Does telephone follow-up improve blood pressure after minor stroke or TIA?

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Abstract

Background: hypertension is a common risk factor for stroke/transient ischaemic attack (TIA) and there is good evidence that blood pressure (BP) control prevents recurrent stroke. We investigated whether telephone follow-up (TFU) improved risk factor management in hypertensive patients after stroke/TIA.

Methods: we conducted a randomised controlled trial and assigned hypertensive patients within 1 month of stroke or TIA to receive usual care (n = 27) or usual care plus regular TFU (n = 29). Primary outcome was the difference in 12 h ambulatory systolic BP change from baseline to 6 months (ΔSBP) in both groups. TFU at 7 days, 1, 2 and 4 months included patient-focused education and goal setting.

Results: mean baseline BP was 145/83 mm Hg (standard deviation (SD) 21/14). There was no significant difference in ΔSBP over 6 months with TFU. Median ΔSBP was 0 mm Hg (interquartile range 19.5) in the TFU group and 3.0 mm Hg (20) fall in the usual care group (P = 0.29). Post hoc analysis showed that statin use increased from baseline to 6 months (P = 0.02) and cholesterol was significantly lower at 6 months in all patients (mean reduction 0.95 mmol/l; P < 0.001).

Conclusion: our study found TFU that promoted patient-led management of risk factors did not improve BP control over 6-month follow-up in primary care after stroke/TIA.

Keywords: telephone, prevention, stroke, TIA, risk factors, hypertension, elderly

Introduction

Despite evidence that reduction of blood pressure (BP) after stroke or transient ischaemic attack (TIA) prevents further vascular events [1, 2], half of patients starting on antihypertensive medication will have stopped taking it by the end of the first year [2, 3]. Non-adherence with medication in hypertensive patients following stroke is associated with increased risk of stroke recurrence [4]. Reasons for non-adherence include quality of information given, impact on the patient’s life, physical and cognitive function, social circumstances and patient’s beliefs regarding their health and medication [5]. Systematic reviews of interventions to change knowledge, beliefs or behaviour of stroke patients found no conclusive evidence for effectiveness [6, 7]. Telephone interventions improve outcome in secondary prevention of cardiovascular disease, hyperlipidaemia, smoking cessation and heart failure [8–11]. A study using telephone liaison in patients following carotid endarterectomy showed improved knowledge and lifestyle changes [12], but no effects on BP or cholesterol. Adding 12 months regular telephone and email contact from a pharmacist to usual care for younger hypertensive patients in primary prevention resulted in more antihypertensive medication prescribed and a significant fall in systolic BP (SBP) [13].

We investigated the effect of telephone follow-up (TFU) on the uptake of secondary prevention in hypertensive patients with minor stroke or TIA.

Methods

Patients

This randomised controlled trial was conducted from April 2007 to November 2008 (Consort flow diagram, Figure 1, see Supplementary data available in Age and Ageing online). Fifty-six patients aged over 18 years within 1 month of minor stroke or TIA were recruited from the daily neurovascular clinic or on discharge from the stroke unit at the Royal Devon & Exeter Hospital, UK. Twenty-one patients who declined to take part were similar with regards to age, gender
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and diagnosis (age 74.9 (standard deviation; SD 8.3), 54% female, 54% stroke, 46% TIA).

Inclusion criteria were a clinic SBP of 140 mm Hg or greater and living at home at time of follow-up. Exclusion criteria included known dementia, significant disability or co-morbidity which would impair ability to consent or cause undue distress. Written informed consent was obtained from each participant. Local research ethics and institutional approvals were obtained. Participants were randomised to usual care or additional TFU using block randomisation at the end of their first study visit (baseline; month 0) by sequential opaque envelopes stratified by stroke or TIA. All other routine management was continued for both groups. Usual care did not include follow-up visits in secondary care, but involved instructions for follow-up with their general practitioner (GP). All participants were reviewed at the research clinic at 6 months.

