking training



Persistence in the trial

After 12 months, complete primary end point data (systolic blood pressure) were available from 234 (89%) cases assigned to intervention and 29 (11%) either did not attend follow up (27) or had no primary end point data available (2) (Figure 49). Of those with primary end point data, 31 (13%) had withdrawn from self-management of whom 12 (5%) were self-monitoring only, and 19 (8%) had withdrawn completely from the intervention but attended follow-up. All but 4 (2%) of the withdrawals from self-management occurred in the first six months. A further 15 (7%) did not monitor their blood pressure at least 90% of the expected time. This left 188 (72% of those randomised) patients who completed at least 90% of the expected readings, self-managed throughout, and had complete data in terms of the primary end points. All results presented below are based on this cohort of 188 patients unless otherwise stated. Table 10 shows baseline data for this self-managing cohort compared to data for all intervention patients who completed follow up (n=234).

Table 10: Baseline data for self-managing cohort compared to complete cases

	Complete case intervention patients (n=234) **Mean (SD) unless otherwise stated**	**Self-managing complete case patients (n=188)** **Mean (SD) unless otherwise stated**
Age	66.6 (8.8)	66.4 (8.7)
Gender (proportion male)	110 (47%)	89 (47%)
Baseline SBP	152.1 (11.9) mmHg	152.3 (12.1) mmHg
Baseline DBP	85.0 (8.5) mmHg	84.9 (8.0) mmHg
Index of Multiple Deprivation	16.7 (13.3)	16.9 (13.2)
Anxiety score	10.1 (3.3)	13.2 (2.0)
Number of Anti hypertensive medications	1.5 (0.5)	1.5 (0.5)

Self-monitoring

Patients took a median of 154 (138-168) and a mean of 152 blood pressure readings. Of those where the time between readings was known (n=186, 99%), 157 (84%) complied with the recommended five minutes between readings at least 90% of the time. Twenty-one (11%) patients obtained a high red reading with six (29%) following this up with the correct action, and 22 (12%) patients obtained a low red reading, with one (5%) following the correct action.

