Do Patients Actually Do What We Ask? Patient Fidelity and Persistence to the TASMIN-SR Blood Pressure Self-Management Intervention

Running Head: Fidelity and persistence to the TASMIN-SR Trial

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Conflicts

RM Has received BP monitoring equipment from Omron and Lloyds Pharmacies. The other authors declare no conflict of interest.

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Abstract

Objective

Self-management of hypertension can reduce and control blood pressure (BP) compared to clinic monitoring. However, self-management relies on patients following an algorithm which may be variably adhered to. This study reports fidelity of high-risk patients to the self-management algorithm set by the TASMIN-SR trial.

Methods

Patients with hypertension, above target clinic BP and one or more of stroke, diabetes, coronary heart disease or chronic kidney disease, were invited to self-monitor following an individualised self-titration algorithm. Home BP readings and medication change details were submitted monthly for 12 months. Readings downloaded from patients' electronic monitors were compared to written submissions and protocol fidelity was assessed.

Results

276 patients were randomised to self-management and 225 (82%) completed the required training sessions. Of these, 166 (74%) completed self-management. 11,385/12,707 (89.6%) submitted readings were accurate compared to corresponding downloaded monitor readings. Mean error rate was 5.2% per patient, which increased with age but not co-morbidities.

Patients made 475/683 (69.5%) algorithm recommended medication changes, equating to nearly three medication changes per patient. Mean systolic BP for patients who completed training and made all recommended changes dropped from 141mmHg (95% CI 138.26-144.46) to 121mmHg (95% CI 118.30-124.17mmHg) compared to 129mmHg (95% CI 125.27-136.73mmHg) for patients who made none.

Conclusion

Most patients randomised to self-management completed training; however, 36% of these had dropped out by 12 months. Self-monitoring was largely undertaken properly and accurately recorded. Fidelity with self-management was associated with lower achieved systolic BP. Successful implementation of self-management into daily practice requires careful training and should be accompanied by monitoring of fidelity.

Keywords:

Self-management of blood pressure, fidelity to intervention, adherence, persistence, training and education

Introduction

Self-monitored blood pressure (BP) correlates better with cardiovascular outcomes than office BP.[1] Self-monitoring has become more popular in recent years, as availability of monitors and convenience of home measurement has increased,[2] and in a UK internet-based survey, 97% of GPs (general practioners) were found to have patients who self-monitor.[3] Self-monitoring alone results in small reductions of BP, but co-interventions including self-management can lead to greater effect sizes which are longer lasting. The TASMINH2 and TASMIN-SR trials have shown the efficacy of self-management of hypertension in a hypertensive population and a hypertensive population with co-morbidities. Previous work has evaluated performance and persistence of self-management in the TASMINH2 trial[4] showing that, although adherence to recommended medication changes reduced over the study, patients made more medication changes than equivalent trials which used physician titration.[5]

The TASMIN-SR trial adapted a self-management intervention used used in a previous trial[6] for implementation in a high-risk, hypertensive patient population. The intervention involved patients self-monitoring their BP and making changes to their medication based on an agreed titration schedule with their GP. It resulted in greater reductions in systolic BP at 12 months and an increase in medication use when compared to office management.[7] This study aimed to evaluate fidelity to the self-management intervention along with the accuracy of reporting self-monitored BP in a high-risk, older population with the view to explore this as a possible co-intervention to implement in primary care.

Methods

Population

Targets and self-management for the control of BP in stroke and at-risk groups (TASMIN-SR) was a randomised controlled trial based in primary care. Methods have been described in detail elsewhere and are reported here in brief.[7, 8]

Patients were recruited from 56 UK GP practices. Eligibility criteria were: age ≥35 years, at least one high-risk condition (cardiovascular disease, diabetes, stage 3 chronic kidney disease, and/or coronary heart disease), and a baseline BP reading ≥130/80mmHg whether or not treated. Key exclusions were dementia; BP>180/100mmHg; postural hypotension; prescribed more than 3 antihypertensive medications; pregnancy; current specialist hypertension care; or acute cardiovascular event in the previous three months. Participants were randomised to either self-management (self-monitoring with self-titration) or usual care and the primary outcome was office systolic BP after one year (the mean of 2nd/3rd readings). Follow-up occurred at six and twelve months.