Intervention

The TFU intervention was based on social cognitive theory and used a brief motivational intervention based on similar models in other diseases [14, 15]. Participants randomised to TFU received a 20-min telephone-based counseling intervention at 7–10 days, 1, 2 and 4 months by one researcher (K.A.) targeting participant-specific goals relating to lifestyle change. Each TFU discussion reviewed medication, BP and cholesterol control, smoking (if applicable), diet and exercise. Educational material was supplied, tailored to patients’ needs. Participants with high BP were encouraged to see their GP for adjustment of medication. Agreed goals were followed up at the next TFU (see Supplementary data available in Age and Ageing online for further information on TFU intervention).

Outcome measures

The primary outcome was the difference between TFU and usual care groups in 12 h ambulatory SBP change from baseline to 6 months (ΔSBP). Secondary outcomes were differences in antihypertensive and cholesterol-lowering medication, random total cholesterol, self-reported exercise, number of health care contacts, smoking status and medication knowledge.

Inclusion BP was measured at the neurovascular clinic (or on the stroke unit) by nursing staff. Baseline and 6 months BP were measured by researcher (K.A.) after 10 min seated rest. Twelve-hour ambulatory BP (ABP) was measured with SpaceLabs 90207 monitors (SpaceLabs Inc, Redmond, WA, USA). Mean 12 h SBP and diastolic BP (DBP) were derived, together with the percentage and number of successful readings and actual recording time. Twelve-hour day time ABP was preferred to clinic measurement as it is more reproducible [16], sufficiently accurate in comparison to 24 h readings [18] and gives increased study power with fewer subjects [17].

Participation was measured using the modified Rankin Scale (mRS) [18], and for stroke type, the Oxfordshire Community Stroke Project Classification for Stroke was used [19]. Health-related quality of life (HRQOL) was measured using the EuroQOL EQ-5D [20].

Statistical analysis

Descriptive statistics are given as mean (SD) or median (interquartile range; IQR); parametric or non-parametric tests were used according to data distribution. The study had 90% power to detect a difference in mean ambulatory SBP of 8 mmHg with a sample size of 56 (between-measures SD of the difference of 8 mm Hg [16, 21], using two-sample t-test, \( a = 0.05 \), allowing 20% attrition). Statistical analysis was performed using SPSS 15.0.

Results

All 56 participants completed the study. Mean age was 72.5 years (range 54–90 years). Thirty-nine (69.7%) had a history of hypertension and 12 (21.5%) had known hypercholesterolaemia (Table 1, see Supplementary data available in Age and Ageing online). Twenty-four participants had a TIA (43%) and 32 had a minor stroke (57%); seven subjects had a previous stroke or TIA other than their qualifying event. Ten (18%) participants were current smokers, significantly more of whom were randomised to the usual care group (8 versus 2; \( P = 0.008 \)). There were no other significant differences between groups at baseline (Table 1, see Supplementary data available in Age and Ageing online). Seventeen participants (30%) had a mRS of 0 (no disability) and 36 patients (64%) had a mRS of 1 or 2 at baseline (minor disability). Participants commenced in the study at a mean of 16 days (SD 8) following event. Baseline clinic BP was 145/83 mm Hg (SD 21/14) (Table 1). Participants were taking a median of 2 antihypertensive medications (range 0–5) and twelve participants (21%) knew all their medication at baseline.

At 6-month follow-up the median 12 h SBP was 129.0 mm Hg (IQR 14) in the TFU group and 123.0 (IQR 15) in the usual care group (Table 1). The primary outcome of median change in 12 h SBP (ΔSBP) from baseline to follow-up was 0 mm Hg (IQR 19) in the TFU group and 3 mm Hg (IQR 15) reduction in the usual care group (Table 2). ΔSBP was not significantly different between groups (Figure 1).