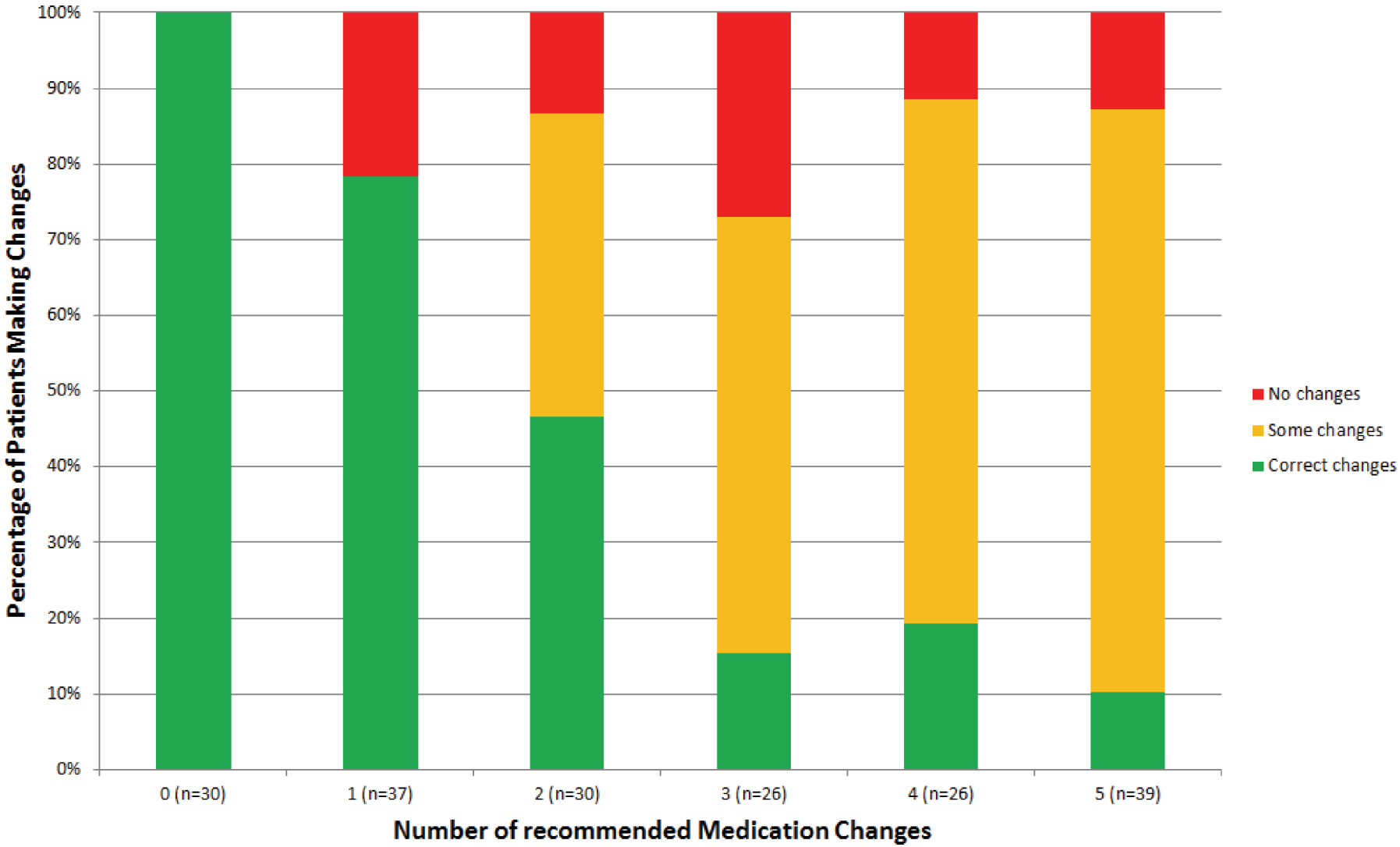
Self-titration

Overall, 55% (268/483) of management changes recommended by the algorithm were actually made by patients. Considering individuals, 77 patients (41%) made the correct management decision (to either change medication or not to change medication) every month they monitored throughout the trial, with 106 (56%) correct at least 90% of the time (Table 11). 30 (16%) patients had controlled blood pressure throughout the year and made no change to their medication, whilst 158 (84%) patients were recommended by the algorithm to make one or more medication changes during the course of the year. Of these, 131 (83%) made at least one change, but 27 (17%) didn't make any of the recommended changes (Figure 50). As the trial progressed, participants whose blood pressure remained outside of target were less likely to make all of the recommended changes including 5 (3%) who ignored five possible medication changes (Figure 13).

Table 11: Absolute and cumulative frequencies for patients implementing correct monthly management decision

Months making correct management decision (%)	Absolute figures		Cumulative Figures	
	N	%	N	%
100	77	41	77	41
90-99	29	15	106	56
80-89	28	15	134	71
70-79	26	14	160	85
60-69	16	9	176	94
50-59	8	4	184	98
40-49	3	2	187	99
30-39	0	0	187	99
20-29	1	1	188	100
10-19	0	0	188	100
0-9	0	0	188	100

Figure 13: Medication Changes



Discussion

This section presented data on the persistence and fidelity of a patient self-titration intervention in hypertension. It shows that the vast majority of those agreeing to self-manage can be successfully trained to self-monitor blood pressure and self-titrate medication. However, long term adherence to the intervention is less straightforward with 188 (72%) maintaining both self-monitoring and self-titration throughout. Within this adherent group, only 55% of medication changes recommended by the algorithm were implemented. Even so, this was enough to lead to significantly reduced blood pressure compared to usual care, reflecting the fact that the majority made at least one medication change and that there is considerable inertia to treatment changes in usual care.

Strengths and weaknesses

The TASMINH2 trial was the first adequately powered study of self-titration of antihypertensives with follow-up long enough to ascertain efficacy of both the intervention and the training accompanying it.[13] Patients in TASMINH2 were asked to measure blood pressure twice each morning for a week at a time which is less intensive than subsequently recommended in guidelines, published after the trial had started, but consistent with evidence that morning hypertension is most important in terms of end organ damage.[18] It was also a pragmatic decision to reduce the intervention intensity given that patients were in the trial for 12 months.