Self-Monitoring Protocol

The intervention was developed from the previous TASMINH2 trial.[6] Patients were asked to self-monitor their BP for the first week of each month of the study and take morning measurements using a validated monitor (MicrolifeWatchBP Home).[9] The BP target used was 130/80mmHg, recommended at the time for high-risk patients by the British Hypertension Society[10] and Joint British Societies[11]. The British Hypertension Society suggested an adjustment of 10/5mmHg for home readings, so the home BP target in TASMIN-SR was 120/75mmHg. Patients were provided with a simple colour coded chart to help them interpret their readings: Red (high) >180/100mmHg, Amber (above target) 121-180/76 – 100mmHg, Green (normal) 100-120/≤75mmHg, Blue (very low) SBP <100mmHg (Figure A1 – appendix).

Patients were trained to measure their BP in a seated position with the arm supported on a flat surface so the cuff was at the level of the heart. They were asked to take two readings, with a minute rest between them, and to colour code the second of the readings using the

algorithm above. In each week of monitoring any very high or low readings, that persisted when a third reading was taken 5 minutes after the second, required the patient to contact their surgery for advice. Patients needed to have at least four readings of the same colour in order to make a management decision. Four or more raised readings over two consecutive months resulted in a recommendation for change in medication. Four or more normal readings simply required the patient to continue monitoring the following month. Participants used a paper form to record daily readings and any resulting actions.

Self – Titration

All patients were given a medication review at baseline. Intervention patients were also provided with an individualised three-step self-management plan with each step recommending a single medication change (increased dose or additional medication), along with any required blood tests or other investigations. Medication choices remained at the discretion of the GP. An example titration plan is available in the supplementary content (Figure A2 – appendix). When a change was required, the patient indicated which step it was on their BP measurement form and sent it in to the practice. The practice then issued the prescription for the patient to collect as usual. Three medication changes covered the patient for a minimum of eight months and they returned to the GP if further medication changes were required.

Training

Patients randomised to self-management were offered two training sessions: both lasted approximately an hour with the possibility of a third session if this was required. The first session included the requirements of the study, knowing who to contact in case of queries or emergencies and learning how to follow the self-monitoring protocol. The second session involved explanation of how to colour code the week and when to implement a medication change. Patients were assessed to ensure they were capable of self-management. This included demonstrating correct use of the BP monitor, recording results, correct application of the colour coding system and good knowledge and application of required actions and medication changes. Patients were classed as competent if they showed no problems or minimal errors they could correct with prompting. Those unable to reliably measure, record or colour code BP readings were invited to a third training session. Those assessed as

competent to self-monitor but not to self-manage were able to continue in the study simply monitoring. Those unable to self-monitor were withdrawn from the intervention and returned to usual care (though for the purposes of the trial were analysed on an intention-to-treat basis).

Outcome data

Patients sent a paper copy of their readings each month to the research team, providing a full record of BP readings they had recorded over 12 months. If patients initiated a medication change, they sent back a form to the research team. Patients were asked to bring their monitor to follow-up clinics when BP data were downloaded to provide a record of all readings taken. Patients were not made aware of this until the 6 month follow-up. The Microlife Home BP monitor has a memory capacity of 250 readings which enabled the full 12 months of data to be collected during the two follow up visits.