There was no significant difference between TFU and usual care groups in change in weight, total cholesterol, exercise duration or HRQOL (Table 2). The median number of BP medications participants was taking did not change over 6 months (Table 1). Medication knowledge was not different between the groups at baseline but significantly higher in the TFU group at follow-up (Tables 1 and 2).

Inclusion SBP for all participants was significantly higher than SBP measured at the baseline study visit (165.3 versus 145.0 mm Hg, respectively; 95% CI 13.3–25.6, \( P < 0.001 \)). Twelve-hour DBP for all participants fell between baseline
and 6 months (from 76.1 to 73.5 mm Hg; 95% CI 1.04–5.49, \( P < 0.01 \)). Post hoc subgroup analysis of participants with previous stroke or TIA showed no significant difference in ΔSBP in comparison to participants with first event (Table 3, see Supplementary data available in Age and Ageing online). There was a significant reduction in total cholesterol in all participants by a mean of 0.95 mmol/l at 6 months (95% CI 0.63–1.26, \( P < 0.001 \)), with a small increase in participants taking cholesterol-lowering medication from 42 (75%) at baseline to 47 (84%) at 6 months (Fisher’s exact test, \( P = 0.05 \)). There was no difference between the two groups in the change in total cholesterol (Table 2). The proportion of all participants treated to a cholesterol target of 4.0 mmol/l rose significantly from 10.7% at baseline to 37.5% at 6 months (Fisher’s exact test, \( P = 0.024 \)).

Median mRS at baseline was 2 (IQR 2) in both groups, indicating slight disability. By 6 months patients in both groups had improved to a median mRS of 0 (IQR 1), indicating no symptoms.

A significantly higher number of smokers were recruited into the usual care group by chance (8 versus 2 in the TFU group). By 6 months both participants had given up smoking in the TFU group and three in the usual care group (\( P = NS \)).

HRQOL was not significantly different at baseline or 6 months between the two groups (Table 2). There was also no significant difference between the groups in the number of contacts with health professionals. Participants contacted their GP a median of 4 times (IQR 4), nurses were contacted once (IQR 5) and hospitals were visited less than once per patient (IQR 1) during the study period (Table 3, see Supplementary data available in Age and Ageing online).

### Discussion

This study of a 6-month telephone intervention to improve uptake of secondary prevention after stroke or TIA did not show a difference in the primary outcome of change in 12 h ambulatory SBP when compared to usual care. There were also no significant differences between TFU and usual care in the changes in total cholesterol, achievement of cholesterol or BP targets, reported exercise and HRQOL. Post hoc analysis showed a significant increase in the number of patients taking cholesterol medication and a significant reduction in total cholesterol at 6 months by nearly 1 mmol/l in all participants.

### Table 1. Baseline and 6-month follow-up data

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TFU ( n = 29 )</td>
<td>Usual care ( n = 27 )</td>
</tr>
<tr>
<td>Inclusion systolic BP ( * )</td>
<td>163.7 (19.3)</td>
<td>167.0 (15.5)</td>
</tr>
<tr>
<td>Inclusion diastolic BP</td>
<td>87.6 (11.4)</td>
<td>82.8 (14.7)</td>
</tr>
<tr>
<td>Clinic systolic BP</td>
<td>144.6 (21.6)</td>
<td>147.0 (20.8)</td>
</tr>
<tr>
<td>Clinic diastolic BP</td>
<td>85.7 (13.7)</td>
<td>80.5 (13.1)</td>
</tr>
<tr>
<td>12 h systolic BP</td>
<td>128.0 (22.9)</td>
<td>131 (25)</td>
</tr>
<tr>
<td>12 h diastolic BP</td>
<td>77.1 (10.9)</td>
<td>76.3 (10.6)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>77.5 (11.9)</td>
<td>77.9 (17.2)</td>
</tr>
<tr>
<td>Cholesterol (mmol/l)</td>
<td>5.3 (1.2)</td>
<td>5.1 (0.8)</td>
</tr>
<tr>
<td>Exercise (minutes/week)</td>
<td>210 (350)</td>
<td>210 (300)</td>
</tr>
<tr>
<td>EQ-5D Health Index</td>
<td>0.80 (0.1)</td>
<td>0.83 (0.2)</td>
</tr>
<tr>
<td>EQ-5D VAS</td>
<td>69.2 (16.9)</td>
<td>68.9 (15.5)</td>
</tr>
<tr>
<td>Number of BP meds</td>
<td>2 (1)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Modified Rankin Score</td>
<td>2 (3)</td>
<td>2 (3)</td>
</tr>
<tr>
<td>Medication knowledge in %</td>
<td>66 (100)</td>
<td>29 (67)</td>
</tr>
</tbody>
</table>