The high percentage of patients completing the training suggests that the programme was successful in the short term, but after a year, almost 30% had stopped self-managing, perhaps reflecting the complexity of the intervention. The key data presented here are from those people completing the study and continuing to self-manage. Ideally all patients' data would be presented but it was impossible to assess whether or not an individual had followed the trial protocol without the blood pressure measurements to back this up.

Most patients who continued to self-manage made at least one medication change illustrating that the concept of self-management could be successfully implemented. However, as the trial progressed, the proportion of patients choosing not to implement a subsequent medication change increased. Data from the trial (not shown) showed that this was a conscious decision often made when their BP readings were borderline raised/normal.[19] We already know that the intervention did not increase anxiety compared to control.[13]

Some areas of training and of the intervention required further development. There was a relatively low level of correct action following a RED reading, and it may be that clearer instructions were required on this aspect. In later work, the lower "Red" zone has been replaced by blue to avoid confusion between high and low readings. The trial participants used simple colour charts to understand their readings and newer technology incorporating the use of mobile phones and/or web interfaces may make data transmission and interpretation easier, allowing real time feedback and potentially improving persistence and adherence to the intervention.

Comparison with other literature

Prior to undertaking this work, only one previous randomised study had evaluated self-monitoring with self-titration of medication.[14] That study published the patient guideline (which was adapted for the current study), but provided little information on the training or its success. A subsequent cluster

randomised trial found that a web based self-titration intervention increased blood pressure monitoring but did not affect blood pressure.[20] One unrandomised pilot of self-titration, using a set titration schedule showed reduced blood pressure over time and good patient satisfaction.[21] Another trial combining home-titration with coaching, involved physicians at the point of titration and so is not immediately comparable.[22]

Interestingly, in comparison to a recent trial of self-monitoring with titration by physicians (the HINTs study), the patients in TASMINH2 appear more likely to implement medication changes in the light of persistently raised blood pressure: 55% vs 41%.[23] In the latter trial, a lack of action was put down to a combination of "good clinical judgement" and clinical inertia. The HINTS data are for all patients and the results would be much more similar if those not self-managing throughout are assumed not to have made any medication changes. However, comparing outcomes, the TASMINH2 self-titration intervention resulted in larger reductions in systolic blood pressure compared to usual care than in the HINTS study: 5.4 (2.4 to 8.5) vs 2.4 (-6.5 to 1.7) [12 month data, TASMINH2 intervention group compared to HINTs physician medication management group].[38624] This suggests that the differences are real and that patients have a version of clinical inertia as well as physicians.

Perspectives

This study has shown both the potential for patients to take a very active role in their own management and the limitations of the approach used. Significant clinical input was needed to achieve self-titration (one group and one individual training session with a few people requiring a third session) and almost one third did not maintain the intervention. Given that this was achieved under trial conditions, implementation of self-titration in practice is therefore likely to require changes to current practice. Further development of the intervention to simplify procedures and improve adherence to the algorithm is on-going and is hoped will lead to improved outcomes. This may be aided in the future by on-going work aiming to automate the self-management decisions via web based or mobile phone based systems.

References

[1] National Institute for Clinical Excellence. Hypertension: clinical management of primary hypertension in adults. *CG127* 2011.

[2] British National Formulary. 65th Edition. London: BMJ Books 2013.

[3] Department of Health, Medical/Vascular Policy Team. Economic modelling for vascular checks: A technical consultation on the work undertaken to establish the clinical and cost effectiveness evidence base for the Department of Health's policy of vascular checks. *DoH* 2008.

[4] Richardson G, Woerden H, Morgan L, et al. Healthy hearts—a community-based primary prevention programme to reduce coronary heart disease. *BMC Cardiovasc Disord* 2008; **8**:18.

[5] Anderson KM, Odell PM, Wilson PW, Kannel WB. Cardiovascular disease risk profiles. *Am Heart J* 1991; **121**(1 Pt 2):293-298.

[6] National Institute for Clinical Excellence. Lipid modification: Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease (Update). CG067. *NICE* 2010.

[7] Davies M, Khunti K, Webb D, Mostafa S, Gholap N, Crasto W et al. The handbook for Vascular Risk Assessment, Risk Reduction and Risk Management. 2012. University of Leicester and the UK National Screening Committee; 2012.