Analysis

This was a post-hoc analysis of the TASMIN-SR trial data. Analyses were performed using Stata 14 (Stata-Corp). Electronic BP readings were compared to the paper records from patients and scores compiled on accuracy of reporting, how well patients followed the protocol and whether they interpreted readings correctly. Student t-test was used to compare subgroups on age (under 65 vs over 65 years), months 1-5 of the study vs months 6-11 and one vs multiple co-morbidities.[12] A Wilcoxon-type test for trend[13] was used to explore the association between proportion of recommended medication changes made to the systolic BP at 12 month follow-up.

Ethical Approval

Ethical approval for the original TASMIN-SR trial was obtained from the North West Greater Manchester East ethics committee (reference: 10/H1013/60) and site-specific research approval was obtained from the relevant primary care organizations.

Results

Completion of Training

Of 276 patients randomised to the intervention, 225 (82%) completed both training sessions (Figure 1). Fifty-one patients did not complete the training: fifty did so of their own choice: one was withdrawn from training and the trial on advice from his/her GP (Figure 1).

Persistence with self-management throughout the study

At the start of the study 15/225 (7%) patients were unable to self-manage therefore switched to self-monitoring alone (Figure 1). Four of these patients had no self-titration plan provided by their GP. The remaining 11 (73%) were either unable or unwilling to self-titrate. Over the study period a further nine patients switched to self-monitoring alone: six were advised not to self-manage by their GP, and three chose not to self-manage. Eight of the fifteen patients who were self-monitoring alone stopped monitoring completely. By twelve months, 182/225 (81%) patients who had completed training, continued to self-manage (166, 74%) or had switched to self-monitoring alone (16, 7%).

Persistence with self-monitoring/management of blood pressure and medication use

Of the 43 (19.1%) participants who stopped self-monitoring completely, 38 (16.9%) attended final follow-up. No significant differences existed in baseline characteristics between patients that persisted with self-monitoring (n=182) versus those that did not (n=38) (Table A1 - Appendix). Primary outcome of the trial was mean of $2^{nd}/3^{rd}$ systolic BP readings at 12 months. Mean office systolic BP was significantly lower for patients who self-monitored/self-managed, when compared with those patients who did not ((126mmHg (95% CI 123-128) vs 141mmHg (95% CI 134-147)). Patients who completed self-management (n = 166) were prescribed more medication (defined daily dose) at 12 months compared to the patients (n = 38) that stopped self-monitoring completely (3.6 (95% CI 3.3 -3.9) vs 2.3 (95% CI 1.7-2.9) (Table A1 - Appendix).

Self-Monitoring Protocol

For one intervention patient no monitor readings were available meaning that the following analyses comprise 181 participants (99%) who continued to self-monitor or self-manage throughout the study.

Readings downloaded from the monitor showed that 1861/1936 (96%) of monitored months in the study period included sufficient readings for a management decision to be made. In nearly all cases 12,836/12,929 (99%), based on the monitor clock from the downloaded readings, at least one minute was allowed between consecutive readings. 13% of the monitoring months were in the target range. The proportion of months in target was significantly higher in the second six months of the study (6.6% vs 19.2%, $p<0.001$).

Response to very high and low readings

Participants took two readings on each occasion and acted on the second. In the case of very high second readings (≥181mmHg systolic or ≥101mmHg diastolic), patients were instructed to take a third reading, and followed these instructions 83% of the time. Very high readings (ranged here from 181–209mmHg systolic or 101–148mmHg diastolic) occurred in 3% of study months requiring urgent GP follow-up for 32 patients. Details of appointments from practice medical records evidenced that 53% of patients followed up a very high reading with their GP practice. 9/19 (47%) patients with only one very high reading followed this up with their GP. This was slightly higher for patients with more than one very high reading, with 8/13 (62%) patients contacting their GP at least once.

In the case of very low second readings (i.e. systolic <100mmHg, 1% of study months), patients took a third reading 68% of the time. This affected 19 patients of whom 7 (37%) followed up with a health professional according to their medical records. Seven patients reported more than one very low reading, but were no more likely to seek medical advice than patients with only one.