\( ^\* \)SBP at neurovascular clinic or before discharge from acute stroke unit.

\( ^{\text{a}} \)Median (interquartile range).

\( ^{\text{c}} \)Mann-Whitney \( U \) test.

### Table 2. Outcome data: change in variables from baseline to 6 months

<table>
<thead>
<tr>
<th>Changes in variable</th>
<th>TFU ( n = 29 )</th>
<th>Usual care ( n = 27 )</th>
<th>( P )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic systolic BP (mm Hg)( ^{\text{a}} )</td>
<td>-2.6 (25.0)</td>
<td>-4.6 (22.4)</td>
<td>0.40</td>
</tr>
<tr>
<td>Clinic diastolic BP (mm Hg)</td>
<td>-10.0 (12.0)</td>
<td>-8.4 (14.0)</td>
<td>0.45</td>
</tr>
<tr>
<td>12 h systolic BP (ΔSBP) (mm Hg)</td>
<td>0.0 (19.5)</td>
<td>-3.0 (15.0)</td>
<td>0.29</td>
</tr>
<tr>
<td>12 h diastolic BP (mm Hg)</td>
<td>-3.5 (8.8)</td>
<td>-3.0 (7.8)</td>
<td>0.79</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>0.2 (2.8)</td>
<td>0.1 (3.0)</td>
<td>0.94</td>
</tr>
<tr>
<td>Cholesterol (mmol/l)</td>
<td>-0.9 (1.2)</td>
<td>-0.9 (1.1)</td>
<td>0.98</td>
</tr>
<tr>
<td>Exercise (minutes/week)</td>
<td>0 (357.5)</td>
<td>0 (220.0)</td>
<td>0.35</td>
</tr>
<tr>
<td>EQ-5D Health Index</td>
<td>0 (0.15)</td>
<td>0 (0.12)</td>
<td>0.84</td>
</tr>
<tr>
<td>EQ-5D VAS</td>
<td>0.6 (19.1)</td>
<td>5.6 (18.1)</td>
<td>0.63</td>
</tr>
<tr>
<td>Modified Rankin Score</td>
<td>0 (1)</td>
<td>1 (2)</td>
<td>0.57</td>
</tr>
<tr>
<td>Medication knowledge in %</td>
<td>25.0 (63.5)</td>
<td>0 (25.0)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

\( ^{\text{a}} \)A negative value means a fall in BP or cholesterol from baseline to follow-up. All data are mean (SD) and two-tailed non-paired \( t \)-test unless denoted otherwise.

\( ^{\text{b}} \)Median (interquartile range).

\( ^{\text{c}} \)Mann-Whitney \( U \)-test.