[8] Logan AG, Dunai A, McIsaac WJ, Irvine MJ, Tisler A. Attitudes of primary care physicians and their patients about home blood pressure monitoring in Ontario. *J Hypertens* 2008; **26**(3):446-452.

[9] Baral-Grant S, Haque MS, Nouwen A, Greenfield SM, McManus RJ. Self-Monitoring of Blood Pressure in Hypertension: A UK Primary Care Survey. *Int J Hypertens* 2012; **2012**:582068.

[10] Bray EP, Holder R, Mant J, McManus RJ. Does self-monitoring reduce blood pressure? Meta-analysis with meta-regression of randomized controlled trials. *Ann Med* 2010; **42**(5):371-386.

[11] McManus RJ, Bray EP, Mant J, Holder R, Greenfield S, Bryan S et al. Protocol for a randomised controlled trial of telemonitoring and self-management in the control of hypertension: telemonitoring and self-management in hypertension. [ISRCTN17585681]. *BMC Cardiovasc Disord* 2009; **9**:6.

[12] Verberk WJ, Kroon AA, Kessels AG, de Leeuw PW. Home blood pressure measurement: a systematic review. *J Am Coll Cardiol* 2005; **46**(5):743-751.

[13] McManus RJ, Mant J, Bray EP, Holder R, Jones MI, Greenfield S et al. Telemonitoring and self-management in the control of hypertension (TASMINH2): a randomised controlled trial. *Lancet* 2010; **376**(9736):163-172.

[14] Zarnke KB, Feagan BG, Mahon JL, Feldman RD. A randomized study comparing a patient directed hypertension management strategy with usual office-based care. *Am J Hypertens* 1997; **10**:58-67.

[15] Fukunaga H, Ohkubo T, Kobayashi M, Tamaki Y, Kikuya M, Obara T et al. Cost-effectiveness of the introduction of home blood pressure measurement in patients with office hypertension. *J Hypertens* 2008; **26**(4):685-690.

[16] Williams B, Poulter NR, Brown MJ, Davis M, McInnes GT, Potter JF et al. Guidelines for management of hypertension: report of the fourth working party of the British Hypertension Society, 2004-BHS IV. *J Hum Hypertens* 2004; **18**(3):139-185.

[17] McManus RJ, Mant J, Roalfe A, Oakes RA, Bryan S, Pattison HM et al. Targets and self monitoring in hypertension: randomised controlled trial and cost effectiveness analysis. *bmj* 2005; **331**(7515):493.

[18] Fukunaga H, Ohkubo T, Kobayashi M, Tamaki Y, Kikuya M, Obara T et al. Cost-effectiveness of the introduction of home blood pressure measurement in patients with office hypertension. *J Hypertens* 2008; **26**(4):685-690.

[19] Jones MI, Greenfield SM, Bray EP, Baral-Grant S, Hobbs FD, Holder R et al. Patients' experiences of self-monitoring blood pressure and self-titration of medication: the TASMINH2 trial qualitative study. *Br J Gen Pract* 2012; **62**(595):e135-e142.

[20] Watson AJ, Singh K, Myint U. Evaluating a web-based self-management program for employees with hypertension and prehypertension: a randomized clinical trial. *Am Heart J* 2012; **164**(4).

[21] Bobrie G, Postel-Vinay N, Delconca J, Corvol P for the SETHI Investigators. Self-measurement and self-titration in hypertension: a pilot telemedicine study. *Am J Hypertens* 2007; **20**(1314):1320.

[22] Margolious D, Bodenheimer, Bennett H, et al. Health coaching to improve hypertension treatment in a low-income, minority population. *Annals of Family Medicine* 2012; **10**(3):199-205.

[23] Crowley M, Smith V, Olsen M, et al. Treatment Intensification in a Hypertension Telemanagement Trial Clinical Inertia or Good Clinical Judgment? *Hypertension* 2011; **58**(4):552-558.

[24]Bosworth HB, Powers BJ, Olsen MK, McCant F, Grubber J, Smith V et al. Home blood pressure management and improved blood pressure control: results from a randomized controlled trial. *Arch Intern Med* 2011; **171**(13):1173-1180.