Accuracy of Reporting BP Readings

Out of 13093 readings taken during the study from whom data were available, 12707 (97.1%) downloaded readings could be matched to a paper record by date. There were 224/13093 (1.7%) readings present in the monitor memory not reported on paper and 162/13093 (1.2%) readings reported on paper which were not present in the monitor memory. Of the 12707 readings matched by date, 11385/12707 (89.6%) readings matched exactly for blood pressure level between paper and monitor memory. A further 373 /12707 (2.9%) were within 5mmHg of readings downloaded from the monitor memory. In 461/12707 (3.6%) cases patients took three readings and selected two to report. The remaining 493/12707 (3.9%) readings were misreported and the reading did not correspond with any monitor reading taken the same date. Misreporting and selective reporting led to subsequent management being potentially affected in 40/1828 (2.2%) months. In 4/40 (10%) of these months, readings were close to a threshold, where a difference of 1 or 2mmHg between paper and downloaded readings, changed the outcome of a given months readings. These discrepancies made very little difference to the overall mean BP between the downloaded and reported readings ((-0.26mmHg systolic (95% CI -0.30-0.22) (-0.17mmHg diastolic (95% CI -0.21-0.14)). 5223/5850 (89.3%) BP readings matched exactly in months 1-5, compared to 6162/6857 (89.9%) in months 6 – 12 following the 6 month follow up when patients would be made aware of the study nurse downloading readings from the monitor memory.

Overall the mean error rate per patient was 5.2%. This was not affected by the number of co-morbidities, but patients over 65 years had a higher error rate compared to those below, 6.1% (95% CI 4.8-7.4) vs 3.1% (95% CI 2.1-4.0) $p<0.05$. A small proportion, 9/181 (5%) patients, reported their BP with ≤80% accuracy.

Self-Titration

Based on the downloaded BP readings for patients who completed self-management (n=166), 683 medication changes were expected. This equates to treatment intensification for 40% of all monitoring months and just over four recommended medication changes per patient. Patients made two-thirds of these medication changes (475/683, 69.5%), equating to nearly

three changes per patient. Implemented medication changes were accompanied by health professional contact in around a third of cases (171/475, 36%).

The proportion of medication changes implemented was associated with achieved mean systolic BP at 12 months, ranging from 129mmHg (no recommended changes made) to 121mmHg (all changes made) (Table 1). A test for trend[13] showed that the drop in BP was significant according to the proportion of medication changes made ($p<0.05$).

Of the 208 (30.5%) recommended medication changes not carried out, 106 (51%) reported a reason and 102 (49%) did not (Figure 2). The decision not to make a medication change was guided by a health professional about a third of the time and made exclusively by the patient the remaining two-thirds. Reasons given included side effects and borderline readings (Figure 2).

Discussion

People in a high-risk, older, hypertensive population can be successfully trained to self-monitor their BP and make appropriate management decisions concerning self-titration. The majority of trained patients completed self-management over an extended period and followed a structured management decision resulting in significantly lower BP than the control group and patients randomised to self-management who withdrew. Monitoring was carried out to a high standard and almost all monitoring months included sufficient readings to make a management decision.

For self-management to be a reality, safety is a prime concern. In the case of very high readings, patients took an additional reading in the majority of cases and there was evidence that almost half were followed up by a health professional. Of those that did not contact their GP immediately, BP subsequently stabilised or they contacted their GP the following month. Performance following very low readings was less faithful to the protocol and many patients did not follow-up with additional readings or GP contact. However, reported symptomatic postural hypotension was rare and led to GP contact in all cases. Arguably, as most people were asymptomatic such additional contact could probably be optional in practice.