VAS: visual analogue scale.
The addition of TFU to usual care showed increased medication knowledge, but this did not lead to increased BP medication uptake nor reductions in BP in this study, and the percentage of patients treated to target BP at 6 months (32%) corresponded to our previous study in similar patients [22]. Our findings are similar to those from a study using telephone intervention in patients following carotid endarterectomy [12], which found no BP reduction with the intervention. Another study found significant reductions in BP, weight and salt intake in hypertensive patients using intense face to face motivational interviewing in comparison to TFU [23], possibly accounted for by the intensity of the intervention. The recent study of Green et al. [13] used an intensive programme including home BP monitor, access to an interactive website, telephone calls and ongoing email support (to patient and physician) from a pharmacist with stepped medication protocols to improve BP control. The provision of information has been recommended as a key component of service provision for people after stroke [24, 25], but a Cochrane review has found that information provision alone has no effect on mood, perceived health status or HRQOL for patients or carers [7]. Translating knowledge into healthy behaviours remains a challenging task in health promotion [26]. This study showed that improved medication knowledge after stroke/TIA did not lead to improved BP control.

We did find a significant reduction in total cholesterol and an increased uptake of cholesterol medication among all participants at follow-up. The simplicity of statin therapy may mean that cholesterol reductions can be achieved with very little engagement from the patient, whereas achieving significant reductions in BP requires a greater level of participation in treatment regimens that are often complex. It may be that a simplified approach to BP management (e.g. commencing fixed-dose combination medication in the clinic) is more effective than customary dose-titration regimens requiring frequent follow-up. Our study suggests that telephone support is itself insufficient to increase patient participation in customary dose-titration regimens, with no increase in either numbers of primary care consultations or in antihypertensive medications taken.

This study may have been limited by the short follow-up period, but previous studies using TFU have shown significant change over similar or shorter periods of time, including reductions in smoking and LDL cholesterol within 2 months [8] and improved stroke knowledge and changes in lifestyle at 3 months [12]. Studies using motivational interviewing have demonstrated weight reduction, BP reduction and improved compliance with cholesterol medication within 4–6 months [8, 23]. Early management of risk factors is important as up to 20% of patients will have a recurrent event within 3 months of stroke or TIA; in the EXPRESS

Figure 1. Comparison of median 12 h systolic BP at baseline and follow-up.
study, treatment initiation at TIA clinic visit in comparison to advice to GPs led to a significant early reduction in stroke/TIA recurrence [1]. Other limitations include the small sample size, which prevented meaningful subgroup analysis. The reduction in BP seen on initial study visit compared to inclusion BP is likely due to habituation and regression to the mean, which will need to be taken into account in further study designs.

Modelling studies suggest that the use of optimal risk factor interventions after stroke/TIA should reduce the long-term risk of recurrence by 80–90% [27]. Despite this, several studies have demonstrated a failure to replicate in primary care-based follow-up after stroke/TIA the levels of intervention seen in the randomised controlled trials [22]. This failure to optimise secondary prevention leaves patients at increased risk of recurrence. Although research efforts are often concentrated on improving secondary prevention after stroke and TIA through examining small marginal benefits [28], the greater need is to implement existing evidence-based interventions more effectively. Further studies are needed to investigate how to support patients to adopt and maintain beneficial health behaviours important to secondary prevention after stroke or TIA.

Key points
- Regular TFU that promoted patient-led management of risk factors did not improve BP control in patients after minor stroke or TIA.
- TFU did not increase BP medication use, improve HRQOL or increase exercise in patients after stroke/TIA.
- Total cholesterol levels reduced and statin use increased in all patients at follow-up in comparison to baseline.

Supplementary data
Supplementary data mentioned in the text is available to subscribers in Age and Ageing online.

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Conflicts of interest
None declared.

Clinical trials
Trial was registered in April 2007 with the UK National Research Registry (http://www.nrr.nhs.uk/). Trial number: 1405.

References
Lower blood pressure associated with higher mortality in elderly diabetic patients (ZODIAC-12)

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Abstract

Objective: to investigate the relationship between blood pressure over time and mortality in elderly patients with type 2 diabetes mellitus (T2DM).

Design: prospective observational cohort study.


Subjects: patients with T2DM aged 60 years and older (n = 881). The cohort was divided into two age categories: 60–75 years and older than 75 years.

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Blood pressure over time and mortality