Patients reported their BP reasonably accurately with a close match between downloaded and reported readings. Misreporting or selective reporting changed the outcome for a very small percentage of months and overall mean BP between the downloaded and reported readings was almost identical. Patients over 65 years old had a significantly higher error rate, but the absolute error values were low suggesting it would be unlikely to affect outcome. Furthermore, the effect size of self-management in the trial was at least as great in people over the age of 65 as in people below that age. Patients who made all their recommended medication changes had significantly lower mean systolic BP at the final follow-up than those who made none. However patients who made no changes still had a lower mean BP at 12 months compared to the usual care patients. Three patients had no recommended medication changes and a mean systolic of 119.8mmHg at 12 months suggesting that they had a white coat effect at baseline, which attenuated over time.

Comparison with other literature

One other trial has evaluated large scale self-management and included 526 patients with largely uncomplicated but poorly controlled hypertension.[6] Higher proportions of patients in that trial completed self-management training (92% vs 82%) and subsequently completed the trial continuing to self-manage than did here (77% vs 66%).[6] Patients in the current trial were older, with a higher number of morbidities, so it is perhaps expected that self-management may have been more challenging. However, once trained, very similar proportions persisted with self-management (79% vs 78%).

Interestingly, the overall BP reduction in TASMIN-SR was greater than that in TASMINH2 (9.2mmHg vs 5.4mmHg) despite lower baseline BP (144mmHg vs 155mmHg). This might reflect both a lower target (130/85mmHg vs 140/90mmHg) leading to more medication change recommendations per person (4.1 (683/166) vs 2.6 (483/188)) and a higher acceptance of medication changes in the former: 69% (475/683) vs 55% (268/483). Similarly a greater proportion of active patients in the current study made a medication change compared to TASMINH2 (140 (84%) vs 131 (70%)).[6] This was achieved in both trials with very little in the way of adverse effects reported compared to control.[6, 7]

Others have found evidence of reporting bias in situations where the patient records their BP on paper and takes it into the doctor.[14] The level of reporting accuracy here may be due in part to the Hawthorne Effect, where a research study influences the behaviour of the patient.[15,16] In cases where readings have been compared in routine clinical practice, without the patient being aware of the memory capacity of the monitor, the comparison between readings on the monitor and those recorded on paper appears to be less close.[17, 18] However here there was very little difference in the accuracy of reported readings whether patients were aware that readings would be downloaded or not.

Training given to patients at baseline is likely to have affected fidelity to the protocol. A recent Canadian study highlighted poor reporting and persistence with self-monitoring procedures following the implementation of a passive educational strategy four years earlier.[19] Health professionals were encouraged to explain home BP monitoring to patients and educational materials were distributed in primary care centres. In contrast the training reported in the current study was standardised and took place on at least two sessions with structured assessments to ensure patients understood the procedures and algorithm to follow at home.

Two-thirds of the algorithm derived medication changes were implemented in the TASMIN-SR trial which is higher than the HINTS trial (45%) in Canada which used physician titration.[5] In that trial, the main reason for not implementing medication intensification appeared to be borderline readings.[5] Borderline or improving readings were also a factor in patients choosing not to initiate a medication change here (Figure 2) and qualitative work showed that this was also a finding for TASMINH2 patients.[20]

Side effects or adverse reactions were not different overall between intervention and control groups in the trial.[7] However, they were cited by patients as a reason not to initiate a medication change. Unfortunately, we were not able to relate adherence to the type of medication change. Adverse events leading to discontinuations of treatment were reviewed in a recent meta-analysis which found similar rates of adverse events, leading to discontinuation of treatment, between antihypertensive drug classes, with the exception of angiotensin receptor blockers which showed a significantly lower risk. However discontinuation of treatment due to adverse events was also related to the number of

cardiovascular prevention drugs which is relevant in any intervention resulting in up-titration of medication.[21]

In the TASMIN-SR trial it appears that even patients who made no recommended medication changes had lower BP following the intervention, (Table 3). This may be because self-monitoring increases adherence to medication.[22] Decisions not to implement treatment intensification may have been countered by an increased willingness to take existing medications, possibly because the self-monitoring schedule acted as a prompt for patients to take their medications.

Strengths and Limitations

TASMIN-SR was the first trial adequately powered to show the feasibility and efficacy of a self-management intervention for an older, at-risk population.[7] Patients showed willingness to complete the training, but only 65% remained self-monitoring at 12 months. Although a more intensive measurement schedule for self-monitoring is now recommended in the guidelines[23] given the challenges in getting patients to continue self-managing one might argue that our schedule is more acceptable for patients.[24] The prognostic significance of morning BP has also been highlighted, consistent with our approach to base management decisions on morning BP readings.[25] Of patients who completed training, 73% remained self-managing at 12 months and 9% opted to self-monitor only during the trial, therefore it is unlikely that all patients would be able to self-titrate. However, this appears to be related to individual choice and not age or health condition. Similarly age or co-morbidities did not seem to influence whether patients would complete the training and persist with the intervention but these results were underpowered to draw any firm conclusions.

Patients did not always follow-up very low or very high readings. This may be because they felt they had to wait for an appointment to see the study GP rather than contacting the surgery as an emergency or they waited to discuss it with their own GP. There was some misreporting and selective reporting, however, given it was a very small number it could equally have been due to a transcription error. This aspect of the intervention may require further refinement to ensure patient safety and minimise selective reporting. Patients above 65 years were not quite as accurate in reporting their readings suggesting this group needs

more supportive and intensive training which may be challenging to implement in general practice. However, the error rate for these patients was still fairly low showing that older patients are competent to monitor at home and understand what to do with the readings. It should be noted that the Hawthorn effect[15] may have caused patients to be more adherent to the intervention simply by being part of the study. A high proportion of these patients had professional or skilled occupations and few came from areas of low deprivation (Table A1 – Appendix), therefore the generalisability of these results to the wider population may be limited.

BP control significantly increased over the 12 months of the trial as patients made more medication changes. However analysis of home readings showed only 19.2% of months were considered in target range at 12 months. The BP targets in the TASMIN-SR trial were lower than the current guidelines suggest and more in line with the tight BP targets of the recent SPRINT trial.[26] This was challenging in an older, sicker population as any changes in medication had to be weighed up by the patient against the number of medications they were already prescribed and any side effects they experienced. The results of the SPRINT trial have inspired lower BP targets in the Canadian guidelines[27] for selected patients at high cardiovascular risk but the reality of achieving these targets in patients is uncertain. Self-management provides a means for patients to optimise their individual BP control by balancing their medications against achieving their BP target.

The growing popularity of telemonitoring and smart phones[28-30] is likely to have a role in the future of home BP monitoring. Our protocol could easily adapt to these technologies. However, the patient training is intensive and work is needed in order to effectively implement it into primary care.

Conclusion

This study has shown the feasibility of a self-management protocol in an older, at-risk patient group, with a high proportion following the protocol reasonably closely and reporting their readings accurately. Patients were willing to make changes to intensify their treatment two-thirds of the time but a third of treatment changes involved consultation with the GP

beforehand, showing communication between the health professional and patient remains essential even for self-management. Treatment intensification resulting from self-management resulted in similar achieved BP to the intensive group in SPRINT[26] (Table A1 – Appendix).

Self-monitoring features significantly in best practice guidelines in the UK[23] and internationally[27, 31] and is becoming a routine part of hypertension management in primary care.[32] However there are inconsistencies in how it is measured and how patients report readings to GPs. A recent individual patient data analysis on self-monitoring of hypertension highlighted the importance of professional support in achieving reductions in BP.[33] The self-management intervention here features a structured training programme and a clear, specific algorithm for patients to follow. Further implementation work is needed to adapt these trial materials and the intervention training for delivery by practice nurses or other general practice staff. Self-management of hypertension is effective and feasible. Standardising this intervention on a wider scale with delivery by clinical staff not researchers will allow the full potential of self-monitoring and self-management to be available to the wider hypertensive population.

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